REHABILITATION INCORPORATING GAIT TRAINING DEVICES FOR CHRONIC ANKLE INSTABILITY

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ABSTRACT

Individuals with chronic ankle instability (CAI) have deficits of range of motion, strength, postural control and altered gait patterns. Specifically, on average individuals with CAI maintain a more inverted foot position through the gait cycle compared to healthy individuals. Rehabilitation studies often study the effects of a specific intervention on one deficit, which is invaluable in determining the best treatment for a specific condition. However, since CAI is a multi-dimensional condition, we believe clinicians should assess and treat each common deficit associated with CAI. We recently developed a rehabilitation paradigm built on impairment based progression strategies to improve self-reported outcome in patients with CAI. The paradigm also stresses the importance of incorporating gait training exercises, however, the effects of implementing this paradigm in clinical practice remains unclear. Ankle destabilization devices have been developed to improve the faulty motor response and detection of increased inversion associated with CAI by implementing a feed-forward mechanism in response to an anticipated bout of instability. Therefore, the purpose of this study is to determine the effects of a progressive impairment based rehabilitation program that incorporates ankle destabilization devices on self-reported function, range of motion, strength, and balance (Manuscript 1) when compared to a no device group who utilizes traditional unstable surfaces during rehabilitation.. Furthermore, to determine whether incorporating ankle destabilization devices in a 4 week progressive rehabilitation program improves gait in patients with CAI (Manuscript 2). Finally, the purpose of Manuscript 3 was to determine the effects of using an auditory biofeedback device on plantar pressure during walking in

individuals with CAI during one session. We found an increase in self-reported function, range of motion, strength and balance after a 4 week rehabilitation intervention in both groups after the study, but there were no differences between the groups after rehabilitation. Furthermore, we found that incorporating ankle destabilization devices in rehabilitation caused an increase in dorsiflexion during the stance phase of gait. However, there were no other kinematic or kinetic differences during gait after the intervention for either group. Finally, we found that an auditory biofeedback device is effective at decreasing lateral foot pressure during gait. Based on these finding, it appears that ankle destabilization devices are as effective at improving self-reported function, range of motion, strength and balance as traditional unstable surfaces. In addition, using a progressive rehabilitation program to treat patients with CAI is effective at improving clinical measures. However, after rehabilitation neither group had improved frontal plane kinematics or kinetics during walking. We believe clinicians should implement progressive impairment based rehabilitation programs when treating patients with CAI, but should also develop more specific gait training techniques that may improve frontal plane motion. Researchers should continue to explore other intervention strategies, like the auditory biofeedback device, that could improve gait patterns that are commonly associated with CAI.

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SECTION II: MANUSCRIPT I

REHABILITATION FOR CHRONIC ANKLE INSTABILITY WITH AND WITHOUT DESTABILIZATION DEVICES: A RANDOMIZED CONTROLLED TRIAL

ABSTRACT

Context: Individuals with chronic ankle instability (CAI) have deficits in neuromuscular control and altered movement patterns. Ankle destabilization devices have been shown to increase lower extremity muscle activity during functional tasks and may be a useful tool in improving common deficits and self-reported function. **Objective:** To determine whether a 4-week rehabilitation program that includes ankle destabilization devices (Device) has greater beneficial effects on self-reported function, ankle range of motion (ROM), ankle strength and balance compared to rehabilitation without destabilization devices (No Device) in CAI patients. **Design:** Single-blind randomized controlled trial. **Setting:** Athletic training laboratory. **Patients or Other Participants:** Twenty-six participants with CAI (age=21.34, sex=(M=7,F=19), height=168.96cm, weight=70.73kg). **Interventions:** Participants completed baseline self-reported function questionnaires, ROM, strength, balance measures and were randomized into no device and device groups. Both groups completed 4-weeks of supervised rehabilitation with or without destabilization devices and then repeated the questionnaires, ROM, strength, and balance measures. **Main Outcome Measures:** Self reported function, strength, static balance, and dynamic balance. All measures were compared using a mixed-model ANOVA and appropriate post-hoc tests with *a priori* significance level of $P \leq 0.05$. **Results:** There were no significant differences between the no device and device groups in self-reported function, ROM, strength or balance after rehabilitation. However, both groups had significant improvements in self-reported function, ROM, strength and balance after rehabilitation. **Conclusion:** Incorporating ankle destabilization devices into rehabilitation

is not more effective at improving self-reported function, ROM, strength and balance when compared to traditional rehabilitation tools as both interventions resulted in similar improvements. Progressive impairment-based rehabilitation is effective at improving clinical outcomes associated with CAI and should be used when treating CAI.

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INTRODUCTION

Lateral ankle sprains have been shown to be among the most common musculoskeletal injury among competitive athletes[1-2] and those who are recreationally active.[3] Furthermore, it is estimated that approximately 47 to 74% of people who suffer a lateral ankle sprain will go on to have recurrent sprains 6 to 18 months after their first ankle sprain.[4] Approximately 30% of patients who sprain their ankle will go on to have residual symptoms of instability and repetitive ankle sprains that lasts greater than a year[5] which is known as chronic ankle instability (CAI).[6]

The specific cause of CAI remains unclear; however, multiple characteristics have been identified to be different in patients with CAI compared to healthy patients. These characteristics include, but are not limited to impaired proprioception,[7-11] decreased neuromuscular control,[12-16] decreased range of motion (ROM),[17-19] decreased strength,[7, 12, 20] and altered gait.[21-25] Treatment of CAI is often done through conservative rehabilitation programs that are designed to improve ROM, strength, proprioception and neuromuscular control.[26-27] Traditionally, rehabilitation programs incorporate tools, such as foam pads on which to perform balance exercises, to improve neuromuscular control. Past studies have shown that incorporating unstable surfaces during rehabilitation is effective at improving self-reported function and balance in participants with CAI.[14, 28] However, due to the nature of these tools, they are limited to being used for relatively non-functional exercises such as static balance. This limitation may decrease clinicians' ability to maximize improvement of patients in functional activities. Ankle destabilization devices are devices that consist of either a boot or sandal with an

articulator below the heel designed to mimic the motion that occurs at both the subtalar and talocrural joints during walking and other functional movements. The goal of these devices is to force the patient into ankle plantar flexion, inversion, and internal rotation in a controlled manner while completing functional tasks. Unlike traditional unstable surfaces, these devices can be worn like shoes. It is thought that by causing an anticipated perturbation at the ankle, surrounding musculature will contract via feed-forward mechanisms to prevent the ankle from going into the vulnerable position.[29-31]

We have completed laboratory studies[32-33] on two specific ankle destabilization devices, the Myolux Athletik (boot) and Myolux II (sandal) (Cevres Santé, Le Bourget-du-Lac, France)(Figure 1.1). We assessed surface electromyography (sEMG) measures of six lower extremity muscles during balance, star excursion balance test (SEBT), lateral hopping and walking comparing the two ankle destabilization devices to a shod control condition in 15 CAI patients.[31] We found an alteration in muscle activity when compared to shod when the participants were wearing the devices for each functional task. Specifically, there was a pronounced increase in the peroneus longus EMG amplitude during all tasks, which shows the potential for these devices to increase lateral stability of the ankle joint. Since there is an increase in peroneus longus activity in each functional task, we believe these devices may not only be able to improve neuromuscular control, but also provide a method to cause strength increases during closed kinetic exercises if incorporated into a progressive rehabilitation program as a result of increased muscle activity.

In addition to determining the effectiveness of incorporating ankle destabilization devices in rehabilitation on clinical measures, a secondary aim is to determine the effects of an impairment based progressive rehabilitation program. Over the past several years multiple intervention studies have been completed to determine whether or not specific rehabilitation techniques improve characteristics associated with CAI.[14, 34-42] Specifically, Hoch et al.[42] found that a 2-week joint mobilization program improves self-reported function, dorsiflexion ROM, and dynamic stability in patients with CAI. Furthermore, Docherty et al.[36] found that strength training in patients with functional ankle instability increases strength of the surrounding ankle musculature. Moreover, McKeon et al.[14] reported that a four-week supervised balance intervention caused an increase in self-reported function and improved balance in CAI patients.

Although these studies found positive improvements in CAI patients, they each only included one type of exercise or rehabilitation technique in their protocol. Combining multiple treatment techniques, as is typical in clinical practice, may cause a larger improvement in symptoms and function in CAI patients. Specifically, Hoch et al.[42] and McKeon et al.[14] found similar magnitude of change in self-reported function after completing a 2-week mobilization intervention and 4-week balance intervention respectively. Even though both interventions caused a significant improvement when compared to pre-intervention scores, their post-intervention self-reported function would still be considered significantly lower than that of a healthy individual.

We recently presented a new paradigm for the conservative treatment of CAI patients (Figure 1.2).[27] We assert that rehabilitation should encompass exercises for all

impairments detected in a patient with CAI within 4 broad domains of ROM, strength, balance, and functional activities. We believe this can be achieved by an "assess, treat, re-assess" approach in each domain of impairments. Furthermore, we emphasize the importance of implementing gait retraining into the rehabilitation of CAI patients. Recently, we have modified the rehabilitation paradigm (Figure 1.3) to incorporate the importance of assessing self-reported function throughout the rehabilitation process.

The primary purpose of this study is to examine the effects of a 4-week supervised rehabilitation intervention that encompasses ROM, strength exercises, balance and functional exercises with and without ankle destabilization devices in CAI patients. The primary dependent variables are self-reported function and measures of ankle ROM, strength and static and dynamic balance. The secondary dependent variables are sEMG amplitude measures during strength and balance testing.

METHODS:

Study Design: We performed a single-blinded randomized clinical trial comparing 4 weeks of supervised rehabilitation with and without destabilization devices on measures of self-reported function, ankle ROM, ankle strength, and balance. Our independent variables were group (no device rehabilitation vs. rehabilitation with ankle destabilization devices) and time (pre and post-rehabilitation). The primary dependent variables were: self-reported function (Foot and Ankle Ability Measure (FAAM) activities of daily living (ADL) and Sport scales, Single Assessment Numeric Evaluation (SANE) for ADLs andSport, and global rating of change score), ROM (standing straight knee dorsiflexion, standing bent knee dorsiflexion, seated inversion, seated eversion, seated plantar flexion

and posterior glide test), strength (dorsiflexion, inversion, eversion neutral, eversion in plantar flexion, and plantar flexion) static balance (eyes open center or pressure (COP) area, eyes open COP velocity, eyes closed COP area, eyes closed COP velocity), and dynamic balance (Star Excursion Balance Test (SEBT)). Our secondary dependent variables were sEMG amplitudes of the anterior tibialis, peroneus brevis, peroneus longus, and medial gastrocnemius during the strength and balance tests. We did not include a true control group because previous research has shown that self-reported function, ROM, strength and balance do not change in patients with CAI over 4 weeks if they maintain their current ADL.[14, 43] This study was approved by the University's institutional review board. All participants provided informed consent.

Participants: Twenty-six young adults (age=21.34 years, sex=(M=7,F=19), height=168.96cm, weight=70.73kg) with CAI were recruited from a University setting and surrounding community to participate in this study. The inclusion criteria for the CAI group was a history of more than one ankle sprain with the initial sprain occurring greater than one year ago and current self reported functional deficits due to ankle symptoms that was qualified by a score of <85% on the FAAM Sport scale and a ≥10 on the Identification of Functional Instability scale (IdFAI).[44] All subjects were physically active (at least 20 minutes of exercise a day at least 3 days a week) and have no history of lower extremity injury, including ankle sprains within the six weeks prior to the study, and no history of lower extremity surgery, balance disorders, neuropathies, diabetes, or other conditions known to affect balance (ex. lumbosacral radiculopathy, Marfan syndrome, vestibular conditions, or other musculoskeletal conditions that could affect

outcomes).[44] Participant demographics are presented in Table 1.1. There were no differences in participant demographics between groups.

Instruments:

Ankle Destabilization Devices

The Myolux Athletik and Myolux II (Cevres Santé, Le Bourget-du-Lac, France) were the destabilization devices used in the experimental group (Fig. 2). The Myolux Athletik has been previously demonstrated to have effects associated with increased neuromuscular activation of muscles around the ankle during walking gait.[30-31] This device consists of a half shoe with an articulator located beneath the heel and a puck that is worn beneath the metatarsal heads. The articulator allows for approximately 45 degrees of inversion. The Myolux II is a full length sandal and allows for approximately 30 degrees of inversion. The articulator is different in that of the Myolux Athletik, not only does it allow less motion, but the articulator has a smaller lever-arm and has a cradle shape. The Myolux II was designed for earlier stages in functional rehabilitation, while the Myolux Athletik was intended for later phases of rehabilitation and sport performance. Both devices were used by the experimental group.

Surface Electromyography

Surface EMG was measured using DE 2.1 differential EMG sensors (Delsys, Boston, MA). These rectangular sensors consisted of two parallel bars separated by 1cm, where each bar was 1cm long and 1mm wide. They were placed over the mid-belly of each muscle, parallel to fiber orientation. Prior to placement, skin was shaven, abraded, and cleaned using alcohol. Input impedance was $>10^{15}\Omega//0.2$pF with a signal to noise

ratio of 1.2uV. The signal was amplified with a gain of 1000 and digitized with a 4 channel acquisition system (Bagnoli EMG system, Delsys, Boston, MA) at 1000 Hz. Data was collected using Motion Monitor software (Innovative Sports Training, Inc., Chicago, Illinois) and processed by using EMGworks software (version 4.1.1, Delsys, Boston, MA). Data processing methods were the same as previous studies.[32] Data was filtered using a 10-500 band-pass filter and smoothed using a 50-sample moving window root mean square (RMS) algorithm as recommended by Konrad et al.[45]

Static Balance

Static balance was assessed using the Accusway Plus forceplate (AMTI, Watertown, MA). Center of pressure 95% confidence eclipse area ($cm^{2)}$ and average velocity (cm/s) were calculated from the 3-dimensional forces and moments that resulted from the foot/forceplate interface. Data was sampled at a rate of 50 Hz and a fourth-order low zero lag, low-pass filter with a cutoff frequency of 5 Hz was used to filter the COP data with the Balance Clinic Software (AMTI, Watertown, MA).[46]

Procedures

Participants completed a general health history questionnaire, the FAAM-ADL and Sport scale, the IdFAI and the Godin Leisure-Time Activity questionnaires. Next, participants had general foot and ankle descriptive measures, ROM, strength, and balance assessed. After data collection was completed, the participant was enrolled into rehabilitation. At this time they were randomly assigned treatment groups via concealed envelop. Each participant completed 12 supervised rehabilitation sessions over a 4-week period. After rehabilitation was completed, participants returned to the lab between 2 and

7 days and repeated their baseline testing. Procedures are outlined in a consort flow chart Figure 1.4. The investigator who collected the data was blinded to group assignment until all data was processed. Likewise the clinicians supervising the rehabilitation programs were not involved in the baseline or follow-up measurement sessions.

Foot and Ankle Descriptive Measures

We included descriptive measures of the foot and ankle to get an estimation of foot type and ankle laxity.

Standing Rear-foot alignment

Standing rear-foot alignment was measured using a goniometer and by using the same measurement technique as previously described.[47] Participants stood with their feet shoulder width apart and marched in place. Using a goniometer, we took one measure of the angle of the mid-line of the calcaneus in relation to the mid-line of the calf.

Navicular Drop Test

Navicular drop test was completed one time using a height gauge (Z-Height E, Fowler Company, Newton, MA) using the procedures as recommended by Picciano et al.[48] Participants sat on an adjustable stool with feet flat on the ground shoulder width apart. The individual's foot was placed in sub-talar neutral and the most prominent portion of the navicular was marked. Using the height gauge, the seated height of the navicular was measured. The participant was instructed to standing up without moving their feet and the height of the navicular was re-measured. The difference between the seated and standing position was recorded.

Range of Motion Measures

Range of motion was measured using a bubble inclinometer and goniometer. Dorsiflexion was measured in both the standing straight knee and standing bent knee positions with a bubble inclinometer.[49] Inversion and eversion were measured with the participant in a supine position using a goniometer. The posterior talar glide test was measured with using the bubble inclinometer as described by Cosby and Hertel.[50] All ROM positions were measured one time, except the mean of three trials was recorded for the posterior talar glide test.

Ankle Laxity

Ankle laxity was measured with an ankle arthrometer (Blue Bay Research Inc, Navarre, FL) using previously described methods.[51] Participants lied supine with their foot placed in the arthrometer. Anterior displacement was measured by the investigator fixing the tibia and translating the calcaneus and talus anteriorly using a standard 125 N of force while the participant was in a neutral ankle position. For inversion displacement, the same participant position was used, but the investigator displaced the foot into inversion using a standard 4000 N*mm of force. Anterior and inversion displacement was processed using a custom software program written in LabView (National Instruments Corp, Austin, TX). We took the mean of three measures of the anterior drawer displacement and inversion displacement.

Surface EMG Set-up

Surface EMG set-up was completed by using previously established standard methods.[52-53] Skin was prepared by shaving excessive hair and cleaning with 99% isopropyl alcohol. Electrodes were placed over the muscle belly of the anterior tibialis,

peroneus longus, peroneus brevis and medial gastrocnemius. Electrode placement was verified by having the individual contract each muscle independently while the investigator simultaneously inspected the data stream for cross-talk of surrounding muscles.

Strength

Ankle strength (dorsiflexion, inversion, eversion neutral, eversion in a relaxed planter flexion position, and plantar flexion) was measured using a hand-held dynamometer (HHD) (Accelerated Care Plus Corp, Reno, NV). Hand-held dynamometry has been shown to be a reliable measure in assessing strength at the ankle.[54-55] Prior to testing, each participant walked at a self-selected pace for 5 minutes to serve as a warm-up. Next, we outlined the HHD on the individual's foot in each of the positions to ensure we placed the HHD in the same place for each trial. For dorsiflexion the HHD was placed of the dorsal surface of the foot in line with the shaft of the first metatarsal. The HHD was placed along the medial border of the first metatarsal for inversion. During the eversion trials, the HHD was placed along the lateral border of the fifth metatarsal. The HHD was placed on the plantar surface of the foot along the first metatarsal for the plantar flexion trials. For each position, the individual was instructed to complete the task at a 50% effort and a 75% effort before completing the maximal effort trials. Participants were instructed to contract as hard as they can while only moving their ankle until they were instructed to relax. The investigator provided verbal encouragement for all trials. Three 5-second isometric trials were completed for each motion. Each participant received 15 seconds to rest in between trials. We used the same testing position as

recommended by Kelln et al.[54] For dorsiflexion, inversion, and eversion, the participant was supine with their hips and knees extended. Plantar flexion was tested with the participant prone with their knee bent. During all trials, the investigator stabilized the lower extremity to minimize proximal joint involvement during the trials. We chose to include a second eversion position (eversion while the foot is in a relaxed plantar flexed position) to gain a better understanding of the lateral strength of the ankle while in an open-packed position. The mean Force (N) during the three trials was calculated and normalized to body mass (kg) and were subjected to statistical analysis. We collected sEMG during all maximum voluntary isometric contraction (MVIC) trials.

Balance

Static Balance

Participants completed three eyes open and three eyes closed single limb balance trials on a forceplate (Accusway Plus, AMTI, Watertown, MA) for 10 seconds. Participants stood with one foot in the center of the forceplate, crossed their arms in front of their chest, lifted their uninvolved limb to about 30 degrees of hip flexion and 45 degrees of knee flexion, and stood as still as possible for the 10 second trials.[14] Trials were considered unsuccessful if the uninvolved limb touched the ground, the standing limb, or if the individual was unable to maintain the testing period for the entire 10 second trial. The mean area and velocity were calculated from the 3 successful trials.

Dynamic Balance

We used the Star Excursion Balance Test (SEBT) to assess dynamic balance. The SEBT has been shown to be a reliable test to detect dynamic stability impairments in

individuals with CAI.[16, 56-57] Each individual completed 3 trials in the anterior, posteromedial, and posterolateral directions, using the same testing procedures as recommended by Gribble et al.[58] The average of the 3 trials in each direction were calculated and normalized to the individual's leg length to form a composite reach distance percentage of the individual's leg length.

Data Reduction of the Surface EMG Amplitudes

Amplitude during MVIC

The area under the RMS curve was calculated for the middle 3 second period of each individual strength trial for the corresponding muscle (Dorsiflexion=anterior tibialis, Inversion= anterior tibialis, Eversion Neutral= peroneus brevis/longus, Eversion in Plantar Flexion= peroneus brevis/longus, Plantar Flexion=Medial Gastrocnemius) and averaged. The average area under the RMS curve was normalized to a 3 second period collected during a quiet resting period.

Single Limb Eyes Open and Eyes Closed Balance Amplitudes

During both the eyes open and eyes closed trials, the area under the RMS curve was calculated for the middle 3 seconds of each trial and normalized to the area under the RMS curve of a 3 second quiet resting period. The mean amplitudes of the three trials for both eyes open and eyes closed were calculated.

Star Excursion Balance Test Amplitudes

A composite mean area under the RMS curve of the stance leg during the SEBT was calculated for a 500ms period prior to maximal reach distance. The composite mean amplitude was normalized to a time match 500ms period during quiet resting. Maximum

reach distance was determined by having a second investigator depress a forceplate simultaneously as the participant reached maximum distance.

Rehabilitation Programs

The first day of rehabilitation occurred a minimum of 48 hours after pre-test measurements. Participants completed 3 supervised rehabilitation sessions per week for 4 weeks. Each rehabilitation session lasted approximately 1 hour and was supervised by an athletic trainer with 4 years of clinical experience. Both rehabilitation groups were prescribed exercises that addressed deficits in ROM, strength, balance, and functional activity, and reflected the previously described rehabilitation paradigm .[27] However, the device group used both ankle destabilization devices during weight bearing activities throughout their rehabilitation. Initial intensity and duration of each exercise was based on clinical judgment of the athletic trainer. In depth rehabilitation protocols and progression criteria can be found in Appendix 1. The supervising clinician kept track of the participants' progression by using the rehabilitation program data collection sheets. Both the no device group and device group, on average, had the same length of rehabilitation sessions and training volume throughout the intervention.

ROM Exercises

If an arthrokinematic joint restriction was found at the talocrural, distal tibiofibular, proximal tibiofibular or calcaneocuboid joints and the participant has no contraindications to joint mobilizations, participants received 2 sets of 2 minutes grade III joint mobilization as described by Hoch et al.,[42] which was shown to increase ROM. Participants arthrokinemtics were assessed before each session and were treated

according to clinical indication. In addition to joint mobilizations participants completed seated towel stretches and standing stretches with the knee in a straight position and in a bent position. Range of motion exercises lasted for a total of 5-10 minutes per session. Eight participants from the no device group and 6 participants from the device group received joint mobilizations.

Strength Exercises

Strength exercises consisted of double legged heel raises, double legged forefoot raises, 4-way manual ankle resistance, D1 and D2 PNF patterns, 4-way walks, and short foot exercises. Once a participant can complete 3x10 of the double legged heel and forefoot raises they progressed to single legged stance heel and forefoot raises. For the 4-way manual ankle resistance and D1/D2 patterns, participants complete 3 sets of 10 repetitions of each. The clinician increased resistance if the participant did not feel the exercise was challenging. The 4-way walks consisted of the participant walking on their heels, toes, medial aspect of their foot and lateral aspect of their foot for 10 meters. Once they completed 10 meters with ease in any of the positions, they increased the distance by 10 meters in that position. Strength exercises were completed for 10-15 minutes per session.

Balance Exercises

Balance exercises followed a similar protocol to McKeon et al.[14] because it was shown to improve self-reported function and postural control in CAI patients. Furthermore, balance exercises were broken into two categories (static and functional). Both categories were completed together and progressed independently of each other.

Static: The static balance exercises for the no device exercise group and the device group will consist of 6 phases of single leg balance exercises. Participants progressed to the next phase after they successfully completed 3 sets of 30 seconds.

Dynamic

Functional balance consisted of a reaching task and hop to stabilization exercises. Each of these exercises was progressed independently of each other.

Reaching Tasks

Participants stood on one limb and reached with the contralateral leg as far as they could in a total of 8 directions that were in all planes of motion. The reaching task for the both groups had 3 phases. Participants completed 2 sets of 10 reaches in random directions in each condition. Once they completed 2 sets of 10 reaches, they progressed to the next phase.

Hop to Stabilization

The hop to stabilization exercises used the same protocol used in the McKeon et al.[14] study. Participants performed 10 hops in each of these four directions: (medial to lateral, anterior to posterior, anterior medial to posterior lateral, and anterior lateral to posterior medial). Each repetition consisted of a hop from the starting position to the target position and then back to the starting position. There are 12 total phases of this exercise for the no device exercise group and the experimental exercise group. The Mylolux II device was not included in this progression because it is not designed to with stand the forces of such exercises. Participants progressed to the next level after they completed 10 error free hops. Balance exercises were completed in 15 minutes.

Functional Exercises

Each participant progressed through lunges, step-ups and step-downs, forward running, dot drill jumps/cutting, and gait training exercises. Each of these exercises was progressed independently of each other.

Lunges

For both groups lunges were performed with the participant having their hands on their hips, lunging forward to a 90/90 position, touching their knee to the ground, and returning to the starting position. Lunges were completed on both legs. Participants in the no device and experimental exercise group completed 3 phases of lunges. Participants progressed to the next phase after they completed 2x10 error free lunges.

Step-up and Step-downs

For both groups, this exercise required the participant to step on to a 30cm box with their injured leg and then step off the box on to their injured leg. They completed this by stepping forward onto/off the box and stepping laterally onto/off the box. The no device exercise group and experimental exercise group completed 3 phases in each direction, which was progressed independently of each other.

Dot Drill Jumps/Cutting

The dots were separated by 24 inches. Participants were asked to jump dot to dot as fast as they can while feeling comfortable. The no device exercise group completed 2 phases. The first phase included double legged lateral to medial hops, double legged anterior to posterior jumps, double legged figure 8 randomized jumps. The second phase was single legged lateral to medial jumps, single legged anterior to posterior jumps, and

single legged figure 8 randomized jumps. The figure 8 randomized jumps were done by the athletic trainer telling the participant which dot to jump on prior to each trial so each task was unique. Participants in this group progressed from phase 1 to phase 2 after they completed 3 sets of 30 seconds of phase one in each direction. Once they reached the single leg jump phase, they progressed the duration by 15 seconds after being able to complete 3 successful trials at the previous duration. The experimental group completed 4 phases. Phase 1 was double legged lateral to medial hops, double legged anterior to posterior jumps, double legged figure 8 randomized jumps. Phase 2 was double legged lateral to medial hops, double legged anterior to posterior jumps, double legged figure 8 randomized jumps while wearing the Myolux Athletik devices. Phase 3 was single legged lateral to medial jumps, single legged anterior to posterior jumps, and single legged figure 8 randomized jumps. Phase 4 was single legged lateral to medial jumps, single legged anterior to posterior jumps, and single legged figure 8 randomized jumps while wearing the Myolux Athletik devices. Participants in this group progressed from phase 1 to 2, phase 2 to 3, and phase 3 to 4 double after they completed 3 sets of 30 seconds in each phase. Once they reached the single leg jump with the Myolux Athletik device phase, they progressed the duration by 15 seconds after being able to complete 3 successful trials at the previous duration.

Treadmill Walking

Each group walked on treadmill starting at 5 minutes and progressing to 15 over the first 6 sessions. Both groups continued to complete 15 minutes of treadmill walking for the remaining 6 sessions. The no device group was instructed to walk at their

preferred walking speed. The device group completed the treadmill walking while wearing the devices. Functional exercises were completed in 15-30 minutes.

Follow-Up Testing

After completing the 4 weeks of rehabilitation, participants completed another FAAM-ADL/Sport questionnaire, a global rating of change (GROC) and had their ankle ROM, strength and balance re-tested between 48 and 96 hours after their last rehabilitation visit. The GROC was a likert based questionnaire, where participants selected a number that ranged from -7 (A very great deal worse) to a 7 (A very great deal better) after being asked to rate their overall condition of their ankle from the time you began treatment until now.

Statistical Analysis

For primary dependent variables (self-reported function, ROM, strength and balance) and secondary dependent variables (sEMG strength amplitudes, and sEMG balance amplitudes) a 2x2 mixed model ANOVA was conducted. The between factor was group (no device rehabilitation and rehabilitation with ankle destabilization devices) and the within factor with repeated measures was time (pre, post). Tukey's post hoc tests were used to identify specific significant differences in the presence of significant interactions. The level of significance was set *a priori* at $P \leq 0.05$ for all analyses. We chose not to control for multiple comparisons as recommended by Hopkins et al.[59] Cohen's *d* effect size and associated 95% CIs were calculated comparing pooled group post-rehabilitation means to pre-rehabilitation group means. Effect sizes were interpreted as ≥ 0.80 was large, 0.50 to 0.79 as moderate, 0.49 to 0.20 as small and <0.20 as trivial.

Data was analyzed using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc, Chicago, IL).

RESULTS:

Self-Reported Function

FAAM-ADL %, FAAM-Sport %, SANE ADL, SANE Sport, and GROC

There was no significant interaction or group main effect in FAAM-ADL %, FAAM-Sport %, SANE ADL, or SANE Sport scores. There was a significant time-main effect where combined groups had higher self-reported function scores after completing rehabilitation [FAAM-ADL %: (Pre-Rehab: (Mean and Standard Deviation) 86.71±7.53, Post-Rehab: 95.79±4.55, P<0.001), FAAM-Sport %: (Pre-Rehab: 66.47±13.42, Post-Rehab: 86.33±9.79, P<0.001), SANE ADL: (Pre-Rehab: 85.42±16.53, Post-Rehab: 94.81, 8.41, P=0.006), SANE Sport: (Pre-Rehab: 73.19±18.30, Post-Rehab: 89.62±9.33, P<0.001)]. In addition, the increase in the FAAM-ADL %, FAAM-Sport %, and SANE Sport after rehabilitation was a large effect and the increase in the SANE ADL was moderate. The average GROC score of the pooled groups was 4.62, which is between "moderately better" and "quite a bit better". All means, standard deviations, p-values and effects sizes are presented in Table 1.2.

Range of Motion

Dorsiflexion and Posterior Talar Glide

All range of motion means, standard deviations, p-values and effects sizes are presented in Table 1.3. There is a significant group-main effect for standing straight knee dorsiflexion and standing bent knee dorsiflexion between the no device and device group.

However, the two groups were significantly different at baseline. When groups were combined, both standing straight knee dorsiflexion (Pre-Rehab:38.12±9.56°, Post-Rehab: 42.81±8.66°, P=0.022), standing bent knee dorsiflexion (Pre-Rehab:42.23±10.08°, Post-Rehab: 47.27±9.80°, P=0.001), and posterior talar glide (Pre-Rehab:12.26±9.05, Post-Rehab: 15.77±7.74, P=0.023) increased. There were no significant interactions. In terms of effect sizes, there was a moderate increase in standing bent knee dorsiflexion and small increases in standing straight knee dorsiflexion and posterior talar glide.

Plantar Flexion, Inversion, and Eversion

After rehabilitation, the combined groups had a significant increase in plantar flexion range of motion (Pre-Rehab:64.31±8.37°, Post-Rehab: 67.62±8.36°, P=0.003). There was no significant group by time interaction or group differences in plantar flexion. With regards to inversion and eversion, there were no differences over time or between groups. Both plantar flexion and eversion had small effect sizes and inversion had a trivial effect size.

Strength

Strength increased over time for the combine group for all motions (Force=N/kg) [Dorsiflexion: (Pre-Rehab: 1.80±0.60N/kg, Post-Rehab: 2.13±0.61 N/kg, P<0.001), Inversion (Pre-Rehab: 1.41±0.31 N/kg, Post-Rehab: 1.82±0.44 N/kg, P=), Eversion Neutral (Pre-Rehab: 1.64±0.39 N/kg, Post-Rehab: 2.08±0.49 N/kg, P=), Eversion in Plantar Flexion (Pre-Rehab: 1.41±0.33 N/kg, Post-Rehab: 1.74±0.43 N/kg, P<0.001), and Plantar Flexion in neutral (Pre-Rehab: 3.34±0.87 N/kg, Post-Rehab: 3.93±1.15 N/kg, P=0.002)]. There was no significant group by time interactions or group differences for

any measure except for dorsiflexion, which had a significant group difference, but was due to differences in baseline measures. Inversion, eversion neutral and eversion in a plantar flexion position had large effect sizes, while dorsiflexion and plantar flexion had moderate effect sizes. All means, standard deviations, p-values, and effect-sizes are presented in Table 1.4.

Balance

Static Balance

All static balance measures' means, standard deviations, p-values, and effect sizes are presented in Table 1.5. There was no significant group by time interaction or group main effect for any of the static balance measures. There was a significant decrease in eyes open area (Pre-Rehab: 7.34±2.49 cm^2, Post-Rehab: 6.30±2.19cm^2, p-value=0.037), eyes closed area (Pre-Rehab: 28.09±9.83 cm^2, Post-Rehab: 23.02±7.12 cm^2, p-value=0.047), and eyes closed average velocity (Pre-Rehab: 9.83±2.82cm/s, Post-Rehab: 9.00±2.32cm/s, p-value=0.033) after the combined group completed rehabilitation. There was no pre-post rehabilitation difference in eyes open average velocity. There was a moderate decrease in eyes closed area and a small effect size for eyes open area and eyes closed average velocity.

Dynamic Balance

There was a significant increase in composite reach distances during the SEBT (Pre-Rehab: 75.11±7.82cm, Post-Rehab: 79.11±6.66cm, P=0.003) when comparing combined group's pre to post rehabilitation scores. In addition, there was a significant group difference; however, this is due to the groups being difference at baseline. The no

device group's baseline reach distance of 71.65cm and a post reach distance of 76.61. The device group had a baseline reach distance of 78.57cm and a post distance of 81.60cm. We believe the significant group difference is a result of the nearly 7 cm difference in baseline scores. There was no significant group by time interaction.

Strength sEMG Amplitudes

There were no significant differences in sEMG amplitudes for the anterior tibialis during dorsiflexion or medial gastrocnemius during plantar flexion. There was no significant group by time interactions or group-main effects for the anterior tibialis during inversion, the peroneus brevis and peroneus longus during eversion neutral, and the peroneus brevis and peroneus longus during eversion in the plantar flexion position. However, there was a significant increase in sEMG amplitudes when comparing pre-rehabilitation to post-rehabilitation values for the combined groups [Anterior Tibialis Inversion (Pre-Rehab: 15.37±11.93, Post-Rehab: 25.34±12.23, P=0.004), Peroneus Brevis Eversion Neutral: (Pre-Rehab: 38.59±27.92, Post-Rehab: 53.03±34.95, P=0.026), Peroneus Longus Eversion Neutral: (Pre-Rehab: 26.71±14.70, Post-Rehab: 43.13±29.39, P=0.006), Peroneus Brevis Eversion Plantar Flexion: (Pre-Rehab: 37.72±26.16, Post-Rehab: 55.57±34.14, P=0.011), Peroneus Longus Eversion Plantar Flexion: (Pre-Rehab: 31.94±17.84, Post-Rehab: 45.86±28.25, P=0.012)]. There was a large effect size for the anterior tibialis during inversion and for the peroneus longus during eversion neutral. Furthermore, there were moderate effect sizes for the peroneus brevis during (eversion neutral and eversion plantar flexion), and the peroneus longus during eversion plantar

flexion. All means, standard deviation, p-values, and effect sizes are presented in Table 1.6.

Balance sEMG Amplitudes

There were no significant differences (group by time interaction, group main effect, or time main effect) in sEMG amplitudes of the anterior tibialis, peroneus brevis, peroneus longus, or medial gastrocnemius during single limb eyes open balance, single limb eyes closed balance, or the SEBT composite. There was a moderate effect size that represented an increase in peroneus brevis activation after rehabilitation during the single limb eyes open task. All other effects were trivial to small. All means, standard deviation, p-values and effect sizes can be found in Table 1.7.

DISCUSSION:

Our primary findings of this study were that incorporating ankle destabilization devices into a 4-week progressive rehabilitation program for CAI patients did not have greater changes in self-reported function, ROM, strength, balance, sEMG amplitude during strength and balance measures than a group that did not use the device. However, when the groups were combined, we found that an impairment-based progressive rehabilitation program is effective at improving self-reported function, ROM, strength, and balance in CAI patients.

Ankle Destabilization Devices

Ankle destabilization devices were effective at improving self-reported function, ROM, strength and balance in participants with CAI, however, the use was no more effective than the use of traditional unstable surfaces. It was hypothesized that the

destabilization devices may be more effective at improving clinical outcomes than traditional unstable surfaces because of its ability to isolate and increase the sEMG amplitude of the peroneus longus during functional tasks while wearing the devices.[31-32] However, we found that after 4-weeks of rehabilitation, neither group increased sEMG amplitudes during the balance measures, which shows that the devices were not capable of causing lasting changes in muscle activity (e.g., when the device is removed). We believe the positive change may have occurred because both the destabilization devices and unstable surfaces (foam and Dynadisc^{TM}) were incorporated into functional tasks, such as, lunging, step-ups, and hopping, which made it possible to challenge the individual throughout the entire protocol.

Progressive Rehabilitation

Based on our results when both groups are combined, it is clear that progressive impairment based rehabilitation is effective at increasing self-reported function, dorsiflexion ROM, strength, static and dynamic balance. We believe a key component to our study is that we developed methods to make each exercise more difficult by introducing some instability tool. Based on other studies that only looked at one deficit associated with CAI,[14, 34-42] it appears that an all inclusive rehabilitation program provides an increased improvement in self-reported function.

Self-reported Function

A study completed by Hale et al.[60] completed a 4-week comprehensive rehabilitation program and found that individuals with CAI had improved FADI-Sport (renamed the FAAM-Sport) scores and improved reach distances on the SEBT after

completing the rehabilitation. Their results are similar to ours, except the magnitude of change of for the FAAM-Sport was much higher in our study (20% compared to 11% respectively). We believe this is due to our program being exclusively supervised and from it incorporating unstable surfaces or ankle destabililization devices into the functional exercises. In addition, our program used an impairment based model in our progression of exercises verses starting each participant at the same level. We also found that our progressive rehabilitation protocol had a greater magnitude of change of the FAAM-Sport when compared to a study by McKeon et al.[14] that tested the effects of balance training, and Hoch et al.[42] that examined joint mobilizations (20%, 15% and 15%) respectively. It is of particular interest because we incorporated the same balance training program that McKeon et al.[14] used for their study. We believe this shows that balance training is extremely effective at improving self-reported function; however, by including ROM and strength exercises we are capable of having a greater improvement in self-reported function. It is also important to note that based on our definition of CAI, on average, our participants would no longer qualify as having CAI since their post FAAM-Scores exceeded the 85% inclusion threshold.

Range of Motion

In addition to improvements to self-reported function, we found that standing straight knee and standing bent knee dorsiflexion improved by approximately 4 and 5 degrees respectively. Our ROM improvements are consistent with the finding by Hoch et al.[42] which examined the effects of a 2-week joint mobilization intervention. We also found improvements in the posterior talar glide test PTGT. The PTGT is primarily used

to assess for Arthrokinematic restrictions at the talocrural joint.[35, 61] However, we found no differences in the PTGT when comparing individuals who received joint mobilizations to individuals who did not. Therefore, it remains unclear whether the improvements in dorsiflexion ROM were due to stretching, joint mobilizations or the combination of both.

Strength

We found that ankle dorsiflexion, inversion, eversion neutral, eversion in plantar flexion, and plantar flexion improved after rehabilitation. Our largest improvements were during inversion and the eversion positions. These results are consistent with past findings.[36, 62-63] In addition to increased force production, we found an increase in sEMG amplitudes for the anterior tibialis during inversion and the peroneus longus and peroneus brevis during both eversion positions, which shows that the strength portion of the study was capable of improving motor recruitment of a muscle. Although this finding has not been previously reported in the ankle literature, an increase in neural drive represented by an increase in sEMG amplitudes of the quadriceps has been established after a knee extension strength program.[64]

Balance

After rehabilitation, we found that our rehabilitation program improved both static (eyes open/closed single limb balance) and dynamic balance (SEBT) in our participants. With regards to our static balance measure, we found significant differences with both eyes open and eyes closed single limb balance COP area and eyes closed single limb balance COP average velocity. This is of particular interest because once again, we completed the same protocol and balance data collection procedures as McKeon et al.[14]

which found improvement in balance after doing a time to boundary (TTB) analysis, but did not find changes in COP area or velocity. TTB has been shown to be a reliable method to detect changes in postural control during balance tasks and to be a more sensitive measure than traditional assessments postural control during balance.[65] Therefore, since we were able to show differences in both COP area and COP average velocity, we believe this shows that a comprehensive progressive program is more effective at improving balance than completing a balance program alone. Our SEBT improvements are consistent previous studies.[60]

Surface EMG Amplitude during Static and Dynamic Balance

We found no differences in sEMG amplitude for the anterior tibialis, peroneus brevis, peroneus longus, or medial gastrocnemius during the single limb eyes open/closed tasks or during the SEBT. Recent research has shown that individuals with CAI have decreased sEMG amplitudes in lower leg musculature during static and dynamic balancing tasks, which is thought to contribute balance deficits associated with CAI.[66] However, we found that improvements in static and dynamic balance are possible without having alterations in lower leg muscle activation. We believe balance could improve without changes in muscle activation for multiple reasons. First, we believe an increase in afferent sensory input could have occurred, which would allow the individual to have better awareness of their postural sway during the balance trials and not rely on an increased activation of lower leg muscles. In addition to the potential to increase afferent sensory input, we only measured sEMG of 4 lower extremity muscles during the

balance trials, which suggests that changes in muscle activity may be present in other lower leg muscles or proximal muscles.

Limitations and Future Research

We did not record how hard each individual perceived they were working for each treatment session. However, since no individual ever completed the most difficult exercise for all categories, we believe every participant was consistently challenged throughout the protocol. In addition, the clinician used their clinical judgment and started each participant at a level of the category that was challenging from the beginning and therefore, not all participants started at the same level. We believe this drastically strengthens the study and its external validity because we know we were treating deficits the entire time.

Furthermore, we did not assess for the long-term effects of this rehabilitation program. Therefore, we do not know how long self-reported function, ROM, strength, and balance will stay improved. In addition, we do not know the effects an impairment progressive based rehabilitation program has on recurrent ankle sprains. We hypothesize that these individuals will have a decrease in bouts of instability since balance training has shown to decrease the prevalence of ankle sprains.[41]

Finally, we only quantified the average amount of time each rehabilitation session lasted to show that the total volume was the same between each group. We did not quantify to see if each group progressed through rehabilitation similarly. We believe this would not alter the results because this was an impairment based program and everybody followed the same guidelines before progressing to the next stage of the exercise.

We believe it is important to continue to study individual treatments to assess their overall effectiveness when treating CAI. However, we believe once we establish the best treatments to improve ROM, strength, balance, and functional deficits associated with CAI, we should study the effects of these treatments in conjunction with each other using an impaired based progressive rehabilitation model and determine the long-term effects of the treatment.

CONCLUSION:

Overall, we found that incorporating ankle destabilization devices in an impairment-based progressive rehabilitation program does not improve clinical measures of self-reported function, ROM, strength or balance any more than incorporating traditional unstable surfaces. In addition, we found that a 4-week impairment based progressive rehabilitation program for treatment of CAI is effective at improving self-reported function, ROM, strength and balance. Our findings had greater changes in self-reported function than studies that provided one type of treatment to individuals with CAI. Therefore, we recommend using an impairment based progressive rehabilitation model when treating individuals with CAI that incorporates unstable surfaces during functional exercises.

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TABLES:

TABLE 1.1. Participant Demographics (n=13 per group)

	No Device				Device			
	Minimum	Maximum	Mean	Standard Deviation	Minimum	Maximum	Mean	Standard Deviation
Age	18.0	30.0	21.46	2.88	18.0	28.0	21.31	3.35
Height (cm)	152.40	185.42	169.11	10.61	154.94	181.61	168.81	6.89
Mass (kg)	58.97	102.51	75.33	13.70	48.53	92.08	66.12	12.90
Number of Sprains	1.00	5.00	3.08	1.50	2.00	20.00	6.15	5.37
Last Sprain (months)	3.00	60.00	24.46	22.51	2.00	36.00	10.27	9.82
First Sprain (years)	1.00	15.00	5.58	3.57	1.50	20.00	7.92	5.22
Baseline FAAM-ADL	72.73	95.24	87.65	7.96	75.00	95.24	85.76	7.26
Baseline FAAM-Sport	25.00	84.38	65.87	18.24	43.75	84.38	67.07	13.42
IdFAI	20.00	26.00	22.92	1.71	13.00	30.00	23.23	5.15
Godin Leisure-Time	31.00	81.00	58.77	16.45	48.00	155.00	79.69	31.66
Standing Rear-Foot angle (degrees)	3.00	13.67	5.67	2.93	3.00	6.00	4.15	0.99
Navicular Drop (mm)	3.38	14.47	6.85	3.03	3.85	10.87	6.85	2.30
Anterior Drawer Arthrometer (mm)	2.88	17.57	9.37	4.34	1.72	20.51	11.72	5.15
Inversion Arthrometer (mm)	29.13	57.42	45.67	9.82	34.11	55.69	45.07	7.45
Average Time (minutes) per Rehabilitation Session	56.00	75.73	65.18	4.69	55.13	77.33	66.25	7.98

TABLE 1.2. Self-reported function scores for the no device and device groups and Cohen's d effect sizes with 95% confidence intervals

	No Device Group				Device Group							
	Pre Rehab		Post Rehab		Pre Rehab		Post Rehab		Time-Main Effect	Group-Main Effect	Group*Time Interaction	Pooled Pre-Post Effect Size
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value	P-value	Cohen's d (UL, LL)
FAAM-ADL %	87.65	7.96	95.60	3.31	85.76	7.26	95.97	4.55	<0.001	0.688	0.457	1.21 (0.62,1.80)
FAAM-Sport %	65.87	18.24	86.85	11.39	67.07	13.42	85.82	8.33	<0.001	0.984	0.707	1.27 (0.67,1.86)
SANE-ADL	87.85	11.15	95.08	4.35	83.00	20.49	94.54	8.41	0.006	0.491	0.493	0.57 (0.02,1.13)
SANE-Sport	72.62	20.89	90.23	8.35	73.77	16.14	89.00	10.54	<0.001	0.994	0.712	0.90 (0.33,1.47)
Global Rating of Change	____	____	4.77	1.42	____	____	4.46	1.94	____	0.649	____	____

Rehab=Rehabilitation, SD=Standard Deviation, UL=Upper Limit, LL=Lower Limit

Effect sizes were calculated comparing pooled group's pre and post scores where a positive effect size denotes an increase in self-reported function after rehabilitation.

TABLE 1.3. Range of motion in degrees for the no device and device groups and Cohen's d effect sizes with 95% confidence intervals

	No Device Group				Device Group							
	Pre Rehab		Post Rehab		Pre Rehab		Post Rehab		Time-Main Effect	Group-Main Effect	Group*Time Interaction	Pooled Pre-Post Effect Size
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value	P-value	Cohen's d (UL, LL)
Standing Straight Leg Dorsiflexion	34.15	10.38	38.31	7.99	42.08	6.98	47.31	6.96	0.022	0.003	0.782	0.49 (-0.06,1.04)
Standing Bent Knee Dorsiflexion	38.08	11.12	43.46	10.68	46.38	7.12	51.08	7.38	0.001	0.026	0.806	0.50 (-0.05,1.04)
Posterior Talar Glide	9.10	8.71	14.49	9.77	15.41	8.56	17.05	5.08	0.023	0.137	0.208	0.39 (-0.16,0.94)
Seated Plantar Flexion	64.00	9.70	67.38	10.65	64.62	7.18	67.85	5.67	0.003	0.868	0.939	0.40 (-0.15,0.94)
Seated Inversion	32.67	10.42	34.69	8.51	36.92	7.43	35.85	8.16	0.724	0.398	0.254	0.05 (-0.49,0.60)
Seated Eversion	14.31	7.45	18.69	6.10	15.92	6.30	16.85	5.89	0.111	0.954	0.292	0.39 (-0.16,0.94)

Rehab=Rehabilitation, SD=Standard Deviation, UL=Upper Limit, LL=Lower Limit

Effect sizes were calculated comparing pooled group's pre and post scores where a positive effect size denotes an increase in range of motion after rehabilitation.

TABLE 1.4. Strength normalized to mass (N/kg) for the no device and device groups and Cohen's d effect sizes with 95% confidence intervals

	No Device Group				Device Group							
	Pre Rehab		Post Rehab		Pre Rehab		Post Rehab		Time-Main Effect	Group-Main Effect	Group*Time Interaction	Pooled Pre-Post Effect Size
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value	P-value	Cohen's d (UL, LL)
Dorsiflexion	1.62	0.32	1.83	0.37	1.98	0.60	2.42	0.68	<0.001	0.018	0.122	0.64 (0.08,1.19)
Inversion	1.32	0.28	1.72	0.41	1.49	0.34	1.93	0.46	<0.001	0.173	0.767	1.33 (0.73,1.93)
Eversion Neutral	1.61	0.44	1.96	0.49	1.68	0.34	2.19	0.48	<0.001	0.364	0.227	1.12 (0.54,1.71)
Eversion Plantar Flexion	1.34	0.32	1.66	0.43	1.48	0.33	1.83	0.44	<0.001	0.235	0.888	1.01 (0.43,1.59)
Plantar Flexion	3.10	0.86	3.48	0.98	3.58	0.85	4.38	1.17	0.002	0.055	0.237	0.68 (0.12,1.24)

Rehab=Rehabilitation, SD=Standard Deviation, UL=Upper Limit, LL=Lower Limit

Effect sizes were calculated comparing pooled group's pre and post scores where a positive effect size denotes an increase in strength after rehabilitation.

TABLE 1.5. Static and dynamic balance for the no device and device groups and Cohen's d effect sizes with 95% confidence intervals

	No Device Group				Device Group							
	Pre Rehab		Post Rehab		Pre Rehab		Post Rehab		Time-Main Effect	Group-Main Effect	Group*Time Interaction	Pooled Pre-Post Effect Size
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value	P-value	Cohen's d (UL, LL)
Eyes Open Single Limb Balance Area	7.23	2.70	5.75	1.78	7.44	2.37	6.85	2.48	0.037	0.420	0.355	-0.42 (-0.97,0.13)
Eyes Open Single Limb Balance Velocity	4.26	1.26	3.85	0.89	4.51	1.70	4.51	1.44	0.383	0.353	0.388	-0.14 (-0.68,0.41)
Eyes Closed Single Limb Area	29.71	10.18	24.36	8.55	26.44	9.63	21.79	5.57	0.047	0.256	0.883	-0.51 (-1.07.0.06)
Eyes Closed Single Limb Velocity	9.96	2.99	8.91	2.41	9.71	2.77	9.08	2.33	0.033	0.970	0.579	-0.30 (-0.85,0.26)
SEBT Composite Score %	71.65	8.07	76.61	7.42	78.57	6.03	81.60	4.88	0.003	0.018	0.430	0.51 (-0.04,1.06)

Rehab=Rehabilitation, SD=Standard Deviation, UL=Upper Limit, LL=Lower Limit, SEBT= Star Excursion Balance Test
Effect sizes were calculated comparing pooled group's pre and post scores where a negative effect size denotes an increase in static balance after rehabilitation and a positive effect size denotes an increase in reach distance for the SEBT.

TABLE 1.6. Surface EMG amplitudes normalized to quiet resting during maximum voluntary isometric contractions for the no device and device groups and Cohen's d effect sizes with 95% confidence intervals

	No Device Group				Device Group							
	Pre Rehab		Post Rehab		Pre Rehab		Post Rehab		Time-Main Effect	Group-Main Effect	Group*Time Interaction	Pooled Pre-Post Effect Size
Motion and Muscle	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value	P-value	Cohen's d (UL, LL)
Dorsiflexion Anterior Tibialis	40.71	24.50	55.28	20.50	52.82	22.27	53.19	13.37	0.098	0.469	0.114	0.31 (-0.23,0.86)
Inversion Anterior Tibialis	13.17	9.17	27.82	11.69	17.56	14.21	22.87	12.72	0.004	0.939	0.145	0.84 (0.27,1.40)
Eversion Neutral Peroneus Brevis	36.15	29.70	48.05	30.52	41.04	26.99	58.01	39.50	0.026	0.506	0.680	0.52 (-0.04,1.07)
Eversion Neutral Peroneus Longus	28.79	17.77	39.11	19.38	24.62	11.17	47.14	37.27	0.006	0.797	0.276	1.12 (0.53,1.70)
Eversion Plantar Flexion Peroneus Brevis	33.25	30.20	49.11	26.97	42.20	21.69	62.02	40.14	0.011	0.288	0.762	0.68 (0.12,1.24)
Eversion Plantar Flexion Peroneus Longus	33.03	20.93	42.79	22.95	30.85	14.91	48.92	33.41	0.012	0.804	0.427	0.78 (0.22,1.34)
Plantar Flexion Medial Gastrocnemius	18.48	13.35	19.95	11.74	25.70	10.44	27.41	10.97	0.525	0.069	0.962	0.13 (-0.41,0.67)

Rehab=Rehabilitation, SD=Standard Deviation, UL=Upper Limit, LL=Lower Limit

Effect sizes were calculated comparing pooled group's pre and post scores where a positive effect size denotes an increase in sEMG amplitudes during maximum voluntary isometric contractions.

TABLE 1.7. Surface EMG amplitudes normalized to quiet resting during static and dynamic balance for the no device and device groups and Cohen's d effect sizes with 95% confidence intervals

Task and Muscle	No Device Group				Device Group				Time-Main Effect	Group-Main Effect	Group*Time Interaction	Pooled Pre-Post Effect Size
	Pre Rehab		Post Rehab		Pre Rehab		Post Rehab					
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value	P-value	Cohen's d (UL, LL)
Single Limb Eyes Open Anterior Tibialis	9.83	7.18	8.83	6.51	11.79	8.36	8.86	5.81	0.163	0.690	0.485	-0.26 (-0.82,0.30)
Single Limb Eyes Closed Anterior Tibialis	15.16	8.65	19.93	9.96	22.57	11.60	19.41	8.05	0.719	0.290	0.086	0.06 (-0.49,0.61)
Single Limb Eyes Open Peroneus Brevis	8.22	6.45	13.55	13.64	7.99	5.16	9.74	4.63	0.164	0.358	0.475	0.61 (0.04,1.18)
Single Limb Eyes Closed Peroneus Brevis	19.62	13.06	27.69	18.84	20.37	10.32	17.86	9.60	0.422	0.281	0.133	0.22 (-0.33,0.78)
Single Limb Eyes Open Peroneus Longus	11.84	4.20	12.06	7.42	10.84	4.27	14.46	12.53	0.302	0.792	0.359	0.47 (-0.09,1.04)
Single Limb Eyes Closed Peroneus Longus	24.35	11.98	25.04	13.37	17.53	7.40	19.44	11.62	0.614	0.109	0.814	0.13 (-0.43,0.68)
Single Limb Eyes Open Medial Gastrocnemius	10.08	7.33	7.47	3.36	17.45	8.68	16.32	12.36	0.362	0.009	0.716	-0.21 (-0.77,0.35)
Single Limb Eyes Closed Medial Gastrocnemius	14.49	9.33	9.18	3.90	23.35	12.07	20.14	16.61	0.144	0.013	0.711	-0.37 (-0.92,0.19)
SEBT Composite Anterior Tibialis	5.35	3.14	6.63	4.05	7.84	3.71	7.62	4.28	0.349	0.223	0.187	0.15 (-0.40,0.69)
SEBT Composite Peroneus Brevis	2.95	2.49	6.15	6.17	5.53	11.46	4.23	6.13	0.425	0.902	0.066	0.12 (-0.43,0.66)
SEBT Composite Peroneus Longus	3.85	3.18	6.72	10.40	4.88	7.14	3.78	5.21	0.552	0.685	0.189	0.16 (-0.38,0.71)
SEBT Composite Medial Gastrocnemius	1.28	1.00	1.78	2.13	5.36	10.04	2.56	3.75	0.452	0.126	0.285	-0.16 (-0.70,0.39)

Rehab=Rehabilitation, SD=Standard Deviation, UL=Upper Limit, LL=Lower Limit, SEBT= Star Excursion Balance Test. Effect sizes were calculated comparing pooled group's pre and post scores where a positive effect size denotes an increase in sEMG amplitudes during single limb balance and the SEBT

FIGURES:

Figure 1.1. Myolux Athletik (top) and Myolux II (bottom)

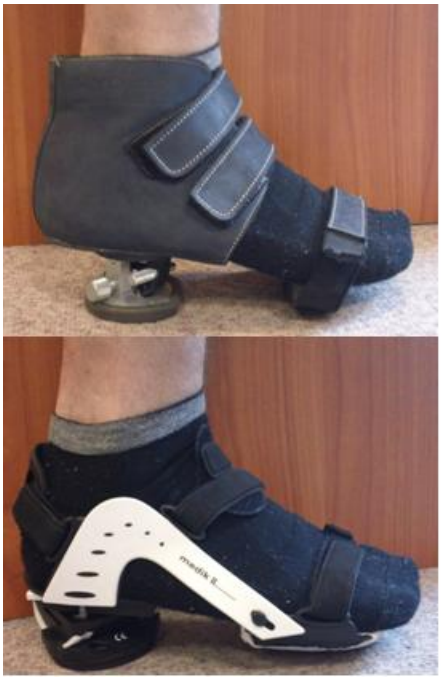


Figure 1.2.

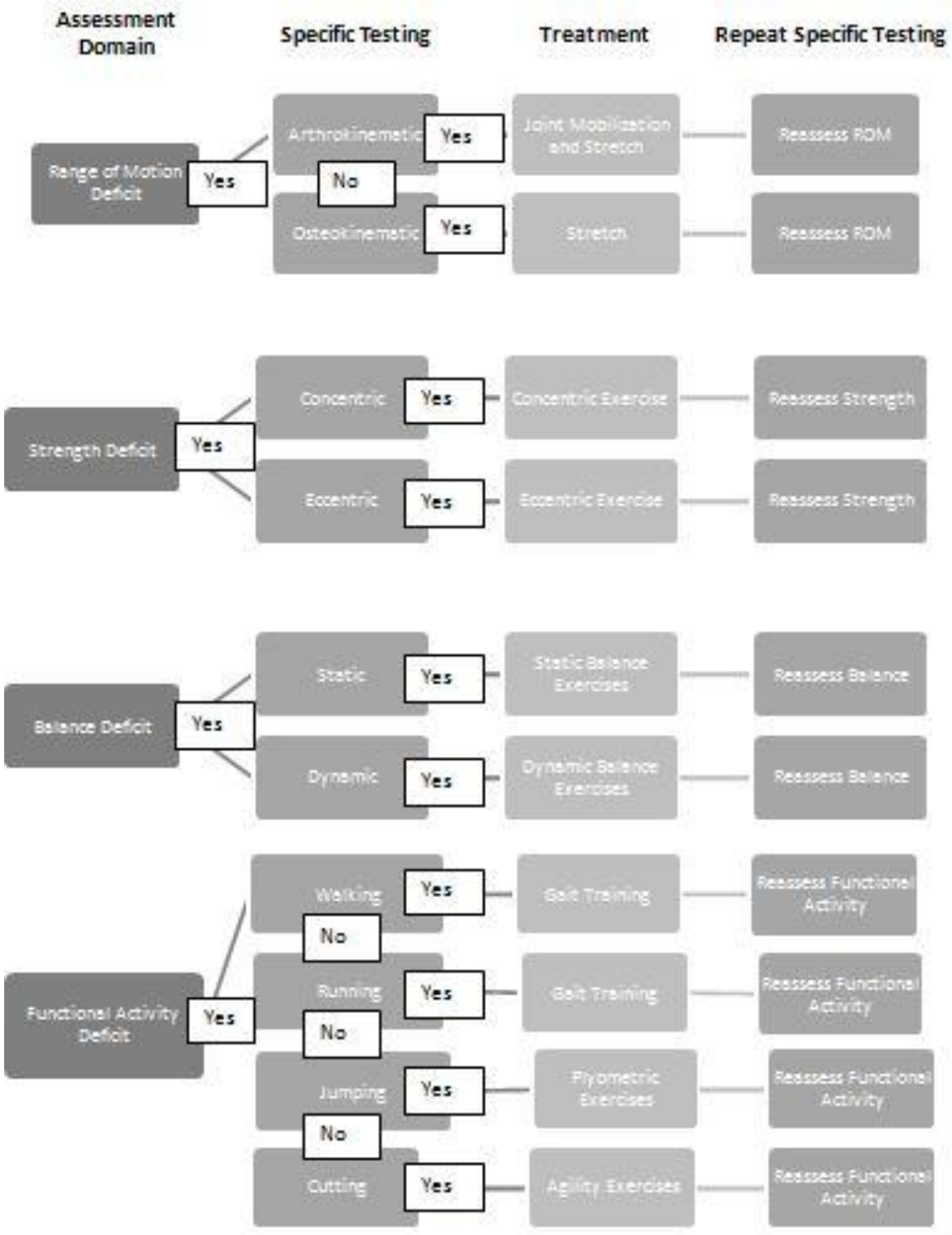

Assessment Domain
Specific Testing
Treatment
Repeat Specific Testing
Range of Motion Deficit
Yes
Arthrokinematic
Yes
Joint Mobilization and Stretch
Reassess ROM
No
Osteokinematic
Yes
Stretch
Reassess ROM
Strength Deficit
Yes
Concentric
Yes
Concentric Exercise
Reassess Strength
Eccentric
Yes
Eccentric Exercise
Reassess Strength
Balance Deficit
Yes
Static
Yes
Static Balance Exercises
Reassess Balance
Dynamic
Yes
Dynamic Balance Exercises
Reassess Balance
Functional Activity Deficit
Yes
Walking
Yes
Gait Training
Reassess Functional Activity
No
Running
Yes
Gait Training
Reassess Functional Activity
No
Jumping
Yes
Plyometric Exercises
Reassess Functional Activity
No
Cutting
Yes
Agility Exercises
Reassess Functional Activity

Figure 1.3.

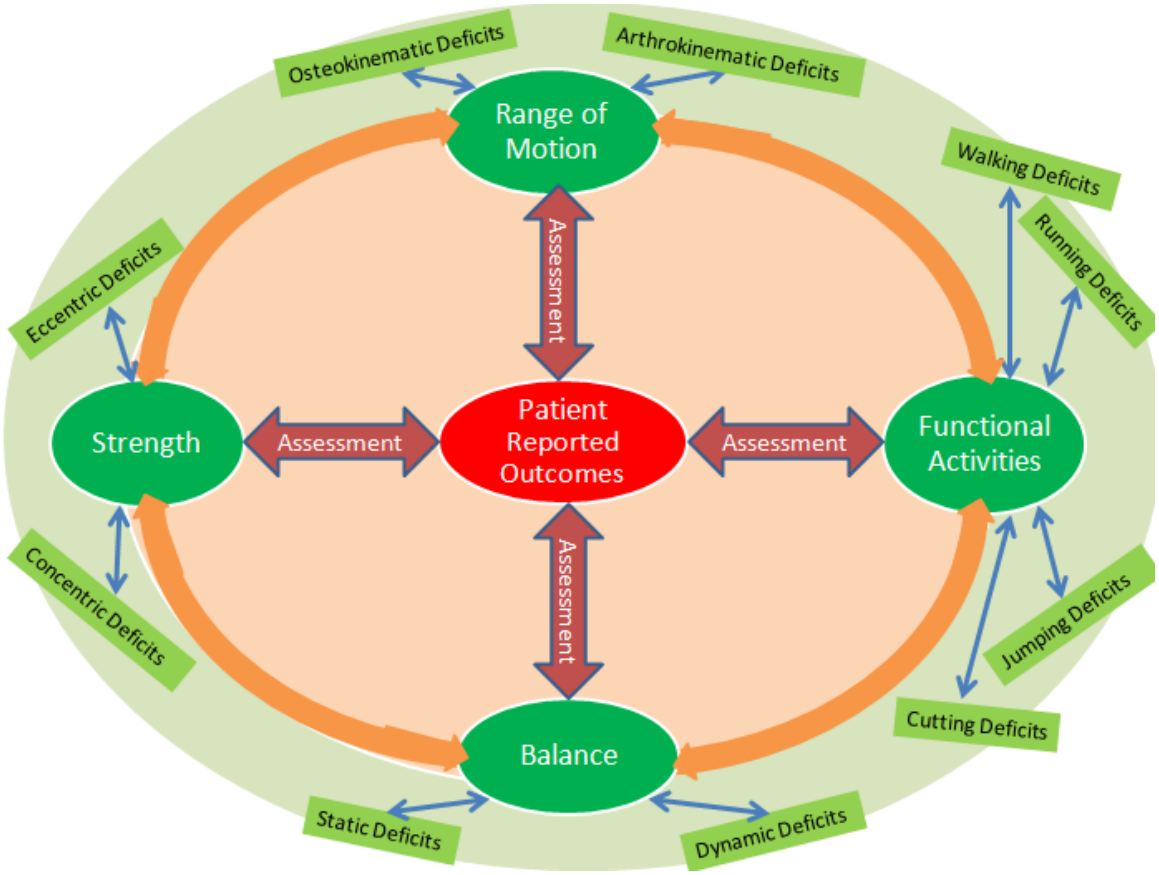
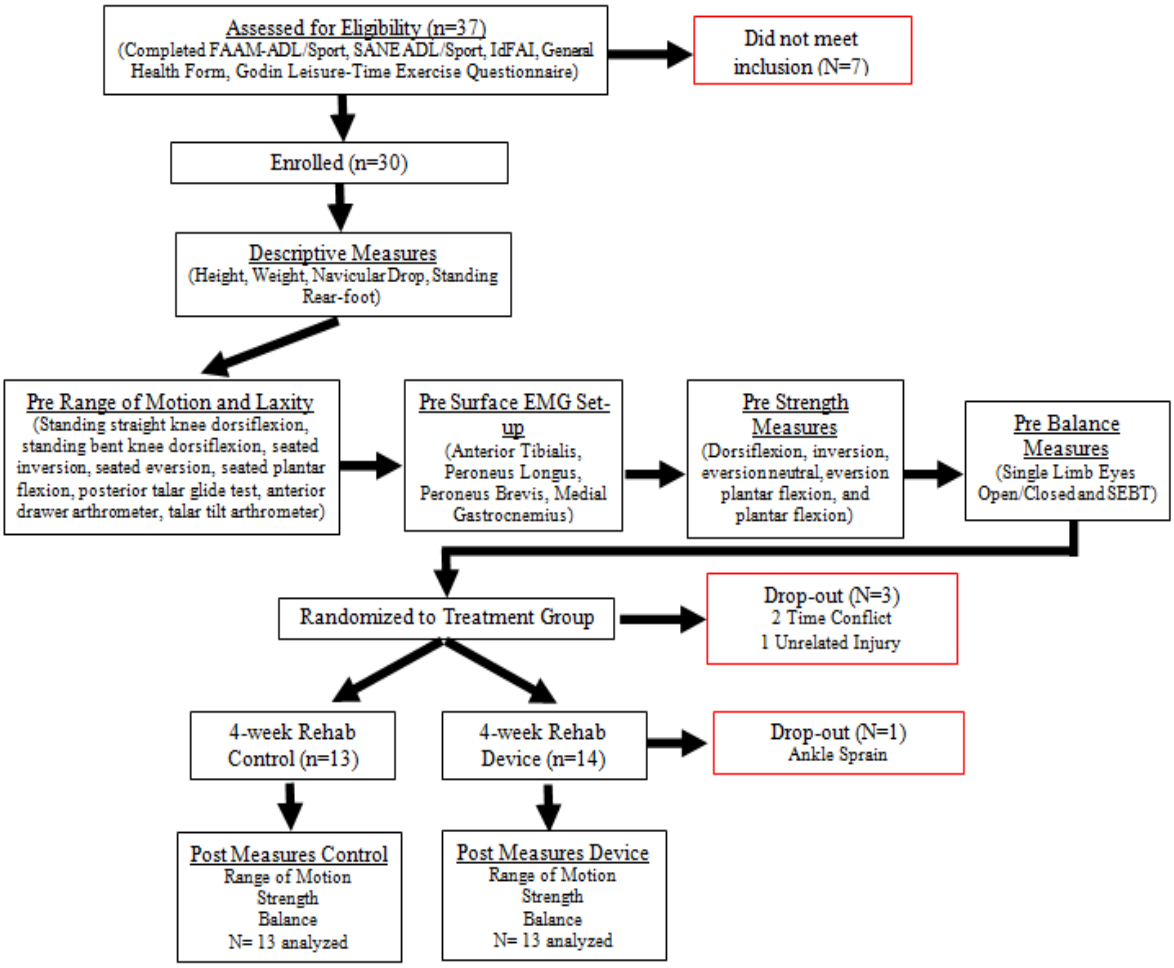

Osteokinematic Deficits
Arthrokinematic Deficits
Range of Motion
Walking Deficits
Running Deficits
Eccentric Deficits
Assessment
Strength
Assessment
Patient Reported Outcomes
Assessment
Functional Activities
Concentric Deficits
Assessment
Jumping Deficits
Cutting Deficits
Balance
Static Deficits
Dynamic Deficits

Figure 1.4.


Assessed for Eligibility (n=37)
(Completed FAAM-ADL/Sport, SANE ADL/Sport, IdFAI, General Health Form, Godin Leisure-Time Exercise Questionnaire)
Did not meet inclusion (N=7)
Enrolled (n=30)
Descriptive Measures
(Height, Weight, Navicular Drop, Standing Rear-foot)
Pre Range of Motion and Laxity
(Standing straight knee dorsiflexion, standing bent knee dorsiflexion, seated inversion, seated eversion, seated plantar flexion, posterior talar glide test, anterior drawer arthrometer, talar tilt arthrometer)
Pre Surface EMG Set-up
(Anterior Tibialis, Peroneus Longus, Peroneus Brevis, Medial Gastrocnemius)
Pre Strength Measures
(Dorsiflexion, inversion, eversion neutral, eversion plantar flexion, and plantar flexion)
Pre Balance Measures
(Single Limb Eyes Open/Closed and SEBT)
Randomized to Treatment Group
Drop-out (N=3)
2 Time Conflict
1 Unrelated Injury
4-week Rehab Control (n=13)
4-week Rehab Device (n=14)
Drop-out (N=1)
Ankle Sprain
Post Measures Control
Range of Motion
Strength
Balance
N= 13 analyzed
Post Measures Device
Range of Motion
Strength
Balance
N= 13 analyzed

Appendix 1. Rehabilitation protocol for the no device and device group.

Range of Motion

Arthrokinematic restriction present? If yes, list joints:

Joint Mobilization Type/Grade	Sets	Duration (minutes)

Stretching exercises:

Stretch Position	Sets	Duration (seconds)
Seated Straight Knee		
Seated Bent Knee		
Standing Straight Knee		
Standing Bent Knee		

Strength

Exercise (circle appropriate)	Sets	Repetitions
Double legged/Single legged heel raises		
Double legged/Single legged forefoot raises		
4-way manual resistance		
D1/D2 PNF		
4-way walks		
Short Foot Progression		

Balance

Static Balance (circle appropriate phase) Goal 3x30 seconds	Sets	Duration (seconds)
1. Eyes Open Single leg balance		
2. Eyes Open Single leg balance on a (foam or ankle destabilization sandal)		
3. Eyes Open Single leg balance on (Dynadisc™ or ankle destabilization boot)		
Eyes Closed Progression		
1. Eyes Closed Single leg balance		
2. Eyes Closed Single leg balance on a (foam or ankle destabilization sandal)		
3. Eyes Closed Single leg balance on (Dynadisc™ or ankle destabilization boot)		

Reach Tasks (circle appropriate phase) Goal 2x10 each direction	Sets	Repetitions
1.Completing the exercise standing on a firm surface		

2. Completing the exercise on (foam or ankle destabilization sandal)		
3. Completing the exercise standing on (Dynadisc™ or ankle destabilization boot)		

Hop to Stabilization (circle appropriate phase) Goal is 10 consecutive trials	Repetitions Completed
1. 18 inch hop with arm assistance	
2. 18 inch hop with hands on hips	
3. 27 inch hop with arm assistance	
4. 27 inch hop with hands on hips	
5. 36 inch hop with arm assistance	
6. 36 inch hop with hands on hips	
Hops with (foam or ankle destabilization boot)	
1. 18 inch hop with arm assistance while jumping on to a (foam or ankle destabilization boot)	
2. 18 inch hop with hands on hips while jumping onto a (foam or ankle destabilization boot)	
3. 27 inch hop with arm assistance while jumping onto a (foam or ankle destabilization boot)	
4. 27 inch hop with hands on hips while jumping onto a (foam or ankle destabilization boot)	

5. 36 inch hop with arm assistance while jumping onto a (foam or ankle destabilization boot)	
6. 36 inch hop with hands on hips while jumping onto a (foam or ankle destabilization boot)	

Functional Exercises

Lunges (circle appropriate phase) Goal is 2x10 each leg	Sets	Repetitions
1.Complete lunges on a firm surface		
2.Complete lunges with (foam or wearing ankle destabilization sandal) beneath stance leg and lunge on top another (foam or wearing ankle destabilization sandal)		
3.Complete lunges with (Dynadisc™ or wearing ankle destabilization boot) beneath the stance leg and lunge on top another (Dynadisc™ or wearing ankle destabilization boot)		

Forward Step-ups and Step-downs (circle appropriate phase) Goals is 3x10	Sets	Repetitions

1. Step on and off a box		
2. Step on and off a box (foam or ankle destabilization sandal) on top and beneath it		
3. Step on and off a box (Dynadisc™ or ankle destabilization boot) on top and beneath		

Lateral Step-ups and Step-downs (circle appropriate phase) Goal is 3x10	Sets	Repetitions
1. Step on and off a box		
2. Step on and off a box (foam or ankle destabilization sandal) on top and beneath it		
3. Step on and off a box (Dynadisc™ or ankle destabilization boot) on top and beneath it		

Dot Jumping Drill (circle appropriate phase) Goal is 3x30seconds	Sets	Duration (seconds)
1. Double legged lateral to medial hops, double legged		

anterior to posterior jumps, double legged figure 8 jumps (shod or ankle destabilization boot)		
2. Single legged lateral to medial jumps, single legged anterior to posterior jumps, and single legged figure 8 jumps (shod or ankle destabilization boot)		

Walking (Condition)	Time	Speed

SECTION II: MANUSCRIPT II

EFFECTS OF ANKLE DESTABILIZATION DEVICES IN REHABILITATION ON GAIT MEASURES IN CHRONIC ANKLE INSTABILITY PATIENTS: A RANDOMIZED CONTROLLED TRIAL

ABSTRACT

Context: Individuals with chronic ankle instability (CAI) have altered gait patterns, which is characterized by increased inversion positioning during mid-swing through the stance phase of gait. Ankle destabilization devices may improve neuromuscular control by increasing lower extremity muscle activation, which may improve gait patterns. **Objective:** To determine whether a 4-week impairment based rehabilitation program that includes ankle destabilization devices (device group) had beneficial effects on ankle, knee, hip sagittal and frontal plane kinematics, kinetics, and surface electromyography (sEMG) of lower leg muscles during gait compared to impairment based rehabilitation without destabilization devices (no device group) in CAI patients. **Design:** Single-blinded randomized controlled trial. **Setting:** Athletic training laboratory. **Patients or Other Participants:** Twenty-six participants (age=21.34, sex=(M=7,F=19), height=168.96cm, weight=70.73kg) participated in a randomized controlled trial. **Intervention(s):** Participants completed baseline self-reported function questionnaires and walking gait trials and were randomized into no device and device groups. Both groups completed 4-weeks of supervised rehabilitation with or without destabilization devices and then repeated the questionnaires and walking trials. **Main Outcome Measures:** Ankle, knee, and hip sagittal and frontal plane kinematics and kinetics and sEMG activity for lower leg muscles. For each measure, group means and 90% confidence intervals for each condition were calculated across the entire gait cycle and areas where confidence intervals did not overlap were considered significantly different. **Results:** The device group had significantly more dorsiflexion during mid to late stance phase (45-64%) after

rehabilitation. In addition, the device group had lower sEMG activation for the peroneus longus during early stance (4-7%) and mid-swing (73-76%) phases after rehabilitation. The no device group had significantly less sEMG activation of the peroneus brevis during earlier stance (4-13%) after rehabilitation. There was no difference pre to post rehabilitation for all other ankle, knee, hip kinematics, kinetics, and sEMG for either group or when the groups were combined. **Conclusion:** Incorporating ankle destabilization devices in a 4-week rehabilitation program is an effective method of improving dorsiflexion during the stance phase of gait. However, progressive rehabilitation is not effective at improving frontal plane motion during gait. Other gait training techniques need to be developed to improve gait patterns associated with CAI.

Word Count: 347

Key Words: Neuromuscular control, Self-reported Function, Surface electromyography

INTRODUCTION:

Lateral ankle sprains have been determined to be one of the most common musculoskeletal injuries to occur in people who participate in athletics[1-2] and recreational activity.[3] Recurrence rates have been estimated to be as high as 70% after an isolated ankle sprain.[67] Furthermore, it is estimated that approximately 30% percent of people who suffer from an ankle sprain will continue to have symptoms that last greater than 1 year after their initial sprain.[5] Symptoms of repetitive ankle sprains and episodes of instability that occurs greater than one year after an initial ankle sprain has been termed chronic ankle instability (CAI).[6] Many characteristics of CAI have been described, although the cause of CAI still remains unclear. These characteristics include impaired proprioception,[7-11] decreased neuromuscular control,[12-16] decreased range of motion (ROM),[17-19] decreased strength,[7, 12, 20] and altered gait.[21-25]

With regards to gait, CAI patients show greater ankle inversion positioning during late swing through early stance phase and spend a longer time on the lateral aspect of the foot during the stance phase, which may predispose them to recurrent ankle sprains.[21-22, 68] Furthermore, individuals demonstrate decreased foot clearance during the swing phase, which is a result of decreased dorsiflexion.[24] It has been hypothesized that these alterations could be a result of mechanical changes of the lateral ankle after injury,[69-70] a change in pre-programmed motor response,[12, 25] a decrease in the ability to detect this pathological position,[12] or a combination of both mechanical and sensoriomotor deficits associated with CAI. Ankle destabilization devices have been developed to improve the faulty motor response and detection of increased inversion associated with CAI by

implementing a feed-forward mechanism in response to an anticipated bout of instability.[29]

Ankle destabilization devices have not been well defined, but for this project we will operationally define them as devices that consist of either a boot or sandal with an articulator below the heel designed to mimic the motion that occurs at both the subtalar and talocrural joints during walking. The articulator forces the patient into plantar flexion, inversion, and internal rotation in a controlled manner. These devices are unique because they can be used during functional exercises. It is thought that by causing an anticipated perturbation at the ankle, surrounding musculature will contract via feed-forward mechanisms to prevent the ankle from going into the vulnerable hypervinverted position.[29-31] Furthermore, it is thought that if appropriately implemented into a rehabilitation program, the devices have potential to provide long-term changes to a patient's gait.[29]

Studies on two specific ankle destabilization devices, the Myolux Athletik (boot) and Myolux II (sandal) (Cevres Santé, Le Bourget-du-Lac, France)(Figure 2.1) found a pronounced increase in the peroneus longus surface electromyography (sEMG) amplitude prior to initial contact while individuals with CAI wore the device during treadmill walking.[31] This shows the potential for these devices to increase activation of the peroneus longus prior to initial contact, which may provide more stability to the ankle joint by keeping the ankle out of the inverted position in late swing. As the devices caused alterations prior to initial contact, it shows their ability to cause a feed-forward response mechanism that may be learned over time if implemented into a rehabilitation

program for CAI. Therefore, the purpose of this study is to determine whether incorporating ankle destabilization devices in an impairment based 4-week rehabilitation program improves ankle, knee, and hip kinematics, kinetics, and lower leg sEMG measures when compared to a no device group. We hypothesize that the device group will have greater reduction in inversion motion, inversion moments and an increase in sEMG activation of the peroneus brevis and peroneus longus during gait.

METHODS:

Study Design: We performed a single-blinded randomized clinical trial comparing 4 weeks of supervised impairment based progressive rehabilitation with (device group) and without ankle destabilization (no device group) on frontal and sagittal plane ankle, knee, and hip kinematics and kinetics and sEMG activity (anterior tibialis, peroneus brevis, peroneus longus, and medial gastrocnemius) in young adults with CAI. All procedures were approved by the Institution's investigational review board prior to enrolling participants. We used the same participants and rehabilitation program as manuscript 1.

Participants: Twenty-six young adults (age=21.34, sex=(M=7,F=19), height=168.96cm, weight=70.73kg) with CAI were recruited from a University setting and surrounding community to participate in this study. Participants were classified as having CAI if they had a history of more than one ankle sprain with the initial sprain occurring greater than one year ago, current self reported functional deficits due to ankle symptoms that was qualified by a score of <85% on the Foot and Ankle Ability Measure (FAAM) Sport scale and a ≥10 on the Identification of Functional Instability scale (IdFAI).[44] Participants were excluded if they had an ankle fracture, ankle surgery, an ankle sprain within the

past 6 weeks, or any other current lower extremity pathology.[44] Participant demographics are presented in Table 2.1. There were no between group differences in participant demographics.

Instruments:

Ankle Destabilization Devices

The Myolux Athletik and Myolux II (Cevres Santé, Le Bourget-du-Lac, France) were the destabilization devices used in the device group. Both of these devices have been shown to cause an increase in peroneus longus sEMG amplitudes during functional tasks.[31] The Myolux Athletik consists of a half boot with an articulator beneath the calcaneus that allows for approximately 45 degrees of combined inversion, internal rotation and plantar flexion verses the Myolux II, which is a full length sandal that allows for about 30 degrees of motion. Both devices were used in the device group of this study.

Motion Capture System

Three-dimensional joint kinematics of the ankle, knee, and hip were measured using the *TrackSTAR* (Ascension Technologies, Inc., Burlington, Vermont) electromagnetic motion analysis system controlled by Motion Monitor software (Version 8, Innovative Sports Training, Inc., Chicago, Illinois) at a sampling rate of 144 Hz. A non-conductive forceplate (Bertec Corporation, Columbus, Ohio) with a sampling rate of 1440 Hz was embedded into a walk-way and synchronized with the electromagnetic tracking device and used to collect ground reaction forces and for determination of initial contact and terminal stance during walking trials.

Surface Electromyography

Surface EMG was measured using rectangular DE 2.1 differential EMG sensors (Delsys, Boston, MA). The sensors consisted of two 1mm parallel bars separated by about 1 cm and were placed over the middle portion of the muscle belly parallel to muscle fiber orientation. The signal was amplified with a gain of 1000 and digitized with a 4 channel acquisition system (Bagnoli EMG system, Delsys, Boston, MA) at 1000 Hz. Input impedance was $>10^{15}\Omega//0.2pF$ with a signal to noise ratio of 1.2uV. Data was collected and processed using Motion Monitor software (Innovative Sports Training, Inc., Chicago, Illinois).

Participant Set-Up:

Surface EMG electrodes were placed over the anterior tibialis, peroneus brevis, peroneus longus and medial gastrocnemius after the skin had been properly prepped.[45] Electrode placement was visually analyzed for cross-talk by individually manual muscle testing each muscle. Next, 10 electromagnetic sensors (4 each limb) were placed on the participant's (posterior calcaneus, dorsal aspect of the first metatarsal, lateral mid-shank, lateral mid-thigh, the base of the sacrum , and the 12^{th} vertebrae of the thoracic spine) using double-sided tape and secured with Leuokotape® and elastic wraps to minimize movement. With regards to the calcaneus sensors, holes were cut from the shoes to ensure these sensors could be placed directly on the skin.[71] An 11^{th} moveable sensor was attached to a stylus and used to for digitization of each joint. Digitization of the segments and joints were completed by pointing out proximal and distal longitudinal landmarks and proximal and distal horizontal landmarks using the stylus. Specific landmarks were: right/left ASIS, cervical spine vertebrae 7, thoracic spine vertebrae 12, lumbar spine

vertebrae 5, right/left medial knee joint line, right/left lateral knee joint line, right/left medial malleolus, right/left lateral malleolus, and right/left 2nd toe.

Procedures:

Participants provided informed consent and completed the subjective ankle questionnaires. Each participant was fitted in a neutral shoe (Brooks Defyance, Seattle, WA) and were then set-up with the sEMG electrodes and the electromagnetic tracking sensors as previously described. Next, participants were instructed to walk across the walk-way at their normal pace. The investigator altered their starting place to ensure their involved limb landed on the forceplate for each trial. Once the participant felt that they were walking normally and were consistently stepping on the forceplate each trial, they completed 15 separate walking trials across the 6 meter walk-way. After the 15 trials were recorded; participants were instructed to return to the lab 2 days later for their first rehabilitation session. At this time, they were randomly assigned either the no device or device group via concealed enveloped method. Participants completed 12 rehabilitation sessions over 4-weeks. After they completed the program, they returned to the lab 2 to 7 days later and repeated the gait trials as previously described. The investigator who completed data collected was blinded to group assignment throughout data collection and data reduction.

Rehabilitation Program:

All rehabilitation was directly supervised and progressed by a Certified Athletic Trainer (ATC). On average, all sessions took the same amount of time to complete for both groups. The rehabilitation program was created based on our recommendations of a

new rehabilitation paradigm for treatment of patients with CAI.[27] The rehabilitation program for both groups consisted of exercises that address deficits in range of motion (ROM), strength, balance, and functional activity. The ATC used clinical judgment for initial intensity of each exercise and progressed them to the next exercise after they could successfully meet our pre-established progression criteria. A detailed description of the exercises and progression can be found in manuscript 1 and Appendix 1. The no device group incorporated traditional unstable surfaces such as foam pads and Dynadiscs™ during the balance and functional exercises, while the device group incorporated both ankle destabilization devices during the balance and functional exercises. In addition, the device group used the ankle destabilization devices during treadmill walking, while the no device group completed shod treadmill walking. The treadmill walking portion of the rehabilitation program was match for time between each group.

Data Reduction

Surface EMG

Data was filtered using a 10-500 band-pass filter and smoothed using a 50-sample moving window root mean square (RMS) algorithm as recommended by Konrad et al.[45] In addition, notch filters were automatically applied to each sensor using the Motion Monitor software as recommended by Pidcoe,[72] to account for noise generated by the electromagnetic field. Data for each muscle was normalized to the corresponding muscle during quiet standing.

Kinematics and Kinetics

The axes system was created so the following motions (dorsiflexion flexion/flexion, inversion/adduction) and the following internal moments (plantar flexion/extension, eversion/adduction) are positive regardless of limb side. The kinematic data were filtered with a low-pass 4th-order, Butterworth filter at a cut-off frequency of 14.5 Hz.[73] Euler rotation method (Y, X, Z) or (flexion/extension, adduction/abduction, internal/external rotation) was used to calculate ankle, knee, and hip joint rotations. Vertical ground reaction force (vGRF) (N) was normalized to each participant's body mass (kg) and internal joint moments (N*m/kg) were normalized to the participants height and mass.[74]

Using the Motion Monitor software, the 15 stride cycles of the involved limb were re-sampled to 100 frames so that each frame represents one percent of the stride cycle. One complete stride cycle was the time between one heel strike until the next heel strike of the same foot occurs. This was completed for all ankle, knee, and hip kinematics and kinetics and for the normalized sEMG activity of the anterior tibialis, peroneus brevis, peroneus longus, and medial gastrocnemius. This data reduction technique has been well reported using other software programs.[43, 71]

Statistical Analysis:

For the dependent variables ankle, knee, and hip frontal and sagittal kinematics and for sEMG activity of the anterior tibialis, peroneus brevis, peroneus longus, and medial gastrocnemius, group means and associated 90% confidence intervals (CIs) were calculated across all 100 points of the gait cycle. A times series CI analysis was performed across the entire gait cycle to determine any increments where the CIs do not

overlap between the two groups (pre and post rehabilitation) and the pooled group (pre and post rehabilitation). If CIs do not overlap for at least 3 consecutive time increments, those increments in the gait cycle were considered statistically significant.[17, 21, 43]

RESULTS:

Frontal plane kinematics, kinetics, and sEMG activity (Peroneus Brevis/Peroneus Longus)

There were no significant differences in ankle, knee, and hip frontal plane kinematics and kinetics for the device, no device, and pooled groups (Figures 2.2-2.4) comparing pre to post rehabilitation. There was a significant pre-post decrease in peroneus brevis sEMG activation during early stance (4-13%) in the no device group (1.3) after rehabilitation. In addition, after rehabilitation, there was a significant decrease in peroneus longus sEMG activity during early stance (4-7%) and mid-swing (73-76%) for the device group.

Sagittal plane kinematics, kinetics, and sEMG activity (Anterior Tibialis/Medial Gastrocnemius)

There was a significant increase in dorsiflexion motion during mid-late stance (45-64%) for the device group after rehabilitation (Figure 2.5). The mean difference in pre and post rehabilitation peaks during this significant time frame was 6.17 degrees. There were no corresponding differences in ankle dorsiflexion/plantar flexion internal moment or sEMG activation of the anterior tibialis or medial gastrocnemius in the device group after rehabilitation (Figure 2.5). There were no other differences in sagittal plane

kinematics, kinetics, or sEMG activity of the anterior tibialis or medial gastrocnemius after rehabilitation for the device, no device or pooled groups (Figures 2.5-2.7).

Vertical Ground Reaction Force

There were no differences in vGRF after rehabilitation for the device, no device, or pooled groups (Figure 2.8).

DISCUSSION:

Our primary findings were that incorporating ankle destabilization devices into a progressive rehabilitation program does not improve ankle inversion during gait. Furthermore, we found that when we combined both groups, there were no improvements in ankle inversion kinetics or kinematics during gait after rehabilitation. However, we did find that ankle destabilization devices caused an increase in dorsiflexion during the mid to late stance phase of gait. In addition, we also found a decrease in peroneus brevis sEMG activity during early stance in the no device group and a decrease in peroneus longus sEMG activity during early stance and mid-swing in the device group after rehabilitation. Finally, after rehabilitation, we found no changes in proximal joint kinematics or kinetics for the device, no device, or pooled groups.

Ankle Frontal Plane Kinematics and Kinetics

We found no alterations after rehabilitation in inversion-eversion motion or inversion-eversion moments for the device, no device or pooled groups. These findings are of particular interest because the participants of this study were shown to have large improvements in self-reported function (FAAM-Sport Pre=66.47 Post=86.33), dorsiflexion ROM, ankle strength, and balance after rehabilitation as part of another

study (Manuscript 1). This suggests that improvements in these other clinical measures associated with CAI do not alter ankle frontal plane kinematics and kinetics. These results are consistent with McKeon et al.[43], who examined the effects of a balance training protocol on ankle gait measures during treadmill walking and a case-report by O'Driscoll et al.,[75] who examined the effects of a 6-week dynamic neuromuscular training program on ankle joint function. Neither study found changes in ankle inversion motion throughout the gait cycle, however, the McKeon et al.[43] study found improved shank/rearfoot coupling stability measured by a reduction in shank/rearfoot coupling variability using a continuous relative phase analysis, and the O'Driscoll et al[75] study found decrease plantar flexion during a jump landing task and decrease vGRF during gait.

Based off these studies, it appears that in order to decrease ankle inversion positioning throughout gait in individuals with CAI, clinicians must incorporate specific gait training modalities. We do not want to discredit our rehabilitation program or the other programs used in the other studies because they clearly improved clinical outcomes associated with CAI. However, since all programs included multiple functional exercises that included jumping and cutting tasks, which were made more challenging by the use of ankle destabilization devices or unstable surfaces, we believe gait training at the ankle needs to be more specific to walking and running. Gait training using visual feed-back from a 3-dimensional motion capture system, has been shown to effectively reduce the knee adduction moment in healthy knee varus aligned individuals over 8 treatment sessions.[76] This study shows that it is possible to alter frontal plane movement patterns,

however, to our knowledge there has not be a gait training technique at the ankle to cause lasting reduction in inversion motion during walking. We believe it is important to continue to develop and test gait training techniques that decreases ankle inversion and incorporate them into a progressive rehabilitation programs. Even though our impairment-based rehabilitation program improved FAAM-Sport score to 86%, which would no longer qualify these individuals of being in this study based on recent recommendations,[44] we recognize that there is still a 14% deficit in self-reported function.

Ankle Sagittal Plane Kinematics and Kinetics

We found approximately a 6 degree increase in ankle dorsiflexion ROM in the device group after rehabilitation during the mid to late stance phases of gait. However, we did not find differences in sEMG activity of the anterior tibialis or medial gastrocnemius or differences in dorsiflexion/planter flexion moments that correspond to this improvement in dorsiflexion ROM. Furthermore, we found that both groups had equal improvements in standing straight knee/standing bent knee dorsiflexion after rehabilitation. We believe the increase in dorsiflexion may be a result of the design of the devices with regards to the amount of plantar flexion it forces individuals to be in during ground contact phases of walking or other functional tasks. These devices may have implemented a feed-forward response to the amount of plantar flexion they were undergoing during the stance phase of gait. Even though there was not a statistically significant reduction in medial gastrocnemius activity during mid-late stance after rehabilitation, there was about a 10% reduction in mean sEMG activity after

rehabilitation during the phase where the improvements of dorsiflexion were found. Our study may have been underpowered for the sEMG analyses since the sEMG measures are more variable than gait kinematics. Improvement in dorsiflexion during the stance phase of gait, may cause an increase in joint stability since it increases the boney congruency of the joint.

Surface EMG Activity of the Peroneus Brevis and Peroneus Longus

We found a small reduction in peroneus brevis activation during early stance in the no device group after rehabilitation and a small reduction in peroneus longus activation during early stance and during mid-swing in the device group after rehabilitation. These findings refute our original hypothesis that both unstable surfaces and destabilization devices would increase muscle activity during gait and that the ankle destabilization devices would cause an isolated increase in peroneus brevis and peroneus longus sEMG activation. Even though these sEMG activation differences were statistically significant, they were not large enough to cause alterations in kinematics or kinetics during walking, but they do suggest that rehabilitation may cause a preservation strategy during walking where individuals can complete the same task with less muscle activity. In a study completed by Feger et al,[77] they found that the peroneus longus was activated for approximately 15% longer of the gait cycle than healthy individuals. The authors concluded that the increased peroneal activation may cause a fatiguing response of the muscle, which decreases its ability to adequately protect against sudden perturbations. Based off our study design, we cannot conclude that the reduction in sEMG activity of ankle evertors is a advantageous, but similar sEMG activation patterns

have been shown during the application of ankle bracing in participants with CAI,[78] which are devices that are successful at decreasing lateral ankle sprains.[79-80] Furthermore, it has been shown that healthy individuals do not activate their evertor musculature until mid-stance.[22, 77]

Limitations

Although progressive rehabilitation did not change frontal plane gait kinematics or kinetics, we did not include any joint coupling variability measures.[43, 81] These analyses may provide more insight on gait alterations after rehabilitation. Furthermore, this study was limited to one follow-up data collection session. Therefore, it remains unclear of how successful this rehabilitation program is at reducing recurrent ankle sprains.

CONCLUSION:

Despite causing improvements in self-reported function, a four week progressive rehabilitation program that incorporates ankle destabilization devices or unstable surfaces during balance and functional exercises does not alter frontal plane kinematics or kinetics of the ankle, knee and hip joint in participants with CAI. Ankle destabilization devices caused an increase in dorsiflexion ROM during mid to late stance during gait after rehabilitation, which may contribute to an increase in ankle joint stability. Rehabilitation programs to treat CAI should encompass exercises to improve all deficits associated with CAI and include specific gait training exercises to decrease excessive inversion ROM throughout the gait cycle.

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TABLES:

TABLE 2.1. Participant Demographics (n=13 per group)

	No Device				Device			
	Minimum	Maximum	Mean	Standard Deviation	Minimum	Maximum	Mean	Standard Deviation
Age	18.0	30.0	21.46	2.88	18.0	28.0	21.31	3.35
Height (cm)	152.40	185.42	169.11	10.61	154.94	181.61	168.81	6.89
Mass (kg)	58.97	102.51	75.33	13.70	48.53	92.08	66.12	12.90
Number of Sprains	1.00	5.00	3.08	1.50	2.00	20.00	6.15	5.37
Last Sprain (months)	3.00	60.00	24.46	22.51	2.00	36.00	10.27	9.82
First Sprain (years)	1.00	15.00	5.58	3.57	1.50	20.00	7.92	5.22
Baseline FAAM-ADL	72.73	95.24	87.65	7.96	75.00	95.24	85.76	7.26
Baseline FAAM-Sport	25.00	84.38	65.87	18.24	43.75	84.38	67.07	13.42
IdFAI	20.00	26.00	22.92	1.71	13.00	30.00	23.23	5.15
Godin Leisure-Time	31.00	81.00	58.77	16.45	48.00	155.00	79.69	31.66
Standing Rear-Foot angle (degrees)	3.00	13.67	5.67	2.93	3.00	6.00	4.15	0.99
Navicular Drop (mm)	3.38	14.47	6.85	3.03	3.85	10.87	6.85	2.30
Anterior Drawer Arthrometer (mm)	2.88	17.57	9.37	4.34	1.72	20.51	11.72	5.15
Inversion Arthrometer (mm)	29.13	57.42	45.67	9.82	34.11	55.69	45.07	7.45
Average Time (minutes) per Rehabilitation Session	56.00	75.73	65.18	4.69	55.13	77.33	66.25	7.98

FIGURES

Figure 2.1. Myolux Athletik (top) and Myolux II (bottom)

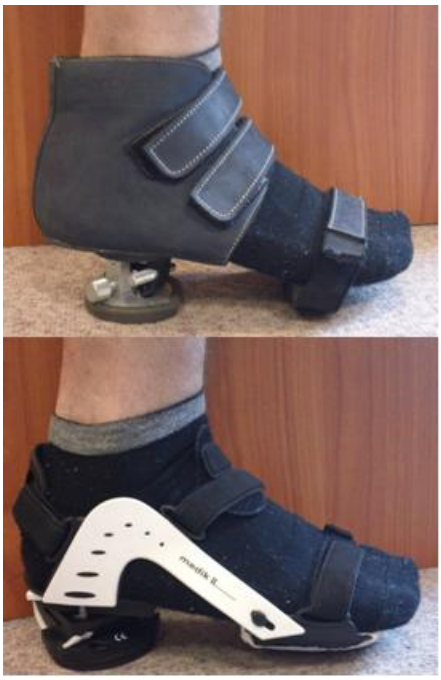
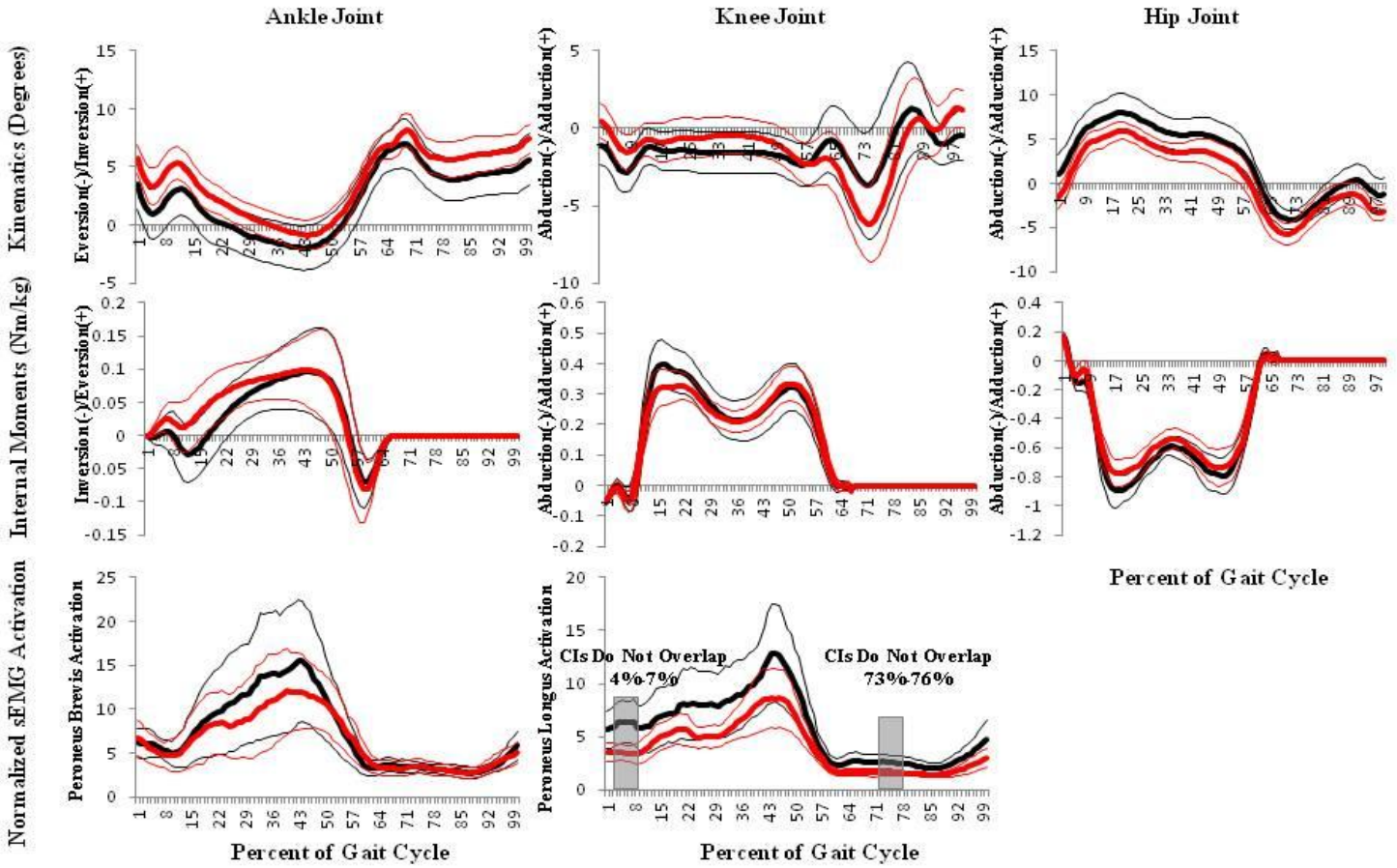
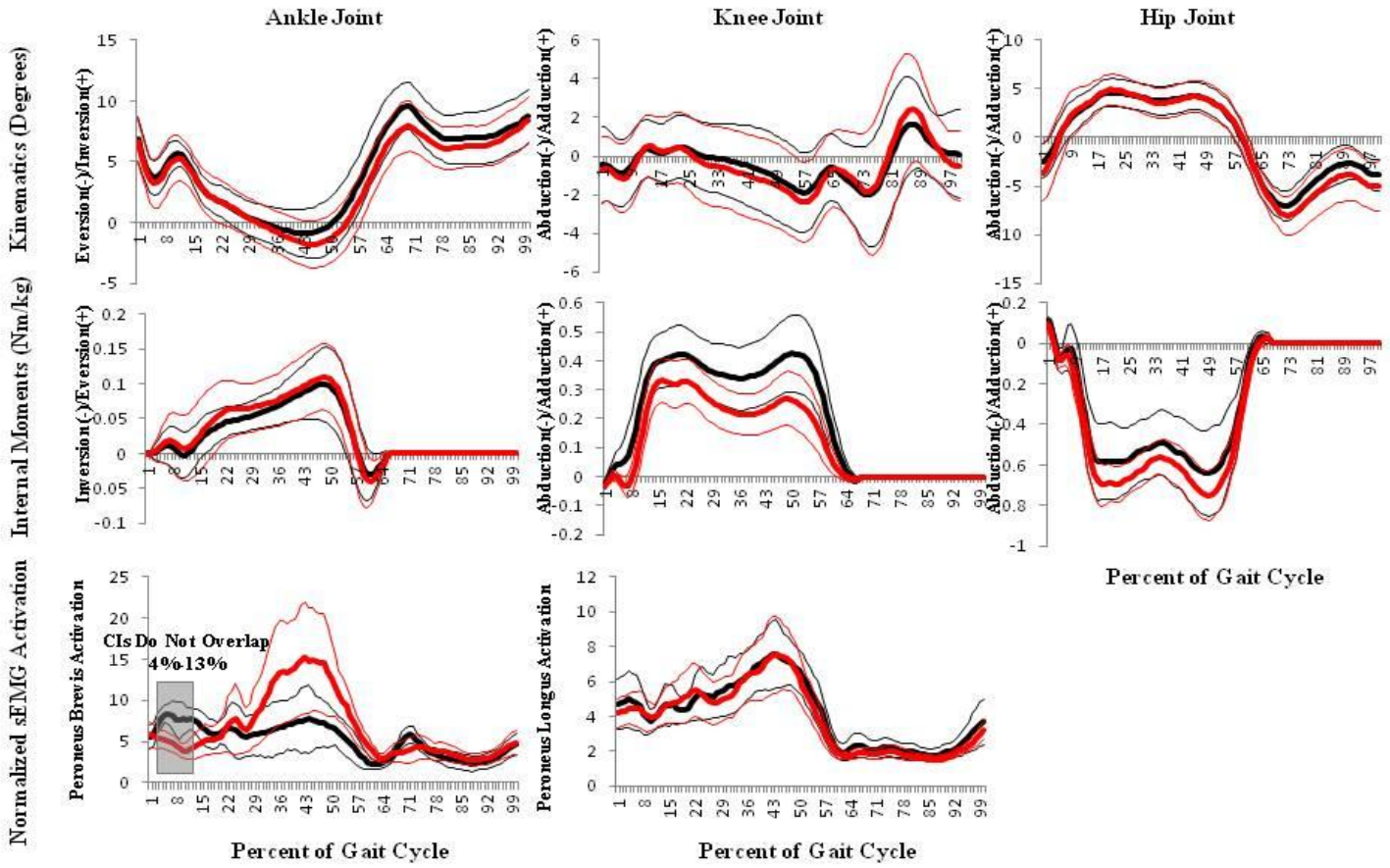


Figure 2.2.



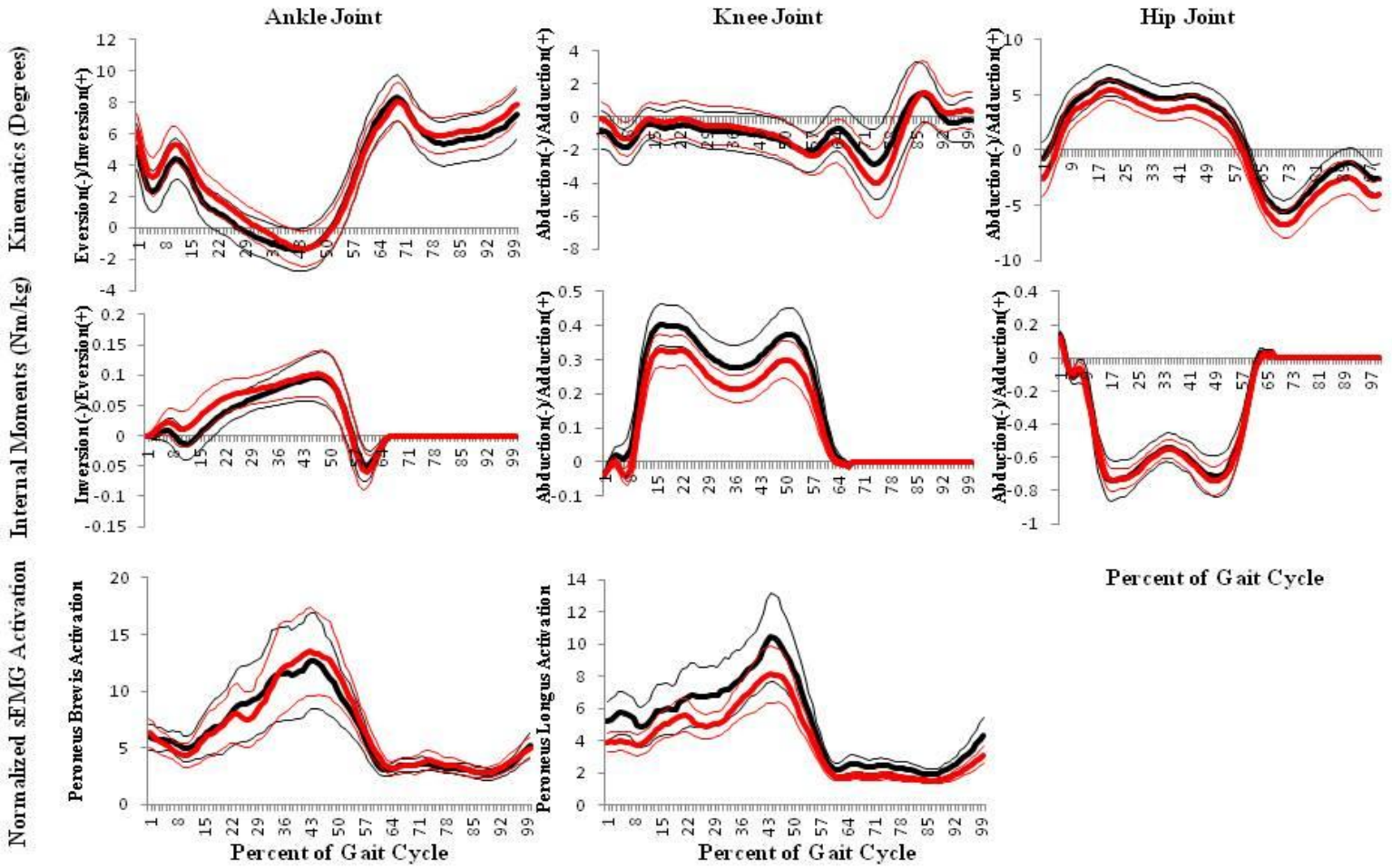
Device group means with 90% confidence intervals (CIs) for frontal plane ankle, knee, and hip kinematics, internal moments and sEMG activation during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

Figure 2.3.



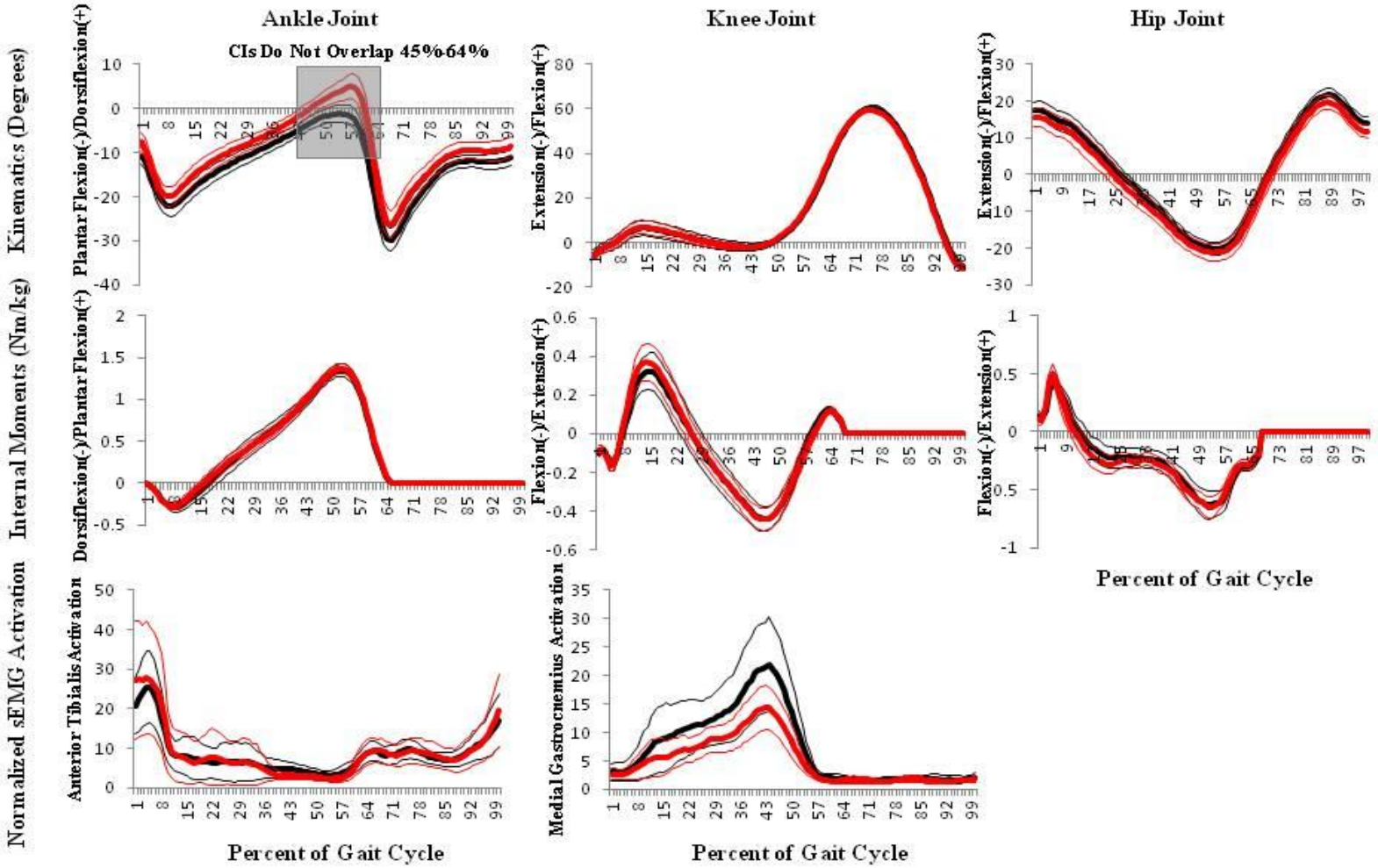
No device group means with 90% confidence intervals (CIs) for frontal plane ankle, knee, and hip kinematics, internal moments and sEMG activation during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

Figure 2.4.



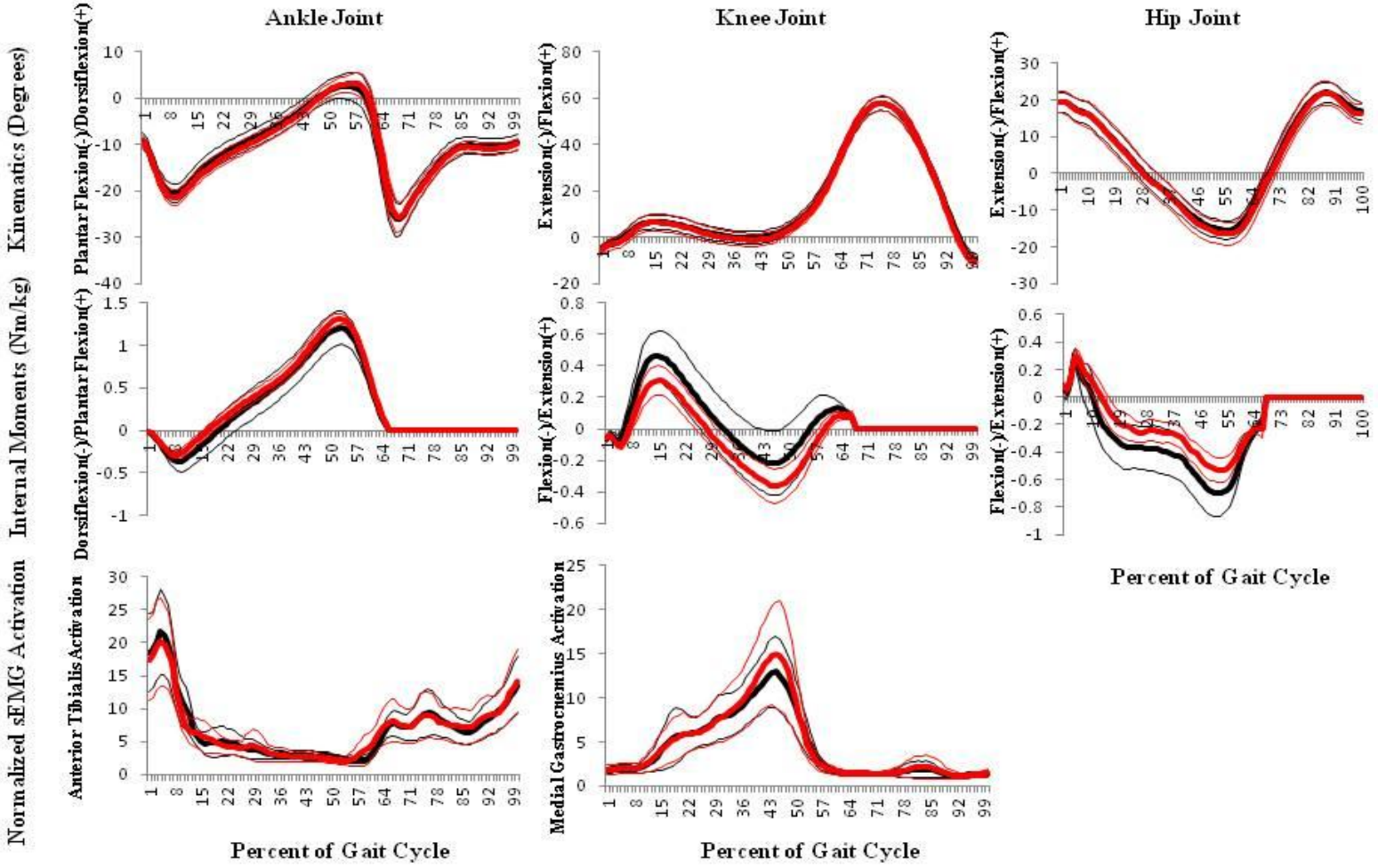
Pooled group means with 90% confidence intervals (CIs) for frontal plane ankle, knee, and hip kinematics, internal moments and sEMG activation during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

Figure 2.5.



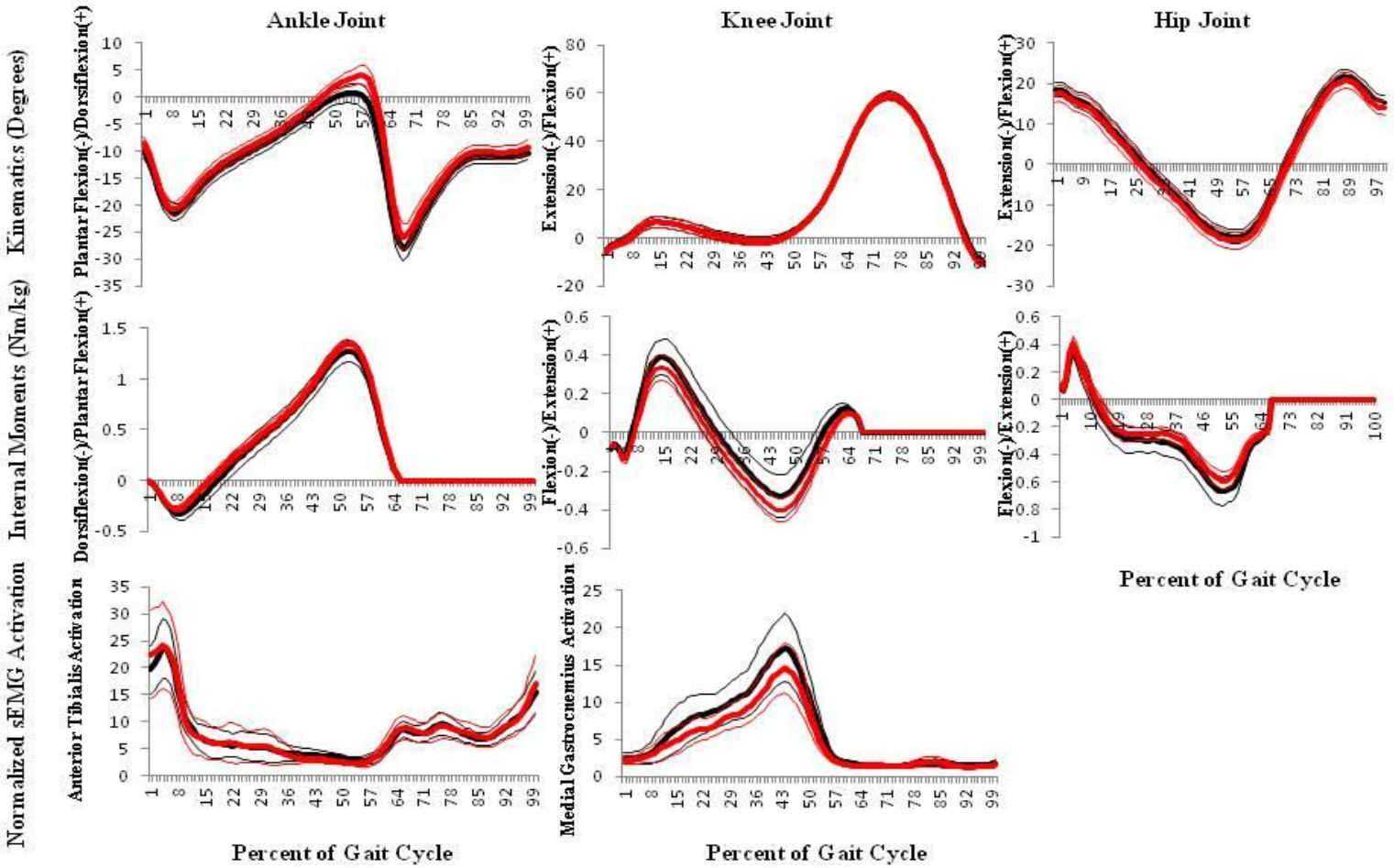
Device group means with 90% confidence intervals (CIs) for sagittal plane ankle, knee, and hip kinematics, internal moments and sEMG activation during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

Figure 2.6.



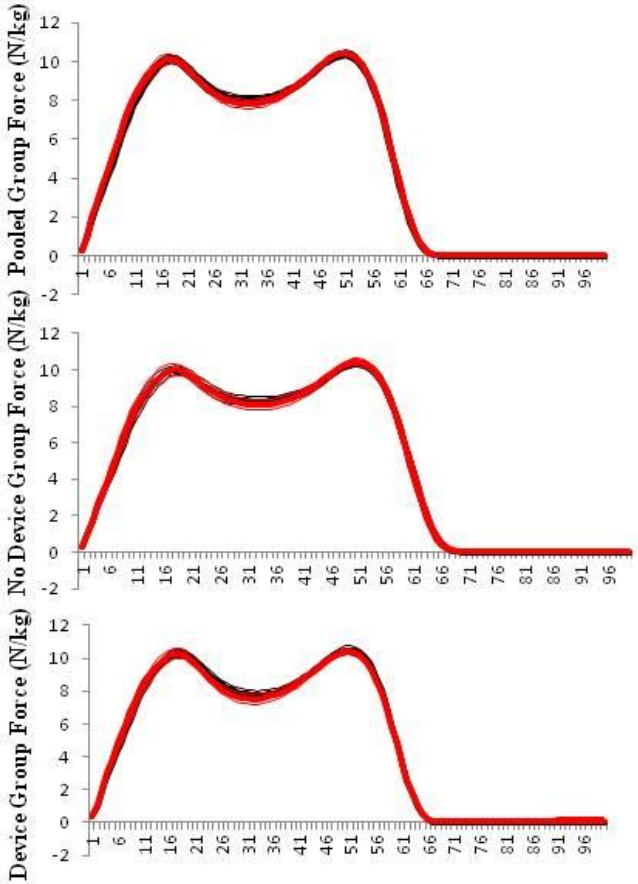
No device group means with 90% confidence intervals (CIs) for sagittal plane ankle, knee, and hip kinematics, internal moments and sEMG activation during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

Figure 2.7.



Pooled group means with 90% confidence intervals (CIs) for sagittal plane ankle, knee, and hip kinematics, internal moments and sEMG activation during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

Figure 2.8.



Vertical ground reaction force (VGRF) normalized to mass means with 90% confidence intervals (CIs) during the gait cycle (1%-100%) pre and post rehabilitation. Stance phase represents approximately 0-68% of the gait cycle. Black represents pre rehabilitation and red represents post rehabilitation.

SECTION II: MANUSCRIPT III

EFFECTS OF AN AUDITORY BIOFEEDBACK DEVICE ON PLANTAR PRESSURE IN PARTICIPANTS WITH CHRONIC ANKLE INSTABILITY

ABSTRACT

Context: Chronic ankle instability (CAI) is a complex condition that has many characteristics associated with it. Individuals with CAI have been shown to be more inverted during the swing phase and have a greater amount of plantar pressure on the lateral column of the foot throughout the stance phase. To date, traditional rehabilitation for ankle instability has been unable to specifically correct gait deficits associated with CAI. We have developed a custom auditory biofeedback device that can be worn in standard athletic shoes that elicits a noise when an excessive amount of pressure is applied to a sensor. **Objective:** To determine if using this device can decrease lateral plantar pressure in participants with CAI and alter surface electromyography sEMG amplitudes. **Design:** Descriptive Laboratory. **Setting:** Laboratory **Patients or Other Participants:** Ten participants with CAI(age=21.5, sex (male=3, female=7), height=166cm, mass=65.6kg) participated in a laboratory study. **Intervention(s):** Participants completed 30 seconds of treadmill with pressure insoles inserted in their shoes. Next, the auditory biofeedback device was placed into the shoe and set to a threshold that would elicit audible noise during the participant's normal gait. Then, participants were given instruction to walk in a manner that would cause the device to not make a noise, while 30 more seconds of data were collected. **Main Outcome Measures:** Plantar pressure measures of 9 regions of the foot and sEMG amplitudes of lower extremity muscles were compared during shod (baseline) and auditory feedback (AUD FB) conditions using paired t-tests with *a priori* significance level of $P \leq 0.05$. **Results:** There was a significant reduction in peak pressure (kPa) in the lateral midfoot (Baseline

(Mean±SD):133.48±24.11kPa vs. AUD FB: 80.67±12.00 kPa, P=0.001), the central forefoot (Baseline: 176.08±22.23 kPa vs. AUD FB: 146.31±20.25 kPa, P=0.010), and the lateral forefoot (Baseline: 158.97±29.34 kPa vs. AUD FB: 101.20±18.10 kPa, P<0.001) during the AUD FB condition. There was a significant increase in peak pressure (kPa) in the hallux (Baseline: 212.70±63.87 kPa vs. AUD FB: 304.38±115.46 kPa, P=0.006) during the AUD FB condition. In addition, there were significant increases in peroneus longus (Baseline: 333.94±183.51mV vs. AUD FB: 534.02±305.77mV, P=0.006) and medial gastrocnemius (Baseline: 283.85±221.22mV vs. AUD FB: 517.18±440.18mV, P=0.027) sEMG amplitudes (mV) 200 ms post initial contact during the AUD FB condition. **Conclusion:** Auditory feedback devices are capable of decreasing lateral pressure during treadmill walking in individuals with CAI. The reduction in plantar pressure in the lateral column of the foot may be a result of an increase in sEMG activation of the peroneus longus and medial gastrocnemius.

Word Count: 413

Key Words: Gait retraining, rehabilitation, surface electromyography

INTRODUCTION:

Lateral ankle sprains are a common musculoskeletal injury for people who participate in sports[1-2] and recreational activities.[3] Approximately 30% of people who sprain their ankle will go on to have symptoms of instability and dysfunction that lasts greater than one year after their initial sprain.[5] People who have residual symptoms of "giving way" and "a feeling of instability" have been termed to have chronic ankle instability (CAI).[6] CAI is a complex condition that encompasses a wide variety of dysfunctions which include decreased range of motion (ROM),[17-19, 82] decreased strength, [7, 12, 20] impaired proprioception,[7-11] decreased neuromuscular control,[12-16] decreased postural control,[13] altered gait kinetics and kinematics.[21-25, 83-84]

With regards to gait kinetics, pressure insoles and pressure mats are commonly used to assess for gait abnormalities in pathologic populations. These tools can be used to quantify the amount of pressure and timing of pressure over various regions of the foot. Previous studies have shown that individuals with CAI have increased lateral loading, increased plantar pressure on the lateral aspect of their foot and an increased contact time of the lateral aspect of their foot when compared to healthy individuals. [23, 83, 85] This altered gait pattern is thought to contribute to the high recurrence rate of ankle sprains and episodes of instability.

In addition to the alterations in kinetics during gait, individuals with CAI demonstrate an increase in surface electromyography (sEMG) across a gait cycle when compared to healthy controls.[77] Furthermore, the peroneus longus activates prior to initial contact in individuals with CAI, as opposed to mid-stance in healthy individuals.[77] This

alteration in peroneus longus activation may be in response to the supinated foot to either pull the foot out of its current position or to provide more stability.

We believe incorporating gait training, in addition to traditional interventions, to rehabilitation may cause a reduction in recurrent ankle sprains.[27] Traditional gait training interventions for the knee and hip use verbal or visual feedback (mirrors or cameras) to correct abnormal motions,[76] however, due to the complex motions that quickly occur at the ankle during walking as well as difficulties in visualizing the ankle with a mirror or anteriorly placed camera throughout the gait cycle, these techniques may be implausible to use to correct faulty ankle mechanics. Therefore, we developed a custom made auditory biofeedback device that can be worn without altering shoes.

This device will elicit an audible noise when an excessive amount of pressure occurs over a small force sensitive resistor sensor placed between the foot and the shoe. We believe we can alter plantar pressure by placing the device's sensor beneath the head of the 5th metatarsal, which is a common place for individuals with CAI to have increased plantar pressure. If the device elicits a noise during walking, this will signify an increased lateral pressure and allow the individual to correct their next step by placing their foot in a more neutral or pronated position prior to heel contact and by shifting their center of pressure (COP) more medially after heel contact, which in return puts their foot in a more favorable position to avoid lateral ankle sprain. The medial shift in COP can be completed by increased muscle activity of lateral ankle dynamic stabilizers, such as the peroneus longus. However, before incorporating this device into rehabilitation programs, its effectiveness of altering plantar pressure during walking must be evaluated. Therefore,

the purpose of this study is to determine if using a custom made auditory biofeedback device in an athletic shoe can alter plantar pressure in participants with CAI during a single intervention session. The secondary purpose is to determine whether these alterations correspond to increased muscle activity measured by surface electromyography (sEMG).

METHODS:

Study Design

We performed a descriptive laboratory study comparing treadmill gait using standard athletic shoes and shoes with an auditory biofeedback device with verbal feedback on measures of plantar pressure and sEMG during walking in young adults with CAI. Our independent variables were condition: (1. shod with no auditory biofeedback device (Baseline) and 2. shod with an auditory biofeedback device with verbal feedback (AUD FB)). The primary dependent variables were measures of plantar pressure (peak pressure, pressure time integral, time to peak pressure, contact area and contact time) at 9 regions of the foot (medial heel, lateral heel, medial midfoot, lateral midfoot, medial forefoot, central forefoot, lateral forefoot, hallux, and toes 2-5) and measures of sEMG amplitudes pre and post initial contact for lower extremity muscles (anterior tibialis, peroneus longus, medial gastrocnemius and gluteus medius).

Participants

Ten young adults (age=21.5, sex (male=3, female=7), height=166cm, mass=65.6kg) with CAI (Table 3.1.) were recruited from a University setting and surrounding community to participate in this study. The inclusion criteria for the CAI

group was a history of more than one ankle sprain with the initial sprain occurring greater than one year ago, no sprain within the past 6 weeks and current self reported functional deficits due to ankle symptoms that was qualified by a score of <85% on the FAAM Sport scale and a ≥10 on the Identification of Functional Instability scale (IdFAI).[44] All participants were physically active (at least 20 minutes of exercise a day at least 3 days a week) and had no other known lower extremity injuries or pathologies.

Instruments:

Plantar Pressure

Plantar pressure was measured using the Pedar-x plantar pressure system (Novel Inc, St Paul MN) with in-shoe insoles that had a sampling rate of 100 Hz. Participants used a standard athletic shoe properly fitted to foot size (Brooks Defyance 3, Brooks Sports Inc., Seattle, WA).

Auditory Biofeedback Device

The auditory biofeedback device was custom made using a force sensor (FlexiForce, Tekscan Inc., South Boston, MA), piezo buzzer (Intervox, International Components Corporation, Bohemia, NY), trimpot, and a12volt battery (Figure 3.1). The device was designed to elicit an audible noise when a subject's vertically directed force exceeded the threshold of the force sensor. The force sensor threshold could be set to various thresholds using the trimpot. We set the threshold so that a loud continuous noise was elicited as an individual rocked from their heels towards their toes while standing on one limb. All trials were completed on a standard treadmill (Gait Trainer^{TM} 3, Biodex, Shirley, NY).

Surface Electromyography

Surface EMG was collected using 2 parallel bar rectangular sensors. Each bar was 1mm wide and 1 cm long and separated by 1 cm. The sensors were DE 2.1 differential EMG sensors (Delsys, Boston, MA). The signal was amplified with a gain of 1000 and digitized with a 4 channel acquisition system (Bagnoli EMG system, Delsys, Boston, MA) at 1000 Hz. Input impedance was $>10^{15}\Omega$//0.2pF with a signal to noise ratio of 1.2uV. Data was collected using Motion Monitor software (Innovative Sports Training, Inc., Chicago, Illinois) and processed by using EMGworks software (version 4.1.1, Delsys, Boston, MA). Using the Motion Monitor software, data was filtered using a 10-500 band-pass filter and smoothed using a 50-sample moving window root mean square (RMS) algorithm as recommended by Konrad et al.[45] Initial heel contact was identified using a foot switch placed beneath the heel of the involved limb (Delysis, Boston, MA).

Procedures

Participants provided informed consent and completed a general healthy history questionnaire, the FAAM activity of daily living and sport scales, and the IdFAI questionnaire. Next, participants were fitted for standard lab shoes (Brooks Defyance 3, Seattle WA) and preformed walking trials. These shoes were chosen because they were considered a neutral shoe. Participants were instructed to walk at a normal pace on the treadmill and give feedback to the point they felt they were walking at their "normal" gait. At this point, the tester collected 30 seconds of baseline gait. After completing the 30 seconds of treadmill walking, the tester inserted the auditory biofeedback device in the shoe. The sensor was placed beneath the head of the 5^{th} metatarsal (Figure 3.1b). The

device was adjusted to elicit a noise when the participant walked normally. The participant walked on the treadmill at the same self-selected speed they used during their baseline measure. During this trial the device elicited a noise during every step, however, the participant was instructed to walk in a normal manner and ignore the noise that was elicited. The purpose of this trial was to ensure the device was set at a proper threshold so that each step would elicit a loud noise. Finally, the participant completed 30 more seconds of treadmill walking at the same previous speeds while using the device and instructed to walk in a manner that a noise would not be elicited. Participants did not stop walking between the final two trials.

Data Reduction:

Pressure Measures

For peak pressure, pressure time integral, time to peak pressure, contact area and contact time the mean of 10 consecutive steps of the involved limb were processed using Novel Database Pro 1/14 and Automask software packages (Novel Inc, St Paul, MN). This was completed for all 9 regions of the foot (medial heel, lateral heel, medial midfoot, lateral midfoot, medial forefoot, central forefoot, lateral forefoot, hallux, and toes 2-5). Peak pressure represented the highest point of pressure in a given region of the foot during stance phase of gait. The pressure time integral is the total plantar pressure acting on a specific region of the foot over the time spent in stance. Percentage of stance where the peak pressure occurred for each region was represented by the time to peak pressure measure. Contact area and contact time indicated how large of an area each region was in contact with the ground and how long each region was in contact with the

ground during the stance phase of gait. Due to equipment malfunction, only 9 individuals were subjected to statistically analysis for pressure measures.

Surface Electromyography Amplitudes

Using EMGworks software (version 4.1.1, Delsys, Boston, MA) sEMG amplitudes for the anterior tibialis, peroneus longus, medial gastrocnemius, and gluteus medius were calculated for a 200 ms time period prior to initial contact and for a 200 ms time period immediately after initial contact. Amplitude was represented by the area under the RMS curve for each of these muscles. The average amplitude of 10 strides was calculated for both pre and post initial contact. We did not normalize the sEMG values because all comparisons were within participants in the same testing session.

Statistical Analysis:

For each dependent variable, paired t-tests were conducted with the level of significance set *a priori* at $P \leq 0.05$ for all analyses. We chose not to control for multiple comparisons as recommended by Hopkins et al.[59] Cohen's *d* effect size and associated 95% confidence intervals were also calculated. Effect sizes were interpreted as ≥ 0.80 was large, ≥ 0.50 was moderate and ≥ 0.20 was small. Data was analyzed using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc, Chicago, IL).

RESULTS:

Due to the number of dependent variables, we only reported variables in the text which had p-values less that 0.05 and effect size 95% confidence intervals that did not cross 0.

Plantar Pressure Measures

Peak Pressure (kPa)

There was a significant reduction in peak pressure (kPa) during the AUD FB condition in the lateral midfoot (Baseline (Mean±SD):133.48±24.11 kPa vs. AUD FB: 80.67±12.00 kPa, P=0.001), the central forefoot (Baseline: 176.08±22.23 kPa vs. AUD FB: 146.31±20.25 kPa, P=0.010), and the lateral forefoot (Baseline: 158.97±29.34 kPa vs. AUD FB: 101.20±18.10 kPa, P<0.001) (Figure 3.2). There was a significant increase in peak pressure (kPa) in the hallux (Baseline: 212.70±63.87 kPa vs. AUD FB: 304.38±115.46 kPa, P=0.006) during the AUD FB condition (Figure 3.2). All peak pressure means, standard deviations, and effect sizes are reported in Table 3.2 for the total foot and 9 regions of the foot.

Pressure Time Integral (kPa/second)

All pressure time integral means, standard deviations, and effects sizes are reported in Table 3.3 for the total foot and 9 regions of the foot. There was an overall increase in pressure time integral for the total foot during the AUD FB walking trial (Baseline: 107.68±12.40kPa/s vs. AUD FB: 126.32±23.17kPa/s, P=0.014). In addition, the AUD FB condition caused a reduction in lateral midfoot (Baseline: 66.92±9.35kPa/s vs. AUD FB: 38.49±8.78kPa/s, P<0.001) and lateral forefoot (Baseline: 71.19±13.22kPa/s vs. AUD FB: 42.13±8.60kPa/s, P<0.001) pressure time integral (Figure 3.3). Finally, when compared to baseline, there was an increase in hallux pressure time integral (Baseline: 60.57±17.31kPa/s vs. AUD FB: 91.91±37.92kPa/s, P=0.013) (Figure 3.3).

Instant of Peak Pressure (% of Stance)

Peak pressure was reached significantly earlier in the lateral midfoot region during the AUD FB condition (Baseline: 54.96±16.64% vs. AUD FB: 39.09±15.02%, P=0.003) (Figure 3.4). All instant of peak pressure means, standard deviations, and effect sizes are reported in Table 3.4 for the total foot and 9 regions of the foot.

Contact Area (cm^2)

There was less contact area in the lateral midfoot (Baseline: 23.92±1.75cm^2 vs. AUD FB: 19.61±4.33 cm^2, P=0.005) and toes 2-5 (Baseline: 16.01±1.99 cm^2 vs. AUD FB: 14.04±4.00 cm^2, P=0.043) regions when comparing baseline to the AUD FB group (Figure 3.5). All contact area means, standard deviations, and effect sizes are reported in Table 3.5 for the total foot and 9 regions of the foot.

Contact Time (ms)

All contact time means, standard deviations, and effect sizes are reported in Table 3.6 for the total foot and 9 regions of the foot. There were no differences in contact time between conditions for the total foot or for any of the 9 regions of the foot (Figure 3.6).

Surface Electromyography Amplitudes

Pre-Initial Contact (200ms)

There were no differences in pre-initial contact amplitudes for the anterior tibialis, peroneus longus, medial gastrocnemius, or gluteus medius. Pre-initial contact amplitude means, standard deviation, and effect sizes can be found in Table 3.7 for each muscle.

Post-Initial Contact (200ms)

When comparing conditions, there were significant increases in peroneus longus (Baseline: 333.94±183.51mV vs. AUD FB: 534.02±305.77mV, P=0.006) and medial

gastrocnemius (Baseline: 283.85±221.22mV vs. AUD FB: 517.18±440.18mV, P=0.027) sEMG amplitudes post initial contact during gait (Table 3.8).

DISCUSSION:

We found pronounced reductions in peak pressure and pressure time integral of the lateral midfoot and lateral forefoot while participants were using the AUD FB device and instructed to walk in a manner that caused the device to not elicit a noise. The reduction of these measures appears to be transferred to the hallux during gait. An increase in sEMG amplitudes of the peroneus longus and medial gastrocnemius may contribute to this medial shift in plantar pressure. We also found reductions in the instant of peak pressure in the lateral midfoot region while using the AUD FB device and a reduction in contact time of lateral midfoot. We did not see a decrease in contact time of the total foot, which shows that individuals were not spending less time on their involved limb and more time on their uninvolved limb, but were completing a medial shift in center pressure to make the device not elicit a noise.

Our results indicate that our AUD FB device is capable of changing commonly altered plantar pressure measures associated with CAI when it is being used. Specifically, Schmidt et al[85] found increases in peak pressure of the lateral midfoot and lateral forefoot and pressure-time integral in the lateral midfoot in individuals with CAI when compared to healthy individuals. In addition, we found that by placing the sensor of the device beneath the head of the fifth metatarsal, we were able to alter regions of the foot proximal to the sensor that were shown by Schmidt et al[85] to have plantar pressure alterations. We

believe the proximal alterations are due to an anticipatory response of the device eliciting a noise.

To our knowledge, this is the first study that has examined the use of auditory biofeedback to alter increased lateral plantar pressure in a CAI population. However, auditory biofeedback is commonly used in children to promote heel-toe walking.[86] A case-series by Marcus et al[87] used a product called GaitSpot Auditory Squeakers to try to promote heel-toe gait patterns in autistic children with idiopathic to-walking patterns. This product consists of a squeaker that can be placed beneath the patient's heel of their shoes. Patients were instructed to walk in a manner that causes the device to make a noise. After the intervention, they found that the children had increases in heel contact during gait. Even though our study used a different population, device and instructions, it suggests habit reversal is possible with the use of auditory feedback devices.

Limitations

This preliminary study of a custom made auditory biofeedback device has several limitations. First, we only made comparisons in pressure measures of the involved limb during baseline walking to the AUD FB condition and cannot assume there were no changes in planter pressure measures of the uninvolved limb. We believe alterations in plantar pressure measures of the uninvolved limb were minimized because the treadmill speed was held constant and there was not a significant increase in contact time or contact area of the involved limb. In addition, even though would could alter the force threshold for the device to elicit a noise, there may have been some inconsistencies between participants on the specific amount of force needed to make the device elicit a

noise since we only required the device to make a loud continuous noise while individuals shifted their weight posterior to anterior. Furthermore, we completed the same testing order for each participant. We did this, opposed to randomizing order, to get a true baseline prior to introducing the device. Finally, we only measured planter pressure and do not know how well a change in lateral plantar pressure correlates with a change in kinematics of the foot.

CONCLUSION:

A custom made auditory biofeedback device was capable of decreasing plantar pressure measures in the lateral column of the foot and sEMG amplitudes of the peroneus longus and medial gastrocnemius during treadmill walking. Such changes may be advantageous in CAI patients, however the long-term effects of using this device should be evaluated before providing clinical recommendations.

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TABLES:

TABLE 3.1: Participant Demographics (n=10)

	Mean (SD)
Age (years)	21.5 (3.1)
Sex	Male:3, Female:7
Height (cm)	166.0 (6.3)
Mass (kg)	65.6 (10.4)
Godin Score	73.9 (24.5)
FAAM ADL %	86.3 (7.8)
FAAM Sport %	68.1 (15.0)
Number of Ankle Sprains	4.8 (3.2)
Time Since Last Sprain (months)	11.5 ± 9.3

SD – Standard Deviation
cm – Centimeter
kg – Kilogram

TABLE 3.2: Peak pressure measured in kilopascals of the total and nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

Regions of Foot	Pressure Time Integral Mean (SD)		Paired T-Test	Effect Size (Lower Limit, Upper Limit)
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Total Foot	234.08 (49.54)	312.01 (105.89)	0.014	1.57 (0.52,2.63)
Lateral Heel	146.20 (14.99)	150.30 (22.88)	0.476	0.27 (-0.65,1.20)
Medial Heel	144.03 (11.82)	156.64 (18.90)	0.056	1.07 (0.08,2.05)
Lateral Midfoot	133.48 (24.11)	80.67 (12.00)	0.001	-2.19 (-3.36,-1.02)
Medial Midfoot	90.44 (13.68)	96.88 (19.51)	0.294	0.47 (-0.47,1.41)
Lateral Forefoot	158.97 (29.34)	101.20 (18.10)	<0.001	-1.97 (-3.09,-0.84)
Central Forefoot	176.08 (22.23)	146.31 (20.25)	0.010	-1.34(-2.36,-0.32)
Medial Forefoot	161.41 (23.49)	183.71 (55.55)	0.200	0.96 (-0.01,1.94)
Toes 2-5	149.97 (20.00)	149.18 (39.26)	0.958	-0.04 (-0.96,0.88)
Hallux	212.70 (63.87)	304.38 (115.46)	0.006	1.44 (0.40,2.47)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Negative effect size represents less peak pressure in the AUD FB condition

TABLE 3.3: Pressure time integral measured in kilopascals times seconds (kPa/s) of the total and nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

Regions of Foot	Pressure Time Integral Mean (SD)		Paired T-Test	Effect Size (Lower Limit, Upper Limit)
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Total Foot	107.68 (12.40)	126.32 (23.17)	0.014	1.50 (0.46,2.55)
Lateral Heel	49.57 (12.78)	49.81 (19.99)	0.947	0.02 (-0.90,0.94)
Medial Heel	47.70 (10.26)	51.36 (18.72)	0.332	0.36 (-0.57,1.29)
Lateral Midfoot	66.92 (9.35)	38.49 (8.78)	<0.001	-3.04 (-4.40,-1.68)
Medial Midfoot	41.19 (9.03)	43.83 (13.10)	0.310	0.29 (-0.64,1.22)
Lateral Forefoot	71.19 (13.22)	42.13 (8.60)	<0.001	-2.20(-3.37,-1.03)
Central Forefoot	61.96 (15.36)	51.68 (13.14)	0.035	-0.67 (-1.62,0.28)
Medial Forefoot	55.20 (12.06)	61.64 (20.88)	0.283	0.53 (-0.41,1.47)
Toes 2-5	48.06 (10.39)	47.16 (14.29)	0.873	-0.09 (-1.01,0.84)
Hallux	60.57 (17.31)	91.91 (37.92)	0.013	1.81 (0.71,2.91)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Negative effect size represents less pressure time integral in the AUD FB condition

TABLE 3.4: Instant of peak pressure, measured in percentage of stance, of the total and nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

Regions of Foot	Instant of Peak Pressure Mean (SD)		Paired T-Test	Effect Size (Lower Limit, Upper Limit)
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Total Foot	78.44 (2.17)	74.77 (11.61)	0.318	-1.70 (-2.77,-0.62)
Lateral Heel	16.92 (3.71)	18.83 (4.55)	0.019	0.51 (-0.42,1.45)
Medial Heel	17.14 (3.77)	18.68 (4.73)	0.131	0.41 (-0.53,1.34)
Lateral Midfoot	54.96 (16.24)	39.09 (15.02)	0.003	-0.98 (-1.95,0.00)
Medial Midfoot	50.62 (23.16)	53.16 (18.89)	0.578	0.11 (-0.82,1.03)
Lateral Forefoot	72.31 (9.16)	69.89 (14.31)	0.252	-0.26 (-1.19,0.66)
Central Forefoot	77.37 (3.76)	74.76 (4.97)	0.003	-0.69 (-1.65,0.26)
Medial Forefoot	76.69 (3.48)	76.43 (3.78)	0.753	-0.07 (-1.00,0.85)
Toes 2-5	79.17 (3.70)	78.68 (4.23)	0.382	-0.13 (-1.06,0.79)
Hallux	81.98 (2.00)	81.47 (2.81)	0.406	-0.26 (-1.18,0.67)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Negative effect size represents instant of peak pressure to occur sooner in the AUD FB condition

TABLE 3.5: Contact area measured in centimeters squared of the total and the nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

Regions of Foot	**Pressure Time Integral Mean (SD)**		**Paired T-Test**	**Effect Size (Lower Limit, Upper Limit)**
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Total Foot	141.57 (11.39)	136.59 (13.40)	0.005	-0.44 (-1.37,0.50)
Lateral Heel	18.85 (1.18)	18.63 (1.21)	0.340	-0.18 (-1.11,0.74)
Medial Heel	20.29 (1.37)	20.55 (1.11)	0.189	0.19 (-0.73,1.12)
Lateral Midfoot	23.92 1.75	19.61 (4.33)	0.005	-2.47(-3.69,-1.24)
Medial Midfoot	13.86 (6.71)	16.08 (6.61)	0.121	0.33 (-0.60,1.26)
Lateral Forefoot	13.24 (0.78)	12.37 (1.64)	0.082	-1.11(-2.10,-0.12)
Central Forefoot	13.75 (0.65)	13.73 (0.65)	0.392	-0.02 (-0.94,0.91)
Medial Forefoot	11.94 (0.83)	12.21 (0.64)	0.144	0.33(-0.60,1.26)
Toes 2-5	16.01 (1.99)	14.04 (4.00)	0.043	-0.99 (-1.97,-0.01)
Hallux	9.64 (1.06)	9.25 (1.117)	0.074	-0.36 (-1.29,0.57)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Negative effect size represents less contact area in the AUD FB condition

TABLE 3.6: Contact time measured in miliseconds of the total and nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

Regions of Foot	Contact Time Mean (SD)		Paired T-Test	Effect Size (Lower Limit, Upper Limit)
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Total Foot	766.78 (84.55)	734.33 (81.00)	0.024	-0.38 (-1.32,0.55)
Lateral Heel	632.33 (123.7)	540.11 (137.2)	0.023	-0.75 (-1.70,0.21)
Medial Heel	581.00 (104.5)	522.78 (117.9)	0.070	-0.56 (-1.50,0.38)
Lateral Midfoot	762.00 (76.38)	715.56 (53.19)	0.031	0.48 (-1.55,0.34)
Medial Midfoot	714.00 (73.72)	666.11 (66.84)	0.005	-0.65 (-1.60,0.30)
Lateral Forefoot	761.00 (76.73)	721.22 (64.86)	0.017	-0.52 (-1.46,0.42)
Central Forefoot	686.33 (111.9)	624.33 (123.8)	0.007	-0.55 (-1.50,0.39)
Medial Forefoot	638.44 (105.9)	612.67 (118.6)	0.205	-0.24 (-1.17,0.68)
Toes 2-5	662.56 (95.62)	615.56 (81.52)	0.099	-0.49 (-1.43,0.45)
Hallux	608.89 (100.1)	614.89 (88.29)	0.816	0.47 (-0.86,0.98)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Negative effect size represents shorter contact time in the AUD FB condition

TABLE 3.7: 200 ms pre- initial contact sEMG amplitudes during walking during baseline and auditory feedback conditions

Muscles	Pre Initial Contact Mean (SD)		Paired T-Test	Effect Size (Lower Limit, Upper Limit)
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Anterior Tibialis	604.02 (303.6)	665.97 (313.1)	0.296	0.20 (-0.67,1.08)
Peroneus Longus	140.76 (84.20)	202.55 (98.51)	0.004	0.73 (-0.17,1.64)
Medial Gastrocnemius	245.64 (304.8)	458.96 (600.3)	0.069	0.70 (-0.20,1.60)
Gluteus Medius	148.02 (94.97)	113.80 (71.27)	0.043	-0.36 (-1.24,0.52)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Positive effect size represents higher amplitude in the AUD FB condition

TABLE 3.8: 200 ms post initial contact sEMG amplitudes during walking during baseline and auditory feedback conditions

Muscles	Pre Initial Contact Mean (SD)		Paired T-Test	Effect Size (Lower Limit, Upper Limit)
	Baseline	**AUD FB**	**P-value**	**Baseline-AUD FB**
Anterior Tibialis	1325.57 (731.76)	1544.42 (830.09)	0.024	0.30 (-0.58,1.18)
Peroneus Longus	333.94 (183.51)	534.02 (305.77)	0.006	1.09 (0.15,2.03)
Medial Gastrocnemius	283.85 (221.22)	517.18 (440.18)	0.027	1.05 (0.12,1.99)
Gluteus Medius	219.51 (174.53)	213.32 (128.14)	0.808	-0.04 (-0.91,0.84)

SD= Standard Deviation, Baseline=No Feedback, AUD FB=Auditory Feedback
Positive effect size represents higher amplitude in the AUD FB condition

FIGURES

Figure 3.1a. Auditory biofeedback device comprised of a force resistor sensor, 12 volt battery, piezobuzzer, and trimpot

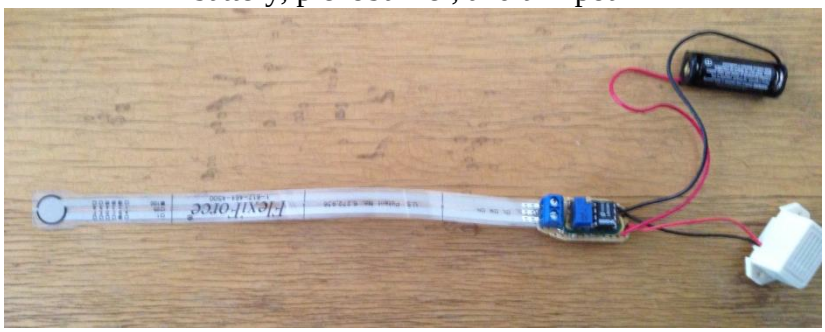


Figure 3.1b. Auditory biofeedback device inserted in a shoe at the head of the 5th metatarsal

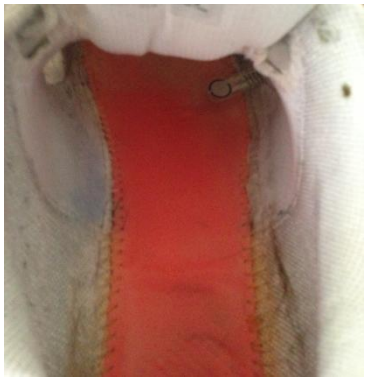


Figure 3.2. Means and standard deviations of peak pressure (kPa) of the nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

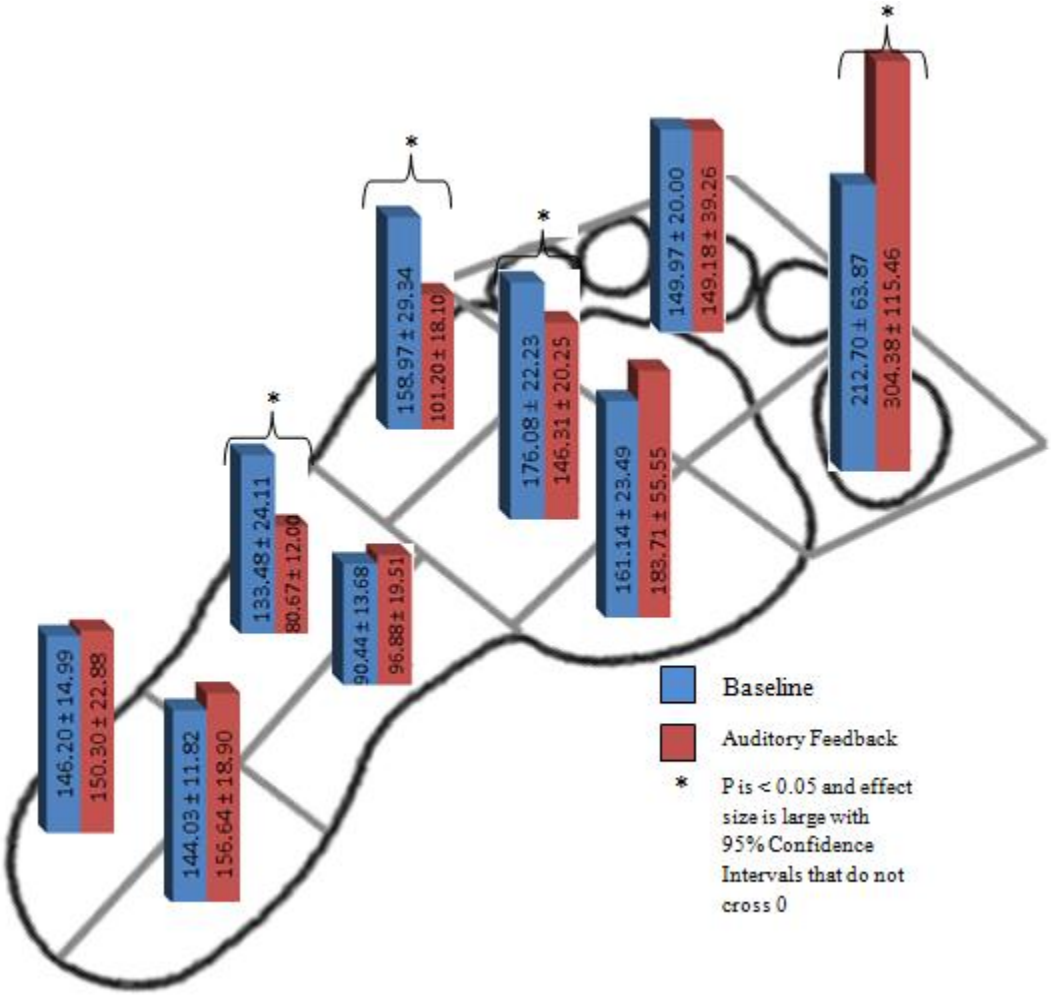


Figure 3.3. Means and standard deviations of pressure time integral (kPa/s) of the nine regions of the foot during treadmill walking

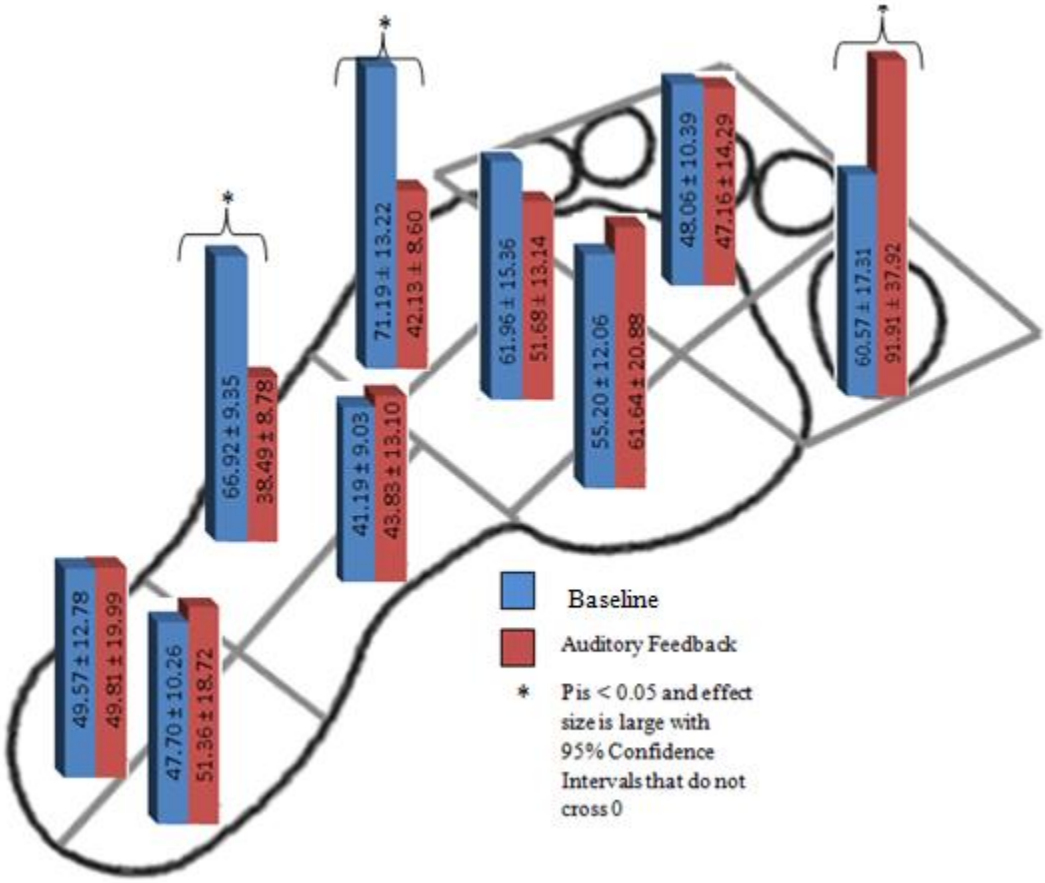


Figure 3.4. Means and standard deviations of instant of peak pressure (% of stance) of the nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions

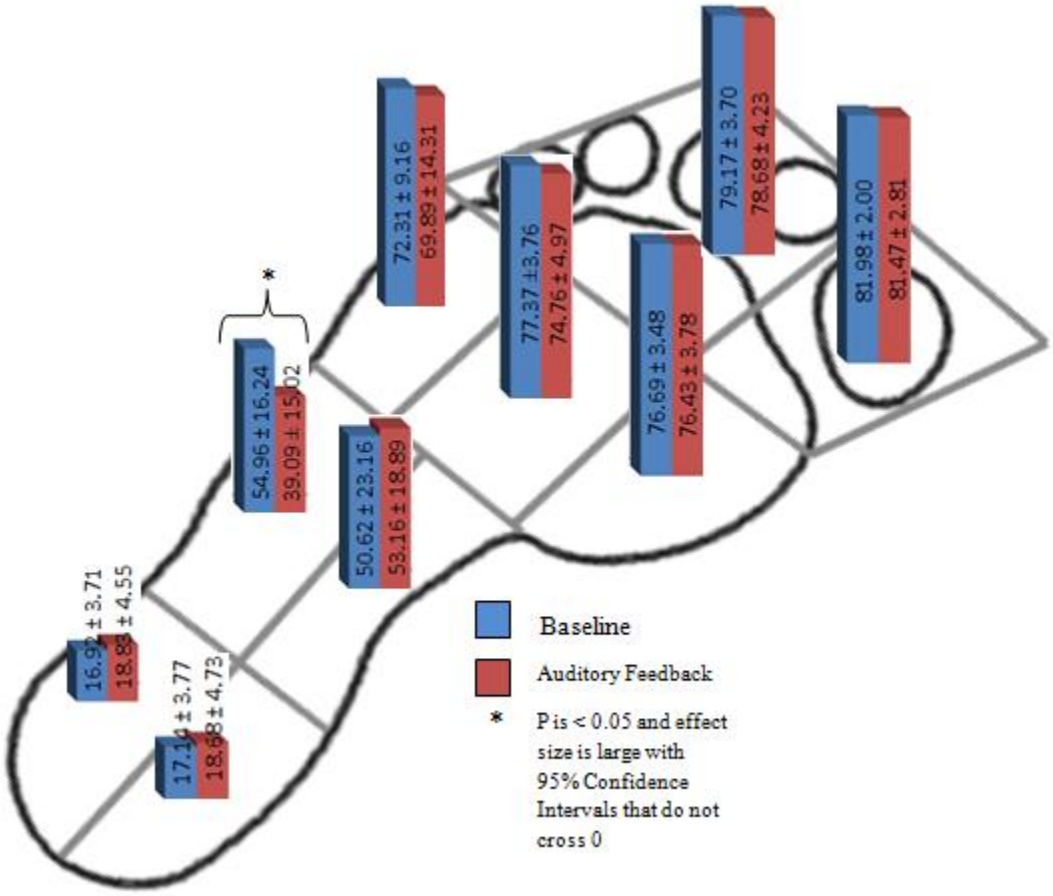


Figure 3.5. Means and standard deviations of contact area (cm^2) of the nine regions of the foot during treadmill walking

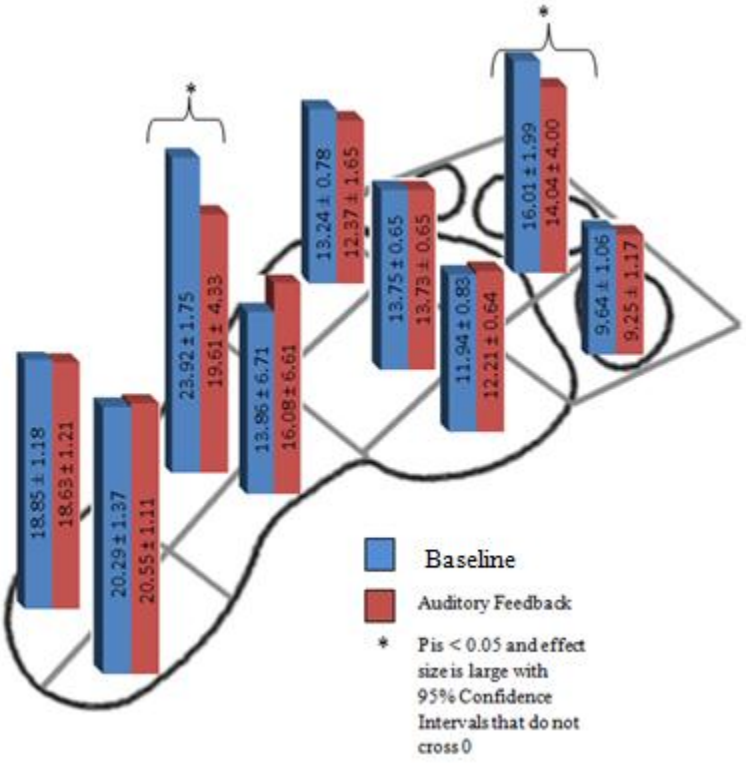
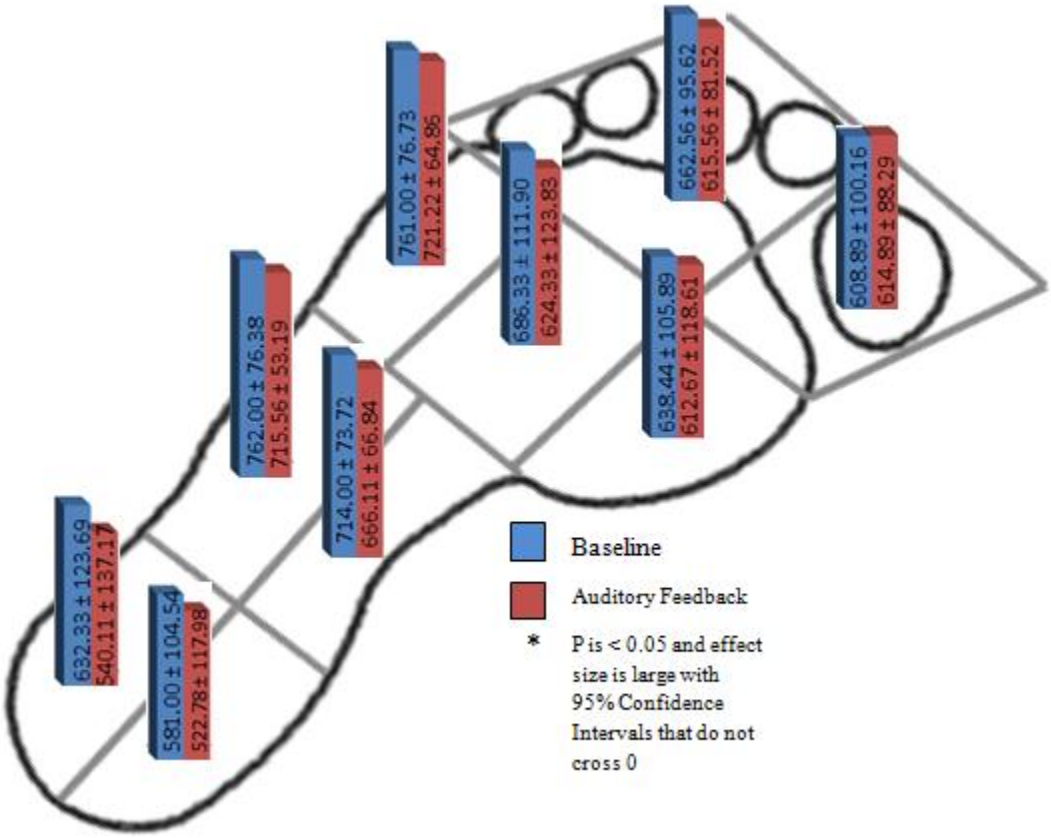


Figure 3.6. Means and standard deviations of contact time (ms) of the nine regions of the foot during treadmill walking during no feedback and auditory feedback conditions



SECTION III: APPENDICES

APPENDIX A

The Problem

Statement of the Problem

Lateral ankle sprains have been shown to be among the most common musculoskeletal injury among competitive athletes[1-2] and those who are recreationally active.[3] Furthermore, it is estimated that approximately 47 to 74% of people who suffer a lateral ankle sprain will go on to have recurrent sprains 6 to 18 months after their first ankle sprain.[4] Approximately 30% of patients who sprain their ankle will go on to have residual symptoms of instability and repetitive ankle sprains that lasts greater than a year which is known as chronic ankle instability (CAI).[6]

The specific cause of CAI remains unclear; however, multiple characteristics have been identified to be different in patients with CAI compared to healthy patients. These characteristics include, but are not limited to impaired proprioception,[7-11] decreased neuromuscular control,[12-16] decreased range of motion (ROM),[17-19] decreased strength,[7, 12, 20] and altered gait.[21-25] With regards to gait, CAI patients show greater ankle inversion and plantar flexion positioning during the swing phase and spend a longer time on the lateral aspect of the foot during the stance phase, which may predispose them to ankle sprains.[21-22, 68] Treatment of CAI is often done through conservative rehabilitation programs that are designed to improve ROM, strength, proprioception and neuromuscular control.[26-27]Over the past several years multiple intervention studies have been completed to determine whether or not specific rehabilitation techniques improve characteristics associated with CAI.[14, 34-42] Specifically, Hoch et al.[42] found that a 2 week joint mobilization program improves self-reported function, dorsiflexion ROM, and dynamic stability in patients with CAI. Furthermore, Docherty et al.[36] found that strength training in patients with functional ankle instability increases strength of the surrounding ankle musculature. Moreover, McKeon et al.[14] completed a four week balance intervention and found that the intervention caused an increase in self-reported function and improved balance in patients with CAI. Although these studies found positive improvements with patients with CAI, they only included one type of exercise or rehabilitation technique in their protocol. Combining multiple treatment techniques, may cause a larger improvement in symptoms and deficits in patients with CAI. Specifically, Hoch et al.[42] and McKeon et al.[14] found similar improvements in self-reported function after completing a 2-week mobilization intervention and 4-week balance intervention respectively. Even though both interventions caused a significant improvement when compared to pre-intervention scores, their post-intervention self-reported function would still be considered significantly lower than that of a healthy individual. In addition to studies only examining one intervention, there has not been an intervention that has been shown to improve the altered gait patterns associated with CAI. This may due to the complex motions that occur quickly at the ankle. However, ankle destabilization devices

have been developed to help treat CAI and are thought to have potential to help alter gait patterns associated with CAI.

Ankle destabilization devices have not been well defined, but for this project we will operationally define them as devices that consist of either a shoe or sandal with an articulator below the heel designed to mimic the motion that occurs at both the subtalar and talocrural joints during walking. The goal of these devices is to force the patient into plantar flexion, inversion, and internal rotation in a controlled manner while completing functional tasks. It is thought that by causing an anticipated perturbation at the ankle, surrounding musculature will contract via feed forward mechanisms to prevent the ankle from going into the vulnerable position.[29-31] Furthermore, it is thought that if appropriately implemented into a rehabilitation program, the devices have potential to provide long-term changes to a patient's gait.[29] We have completed preliminary studies on two specific ankle destabilization devices, the Myolux Athletik and Myolux II (Cevres Santé, Le Bourget-du-Lac, France). We assessed surface EMG measures of six different lower extremity muscles during walking comparing the two ankle destabilization devices to a shod control condition in 15 patients with CAI.[31] We found an alteration in muscle activity when compared to shod. There was a pronounced increase in the peroneus longus EMG amplitude prior to initial contact with the ankle destabilization devices. This shows the potential for these devices to increase activation of the peroneus longus prior to initial contact, which may provide more stability to the ankle joint by keeping the ankle out of the inverted position in late swing. As the devices caused alterations prior to initial contact, it shows their ability to cause a feed-forward response mechanism that may be learned over time.

We have also recently presented a new paradigm for the conservative treatment of patients with CAI.[27] We assert that rehabilitation should encompass exercises for all impairments detected in a patient with CAI within 4 broad domains of ROM, strength, balance, and functional activities. We believe this can be achieved by an "assess, treat, re-assess" approach in each domain of impairments. Furthermore, we emphasize the importance of implementing gait retraining into the rehabilitation of CAI patients. Therefore, the purpose of my dissertation is to examine the effects of a 4-week supervised rehabilitation intervention that encompasses ROM, strength exercises, balance and gait training exercises with and without ankle destabilization devices on patients with CAI. The rehabilitation program will be based off the paradigm we recently developed[27] and will compare a group who completes the rehabilitation program with no ankle destabilization device to a group that completes the same rehabilitation program with ankle destabilization devices. The primary dependent variables will be self-reported function, ankle ROM, strength, balance, inversion/eversion kinematics throughout the walking gait cycle, and dorsiflexion/plantar flexion kinematics throughout the walking gait cycle. In addition, we want to assess the ability to alter plantar pressure measures using an auditory biofeedback device during treadmill walking.

Research Questions

1. Do the effects of a 4-week intervention that incorporates ankle destabilization devices (experimental group) when compared to a 4-week intervention that does not incorporate ankle destabilization devices (control group) improve self-reported function of patients with CAI?

2. Do the effects of a 4-week intervention that incorporates ankle destabilization devices when compared to a 4-week intervention that does not incorporate ankle destabilization devices improve clinical measures of ankle ROM, strength, and balance?

3. Do the effects of a 4-week intervention that incorporates ankle destabilization devices when compared to a 4-week intervention that does not incorporate ankle destabilization devices improve dorsiflexion and inversion ROM during the walking gait cycle?

4. Does incorporating an auditory biofeedback device during treadmill walking decrease lateral mid/forefoot pressure during a single session?

Experimental Hypothesis

1. The experimental group will have higher self-reported function gains when compared to the control group.

2. Following the intervention, the experimental group will have significantly greater measures of ankle ROM, strength and balance than the control group.

3. After the interventions, the experimental group will have significantly greater dorsiflexion and less inversion when compared to the control group.

4. The use of an auditory biofeedback device will decrease lateral plantar pressure during treadmill walking.

Assumptions

- All participants will be honest when reporting self-reported function
- All participants will use their best effort during rehabilitation
- All participants will walk normally during all data collection
- All participants will perform maximum effort during ROM, strength, and balance trials
- All measurement tools will accurately collect data

Delimitations

- Participants were limited to our inclusion criteria
- Participants were recruited through the University and Community and not seeking medical care for their ankle

- Participants wore standard lab shoes for all gait data collection procedures

Limitations

We did not include long-term follow-up data collection sessions to evaluate long-term effects of 4-weeks of rehabilitation on self-reported function, ROM, strength, and gait.

Significance of the Study

A 4-week progressive impairment based rehabilitation program improved self-reported function, ROM, strength and balance in patients with CAI. Incorporating ankle destabilization devices into rehabilitation was not more effective at improving clinical measures than traditional unstable surfaces. Progressive rehabilitation was not effective at improving frontal plane kinematics or kinetics during walking. Finally, the use of an auditory biofeedback device is effective at decrease lateral mid/forefoot plantar pressure during treadmill walking.

APPENDIX B

Literature Review

The purpose of this literature review is to: 1. present current epidemiology of lateral ankle sprains, 2. define chronic ankle instability (CAI) and common characteristics, 3.describe current methods of assessing self-reported function, range of motion, strength, balance and gait, 4. Present current rehabilitation techniques and a rehabilitation paradigm, and 5. describe gait training instruments such as ankle destabilization devices and an auditory biofeedback device.

Epidemiology of Lateral Ankle Sprains

Lateral ankle sprains are the most common musculoskeletal injury that occur in intercollegiate[1] and interscholastic sports.[2, 88] Specifically, approximately 11,000 ankle sprains occur a year in intercollegiate athletics at a rate of 0.83 per 1,000 athletic exposures and about 326,396 sprains occur in high school athletes at a rate of 0.52 per 1,00 exposures. In addition to sports, lateral ankle sprains commonly occur in recreationally active individuals at a rate of 2.15 per 1000 person-years.[3] Between 30-70% of individuals who sustain a lateral ankle sprain, will have residual symptoms that last greater than 1 year.[5] Individuals that have prolonged symptoms of ankle instability that lasts great than 1 year have been are classified as having a condition known at chronic ankle instability (CAI).

Definition of Chronic Ankle Instability and Common Characteristics

Definition and Inclusion Criteria of CAI

Chronic ankle instability has been described as a condition that is associated with both mechanical and functional insufficiencies as a result of a lateral ankle sprain.[89] This model has been progressed to view CAI as a full spectrum of sensoriomotor alterations, which better identifies deficits ranging from passive phenomena such as proprioception all the way to active functional movements.[90] Over the years, the true definition of CAI has varied between researchers and clinicians. Recently, Delahunt et al.[6] has defined CAI as a condition where an individual has residual symptoms of "given way" or repetitive ankle sprains that are a result of a previous sprain that occurred greater than 1 year ago. Since the definition of CAI is fairly broad, to ensure researchers and clinicians are studying the same population the International Ankle Consortium (IAC) created a position statement on selection criteria for patients with CAI. The IAC recommends that in order to be included in a research study as a CAI subject, one must had at least 1 significant ankle sprain that occurred at least 12 months prior to the study that resulted in pain/swelling and interrupted at least 1 day of desired physical activity.[44] In addition, individuals must have recurrent bouts of instability and/or recurrent ankle sprain(s) of their originally injured limb.[44] They recommend using the identification of functional ankle instability (IdFAI), to quantify bouts of instability and repetitive ankle sprains. Finally, self-reported function of the involved limb should be reported for all studies, but only be an inclusion criteria if self-reported function is important to the research question.[44] The IAC recommends the use of the foot and ankle ability measure (FAAM) activities of daily living (ADL) and sport questionnaires to quantify self-reported function. Although the cause of CAI remains unclear, associated characteristics in

comparison to healthy individuals have been well established. These characteristics include but are not limited to deficits in dorsiflexion range of motion, decreased ankle strength, deficits in postural control, and altered gait patterns.

Characteristics Associated with CAI

Dorsiflexion ROM deficits commonly occurs after ankle sprains and remain present in individuals with CAI.[18] One reason is that there may be a subluxation of the talus, proximal fibula, or distal fibula, which is known as the positional fault theory.[91-93] This dorsiflexion deficit is not only present during seated or standing measures,[82] but has also been seen during the swing phase of the jogging gait cycle.[17] The decrease in dorsiflexion may contribute to recurrent sprains because dorsiflexion is a more stable position of the ankle as a result of the bony congruency. There has been both concentric and eccentric deficits reported in individuals with CAI.[20, 94] Specifically, eversion strength deficits may contribute to chronic ankle instability because the role of the evertor musculature in providing dynamic instability to the ankle joint.[95] In addition to ROM and strength deficits, proprioception[7, 9, 96] and postural control are diminished in individuals with CAI.[15, 46, 65, 82, 97-98] Finally, differences in gait patterns have been shown between healthy and CAI individuals.[17, 23-25, 71, 81, 99] With regards to gait, CAI patients show greater ankle inversion and plantar flexion positioning during the swing phase and spend a longer time with a greater amount of force on the lateral aspect of the foot during the stance phase, which may predispose them to ankle sprains.[21-22, 68]

Measurement Techniques

Assessment Self-reported Function

The foot and ankle ability measure activities (FAAM) of daily living (ADL) and sport are two questionnaires that are used to assess patient level of function for individuals with CAI.[100-101] Furthermore, both questionnaires have been shown to be reliable at detecting change after an intervention for patients with CAI: intraclass correlation coefficients (ICC) of 0.89 for the FAAM-ADL and 0.84 for the FAAM-Sport.[102] In addition to the FAAM ADL/Sport, the identification of functional ankle instability (IdFAI), is a reliable tool at determining whether an individual has functional ankle instability (FAI).[103]

Assessment Range of Motion Measures

Since arthrokinematic joint restrictions may be present due to the positional fault associated with ankle sprains, ankle dorsiflexion ROM should be assessed to identify both arthrokinematic and osteokinematic deficits.[27] A common test to assess for arthrokinematic restrictions is the posterior talar glide test (PTGT). During the test, the clinician places the patient in a seated position and glides their foot in the posterior direction to assess for any firm end feel restrictions. This test has been shown to have high intrarater reliability with ICC ranging from 0.85 to 0.99.[18, 35, 50] Osteokinematic dorsiflexion deficits can be assessed by using a bubble inclinometer in both seated and standing positions. The use of an inclinometer to asses for ROM deficits at the ankle has been shown to be a reliable measure with ICC ranging from 0.93-0.98.[104]

Assessment of Strength

Ankle strength can be accurately measured by using a hand-held dynamometer for both baseline and training effect measures.[54] The intratester reliability (ICC) for ankle

inversion is 0.92, ankle eversion is 0.94, ankle dorsiflexion 0.94 during one session of testing.[54] The intersession reliability decrease, however, the ICC for each position are still considered to have excellent reliability (dorsiflexion=0.85, eversion=0.87, dorsiflexion=0.90).

Assessment of Static and Dynamic Balance

Static balance is commonly assessed by using a forceplate to measure center of pressure (COP) area and COP average velocity.[14, 105] Center of pressure area (cm^2) provides insight to how much sway an individual is doing during a balance trial, while COP average velocity (cm/second) represents the rate of change of the position over the given trial. Therefore, a smaller COP area and COP velocity represents less variability during a balance task. Center or pressure has acceptable reliability of 0.64, while COP velocity has very high reliable of 0.91 during single limb eyes closed balance.[106] Static balance is often measured in multiple positions with multiple constraints. Chronic ankle instability deficits have been detected during single limb balance, with the participants hands on their hips or crossed in front of their chest, the opposite leg flexed to 30 degrees at the hip and 45 degrees at the knee.[14] This is often completed with the individual's eyes open and closed.

A common test to assess for dynamic balance deficits in individuals with CAI is the star excursion balance test (SEBT).[16, 56] The SEBT has been reported to have high intertester reliability (0.81-0.93) and intratester reliability (0.82-0.96).[57] Completion of the SEBT requires the individual to stand on one limb and reach as far as they can with their opposite limb while maintaining their hands on their hips and without losing their

balance and returning to the starting position.[107] The most common reaching positions used for the SEBT are the anterior, posteriomedial, and posteriolateral directions.[107]

Assessment of Kinematics and Kinetics during Walking

As previously described, individuals with CAI, on average, walk with a more inversion prior to initial contact,[22] have less dorsiflexion during the swing phase,[24] maintain more inversion throughout the stance phase,[22] have more lateral displaced COP,[22] and have an increased lateral load during walking.[85] Electromagnetic 3-D motion analysis systems have been shown to be reliable motion capture systems at detecting differences in ankle kinematics and kinetics during gait.[108] Specifically, the Flock of Birds (Ascension Technology, Burlington, Vermont, USA) now referred to as the *TrackSTAR* system has been shown mean errors angles being less than 1 degree for rotation and less than 1mm for translations at the ankle joint complex.[108] Typically, sensors are placed on the calcaneus, dorsal aspect of the foot, lower leg, mid thigh, sacrum, and thoracic spine.[73, 108] For our study, three-dimensional joint kinematics of the ankle, knee, and hip were measured using the *trackSTAR* (Ascension Technologies, Inc., Burlington, Vermont) electromagnetic motion analysis system controlled by Motion Monitor software (Version 8, Innovative Sports Training, Inc., Chicago, Illinois) at a sampling rate of 144 Hz. A non-conductive forceplate (Bertec Corporation, Columbus, Ohio) with a sampling rate of 1440 Hz was embedded into a walk-way and synchronized with the electromagnetic tracking device and used to collect ground reaction forces and for determination of initial contact and terminal stance during walking trials

In addition to 3-D motion capture systems, plantar pressure measurement systems are a valid method of quantifying pressure distribution of the foot during walking or jogging tasks.[109] With regards to CAI, plantar pressure alterations have been shown when compared to healthy individuals.[83, 85] A study by Nawata et al,[83] found that individuals with CAI maintain a more supinated foot during the stance phase of gait. Furthermore, similar results were reported by Becker et al.[110] and Schmidt et al.,[85] who found an increase in lateral plantar pressure during the gait cycle. The Pedar plantar pressure system (Novel Electronics Inc., St Paul, MN, USA) is an insole system that allows for in shoe plantar pressure measures. This system allows investigator to examine various measures of plantar pressure in specific regions of the foot. Common measures are peak pressure, pressure-time integral, time to peak pressure, contact time, and contact area.[85]

Surface Electromyography

Surface electromyography (sEMG) is an instrument that measures the electrical activity of muscle in response to detection of activation of a motor unit within muscle.[45] With regards to CAI, sEMG is often used to measure muscle activation amplitude, and muscle activation timing. Multiple studies have identified activation differences in the peroneus longus in CAI participants when compared to healthy controls during walking and functional tasks.[22, 66, 77] Specifically, individuals with CAI activate their peroneus longus prior to initial contact during walking, as opposed to healthy individuals who activate their peroneus longus after initial contact[22, 77] and activate their peroneus longus for a longer period of time across the stride cycle.[77] In addition, during functional tasks such as balance and hopping, individuals with CAI have decreased total lower limb

muscle activity than healthy individuals.[66] Surface EMG has been shown to be a reliable technique to detect changes in muscle activity in the presence of an intervention. The use of ankle braces have been shown to increase the stretch reflex of the peroneus longus[111] and cause a delayed activation of the peroneus longus during gait.[78]

For our study, sEMG was measured using DE 2.1 differential EMG sensors (Delsys, Boston, MA). These rectangular sensors consisted of two parallel bars separated by 1cm, where each bar was 1cm long and 1mm wide. They were placed over the mid-belly of each muscle, parallel to fiber orientation. Prior to placement, skin was shaven, abraded, and cleaned using alcohol. Input impedance was $>10^{15}\Omega//0.2$pF with a signal to noise ratio of 1.2uV. The signal was amplified with a gain of 1000 and digitized with a 4 channel acquisition system (Bagnoli EMG system, Delsys, Boston, MA) at 1000 Hz. Data was collected using Motion Monitor software (Innovative Sports Training, Inc., Chicago, Illinois) and processed by using EMGworks software (version 4.1.1, Delsys, Boston, MA). Data processing methods were the same as previous studies.[32] Data was filtered using a 10-500 band-pass filter and smoothed using a 50-sample moving window root mean square (RMS) algorithm as recommended by Konrad et al.[45]

Current Rehabilitation Techniques

Comprehensive Rehabilitation Program

A study completed by Hale et al.[60] completed a 4-week comprehensive rehabilitation program and found that individuals with CAI had improved FADI-Sport (renamed the FAAM-Sport) scores and improved reach distances on the SEBT after completing the rehabilitation. Their magnitude of change in the FAAM-Sport was 11%,

which is considered clinically meaningful; however, their patients still had a large decreases in self-reported function. We believe this is due to their program being split between supervised and unsupervised rehabilitation sessions. An exclusively supervised program allows the clinician to implement an impairment based progressive rehabilitation program. To our knowledge, there has not been a study examining the effects of an impairment based progressive rehabilitation program.

Range of Motion

Treatment of range of motion should include exercises that address arthrokinematic and osteokinematic deficits.[27] Both Hoch et al.[42] and Vicenzino et al.[35] found that the use of joint mobilizations or mobilization with movement caused an increase dorsiflexion ROM and posterior talar glide.

Strength

Strength has been shown to improve with progressive ankle strengthening exercises utilizing tubing exercises and manual resistance.[36, 62-63] However, the has not been a study that has evaluated the effectiveness comparing tubing exercises to manual therapy. We believe manual therapy would be more effective at improvement strength of the ankle because the clinician can provide more resistance and therefore maximize principals of gaining strength.

Balance

Based on past research, it is clear that balance training improves both static and dynamic balance in individuals with CAI.[14, 28, 40] Based on these studies, balance training should consist of both static and dynamic exercises and incorporate unstable devices to

make the exercise more challenging. In a study by McKeon et al.,[14] they found that a 4-week balance progression protocol improved postural control measured by time-to-boundary (TTB). This protocol had patients with CAI complete eyes open/closed static balance, dynamic reaching tasks, and hop to stabilization tasks. It addition, to challenging the patients by having them close their eyes during static balance, they also incorporated unstable surfaces during the static, dynamic, and hop to stabilization exercises.

Gait Retraining for Patients with CAI

There has been only a few studies that examined the effects of rehabilitation on functional activities in patients with CAI, McKeon et al.[43], who examined the effects of a balance training protocol on ankle gait measures during treadmill walking and a case-report by O'Driscoll et al.,[75] who examined the effects of a 6-week dynamic neuromuscular training program on ankle joint function. Neither study found changes in ankle inversion motion throughout the gait cycle, however, the McKeon et al.[43] study found improved shank/rearfoot coupling stability measured by a reduction in shank/rearfoot coupling variability using a continuous relative phase analysis, and the O'Driscoll et al[75] study found decrease plantar flexion during a jump landing task and decrease vGRF during gait.

Based off these studies, it appears that in order to decrease ankle inversion positioning throughout gait in individuals with CAI, clinicians must incorporate specific gait training modalities. We do not want to discredit these programs used because they clearly improved clinical outcomes associated with CAI. However, since all programs included multiple functional exercises that included jumping and cutting tasks, which

were made more challenging by the use of unstable surfaces, we believe gait training at the ankle needs to be more specific to walking and running. Gait training using visual feed-back from a 3-dimensional motion capture system, has been shown to effectively reduce the knee adduction moment in healthy knee varus aligned individuals over 8 treatment sessions.[76] This study shows that it is possible to alter frontal plane movement patterns, however, to our knowledge there has not be a gait training technique at the ankle to cause lasting reduction in inversion motion during walking.

Gait Training Instruments

Ankle Destabilization Devices

Ankle destabilization devices are devices that consist of either a boot or sandal with an articulator below the heel designed to mimic the motion that occurs at both the subtalar and talocrural joints during walking and other functional movements. The goal of these devices is to force the patient into ankle plantar flexion, inversion, and internal rotation in a controlled manner while completing functional tasks. Unlike traditional unstable surfaces, these devices can be worn like shoes. It is thought that by causing an anticipated perturbation at the ankle, surrounding musculature will contract via feed-forward mechanisms to prevent the ankle from going into the vulnerable position.[29-31]

We have completed laboratory studies[32-33] on two specific ankle destabilization devices, the Myolux Athletik (boot) and Myolux II (sandal) (Cevres Santé, Le Bourget-du-Lac, France)(Figure 1.1). We assessed surface electromyography (sEMG) measures of six lower extremity muscles during balance, star excursion balance test (SEBT), lateral hopping and walking comparing the two ankle destabilization devices to a shod control

condition in 15 CAI patients.[31] We found an alteration in muscle activity when compared to shod when the participants were wearing the devices for each functional task. Specifically, there was a pronounced increase in the peroneus longus EMG amplitude during all tasks, which shows the potential for these devices to increase lateral stability of the ankle joint. Since there is an increase in peroneus longus activity in each functional task, we believe these devices may not only be able to improve neuromuscular control, but also provide a method to cause strength increases during closed kinetic exercises if incorporated into a progressive rehabilitation program as a result of increased muscle activity.

Auditory Biofeedback Device

We believe auditory biofeedback could be used to help decrease lateral plantar pressure during gait in patients with CAI. Auditory biofeedback is commonly used in children to promote heel-toe walking as a form of positive reinforcement because children enjoy making their shoe squeak during gait.[86] A case-series by Marcus et al[87] used a product called GaitSpot Auditory Squeakers to try to promote heel-toe gait patterns in autistic children with idiopathic to-walking patterns. This product consists of a squeaker that can be placed beneath the patient's heel of their shoes. Patients were instructed to walk in a manner that causes the device to make a noise. After the intervention, they found that the children had increases in heel contact during gait. To treat CAI, clinicians could use the noise to deter faulty movement patterns opposed to promoting it.

A custom auditory biofeedback device was made using a force sensor (FlexiForce, Tekscan Inc., South Boston, MA), piezo buzzer (Intervox, International Components Corporation, Bohemia, NY), trimpot, and a12volt battery (Figure 3.1). The device was designed to elicit an audible noise when a subject's vertically directed force exceeded the threshold of the force sensor. The force sensor threshold could be set to various thresholds using the trimpot. Unlike with the previous study that was using auditory feedback to encourage heel toe walking, we would use this technology to notify patients that they are excessively loading the lateral aspect of their foot. We believe if individuals consciously know they are using a faulty movement patterns that may contribute to recurrent ankle instability, they may be able to modify their gait pattern to further protect them from ankle sprains.

Conclusion

Chronic ankle instability is a multi-faceted condition that has common characteristics associated with it that may be contributing to bouts of instability and recurrent ankle sprains. Studies have been conducted to determine effective interventions to treat these common characteristics; however, the interaction of these interventions remains unclear. In addition, there has not been a gait retraining technique that has been shown to be effective at improving gait patterns in patients with CAI. An impairment based progressive rehabilitation program that incorporates ankle destabilization devices may provide more insight on treating CAI and on whether gait patterns can be altered using these devices.

APPENDIX C
Additional Methods

Table C1

1. Questionnaires

- Foot and Ankle Ability Measure ADL/Sport
- Identification of FAI
- VR-12
- Godin Leisure-time exercise questionnaire
- Ankle Activity Score (Halasi, 2004)
- Global Rating Change Score

2. Motion Monitor Data Collection Procedures (General Set-up)

1. EMG Electrode Placement
    a. Double sided toupee tape was pre-applied to the active electrodes prior to subject arrival at the Exercise and Sport Injury Laboratory
2. EMG Electrode Placement
        i. This area was shaved using a disposable razor
        ii. The area was then lightly debrided using a brillo pad
        iii. The area was cleansed using isopropyl alcohol
        iv. A small mark was made at the location site for the electrode Subjects were instructed to leave the table and walk to the platform containing the Motion Monitor
3. The other side of the double-sided toupee tape covering was removed from the electrode
    a. The electrode was placed directly over the mark
    b. The electrode was secured in place with Leuokotape

4. The ground electrode was applied to the tibia of the nondominant limb
    a. This area was shaved using a disposable razor
    b. The area was then lightly debrided using a brillo pad
    c. The area was cleansed using isopropyl alcohol
5. Motion Monitor Sensor Placement (Figure C3)
    a. All areas were shaved as needed
    b. All sensors had double sided toupee tape attached to them
    c. Sensor 1 was placed on the dorsum of the right midfoot
        i. Sensor was secured in place using Leuokotape
        ii. Sensor cord was looped into the Leuokotape to avoid a tripping hazard
    d. Sensor 2 was placed on the dorsum of the left midfoot
        i. Sensor was secured in place using Leuokotape
        ii. Sensor cord was looped into the Leuokotape to avoid a tripping hazard
    e. Sensor 3 was placed on the right lateral shank

i. Sensor was secured in place using Leuokotape
ii. Sensor cord from sensor number 1 was gathered together with the cord for sensor 3
iii. Cords were not pulled taught in order to allow free movement of the joint and body segments
iv. Sensor cords were looped into the Leuokotape to avoid a tripping hazard

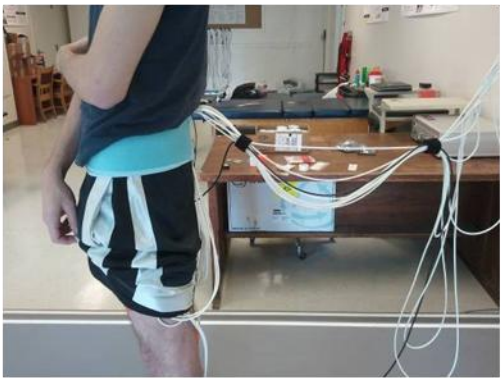
f. Sensor 4 was placed on the left lateral shank
    i. Sensor was secured in place using Leuokotape
    ii. Sensor cord from sensor number 2 was gathered together with the cord for sensor 4
    iii. Cords were not pulled taught in order to allow free movement of the joint and body segments
    iv. Sensor cords were looped into the Leuokotape to avoid a tripping hazard
g. Sensor 5 was placed on the right lateral thigh
    i. Sensor was secured in place using Leuokotape
    ii. Sensor cords from sensor numbers 1 and 3 were gathered together with the cord for sensor 5
    iii. Cords were not pulled taught in order to allow free movement of the joint and body segments
    iv. Sensor cords were looped into the Leuokotape to avoid a tripping hazard
h. Sensor 6 was placed on the left lateral thigh
    i. Sensor was secured in place using Leuokotape
    ii. Sensor cords from sensor numbers 2 and 4 were gathered together with the cord for sensor 6
    iii. Cords were not pulled taught in order to allow free movement of the joint and body segments
    iv. Sensor cords were looped into the Leuokotape to avoid a tripping hazard
i. Sensor 7 was placed on the sacrum
    i. Sensor was secured in place using electric tape and an elastic wrap
    ii. Sensor cords from sensor numbers 1-6 were gathered together with the cord for sensor 7
    iii. The cord for sensor 8 was also gathered into this bundle
    iv. Cords were not pulled taught in order to allow free movement of the joint and body segments
    v. Sensor cords were looped into the elastic wrap to avoid a tripping hazard
        1. This created a tail of cords behind the subject
        2. Two Velcro straps were applied around the cords to keep them together
j. Sensor 8 was placed over the thorax

i. Sensor was secured in place using electric tape
ii. The cord for sensor 8 was gathered into the bundle of cords 1-7

k. Sensor 10 is placed on midline of the right calcaneus
l. Sensor 11 is placed on midline of the right calcaneus
m. Tape was placed on the calcaneus and traced to ensure the shoe fit properly over the sensor

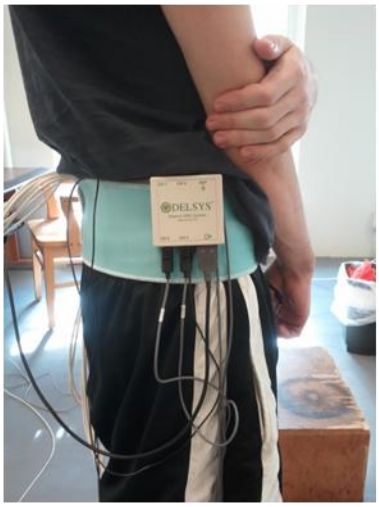
n. The cords from the EMG electrodes were also gathered into the posterior tail (Figure C4)

Figure C4. Posterior tail formed by the EMG and motion sensor cords. Secured using Velcro ties.



o. The EMG box was clipped onto the elastic wrap at the subject's right hip (Figure C5)

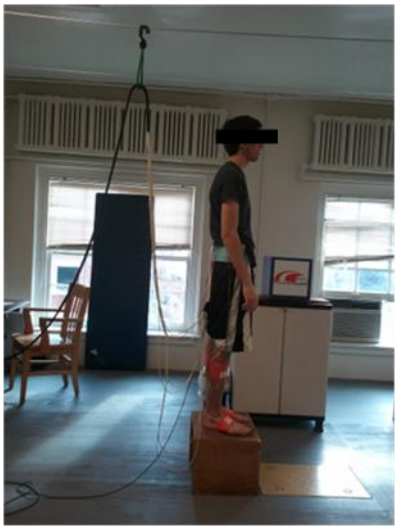
Figure C5. EMG signal box clipped at the right hip to the belt surrounding the participant's waist.



p. Sensor 9 was the stylus

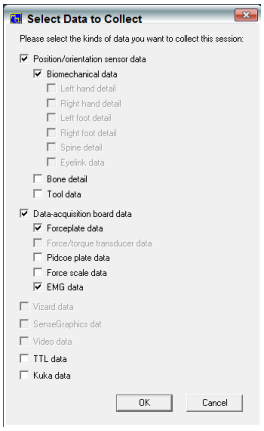
q. An overhead wiring system allowed free movement of the subject as the cords were suspended and slid freely (Figure C6)

Figure C6. Overhead wiring system allowing free movement of the participant during the activity.

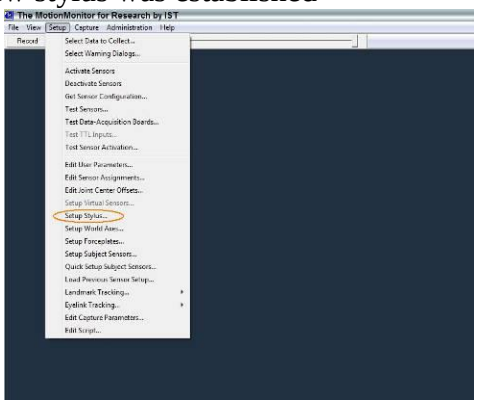


Motion Monitor Hardware and Software Set-up

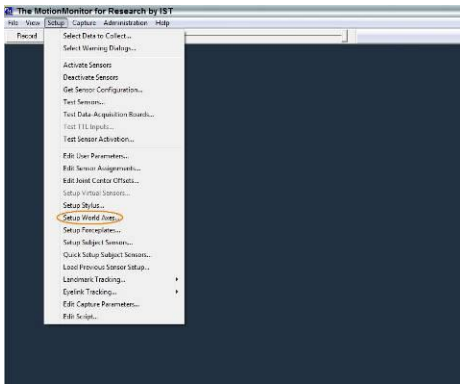
1. Prior to the subject arriving:
    a. The data to collect was chosen as biomechanical, forceplate, and EMG



    b. The stylus was set up
        i. Under the set-up tab, “set-up stylus” was selected
        ii. A new stylus was established



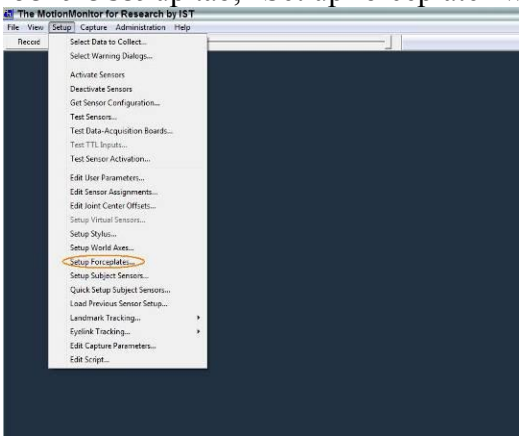
        iii. The stylus was placed on the force plate and rotated into ten different positions without moving the tip of the stylus
            1. If the error was 0.002 or less, the stylus set-up was accepted. If not, this process was repeated
    a. The world axes were set up
        i. Under the set-up tab, “Set-up world axes” was selected



iv. A new axis system was defined
v. The origin was designated as the bottom right corner of the forceplate
vi. The positive x-axis was defined as the direction the person faces
vii. The positive y-axis was defined as the direction to the left side of the subject

a. The force plate was set up

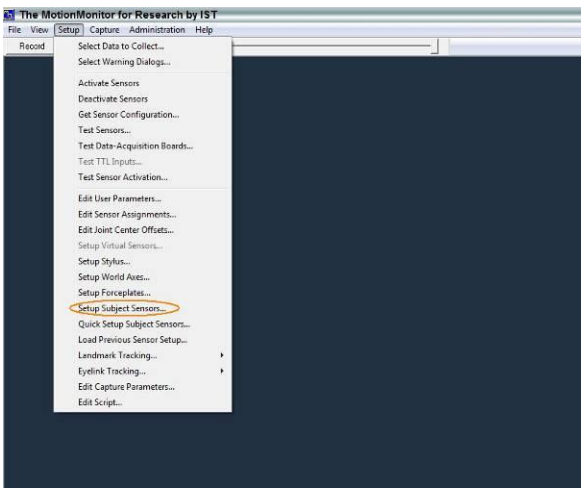
viii. Under the set-up tab, “Set up forceplate” was selected



ix. The stylus was placed on the forceplate in 3 non-linear positions as cued by the Motion Monitor system
x. The stylus was held aloft with 24 inches above the forceplate
xi. If the error was 0.002 or less, the forceplate set-up was accepted. If not, this process was repeated

2. The subject stood next to, but not on the force plate

a. Under the set-up tab, “Set up subject sensors” was selected



b. The subject was asked to step onto the force plate
c. The left anterior superior iliac spine (ASIS) was palpated by the researcher and the location was marked with the stylus.
    i. This process was repeated for the right ASIS
d. A digital model of the subject was constructed by placing the stylus at the following locations when cued by the Motion Monitor system:
    i. Top of the head
    ii. C7/T1 vertebrae
    iii. T12/L1 vertebrae
    iv. L5/S1 vertebrae
    v. Left medial knee
    vi. Left lateral knee
    vii. Left medial malleolus
    viii. Left lateral malleolus
    ix. Tip of the left second phalanx
    x. Right medial knee
    xi. Right lateral knee
    xii. Right medial malleolus
    xiii. Right lateral malleolus
    xiv. Tip of right second phalanx

Walking Procedures

1. Ten seconds of quiet, double limb stance was recorded for EMG normalization purposes
2. Participant was instructed to walk across the platform at a self-selected pace attempting land their involved foot on the forceplate
3. They were able to practice this until they felt comfortable
4. Participants completed 15 walking trials

Jump Landing Procedures

1. Ten seconds of quiet, single limb stance on the dominant leg was recorded for EMG normalization purposes
2. Drop-Vertical Jump (DVJ) (C7-C8)

a. Participants stand atop a 30cm box located in front of the forceplate
    i. The box was placed a standardized distance from the forceplate, at one-half of the participant's height
b. A cue of "Ready? Go!" was given to signal to participants to begin the activity
c. The participants dropped off the box onto the forceplate, landing on both limbs
    i. Participants landed on the force plate with their injured leg
d. A maximal effort vertical jump was performed immediately upon landing from the initial drop
e. Participants landed on the forceplate following the vertical jump

3. Descriptive Measures

a. Age
b. Height
c. Weight
d. Standing Hindfoot ailignment
    1. Mark midline of calcaneus and calf
    2. Participant will complete 10 marches in place and stand comfortably
    3. Tester will measure the angle from calcaneus to mid-calf with goniometer
    4. Repeat steps 1-3 for three trials
e. Navicular Drop
    1. Mark most prominent portion of navicular with participant sitting
    2. Using the Fowler z-height measure the navicular height (mm) (be sure participant is not putting weight over foot)
    3. Have participant stand on one leg and measure navicular height
    4. Repeat steps 1-3 for three trials

4. Osteokinematic Range of Motion Measures

a. Dorsiflexion Standing Straight Knee
    1. Researcher zeroes the bubble inclinometer using a surface known to be flat. The researcher then attaches the bubble inclinometer to the leg along the fibular line using the Velcro strap with the lower edge of the inclinometer 10cm from the inferior angle of the lateral malleolus.
    2. Participant is positioned near a wall with the leg being measured behind them and the other leg in front. The subject is told to lean forward as if they were stretching their calf with the knee straight. The researcher keeps her hand on the posterior aspect of the heel to ensure that it does not come off the ground.

3. The participant takes three trials, with verbal encouragement to reach as far as possible. The subject steps away from the wall between measures and is positioned again. The bubble inclinometer is zeroed using a surface known to be flat between trials.

b. Dorsiflexion Standing Bent Knee

1. Researcher attaches bubble inclinometer to the leg that is to be measured along the fibular line using the Velcro strap with the lower edge of the inclinometer 10cm from the inferior angle of the lateral malleolus.
2. Participant is positioned near a wall with the leg being measured behind them and the other leg in front. They are instructed to keep the heel of the front leg on the floor for balance, and try and squat down, bringing the back knee as close to the floor as possible. The researcher keeps her hand on the posterior aspect of the heel to ensure that it does not come off the ground.
3. The Participant takes three trials, with verbal encouragement to reach as far as possible. The participant steps away from the wall between measures and is positioned again. The bubble inclinometer is zeroed using a surface known to be flat between trials.

c. Dorsiflexion Straight Knee Supine

1. The participant is positioned supine on the table and the bubble inclinometer is attached to the lateral side of the foot along the fifth metatarsal with the top of the inclinometer at the head of the fifth metatarsal, and the base near the heel.
2. Participant is instructed to pull their toes near to the head and to keep the ankle as straight as possible.
3. The subject takes three trials, with verbal encouragement to reach as far as possible. The participant rests with foot relaxed between trials. The bubble inclinometer is zeroed using a surface known to be flat between trials.

d. Dorsiflexion Bent Knee Prone

1. The participant is positioned prone on the table and the bubble inclinometer is attached along the base of the fifth metatarsal with the top of the inclinometer towards the plantar surface of the foot and the bottom of the inclinometer near the dorsal surface of the foot. The researcher holds the knee in 90º of flexion.
2. The participant is instructed to pull his or her toes towards the floor and to keep the ankle as straight as possible.
3. The participant takes three trials, with verbal encouragement to reach as far as possible. The participant rests with foot relaxed between trials. The bubble inclinometer is zeroed using a surface known to be flat between trials.

e. Plantar flexion Straight Knee Supine

1. The participant is positioned supine on the table and the bubble inclinometer is attached to the lateral side of the foot along the fifth

metatarsal with the top of the inclinometer at the head of the fifth metatarsal, and the base near the heel.

2. Participant is instructed to point their toes near to the head and to keep the ankle as straight as possible.

3. The subject takes three trials, with verbal encouragement to reach as far as possible. The participant rests with foot relaxed between trials. The bubble inclinometer is zeroed using a surface known to be flat between trials.

f. Inversion Straight Knee Supine

1. Goniometer axis is placed midline of medial and lateral malleolus
2. Fixed arm is positioned midline of tibia and fibula
3. Moving arm is position midline of 1st ray
4. Participant is instructed to turn foot inward as far as possible
5. Researcher takes three measurements

g. Eversion Straight Knee Supine

1. Goniometer axis is placed midline of medial and lateral malleolus
2. Fixed arm is positioned midline of tibia and fibula
3. Moving arm is position midline of 1st ray
4. Participant is instructed to turn foot outward as far as possible
5. Researcher takes three measurements

5. Arthrokinematic Range of Motion Measures

a. Posterior talar glide test is performed on the subject.

1. The participant is positioned sitting on the table with the knees and legs hanging from the table. The bubble inclinometer is attached to the leg that is to be measured along the fibular line using the Velcro strap with the lower edge of the inclinometer 10cm from the inferior angle of the lateral malleolus.

2. The researcher places the subject's knee at 90º of flexion, puts the ankle in subtalar joint neutral, and instructs the subject to relax. The researcher applies a posterior force on the talus to the point where capsular restriction can be felt. The measurement of dorsiflexion is taken at this point.

3. The researcher takes three trials, allowing the leg and foot to relax between trials. The placement of the hands and foot are repositioned between trials. The bubble inclinometer is zeroed using a surface known to be flat between trials.

b. Anterior Drawer Test using Ankle Arthrometer

1. Computer set up:
   - Researcher will plug the arthrometer into the computer, open the program, and set it to multiple trails with a maximum force of 125N.

2. Participant is placed sitting on the table with the knees and legs off the table and the feet on the ground. The participant's foot and the heel-cup of the arthrometer are sprayed with adhesive spray and allowed to dry.

3. The heel is placed into the heel cup and the arthrometer is adjusted to fit snuggly around the heel. The dorsal pad is placed snuggly over the cuneiforms.
4. The participant is instructed to slide back so the legs are resting on the table while simultaneously placing a half-round foam bolster under his or her knee. The place where the leg meets the end of the table is then marked.
5. Three trials in the anterior direction are then taken with a force of 125N.

c. Talar Tilt using Ankle Arthrometer

1. Computer set up:
   - Researcher will plug the arthrometer into the computer, open the program, and set it to multiple trails with a maximum force of 125N.

2. Participant is placed sitting on the table with the knees and legs off the table and the feet on the ground. The participant's foot and the heel-cup of the arthrometer are sprayed with adhesive spray and allowed to dry.
3. The heel is placed into the heel cup and the arthrometer is adjusted to fit snuggly around the heel. The dorsal pad is placed snuggly over the cuneiforms.
4. The participant is instructed to slide back so the legs are resting on the table while simultaneously placing a half-round foam bolster under his or her knee. The place where the leg meets the end of the table is then marked.
5. Three trials in the frontal plane are then taken with a force of 125N.

d. Internal Rotation using Ankle Arthrometer

6. Manual Ligament Laxity Testing

a. Anterior Drawer

1. Complete 3 anterior drawer tests in a seated position
   -Knee bent over edge of table
   -Researcher stabilizes lower leg
   -Places foot in about 20 degrees of plantar flexion
   -Draw talus forward
2. Scores laxity on a 5 point scale:
   a. 0=Hypomobile
   b. 1= Normal
   c. 2= Mild laxity
   d. 3= Moderate laxity
   e. 4= Gross laxity

b. Talar Tilt

1. Complete 3 talar tilt tests in a seated position
   -The talar tilt test was performed with the subject's foot held in a neutral

sagittal plane position while the examiner tilted the rearfoot into inversion

2. Scores laxity on a 5 point scale:
    a. 0=Hypomobile
    b. 1= Normal
    c. 2= Mild laxity
    d. 3= Moderate laxity
    e. 4= Gross laxity

c. Internal Rotation Test

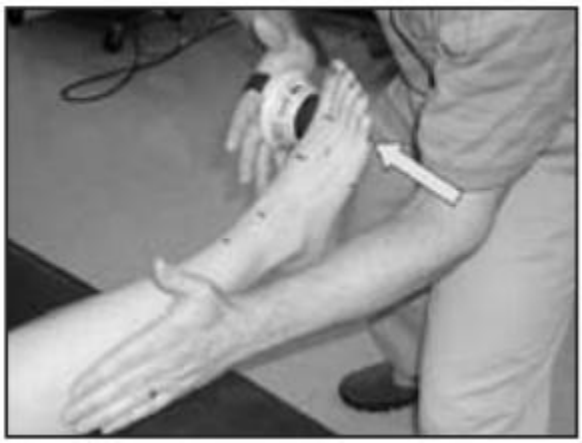
7. Manual Muscle Testing (Use Kelln et al. methods)

a. Each direction will be completed three times

b. Participant will push as hard as they can in the dynamometer for 5 seconds

c. Tester will not let the participant push through a full ROM (Figures from Kelln et al.)

1. Ankle dorsiflexion (stop ROM at neutral position)
2. Ankle inversion (ankle neutral)
3. Ankle eversion (ankle neutral)
4. Ankle eversion (ankle plantar flexed)
5. Ankle plantar flexion (prone knee bent to 90 degrees)
6. Short foot muscle test



8. Balance

Force Plate Procedures

1. Open program
    a. Set data folder → C:\My Documents\Accusway data
    b. Click "select subject"
    c. Click "add record" → fill in subject number
    d. Select protocol, click "select" → C:\Balance Clinic\
    e. Add subject
2. Zero amplifier
3. Zero forceplate
4. Measure individuals foot length and width
5. Position foot in middle of force plate
6. Add tape to force plate to ensure foot is in same position for each tri
7. Explain static balance testing procedure
    a. Balancing on the force plate 3 times with eyes open and 3 times with eyes closed, on both legs
    b. Balance on one leg, hands on hips, look straight ahead at dot on wall, try to remain as motionless as possible

c. Each trial will last 10 seconds

8. Ask subject to tell you when they are ready
9. Collect data
    a. Click "acquire"
    b. Click "save data"
    c. Zero forceplate
    d. Repeat

Star Excursion Balance Test Procedures

1. Measure participant's limb length

2. Demonstrate to the participant how to complete the anterior, posterior medial, and posterior lateral directions (use these cues)
    a. Maintain hands on hips
    b. Keep heel on the ground
    c. Reach as far as possible (may bend at ankle, knee, hip)
    d. Lightly touch tap measure
    e. In a controlled manner return back to original starting position
3. Allow participant 3 practice trials
4. Complete three testing trials in the anterior, posterior medial, and posterior lateral directions (collect in this order)

9. Auditory Biofeedback Device Using the Pedar System

a. Participants were fitted for shoes/insoles and preformed walking trials

b. Participants were instructed to walk at a normal pace on a treadmill for 30 seconds.

c. Tester inserted the auditory biofeedback device in the shoe. The sensor was placed beneath the head of the 5^{th} metatarsal. The device was adjusted to elicit a noise when the participant walked normally.

d. The participant completed 30 more seconds of treadmill walking while using the device and instructed to walk in a normal manner and ignore the noise that was elicited.

e.. The participant completed 30 more seconds of treadmill walking while using the device and instructed to walk in a manner that a noise would not be elicited.

10. Gait Trainer with EMG

<u>Basic Set-up</u>

*same as motion monitor EMG

<u>EMG and Warm-up</u>

1. Shave
2. Debride
3. Cleanse
4. Place markers and trace markers with interelectrode distance of ~2cm
    a. Anterior tibialis

        i. Black ground lead over medial tibial shaft
    b. Peroneus longus
    c. Medial gastrocnemius
    d. Gluteus medius
5. Perform 5 minute warm-up of walking at 3.0 MPH

MVIC (position 1)
Subject: Seated upright on table
Feet hanging off edge, knees at 90 degree angle
Hands across chest

Anterior tibialis
Tester 1: Invert and plantarflex ankle, hand on heel, other over dorsal aspect of foot, instruct subject when signaled by tester 2 to dorsiflex or "pull their foot towards the ceiling" until told to stop by tester 2
Tester 2: Open new AcqKnowledge sheet and save as (Subject # Condition MVIC Ant Tib), press collect, signal tester 1 and subject when to start, collect for approximately 5 seconds and signal tester 1 and subject when to stop, press stop. Save File.

Peroneus brevis/longus
Tester 1: Invert and plantarflex ankle, hand on heel, other on lateral aspect of foot, instruct subject when signaled by tester 2 to evert or "push against my hand that is on your foot" until told to stop by tester 2
Tester 2: Open new AcqKnowledge sheet and save as (Subject # Condition MVIC Per Longus), press collect, signal tester 1 and subject when to start, collect for approximately 5 seconds and signal tester 1 and subject when to stop, press stop. Save File.

MVIC (position 2)
Subject: Have patient lay prone on table with feet off the edge and hands at sides

Medial gastrocnemius
Tester 1: Position ankle in neutral position, place subjects foot on anterior aspect of tester 1's thigh just below hip, use hands to hold on to table, instruct subject when signaled by tester 2 to plantarflex their ankle or "push down on the gas" until told to stop by tester 2
Tester 2: Open new AcqKnowledge sheet and save as (Subject # Condition MVIC Lat Gastroc), press collect, signal tester 1 and subject when to start, collect for approximately 5 seconds and signal tester 1 and subject when to stop, press stop. Save File.

MVIC (position 3)
Subject: Position subject on their side with testing leg on top
Have the bottom hip slightly flexed (20 degrees) and bottom knee flexed (90 degrees)

Gluteus medius

Tester 1: Position subjects top hip externally rotated and in slight extension (10-15 degrees) and abduction (10-15 degree) with knee is straight, position one hand on lateral aspect of ankle and use the other to stabilize the subjects hips, instruct subject when signaled by tester 2 to abduct hip or "push their top leg towards the ceiling" until signaled to stop by tester 2

Tester 2: Open new AcqKnowledge sheet and save as (Subject # Condition MVIC Glut Med), press collect, signal tester 1 and subject when to start, collect for approximately 5 seconds and signal tester 1 and subject when to stop, press stop. Save File.

**Throughout testing tester 2 will evaluate the signal quality to minimize cross talk If necessary electrode placement will be adjusted at this point and the MVIC for that muscle will be redone*

Quiet standing

Subject: Stand with feet shoulder width apart, hands on hips and toes pointed forward with eyes open for 10 seconds.

Tester 2: Open new AcqKnowledge sheet and save as (Subject # Condition QS), press collect, signal tester 1 and subject when to start, collect for approximately 10 seconds and signal tester 1 and subject when to stop, press stop. Save file.

Table C2

IRB-HSR PROTOCOL

Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. That if this study involves any funding or resources from an outside source, or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
5. That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.

6. That all personnel working on this protocol will follow all IRB-HSR Policies and Procedures as stated on the IRB-HSR Website http://www.virginia.edu/vprgs/irb/ and on the School of Medicine Clinical Trials Office Website: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm
7. I will ensure that all those delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training , experience or credentialing to undertake those tasks.
8. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
9. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
10. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
11. That all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
12. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.
13. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
14. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
15. That any serious deviation from the protocol will be reported promptly to the Board in writing.
16. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
17. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
18. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
19. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI is leaving UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
20. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
21. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept at least 6 years after completion of the study.
22. No data/specimens may be taken from UVa without a signed Material Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution.

Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.

23. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.

Investigators Experience

Investigator- Luke Donovan, MEd ATC is a doctoral student in Sports Medicine. He has been working clinically with athletes for 3 years and has over 4 years of experience conduction musculoskeletal research.

Investigator- Joseph Park, MD, a professor in the Medical School, is a renowned foot/ankle orthopedic surgeon.

Investigator- Mark Feger, MEd ATC is a doctoral student in Sports Medicine. He has been working clinically with athletes for 2 years and has over 2 years of experience conduction musculoskeletal research.

Investigator- C. Collin Herb, MEd ATC is a doctoral student in Sports Medicine. He has been working clinically with athletes for 3 years and has over 3 years of experience conduction musculoskeletal research.

PI- Jay Hertel, PhD ATC, a professor in the Curry School, is renowned for his ankle research.

Signatures

Principal Investigator

_____	_____	_____
Principal Investigator Signature	Principal Investigator Name Printed	Date

Department Chair

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

1. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
2. That the Principal Investigator is qualified to perform this study.
3. That the protocol is scientifically relevant and sound.

_____	_____	_____
Department Chair or Designee Signature	Department Chair or Designee Name Printed	Date

The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator

Brief Summary/Abstract

Individuals with chronic ankle instability (CAI) have deficits in neuromuscular control and altered gait patterns. Ankle destabilization shoes are used clinically and may improve neuromuscular control by increasing lower extremity muscle activation, which may improve gait patterns. Our purpose is to determine whether a 4-week rehabilitation program that includes ankle destabilization shoes (experimental) (Figure 1) has beneficial effects on self-reported function and ankle gait kinematics compared to traditional rehabilitation without destabilization shoes (control) in CAI patients. In addition, we will compare ankle strength and balance between CAI patients and healthy individuals with no history of ankle injury prior to the 4-week rehabilitation. We hypothesize the experimental group will have greater improvement in self-reported function and frontal and sagittal plane kinematics during walking compared to the control group. In addition, we hypothesize that patients with CAI will have a decrease in ankle strength and balance when compared to healthy individuals. The design is a single-blinded randomized controlled trial. Forty CAI patients will complete baseline self-reported function questionnaires and walking gait trials and then be randomized into control and experimental groups. Both groups will complete 4-weeks of supervised rehabilitation with or without destabilization shoes and then

repeat the questionnaires and walking trials. Forty healthy participants will complete baseline self-reported function, strength, and balance measures. Self-reported function will be compared using a mixed-model ANOVA and appropriate post-hoc tests with *a priori* significance level of $P \leq 0.05$. Strength and balance measures will be compared using a mixed-model ANOVA and appropriate post-hoc tests with *a priori* significance level of $P \leq 0.05$. For the kinematic measures, group means and 90% confidence intervals for each condition will be calculated across the entire gait cycle and areas where confidence intervals do not overlap will be considered significantly different.

Background

1. Provide the scientific background, rationale and relevance of this project.

Lateral ankle sprains have been shown to be among the most common musculoskeletal injury among competitive athletes[1-2] and those who are recreationally active.[3] Furthermore, it is estimated that approximately 47 to 74% of people who suffer a lateral ankle sprain will go on to have recurrent sprains 6 to 18 months after their first ankle sprain.[4] Approximately 30% of patients who sprain their ankle will go on to have residual symptoms of instability and repetitive ankle sprains that lasts greater than a year which is known as chronic ankle instability (CAI).[6]

The specific cause of CAI remains unclear; however, multiple characteristics have been identified to be different in patients with CAI compared to healthy patients. These characteristics include, but are not limited to impaired proprioception,[7-11] decreased neuromuscular control,[12-16] decreased range of motion (ROM),[17-19] decreased strength,[7, 12, 20] and altered gait.[21-25] With regards to gait, CAI patients show greater ankle inversion and plantar flexion positioning during the swing phase and spend a longer time on the lateral aspect of the foot during the stance phase, which may predispose them to ankle sprains.[21-22, 68] Treatment of CAI is often done through conservative rehabilitation programs that are designed to improve ROM, strength, proprioception and neuromuscular control.[26-27]Over the past several years multiple intervention studies have been completed to determine whether or not specific rehabilitation techniques improve characteristics associated with CAI.[14, 34-42] Specifically, Hoch et al.[42] found that a 2 week joint mobilization program improves self-reported function, dorsiflexion ROM, and dynamic stability in patients with CAI. Furthermore, Docherty et al.[36] found that strength training in patients with functional ankle instability increases strength of the surrounding ankle musculature. Moreover, McKeon et al.[14] completed a four week balance intervention and found that the intervention caused an increase in self-reported function and improved balance in patients with CAI. Although these studies found positive improvements with patients with CAI, they only included one type of exercise or rehabilitation technique in their protocol. Combining multiple treatment techniques, may cause a larger improvement in symptoms and deficits in patients with CAI. Specifically, Hoch et al.[42] and McKeon et al.[14] found similar improvements in self-reported function after completing a 2-week mobilization intervention and 4-week balance intervention respectively. Even though both interventions caused a significant improvement when compared to pre-intervention scores, their post-intervention self-reported function would

still be considered significantly lower than that of a healthy individual. In addition to studies only examining one intervention, there has not been an intervention that has been shown to improve the altered gait patterns associated with CAI. This may due to the complex motions that occur quickly at the ankle. However, ankle destabilization shoes have been developed to help treat CAI and are thought to have potential to help alter gait patterns associated with CAI.

Ankle destabilization shoes have not been well defined, but for this project we will operationally define them as shoes that consist of either a boot or sandal with an articulator below the heel designed to mimic the motion that occurs at both the subtalar and talocrural joints during walking. The goal of these shoes is to force the patient into plantar flexion, inversion, and internal rotation in a controlled manner while completing functional tasks. It is thought that by causing an anticipated perturbation at the ankle, surrounding musculature will contract via feed forward mechanisms to prevent the ankle from going into the vulnerable position.[29-31] Furthermore, it is thought that if appropriately implemented into a rehabilitation program, the shoes have potential to provide long-term changes to a patient's gait.[29] We have completed preliminary studies on two specific ankle destabilization shoes UVA-HSR IRB #15877, the Myolux Athletik and Myolux Medik II (Cevres Santé, Le Bourget-du-Lac, France). We assessed surface EMG measures of six different lower extremity muscles during walking comparing the two ankle destabilization shoes to a shod control condition in 15 patients with CAI.[31] We found an alteration in muscle activity when compared to normal shoes. There was a pronounced increase in the peroneus longus EMG amplitude prior to initial contact with the ankle destabilization shoes. This shows the potential for these shoes to increase activation of the peroneus longus prior to initial contact, which may provide more stability to the ankle joint by keeping the ankle out of the inverted position in late swing. As the shoes caused alterations prior to initial contact, it shows their ability to cause a feed-forward response mechanism that may be learned over time.

We have also recently presented a new paradigm for the conservative treatment of patients with CAI.[27] We assert that rehabilitation should encompass exercises for all impairments detected in a patient with CAI within 4 broad domains of ROM, strength, balance, and functional activities. We believe this can be achieved by an "assess, treat, re-assess" approach in each domain of impairments. Furthermore, we emphasize the importance of implementing gait retraining into the rehabilitation of CAI patients. Therefore, the purpose of this project is to examine the effects of a 4-week supervised rehabilitation intervention that encompasses ROM, strength exercises, balance and gait training exercises with and without ankle destabilization shoes on patients with CAI. The rehabilitation program will be based off the paradigm we recently developed[27] and will compare a group who completes the rehabilitation program with no ankle destabilization shoes to a group that completes the same rehabilitation program with ankle destabilization shoes. The primary dependent variables will be self-reported function, inversion/eversion kinematics throughout the walking gait cycle, and dorsiflexion/plantar flexion kinematics throughout the walking gait cycle. The secondary dependent variables will be clinical measures of ankle ROM, strength and balance and kinematics of the ankle, knee, and hip during a jump landing task.

Figure 1

Myolux Athletik and Myolux Medik II www.myolux.com/en/

Hypothesis to be Tested

Specific Aim 1: To determine the effects of a 4-week intervention that incorporates ankle destabilization shoes (experimental group) when compared to a 4-week intervention that does not incorporate ankle destabilization shoes (control group) on self-reported function of patients with CAI.

Hypothesis 1: The experimental group will have higher self-reported function gains when compared to the control group.

Specific Aim 2: To determine the effects of a 4-week intervention that incorporates ankle destabilization shoes when compared to a 4-week intervention that does not incorporate ankle destabilization shoes on peak dorsiflexion and inversion ROM during the walking gait cycle.

Hypothesis 2: After the interventions, the experimental group will have significantly greater peak dorsiflexion and less peak inversion when compared to the control group.

Specific Aim 3: As a secondary analysis, to determine the effects of a 4-week intervention that incorporates ankle destabilization shoes when compared to a 4-week intervention that does not incorporate ankle destabilization shoes on clinical measures of ankle ROM, strength, and balance.

Hypothesis 3: Following the intervention, the experimental group will have significantly greater measures of ankle ROM, strength and balance than the control group.

Specific Aim 4: As a secondary analysis, to determine the effects of a 4-week intervention that incorporates ankle destabilization shoes when compared to a 4-week intervention that does not incorporate ankle destabilization shoes on kinematics of the ankle, knee and hip during a jump landing task.
Hypothesis 4: After the interventions, the experimental group will have significantly greater peak dorsiflexion and less peak inversion when compared to the control group.
Specific Aim 5: As a secondary analysis, to determine if CAI patients have different ankle strength and balance measures at baseline when compared to healthy individuals.
Hypothesis 5: At baseline, patients with CAI will have decreased strength and balance measures when compared to healthy participants.

Study Design: Biomedical

1. Will controls be used?
Yes. The control group will complete the same traditional rehabilitation protocol as the experimental group, but will not use the ankle destabilization shoe.

We will also use a healthy control group who will not complete the 4-week rehabilitation, but only baseline testing.

2. What is the study design?
Single-blinded randomized controlled trial

3. Does the study involve a placebo?
No

Human Participants

Ages 18-40
Sex Males and Females
Race No Restriction
Subjects- see below

1. Provide target # of subjects (at all sites) needed to complete protocol.
34 CAI participants and 34 Healthy participants

2. Describe expected rate of screen failure/ dropouts/withdrawals from all sites.
35% for CAI participants and 20% for Healthy participants

3. How many subjects will be enrolled at all sites?
50 CAI participants and 40 Healthy participants; i.e. 90 total

4. How many subjects will sign a consent form under this UVa protocol?
50 CAI participants and 40 Healthy participants; i.e. 90 total

5. Provide an estimated time line for the study.

50% of enrolled will be completed in 3 months and 100% of enrollment will be completed in 6 months.

Inclusion/Exclusion Criteria

1. List the criteria for inclusion for CAI participants

- CAI with a history of recurrent ankle sprains, with the first sprain occurring longer than 12 months ago. They will have lingering symptoms, and disability, but have not actively sought treatment for their CAI
- All subjects will be physically active: Participating in some form of physical activity for at least 20 min per day, three times per week.

List the criteria for inclusion for Healthy participants

- All subjects will be physically active: Participating in some form of physical activity for at least 20 min per day, three times per week.
- All subjects will have no history of ankle injury.

2. List the criteria for exclusion for CAI and Healthy participants

- Neurological or vestibular disorders affecting balance
- Currently seeking medical care for CAI
- History of prior ankle surgery
- History of ankle sprain within the past 6 weeks
- History of ankle fracture
- Diabetes mellitus
- Current self-reported disability due to lower extremity pathology that may adversely affect neuromuscular function
- Lumbosacral radiculopathy
- Pregnant
- Soft tissue disorders including Marfan's syndrome and Ehlers-Dandros syndrome
-

3. List any restrictions on use of other drugs or treatments.

Cannot be participating in *Phys Ther* for their CAI.

Statistical Considerations

1. Is stratification/randomization involved?

Yes

►IF YES, describe the stratification/ randomization scheme.

Participants will be randomly assigned to either the control or experimental group by random number generator after baseline testing has been completed via sealed envelope. The investigator who completes the baseline testing will be blinded to group assignment. The investigator who supervises the rehabilitation program will

not be blinded to group assignment. Only a third party disinterested individual will complete the randomization and have access to the randomization scheme.

►**IF YES, who will generate the randomization scheme?**

_____Sponsor
_____UVa Statistician *Insert name*
_____UVa Investigational Drug Service (IDS)
__X___Other- *John Goetschius "Third party disinterested researcher in our lab with no affiliation to this project"*

2. What are the statistical considerations for the protocol?

For primary dependent variables (FAAM-ADL and Sport measures) and secondary dependent variables (ankle ROM, strength, and balance) a 2x2 mixed model ANOVA will be conducted. The between factor will be group (control and experimental) and the within factor with repeated measures will be time (pre, post). Tukey's post hoc tests will be used to identify specific significant differences in the presence of significant interactions or main effects. For secondary dependent variables (strength and balance) a 2x1 mixed model ANOVA will be conducted. The between factor will be group (CAI patients and Healthy participants) and the within factor with repeated measures will be time (baseline). Tukey's post hoc tests will be used to identify specific significant differences in the presence of significant interactions or main effects. The level of significance will be set *a priori* at $P \leq 0.05$ for all analyses. Cohen's *d* effect size and associated 95% CIs will also be calculated. Effect sizes will be interpreted as $\geq$0.80 was large, 0.50 to 0.79 as moderate, 0.49 to 0.20 as small and <0.20 as trivial. Data will be analyzed using Statistical Package for Social Sciences (SPSS) Version 20.0 (SPSS, Inc, Chicago, IL). For the dependent variables degrees of inversion-eversion and dorsi-flexion-plantar flexion motion during gait, group means and associated 90% CIs will be calculated across all 100 points of the gait cycle. A times series CI analysis will be performed across the entire gait cycle to determine any data points where the CIs do not overlap between the two groups (pre and post testing). If CIs do not overlap for at least 3 consecutive time increments, those increments in the gait cycle will be considered statistically significant.[17, 21, 43] **Power Analysis:** We estimated that 17 subjects per group would be sufficient to find statistically significant differences at an alpha level (Type I error) of 0.05 and power (1-β) of 0.8. This was based off of previous research by McKeon et al.[14] using an effect size of 1 with a standard deviation of 12.1 and magnitude of difference of 12.1 for the FAAM-Sport measure. We will match the healthy participants and therefore will need 34.

3. Provide a justification for the sample size used in this protocol.

We will adjust our sample size from 34 to 40 to adjust for possible drop-outs at a rate of 20% for both the CAI patients and the healthy participants. Therefore, we will need a total of 40 CAI patients and 40 healthy participants.

4. What is your plan for primary variable analysis?

We will do an analysis of variance to determine any significant differences in self-reported function measures between the control and experimental group.

5. What is your plan for secondary variable analysis?

For the dependent variables degrees of inversion-eversion and dorsi-flexion-plantar flexion motion during gait, group means and associated 90% CIs will be calculated across all 100 points of the gait cycle. A times series CI analysis will be performed across the entire gait cycle to determine any data points where the CIs do not overlap between the two groups (pre and post testing). If CIs do not overlap for at least 3 consecutive time increments, those increments in the gait cycle will be considered statistically significant.

6. Have you been working with a statistician in designing this protocol?

No

Biomedical Research

1. What will be done in this protocol?

SUMMARY:

Each CAI subject will complete four testing days (2 pre and 2 post intervention) and a 4-week rehabilitation program (intervention). Each healthy subject will complete only the self-reported function forms and the second testing session in one visit. The first testing day will consist of informed consent, self-reported function questionnaires, evaluation of walking/jumping gait, foot alignment, range of motion and laxity. The second testing day will consist of strength, balance and walking testing. After each subject completes the previous steps they will be asked to return to the lab to start the 4-week rehabilitation protocol a minimum of 48 hours later. At this time each subject will be randomly assigned to the experimental group or control group via random number generator by a non-affiliated third party. Both the control group and experimental group will complete a 4-week supervised rehabilitation protocol that will encompass traditional exercises to improve range of motion, strength, balance, and functional activities. The experimental group will differ from the control group by using ankle destabilization shoes during the balance and functional exercises instead of traditional rehabilitation tools. The rehabilitation sessions will be supervised by a Certified Athletic Trainer. After 4 weeks, each group will be asked to return to the lab to complete the 3rd testing day. At this time, both groups will fill out self-reported function questionnaires and have their walking/jumping gait, foot alignment, range of motion and laxity evaluated. On the fourth day they will have their strength and balance re-evaluated. Both the 3rd and 4th session will be completed by the same investigator as the first and second testing day.

Session 1 (Only the CAI patients will complete session 1 procedures)

Self-reported Function Five questionnaires will be administered to each subject This will be completed on the first visit after informed consent has been given and will be completed again on the second visit after 4 weeks

1. Godin Leisure Time Activity Questionnaire- self-report of physical activity over the course of a typical week
2. Foot and Ankle Ability Measure (FAAM)-a region-specific outcome questionnaire requires subjects to assess their perceived ability in both activities of daily living and sports.
3. VR-12: A generic assessment of a subject's physical health to help identify the impact ankle dysfunction has on general health.
4. IdFAI- A questionnaire that provides specific information about their ankle instability
5. Ankle Activity Score- Global representation of ankle function based on participant's level of activity.

- **Walking/Jumping Gait Analysis:** Three-dimensional joint kinematics of the ankle will be measured using the Flock of Birds (Ascension Technologies, Inc., Burlington, Vermont) electromagnetic motion analysis system controlled by Motion Monitor software (Innovative Sports Training, Inc., Chicago, Illinois). A non-conductive forceplate (Bertec Corporation, Columbus, Ohio) will be used to collect ground reaction forces for determination of initial contact and terminal stance during walking trials. A total of 8 sensors (4 on each leg) will be placed on the lateral mid-thigh, lateral mid-shank, posterior calcaneus, and the first metatarsal. Electromygraphy (EMG) of lower extremity musculature (medial gastrocnemius, peroneus brevis, peroneus longus, and anterior tibialis, biceps femoris, rectus femoris, and gluteus medius) will also be collected synchronously using surface EMG electrodes (Delsys Inc., Boston, Massachusetts and Biopac Inc., Aero Camino Goleta, CA). More information concerning the Flock of Birds technology can be found at: http://www.5dt.com/products/pfob.html
- . Information regarding the Motion Monitor software used with this system can be found at: http://www.innsport.com. Once sensor set-up is complete, the participant will be instructed to walk across a 6 meter walk-way at a self-selected pace for a total of 15 trials. After walking trials, the subjects will complete 15 jump landing tasks. Subjects will stand on a 30 cm box place half their height away from the force plate. They will be instructed to jump forward off the box and land on the force plate. Once they land, they will be asked to jump straight into the air as high as they can.
- **Foot alignment:** Each participant will have their foot alignment evaluated using the standing rearfoot assessment test and navicular drop test. Participants will be required to stand facing forward while the investigator measures these alignments using a goniometer. These tests are widely used in assessing people with lower extremity pathologies.
- **Range of motion:** We will collect three measurements of the posterior glide test, seated straight leg dorsiflexion, seated straight leg plantarflexion, seated

inversion, seated eversion, prone bent knee dorsiflexion, prone bent knee plantarflexion, standing straight knee dorsiflexion, and standing bent knee dorsiflexion using an inclinometer.

- **Laxity:** We will assess laxity by doing 3 measures of the anterior drawer test, internal rotation test, and talar tilt test. All tests for laxity are commonly used in the clinical setting.

Session 2 (Both CAI and Healthy subjects will complete the second session)

- Healthy subjects will only complete this session of the study. They will complete the same self-reported function questionnaires that the CAI patients complete on the first session.
- **Strength:** Participants will complete a 5 minute treadmill walking warm-up at a self-selected pace. After completion they will have the same sEMG sensors placed over the same muscles as done with session 1. Dorsiflexion, plantar flexion, inversion, eversion and plantar flexion eversion will be measured using a hand-held dynamometer (Omnitest MMT, Reno, NV). Three 5 second maximum voluntary isometric contraction (MVIC) trials will be completed for each motion. One trial will be completed to determine how long they can generate 90% of their MVIC for each of the 5 previous directions.
- **Balance Testing**: Each subject will complete the Star excursion balance test (SEBT), Balance Error Scoring System, and static balance testing
    - **1**. Star Excursion balance test- The tester will first measure the subject's leg length. The test requires subjects to balance on one foot and reach with the opposite foot as far as they can along a tape measure on the floor then return to standing on both feet. They will reach in three different directions (4, 8, and 12 o'clock) for three trials each direction for a total of nine repetitions on the tested foot. Fifteen seconds of rest is given between repetitions. The tester measures the total distance reached (cm) of each repetition. This test will be completed for both legs.
    - **2**. Stat balance test- Subjects will stand on a force plate (Accusway Plus) with both feet together and their hands on their hips. They will be instructed to raise the leg not being tested off the ground to 90 degrees of flexion. At this point, they will be instructed to balance on one leg while maintaining their hands on their hips for 10 seconds. This will be completed for 3 trials with their eyes open and then three trials with their eyes closed. Both legs will be tested. The investigator will stand close to the subject for each trial to prevent the subject from falling.
- **Treadmill Walking:** Each subject will walk on a treadmill while wearing a standard athletic shoe provided by the lab. This will be done in addition to ground walking because it will allow for more consecutive steps to be taken by the subject, which is needed to get an accurate clinical visual assessment. The subject will walk at a self-selected pace for approximately 5 minutes. The shoes

will have an insole in them that records plantar pressure (Pedar System). During this time, the investigator will complete a visual gait assessment. After completing treadmill walking the subjects will be ask to return to the lab to complete their first session of rehabilitation. Healthy subjects will be completed with the study and not complete rehabilitation.

Rehabilitation Protocol (Only the CAI subjects will complete)

- **Randomization:** Prior to starting rehabilitation, subjects will be randomized into either the control group or experimental group via random number generator. This will be completed by a 3rd party individual with no affiliation with this project from our lab.
- **4-week Rehabilitation:** Subjects will return to the lab a minimum 48 hours after completing their first test day. Subjects will be asked to complete 12 rehabilitation sessions (3x week) over a 4 week period. Subjects must complete 10 rehabilitation sessions in order to be included in the analysis. The investigator for each of the rehabilitation sessions will be a certified Athletic Trainer and blinded to testing day 1 measures. Each rehabilitation session will last approximately 1 hour . Rehabilitation does not need to be completed by the same Athletic Trainer, but each Athletic Trainer will follow a pre-determined progression and record the intensity and duration for each individual session as seen in the data collection sheet. Both groups will complete standard of care rehabilitation that all investigators will have routinely done in clinical practice. Rehabilitation exercises will aim to improve ROM, strength, balance, and neuromuscular control. However, the experimental group will use ankle destabilization shoes throughout their rehabilitation in place of standard destabilization methods, such as foam padding and dynadisc™ that will be used in the control group. We have attached our data collection form with specific standard of care exercises that we will include.

Session 3

- After completing the 4 weeks of rehabilitation, subjects will return to our lab 48 hours later and all outcome measures as described in session one will be completed so that change scores can be calculated and compared between treatment arms. These measures will be collected by the original investigator.

Session 4

- After completing session 3, subjects will return to our lab and all outcome measures as described in session two will be completed so that change scores can be calculated and compared between treatment arms. These measures will be collected by the original investigator.

2. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study?

No

3. List the procedures, in bullet form, that will be done for research as stipulated in this protocol. All procedures are done for the study.

4. Will any of the procedures listed in item # 2 have the potential to identify an incidental finding?

NO

5. Do any of the procedures listed above, under question # 2, utilize any imaging procedures (e.g. ultrasound, CT scans/ x-rays etc.)? **If yes, LIST PROCEDURES:**

No

6. Will you be using viable embryos?

No

7. Will you be using embryonic stem cells?

No

Data and Safety Monitoring Plan

This study has been deemed minimal risk. Because this study poses minimal risk to the subject, **adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

1. Definitions

1.1 How will you define adverse events (AE)?

Do not change this answer

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

1.2 How will you define an unanticipated problem?

Do not change this answer

An unanticipated problem is any issue that involves increased risk(s)

to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g serious loss of social status, loss of job, interpersonal conflict.)

1.3 What is the definition of a protocol violation?

Do not change this answer

A protocol violation is defined as any change, deviation, or departure from the study design or procedures of a research project that is NOT approved by the IRB-HSR prior to its initiation or implementation, OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulations. Protocol violations may or may not be under the control of the study team or UVa staff. These protocol violations may be major or minor violations.

Additional Information: see the IRB-HSR website at http://www.virginia.edu/vpr/irb/HSR_docs/Forms/Protocol_Violations_%20Enrollment_Exceptions_Instructions.doc

1.4 What is the definition of a data breach?

Do not change this answer

A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

Additional Information may be found on the IRB-HSR Website: Data Breach

2. What risks are expected due to the intervention in this protocol?

The risks should be consistent with those in the consent form (if applicable), although they should be written in technical terms in the protocol and in lay terminology in the consent form.
List the most serious or most frequent risk first

Delete last two rows if no additional risks added. Add additional rows to the table below if needed.

Expected Risks related to study participation	**Pick One**
There is a small risk that breaches of privacy and/or confidentiality	Occurs rarely

might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol.	
• Falling while completing balance tasks during rehabilitation	Occurs rarely
• Mild muscle soreness due to exercise	Likely

There is a minimal risk of a subject falling while completing the balancing tasks or walking on the treadmill. An investigator will be close enough during the balance tasks to stop a person from falling if they lose their balance. Subjects will be instructed to put their opposite leg down and grasp a stable surface if they feel that they may lose their balance. There are railings to grab on to around the treadmill and they will be instructed to push the emergency stop button if they feel uncomfortable. During all tasks, a certified Athletic Trainer will be present. All exercises during the rehabilitation sessions are considered usual care and will be monitored by a Certified Athletic Trainer who is an expert at rehabilitation. There is no increase in risk by being in the experimental group.

3. When will recording and reporting of unanticipated problems/adverse events begin?

After subject signs consent

4. When will the recording/reporting of unanticipated problems/adverse events end?

Subject completes participation in the protocol

5. What is your plan for safety monitoring?

Do not change this answer

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

6. What is your plan for reporting a Unanticipated Problem, Protocol Violation or Data Breach?

Do not change this answer

Type of Event	**To whom will it be reported:**	*Time Frame for Reporting*	*How reported?*
Unanticipated Problems that are not adverse events or protocol violations	IRB-HSR	Within 7 calendar days from the time the study team	Unanticipated Problem report form.

This would include a Data Breach.		received knowledge of the event.	*http://www.virginia.edu/vprgs/irb/HSR_docs/Forms/Reporting_Requirements-Unanticipated_Problems.doc)*
Protocol Violations (*The IRB-HSR only requires that MAJ ORTHOP RES violation be reported, unless otherwise required by your sponsor, if applicable.)* Or Enrollment Exceptions	IRB-HSR	Within 7 calendar days from the time the study team received knowledge of the event.	Protocol Violation and Enrollment Exception Reporting Form *http://www.virginia.edu/vprgs/irb/hsr_forms.html* *Go to 3rd bullet from the bottom.*
Data Breach of Protected Health Information	The UVa Corporate Compliance and Privacy Office ITC: if breach involves electronic data UVa Police if breach includes items that are stolen	As soon as possible and no later than 24 hours from the time the incident is identified. As soon as possible and no later than 24 hours from the time the incident is identified. IMMEDIATELY.	UVa Corporate Compliance and Privacy Office- Phone 924-9741 **ITC:** Information Security Incident Reporting procedure, http://www.itc.virginia.edu/security/reporting.html Police: phone- (434) 924-7166

Payment

1. **Are subjects being reimbursed for travel expenses (***receipts /mileage required***)?**
   No

2. Are subjects compensated for being in this study?

Yes - for only the CAI subjects.

2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?

50 dollars

2b. Explain compensation to be given.

CAI subjects will be paid 50 dollars after completing the study.

2c. Is payment pro-rated (*e.g. some compensation is given even if subjects do not complete the entire study)?*

No

If No, explain why payment cannot be pro-rated.

The study only requires 4 data collection visits. The other visits are rehabilitation.

2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?

Yes

Examples of when to say no:

- *Participant payment or other compensation will go directly from the sponsor to the subject. No money or gift cards will come through UVa.*
- *Researcher is using their own personal funds to compensate participants.*
- *Compensation is coming from a UVa Foundation and therefore not subject to UVA financial policies and procedures.*

Examples of when to say yes:

- *Sponsor, via a grant or contract, sends money to OSP/ SOM Grants and Contracts office to cover cost of compensation to be given to subjects. Subjects are then paid via Oracle system*
- *UVA researcher purchases gift cards for distribution to subjects and there is NO outside sponsor.*
- *Sponsor purchases gift cards/ debit cards and sends to UVa for study team to distribute to the subjects.*

►*IF YES, answer the following questions.*

2d(i). How will the researcher compensate the subjects?

___x__Check issued to participant via UVA Oracle or State system
_____ Petty cash account*
**Per UVa Policy petty cash payments are limited to a maximum of $100 per payment and $599 per calendar year per individual.*
_____ Gift card/Debit Card
_____ Other type of compensation: *specify*:_____

2d(ii). Which category/ categories best describes the process of compensation?

___x__ All compensation will be made via check issued to participant via UVA Oracle or State system

---

_____ Compensation will include an alternative method (petty cash, gift card, other) and tax information will be collected, securely stored, and submitted electronically to Procurement Services as required.

►If an alternate method will be used justify why you are unable to issue checks through the UVa Oracle or state system.

IMPORTANT: If you check this box you will be required to submit the subjects' name, Social Security number, full address and amount of payment to Procurement at the end of each calendar year. The Office of the VP for Research will send you instructions on this procedure at a later date.

Note: If the sponsor is proving the gift card/debit card and sending to UVA study team for distribution, please include the statement "SPONSOR REQUEST" under the request for justification.

_____ Compensation will include an alternative method (petty cash, gift card, other) and tax information cannot be collected. Total possible compensation per participant for participating in the research study over one year is limited to <=$50.

►If an alternate method will be used justify why you are unable to issue checks through the UVa Oracle or state system:

►If you are unable to collect the tax information justify why it cannot be collected

Risk/ Benefit Analysis

1. What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?

Study participants may receive benefit from this study. They may benefit from completing a rehabilitative program for their CAI regardless of group assignment. Society can benefit by improved knowledge of the effects interventions targeting ankle injury.

2. Analyze the risk-benefit ratio.

Subjects may benefit from this study. There is minimal risk involved for subjects participating in the study. The majority of the variables collected are typical of a clinical ankle rehabilitative program. All data and rehabilitation sessions will be conducted in a controlled laboratory environment. Overall, the benefits to society outweigh the minimal risks associated. The risk benefit ratio is acceptable.

APPENDIX: Legal/Regulatory

Recruitment

The following procedures will be followed:

- *Finders fees will not be paid to an individual as they are not allowed by UVa Policy*
- *All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.*
- *Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.*

Retention Incentives

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

Clinical Privileges

The following procedures will be followed:

- *Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.*
- *The IRB cannot grant clinical privileges.*
- *Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.*
- *Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.*
- *Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.*

Sharing of Data/Specimens

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- *No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.*
- *No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.*

Prisoners

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

APPENDIX: Recruitment

Recruitment includes identifying, review of records to determine eligibility or any contact to determine a potential subjects interest in the study.

****The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.***

1. **How do you plan to identify potential subjects?**
   To "identify" a potential subject refers to steps you plan to take to determine which individuals would qualify to participate in your study. This does NOT include steps to actually contact those individuals.
   If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being identified by the given method.
   Check the methods you plan to utilize:

   a. __X__ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or quality improvement.

DHHS: Study team requests Waiver of Consent to identify potential subjects.

HIPAA- *Allowed under Preparatory to Research if PHI to be accessed.*

IMPORTANT

Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- *a UVa student working in the UVa HIPAA Covered Entity**
- *a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity**

b. ____ Review of a database that was established to keep data to be used for future research such as the CDR, departmental research database or use of data from a separate current active research protocol.

DHHS: Study team requests Waiver of Consent to identify potential subjects.

HIPAA- *Allowed under Preparatory to Research if PHI to be accessed.*

IMPORTANT

Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they who meet one of the following criteria:

- *a UVa student working in the UVa HIPAA Covered Entity**
- *a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity**

NOTE: The information from which you are obtaining potential subjects must also have an IRB protocol approval.

IRB# _____

If obtaining information from the Clinical Data Repository (CDR) insert IRB # 10797.

c. ____ Patients UVa health care provider supplies the UVa study team with the patients contact information without patients knowledge.

DHHS: Study team requests Waiver of Consent to identify potential subjects.

HIPAA- *Allowed under Preparatory to Research if PHI will be shared by the health care provider.*

IMPORTANT

Keep in mind that PHI may only be given to individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- *a UVa student working in the UVa HIPAA Covered Entity**
- *a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity**

d. __X__ Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating.
DHHS: *NA*
HIPAA: *Allowed under Health Care Operations*
If this choice is checked, check 3d-INDIRECT CONTACT below.

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.
If this choice is checked, check 3d- INDIRECT CONTACT below.
DHHS & HIPAA: *NA*

f. _____ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.
IRB# of registry/ database: _____
DHHS & HIPAA: *NA*

g. ____ Other- *explain*

If item # a, b or c is checked above and if this protocol involves the use of protected health information you confirm the following to be true:

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the
- research purposes.

Yes

2. How will potential subjects be <u>contacted?</u>

To "contact" a potential subjects refers to the initial contact you plan to take to reach a potential subject to determine if they would be interested in participating in your study. This may include direct contact by such methods as by letter, phone, email or in-person or indirect contact such as the use of flyers, radio ads etc.

If your study involves more than one group of subjects (e.g. controls and cases or subjects and caregivers) note below which groups are being contacted by the given method.

Check the methods you plan to utilize:

a.__x__Direct contact of potential subjects by the study team via letter, phone, direct e-mail. Members of study team ARE NOT health care providers of patients. Information will not be collected from psychotherapy notes.

Note: Letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

DHHS/HIPAA: Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:

Keep in mind that if PHI was collected during the identification phase that contact with potential subjects may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- *a UVa student working in the UVa HIPAA Covered Entity**
- *a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity**

b.____Potential subjects will be approached while at UVa Hospital or Health Clinic by a person who is NOT a member of their health care team. Information will not be collected from psychotherapy notes.

DHHS & HIPAA: Study team requests a Waiver of Consent and a Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:
Keep in mind that contacting individuals in a clinical setting may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- *a UVa student working in the UVa HIPAA Covered Entity**
- *a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity**

You should share the following information with the potential subject:

1. *Your name*
2. *Who you are:* ***physician, nurse etc***. at the University of Virginia.
3. *Why you want to speak with them*
4. *Ask if you have their permission to explain the study to them*
5. ***If asked about how you obtained their information use one of the following as an option for response.***
   - ***DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THEIR UVa PHYSICIAN:***
     Your doctor, Dr. ***insert name*** *wanted you to be aware of this research study and gave us permission to contact you.*
   - *We obtained your information from your medical records at UVa.*
     Federal regulations allow the UVa Health System to release your information to researchers at UVa, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.

IF THE PERSON SEEMS ANGRY, HESITANT OR UPSET, THANK THEM FOR THEIR TIME AND DO NOT ENROLL THEM IN THE STUDY. YOU MAY ALSO REFER THEM TO THE IRB-HSR AT 924-9634.

c.__X__Direct contact of potential subjects by the study team by approaching in person at UVa or via letter, phone, direct e-mail. Members of study team contacting potential subjects ARE health care providers of patients.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

DHHS: Study team requests a Waiver of Consent to contact potential subjects

HIPAA: *Allowed under Health Care Operations.*

d.__x__ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.) *The indirect method used (flyer, brochure, TV, broadcast emails) must be approved by the IRB prior to use. The IRB does not need to review any type of script to use when the potential subject responds to the indirect method.*

DHHS & HIPAA: *NA*

e. ___x_ Potential subjects are not patients. The study does not include obtaining subjects health information. Subjects will be contacted directly via email, phone, letter or presentation in group setting with consent then obtained individually in a private setting.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

DHHS: Study team requests a Waiver of Consent to contact potential subjects.

HIPPA: NA

3. Will any additional information be obtained from a potential subject during "prescreening"?

No

4. Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?

No

5. **How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor (if applicable)?**

- The potential subjects will be given a consent form to read. All study procedures will be explained to potential subjects by a study team member in the Exercise & Sport Injury Lab in Memorial Gymnasium and take approximately 10-15 minutes. Afterwards, the subjects will have time to ask any questions about the study and review the consent form. The subject's understanding will be assessed verbally and in writing with signature of the consent form as proof that the subject understands all test procedures.
- Time between written consent and initiation of study procedures is estimated to be zero to 20 minutes. Subjects will be reminded that they may withdrawal from the study at any point.

6. Will subjects sign a consent form for any part of the study? Yes

7. Will the study procedures be started the same day the subject is recruited for the study? Yes

►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.

The subject will be given as much time as they need before starting the procedures and will be reminded that they can stop at anytime without question. To avoid the subject making multiple trips to the University, the investigators will be prepared to begin the study once the subject signs the consent form. However, if a subject requires more time, they can begin at a later time.

►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.

They will be reminded that they may ask questions or stop at anytime during the entire process. They will be asked to provide their

interpretation of what will be done through the study based on what they have read from the consent.

8. Is there the potential to recruit economically or educationally disadvantaged subjects, or other vulnerable subjects such as students or employees? If yes, what protections are in place to protect the rights and welfare of these subjects so that any possible coercion or undue influence is eliminated?

Yes. We believe we may enroll both students and employees of the University. We will protect the rights and welfare of all subjects by clearly informing them that by participating or not participating in this study will not influence any aspect of their well-being.

9. Do you need to perform a "dry run" of any procedure outlined in this protocol?

No

APPENDIX: Privacy Plan for Studies With Consent

1. Answer the questions below (1a-1e) to describe your/central registry's plan to protect the identifiable data from improper use and disclosure.

1a. How will data be stored?

Choose only one of the following options:

___X__ Data, which may include health information, or other highly sensitive data will be stored with HIPAA identifiers.
You MUST choose this option if case report forms will include such items as initials.

_____ Data, which may include health information, or other highly sensitive data will NOT be stored with any HIPAA identifier except date(s). This means:

- Documents such as case report forms will have NO HIPAA identifiers except dates (e.g. no initials or medical record #)
- HIPAA identifiers, except dates will be stored in a different place than the health information/specimens. A code such as subject # 1 will be used to link the identity of the individual (HIPAA identifiers) with the persons health information.
    - *EXAMPLE:* The HIPAA identifiers with the code (*e.g.- John Doe=subject #1*) will be stored in one location (*computer drive ,paper file, memory stick, CD*) and the health information (*diagnosis,*

radiology results) will be stored in a different location *(different computer drive, paper file in a different file cabinet, memory stick).*

1b. Will specimens be stored by the UVa study team? No

1c. Will any of the data be stored electronically by the UVa study team?

Yes

►IF YES, will it include any HIPAA identifiers with health information or other highly sensitive data? Yes

►IF YES, where will it be stored?

_____ a Health Systems Computing Services (HS/CS) managed server that is configured to store data regulated by HIPAA.

_____ an Information Technology Services (ITS) managed server that is configured to store data regulated by HIPAA.

___x__ a server managed by the principal investigator's department or school that is configured to store data regulated by HIPAA or highly sensitive data. *The Principal Investigator should verify with their department that the server they plan to use is configured to store data regulated by HIPAA.*

1d. Will any of the data be collected or stored in hard copy format by the UVa study team (*e.g.- on paper***) ? Yes**

►IF YES, where will it be stored?

_____ case report forms will be stored in a secure area with limited access.

___x__questionnaires/ surveys will be stored in a secure area with limited access.

_____ other -*specify:* **_____**

1e. The following procedures will also be followed.

- Only investigators for this study and clinicians caring for the patient will have access to the data. They will each use a unique log-in ID and password that will keep confidential.

- Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.
  If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.
- UVa Institutional Data Protection Standards will be followed http://itc.virginia.edu/security/dataprotection. Identifiable data is considered to be "Highly Sensitive". A Limited Data Set is usually considered to be "Moderately Sensitive" and de-identified data is usually considered to be "Not Sensitive".
- If identifiable data (*data with health information and HIPAA identifiers*) is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "Electronic Storage of Highly Sensitive Data Policy". Additional requirements may be found in the Universities Requirements for Securing Electronic Devices.
- If identifiable health information is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- The data will be securely removed from the server, additional computer(s), and electronic media according to the University's Electronic Data Removal Policy.
- The data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Policy.
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and UVa Institutional Data Protection Standards .
- The data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.

Summary of Requirements to Comply with UVa Health System, Medical Center and University Policies and Guidance as noted above:

Highly Sensitive Data *is:*
-personal information that can lead to identify theft if exposed or
-health information that reveals an individual's health condition and/or history of health services use.

***PHI**- a type of Highly Sensitive Data, is health information combined with a HIPAA identifier*

- LIMIT- Limit the HIPAA identifiers to the minimal amount needed- e.g. use initials instead of name, use a code instead of initials, limit amount/type of health information collected, and collect and share only those items you state you will in this protocol.
- SECURE- Secure Highly Sensitive Data
    - Because single-use electronic devices and media, such as desktops, laptops, memory sticks, CDs, smartphones etc., can be easily lost or stolen, the University strictly limits the circumstances under which Highly Sensitive Data may be stored on them. In accordance with the University's Electronic Storage of Highly Sensitive Data Policy, you must obtain written approval from your Department AND VP or Dean prior to moving data to single use devices or media by using the Highly Sensitive Data Storage Request Form.
        - *You additionally are responsible for applying all security safeguards covered in that policy, including but not limited to password protecting and encrypting any document on a single access electronic device.*
        - *If you use your smartphone to send email and your phone is not managed was not purchased and/or set up for you by the Health System, you cannot send Highly Sensitive Data via email.*
            - *In addition, do not use Outlook Web to send your email if it contains sensitive data.*
            - *Also, you are not allowed to auto forward your email to outside email systems like Gmail or Yahoo.*
            - *Do not save any email attachment containing Highly Sensitive Data to a single use device.*
        - *You are allowed to access Highly Sensitive Data stored on the University or Health Systems network via a VPN, however you cannot download any of the information onto your desktop or laptop.*
        - *Store files containing Highly Sensitive Data on a network drive specifically designated for storing this type of data, e.g. high-level security servers managed by Information Technology Services or the "F" and "O" managed by Heath Systems Computing Services.*

You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive.

- *If data will be collected and/or viewed via a website, it is critical that the website and associated data file are set up in a highly secured manner. Do not attempt without assistance from:*
  University Side: ITCmicrosystems@virginia.edu
  Health System: Web Development Center: (434-243-6702)

- Encrypt any electronic file containing Highly Sensitive Data that is not on a network drive specifically designated for this purpose. . *See encryption solutions guidance.*
- Password protect any electronic device containing Highly Sensitive Data.
- Lock up hard copies of Highly Sensitive Data.

- PROTECT- Protect Highly Sensitive Data
  - Do not leave a hard copy file open on your desk when not using it and secure your computer when not attended.
  - Have discussions in private.
  - If you lose Highly Sensitive Data, you must report it in accordance with the Information Security Incident Reporting Policy.
  - Do not share Highly Sensitive Data with those not on the study team or those who do not have a need to know.
  - Do not share with sponsor unless subject has already signed a consent form or IRB has approved waiver of consent.
  - If faxing Highly Sensitive Data within UVa
    - Verify fax numbers before faxing, and use fax cover sheets with a confidentiality statement.
    - If printing to a central printer, ensure that names and identifiers on the documents are given to the correct patient.
  - If faxing Highly Sensitive Data outside of UVa to the sponsor or CRO after the subject has signed consent:
    - the receiving fax machine is in a restricted-access location,
    - the intended recipient is clearly indicated,
    - the recipient has been alerted to the pending transmission and is available to pick it up immediately.
    - Verify fax numbers before faxing, and use fax cover sheets with a confidentiality statement.

        - If printing to a central printer, ensure that names and identifiers on the documents are given to the correct patient.
    - Highly Sensitive Data may not be stored in a Drop Box.
    - If you plan to store data in the Cloud, you must consult with UVa Information Technology Services (ITS) to verify all essential security measures are in place. If you have a contract to use the cloud, the contract must include required security measures as outlined by ITS.
    - DO NOT email health information with name, medical record number or Social Security number to or from an email address that does not have an *HS in the address. May use subject initials if within the UVa HIPAA covered entity: The "UVA HIPAA covered entity" includes the hospital, health system, School of Medicine School of Nursing and the VP for Research Office.
    - Be aware: PHI collected without consent/ HIPAA authorization will NOT be allowed to leave UVa in an identifiable form unless the disclosure is tracked with Health Information Services.
    - Any Highly/Moderately Sensitive Data sent outside of UVa (e.g. to sponsor) that was obtained under a consent must be encrypted and password protected.
    - If your electronic device is sent outside of UVa for repair, all institutional data, whether Highly Sensitive or not, must be either encrypted or removed.
    - If transporting Highly/Moderately Sensitive Data in paper format from one UVa building to another, take the following steps to protect it:
        1. Put paper inside a closed container such as a briefcase, or sealed envelope to limit the chance of a losing a piece.
        2. Do not leave Highly Sensitive Data unattended in a public area if it is not locked up.
    - When the study is complete, all electronic files containing Highly/Moderately Sensitive Data must be stored on a network drive specifically designated for that purpose. They may not be stored on a single use device such as a CD.
- STOP, THINK and BE CAREFUL-
    - If this was your Highly Sensitive Data how would you want it protected?

- There are significant monetary fines to the individual and the institution for loss or misuse of sensitive data.
- Your job may also be on the line.

2. Describe your/central registry's plan to destroy the HIPAA identifiers at the earliest opportunity consistent with the conduct of the research and in accordance with any stipulations in the research sponsor contract and UVa records management guidelines.

Check one option below:

_____ NA- the identifiers will not be destroyed. The identifier will be needed to be able to continue to add data in the future.
This is only allowed if this is a database protocol.

_____The HIPAA identifiers (except full dates and or address information if needed) will be destroyed as soon as all data analysis is complete.

___**x**__The HIPAA identifiers (except full dates and or address information if needed) will be destroyed as soon as all publications are complete.
This wording would allow the researcher to keep HIPAA identifiers until all queries/ request for additional information from publisher are addressed

_____ The HIPAA identifiers (except full dates and or address information if needed) will be destroyed as soon as approval is received from the sponsor to delete them.

3. **Do you confirm that you will not reuse the identifiable data (HIPAA identifiers or health information) or disclose any of this information to any other person or entity except as outlined in this protocol, except as required by law, for authorized oversight of the research study, or use it for other research unless approved by the IRB-HSR?**

Yes

This means that after the study is closed at UVa:

- *You cannot contact the subject by any method (you cannot call them, send a letter, talk to them in person about the study, etc) without additional IRB approval*
- *You cannot use the data for any research that is not already described in your IRB protocol without additional IRB approval (if you change your hypothesis you must modify your protocol)*
- *You cannot share your research data with another researcher outside of your study team without additional IRB approval*
- *Any health information with HIPAA identifiers will be shredded or discarded by using recycling bins for confidential material found in clinic*

settings. For large item disposal of confidential material contact Environmental Services at 2-4976 or University Recycling at 2-5050.

TABLE A: HIPAA Identifiers (Limited Data Set)

1. Name
2. Postal address information, other than town or city, state, and zip code
3. Telephone numbers
4 Fax numbers
5. Electronic mail addresses
6. Social Security number
7. Medical Record number
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) address numbers
15. Biometric identifiers, including finger and voice prints
16. Full face photographic images and any comparable images
17. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)

Table C2

Consent of an Adult to Be in a Research Study

Chronic Ankle Instability (CAI) Subjects

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:
Jay Hertel, PhD ATC
University of Virginia
210 Emmet St South
Charlottesville, VA 22904
434-243-8673

What is the purpose of this form?

This form will help you decide if you want to be in the research study. You need to be informed about the study, before you can decide if you want to be in it. You do not have to be in the study if you do not want to. You should have all your questions answered before you give your permission or consent to be in the study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will get a copy of this form.

Who is funding this study?
There is no funding for this study.

Why is this research being done?
The purpose of this study is to determine if a supervised rehabilitation program will improve ankle function in people who have chronic ankle instability (CAI).

CAI is a condition where symptoms from ankle sprain last longer than one year. These symptoms include a feeling of looseness, feeling that you may roll your ankle, or repeated ankle sprains. This study may help clinicians prescribe simple exercises at home to help treat CAI

You are being asked to be in this study, because you are physically active (participate in some form of physical activity for at least 20 minutes per day, three days per week), have Chronic Ankle Instability (CAI), have a history of repetitive episodes of ankle sprains and/or feelings of your ankle giving way and prolonged symptoms, and are not seeking medical treatment/therapy for your CAI.

Up to 90 people will be in this study at UVA.

How long will this study take?
Your participation in this study will require 4 separate testing visits and 12 separate treatment visits over a 4 week period of time. Each testing visit will last about 2 hours and each treatment visit will last about 1 hour.

What will happen if you are in the study?
BASELINE STUDY PROCEDURES (will take about 2 hours to complete):
Visit 1
If you agree to participate, you will sign this consent form before any study related procedures take place.

Ankle Questionnaires:

- A questionnaire asking about your general health as it relates to your ankle injury
- A questionnaire asking about your current physical activity level
- Three questionnaires asking about your ankle function

Walking Testing:

- You will have sensors attached to your skin that will passively record how you walk and how your muscles turn on during walk.
- With the sensors on, you will walk 15 times across a 20 foot platform

Jumping Testing:

- With the same sensors on, you will jump 15 times off a 30 cm box

Foot Alignment:

- You will have your foot alignment measured. You will be asked to stand upright with your feet together. Three measurements will be recorded.

Range of motion:

- Your ankle motion will be measured 3 times in 4 directions. These motions are: pulling your foot toward yourself, pointing your foot away from yourself, turning your foot inward, and turning your foot outward.

Ankle Laxity:

- You will have tests done that will determine how "loose" your ankles are.

You will be asked to return to the lab for you second session within one week.

Visit 2

Ankle Strength:

- You will walk on a treadmill for 5 minutes to warm-up. You will have your skin cleaned and sensors placed over four muscles on your lower leg that passively record muscle activity. You will have your ankle strength tested 3 times in 4 directions. The tester will use a device held in their hand that records how hard you can push using your ankle. These motions are: pulling your foot toward yourself, pointing your foot away from yourself, turning your foot inward, and turning your foot outward.

Balance Testing

- Complete 3 different tasks that will determine how well you balance. The task order is:
    - Star Excursion balance test: This test will require you to stand on one leg with your hands on your hips and reach as far as you can with your opposite leg in various directions. You will reach forward, backwards to your left, and backwards to your right. You will be given rest between each reach.
    - Single leg balance (eyes opened and eyes closed) while standing on a force plate for 10 seconds

Treadmill Walking Testing

- You will be asked to walk on a treadmill for 5 minutes while wearing insoles that measure pressure.

You will be asked to return to the lab after at least 2 days to begin the 12 rehabilitation sessions.

VISITS 3 TO 14 (TREATMENT SESSIONS 1 TO 12)

On your first day of treatment you will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. You have an equal chance of being assigned to any one of the groups. You cannot choose which treatment you are assigned.

GROUP 1: Experimental group

GROUP 2: Control group

Experimental Group:
The experimental group will be asked to complete 4 weeks of treatment that will treat their ankle instability. You will be asked to complete 3 sessions per week for a total of 12 sessions. During the treatment you will complete exercises that are considered standard of care. Each session you will complete ankle motion, strength, balance and functional exercises. During the balance and functional exercises, you will use ankle rehab shoes instead of traditional methods that help improve balance.

Control Group:
The control group will be asked to complete 4 weeks of treatment that will treat their ankle instability. You will be asked to complete 3 sessions per week for a total of 12 sessions. During the treatment you will complete exercises that are considered standard of care. Each session you will complete ankle motion, strength, balance and functional exercises.

FOLLOW UP:

VISIT 15

Both the experimental and control group will return to the lab approximately 48 to 96 hours after their final treatment session. You will complete the same testing as you did on the first day. This will take no longer than 1.5 hours.

VISIT 16

Both the experimental and control group will return to the lab with-in one week after visit 15. You will complete the same testing as you did on the second day. This will take no longer than 1.5 hours.

If you want to know about the results before the study is done:

During the study you are having an investigational test done. The purpose of the test is not to diagnose any disease or abnormality you may have. Because the test is investigational there is no way for the study leader to understand if the results are "normal" or "abnormal". However, if any test results are concerning, your study leader will let you know.

In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

This study poses little risks for physically active individuals.

Risks and side effects related to the procedures and interventions include**:**

Likely

- Mild soreness of muscles involved with the exercises

Rare but serious

- Falling while completing the balance exercises

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

We cannot promise that you will be helped by being in this study.

You may benefit from being in this study. Possible benefits include: decreased symptoms associated with ankle instability**.** In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include: seeking *Phys Ther* for your CAI or wearing braces or tape during your daily activities.

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $50 for finishing this study by check.

You should get your payment about 4-6 weeks after finishing the study. The income may be reported to the IRS as income.

You will not be paid at all if **you** decide not to finish this study. If the study leader says you cannot continue, you will be paid the full amount for the study.

If you owe money to any Virginia state agency, the state can use the money you earn in this study to pay those debts. These state agencies include the UVa Medical Center, VCU Medical Center or a college or university. The money may be withheld to pay back debt for such things as unpaid medical bills, taxes, fines, child support. Even if this happens, the money you earn may be reported to the IRS as taxable income.

Will being in this study cost you any money?

All of the procedures in this study will be provided at no cost to you or your health insurance. You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your principal investigator is concerned about your ankle instability
b) Your ankle instability gets worse
c) The side effects of the study procedure are too dangerous for you
e) You do not follow the study team's instructions

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number only if you are being paid to be in this study
- Your health information. If required for this study, this may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers.
- Tissue or blood samples if you agree to provide them for genetic testing for this study.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- People who pay for the like insurance companies
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. We ask them to protect your privacy. However,

they may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Jay Hertel, PhD ATC
University of Virginia
210 Emmet St South
Charlottesville, VA 22904
434-243-8673

What if you have a concern about a study?

You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908
Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and

details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Consent From Impartial Witness

I agree the information in this informed consent form was presented orally in my presence to the subject and the subject had the opportunity to ask any questions he/she had about the study. I also agree that the subject freely gave their informed consent to participate in this trial.

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Table C3

Foot and Ankle Ability Measure (FAAM)

Please answer **every question** with one response that most closely describes to your condition within the past week.
If the activity in question is limited by something other than your foot or ankle mark not applicable (N/A).

	No difficulty	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
Standing	☐	☐	☐	☐	☐	☐
Walking on even ground	☐	☐	☐	☐	☐	☐
Walking on even ground without shoes	☐	☐	☐	☐	☐	☐
Walking up hills	☐	☐	☐	☐	☐	☐
Walking down hills	☐	☐	☐	☐	☐	☐
Going up stairs	☐	☐	☐	☐	☐	☐
Going down stairs	☐	☐	☐	☐	☐	☐
Walking on uneven ground	☐	☐	☐	☐	☐	☐
Stepping up and down curbs	☐	☐	☐	☐	☐	☐
Squatting	☐	☐	☐	☐	☐	☐
Coming up on your toes	☐	☐	☐	☐	☐	☐
Walking initially	☐	☐	☐	☐	☐	☐
Walking 5 minutes or less	☐	☐	☐	☐	☐	☐
Walking approximately 10 minutes	☐	☐	☐	☐	☐	☐
Walking 15 minutes or greater	☐	☐	☐	☐	☐	☐

Because of your **foot and ankle** how much difficulty do you have with:

	No difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
Home Responsibilities	☐	☐	☐	☐	☐	☐
Activities of daily living	☐	☐	☐	☐	☐	☐
Personal care	☐	☐	☐	☐	☐	☐
Light to moderate work (standing, walking)	☐	☐	☐	☐	☐	☐
Heavy work (push/pulling, climbing, carrying)	☐	☐	☐	☐	☐	☐
Recreational activities	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

.0 %

Table C4.

FAAM Sports Scale

Because of your **foot and ankle** how much difficulty do you have with:

	No difficulty at all	Slight difficulty	Moderate difficulty	Extreme difficulty	Unable to do	N/A
Running	☐	☐	☐	☐	☐	☐
Jumping	☐	☐	☐	☐	☐	☐
Landing	☐	☐	☐	☐	☐	☐
Starting and stopping quickly	☐	☐	☐	☐	☐	☐
Cutting/lateral movements	☐	☐	☐	☐	☐	☐
Low impact activities	☐	☐	☐	☐	☐	☐
Ability to perform activity with your normal technique	☐	☐	☐	☐	☐	☐
Ability to participate in your desired sport as long as you would like	☐	☐	☐	☐	☐	☐

How would you rate your current level of function during your sports related activities from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

.0 %

Overall, how would you rate your current level of function?

Normal Nearly normal Abnormal Severely abnormal

Table C5.

IDENTIFICATION OF FUNCTIONAL ANKLE INSTABILITY (IdFAI)

Instructions: This form will be used to categorize your ankle stability status. A separate form should be used for the right and left ankles. Please fill out the form completely and if you have any questions, please ask the administrator. Thank you for your participation.

Please carefully read the following statement:

"Giving way" is described as a temporary uncontrollable sensation of instability or rolling over of one's ankle.

I am completing this form for my **RIGHT/LEFT** ankle (circle one).

1.) Approximately how many times have you sprained your ankle? _____

2.) When was the last time you sprained your ankle?

❑Never ❑ > 2 years ❑ 1-2 years ❑ 6-12 months ❑ 1-6 months ❑< 1 month

3.) If you have seen an athletic trainer, physician, or healthcare provider how did he/she categorize your most serious ankle sprain?

❑Have **not** seen someone ❑Mild (Grade I) ❑Moderate (Grade II) ❑Severe (Grade III)

4.) If you have ever used crutches, or other device, due to an ankle sprain how long did you use it?

❑Never used a device ❑1-3 days ❑4-7 days ❑1-2 weeks ❑2-3 weeks ❑>3 weeks

5.) When was the last time you had ***"giving way"*** in your ankle?

❑Never ❑> 2 years ❑1-2 years ❑6-12 months ❑ 1-6 months ❑< 1 month

6.) How often does the ***"giving way"*** sensation occur in your ankle?

❑Never ❑Once a year ❑Once a month ❑Once a week ❑Once a day

7.) Typically when you start to roll over (or 'twist') on your ankle can you stop it?

❑Never rolled over ❑Immediately ❑Sometimes ❑Unable to stop it

8.) Following a typical incident of your ankle rolling over, how soon does it return to 'normal'?

❑Never rolled over ❑Immediately ❑ < 1 day ❑1-2 days ❑> 2 days

9.) During "Activities of daily life" how often does your ankle feel ***UNSTABLE***?

❑Never ❑Once a year ❑Once a month ❑Once a week ❑Once a day

10.) During "Sport/or recreational activities" how often does your ankle feel ***UNSTABLE***?

❑Never ❑Once a year ❑Once a month ❑Once a week ❑Once a day

Table C6.

Ankle Activity Score

Category	Sports and Activities	Ankle Activity Score[a] T	C	R
10	American football	10	9	8
	Basketball	10	9	8
	Gymnastics	10	9	8
	Handball	10	9	8
	Rugby	10	9	8
	Soccer	10	9	8
9	Hockey	9	8	7
	Korfball	9	8	7
	Martial arts: judo, karate, kung fu, taekwondo	9	8	7
	Orienteering	9	8	7
	Rhythmic gymnastics	9	8	7
	Volleyball	9	8	7
8	Boxing	8	7	6
	Freestyle snowboarding	8	7	6
	Ice hockey	8	7	6
	Tennis	8	7	6
	Wrestling	8	7	6
7	Aerobics, fitness	7	6	5
	Badminton	7	6	5
	Baseball	7	6	5
	Cross-country running	7	6	5
	Modern pentathlon	7	6	5
	Squash	7	6	5
	Surfing, windsurfing	7	6	5
	Table tennis	7	6	5
	Track and field: field events	7	6	5
	Water skiing	7	6	5
6	Dancing	6	5	4
	Fencing	6	5	4
	Floorball	6	5	4
	Mountain and hill climbing	6	5	4
	Nordic skiing	6	5	4
	Parachuting	6	5	4
	Softball	6	5	4
	Special professions and working activities[b]	6		
5	Diving	5	5	4
	Scuba diving	5	5	4
	Skating, in-line skating	5	5	4
	Track and field: track events	5	5	4
	Triathlon	5	5	4
	Weightlifting, body building	5	5	4
	All competitive sports of categories 4 and 3 with seasonal conditioning	5		
	Heavy physical work	5		
4	Alpine skiing and snowboarding	4	4	4
	Bowling/curling	4	4	4
	Golf	4	4	4
	Mountain biking/bmx	4	4	4
	Power lifting	4	4	4
	Sailing	4	4	4
	Physical work	4		
3	Cycling	3	3	3
	Equestrian	3	3	3
	Motorsports, technical sports	3	3	3
	Rowing, kayaking	3	3	3
	Shooting, archery	3	3	3
	Water polo and swimming	3	3	3
	Able to walk on any uneven ground	3		
2	No sports, everyday activities not limited	2		
1	Able to walk on even ground, but everyday activities limited	1		
0	Unable to walk, disabled because of ankle problems	0		

[a]T, top level (international elite, professional, national team, or first division); C, lower competitive levels; R, recreational level (participation should be considered only if it exceeds 50 hours per year).
[b]Special professions include ballet dancer, professional soldier, special rescue worker, stuntman, and so forth.

Table C7.

THE VETERANS RAND 12 ITEM HEALTH SURVEY (VR-12)

Instructions: This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure how to answer a question, please give the best answer you can.

(Circle one number on each line)

1. In general, would you say your health is:

EXCELLENT	VERY GOOD	GOOD	FAIR	POOR
1	2	3	4	5

2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?	YES, LIMITED A LOT	YES, LIMITED A LITTLE	NO, NOT LIMITED AT ALL
a. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	1	2	3
b. Climbing **several** flights of stairs?	1	2	3

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health?**

	NO, NONE OF THE TIME	YES, A LITTLE OF THE TIME	YES, SOME OF THE TIME	YES, MOST OF THE TIME	YES, ALL OF THE TIME
a. **Accomplished less** than you would like.	1	2	3	4	5
b. Were limited in the **kind** of work or other activities.	1	2	3	4	5

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	NO, NONE OF THE TIME	YES, A LITTLE OF THE TIME	YES, SOME OF THE TIME	YES, MOST OF THE TIME	YES, ALL OF THE TIME
a. **Accomplished less** than you would like.	1	2	3	4	5
b. Didn't do work or other activities as **carefully** as usual.	1	2	3	4	5

5. During the past 4 weeks, how much did **pain** interfere with your normal work (including both work outside the home and house work)?

NOT AT ALL	A LITTLE BIT	MODERATELY	QUITE A BIT	EXTREMELY
1	2	3	4	5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

6. How much of the time during the past 4 weeks:

	ALL OF THE TIME	MOST OF THE TIME	A GOOD BIT OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
a. Have you felt **calm and peaceful?**	1	2	3	4	5	6
b. Did you have **a lot of energy?**	1	2	3	4	5	6
c. Have you felt **downhearted and blue?**	1	2	3	4	5	6

7. During the past 4 weeks, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
1	2	3	4	5

Now, we'd like to ask you some questions about how your health may have changed.

8. Compared to one year ago, how would you rate your **physical health** in general now?

MUCH BETTER	SLIGHTLY BETTER	ABOUT THE SAME	SLIGHTLY WORSE	MUCH WORSE
1	2	3	4	5

9. Compared to one year ago, how would you rate your **emotional problems** (such as feeling anxious, depressed or irritable) **now?**

MUCH BETTER	SLIGHTLY BETTER	ABOUT THE SAME	SLIGHTLY WORSE	MUCH WORSE
1	2	3	4	5

YOUR ANSWERS ARE IMPORTANT.
THANK YOU FOR COMPLETING THIS QUESTIONNAIRE.

Table C8.

Global Rating of Change

Please rate the overall condition of your ankle *FROM THE TIME YOU BEGAN TREATMENT UNTIL NOW* (Check only one)

☐ A very great deal worse (-7)	☐ About the same (0)	☐ A very great deal better (7)
☐ A great deal worse (-6)		☐ A great deal better (6)
☐ Quite a bit worse (-5)		☐ Quite a bit better (5)
☐ Moderately worse (-4)		☐ Moderately better (4)
☐ Somewhat worse (-3)		☐ Somewhat better (3)
☐ A little bit worse (-2)		☐ A little bit better (2)
☐ A tiny bit worse (-1)		☐ A tiny bit better (1)

Table C9.

Godin Leisure-Time Exercise Questionnaire

1. During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

	Times Per Week
a) **STRENUOUS EXERCISE** **(HEART BEATS RAPIDLY)** (e.g., running, jogging, hockey, football, soccer, squash, basketball, cross country skiing, judo, roller skating, vigorous swimming, vigorous long distance bicycling)	_____
b) **MODERATE EXERCISE** **(NOT EXHAUSTING)** (e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)	_____
c) **MILD EXERCISE** **(MINIMAL EFFORT)** (e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)	_____

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
1. ☐	2. ☐	3. ☐

C10.

Inclusion Check List

Criteria	Yes or No
Did their first ankle sprain occur greater than 1 year ago?	
Did they score less than an 85% on the FAAM-Sport Scale?	
Did they score ≥ 10 on the IdFAI?	
Are they between the ages 18 and 40?	
Are they physically active for at least 20 minutes 3x per week?	

Exclusion Check List

Criteria	Yes or No
Are they currently seeking *Phys Ther* for their ankle?	
Have they had ankle surgery?	
Have they had an ankle sprain in the past 6 weeks?	
Have they had a fracture of their ankle?	
Do they have a current self-reported disability due to lower extremity pathology?	
Do they have any neurological or vestibular disorders?	
Do they have diabetes mellitus?	
Do they have lumbosacral radiculopathy?	
Are they pregnant?	
Do they have soft tissue disorders (Marfan's or Ehlers-Dandros syndrome)?	

Chronic Ankle Instability Assessment Data Collection Sheet:

Participant Name:

Age:
Height:
Weight:
Gender:

Right Ankle History:

1. How many times have you sprained your right ankle?
2. How many years/months ago was your first right ankle sprain?
3. How many years/months ago was your most recent right ankle sprain?

Left Ankle History:

1. How many times have you sprained your left ankle?
2. How many years/months ago was your first left ankle sprain?
3. How many years/months ago was your most recent left ankle sprain?

Subjective Questionnaires:

Name	Score
FAAM-ADL	
FAAM-Sport	
IdFAI (Only Pre-treatment)	
Global Rating Score (Only post-treatment)	
Ankle Activity Score	
VR-12	
Godin Leisure-time questionnaire	

Tester 1

Walking	Yes/No	Total Duration Spent Walking
Able to maintain a foot progression angle of about 10-15 degrees?		
Heel contact to medial column toe off?		
Able to avoid foot position from crossing midline in relationship to upper body?		
Able to avoid excessive ankle inversion through mid to late stance?		
Was knee slightly flexed during stance phase?		

Was knee in line with hip and toe?		
Did they avoid excessive list over stance foot and a trendelenberg gait pattern?		

Tester 2

Walking	Yes/No	Total Duration Spent Walking
Able to maintain a foot progression angle of about 10-15 degrees?		
Heel contact to medial column toe off?		
Able to avoid foot position from crossing midline in relationship to upper body?		
Able to avoid excessive ankle inversion through mid to late stance?		
Was knee slightly flexed during stance phase?		
Was knee in line with hip and toe?		
Did they avoid excessive list over stance foot and a trendelenberg gait pattern?		

Descriptive Measures:

Name of Test	**Measurement (degrees) or (cm)**		
Standing Hindfoot Ailignment			
Navicular Drop Test			
Leg Length	**Right=**	**Left=**	
Foot Length	**Right=**	**Left=**	
Foot Width	**Right=**	**Left=**	

Range of Motion

Range of Motion	**Right Leg (Degrees)**			**Left Leg (Degrees)**		
Seated Straight Leg Dorsiflexion						
Seated Straight Leg Plantarflexion						
Seated Inversion						
Seated Eversion						

Prone Bent Knee Dorsiflexion						
Standing Straight Knee Dorsiflexion						
Standing Bent Knee Dorsiflexion						
***Posterior talar glide test**						

Ankle Arthrometer Measures

	Right Leg (displacement)			**Left Leg (displacement)**		
Anterior Drawer						
Talar Tilt						
Internal Rotation						

Manual Ligament Laxity Testing

Test	**Grade**		
Anterior Drawer			
Talar Tilt			
Internal Rotation			

Strength assessment using a hand-held dynamometer

Motion	**Right Leg (kg)**			**Left Leg (kg)**		
Dorsiflexion						
Plantar flexion						
Inversion						
Eversion						
Eversion+Plantar flexion						

Dynamic Balance using the Star Excursion Balance Test

Direction	Right Leg (cm)			Left Leg (cm)		
Anterior						
Posteriomedial						
Posteriolateral						

Static Balance: Right Foot Eyes OPEN

COP area95			
COP velocity			

Static Balance: Left Foot Eyes OPEN

COP area95			
COP velocity			

Static Balance: Right Foot Eyes CLOSED

COP area95			
COP velocity			

Static Balance: Left Foot Eyes CLOSED

COP area95			
COP velocity			

Table C11

Range of Motion

Arthrokinematic restriction present? If yes, list joints:

Joint Mobilization Type/Grade	Sets	Duration (minutes)

Stretching exercises:

Stretch Position	Sets	Duration (seconds)
Seated Straight Knee		
Seated Bent Knee		
Standing Straight Knee		
Standing Bent Knee		

Strength

Exercise (circle appropriate)	Sets	Repetitions
Double legged/Single legged heel raises		
Double legged/Single legged forefoot raises		
4-way manual resistance		
D1/D2 PNF		
4-way walks		
Short Foot Progression		

Balance

Static Balance (circle appropriate phase) Goal 3x30 seconds	Sets	Duration (seconds)
1. Eyes Open Single leg balance		
2. Eyes Open Single leg balance on a (foam or ankle destabilization sandal)		
3. Eyes Open Single leg balance on (Dynadisc™ or ankle destabilization boot)		
Eyes Closed Progression		
1. Eyes Closed Single leg balance		
2. Eyes Closed Single leg balance on a (foam or ankle destabilization sandal)		
3. Eyes Closed Single leg balance on (Dynadisc™ or ankle destabilization boot)		

Reach Tasks (circle appropriate phase) Goal 2x10 each direction	Sets	Repetitions
1.Completing the exercise standing on a firm surface		
2. Completing the exercise on (foam or ankle destabilization sandal)		
3. Completing the exercise standing on (Dynadisc™ or ankle destabilization boot)		

Hop to Stabilization (circle appropriate phase) Goal is 10 consecutive trials	Repetitions Completed
1. 18 inch hop with arm assistance	
2. 18 inch hop with hands on hips	
3. 27 inch hop with arm assistance	
4. 27 inch hop with hands on hips	
5. 36 inch hop with arm assistance	
6. 36 inch hop with hands on hips	
Hops with (foam or ankle destabilization boot)	
1. 18 inch hop with arm assistance while jumping on to a (foam or ankle destabilization boot)	
2. 18 inch hop with hands on hips while jumping onto a (foam or ankle destabilization boot)	
3. 27 inch hop with arm assistance while jumping onto a (foam or ankle destabilization boot)	
4. 27 inch hop with hands on hips while jumping onto a (foam or ankle destabilization boot)	
5. 36 inch hop with arm assistance while jumping onto a (foam or ankle destabilization boot)	
6. 36 inch hop with hands on hips while jumping onto a (foam or ankle destabilization boot)	

Functional Exercises

Lunges (circle appropriate phase) Goal is 2x10 each leg	Sets	Repetitions
1.Complete lunges on a firm surface		
2.Complete lunges with (foam or wearing ankle destabilization sandal) beneath stance leg and lunge on top another (foam or wearing ankle destabilization sandal)		
3.Complete lunges with (Dynadisc™ or wearing ankle destabilization boot) beneath the stance leg and lunge on top another (Dynadisc™ or wearing ankle destabilization boot)		

Forward Step-ups and Step-downs (circle appropriate phase) Goals is 3x10	Sets	Repetitions
1. Step on and off a box		
2. Step on and off a box (foam or ankle destabilization sandal) on top and beneath it		
3. Step on and off a box (Dynadisc™ or ankle destabilization boot) on top and beneath		

Lateral Step-ups and Step-downs (circle appropriate phase) Goal is 3x10	Sets	Repetitions
1. Step on and off a box		
2. Step on and off a box (foam or ankle destabilization sandal) on top and beneath it		

3. Step on and off a box (Dynadisc™ or ankle destabilization boot) on top and beneath it		

Dot Jumping Drill (circle appropriate phase) Goal is 3x30seconds	Sets	Duration (seconds)
1. Double legged lateral to medial hops, double legged anterior to posterior jumps, double legged figure 8 jumps (shod or ankle destabilization boot)		
2. Single legged lateral to medial jumps, single legged anterior to posterior jumps, and single legged figure 8 jumps (shod or ankle destabilization boot)		

Walking (Condition)	Time	Speed

APPENDIX D

Additional Results

Table D1. Group descriptive statistics

Group Statistics

	Group (0=Contol,1=myolux)	N	Mean	Std. Deviation	Std. Error Mean
Age	0	**13**	**21.462**	**2.8756**	**.7976**
	1	**13**	**21.308**	**3.3512**	**.9295**
Height (cm)	0	**13**	**169.1054**	**10.61098**	**2.94296**
	1	**13**	**168.8123**	**6.88737**	**1.91021**
Weight (kg)	0	**13**	**75.3312**	**13.70126**	**3.80005**
	1	**13**	**66.1198**	**12.89903**	**3.57755**
Number of Sprains	0	**13**	**3.0769**	**1.49786**	**.41543**
	1	**13**	**6.1538**	**5.36728**	**1.48862**
Last Sprain (months)	0	**13**	**24.4615**	**22.51154**	**6.24358**
	1	**13**	**10.2692**	**9.82475**	**2.72489**
First Sprain (years)	0	**13**	**5.5769**	**3.56982**	**.99009**
	1	**13**	**7.9231**	**5.21555**	**1.44653**
Pre-FAAM-ADL %	0	**13**	**87.6457**	**7.96219**	**2.20831**
	1	**13**	**85.7647**	**7.26157**	**2.01400**
Pre-FAAM-Sport %	0	**13**	**65.8654**	**18.24233**	**5.05951**
	1	**13**	**67.0673**	**13.41783**	**3.72144**
IdFAI	0	**13**	**22.9231**	**1.70595**	**.47314**
	1	**13**	**23.2308**	**5.15030**	**1.42844**
Godin Leisure-Time	0	**13**	**58.7692**	**16.44766**	**4.56176**
	1	**13**	**79.6923**	**31.65803**	**8.78036**

Table D2. Summary of results for self-reported function measures

Within-Subjects Factors

Measure	Pre_Post	Dependent Variable
FAAM_ADL	1	**PreFAAMADL_A**
	2	**PostFAAMADL_A**
ADL_SANE	1	**PreSANEADL**
	2	**PostSANEADL**

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre-FAAM-ADL %	0	**87.6457**	**7.96219**	**13**
	1	**85.7647**	**7.26157**	**13**
	Total	**86.7052**	**7.52734**	**26**
Post-FAAM-ADL %	0	**95.6044**	**3.31003**	**13**
	1	**95.9707**	**4.54721**	**13**
	Total	**95.7875**	**3.90114**	**26**
Pre-SANE-ADL	0	**87.8462**	**11.14934**	**13**
	1	**83.0000**	**20.48983**	**13**
	Total	**85.4231**	**16.34912**	**26**
Post-SANE-ADL	0	**95.0769**	**4.34859**	**13**
	1	**94.5385**	**8.41244**	**13**
	Total	**94.8077**	**6.56670**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	FAAM_ADL	Sphericity Assumed	**1072.364**	**1**	**1072.364**	**37.385**	**.000**	**37.385**
		Greenhouse-Geisser	**1072.364**	**1.000**	**1072.364**	**37.385**	**.000**	**37.385**
		Huynh-Feldt	**1072.364**	**1.000**	**1072.364**	**37.385**	**.000**	**37.385**
		Lower-bound	**1072.364**	**1.000**	**1072.364**	**37.385**	**.000**	**37.385**
	ADL_SANE	Sphericity Assumed	**1144.923**	**1**	**1144.923**	**9.206**	**.006**	**9.206**
		Greenhouse-Geisser	**1144.923**	**1.000**	**1144.923**	**9.206**	**.006**	**9.206**
		Huynh-Feldt	**1144.923**	**1.000**	**1144.923**	**9.206**	**.006**	**9.206**

		Lower-bound	1144.923	1.000	1144.923	9.206	.006	9.206
Pre_Post * Group0Contol1myolux	FAAM_ADL	Sphericity Assumed	16.414	1	16.414	.572	.457	.572
		Greenhouse-Geisser	16.414	1.000	16.414	.572	.457	.572
		Huynh-Feldt	16.414	1.000	16.414	.572	.457	.572
		Lower-bound	16.414	1.000	16.414	.572	.457	.572
	ADL_SANE	Sphericity Assumed	60.308	1	60.308	.485	.493	.485
		Greenhouse-Geisser	60.308	1.000	60.308	.485	.493	.485
		Huynh-Feldt	60.308	1.000	60.308	.485	.493	.485
		Lower-bound	60.308	1.000	60.308	.485	.493	.485
Error(Pre_Post)	FAAM_ADL	Sphericity Assumed	688.427	24	28.684			
		Greenhouse-Geisser	688.427	24.000	28.684			
		Huynh-Feldt	688.427	24.000	28.684			
		Lower-bound	688.427	24.000	28.684			
	ADL_SANE	Sphericity Assumed	2984.769	24	124.365			
		Greenhouse-Geisser	2984.769	24.000	124.365			
		Huynh-Feldt	2984.769	24.000	124.365			
		Lower-bound	2984.769	24.000	124.365			

Tests of Between-Subjects Effects

Transformed Variable: Average Source	Measure	Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter	Observed Power[a]
Intercept	FAAM_ADL	432946.686	1	432946.686	9579.379	.000	9579.379	1.000
	ADL_SANE	422280.692	1	422280.692	2193.155	.000	2193.155	1.000
Group0Contol1myolux	FAAM_ADL	7.457	1	7.457	.165	.688	.165	.068
	ADL_SANE	94.231	1	94.231	.489	.491	.489	.103
Error	FAAM_ADL	1084.697	24	45.196				
	ADL_SANE	4621.077	24	192.545				

a. Computed using alpha = .05

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre-FAAM-Sport %	0	**65.8654**	**18.24233**	**13**
	1	**67.0673**	**13.41783**	**13**
	Total	**66.4663**	**15.70126**	**26**
Post-FAAM-Sport %	0	**86.8475**	**11.38847**	**13**
	1	**85.8173**	**8.32832**	**13**
	Total	**86.3324**	**9.78897**	**26**
Pre-SANE-Sport	0	**72.6154**	**20.89074**	**13**
	1	**73.7692**	**16.14081**	**13**
	Total	**73.1923**	**18.29977**	**26**
Post-SANE-Sport	0	**90.2308**	**8.34819**	**13**
	1	**89.0000**	**10.53565**	**13**
	Total	**89.6154**	**9.33414**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	FAAM_Sport	Sphericity Assumed	**5130.590**	**1**	**5130.590**	**46.004**	**.000**	**46.004**
		Greenhouse-Geisser	**5130.590**	**1.000**	**5130.590**	**46.004**	**.000**	**46.004**
		Huynh-Feldt	**5130.590**	**1.000**	**5130.590**	**46.004**	**.000**	**46.004**
		Lower-bound	**5130.590**	**1.000**	**5130.590**	**46.004**	**.000**	**46.004**
	Sport_SANE	Sphericity Assumed	**3506.327**	**1**	**3506.327**	**26.507**	**.000**	**26.507**
		Greenhouse-Geisser	**3506.327**	**1.000**	**3506.327**	**26.507**	**.000**	**26.507**
		Huynh-Feldt	**3506.327**	**1.000**	**3506.327**	**26.507**	**.000**	**26.507**
		Lower-bound	**3506.327**	**1.000**	**3506.327**	**26.507**	**.000**	**26.507**
Pre_Post * Group0Contol1myolux	FAAM_Sport	Sphericity Assumed	**16.193**	**1**	**16.193**	**.145**	**.707**	**.145**
		Greenhouse-Geisser	**16.193**	**1.000**	**16.193**	**.145**	**.707**	**.145**
		Huynh-Feldt	**16.193**	**1.000**	**16.193**	**.145**	**.707**	**.145**
		Lower-bound	**16.193**	**1.000**	**16.193**	**.145**	**.707**	**.145**
	Sport_SANE	Sphericity Assumed	**18.481**	**1**	**18.481**	**.140**	**.712**	**.140**
		Greenhouse-Geisser	**18.481**	**1.000**	**18.481**	**.140**	**.712**	**.140**
		Huynh-Feldt	**18.481**	**1.000**	**18.481**	**.140**	**.712**	**.140**
		Lower-bound	**18.481**	**1.000**	**18.481**	**.140**	**.712**	**.140**
Error(Pre_Post)	FAAM_Sport	Sphericity Assumed	**2676.578**	**24**	**111.524**			
		Greenhouse-Geisser	**2676.578**	**24.000**	**111.524**			

	Huynh-Feldt	2676.578	24.000	111.524
	Lower-bound	2676.578	24.000	111.524
Sport_SANE	Sphericity Assumed	3174.692	24	132.279
	Greenhouse-Geisser	3174.692	24.000	132.279
	Huynh-Feldt	3174.692	24.000	132.279
	Lower-bound	3174.692	24.000	132.279

Table D3. Summary of the results for laxity and range of motion

Group Statistics

	Group (0=Contol,1=myolux)	N	Mean	Std. Deviation	Std. Error Mean
Pre-Standing Hindfoot	0	13	5.666667	2.9344695	.8138754
	1	13	4.153846	.9870962	.2737712
Pre-Navicular Drop	0	13	6.850256	3.0270578	.8395548
	1	13	6.853846	2.3009329	.6381640
Anterior Drawer Arthrometer Avg	0	13	9.366154	4.3439543	1.2047961
	1	13	11.721538	5.1535428	1.4293356
Talar Tilt Arthr Avg	0	13	45.670769	9.8218867	2.7241012
	1	13	45.070256	7.4466493	2.0653289
Manual Ant Drawer	0	13	1.92	.641	.178
	1	13	2.00	.707	.196
Manual Talar Tilt	0	13	1.46	.660	.183
	1	13	1.54	.877	.243
Manual Internal Rot	0	13	2.46	.660	.183
	1	13	2.23	.927	.257

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Seated Dorsiflexion	0	7.38	6.345	13
	1	10.77	6.648	13
	Total	9.08	6.597	26
Post Seated Dorsiflexion	0	9.54	7.457	13
	1	12.15	5.178	13

	Total	**10.85**	**6.429**	**26**
Pre Prone Bent Knee Dorsi	0	**14.256410**	**8.0566902**	**13**
	1	**16.076923**	**8.0670269**	**13**
	Total	**15.166667**	**7.9533361**	**26**
Post Prone Bent Knee Dorsi	0	**14.31**	**7.931**	**13**
	1	**17.46**	**6.802**	**13**
	Total	**15.88**	**7.415**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	Seated_DorsiFlexion	Sphericity Assumed	**40.692**	**1**	**40.692**	**3.067**	**.093**
		Greenhouse-Geisser	**40.692**	**1.000**	**40.692**	**3.067**	**.093**
		Huynh-Feldt	**40.692**	**1.000**	**40.692**	**3.067**	**.093**
		Lower-bound	**40.692**	**1.000**	**40.692**	**3.067**	**.093**
	Prone_Bent_DorsiFlexion	Sphericity Assumed	**6.701**	**1**	**6.701**	**.317**	**.579**
		Greenhouse-Geisser	**6.701**	**1.000**	**6.701**	**.317**	**.579**
		Huynh-Feldt	**6.701**	**1.000**	**6.701**	**.317**	**.579**
		Lower-bound	**6.701**	**1.000**	**6.701**	**.317**	**.579**
Pre_Post * Group0Contol1myolux	Seated_DorsiFlexion	Sphericity Assumed	**1.923**	**1**	**1.923**	**.145**	**.707**
		Greenhouse-Geisser	**1.923**	**1.000**	**1.923**	**.145**	**.707**
		Huynh-Feldt	**1.923**	**1.000**	**1.923**	**.145**	**.707**
		Lower-bound	**1.923**	**1.000**	**1.923**	**.145**	**.707**
	Prone_Bent_DorsiFlexion	Sphericity Assumed	**5.778**	**1**	**5.778**	**.273**	**.606**
		Greenhouse-Geisser	**5.778**	**1.000**	**5.778**	**.273**	**.606**
		Huynh-Feldt	**5.778**	**1.000**	**5.778**	**.273**	**.606**
		Lower-bound	**5.778**	**1.000**	**5.778**	**.273**	**.606**
Error(Pre_Post)	Seated_DorsiFlexion	Sphericity Assumed	**318.385**	**24**	**13.266**		
		Greenhouse-Geisser	**318.385**	**24.000**	**13.266**		
		Huynh-Feldt	**318.385**	**24.000**	**13.266**		
		Lower-bound	**318.385**	**24.000**	**13.266**		
	Prone_Bent_DorsiFlexion	Sphericity Assumed	**507.744**	**24**	**21.156**		
		Greenhouse-Geisser	**507.744**	**24.000**	**21.156**		

	Huynh-Feldt	507.744	24.000	21.156
	Lower-bound	507.744	24.000	21.156

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Standing Straight Dorsi	0	34.15	10.375	13
	1	42.08	6.982	13
	Total	38.12	9.560	26
Post Standing Straight Dorsi	0	38.31	7.994	13
	1	47.31	6.957	13
	Total	42.81	8.658	26
Pre Standing Bent Dorsi	0	38.08	11.124	13
	1	46.38	7.124	13
	Total	42.23	10.085	26
Post Standing Bent Dorsi	0	43.46	10.682	13
	1	51.08	7.376	13
	Total	47.27	9.796	26

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	Standing_Straight_DorsiFlexion	Sphericity Assumed	286.231	1	286.231	5.958	.022
		Greenhouse-Geisser	286.231	1.000	286.231	5.958	.022
		Huynh-Feldt	286.231	1.000	286.231	5.958	.022
		Lower-bound	286.231	1.000	286.231	5.958	.022
	Standing_Bent_DorsiFlexion	Sphericity Assumed	330.019	1	330.019	13.050	.001
		Greenhouse-Geisser	330.019	1.000	330.019	13.050	.001
		Huynh-Feldt	330.019	1.000	330.019	13.050	.001
		Lower-bound	330.019	1.000	330.019	13.050	.001
Pre_Post * Group0Contol1myolux	Standing_Straight_DorsiFlexion	Sphericity Assumed	3.769	1	3.769	.078	.782
		Greenhouse-Geisser	3.769	1.000	3.769	.078	.782
		Huynh-Feldt	3.769	1.000	3.769	.078	.782

		Lower-bound	3.769	1.000	3.769	.078	.782
	Standing_Bent_DorsiFlexion	Sphericity Assumed	1.558	1	1.558	.062	.806
		Greenhouse-Geisser	1.558	1.000	1.558	.062	.806
		Huynh-Feldt	1.558	1.000	1.558	.062	.806
		Lower-bound	1.558	1.000	1.558	.062	.806
Error(Pre_Post)	Standing_Straight_DorsiFlexion	Sphericity Assumed	1153.000	24	48.042		
		Greenhouse-Geisser	1153.000	24.000	48.042		
		Huynh-Feldt	1153.000	24.000	48.042		
		Lower-bound	1153.000	24.000	48.042		
	Standing_Bent_DorsiFlexion	Sphericity Assumed	606.923	24	25.288		
		Greenhouse-Geisser	606.923	24.000	25.288		
		Huynh-Feldt	606.923	24.000	25.288		
		Lower-bound	606.923	24.000	25.288		

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre_Posterior_Talar_Glide	0	9.103	8.7097	13
	1	15.410	8.5637	13
	Total	12.256	9.0531	26
Post Post. Talar Glide Avg	0	14.49	9.774	13
	1	17.05	5.077	13
	Total	15.77	7.742	26
Pre Seated Plantar Flexion	0	64.00	9.695	13
	1	64.62	7.183	13
	Total	64.31	8.365	26
Post Seated Plantar Flexion	0	67.38	10.650	13
	1	67.85	5.669	13
	Total	67.62	8.362	26

Univariate Tests

Source	Measure	Type III Sum of Squares	df	Mean Square	F	Sig.

Pre_Post	Posterior_Talar_Glide	Sphericity Assumed	160.419	1	160.419	5.887	.023
		Greenhouse-Geisser	160.419	1.000	160.419	5.887	.023
		Huynh-Feldt	160.419	1.000	160.419	5.887	.023
		Lower-bound	160.419	1.000	160.419	5.887	.023
	PlantarFlexion	Sphericity Assumed	142.231	1	142.231	10.987	.003
		Greenhouse-Geisser	142.231	1.000	142.231	10.987	.003
		Huynh-Feldt	142.231	1.000	142.231	10.987	.003
		Lower-bound	142.231	1.000	142.231	10.987	.003
Pre_Post * Group0Contol1myolux	Posterior_Talar_Glide	Sphericity Assumed	45.547	1	45.547	1.671	.208
		Greenhouse-Geisser	45.547	1.000	45.547	1.671	.208
		Huynh-Feldt	45.547	1.000	45.547	1.671	.208
		Lower-bound	45.547	1.000	45.547	1.671	.208
	PlantarFlexion	Sphericity Assumed	.077	1	.077	.006	.939
		Greenhouse-Geisser	.077	1.000	.077	.006	.939
		Huynh-Feldt	.077	1.000	.077	.006	.939
		Lower-bound	.077	1.000	.077	.006	.939
Error(Pre_Post)	Posterior_Talar_Glide	Sphericity Assumed	654.034	24	27.251		
		Greenhouse-Geisser	654.034	24.000	27.251		
		Huynh-Feldt	654.034	24.000	27.251		
		Lower-bound	654.034	24.000	27.251		
	PlantarFlexion	Sphericity Assumed	310.692	24	12.946		
		Greenhouse-Geisser	310.692	24.000	12.946		
		Huynh-Feldt	310.692	24.000	12.946		
		Lower-bound	310.692	24.000	12.946		

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Seated Inversion	0	32.666667	10.4216655	13
	1	36.923077	7.4326032	13
	Total	34.794872	9.1302072	26
Post Seated Inversion	0	34.69	8.509	13
	1	35.85	8.163	13
	Total	35.27	8.191	26

Pre Seated Eversion	0	**14.31**	**7.454**	**13**
	1	**15.92**	**6.304**	**13**
	Total	**15.12**	**6.814**	**26**
Post Seated Eversion	0	**18.69**	**6.102**	**13**
	1	**16.85**	**5.886**	**13**
	Total	**17.77**	**5.948**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	Inversion	Sphericity Assumed	**2.925**	**1**	**2.925**	**.128**	**.724**	**.128**
		Greenhouse-Geisser	**2.925**	**1.000**	**2.925**	**.128**	**.724**	**.128**
		Huynh-Feldt	**2.925**	**1.000**	**2.925**	**.128**	**.724**	**.128**
		Lower-bound	**2.925**	**1.000**	**2.925**	**.128**	**.724**	**.128**
	Eversion	Sphericity Assumed	**91.558**	**1**	**91.558**	**2.733**	**.111**	**2.733**
		Greenhouse-Geisser	**91.558**	**1.000**	**91.558**	**2.733**	**.111**	**2.733**
		Huynh-Feldt	**91.558**	**1.000**	**91.558**	**2.733**	**.111**	**2.733**
		Lower-bound	**91.558**	**1.000**	**91.558**	**2.733**	**.111**	**2.733**
Pre_Post * Group0Contol1myolux	Inversion	Sphericity Assumed	**31.284**	**1**	**31.284**	**1.367**	**.254**	**1.367**
		Greenhouse-Geisser	**31.284**	**1.000**	**31.284**	**1.367**	**.254**	**1.367**
		Huynh-Feldt	**31.284**	**1.000**	**31.284**	**1.367**	**.254**	**1.367**
		Lower-bound	**31.284**	**1.000**	**31.284**	**1.367**	**.254**	**1.367**
	Eversion	Sphericity Assumed	**38.942**	**1**	**38.942**	**1.162**	**.292**	**1.162**
		Greenhouse-Geisser	**38.942**	**1.000**	**38.942**	**1.162**	**.292**	**1.162**
		Huynh-Feldt	**38.942**	**1.000**	**38.942**	**1.162**	**.292**	**1.162**
		Lower-bound	**38.942**	**1.000**	**38.942**	**1.162**	**.292**	**1.162**
Error(Pre_Post)	Inversion	Sphericity Assumed	**549.179**	**24**	**22.882**			
		Greenhouse-Geisser	**549.179**	**24.000**	**22.882**			
		Huynh-Feldt	**549.179**	**24.000**	**22.882**			
		Lower-bound	**549.179**	**24.000**	**22.882**			
	Eversion	Sphericity Assumed	**804.000**	**24**	**33.500**			
		Greenhouse-Geisser	**804.000**	**24.000**	**33.500**			
		Huynh-Feldt	**804.000**	**24.000**	**33.500**			

	Lower-bound	**804.000**	**24.000**	**33.500**

Table D4. Summary of results for strength

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Dorsi Normalized Force	0	**1.622225**	**.3153742**	**13**
	1	**1.984043**	**.6024811**	**13**
	Total	**1.803134**	**.5059749**	**26**
Post Dorsi Normalized Force	0	**1.828943**	**.3696862**	**13**
	1	**2.422524**	**.6758417**	**13**
	Total	**2.125733**	**.6135588**	**26**
Pre Inversion Normalized Force	0	**1.322306**	**.2779086**	**13**
	1	**1.490294**	**.3357031**	**13**
	Total	**1.406300**	**.3138526**	**26**
Post Inversion Normalized Force	0	**1.719033**	**.4097370**	**13**
	1	**1.925906**	**.4618996**	**13**
	Total	**1.822470**	**.4405907**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	DorsiFlexion	Sphericity Assumed	**1.353**	**1**	**1.353**	**19.946**	**.000**	**19.946**
		Greenhouse-Geisser	**1.353**	**1.000**	**1.353**	**19.946**	**.000**	**19.946**
		Huynh-Feldt	**1.353**	**1.000**	**1.353**	**19.946**	**.000**	**19.946**
		Lower-bound	**1.353**	**1.000**	**1.353**	**19.946**	**.000**	**19.946**
	Inversion	Sphericity Assumed	**2.252**	**1**	**2.252**	**41.251**	**.000**	**41.251**
		Greenhouse-Geisser	**2.252**	**1.000**	**2.252**	**41.251**	**.000**	**41.251**
		Huynh-Feldt	**2.252**	**1.000**	**2.252**	**41.251**	**.000**	**41.251**
		Lower-bound	**2.252**	**1.000**	**2.252**	**41.251**	**.000**	**41.251**
Pre_Post * Group0Contol1myolux	DorsiFlexion	Sphericity Assumed	**.175**	**1**	**.175**	**2.574**	**.122**	**2.574**
		Greenhouse-Geisser	**.175**	**1.000**	**.175**	**2.574**	**.122**	**2.574**

		Huynh-Feldt	.175	1.000	.175	2.574	.122	2.574
		Lower-bound	.175	1.000	.175	2.574	.122	2.574
	Inversion	Sphericity Assumed	.005	1	.005	.090	.767	.090
		Greenhouse-Geisser	.005	1.000	.005	.090	.767	.090
		Huynh-Feldt	.005	1.000	.005	.090	.767	.090
		Lower-bound	.005	1.000	.005	.090	.767	.090
Error(Pre_Post)	DorsiFlexion	Sphericity Assumed	1.628	24	.068			
		Greenhouse-Geisser	1.628	24.000	.068			
		Huynh-Feldt	1.628	24.000	.068			
		Lower-bound	1.628	24.000	.068			
	Inversion	Sphericity Assumed	1.310	24	.055			
		Greenhouse-Geisser	1.310	24.000	.055			
		Huynh-Feldt	1.310	24.000	.055			
		Lower-bound	1.310	24.000	.055			

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Eversion Normalized Force	0	1.609995	.4394172	13
	1	1.679495	.3400085	13
	Total	1.644745	.3865600	26
Post Eversion Normalized Force	0	1.964554	.4870199	13
	1	2.191689	.4768709	13
	Total	2.078122	.4862290	26
Pre Eversion/Plantar Normalized Force	0	1.337080	.3229765	13
	1	1.483524	.3298584	13
	Total	1.410302	.3284413	26
Post Eversion/Plantar Normalized Force	0	1.658569	.4283486	13
	1	1.826948	.4376380	13
	Total	1.742758	.4328694	26

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	Eversion_Neutral	Sphericity Assumed	**2.442**	**1**	**2.442**	**46.383**	**.000**	**46.383**
		Greenhouse-Geisser	**2.442**	**1.000**	**2.442**	**46.383**	**.000**	**46.383**
		Huynh-Feldt	**2.442**	**1.000**	**2.442**	**46.383**	**.000**	**46.383**
		Lower-bound	**2.442**	**1.000**	**2.442**	**46.383**	**.000**	**46.383**
	Eversion_PF	Sphericity Assumed	**1.437**	**1**	**1.437**	**18.749**	**.000**	**18.749**
		Greenhouse-Geisser	**1.437**	**1.000**	**1.437**	**18.749**	**.000**	**18.749**
		Huynh-Feldt	**1.437**	**1.000**	**1.437**	**18.749**	**.000**	**18.749**
		Lower-bound	**1.437**	**1.000**	**1.437**	**18.749**	**.000**	**18.749**
Pre_Post * Group0Contol1myolux	Eversion_Neutral	Sphericity Assumed	**.081**	**1**	**.081**	**1.534**	**.227**	**1.534**
		Greenhouse-Geisser	**.081**	**1.000**	**.081**	**1.534**	**.227**	**1.534**
		Huynh-Feldt	**.081**	**1.000**	**.081**	**1.534**	**.227**	**1.534**
		Lower-bound	**.081**	**1.000**	**.081**	**1.534**	**.227**	**1.534**
	Eversion_PF	Sphericity Assumed	**.002**	**1**	**.002**	**.020**	**.888**	**.020**
		Greenhouse-Geisser	**.002**	**1.000**	**.002**	**.020**	**.888**	**.020**
		Huynh-Feldt	**.002**	**1.000**	**.002**	**.020**	**.888**	**.020**
		Lower-bound	**.002**	**1.000**	**.002**	**.020**	**.888**	**.020**
Error(Pre_Post)	Eversion_Neutral	Sphericity Assumed	**1.263**	**24**	**.053**			
		Greenhouse-Geisser	**1.263**	**24.000**	**.053**			
		Huynh-Feldt	**1.263**	**24.000**	**.053**			
		Lower-bound	**1.263**	**24.000**	**.053**			
	Eversion_PF	Sphericity Assumed	**1.839**	**24**	**.077**			
		Greenhouse-Geisser	**1.839**	**24.000**	**.077**			
		Huynh-Feldt	**1.839**	**24.000**	**.077**			
		Lower-bound	**1.839**	**24.000**	**.077**			

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Plantar Normalized Force	0	**3.095930**	**.8584575**	**13**
	1	**3.578857**	**.8464899**	**13**
	Total	**3.337394**	**.8708123**	**26**
Post Plantar Normalized Force	0	**3.481626**	**.9756212**	**13**
	1	**4.376905**	**1.1727451**	**13**

	Total	**3.929266**	**1.1512761**		**26**

Tests of Within-Subjects Effects

Measure: PlantarFlexion

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter	Observed Power[a]
Pre_Post	Sphericity Assumed	**4.554**	**1**	**4.554**	**12.137**	**.002**	**12.137**	**.916**
	Greenhouse-Geisser	**4.554**	**1.000**	**4.554**	**12.137**	**.002**	**12.137**	**.916**
	Huynh-Feldt	**4.554**	**1.000**	**4.554**	**12.137**	**.002**	**12.137**	**.916**
	Lower-bound	**4.554**	**1.000**	**4.554**	**12.137**	**.002**	**12.137**	**.916**
Pre_Post * Group0Contol1myolux	Sphericity Assumed	**.553**	**1**	**.553**	**1.473**	**.237**	**1.473**	**.214**
	Greenhouse-Geisser	**.553**	**1.000**	**.553**	**1.473**	**.237**	**1.473**	**.214**
	Huynh-Feldt	**.553**	**1.000**	**.553**	**1.473**	**.237**	**1.473**	**.214**
	Lower-bound	**.553**	**1.000**	**.553**	**1.473**	**.237**	**1.473**	**.214**
Error(Pre_Post)	Sphericity Assumed	**9.005**	**24**	**.375**				
	Greenhouse-Geisser	**9.005**	**24.000**	**.375**				
	Huynh-Feldt	**9.005**	**24.000**	**.375**				
	Lower-bound	**9.005**	**24.000**	**.375**				

a. Computed using alpha = .05

Table D5. Summary of results for static and dynamic balance

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Eyes Open Area Avg	0	**7.232590**	**2.7016355**	**13**
	1	**7.442821**	**2.3732334**	**13**
	Total	**7.337705**	**2.4936731**	**26**
Post Eyes Open Area Avg	0	**5.75**	**1.780**	**13**
	1	**6.85**	**2.476**	**13**
	Total	**6.30**	**2.185**	**26**

Pre Eyes Open Velocity Avg	0	**4.255641**	**1.2569373**	**13**
	1	**4.508718**	**1.6991025**	**13**
	Total	**4.382179**	**1.4699442**	**26**
Post Eyes Open Velocity Avg	0	**3.85**	**.895**	**13**
	1	**4.51**	**1.443**	**13**
	Total	**4.18**	**1.223**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	Eyes_Open_Area	Sphericity Assumed	**14.051**	**1**	**14.051**	**4.903**	**.037**
		Greenhouse-Geisser	**14.051**	**1.000**	**14.051**	**4.903**	**.037**
		Huynh-Feldt	**14.051**	**1.000**	**14.051**	**4.903**	**.037**
		Lower-bound	**14.051**	**1.000**	**14.051**	**4.903**	**.037**
	Eyes_Open_Velocity	Sphericity Assumed	**.538**	**1**	**.538**	**.790**	**.383**
		Greenhouse-Geisser	**.538**	**1.000**	**.538**	**.790**	**.383**
		Huynh-Feldt	**.538**	**1.000**	**.538**	**.790**	**.383**
		Lower-bound	**.538**	**1.000**	**.538**	**.790**	**.383**
Pre_Post * Group0Contol1myolux	Eyes_Open_Area	Sphericity Assumed	**2.554**	**1**	**2.554**	**.891**	**.355**
		Greenhouse-Geisser	**2.554**	**1.000**	**2.554**	**.891**	**.355**
		Huynh-Feldt	**2.554**	**1.000**	**2.554**	**.891**	**.355**
		Lower-bound	**2.554**	**1.000**	**2.554**	**.891**	**.355**
	Eyes_Open_Velocity	Sphericity Assumed	**.527**	**1**	**.527**	**.774**	**.388**
		Greenhouse-Geisser	**.527**	**1.000**	**.527**	**.774**	**.388**
		Huynh-Feldt	**.527**	**1.000**	**.527**	**.774**	**.388**
		Lower-bound	**.527**	**1.000**	**.527**	**.774**	**.388**
Error(Pre_Post)	Eyes_Open_Area	Sphericity Assumed	**68.781**	**24**	**2.866**		
		Greenhouse-Geisser	**68.781**	**24.000**	**2.866**		
		Huynh-Feldt	**68.781**	**24.000**	**2.866**		
		Lower-bound	**68.781**	**24.000**	**2.866**		
	Eyes_Open_Velocity	Sphericity Assumed	**16.343**	**24**	**.681**		
		Greenhouse-Geisser	**16.343**	**24.000**	**.681**		
		Huynh-Feldt	**16.343**	**24.000**	**.681**		

		Lower-bound	**16.343**	**24.000**	**.681**

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre Eyes Closed Area Avg	0	**29.713889**	**10.1787405**	**12**
	1	**26.441026**	**9.6338512**	**13**
	Total	**28.012000**	**9.8324463**	**25**
Post Eyes Closed Area Avg	0	**24.36**	**8.550**	**12**
	1	**21.79**	**5.567**	**13**
	Total	**23.02**	**7.121**	**25**
Pre Eyes Closed Velocity Avg	0	**9.959167**	**2.9857128**	**12**
	1	**9.712821**	**2.7656005**	**13**
	Total	**9.831067**	**2.8152896**	**25**
Post Eyes Closed Velocity Avg	0	**8.91**	**2.407**	**12**
	1	**9.08**	**2.326**	**13**
	Total	**9.00**	**2.317**	**25**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	Eyes_Closed_Area	Sphericity Assumed	**312.233**	**1**	**312.233**	**4.408**	**.047**
		Greenhouse-Geisser	**312.233**	**1.000**	**312.233**	**4.408**	**.047**
		Huynh-Feldt	**312.233**	**1.000**	**312.233**	**4.408**	**.047**
		Lower-bound	**312.233**	**1.000**	**312.233**	**4.408**	**.047**
	Eyes_Closed_Velocity	Sphericity Assumed	**8.825**	**1**	**8.825**	**5.130**	**.033**
		Greenhouse-Geisser	**8.825**	**1.000**	**8.825**	**5.130**	**.033**
		Huynh-Feldt	**8.825**	**1.000**	**8.825**	**5.130**	**.033**
		Lower-bound	**8.825**	**1.000**	**8.825**	**5.130**	**.033**
Pre_Post * Group0Contol1myolux	Eyes_Closed_Area	Sphericity Assumed	**1.559**	**1**	**1.559**	**.022**	**.883**
		Greenhouse-Geisser	**1.559**	**1.000**	**1.559**	**.022**	**.883**
		Huynh-Feldt	**1.559**	**1.000**	**1.559**	**.022**	**.883**
		Lower-bound	**1.559**	**1.000**	**1.559**	**.022**	**.883**
	Eyes_Closed_Velocity	Sphericity Assumed	**.546**	**1**	**.546**	**.317**	**.579**
		Greenhouse-Geisser	**.546**	**1.000**	**.546**	**.317**	**.579**

		Huynh-Feldt	.546	1.000	.546	.317	.579
		Lower-bound	.546	1.000	.546	.317	.579
Error(Pre_Post)	Eyes_Closed_Area	Sphericity Assumed	1629.322	23	70.840		
		Greenhouse-Geisser	1629.322	23.000	70.840		
		Huynh-Feldt	1629.322	23.000	70.840		
		Lower-bound	1629.322	23.000	70.840		
	Eyes_Closed_Velocity	Sphericity Assumed	39.566	23	1.720		
		Greenhouse-Geisser	39.566	23.000	1.720		
		Huynh-Feldt	39.566	23.000	1.720		
		Lower-bound	39.566	23.000	1.720		

Descriptive Statistics

	Group (0=Contol,1=myolux)	Mean	Std. Deviation	N
Pre_SEBT_Composite	0	71.646	8.0701	13
	1	78.570	6.0266	13
	Total	75.108	7.8205	26
Post_SEBT_Composite	0	76.610	7.4186	13
	1	81.601	4.8774	13
	Total	79.106	6.6567	26

Tests of Within-Subjects Effects

Measure: SEBT_Composite

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter	Observed Power[a]
Pre_Post	Sphericity Assumed	207.760	1	207.760	10.993	.003	10.993	.889
	Greenhouse-Geisser	207.760	1.000	207.760	10.993	.003	10.993	.889
	Huynh-Feldt	207.760	1.000	207.760	10.993	.003	10.993	.889
	Lower-bound	207.760	1.000	207.760	10.993	.003	10.993	.889
Pre_Post * Group0Contol1myolux	Sphericity Assumed	12.155	1	12.155	.643	.430	.643	.120
	Greenhouse-Geisser	12.155	1.000	12.155	.643	.430	.643	.120
	Huynh-Feldt	12.155	1.000	12.155	.643	.430	.643	.120
	Lower-bound	12.155	1.000	12.155	.643	.430	.643	.120

Error(Pre_Post)	Sphericity Assumed	**453.582**	**24**	**18.899**
	Greenhouse-Geisser	**453.582**	**24.000**	**18.899**
	Huynh-Feldt	**453.582**	**24.000**	**18.899**
	Lower-bound	**453.582**	**24.000**	**18.899**

Table D6. Summary of results for sEMG amplitudes during strength measures

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Normalized DorsiFlexion	0	**40.71**	**24.501**	**13**
	1	**52.82**	**22.274**	**13**
	Total	**46.77**	**23.757**	**26**
Post Normalized DorsiFlexion	0	**55.28**	**20.499**	**13**
	1	**53.19**	**13.374**	**13**
	Total	**54.23**	**16.991**	**26**
Normalized Inversion Ant Tib	0	**13.17**	**9.169**	**13**
	1	**17.56**	**14.210**	**13**
	Total	**15.37**	**11.929**	**26**
Post Normalized Inversion Ant Tib	0	**27.82**	**11.692**	**13**
	1	**22.87**	**12.722**	**13**
	Total	**25.34**	**12.234**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	DorsiFlexion_AnteriorTib	Sphericity Assumed	**724.554**	**1**	**724.554**	**2.969**	**.098**
		Greenhouse-Geisser	**724.554**	**1.000**	**724.554**	**2.969**	**.098**
		Huynh-Feldt	**724.554**	**1.000**	**724.554**	**2.969**	**.098**
		Lower-bound	**724.554**	**1.000**	**724.554**	**2.969**	**.098**

	Inversion_AnteriorTib	Sphericity Assumed	1293.691	1	1293.691	10.393	.004
		Greenhouse-Geisser	1293.691	1.000	1293.691	10.393	.004
		Huynh-Feldt	1293.691	1.000	1293.691	10.393	.004
		Lower-bound	1293.691	1.000	1293.691	10.393	.004
Pre_Post * Group0Control1Device	DorsiFlexion_AnteriorTib	Sphericity Assumed	655.367	1	655.367	2.685	.114
		Greenhouse-Geisser	655.367	1.000	655.367	2.685	.114
		Huynh-Feldt	655.367	1.000	655.367	2.685	.114
		Lower-bound	655.367	1.000	655.367	2.685	.114
	Inversion_AnteriorTib	Sphericity Assumed	283.153	1	283.153	2.275	.145
		Greenhouse-Geisser	283.153	1.000	283.153	2.275	.145
		Huynh-Feldt	283.153	1.000	283.153	2.275	.145
		Lower-bound	283.153	1.000	283.153	2.275	.145
Error(Pre_Post)	DorsiFlexion_AnteriorTib	Sphericity Assumed	5857.837	24	244.077		
		Greenhouse-Geisser	5857.837	24.000	244.077		
		Huynh-Feldt	5857.837	24.000	244.077		
		Lower-bound	5857.837	24.000	244.077		
	Inversion_AnteriorTib	Sphericity Assumed	2987.584	24	124.483		
		Greenhouse-Geisser	2987.584	24.000	124.483		
		Huynh-Feldt	2987.584	24.000	124.483		
		Lower-bound	2987.584	24.000	124.483		

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Normalized EversionNeutral Peroneus Brev	0	36.15	29.703	13
	1	41.04	26.987	13
	Total	38.59	27.916	26
Post Normalized EversionNeutral Peroneus Brev	0	48.05	30.522	13
	1	58.01	39.498	13
	Total	53.03	34.954	26
Normalized EversionNeutral Peroneus Longus	0	28.79	17.769	13
	1	24.62	11.174	13
	Total	26.71	14.697	26
Post Normalized EversionNeutral Peroneus Longus	0	39.11	19.376	13
	1	47.14	37.269	13
	Total	43.13	29.388	26

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	Eversion_Neutral_Brevis	Sphericity Assumed	**2708.950**	**1**	**2708.950**	**5.653**	**.026**
		Greenhouse-Geisser	**2708.950**	**1.000**	**2708.950**	**5.653**	**.026**
		Huynh-Feldt	**2708.950**	**1.000**	**2708.950**	**5.653**	**.026**
		Lower-bound	**2708.950**	**1.000**	**2708.950**	**5.653**	**.026**
	Eversion_Neutral_Longus	Sphericity Assumed	**3504.747**	**1**	**3504.747**	**9.025**	**.006**
		Greenhouse-Geisser	**3504.747**	**1.000**	**3504.747**	**9.025**	**.006**
		Huynh-Feldt	**3504.747**	**1.000**	**3504.747**	**9.025**	**.006**
		Lower-bound	**3504.747**	**1.000**	**3504.747**	**9.025**	**.006**
Pre_Post * Group0Control1Device	Eversion_Neutral_Brevis	Sphericity Assumed	**83.559**	**1**	**83.559**	**.174**	**.680**
		Greenhouse-Geisser	**83.559**	**1.000**	**83.559**	**.174**	**.680**
		Huynh-Feldt	**83.559**	**1.000**	**83.559**	**.174**	**.680**
		Lower-bound	**83.559**	**1.000**	**83.559**	**.174**	**.680**
	Eversion_Neutral_Longus	Sphericity Assumed	**483.453**	**1**	**483.453**	**1.245**	**.276**
		Greenhouse-Geisser	**483.453**	**1.000**	**483.453**	**1.245**	**.276**
		Huynh-Feldt	**483.453**	**1.000**	**483.453**	**1.245**	**.276**
		Lower-bound	**483.453**	**1.000**	**483.453**	**1.245**	**.276**
Error(Pre_Post)	Eversion_Neutral_Brevis	Sphericity Assumed	**11501.515**	**24**	**479.230**		
		Greenhouse-Geisser	**11501.515**	**24.000**	**479.230**		
		Huynh-Feldt	**11501.515**	**24.000**	**479.230**		
		Lower-bound	**11501.515**	**24.000**	**479.230**		
	Eversion_Neutral_Longus	Sphericity Assumed	**9319.741**	**24**	**388.323**		
		Greenhouse-Geisser	**9319.741**	**24.000**	**388.323**		
		Huynh-Feldt	**9319.741**	**24.000**	**388.323**		
		Lower-bound	**9319.741**	**24.000**	**388.323**		

Descriptive Statistics

Group (0=Control, 1=Device)	Mean	Std. Deviation	N

Normalized Eversion PlantarFlexed Peroneus Brev	0	**33.25**	**30.203**	**13**
	1	**42.20**	**21.689**	**13**
	Total	**37.72**	**26.162**	**26**
Post Normalized Eversion PlantarFlexed Peroneus Brev	0	**49.11**	**26.970**	**13**
	1	**62.02**	**40.136**	**13**
	Total	**55.57**	**34.143**	**26**
Normalized Eversion PlantarFlexed Peroneus Long	0	**33.03**	**20.932**	**13**
	1	**30.85**	**14.911**	**13**
	Total	**31.94**	**17.840**	**26**
Post Normalized Eversion PlantarFlexed Peroneus Long	0	**42.79**	**22.947**	**13**
	1	**48.92**	**33.409**	**13**
	Total	**45.86**	**28.254**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	Eversion_PF_Brevis	Sphericity Assumed	**4138.797**	**1**	**4138.797**	**7.588**	**.011**
		Greenhouse-Geisser	**4138.797**	**1.000**	**4138.797**	**7.588**	**.011**
		Huynh-Feldt	**4138.797**	**1.000**	**4138.797**	**7.588**	**.011**
		Lower-bound	**4138.797**	**1.000**	**4138.797**	**7.588**	**.011**
	Eversion_PF_Longus	Sphericity Assumed	**2516.872**	**1**	**2516.872**	**7.322**	**.012**
		Greenhouse-Geisser	**2516.872**	**1.000**	**2516.872**	**7.322**	**.012**
		Huynh-Feldt	**2516.872**	**1.000**	**2516.872**	**7.322**	**.012**
		Lower-bound	**2516.872**	**1.000**	**2516.872**	**7.322**	**.012**
Pre_Post * Group0Control1Device	Eversion_PF_Brevis	Sphericity Assumed	**51.121**	**1**	**51.121**	**.094**	**.762**
		Greenhouse-Geisser	**51.121**	**1.000**	**51.121**	**.094**	**.762**
		Huynh-Feldt	**51.121**	**1.000**	**51.121**	**.094**	**.762**
		Lower-bound	**51.121**	**1.000**	**51.121**	**.094**	**.762**
	Eversion_PF_Longus	Sphericity Assumed	**224.406**	**1**	**224.406**	**.653**	**.427**
		Greenhouse-Geisser	**224.406**	**1.000**	**224.406**	**.653**	**.427**
		Huynh-Feldt	**224.406**	**1.000**	**224.406**	**.653**	**.427**
		Lower-bound	**224.406**	**1.000**	**224.406**	**.653**	**.427**
Error(Pre_Post)	Eversion_PF_Brevis	Sphericity Assumed	**13090.812**	**24**	**545.451**		
		Greenhouse-Geisser	**13090.812**	**24.000**	**545.451**		
		Huynh-Feldt	**13090.812**	**24.000**	**545.451**		

		Lower-bound	13090.812	24.000	545.451
	Eversion_PF_Longus	Sphericity Assumed	8249.603	24	343.733
		Greenhouse-Geisser	8249.603	24.000	343.733
		Huynh-Feldt	8249.603	24.000	343.733
		Lower-bound	8249.603	24.000	343.733

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
NormalizedPlantFlex Medial Gastroc	0	18.48	13.350	13
	1	25.70	10.436	13
	Total	22.09	12.304	26
Post Normalized PlantFlex Medial Gastroc	0	19.95	11.743	13
	1	27.41	10.973	13
	Total	23.68	11.767	26

Tests of Within-Subjects Effects

Measure: PlantarFlexion_Gastroc

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter	Observed Power[a]
Pre_Post	Sphericity Assumed	32.983	1	32.983	.417	.525	.417	.095
	Greenhouse-Geisser	32.983	1.000	32.983	.417	.525	.417	.095
	Huynh-Feldt	32.983	1.000	32.983	.417	.525	.417	.095
	Lower-bound	32.983	1.000	32.983	.417	.525	.417	.095
Pre_Post * Group0Control1Device	Sphericity Assumed	.188	1	.188	.002	.962	.002	.050
	Greenhouse-Geisser	.188	1.000	.188	.002	.962	.002	.050
	Huynh-Feldt	.188	1.000	.188	.002	.962	.002	.050
	Lower-bound	.188	1.000	.188	.002	.962	.002	.050
Error(Pre_Post)	Sphericity Assumed	1899.173	24	79.132				
	Greenhouse-Geisser	1899.173	24.000	79.132				
	Huynh-Feldt	1899.173	24.000	79.132				
	Lower-bound	1899.173	24.000	79.132				

Table D7. Summary of results for sEMG amplitudes during static and dynamic balance

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Normalized Peroneus Brevis Eyes Closed Pre	0	**19.62**	**13.060**	**12**
	1	**20.37**	**10.320**	**13**
	Total	**20.01**	**11.471**	**25**
Normalized Peroneus Brevis Eyes Closed Post	0	**27.69**	**18.843**	**12**
	1	**17.86**	**9.600**	**13**
	Total	**22.58**	**15.295**	**25**
Normalized Peroneus Brevis Eyes Open Pre	0	**8.22**	**6.453**	**12**
	1	**7.99**	**5.156**	**13**
	Total	**8.10**	**5.691**	**25**
Normalized Peroneus Brevis Eyes Open Post	0	**13.55**	**13.640**	**12**
	1	**9.74**	**4.635**	**13**
	Total	**11.57**	**9.990**	**25**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	EyesClosed_Brevis	Sphericity Assumed	**96.053**	**1**	**96.053**	**.669**	**.422**	**.669**
		Greenhouse-Geisser	**96.053**	**1.000**	**96.053**	**.669**	**.422**	**.669**
		Huynh-Feldt	**96.053**	**1.000**	**96.053**	**.669**	**.422**	**.669**
		Lower-bound	**96.053**	**1.000**	**96.053**	**.669**	**.422**	**.669**
	EyesOpen_Brevis	Sphericity Assumed	**156.777**	**1**	**156.777**	**2.067**	**.164**	**2.067**
		Greenhouse-Geisser	**156.777**	**1.000**	**156.777**	**2.067**	**.164**	**2.067**
		Huynh-Feldt	**156.777**	**1.000**	**156.777**	**2.067**	**.164**	**2.067**
		Lower-bound	**156.777**	**1.000**	**156.777**	**2.067**	**.164**	**2.067**
Pre_Post * Group0Control1Device	EyesClosed_Brevis	Sphericity Assumed	**349.097**	**1**	**349.097**	**2.431**	**.133**	**2.431**
		Greenhouse-Geisser	**349.097**	**1.000**	**349.097**	**2.431**	**.133**	**2.431**
		Huynh-Feldt	**349.097**	**1.000**	**349.097**	**2.431**	**.133**	**2.431**
		Lower-bound	**349.097**	**1.000**	**349.097**	**2.431**	**.133**	**2.431**
	EyesOpen_Brevis	Sphericity Assumed	**39.962**	**1**	**39.962**	**.527**	**.475**	**.527**

		Greenhouse-Geisser	**39.962**	**1.000**	**39.962**	**.527**	**.475**	**.527**
		Huynh-Feldt	**39.962**	**1.000**	**39.962**	**.527**	**.475**	**.527**
		Lower-bound	**39.962**	**1.000**	**39.962**	**.527**	**.475**	**.527**
Error(Pre_Post)	EyesClosed_Brevis	Sphericity Assumed	**3303.358**	**23**	**143.624**			
		Greenhouse-Geisser	**3303.358**	**23.000**	**143.624**			
		Huynh-Feldt	**3303.358**	**23.000**	**143.624**			
		Lower-bound	**3303.358**	**23.000**	**143.624**			
	EyesOpen_Brevis	Sphericity Assumed	**1744.439**	**23**	**75.845**			
		Greenhouse-Geisser	**1744.439**	**23.000**	**75.845**			
		Huynh-Feldt	**1744.439**	**23.000**	**75.845**			
		Lower-bound	**1744.439**	**23.000**	**75.845**			

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Normalized Peroneus Longus Eyes Closed Pre	0	**24.35**	**11.983**	**12**
	1	**17.53**	**7.405**	**13**
	Total	**20.81**	**10.262**	**25**
Normalized Peroneus Longus Eyes Closed Post	0	**25.04**	**13.369**	**12**
	1	**19.44**	**11.622**	**13**
	Total	**22.13**	**12.554**	**25**
Normalized Peroneus Longus Eyes Open Pre	0	**11.84**	**4.202**	**12**
	1	**10.84**	**4.275**	**13**
	Total	**11.32**	**4.182**	**25**
Normalized Peroneus Longus Eyes Open Post	0	**12.06**	**7.419**	**12**
	1	**14.46**	**12.528**	**13**
	Total	**13.31**	**10.257**	**25**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	EyesClosed_Longus	Sphericity Assumed	**21.017**	**1**	**21.017**	**.261**	**.614**	**.261**
		Greenhouse-Geisser	**21.017**	**1.000**	**21.017**	**.261**	**.614**	**.261**

		Huynh-Feldt	21.017	1.000	21.017	.261	.614	.261
		Lower-bound	21.017	1.000	21.017	.261	.614	.261
	EyesOpen_Longus	Sphericity Assumed	45.808	1	45.808	1.113	.302	1.113
		Greenhouse-Geisser	45.808	1.000	45.808	1.113	.302	1.113
		Huynh-Feldt	45.808	1.000	45.808	1.113	.302	1.113
		Lower-bound	45.808	1.000	45.808	1.113	.302	1.113
Pre_Post * Group0Control1Device	EyesClosed_Longus	Sphericity Assumed	4.588	1	4.588	.057	.814	.057
		Greenhouse-Geisser	4.588	1.000	4.588	.057	.814	.057
		Huynh-Feldt	4.588	1.000	4.588	.057	.814	.057
		Lower-bound	4.588	1.000	4.588	.057	.814	.057
	EyesOpen_Longus	Sphericity Assumed	36.074	1	36.074	.876	.359	.876
		Greenhouse-Geisser	36.074	1.000	36.074	.876	.359	.876
		Huynh-Feldt	36.074	1.000	36.074	.876	.359	.876
		Lower-bound	36.074	1.000	36.074	.876	.359	.876
Error(Pre_Post)	EyesClosed_Longus	Sphericity Assumed	1853.218	23	80.575			
		Greenhouse-Geisser	1853.218	23.000	80.575			
		Huynh-Feldt	1853.218	23.000	80.575			
		Lower-bound	1853.218	23.000	80.575			
	EyesOpen_Longus	Sphericity Assumed	947.041	23	41.176			
		Greenhouse-Geisser	947.041	23.000	41.176			
		Huynh-Feldt	947.041	23.000	41.176			
		Lower-bound	947.041	23.000	41.176			

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Normalized Anterior Tibialis Eyes Closed Pre	0	15.16	8.654	12
	1	22.57	11.603	13
	Total	19.01	10.765	25
Normalized Anterior Tibialis Eyes Closed Post	0	19.93	9.963	12
	1	19.41	8.048	13
	Total	19.66	8.829	25
Normalized Anterior Tibialis Eyes Open Pre	0	9.83	7.178	12
	1	11.79	8.356	13
	Total	10.85	7.715	25

Normalized Anterior Tibialis Eyes Open Post	0	**8.83**	**6.513**	**12**
	1	**8.86**	**5.810**	**13**
	Total	**8.85**	**6.026**	**25**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.
Pre_Post	EyesClosed_AnteriorTib	Sphericity Assumed	**8.113**	**1**	**8.113**	**.133**	**.719**
		Greenhouse-Geisser	**8.113**	**1.000**	**8.113**	**.133**	**.719**
		Huynh-Feldt	**8.113**	**1.000**	**8.113**	**.133**	**.719**
		Lower-bound	**8.113**	**1.000**	**8.113**	**.133**	**.719**
	EyesOpen_AnteriorTib	Sphericity Assumed	**47.924**	**1**	**47.924**	**2.080**	**.163**
		Greenhouse-Geisser	**47.924**	**1.000**	**47.924**	**2.080**	**.163**
		Huynh-Feldt	**47.924**	**1.000**	**47.924**	**2.080**	**.163**
		Lower-bound	**47.924**	**1.000**	**47.924**	**2.080**	**.163**
Pre_Post * Group0Control1Device	EyesClosed_AnteriorTib	Sphericity Assumed	**195.813**	**1**	**195.813**	**3.211**	**.086**
		Greenhouse-Geisser	**195.813**	**1.000**	**195.813**	**3.211**	**.086**
		Huynh-Feldt	**195.813**	**1.000**	**195.813**	**3.211**	**.086**
		Lower-bound	**195.813**	**1.000**	**195.813**	**3.211**	**.086**
	EyesOpen_AnteriorTib	Sphericity Assumed	**11.625**	**1**	**11.625**	**.504**	**.485**
		Greenhouse-Geisser	**11.625**	**1.000**	**11.625**	**.504**	**.485**
		Huynh-Feldt	**11.625**	**1.000**	**11.625**	**.504**	**.485**
		Lower-bound	**11.625**	**1.000**	**11.625**	**.504**	**.485**
Error(Pre_Post)	EyesClosed_AnteriorTib	Sphericity Assumed	**1402.669**	**23**	**60.986**		
		Greenhouse-Geisser	**1402.669**	**23.000**	**60.986**		
		Huynh-Feldt	**1402.669**	**23.000**	**60.986**		
		Lower-bound	**1402.669**	**23.000**	**60.986**		
	EyesOpen_AnteriorTib	Sphericity Assumed	**529.985**	**23**	**23.043**		
		Greenhouse-Geisser	**529.985**	**23.000**	**23.043**		
		Huynh-Feldt	**529.985**	**23.000**	**23.043**		
		Lower-bound	**529.985**	**23.000**	**23.043**		

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Normalized Medial Gastroc Eyes Closed Pre	0	**14.49**	**9.329**	**12**
	1	**23.35**	**12.068**	**13**
	Total	**19.10**	**11.537**	**25**
Normalized Medial Gastroc Eyes Closed Post	0	**9.18**	**3.904**	**12**
	1	**20.14**	**16.607**	**13**
	Total	**14.88**	**13.272**	**25**
Normalized Medial Gastroc Eyes Open Pre	0	**10.08**	**7.334**	**12**
	1	**17.45**	**8.681**	**13**
	Total	**13.91**	**8.744**	**25**
Normalized Medial Gastroc Eyes Open Post	0	**7.47**	**3.369**	**12**
	1	**16.32**	**12.366**	**13**
	Total	**12.07**	**10.101**	**25**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	EyesClosed_Gastroc	Sphericity Assumed	**226.444**	**1**	**226.444**	**2.285**	**.144**	**2.285**
		Greenhouse-Geisser	**226.444**	**1.000**	**226.444**	**2.285**	**.144**	**2.285**
		Huynh-Feldt	**226.444**	**1.000**	**226.444**	**2.285**	**.144**	**2.285**
		Lower-bound	**226.444**	**1.000**	**226.444**	**2.285**	**.144**	**2.285**
	EyesOpen_Gastroc	Sphericity Assumed	**43.524**	**1**	**43.524**	**.866**	**.362**	**.866**
		Greenhouse-Geisser	**43.524**	**1.000**	**43.524**	**.866**	**.362**	**.866**
		Huynh-Feldt	**43.524**	**1.000**	**43.524**	**.866**	**.362**	**.866**
		Lower-bound	**43.524**	**1.000**	**43.524**	**.866**	**.362**	**.866**
Pre_Post * Group0Control1Device	EyesClosed_Gastroc	Sphericity Assumed	**13.896**	**1**	**13.896**	**.140**	**.711**	**.140**
		Greenhouse-Geisser	**13.896**	**1.000**	**13.896**	**.140**	**.711**	**.140**
		Huynh-Feldt	**13.896**	**1.000**	**13.896**	**.140**	**.711**	**.140**
		Lower-bound	**13.896**	**1.000**	**13.896**	**.140**	**.711**	**.140**
	EyesOpen_Gastroc	Sphericity Assumed	**6.806**	**1**	**6.806**	**.135**	**.716**	**.135**
		Greenhouse-Geisser	**6.806**	**1.000**	**6.806**	**.135**	**.716**	**.135**
		Huynh-Feldt	**6.806**	**1.000**	**6.806**	**.135**	**.716**	**.135**
		Lower-bound	**6.806**	**1.000**	**6.806**	**.135**	**.716**	**.135**
Error(Pre_Post)	EyesClosed_Gastroc	Sphericity Assumed	**2279.356**	**23**	**99.102**			

		Greenhouse-Geisser	**2279.356**	**23.000**	**99.102**
		Huynh-Feldt	**2279.356**	**23.000**	**99.102**
		Lower-bound	**2279.356**	**23.000**	**99.102**
	EyesOpen_Gastroc	Sphericity Assumed	**1156.035**	**23**	**50.262**
		Greenhouse-Geisser	**1156.035**	**23.000**	**50.262**
		Huynh-Feldt	**1156.035**	**23.000**	**50.262**
		Lower-bound	**1156.035**	**23.000**	**50.262**

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Pre_SEBT_AnteriorTib_EMG_Composite	0	**5.349**	**3.1416**	**13**
	1	**7.843**	**3.7097**	**13**
	Total	**6.596**	**3.6001**	**26**
Post_SEBT_AnteriorTib_EMG_Composite	0	**6.634**	**4.0455**	**13**
	1	**7.620**	**4.2783**	**13**
	Total	**7.127**	**4.1102**	**26**
Pre_SEBT_Brevis_EMG_Composite	0	**2.949**	**2.4908**	**13**
	1	**5.527**	**11.4577**	**13**
	Total	**4.238**	**8.2292**	**26**
Post_SEBT_Brevis_EMG_Composite	0	**6.150**	**6.1679**	**13**
	1	**4.225**	**6.1312**	**13**
	Total	**5.188**	**6.1047**	**26**

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	Anterior_Tibialis	Sphericity Assumed	**3.665**	**1**	**3.665**	**.913**	**.349**	**.913**
		Greenhouse-Geisser	**3.665**	**1.000**	**3.665**	**.913**	**.349**	**.913**
		Huynh-Feldt	**3.665**	**1.000**	**3.665**	**.913**	**.349**	**.913**
		Lower-bound	**3.665**	**1.000**	**3.665**	**.913**	**.349**	**.913**
	Peroneus_Brevis	Sphericity Assumed	**11.715**	**1**	**11.715**	**.660**	**.425**	**.660**

		Greenhouse-Geisser	11.715	1.000	11.715	.660	.425	.660
		Huynh-Feldt	11.715	1.000	11.715	.660	.425	.660
		Lower-bound	11.715	1.000	11.715	.660	.425	.660
Pre_Post * Group0Control1Device	Anterior_Tibialis	Sphericity Assumed	7.399	1	7.399	1.843	.187	1.843
		Greenhouse-Geisser	7.399	1.000	7.399	1.843	.187	1.843
		Huynh-Feldt	7.399	1.000	7.399	1.843	.187	1.843
		Lower-bound	7.399	1.000	7.399	1.843	.187	1.843
	Peroneus_Brevis	Sphericity Assumed	65.881	1	65.881	3.709	.066	3.709
		Greenhouse-Geisser	65.881	1.000	65.881	3.709	.066	3.709
		Huynh-Feldt	65.881	1.000	65.881	3.709	.066	3.709
		Lower-bound	65.881	1.000	65.881	3.709	.066	3.709
Error(Pre_Post)	Anterior_Tibialis	Sphericity Assumed	96.341	24	4.014			
		Greenhouse-Geisser	96.341	24.000	4.014			
		Huynh-Feldt	96.341	24.000	4.014			
		Lower-bound	96.341	24.000	4.014			
	Peroneus_Brevis	Sphericity Assumed	426.298	24	17.762			
		Greenhouse-Geisser	426.298	24.000	17.762			
		Huynh-Feldt	426.298	24.000	17.762			
		Lower-bound	426.298	24.000	17.762			

Descriptive Statistics

	Group (0=Control, 1=Device)	Mean	Std. Deviation	N
Pre_SEBT_Longus_EMG_Composite	0	3.846	3.1782	13
	1	4.884	7.1361	13
	Total	4.365	5.4380	26
Post_SEBT_Longus_EMG_Composite	0	6.724	10.4034	13
	1	3.779	5.2126	13
	Total	5.252	8.2004	26
Pre_SEBT_Gastroc_EMG_Composite	0	1.279	1.0009	13
	1	5.360	10.0376	13
	Total	3.319	7.2919	26
Post_SEBT_Gastroc_EMG_Composite	0	1.775	2.1286	13
	1	2.562	3.7462	13

	Total	**2.169**	**3.0120**	**26**	

Univariate Tests

Source	Measure		Type III Sum of Squares	df	Mean Square	F	Sig.	Noncent. Parameter
Pre_Post	Peroneus_Longus	Sphericity Assumed	**10.220**	**1**	**10.220**	**.363**	**.552**	**.363**
		Greenhouse-Geisser	**10.220**	**1.000**	**10.220**	**.363**	**.552**	**.363**
		Huynh-Feldt	**10.220**	**1.000**	**10.220**	**.363**	**.552**	**.363**
		Lower-bound	**10.220**	**1.000**	**10.220**	**.363**	**.552**	**.363**
	Medial_Gastroc	Sphericity Assumed	**17.215**	**1**	**17.215**	**.585**	**.452**	**.585**
		Greenhouse-Geisser	**17.215**	**1.000**	**17.215**	**.585**	**.452**	**.585**
		Huynh-Feldt	**17.215**	**1.000**	**17.215**	**.585**	**.452**	**.585**
		Lower-bound	**17.215**	**1.000**	**17.215**	**.585**	**.452**	**.585**
Pre_Post * Group0Control1Device	Peroneus_Longus	Sphericity Assumed	**51.564**	**1**	**51.564**	**1.832**	**.189**	**1.832**
		Greenhouse-Geisser	**51.564**	**1.000**	**51.564**	**1.832**	**.189**	**1.832**
		Huynh-Feldt	**51.564**	**1.000**	**51.564**	**1.832**	**.189**	**1.832**
		Lower-bound	**51.564**	**1.000**	**51.564**	**1.832**	**.189**	**1.832**
	Medial_Gastroc	Sphericity Assumed	**35.263**	**1**	**35.263**	**1.198**	**.285**	**1.198**
		Greenhouse-Geisser	**35.263**	**1.000**	**35.263**	**1.198**	**.285**	**1.198**
		Huynh-Feldt	**35.263**	**1.000**	**35.263**	**1.198**	**.285**	**1.198**
		Lower-bound	**35.263**	**1.000**	**35.263**	**1.198**	**.285**	**1.198**
Error(Pre_Post)	Peroneus_Longus	Sphericity Assumed	**675.632**	**24**	**28.151**			
		Greenhouse-Geisser	**675.632**	**24.000**	**28.151**			
		Huynh-Feldt	**675.632**	**24.000**	**28.151**			
		Lower-bound	**675.632**	**24.000**	**28.151**			
	Medial_Gastroc	Sphericity Assumed	**706.369**	**24**	**29.432**			
		Greenhouse-Geisser	**706.369**	**24.000**	**29.432**			
		Huynh-Feldt	**706.369**	**24.000**	**29.432**			
		Lower-bound	**706.369**	**24.000**	**29.432**			

APPENDIX E

Recommendations for Future Research

- Studies that include long-term follow-up measures of self-reported function, recurrent injury, ROM, strength, balance and gait after a progressive rehabilitation program

- Evaluating the long-term effects of incorporating the new rehabilitation paradigm for CAI in patients with acute lateral ankle sprains

- Developing clinical measures to assess for abnormal gait patterns in patients with CAI

- Assessing the effectiveness of incorporating an auditory biofeedback device in a progressive rehabilitation program for patients with CAI on gait patterns

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