Visual Biofeedback and Impairment-Based Rehabilitation for Chronic Ankle Instability

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A Dissertation

Presented to

The Faculty of the Curry School of Education and Human Development

University of Virginia

In Partial Fulfillment

of the Requirement for the Degree

Doctor of Philosophy

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by

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May 2019

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APPROVAL OF THE DISSERTAION

This thesis, "Visual Biofeedback and Impairment-Based Rehabilitation for Chronic Ankle Instability", has been approved by the Graduate Faculty of the Curry School of Education and Human Development in partial fulfillment of the requirements for the degree of Master of Education.

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ACKNOWLEDGEMENTS

First and foremost, I would like to thank my advisor, Jay Hertel, PhD, ATC for his endless support and mentorship during my time as a graduate student at the University of Virginia. Your dedication and influence in the field of athletic training is inspiring. It has truly been an honor to be one of your students. To the remainder of my dissertation committee Sue, Joe, and Dr. Abel, thank you for all the time you've invested in me and for the constructive feedback that you provided for my dissertation. I greatly appreciate your support and assistance throughout the duration of this project. You have all been great mentors in many aspects.

Abbis Jaffri and Alex DeJong, I cannot thank you enough for all of the time and effort put into the assessments and rehabilitation sessions. This project would not have been successful without your help. I would also like to thank Andrea Baellow for her assistance with rehabilitation sessions, Madison Howell for her assistance with data collection and data entry, and Marshall Tumperi and Emily Dooley for their assistance with teaching me how to use Matlab for data processing and statistical analysis.

To my colleagues and friends within the Exercise and Sports Injury Lab, thank you for your support and feedback during presentations. I also appreciate your assistance throughout the development of this project.

I would like to thank the Curry School of Education and Human Development, the Mid-Atlantic Athletic Trainers' Association, and the National Athletic Trainers' Association Research and Education Foundation for funding this study and supporting my research.

Lastly, and most importantly, I would like to thank my wonderful husband, Zach Rolfe, and my family for supporting me unconditionally throughout this chapter of my life. Zach, I cannot wait to start our new adventure together in Texas. You've been my rock and support system for these last 4 years. Mom and Doug, I will never forget the many sacrifices you have made to allow me to pursue my dreams. I love you all and couldn't be more thankful.

ABSTRACT

Background: Lateral ankle sprains (LAS) are a common injury. Many individuals do not seek care after injury and may develop chronic ankle instability (CAI). Individuals with CAI have decreased dorsiflexion range of motion (ROM), ankle eversion strength, and postural control. In addition, those with CAI have been shown to have a more inverted foot position during walking gait compared to healthy controls. Copers are individuals who have had an ankle sprain but learn to cope and return to pre-injury levels of function and may be a better comparison group than healthy controls because they have had the same initial injury. Previously, impairment-based rehabilitation has shown to improve strength, balance, and range of motion (ROM) in individuals with CAI, however, ankle inversion during walking gait remained unchanged. Gait training focused on decreasing ankle inversion may be an appropriate technique to address the altered gait mechanics in those with CAI with hopes to reduce the risk of recurrent ankle sprains.

Purpose: The purpose of Manuscript 1 (M1) was to simultaneously analyze lower extremity walking gait kinematics, kinetics, and surface electromyography (sEMG) between individuals with CAI and copers at a preferred walking speed (PWS), 120% preferred walking speed (120WS), and standardized walking speed (SWS) of 1.34 m/s. The primary purpose for Manuscript 2 (M2) was to analyze the effects of 4-weeks of visual gait biofeedback and impairment-based rehabilitation on gait biomechanics and patient-reported outcomes (PRO) in individuals with CAI. Clinical outcome measures of strength, balance, and ROM were assessed for the biofeedback and no biofeedback groups in Manuscript 3 (M3).

Methods: M1) A case-control study of 36 physically active individuals (Copers: n=18, CAI: n=18) was performed to assess group differences for kinematics in sagittal, frontal, and transverse planes of the ankle, knee, and hip during walking at 3 walking speeds. **M2 & M3)** We performed a single-blinded randomized controlled trial to analyze the effects of 4-weeks of impairment-based rehabilitation and visual gait biofeedback compared to a no biofeedback. **M2)** Lower extremity walking gait biomechanics and PROs were assessed at baseline and follow-up time points. **M3)** Range of Motion (ROM), balance, and strength were assessed at baseline and follow-up time points.

Results: M1) The CAI group had more ankle inversion at IC (PWS: CAI=3.3±3.4º, Coper=-1.1±4.6º; 120WS: CAI=3.6±3.7º, Coper =-1.4±4.1º; SWS: CAI=4.4±4.6, Coper=-2.2±5.0º) and throughout swing at all three walking speeds (Peak inversion: PWS: CAI=5.6±5.1º, Coper=0.4±4.3º; 120WS: CAI=5.6±5.4º, Coper=1.2±4.2º; SWS: CAI=6.8±5.9º, Coper=0.6±4.2º). CAI had greater peak hip adduction during swing (PWS: CAI=-5.1±5.7º, Coper=-0.6±3.4º; 120WS: CAI = -5.1±4.5º, Coper=-1.0±3.3º; SWS: CAI=-5.2±4.2º, Coper=-1.6±3.1º). **M2)** The biofeedback group significantly decreased ankle inversion at IC (pre:4.2±4.6º, post:-3.1±4.1º, *g*=1.6) and throughout the entire stride cycle (peak inversion: pre:6.7±5.0º, post:0.8±4.3º, *g*=1.2). The no biofeedback group did not have any significant changes in gait biomechanics. The groups were significantly different after rehabilitation while accounting for baseline measures for FAAM-ADL (biofeedback:97.1±2.3%, no biofeedback:92.0±5.7%), TSK (biofeedback:29.7±3.7, no biofeedback:34.9±5.8), and GROC (biofeedback:5.5±1.0, no biofeedback:3.9±2.0) with the biofeedback group showing greater improvements than the no biofeedback group. **M3)** The biofeedback group significantly increased in

plantarflexion ROM (pre: 74.1 ±6.9º, post: 82.2±7.4º) compared to the no biofeedback group (pre: 72.3±7.8º, post: 72.3±10.0º). Greater strength improvements (N/kg) were found in the biofeedback group for ankle inversion (biofeedback: pre: 2.3±0.6, post: 3.4±0.7; no biofeedback: pre: 2.6±0.4, post 3.1±0.5), 1st toe flexion (biofeedback: pre: 1.1±0.3, post: 2.1±0.3; no biofeedback: pre: 1.2±0.3, post 1.8±0.4), and hip abduction (biofeedback: pre: 1.9±0.5, post: 2.7±0.5; no biofeedback: 2.3±0.5, 2.5±0.5) compared to the no biofeedback group. There were no significant differences between the groups for balance measures.

Conclusion: Ankle inversion in the CAI group got larger and lasted for more of the gait cycle as the speed increased which may put them at greater risk for recurrent sprains. The coper group used a strategy that resulted in a more everted foot position and abducted hip position which may reduce the risk of injury. Gait training for CAI individuals should be modeled after copers' gait mechanics. In our second study, the biofeedback group successfully decreased ankle inversion angle and had greater improvements in PRO's after the intervention. The biofeedback group adopted a kinematic pattern at the ankle that more closely represented that of the copers in our first study. Impairment-based rehabilitation without biofeedback improved PRO's but did not impact gait biomechanics. Additionally, impairment-based rehabilitation in combination with visual biofeedback resulted in greater improvements in strength and ROM compared to the no biofeedback group. This combination of visual biofeedback and impairment-based rehabilitation is recommended for individuals with CAI.

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SECTION II: MANUSCRIPT I

Gait Kinematics & Kinetics at Three Walking Speeds in Individuals with Chronic Ankle Instability and Ankle Sprain Copers

ABSTRACT

Context: Individuals with CAI have demonstrated a more inverted foot position during walking when compared to a healthy control group. Copers are individuals who have had an ankle sprain but learn to cope and return to pre-injury levels of function and may be a better comparison group than healthy controls because they have had the same initial injury.
Objective: To simultaneously analyze lower extremity walking gait kinematics, kinetics, and surface electromyography (sEMG) between individuals with CAI and copers at a preferred walking speed (PWS), 120% preferred walking speed (120WS), and standardized walking speed (SWS) of 1.34 m/s.
Design: Case-control
Patients or Other Participants: Thirty-six (18 coper, 18 CAI) physically active individuals participated.
Main Outcome Measures: Three-dimensional kinematics and kinetics at the ankle, knee, and hip and sEMG amplitude for fibularis longus, tibialis anterior, medial gastrocnemius, and gluteus medius muscles were analyzed. Ten consecutive strides from each speed were analyzed using statistical parametric mapping (SPM). A 2x3 group by speed ANOVA and post-hoc t-tests were used to compare differences between the coper and CAI groups.
Results: The CAI group had more ankle inversion at IC (PWS: CAI=3.3$\pm$3.4º, Coper=-1.1$\pm$4.6º; 120WS: CAI=3.6$\pm$3.7º, Coper =-1.4$\pm$4.1º; SWS: CAI=4.4$\pm$4.6, Coper=-2.2$\pm$5.0º) and throughout swing at all three walking speeds (Peak inversion: PWS: CAI=5.6$\pm$5.1º, Coper=0.4$\pm$4.3º; 120WS: CAI=5.6$\pm$5.4º, Coper=1.2$\pm$4.2º; SWS: CAI=6.8$\pm$5.9º, Coper=0.6$\pm$4.2º). CAI had greater peak hip adduction during swing (PWS: CAI=-5.1$\pm$5.7º, Coper=-0.6$\pm$3.4º; 120WS: CAI = -5.1$\pm$4.5º, Coper=-1.0$\pm$3.3º; SWS: CAI=-5.2$\pm$4.2º, Coper=-1.6$\pm$3.1º).
Conclusion: Ankle inversion in the CAI group got larger and lasted for more of the gait cycle as the speed increased which may put them at greater risk for recurrent sprains. The coper group used a strategy that resulted in a more everted foot position and abducted hip position which may reduce the risk of injury. Gait training for CAI individuals should be modeled after copers' gait mechanics.

Word Count: 300

Introduction

Lateral ankle sprains are common musculoskeletal injuries among physically active individuals[1–3] and the prevalence of recurrent sprain rates are estimated to be 70%.[4] While lateral ankle sprains are prevalent and recurrence rates are high, unfortunately, many individuals consider lateral ankle sprains to be an insignificant injury. Less than half of individuals with an ankle sprain seek care from a medical professional following their initial injury.[5] This is problematic because 40% of these individuals develop chronic ankle instability (CAI)[6] which is associated with feelings of "giving way," decreased function, and persistent symptoms.[7] Lack of appropriate treatment could contribute to the altered neuromuscular function, poor postural control, and altered gait patterns seen in individuals with a history of CAI.[8,9] In addition, CAI is associated with several long-term consequences such as decreased physical activity across the lifespan,[10] decreased quality of life,[11] and an earlier onset of ankle osteoarthritis.[12]

Individuals with CAI have previously demonstrated an inverted foot position at initial contact (IC) and toe-off, more lateral plantar pressures, and altered muscle activation patterns during walking compared to uninjured healthy controls.[8,13–15] The compromised foot position during the swing phase and lateral plantar pressure during the loading phase of gait may be a contributing factor to the high recurrence rate for reinjury. These adaptations may be an appropriate area for clinicians to target when treating someone with CAI, however, much of the literature in this area to date compared individuals with CAI to an uninjured control group. While it is important to understand

how individuals with CAI compare to an uninjured control, it has been suggested that comparing to a group with the same initial injury that has learned to successfully cope may be more appropriate approach when considering potential treatment techniques.[16] Copers are individuals who have had a lateral ankle sprain but have learned to cope with the injury and return to pre-injury levels of function.[16] Guidelines for inclusion criteria for copers have recently been established.[16]

Only one study to date has identified differences in gait biomechanics between individuals with CAI and ankle sprain copers.[17] Other studies have been conducted to compare individuals with ankle instability and copers during gait, however, their inclusion criteria did not follow the recently published guidelines and should be interpreted with caution.[18,19] Doherty et al.[17] compared gait biomechanics at IC and toe off between copers and CAI during barefoot walking. They found that individuals with CAI were more inverted during the toe off phase than the copers but not at initial contact.[17] Changes up the kinetic chain were also identified where individuals with CAI had decreased hip extension and increased knee flexion at toe off and increased hip flexion at IC.[17] The kinetic profiles were similar between the two groups with the exception of the CAI group demonstrating a decreased knee flexion moment at toe off.[17]

While that study was the first comparing copers and CAI gait biomechanics, it may be advantageous to analyze the entire stride cycle as well as muscle activation via surface electromyography (sEMG) during gait between these groups. Additionally, participants walked at a self-selected speed which may differ from person to person and thus impact the spatiotemporal aspects of the gait measures. Using a standardized speed is one way to control for that potential problem. Therefore, the purpose of this study was

to simultaneously collect gait kinematics, kinetics, and sEMG during treadmill walking at three speeds (preferred walking speed (PWS), 120% of PWS (120WS), and a standardized walking speed (SWS)) between individuals with CAI and copers. We hypothesized that the CAI group would have a more inverted foot position during walking gait than the coper group. Our secondary hypothesis was that group differences would become larger as walking speed increased and became more challenging.

Methods

Study Design

We performed a descriptive laboratory study using a case-control design to evaluate differences in walking gait biomechanics between copers and CAI groups. Our independent variables were group (CAI, coper) and walking speed (PWS, 120WS, SWS). We used 3-dimentional motion capture to simultaneously measure lower extremity kinematics, kinetics, and surface electromyography (EMG) amplitude during the entire stride cycle.

Participants

Thirty-six (18 coper, 18 CAI) individuals volunteered for this study. All participants were physically active for at least 1.5 hours per week. Inclusion criteria for the coper group followed recommended guidelines.[16] Briefly, copers had a history of at least 1 significant lateral ankle sprain at least 12 months prior to study participation and did not have self-reported dysfunction (Foot and Ankle Ability Measure - Sport $\geq$97%) or feelings of instability. Instability was assessed using the Identification of Functional Ankle Instability (IdFAI).[20,21] Copers were included if IdFAI scores were < 10 OR they

a) answered “no” to the question “Do you frequently roll your ankle or feel like it gives way?” AND b) answered “never” or “once a year” for the following questions: 1) “During activities of daily life how often does your ankle feel unstable?” 2) “During sport or recreational activity how often does your ankle feel unstable?” Inclusion criteria for the CAI group followed recommendations of the International Ankle Consortium.[7] Individuals with CAI had a history of at least 1 significant lateral ankle sprain at least 12 months prior to study participation, self-reported dysfunction (Foot and Ankle Ability Measure - Sport $\leq$ 85%), and feelings of instability or “giving way” (IdFAI $\geq$11). When CAI was bilateral, the self-reported worse limb was chosen for data analysis.

Participants were excluded if they had history of lower extremity fracture or surgery, were currently seeking physical therapy, had any conditions known to affect gait (multiple sclerosis, Marfan’s syndrome, lumbosacral radiculopathy, Ehlers-Danlos syndrome, diabetes mellitus), or were pregnant. Individuals with an ankle sprain in the last 6 weeks for CAI or in the last 12 months for copers were also excluded. This study was approved by the university’s Institutional Review Board and all participants provided written informed consent prior to study enrollment.

Instrumentation

Three-dimensional kinematics were collected at 250Hz using a 12-camera Vicon motion capture system (VICON motion systems, CA, USA). Kinetic data were collected at 1000Hz using the Bertec™ Fully Instrumented Treadmill (Columbus, OH, USA) and a threshold of 20N was utilized to identify initial contact and toe off. Surface EMG was collected using Trigno wireless EMG (Delsys, Boston, MA, USA) at 2000Hz with a 10-500Hz bandpass filter and 50-sample average moving window. All gait data were

synchronized using Motion Monitor software (Innovative Sports Training, Inc., Chicago, IL, USA).

Procedures

Participants who met the inclusion criteria were enrolled in the study. Each participant was fitted with reflective markers and standard laboratory shoes (Brooks Defyance; Brooks Sports, Inc., Bothel, WA, USA). Ten rigid clusters with reflective markers were secured on the participant's upper thorax, lumbar spine, and bilaterally on the lateral thighs, lateral shanks, posterior heel, and the dorsum of each foot. Segments were digitized to identify the joint centers for the C7/T1, T12/L1, L5/S1, anterior superior iliac spine, and medial and lateral knee joint lines, and medial and lateral malleoli for each limb.

For EMG, the participant's skin was prepared by shaving, exfoliating, and cleansing using isopropyl alcohol. Rectangular electrodes (37x26x15 mm) with parallel-bar electrodes were placed over the muscle belly of the tibialis anterior (TA), fibularis longus (FL), medial gastrocnemius (MG), and gluteus medius (GMed). Correct electrode placement was confirmed using manual muscle testing for each muscle. EMG data were only collected on the involved limb and not the contralateral side. Prior to walking, a quiet standing trial was conducted for 5-seconds for normalization purposes.

Participants completed 5 minutes of walking on a split-belt treadmill at a self-selected pace prior to data collection as a warm-up. Data were collected for 60-seconds at the preferred walking speed (PWS), 120% of PWS (120WS), and a standardized walking speed (SWS) of 1.34 m/s (3.0 mph). The order in which the walking speeds were

collected were randomized using a Latin square design. Kinematics, kinetics, and surface electromyography were collected simultaneously for 30-seconds during all walking trials.

Data Processing

Ten consecutive strides from walking trials at each speed were analyzed. Data from each stride were reduced to 101 data points representing 0-100% of the gait cycle. The values from the 10 strides were averaged for each participant to evaluate three-dimensional ankle, knee, and hip kinematics and kinetics, and root mean square (RMS) EMG amplitudes of the TA, FL, MG, and GMed. EMG amplitudes were normalized to the mean of a 10 second data epoch during quiet standing for each variable. Data processing was performed using custom code in Matlab version R2018a (MathWorks, Inc., Natick, MA, USA).

Statistical Analysis

An a priori sample size estimate revealed 18 participants per group were needed to identify large effects based on a between group mean difference of 2.5º of inversion and standard deviation of 2º following toe-off during walking between coper and CAI participants.[17]

Independent t-tests were used to compare group demographic information in Statistical Package for Social Sciences (SPSS) version 24.0 (SPSS, Inc., Chicago, IL). Gait biomechanical data were analyzed using the spm1d Version 0.4 for one-dimensional statistical parametric mapping (SPM) analysis software package for Matlab.[22,23] Using SPM, 2x3 group by speed analyses of variance (SPM_{ANOVA}) and post-hoc SPM t-tests ($SPM_{t\text{-}test}$) were used to compare differences between the coper and CAI groups. The a priori level of significance was set at $p \leq 0.05$. Upon post-hoc analysis, statistical

significance was demonstrated where the 95% confidence intervals did not overlap. Cohen's *d* effect sizes were calculated to determine the magnitude of difference between the groups. The effect sizes were interpreted as large (≥0.80), moderate (0.50-0.79), small (0.20-0.49), or trivial (≤ 0.19).[24]

Results

Group demographics are detailed in Table 1. There were no significant differences for age, height, mass, or physical activity levels between the two groups. The CAI group walked at a faster PWS compared to the coper group (CAI: 1.0±0.2 m/s, Coper: 0.9±0.1 m/s; p=0.003, *d* = 0.63) and thus the 120WS was also faster (CAI: 1.2±0.2 m/s, Coper: 1.1±0.2 m/s; p=0.004, *d* = 0.50). The groups differed on ankle health status (total number of sprains, time since last sprain, FAAM-ADL, FAAM-Sport, IdFAI) as expected based on the guidelines for inclusion criteria for each of the groups.

Kinematics

Frontal plane kinematics are presented in Figure 1 for all walking speeds. A significant group by speed interaction was identified at IC and during swing for ankle frontal plane and an interaction was identified during early stance phase for hip frontal plane motion. The CAI group had more ankle inversion than the coper at IC (PWS: CAI = 3.3±3.4º, Coper = -1.1±4.6º, *d* = 1.08; 120WS: CAI = 3.6±3.7º, Coper = -1.4±4.1º, *d* = 1.28; SWS: CAI = 4.4±4.6, Coper = -2.2±5.0º, *d* = 1.37) and throughout the majority of the stride cycle at all three walking speeds (Peak inversion during swing: PWS: CAI = 5.6±5.1º, Coper = 1.4±4.3º, *d* = 0.89; 120WS: CAI = 5.6±5.4º, Coper = 1.2±4.2º, *d* = 0.91; SWS: CAI = 6.8±5.9º, Coper = 0.6±4.2º, *d* =1.21). As the walking speed increased,

the ankle inversion angle increased for the CAI group, but not the coper group. The CAI had significantly greater ankle inversion angle during 71-100% of stride cycle PWS, from 69-100% during 120WS, and from 57-100% during SWS. The groups were significantly different for a total of 34% of the gait cycle during PWS, for 61% during 120WS, and for 90% during SWS. The CAI group also demonstrated increased hip adduction during the swing phase during all three walking speeds (Peak adduction during swing: PWS: CAI = -5.1±5.7º, Coper = -0.6±3.4º, d =0.96; 120WS: CAI = -5.1±4.5º, Coper = -1.0±3.3º, d =-1.04; SWS: CAI = -5.2±4.2º, Coper = -1.6±3.1º, d =0.98). The CAI group had more hip adduction from 61-84% of stride cycle during PWS, from 62-85% during 120WS, and from 66-88% during SWS. No other group differences or interactions were identified for any other kinematic variables.

Speed main effects were identified for all variables suggesting that walking speed impacted kinematics, however, this was not a primary focus of this study. Briefly, walking speed primarily impacted the timing of the movement, but did not change the kinematic motion. Figure 2 shows the differences in ankle sagittal plane motion during the 3 speeds. The changeover from dorsiflexion to plantarflexion, which takes place during late stance when transitioning to toe-off, occurred earlier when walking at the faster speeds. Additionally, there was increased peak plantarflexion at toe-off at the faster walking speeds.

Kinetics

The CAI group demonstrated an increased internal ankle plantarflexion moment during 120WS from 42-50% of the stride cycle and during SWS from 50-60% of the stride cycle (Peak plantarflexion moment: 120WS: CAI = -1.7±0.6 Nm/kg, Coper = -

1.0±0.8 Nm/kg, *d* =0.99; SWS: CAI = -1.8±0.7 Nm/kg, Coper = -1.2±0.7 Nm/kg, *d* =0.86) compared to copers (Figure 3). The vertical ground reaction forces were not different between the two groups at any of the walking speeds. No other significant differences were found between the groups for kinetics.

EMG

No group differences were identified for EMG variables; however, the coper group trended towards higher GMed RMS amplitude compared to the CAI group during the stance phase for all walking speeds and higher FL RMS amplitude during late swing compared to the CAI group during the SWS (Figure 4).

Discussion

The primary findings of this study were the large meaningful differences in frontal plane kinematics demonstrated at the ankle and hip joints between the CAI and control groups at all three walking speeds. The CAI group was 4-6º inverted at the ankle on average at IC and during the swing phase of gait. As the speed increased, the CAI group became more inverted, with the greatest differences seen at SWS which was the fastest speed. The coper group, did not change in ankle inversion angle as the speeds increased. At the hip, the CAI group demonstrated a 4º more adducted position during the swing phase of gait compared to the copers but the magnitude of difference between groups remained relatively consistent as the speed increased.

This compromised kinematic position seen at both IC and throughout the swing phase in the CAI group could contribute to repetitive bouts of instability during simple activities of daily living. The inverted foot position throughout the stride cycle, in

addition to the hip adduction during the swing phase demonstrated by those with CAI, may also explain the more lateral plantar pressure identified by previous studies.[14,25,26] Of additional concern is the fact that as the task became more demanding with the increase in speed, the CAI group became increasingly more inverted while the coper group maintained the same ankle position during all 3 speeds. The coper group appeared to adapt a strategy that potentially allows them to avoid recurrent ankle sprains and the development of CAI by placing the foot in a safer position prior to and following IC. In addition, the copers may widen their base of support by having an abducted hip position during the swing phase prior to IC which could potentially reduce their risk for recurrent ankle injury. Modeling gait training after the copers' biomechanics may be an appropriate rehabilitation intervention for individuals with CAI.

In addition to kinematic changes, we identified an increased internal ankle plantarflexion moment in the CAI group during late stance to toe-off which occurs when the ankle transitions from a dorsiflexed position to a plantarflexed position in preparation for the swing phase. An increased plantarflexion moment may be a compensatory mechanism used by those with CAI to increase their propulsion forces and overcome a more inverted foot position prior to toe off. Our results are in contrast to those of Doherty et. al,[17] but this may be due to differences in study methods. In our study, participants walked on a split belt treadmill at a constant pace and wore standard laboratory shoes, whereas, in the other study, individuals were barefoot and walked across a walkway. Their study identified a decreased knee flexion moment prior to toe off.[17] The authors speculated that the reduced knee flexion moment was representative of a more rigid strategy to accommodate for 'push-off'[17] which may also be supported by our findings of

an increased internal plantarflexion moment in the CAI group. Both studies have identified kinetic alterations in the sagittal plane for the CAI group which verifies the need for further investigation in this area in the future.

It was surprising that there were no differences in muscle activation between the two groups since we saw differences in kinematics and kinetics between the two groups. Although not significant, the coper group appeared to use more GMed activation during the loading response and the CAI group appeared to use more FL activation during late stance. We believe statistically significant results were not obtained for these measures due to the relatively small sample size and naturally high variability when measuring EMG activity. Previous studies have demonstrated that individuals with CAI have had earlier and increased activation of the FL muscle compared to health controls,[14,27] but it is possible that copers must also adapt their walking by using increased FL activation. More work needs to be done in this area to better understand the role of muscle activation in each of these groups during walking and other functional activities.

The increases in walking speed appeared to magnify the differences between the groups for ankle inversion and hip adduction kinematics. When considering the spatiotemporal aspect, toe off occurred earlier in the stride cycle when speed increased (PWS = 64%, 120WS = 62%, SWS = 61%) and therefore increases the importance of standardizing walking speeds when measuring differences between groups during gait analyses. Standardizing the speed would also improve the reproducibility of results between studies. In addition, we recommend using a faster walking speed to provoke greater differences between the two groups. If the task is not challenging enough, it may be difficult to detect meaningful changes between two groups.

Our study has several limitations. The speed at which individuals walked may have been impacted by lack of exposure to a split belt treadmill and the research set up regardless of having a 5-minute familiarization period in which speed could be adjusted prior to data collection. The PWS for both groups was significantly slower than the SWS. Secondly, the study was originally powered to identify differences between the groups for ankle inversion kinematics and did not account for the kinetic and EMG variables. A larger sample size may be needed to identify differences for EMG. Upon calculation for a new sample size estimate using data from our study, we estimate at least 29 individuals per group would be needed to identify differences between CAI and coper groups. Additionally, data for EMG was only collected on the involved limb so we could not make comparisons between limbs.

In conclusion, individuals with CAI had alterations in frontal plane kinematics at all speeds compared to the coper group which may explain why CAI patients experience recurrent ankle sprains. The mean difference for the ankle inversion angle between the groups got larger and lasted for more of the gait cycle as the speed increased. The coper group used a strategy that resulted in a less inverted position throughout the stride cycle as well as a more abducted hip position during the swing phase. Furthermore, the copers exhibited an everted foot position at IC (1-2º eversion) while the CAI group had an inverted foot position at IC (3-4º inversion). The kinematic profile of the coper group should be used for gait retraining of individuals with CAI to potentially reduce the risk for subsequent ankle sprains.

References

1. Doherty C, Delahunt E, Caulfield B, Hertel J, Ryan J, Bleakley C. The Incidence and Prevalence of Ankle Sprain Injury: A Systematic Review and Meta-Analysis of Prospective Epidemiological Studies. *Sports Med*. 2014;44(1):123-140. doi:10.1007/s40279-013-0102-5.

2. Roos KG, Kerr ZY, Mauntel TC, Djoko A, Dompier TP, Wikstrom EA. The Epidemiology of Lateral Ligament Complex Ankle Sprains in National Collegiate Athletic Association Sports. *Am J Sports Med*. 2017;45(1):201-209. doi:10.1177/0363546516660980.

3. Waterman BR. The Epidemiology of Ankle Sprains in the United States. *J Bone Jt Surg Am*. 2010;92(13):2279. doi:10.2106/JBJS.I.01537.

4. Yeung MS, Chan KM, So CH, Yuan WY. An epidemiological survey on ankle sprain. *Br J Sports Med*. 1994;28(2):112-116.

5. McKay GD, Goldie PA, Payne WR, Oakes BW. Ankle injuries in basketball: injury rate and risk factors. *Br J Sports Med*. 2001;35(2):103-108.

6. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Recovery From a First-Time Lateral Ankle Sprain and the Predictors of Chronic Ankle Instability A Prospective Cohort Analysis. *Am J Sports Med*. 2016;44(4):995-1003.

7. Gribble PA, Delahunt E, Bleakley C, Caulfield B, Docherty C, Fourchet F, Fong DT-P, Hertel J, Hiller C, Kaminski T, McKeon P, Refshauge K, Wees P van der, Vincenzino B, Wikstrom E. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Br J Sports Med*. 2014;48(13):1014-1018.

8. Delahunt E, Monaghan K, Caulfield B. Altered Neuromuscular Control and Ankle Joint Kinematics During Walking in Subjects With Functional Instability of the Ankle Joint. *Am J Sports Med*. 2006;34(12):1970-1976.

9. Chinn L, Dicharry J, Hertel J. Ankle kinematics of individuals with chronic ankle instability while walking and jogging on a treadmill in shoes. *Phys Ther Sport*. 2013;14(4):232-239. doi:10.1016/j.ptsp.2012.10.001.

10. Hubbard-Turner T, Turner MJ. Physical Activity Levels in College Students With Chronic Ankle Instability. *J Athl Train*. April 2015. doi:10.4085/1062-6050-50.3.05.

11. Arnold BL, Wright CJ, Ross SE. Functional Ankle Instability and Health-Related Quality of Life. *J Athl Train*. 2011;46(6):634-641. doi:10.4085/1062-6050-46.6.634.

12. Golditz T, Steib S, Pfeifer K, Uder M, Gelse K, Janka R, Hennig FF, Welsch GH. Functional ankle instability as a risk factor for osteoarthritis: using T2-mapping to analyze early cartilage degeneration in the ankle joint of young athletes. *Osteoarthr Cartil OARS Osteoarthr Res Soc*. 2014;22(10):1377-1385. doi:10.1016/j.joca.2014.04.029.

13. Monaghan K, Delahunt E, Caulfield B. Ankle function during gait in patients with chronic ankle instability compared to controls. *Clin Biomech*. 2006;21(2):168-174.

14. Koldenhoven RM, Feger MA, Fraser JJ, Saliba S, Hertel J. Surface electromyography and plantar pressure during walking in young adults with chronic ankle instability. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(4):1060-1070. doi:10.1007/s00167-016-4015-3.

15. Drewes LK, McKeon PO, Paolini G, Riley P, Kerrigan DC, Ingersoll CD, Hertel J. Altered ankle kinematics and shank-rear-foot coupling in those with chronic ankle instability. *J Sport Rehabil*. 2009;18(3):375-388.

16. Wikstrom EA, Brown CN. Minimum Reporting Standards for Copers in Chronic Ankle Instability Research. *Sports Med*. 2014;44(2):251-268. doi:10.1007/s40279-013-0111-4.

17. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Locomotive biomechanics in persons with chronic ankle instability and lateral ankle sprain copers. *J Sci Med Sport*. 2016;19(7):524-530. doi:10.1016/j.jsams.2015.07.010.

18. De Ridder R, Willems T, Vanrenterghem J, Robinson M, Pataky T, Roosen P. Gait kinematics of subjects with ankle instability using a multisegmented foot model. *Med Sci Sports Exerc*. 2013;45(11):2129-2136. doi:10.1249/MSS.0b013e31829991a2.

19. Brown C, Padua D, Marshall SW, Guskiewicz K. Individuals with mechanical ankle instability exhibit different motion patterns than those with functional ankle instability and ankle sprain copers. *Clin Biomech*. 2008;23(6):822-831. doi:10.1016/j.clinbiomech.2008.02.013.

20. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). *Foot Ankle Int*. 2005;26(11):968–983.

21. Donahue M, Simon J, Docherty CL. Reliability and validity of a new questionnaire created to establish the presence of functional ankle instability: the IdFAI. *Athl Train Sports Health Care*. 2013;5(1):38–43.

22. Pataky TC. One-dimensional statistical parametric mapping in Python. *Comput Methods Biomech Biomed Engin*. 2012;15(3):295-301. doi:10.1080/10255842.2010.527837.

23. Pataky TC. Generalized n-dimensional biomechanical field analysis using statistical parametric mapping. *J Biomech*. 2010;43(10):1976-1982. doi:10.1016/j.jbiomech.2010.03.008.

24. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Routledge; 1988.

25. Hopkins JT, Coglianese M, Glasgow P, Reese S, Seeley MK. Alterations in evertor/invertor muscle activation and center of pressure trajectory in participants with functional ankle instability. *J Electromyogr Kinesiol Off J Int Soc Electrophysiol Kinesiol*. 2012;22(2):280-285. doi:10.1016/j.jelekin.2011.11.012.

26. Nawata K, Nishihara S, Hayashi I, Teshima R. Plantar pressure distribution during gait in athletes with functional instability of the ankle joint: preliminary report. *J Orthop Sci Off J Jpn Orthop Assoc*. 2005;10(3):298-301. doi:10.1007/s00776-005-0898-4.

27. Feger MA, Donovan L, Hart JM, Hertel J. Lower extremity muscle activation in patients with or without chronic ankle instability during walking. *J Athl Train*. 2015;50(4):350-357. doi:10.4085/1062-6050-50.2.06.

TABLES:

Table 1.1 Participant demographics for coper and CAI groups.

	Copers (n=18; 16F, 2M)	CAI (n=18; 16F, 2M)	P-value
Age (years)	20.5±1.9	21.5±3.4	0.27
Height (cm)	168.2±6.0	167.5±9.1	0.78
Mass (kg)	66.2±11.3	66.9±14.4	0.86
FAAM-ADL (%)	99.9±0.3	86.1±9.7	**<0.001**
FAAM-Sport (%)	98.9±1.7	68.7±17.3	**<0.001**
IdFAI	10.6±3.6	20.6±3.6	**<0.001**
TSK	30.8±3.6	35.0±6.1	**0.02**
IPAQ	5014.3±2210.0	5133.9±3327.2	0.92
Total number ankle sprains	1.3±0.6	3.5±1.1	**<0.001**
Time since first sprain (months)	70.6±42.1	98.1±52.0	0.10
Time since last sprain (months)	63.2±45.7	18.1±27.4	**.001**
Preferred Walking Speed (m/s)	0.9±0.1	1.0±0.2	**.003**
120% Preferred Walking Speed (m/s)	1.1±0.2	1.2±0.2	**.004**

Abbreviations: Foot and Ankle Ability Measure (FAAM), Activities of Daily Living (ADL), Identification of Functional Ankle Instability (IdFAI), Tampa Scale of Kinesiophobia (TSK), International Physical Activity Questionnaire

FIGURES:

Figure 1.1 Means ± 95% confidence intervals for frontal plane motion at the ankle, knee, and hip between copers and CAI during the preferred, 120%, and standardized walking speeds. Boxes indicate significant differences.

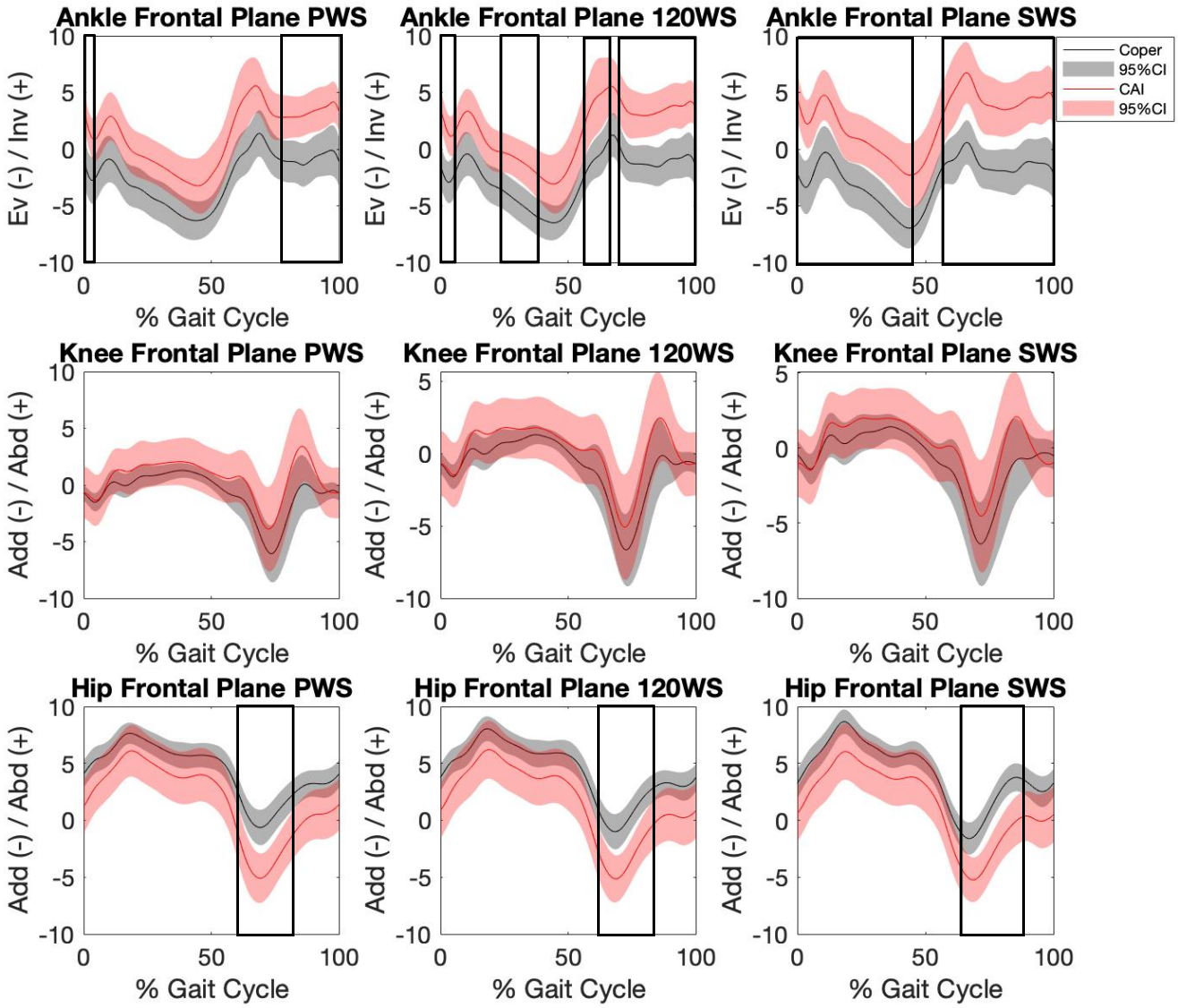


Figure 1.2 Means ± 95% confidence intervals for ankle sagittal plane motion during the preferred, 120%, and standardized walking speeds. Boxes indicate significant difference.

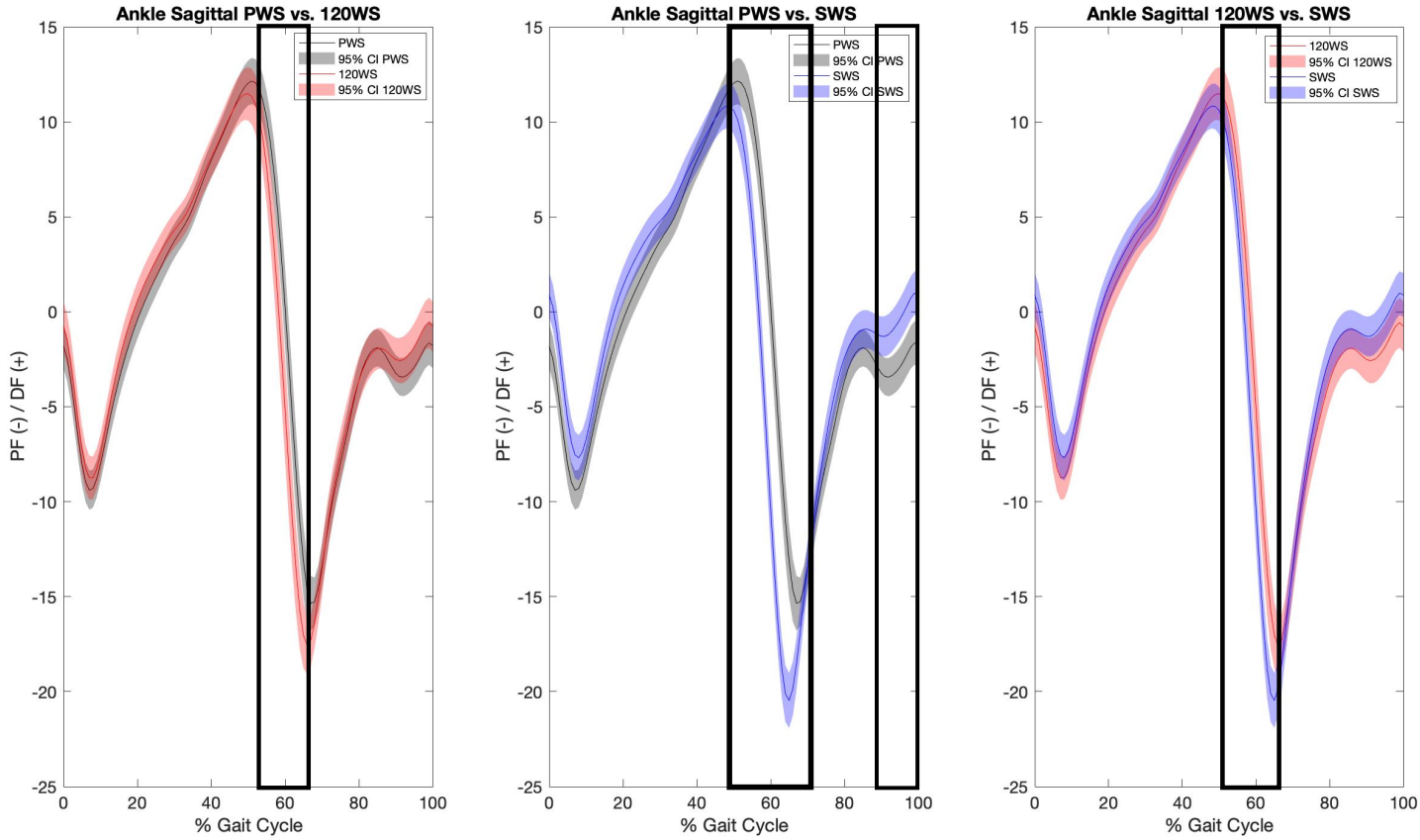


Figure 1.3 Means ± 95% confidence intervals for internal sagittal plane moments during the preferred, 120%, and standardized walking speeds. Boxes indicate significant differences.

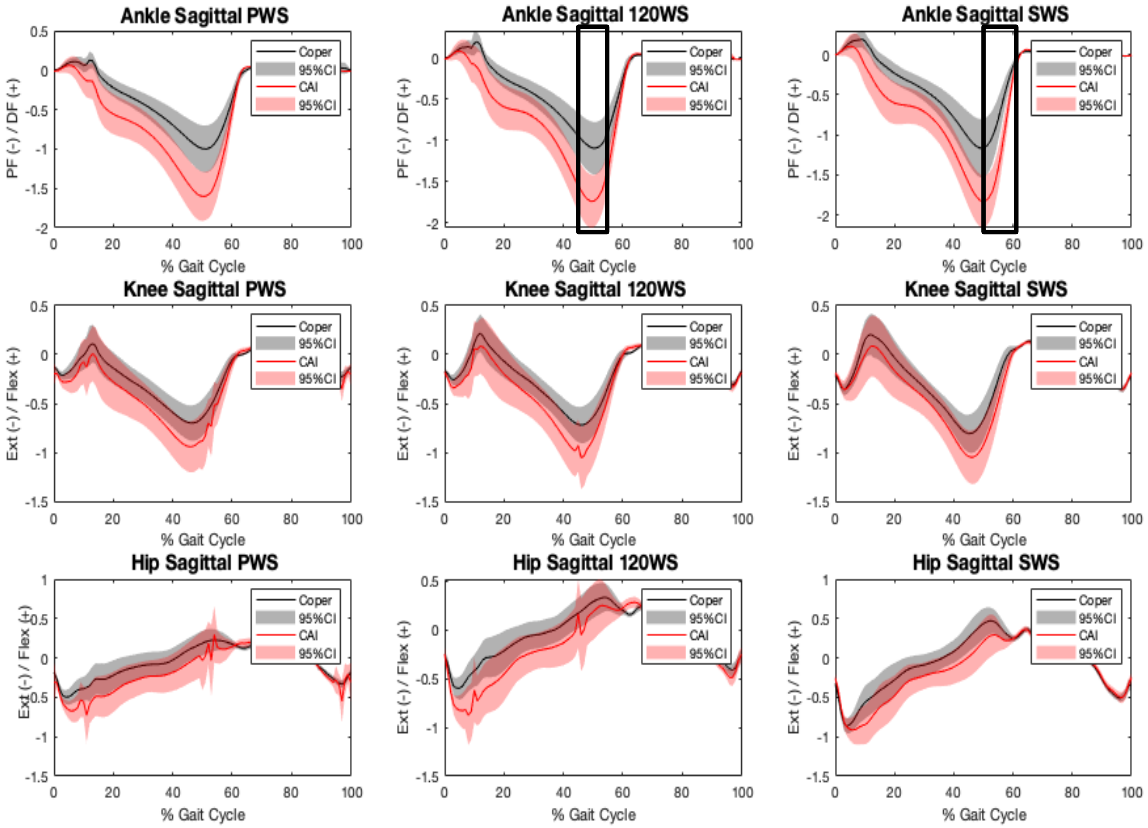
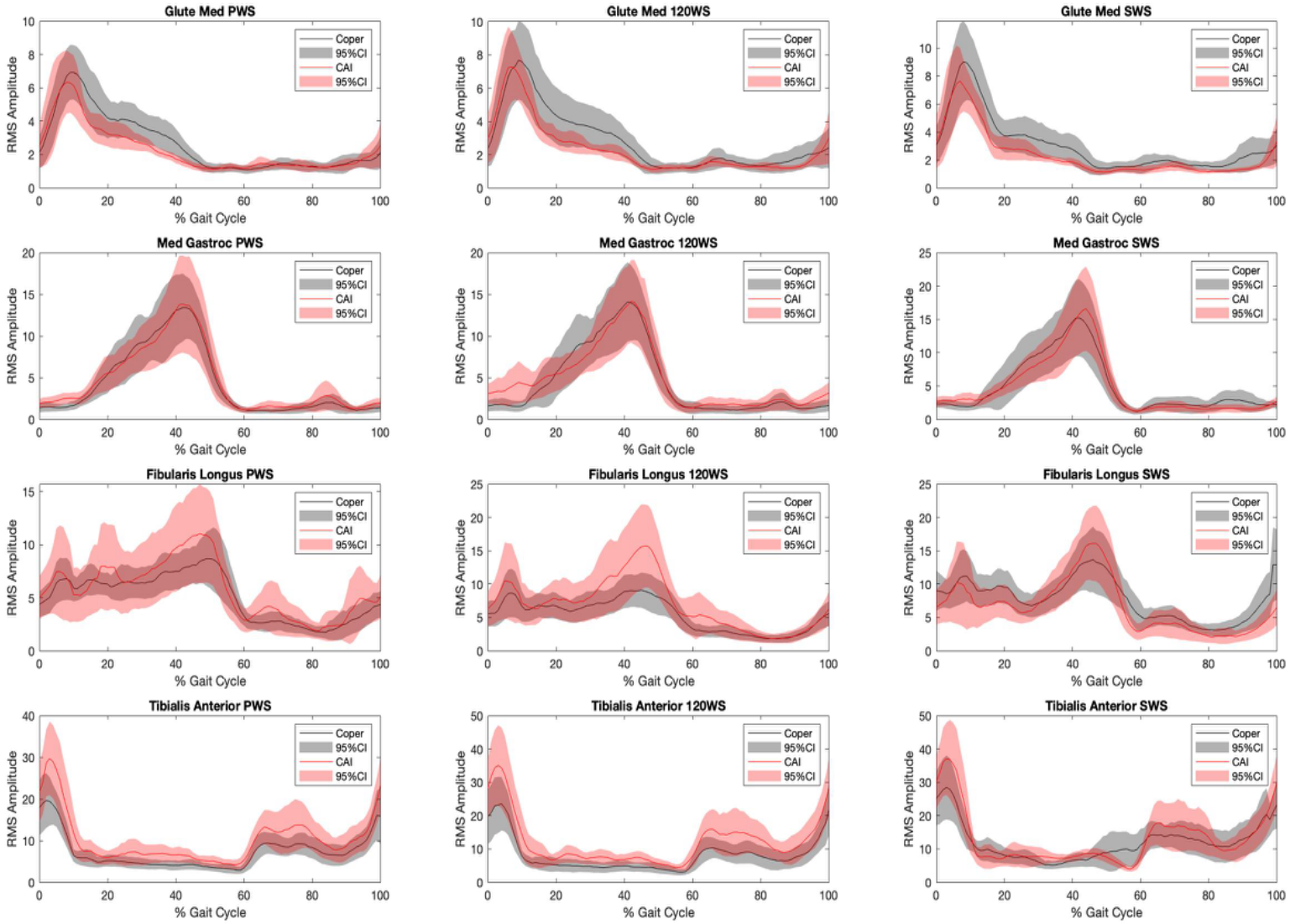


Figure 1.4 Means ± 95% confidence intervals EMG RMS amplitudes during the preferred, 120%, and standardized walking speeds. No significant differences were identified between the groups.



SECTION II: MANUSCRIPT II

MII: Gait Biofeedback and Impairment-based Rehabilitation for Chronic Ankle Instability: A Randomized Controlled Trial

ABSTRACT

Context: On average, individuals with chronic ankle instability (CAI) walk with approximately 6° more inverted foot position than ankle sprain copers throughout the gait cycle. Gait training has been recommended to address this alteration, however, the use of visual biofeedback to accomplish this goal has not been previously examined.
Objective: To analyze the effects of 4-weeks of visual gait biofeedback and impairment-based rehabilitation on gait biomechanics and patient-reported outcomes (PRO) in individuals with CAI.
Design: Randomized controlled trial
Patients or Other Participants: Twenty-seven (14 no biofeedback (NBF), 13 gait biofeedback (GBF)) individuals with CAI participated.
Interventions: Both groups received 8 sessions of impairment-based rehabilitation. The GBF group received visual biofeedback to reduce ankle frontal plane angle at initial contact (IC) during walking. The NBF group walked for equal time during rehabilitation but without biofeedback.
Main Outcome Measures: Three-dimensional kinematics and kinetics at the ankle, knee, and hip, and sEMG amplitudes of 4 lower extremity muscles were analyzed. PROs included the Foot and Ankle Ability Measure Activities of Daily Living (FAAM-ADL), FAAM-Sport, Tampa Scale of Kinesiophobia (TSK), and Global Rating of Change (GROC).
Results: The GBF group significantly decreased ankle inversion at IC (pre:4.2±4.6º, post:-3.1±4.1º, g=1.6) and throughout the entire stride cycle (peak inversion: pre:6.7±5.0º, post:0.8±4.3º, g=1.2). The NBF group did not have any significant changes in gait biomechanics. The groups were significantly different after rehabilitation while accounting for baseline measures for FAAM-ADL (GBF:97.1±2.3%, NBF: 92.0±5.7%), TSK (GBF:29.7±3.7, NBF:34.9±5.8), and GROC (GBF:5.5±1.0, NBF:3.9±2.0) with the GBF group showing greater improvements than the NBF group.
Conclusion: The GBF group successfully decreased ankle inversion angle and had greater improvements in PRO's after the intervention. Impairment-based rehabilitation without biofeedback improved PRO's but did not impact gait biomechanics. Impairment-based rehabilitation combined with visual biofeedback during gait training is recommended for individuals with CAI.

Word Count: 298

Introduction

Following an initial lateral ankle sprain, 40% of individuals develop chronic ankle instability (CAI).[8] This condition involves feelings of instability or "giving way, decreased self-reported function, and recurrent sprains. Deficits with CAI include diminished range of motion, sensorimotor control, proprioception, postural control, and strength.[19] Rehabilitation strategies in prior intervention studies have typically focused on only one treatment domain such as balance, ROM, or strength, and appear to improve the outcome of interest in that treatment domain specifically.[1,18,33] However, taking a multimodal approach addressing individual deficits within each treatment domain may result in greater treatment effects and should be considered when treating individuals with CAI.[12] Impairment-based rehabilitation uses an "assess, treat, re-assess" approach to target deficits and has previously shown to improve patient-reported outcomes associated with CAI.[10,11] Thus, taking a global treatment approach using impairment-based rehabilitation to intervene where deficits are observed is essential.

During walking gait, CAI patients demonstrate alterations in neuromuscular control, plantar pressure, and kinematics.[28] Over time this may represent a larger problem as walking is the primary form of locomotion and is a common daily activity. During walking, individuals with CAI may be at risk for subsequent ankle sprains due to a more inverted position of the foot and ankle during terminal swing and at initial contact (IC) leading into the loading response.[3] Several factors may contribute to the compromised foot position during gait including altered distal and proximal muscle dysfunction, laxity of the lateral ankle ligaments, and decreased proprioception.[24] Individuals with CAI have been shown to be approximately 4-6º more inverted throughout the gait cycle during

walking compared to ankle sprain copers (M1 results) and 6-7º more inverted at IC compared to healthy controls.[6] When the ankle is inverted during the swing phase just prior to IC, it may be susceptible to incurring inversion ankle injuries. This inverted foot position may also translate to the more lateral center of pressure trajectory under the foot during gait in those with CAI.[24]

Impairments associated with CAI are not only found at the ankle joint. Ankle sprain copers have demonstrated a 4-5º more abducted hip position during 66-88% of the stride cycle than individuals with CAI, which may suggest that copers adopt a strategy that widens their base of support prior to IC thus reducing their risk for an ankle sprain (M1 Results). During the stance phase, individuals with CAI also have alterations in hip-ankle coordination and coordination variability.[36] Doherty et al[36] identified an increase in hip adduction relative to ankle eversion in the CAI group compared to the healthy controls during the loading response period when inversion ankle injuries are most likely to happen. In the sagittal plane, individuals with CAI have demonstrated increased hip flexion at IC and decreased hip extension prior to toe-off (TO) compared to ankle sprain copers.[7] Gait retraining has been suggested as a way to address both hip and ankle alterations with aims to reduce the risks of recurrent ankle sprains.[7,24,36]

Previously, gait deficits have been targeted with strength or balance training but such interventions have not been successful at correcting frontal plane kinematics during gait.[27] Likewise, Davis and Futrell[5] noted that strength training without neuromuscular reeducation rarely translates to changes in movement patterns. Weinstein[35] has defined motor learning as "a set of internal processes associated with practice or experience leading to a relatively permanent change in the capability for responding." These

processes are thought to be "complex central nervous system phenomena whereby sensory and motor information is organized and integrated."[35] Therefore, the use of gait training to modify the movement patterns of individuals with CAI is likely necessary to improve frontal plane ankle kinematics during walking.

Gait training with the use of real-time feedback has not been extensively studied in individuals with CAI. To our knowledge, only two published studies have used audio or visual cues to provide feedback during walking gait.[9,34] Donovan et al[9] used auditory biofeedback to alert participants when too much force was placed under the lateral aspect of the foot. Participants were instructed to walk in a way that would not trigger the audible cue.[9] When walking in the auditory feedback condition, the participants with CAI demonstrated large decreases in peak pressure and pressure time integral in the lateral midfoot and forefoot and increases in the hallux.[9] More recently, Torp et al.[34] used a shoe mounted laser to provide visual biofeedback during walking. Individuals with CAI were instructed to alter their gait pattern so that the laser projected on the wall in front of them did not rotate to the right or left of a vertical target. When participants received the external biofeedback, they were able to shift the location of COP medially by 1-2 mm and reduce peak pressure forces on the lateral aspect of the mid- and forefoot.[34] Both of these studies showed that individuals with CAI could alter their gait while feedback was provided during a single intervention session, however, it is unknown how gait training using these techniques impact gait biomechanics after several intervention sessions and after the biofeedback is removed.

A study by Noehren et al.[30] analyzed the effects of real-time gait retraining on hip kinematics in patients with patellofemoral pain and found that pain and function in

participants were improved following gait retraining. The participants completed 8 sessions over 2 weeks and walked on a treadmill while the hip adduction angle of the involved limb was displayed on a monitor in front of the treadmill.[30] Participants were instructed to keep their hip angle within a shaded area on the monitor that represented $\pm$1SD from the mean of a healthy group.[30] Intermittent feedback has been shown to have better long-term effects for gait alterations compared to continuous immediate feedback.[30] During the first 4-sessions participants received 100% continuous immediate feedback and then had faded feedback for the remaining sessions.[30] Runners were able to decrease their hip adduction, internal rotation, and contralateral pelvic drop following the retraining and were able to maintain changes at the 1-month follow up visit.[30] These gait training concepts may be applied to individuals with CAI that walk with a more inverted ankle position. Focusing treatment to adopt a safer movement pattern by reducing the ankle inversion angle during walking may translate to improvements in self-reported function and reduced feelings of instability during activities of daily living.

It has become apparent that in order to change gait mechanics, patients need to perform gait training specifically targeting pathologically mediated gait alterations in addition to standard therapy. Reducing the ankle inversion angle at IC could be beneficial for individuals with CAI to adapt a less risky motor pattern and ultimately reduce the risk of subsequent ankle sprains. The purpose of this study was to analyze the effects of 4-weeks of a visual biofeedback intervention and impairment-based rehabilitation on gait biomechanics and patient reported outcome measures between a gait biofeedback (GBF) group and a no biofeedback (NBF) group. We hypothesized that the GBF group would have a reduced ankle inversion angle at IC that would also translate to a less inverted

position throughout the remainder of the stride cycle. We also hypothesized that the NBF group would not significantly change their gait kinematics from baseline to follow-up time points. Lastly, we hypothesized that both groups would have improvements in patient-reported outcomes after completing rehabilitation but that the GBF group would demonstrate greater improvements.

Methods

Study Design

We performed a single-blinded randomized controlled trial to assess differences in walking gait biomechanics between a visual GBF group and a no biofeedback group. Our independent variables were group (GBF vs. NBF) and time (baseline vs. follow-up). A 3-dimentional motion capture system was used to simultaneously analyze lower extremity kinematics, kinetics, and sEMG amplitude throughout the stride cycle. Global and region-specific patient-reported outcomes measures were evaluated at follow-up and compared to baseline measures.

Participants

Twenty-seven (8 males, 19 females; age = 21.9±3.4 years, mass = 70.7±14.1 kg, height = 170.8±10.2) physically active individuals with self-reported CAI volunteered for and completed this study. A total of 104 individuals were screened for this study. Of the 104 screened for the study, 68 did not meet inclusion criteria (history of fracture, surgery, high self-reported function), 6 chose not to participate due to time commitment required, and 3 dropped out of the study due to time constraints or moved away from the area (Figure 1). Participants were recruited from a university setting and the surrounding community. Inclusion criteria for the CAI group followed established recommendations

of the International Ankle Consortium.[16] All participants had a history of at least 1 significant lateral ankle sprain at least 12 months prior to study participation, self-reported dysfunction (Foot and Ankle Ability Measure (FAAM) Sport ≤85%), and feelings of instability or "giving way" (Identification of Functional Ankle Instability (IdFAI) >10).

Exclusion criteria consisted history of lower extremity fracture or surgery, ankle sprain within past 6 weeks, conditions known to affect gait (multiple sclerosis, Marfan's syndrome, lumbosacral radiculopathy, Ehlers-Danlos syndrome, diabetes mellitus), pregnancy, and currently participating in physical therapy. This study was approved by the university's Institutional Review Board and all participants provided informed consent prior to participation.

Instrumentation

Three-dimensional lower extremity kinematics were collected using a 12-camera Vicon motion capture system (VICON motion systems, CA, USA) and the sampling rate was 250Hz. A Bertec™ Fully Instrumented Treadmill (Columbus, OH, USA) was used to collect kinetic data at 1000Hz and a threshold of 20N was applied to identify initial contact. Surface EMG was collected using Trigno wireless sEMG (Delsys, Boston, MA, USA) at 2000Hz. We used a 10-500Hz bandpass filter and 50-sample average moving window. Data were synchronized using Motion Monitor software (Innovative Sports Training, Inc., Chicago, IL, USA) for all dependent variables. A custom Vizard (WorldViz, Santa Barbara, CA, USA) program was used to integrate real-time data from Vicon and Motion Monitor programs to create the visual biofeedback provided to participants. The sampling rate for visual biofeedback was 100Hz.

Procedures

Self-reported function was assessed using the following questionnaires: FAAM Activities of Daily Living (ADL),[25] FAAM Sport Scale,[25] IdFAI,[17] Tampa Scale of Kinesiophobia (TSK),[21] and the Patient Specific Functional Scale (PSFS).[20] The Global Rating of Change (GROC)[23] and PSFS questionnaires were administered at a half-way time point (2 weeks) and post-rehabilitation time point (4 weeks). Self-reported physical activity was quantified using the International Physical Activity Questionnaire (IPAQ).[2]

Baseline & Follow-up Gait Assessment

Participants were fitted with standard laboratory shoes (Brooks Defyance; Brooks Sports, Inc., Bothel, WA, USA). Gait analysis procedures have been described extensively in the prior manuscript (M1). Briefly, participants wore rigid cluster marker sets secured on the upper thorax, lumbar spine, and bilaterally on the lower extremities. Segments were digitized to identify the joint centers for all lower joints. The participant's skin was prepared for sEMG by shaving, abrading, and cleansing with isopropyl alcohol. Electrodes were placed over the muscle belly of the tibialis anterior (TA), fibularis longus (FL), medial gastrocnemius (MG), and gluteus medius (GMed) on the limb with CAI. Correct electrode placement was ensured by testing each muscle using a manual muscle test. Data were normalized to a 5-second epoch from the middle of a quiet standing trial collected prior to walking.

Participants walked on a split-belt treadmill for 5 minutes at a self-selected pace for familiarization to the treadmill prior to collecting any data. Kinematics, kinetics, and sEMG were collected simultaneously for 60-seconds while participants walked at a standardized walking speed of 1.3 m/s (3.0 mph).

After the baseline data collection, participants were randomly assigned to treatment groups (biofeedback or no biofeedback). A random-number generator was used by an investigator who was not involved in participant screening, outcomes measurement, or intervention administration (J.H.) to determine the randomization sequence for participants. Group assignments were placed in sealed envelopes to ensure concealed allocations. The supervising clinicians (A.F.D., A.H.J.) for the impairment-based rehabilitation was blinded to the gait biofeedback intervention status. Participants were not blinded to the gait biofeedback intervention, but were asked not to discuss group allocation with the impairment-based rehabilitation clinician.

Participants began supervised impairment-based rehabilitation sessions within 1-week of the baseline assessment. Follow-up assessments occurred 24-72 hours after completion of the last rehabilitation session.

Impairment-Based Rehabilitation Protocol

Participants in the biofeedback and no biofeedback groups performed 4-weeks of impairment-based rehabilitation sessions. The impairment-based rehabilitation program was similar to that of Donovan et al.[11] Participants received 8 sessions (2x/week) of supervised rehabilitation with focus on individual impairments in range of motion (ROM), balance, strength, and functional activities. Specific details for the impairment-based rehabilitation protocol can be found in appendix C.

Briefly, for ROM assessment, the supervising clinician performed a clinical assessment to determine if there were any arthrokinematic and osteokinematic restrictions. If restrictions were present, the clinician provided appropriate joint mobilizations ranging from grade II to grade III on the Maitland scale. Participants also

performed triceps surae stretching exercises as deemed necessary. Strengthening exercises were performed for foot, ankle, and hip muscles. Foot exercises included the short foot exercise, great toe extension, extension of toes 2-5, and toe extension and splay.[15] Participants were progressed from seated to bipedal standing to single limb standing. Ankle exercises included heel raises, forefoot raises, 4-way manual resistance, D1/D2 PNF patterns, and heel and toe walks. Hip exercises included quadruped, clamshells with resistance band, 4-way hip with resistance band, and seated internal/external rotation with resistance band. Balance exercises included single leg balance for time, reaching tasks, and hop to stabilization.[26] Functional exercises consisted of lunges, forward and lateral step-ups and step-downs on a 30-cm box, and dot jumping drills.[11] Participants were assessed by a supervising clinician during the first rehabilitation session to determine the appropriate starting point for each exercise category. During each subsequent session, the participant was reassessed and progressed as deemed appropriate by the supervising clinician to maximize the training stimulus received.

Participants were also given a home exercise plan (HEP) to complete on days that they did not have a supervised rehabilitation session (appendix C). The HEP consisted of intrinsic foot muscle exercises,[15] single leg balance, triceps surae stretching, and 4-way ankle exercises using a resistance band. Participants reported the number of days between rehabilitation sessions they completed the HEP at the beginning of each session. Compliance was calculated as a percentage of days the participant completed the HEP for the duration of days between the impairment-based rehabilitation sessions.

Visual Biofeedback Intervention

Participants were randomized into either the NBF or the GBF groups. The goal of the visual GBF intervention was to reduce frontal plane ankle inversion at initial contact. Reference points for the ankle inversion angle were the proximal segment shank cluster, distal segment heel cluster, and the point of rotation was at the ankle joint (Figure 2). Vizard imported the ankle inversion angle at initial contact from The MotionMonitor™ software and visual GBF was projected onto a screen directly in front of the treadmill during visual GBF sessions. A threshold was pre-determined prior to visual GBF sessions based on the ankle inversion angle at initial contact during walking. The threshold for each session was set to decrease the ankle inversion by 20-100% and was calculated using the total excursion from 0º to the average ankle inversion value at initial contact for 10 steps collected at the beginning of each session. The goal was to progressively decrease ankle inversion at initial contact as much as possible by the end of the 8th training session. All gait training sessions were supervised by the same athletic trainer (RMK).

When inversion was greater than the pre-determined threshold, the image would appear red indicating a "bad" step and when the inversion was below the threshold the image would appear green indicating a "good" step (Figure 2). Participants were instructed to avoid walking on the outside of their foot to achieve a good step indicated by the green image and to maintain a gait pattern that resulted in green feedback for as many steps as possible. Participants were progressed to a more difficult threshold (higher percentage of change) for the next training session if 1) majority of steps performed without error, 2) could maintain > 10 consecutive strides without error, 3) participant self-reported success at current threshold by confirming the task was "easy" or "could be

harder." The GBF schedule was adapted from Noehren et al.[30] Participants received feedback for the entire training session during the first 4 sessions. For the last 4 sessions, participants received reduced feedback time that decreased by 4-minutes for each subsequent session. The maximum walking time was 20-minutes. The NBF group walked on the treadmill without biofeedback or targeted instruction for the same amount of time for each session as the GBF group.

Data Processing

Ten consecutive strides from each walking trial were analyzed and were reduced to 101 data points representing 0-100% of the gait cycle. Data for sEMG were normalized to the mean of the RMS amplitude during a 5-second epoch of quiet standing for each muscle. All data processing was performed using Matlab version R2018a (MathWorks, Inc., Natick, MA, USA).

Statistical Analysis

The sample size estimate revealed that 13 participants per group were needed to identify large effects based on a between group mean difference of 6.6º of inversion and standard deviation of 4.6º at IC during walking between control and CAI participants (M1).

Descriptive statistics were calculated for group demographics using Statistical Package for Social Sciences (SPSS) version 24.0 (SPSS, Inc., Chicago, IL). Patient reported outcomes post-rehabilitation were analyzed using an analysis of covariance (ANCOVA) with the baseline scores as the model covariate. In addition, odds ratios (OR) were calculated between the GBF and NBF groups for the change in ankle angle at IC and for patient reported outcomes to determine the likelihood of incurring a good

outcome. The upper limit of the 95% confidence interval for the coper group from M1 was determined to be a "desired" outcome for ankle angle at IC for the OR calculation. MCIDs were used to determine a "desired" outcome for the OR calculation. A score of >3 on the GROC, >8% increase on the FAAM-ADL,[25] >9% increase on the FAAM-Sport, [25] and >6 point decrease on TSK[29] was used as the "desired" outcome for the OR calculation.

The gait measures were assessed using the spm1d Version 0.4 for one-dimensional statistical parametric mapping (SPM) package for Matlab (MathWorks, Inc., Natick, MA, USA).[31,32] A 2x2 group by time SPM repeated measures analysis of variance (SPM_{ANOVA}) and post-hoc SPM t-tests ($SPM_{t\text{-}test}$) were used to compare gait biomechanics between the copers and CAI groups. The a priori level of significance was set at $p \leq 0.05$. Upon post-hoc analysis, statistical significance was demonstrated where the 95% confidence intervals did not overlap. Hedge's *g* effect sizes were calculated to determine the magnitude of difference. A positive effect size indicated that the GBF group improved more than the NBF group.

Results

There were no significant differences between the GBF and NBF groups for any patient demographics at baseline (Table 1). The groups were not significantly different for the HEP compliance (no biofeedback: 78.9±15.2%, biofeedback: 81.5±15.0%) and compliance in both groups ranged from 50-100%.

Patient Reported Outcomes

The groups were significantly different after rehabilitation while accounting for baseline measures for FAAM-ADL (GBF: 97.1±2.3%, NBF: 92.0±5.7%, p=0.016, *g*=1.00), TSK (GBF: 29.7±3.7, NBF: 34.9±5.8, p=0.016 *g*=1.00), and GROC (GBF: 5.5±1.0, NBF: 3.9±2.0, p=0.022, *g*=0.92) with the GBF group showing greater improvements than the NBF group (Table 2).

Individuals in the GBF group were substantially more likely to report a score of 4 (moderately better) or higher than were members of the NBF group (OR=12.0, 95% CI: 1.21 to 118.9; p=0.034) at the conclusion of 4-week intervention (Table 3). Members of the GBF group trended towards being more likely to have a TSK decrease of 6 points or more compared to the NBF group (OR=18.8, 95% CI: 0.92 to 383.1; p=0.057), but this was not statistically significant (Table 3). There were no significant differences between the groups for FAAM-ADL, FAAM Sport, GROC at 2-weeks, and PSFS (Table 3).

Gait Biomechanics

A significant time main effect was identified for ankle frontal plane motion ($p<0.001$) and a group by time interaction was identified for knee transverse plane motion (p=0.039). Figure 3 shows group comparisons of kinematics at baseline and follow up and Figure 4 shows the baseline to follow up comparisons of kinematics for each group. The GBF group had large significant improvements in ankle angle at IC and the NBF group had a small non-significant improvement in ankle angle at IC (Figure 5). The GBF group was substantially more likely to have an improvement in ankle angle at IC at the conclusion of the 4-week intervention compared to the NBF group (OR=6.0, 95% CI:1.11, 32.55; p=0.038). The groups were not significantly different at baseline for any variables. At the follow up time point, the GBF group reduced their ankle inversion ankle

at IC (pre: 4.2±4.6º, post: -3.1±4.1º, g = 1.6) and throughout the entire stride cycle (peak inversion ankle: pre: 6.7±5.0º, post: 0.8±4.3º, g = 1.2). The NBF group did not significantly reduce their ankle inversion ankle at IC (pre: 2.6±4.2º, post: 1.6±3.5º, g = 0.3) or throughout the stride cycle (peak inversion ankle: pre: 4.6±6.0º, post: 3.6±4.4º, g = 0.2). For knee transverse plane, the groups were not different at baseline, but at follow-up the GBF group demonstrated an externally rotated knee compared to an internally rotated knee at baseline during terminal swing (Peak transverse plane motion: pre: -2.0±4.3º, post: 1.2±4.2º, g = 0.7). There were no significant differences for kinetics (Figure 6) or sEMG measures (Figure 7).

Discussion

Our primary hypothesis that the visual GBF group would have reduced ankle inversion at IC and throughout the entire stride cycle at follow-up compared to their baseline measures was confirmed. Additionally, the NBF group did not significantly change their gait mechanics from baseline to follow-up, although there was a small (g = 0.3), but non-significant, shift in decreased inversion throughout the stride cycle. Not only did the GBF group have meaningful improvements in gait mechanics, they also had greater improvements for several patient-reported outcomes compared to the NBF group which supports our original hypothesis.

The GBF intervention in this study specifically targeted frontal plane ankle kinematics during walking. Participants in the GBF group decreased their ankle inversion angle at IC by 7.3º and throughout the gait cycle by approximately 6º and adopted a strategy similar to the copers from M1. In addition, participants in the GBF group were 6

times more likely to have an improvement in the ankle angle at IC compared to the NBF group. A meaningful improvement was determined as being within the range of the upper limit of the 95% CI for the coper group from M1 at the follow-up timepoint. Participants were instructed to reduce ankle inversion by avoiding walking on the outside of their foot in order to shift the feedback image from red to green. We did not provide any additional instruction on how to accomplish this task which is likely why we did not identify additional changes for kinematics, kinetics, or sEMG. The GBF group changed their knee rotation during terminal swing from an internally rotated to an externally rotated position at follow-up compared to baseline, however the 95% confidence intervals overlapped, however, there was a moderate effect size which indicates this finding may clinically important.

Concepts from dynamic systems theory can be applied in the interpretation of the changes in gait mechanics identified in this study.[4] The dynamic systems theory proposes that complex physiological systems can be self-organized in a variety of ways to achieve a specific movement task.[4] Minor changes at proximal segments in the lower extremity kinetic chain may result in greater changes at the distal segments. Although not statistically significant, the GBF group had 2-3º more hip abduction throughout the entire stride cycle at follow up. In addition, after the intervention the GBF group had slightly higher FL and TA activation throughout the stride cycle, but these results were not statistically significant (Figure 6). The sum of these subtle changes may have contributed to the large decrease in ankle inversion angle observed in the GBF group.

The NBF group did not significantly alter their ankle inversion mechanics from baseline to follow-up, however, there was a small 1-2º shift towards a less inverted foot

position. These results are supported by those of McKeon et al.[27] and Donovan et al.[8] who demonstrated similar small and non-significant shifts in ankle inversion kinematics after 4 weeks of balance training[16] and impairment-based rehabilitation without specific gait training[8] in CAI patients. Without gait training to specifically address the frontal plane kinematic alterations during gait, CAI patients do not substantially change their gait mechanics. Our current results do, however, show that an intervention program utilizing real-time GBF of frontal plane ankle position at initial contact coupled with comprehensive impairment-based rehabilitation leads to improvements in self-reported function and a restoration of frontal plane ankle kinematics during walking.

Several gait training studies have been executed for individuals with CAI, yet none were designed specifically to reduce ankle inversion kinematics, but instead used plantar pressure as an outcome measure.[9,13,34] Torp et al.[34] performed a study similar to ours that provided visual GBF with a shoe mounted laser and was able to shift plantar pressure more medially by 1-2mm while participants received feedback. Similarly, Donovan et al.[9] used auditory feedback to reduce lateral plantar pressure during walking. While wearing the auditory feedback device, participants reduced their peak pressure in the lateral midfoot and forefoot.[9] Neither of those studies examined the effects of the feedback after several sessions of gait training.[9,34]

Feger et al.[13] performed 5 sessions of gait training using a novel gait training device[14] that required participants to walk on a treadmill while countering medially directed resistance just proximal the their ankles. The participants were able to shift their plantar pressure medially during the last 90% of the stance phase.[13] The individuals in this study did not receive any other rehabilitation and only participated in the 5 sessions

of gait training each lasting approximately 7-15 minutes.[13] In another study by Donovan et al.,[10] participants wore ankle destabilization devices during walking and other functional exercises as part of an impairment-based rehabilitation for 12-sessions. This gait training approach was not successful in reducing ankle inversion kinematics during walking, but did result in greater dorsiflexion during mid-late stance in the device group compared to the control group.[10] The combination of gait training and impairment-based rehabilitation[10] resulted in greater improvements on the FAAM-Sport compared to the 5-sessions of gait training alone (20% and 10% respectively).[13] Participants in the GBF group of our study improved on the FAAM-Sport by 16% which supports that gait training in combination with impairment-based rehabilitation results in greater improvements in regional patient reported outcomes compared to gait training alone.

It is likely that the medial shift in plantar pressure found in each of these studies may be the result of a less inverted foot position, however, kinematics were not assesed.[9,13,34] While we were the first to focus specifically on reducing ankle inversion kinematics, our study methods would be difficult to implement in a clinical setting due to the instrumentation used. Individuals were instructed to avoid walking on the outside of their foot to achieve a "good" step in our study. Clinicians could potentially implement this simple verbal cue as a form of feedback during walking for individuals with CAI. The shoe-mounted laser technique[34] is most similar to ours and may be easier to implement in the clinical setting than our methods, however, this method needs to be assessed over several sessions of gait training. In addition, future studies should determine if gait training modifications and improvements in self-reported function are

maintained for extended periods of time after completion of gait training sessions using various techniques.

In addition to the improved gait biomechanics, we found greater improvements in several patient-reported outcomes in the GBF group compared to the NBF group. The GROC asks participants to identify how much better or worse they feel from the time they began rehabilitation. The minimally clinically important difference for the GROC has been reported to be 2 points on the 15-point scale.[23] The GBF group reported a change of 3.5 points (somewhat better) at the half-way (2 week) time point and 5.5 points (quite a bit better) after completing 4-weeks of rehabilitation while the NBF group only had an improvement of 2.3 points (a little bit better) at the half-way time point and 3.9 points after rehabilitation. The GBF group was also 12 times more likely to report a "moderately better" or greater improvement than the NBF group for the GROC. The scores for individuals in the GBF group at the half-way time point were similar to those of the NBF at the 4-week time point. Therefore, the GBF group started to feel better earlier on in the rehabilitation process and had greater outcomes at the end of rehabilitation for the GROC compared to the NBF group.

The TSK is designed to measure the fear or movement and reinjury and individuals with CAI have demonstrated increased kinesiophobia compared to healthy controls.[22] Our study is the first to show that gait training in addition to rehabilitation reduced the fear of movement more than rehabilitation alone. Although the results were not significant, the GBF group was 18.8 times (95% CI: 0.92 to 393.1, p=0.057) more likely to have improvements in kinesiophobia than the NBF group. For the FAAM-ADL,

the GBF group showed a 9.3% increase whereas the NBF group improved by only 6.4% ($p=0.016$, $g = 1.00$).

We identified that the GBF group had greater improvements in FAAM-ADL scores following rehabilitation, but there was not a significant difference in the proportion of individuals who exceeded the MCID for improvement (OR: 1.1, 95% CI: 0.23 to 5.37). Nine of the 21 items on the FAAM-ADL questionnaire ask specifically about difficulty during various walking tasks which is likely why we identified a larger improvement in the GBF group since the biofeedback focused on improving walking gait mechanics. The FAAM-Sport assesses the foot and ankle function during higher level functional activities such as running, jumping, landing, starting and stopping quickly, and cutting/lateral movements.[25] Both groups improved by 15-16% for the FAAM-Sport, however, the groups did not significantly differ from each other after rehabilitation on this measure. In addition, only the GBF group had an average score at post-rehabilitation (86.3%) that was higher than our cut-off score ($\leq$85%) for inclusion criteria for CAI prior to study enrollment. In the GBF group, 69% of individuals had a score higher than 85%, while only 36% in the NBF group had a score that was higher than the original cut-off score. The impairment-based rehabilitation program incorporated hopping tasks and tasks that required unanticipated changes in direction. Both groups performed these tasks and may help explain why there were significant increases in both groups, but no differences between the groups after rehabilitation. It appears the GBF facilitated a new gait strategy that was associated with a higher likelihood of having large meaning improvements in global self-reported outcome measures (GROC, TSK), but not for the region-specific outcome measures (FAAM-ADL, FAAM-Sport) compared to the NBF group.

Our study had several limitations. We initially powered the study to identify pre- to post-intervention differences for ankle inversion angle at initial contact (the primary dependent variable) and not for kinetic or sEMG measures. This increases the risk for type 2 error for our secondary analyses. Due to the inherent variability of sEMG, we would need a much larger sample of participants to be able to detect differences between the groups or between time points. Our study had primarily female participants, however, this is reflective of the higher incidence rate of ankle sprains in females compared to males. Additionally, the male to female ratio in our study is similar to other studies of individuals with CAI. Lastly, we elected to include young physically active individuals and our results may not be generalizable to other groups of individuals with CAI.

In conclusion, the GBF intervention was successful at decreasing ankle frontal plane inversion ankle during walking and had a greater impact on patient-reported outcomes compared to the NBF group. The NBF group did not have any significant changes in gait biomechanics which suggests that rehabilitation alone is not successful at altering gait mechanics. The GBF group also had a significant decrease in kinesiophobia in comparison to the NBF group which is clinically meaningful. We recommend that gait training using visual biofeedback to reduce ankle inversion should be added to traditional rehabilitation protocols.

References:

1. Anguish B, Sandrey MA. Two 4-Week Balance-Training Programs for Chronic Ankle Instability. *J Athl Train*. 2018;53(7):662-671. doi:10.4085/1062-6050-555-16.

2. Booth M. Assessment of Physical Activity: An International Perspective. *Res Q Exerc Sport*. 2000;71(sup2):114-120. doi:10.1080/02701367.2000.11082794.

3. Chinn L, Dicharry J, Hertel J. Ankle kinematics of individuals with chronic ankle instability while walking and jogging on a treadmill in shoes. *Phys Ther Sport*. 2013;14(4):232-239. doi:10.1016/j.ptsp.2012.10.001.

4. Davids K, Glazier P, Araújo D, Bartlett R. Movement Systems as Dynamical Systems. *Sports Med*. 2003;33(4):245-260. doi:10.2165/00007256-200333040-00001.

5. Davis IS, Futrell E. Gait Retraining: Altering the Fingerprint of Gait. *Phys Med Rehabil Clin N Am*. 2016;27(1):339-355. doi:10.1016/j.pmr.2015.09.002.

6. Delahunt E, Monaghan K, Caulfield B. Altered Neuromuscular Control and Ankle Joint Kinematics During Walking in Subjects With Functional Instability of the Ankle Joint. *Am J Sports Med*. 2006;34(12):1970-1976.

7. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Locomotive biomechanics in persons with chronic ankle instability and lateral ankle sprain copers. *J Sci Med Sport*. 2016;19(7):524-530. doi:10.1016/j.jsams.2015.07.010.

8. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Recovery From a First-Time Lateral Ankle Sprain and the Predictors of Chronic Ankle Instability A Prospective Cohort Analysis. *Am J Sports Med*. 2016;44(4):995-1003.

9. Donovan L, Feger MA, Hart JM, Saliba S, Park J, Hertel J. Effects of an auditory biofeedback device on plantar pressure in patients with chronic ankle instability. *Gait Posture*. 2016;44:29-36. doi:10.1016/j.gaitpost.2015.10.013.

10. Donovan L, Hart JM, Saliba S, et al. Effects of ankle destabilization devices and rehabilitation on gait biomechanics in chronic ankle instability patients: A randomized controlled trial. *Phys Ther Sport*. 2016;21:46-56. doi:10.1016/j.ptsp.2016.02.006.

11. Donovan L, Hart JM, Saliba SA, et al. Rehabilitation for Chronic Ankle Instability With or Without Destabilization Devices: A Randomized Controlled Trial. *J Athl Train*. 2016;51(3):233-251. doi:10.4085/1062-6050-51.3.09.

12. Donovan L, Hertel J. A New Paradigm for Rehabilitation of Patients with Chronic Ankle Instability. *Phys Sportsmed*. 2012;40(4):41-51. doi:10.3810/psm.2012.11.1987.

13. Feger MA, Hart JM, Saliba S, Abel MF, Hertel J. Gait training for chronic ankle instability improves neuromechanics during walking. *J Orthop Res*. 2018;36(1):515-524. doi:10.1002/jor.23639.

14. Feger MA, Hertel J. Surface electromyography and plantar pressure changes with novel gait training device in participants with chronic ankle instability. *Clin Biomech*. 2016;37:117-124. doi:10.1016/j.clinbiomech.2016.07.002.

15. Fraser JJ, Hertel J. Effects of a 4-Week Intrinsic Foot Muscle Exercise Program on Motor Function: A Preliminary Randomized Control Trial. *J Sport Rehabil*. January 2018:1-32. doi:10.1123/jsr.2017-0150.

16. Gribble PA, Delahunt E, Bleakley C, et al. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Br J Sports Med*. 2014;48(13):1014-1018.

17. Gurav RS, Ganu SS, Panhale VP. Reliability of the Identification of Functional Ankle Instability (IdFAI) Scale Across Different Age Groups in Adults. *North Am J Med Sci*. 2014;6(10):516-518. doi:10.4103/1947-2714.143283.

18. Hall EA, Docherty CL, Simon J, Kingma JJ, Klossner JC. Strength-Training Protocols to Improve Deficits in Participants With Chronic Ankle Instability: A Randomized Controlled Trial. *J Athl Train*. 2015;50(1):36-44. doi:10.4085/1062-6050-49.3.71.

19. Hertel J. Functional anatomy, pathomechanics, and pathophysiology of lateral ankle instability. *J Athl Train*. 2002;37(4):364.

20. Horn KK, Jennings S, Richardson G, van Vliet D, Hefford C, Abbott JH. The Patient-Specific Functional Scale: Psychometrics, Clinimetrics, and Application as a

Clinical Outcome Measure. *J Orthop Sports Phys Ther*. 2012;42(1):30-42. doi:10.2519/jospt.2012.3727.

21. Houston MN, Hoch JM, Hoch MC. Patient-Reported Outcome Measures in Individuals With Chronic Ankle Instability: A Systematic Review. *J Athl Train*. 2015;50(10):1019-1033. doi:10.4085/1062-6050-50.9.01.

22. Houston MN, Van Lunen BL, Hoch MC. Health-Related Quality of Life in Individuals With Chronic Ankle Instability. *J Athl Train*. 2014;49(6):758-763. doi:10.4085/1062-6050-49.3.54.

23. Kamper SJ, Maher CG, Mackay G. Global Rating of Change Scales: A Review of Strengths and Weaknesses and Considerations for Design. *J Man Manip Ther*. 2009;17(3):163-170.

24. Koldenhoven RM, Feger MA, Fraser JJ, Saliba S, Hertel J. Surface electromyography and plantar pressure during walking in young adults with chronic ankle instability. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(4):1060-1070.

25. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Swearingen JMV. Evidence of Validity for the Foot and Ankle Ability Measure (FAAM). *Foot Ankle Int*. 2005;26(11):968-983. doi:10.1177/107110070502601113.

26. Mckeon PO, Ingersoll CD, Kerrigan DC, Saliba E, Bennett BC, Hertel J. Balance Training Improves Function and Postural Control in Those with Chronic Ankle Instability. *Med Sci Sports Exerc*. 2008;40(10):1810-1819. doi:10.1249/MSS.0b013e31817e0f92.

27. McKeon PO, Paolini G, Ingersoll CD, et al. Effects of balance training on gait parameters in patients with chronic ankle instability: a randomized controlled trial. *Clin Rehabil*. 2009;23(7):609-621. doi:10.1177/0269215509102954.

28. Moisan G, Descarreaux M, Cantin V. Effects of chronic ankle instability on kinetics, kinematics and muscle activity during walking and running: A systematic review. *Gait Posture*. 2017;52:381-399. doi:10.1016/j.gaitpost.2016.11.037.

29. Monticone M, Ambrosini E, Rocca B, Foti C, Ferrante S. Responsiveness and minimal clinically important changes for the Tampa Scale of Kinesiophobia after lumbar fusion during cognitive behavioral rehabilitation. *Eur J Phys Rehabil Med*. 2017;53(3):351-358. doi:10.23736/S1973-9087.16.04362-8.

30. Noehren B, Scholz J, Davis I. The effect of real-time gait retraining on hip kinematics, pain and function in subjects with patellofemoral pain syndrome. *Br J Sports Med*. 2011;45(9):691-696. doi:10.1136/bjsm.2009.069112.

31. Pataky TC. Generalized n-dimensional biomechanical field analysis using statistical parametric mapping. *J Biomech*. 2010;43(10):1976-1982. doi:10.1016/j.jbiomech.2010.03.008.

32. Pataky TC. One-dimensional statistical parametric mapping in Python. *Comput Methods Biomech Biomed Engin*. 2012;15(3):295-301. doi:10.1080/10255842.2010.527837.

33. Reid A, Birmingham TB, Alcock G. Efficacy of Mobilization with Movement for Patients with Limited Dorsiflexion after Ankle Sprain: A Crossover Trial. *Physiother Can*. March 2008. doi:10.3138/ptc.59.3.166.

34. Torp DM, Thomas AC, Donovan L. External feedback during walking improves measures of plantar pressure in individuals with chronic ankle instability. *Gait Posture*. 2019;67:236-241. doi:10.1016/j.gaitpost.2018.10.023.

35. Winstein C. Knowledge of results and motor learning--implications for physical therapy. *Phys Ther*. 1991;71(2):140-149.

36. Yen S-C, Chui KK, Corkery MB, Allen EA, Cloonan CM. Hip-ankle coordination during gait in individuals with chronic ankle instability. *Gait Posture*. 2017;53:193-200. doi:10.1016/j.gaitpost.2017.02.001.

TABLES:

Table 2.1 Patient demographics for the no biofeedback and biofeedback groups.

	No Biofeedback (n=14)	Biofeedback (n=13)
Sex (Male:Female)	5:9	3:10
Age (years)	21.5±3.0	22.23±3.8
Height (cm)	174.0±10.7	167±8.8
Mass (kg)	72.1±13.9	69.2±14.7
Total number ankle sprains	4.6±3.7	4.1±2.0
Time since first sprain (months)	89.7±53.8	98.8±51.2
Time since last sprain (months)	15.0±30.6	12.0±8.9

Table 2.2 Patient reported outcomes for the no biofeedback and biofeedback groups (means ± SD) and Hedges *g* effect sizes with 95% confidence intervals.

	No Biofeedback Group		Biofeedback Group		Group Main Effect	Between Groups Hedges *g*
Variable	Pre-rehabilitation	Post-rehabilitation	Pre-rehabilitation	Post-rehabilitation	*P* Value	Effect Size
FAAM-ADL (%)	85.6 (8.9)	92.0 (5.6)	89.8 (7.8)	97.1 (2.3)	**0.016**	1.00
FAAM-Sport (%)	64.3 (15.0)	80.1 (11.9)	70.3 (16.0)	86.3 (8.4)	0.170	0.53
IdFAI	21.8 (3.3)	20.9 (3.5)	21.8 (4.5)	19.2 (4.5)	0.252	0.45
TSK	35.4 (5.8)	34.9 (5.7)	33.1 (5.1)	29.7 (3.7)	**0.016**	1.00
IPAQ (MET)	4735.6 (1946.9)	4846.1 (1972.8)	5223.5 (3774.5)	5035.3 (2248.3)	0.788	0.05
GROC Mid-Rehab	-	2.3 (2.0)	-	3.5 (1.2)	0.076	0.69
GROC Post-Rehab	-	3.9 (2.0)	-	5.5 (1.1)	**0.022**	0.92
PSFS Total Score	6.2 (0.9)	8.0 (1.3)	5.1 (1.8)	8.0 (1.2)	0.644	0.19

Abbreviations: Foot and Ankle Ability Measure (FAAM), Activities of Daily Living (ADL), Identification of Functional Ankle Instability (IdFAI), Tampa Scale of Kinesiophobia (TSK), International Physical Activity Questionnaire (IPAQ), Minutes per week (MET), Global Rating of Change (GROC), Patient Specific Functional Scale (PSFS)

Table 2.3 Percentage of participants exceeding the MCID for improvement on select patient reported outcomes and odds ratios with 95% confidence intervals.

Variable	MCID	No Biofeedback	Biofeedback	OR (95% CI)
FAAM-ADL	>8%	36%	38%	1.1 (0.23, 5.37)
FAAM-Sport	>9%	64%	69%	0.8 (0.16, 3.99)
TSK	>5 points	0%	38%	18.8 (0.92, 393.1)
GROC Mid-Rehab	>3 points	36%	53%	2.1 (0.44, 9.8)
GROC Post-Rehab	>3 points	50%	92%	**12.0 (1.21, 118.9)**
PSFS Total Score	>2 points	57%	69%	3.0 (0.62, 14.61)

Abbreviations: Minimum Clinically Important Difference (MCID), Odds Ratio (OR), Confidence Interval (CI) Foot and Ankle Ability Measure (FAAM), Activities of Daily Living (ADL), Identification of Functional Ankle Instability (IdFAI), Tampa Scale of Kinesiophobia (TSK), Global Rating of Change (GROC), Patient Specific Functional Scale (PSFS)

FIGURES:

Figure 2.1 Consort flow chart for study procedures

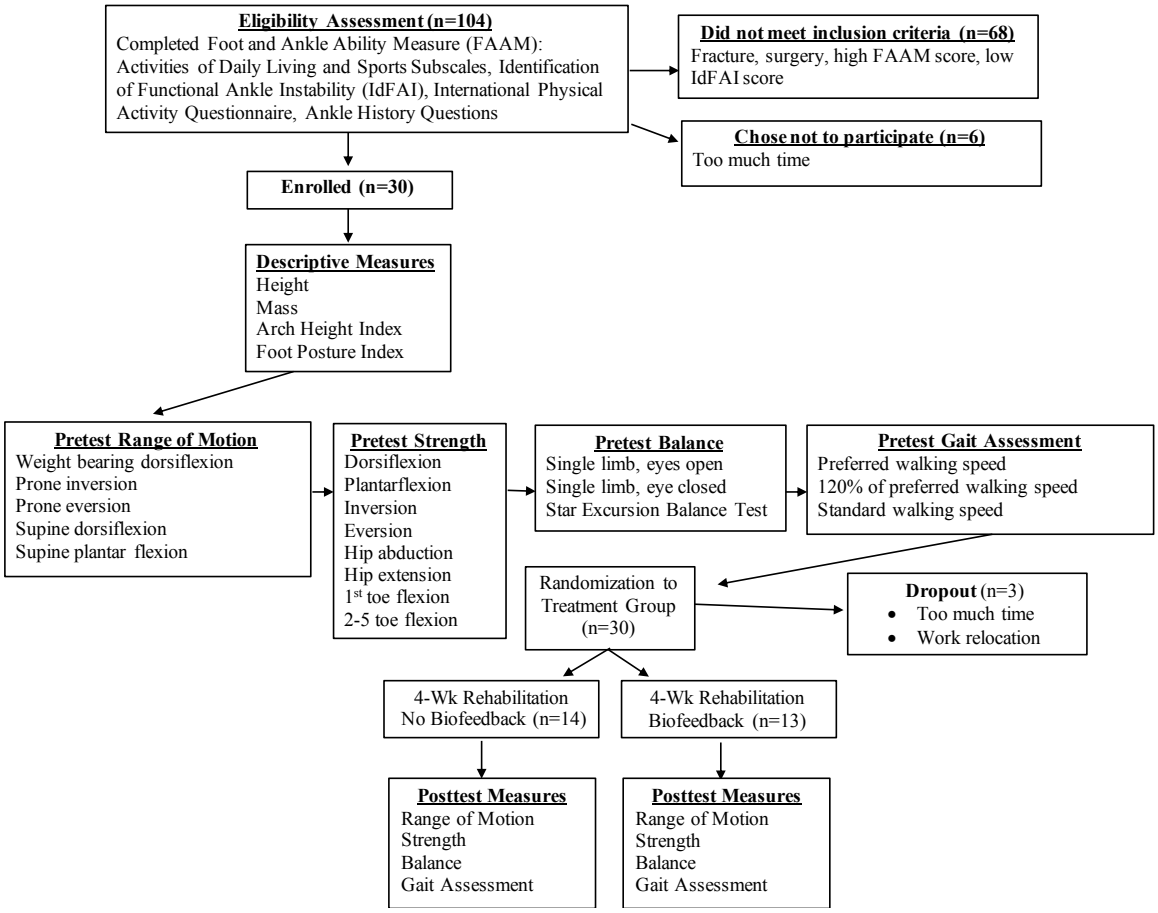


Figure 2.2 Participant setup and visual biofeedback intervention administration. Image on left demonstrates feedback for a "bad" step and image on right demonstrates feedback for a "good" step.

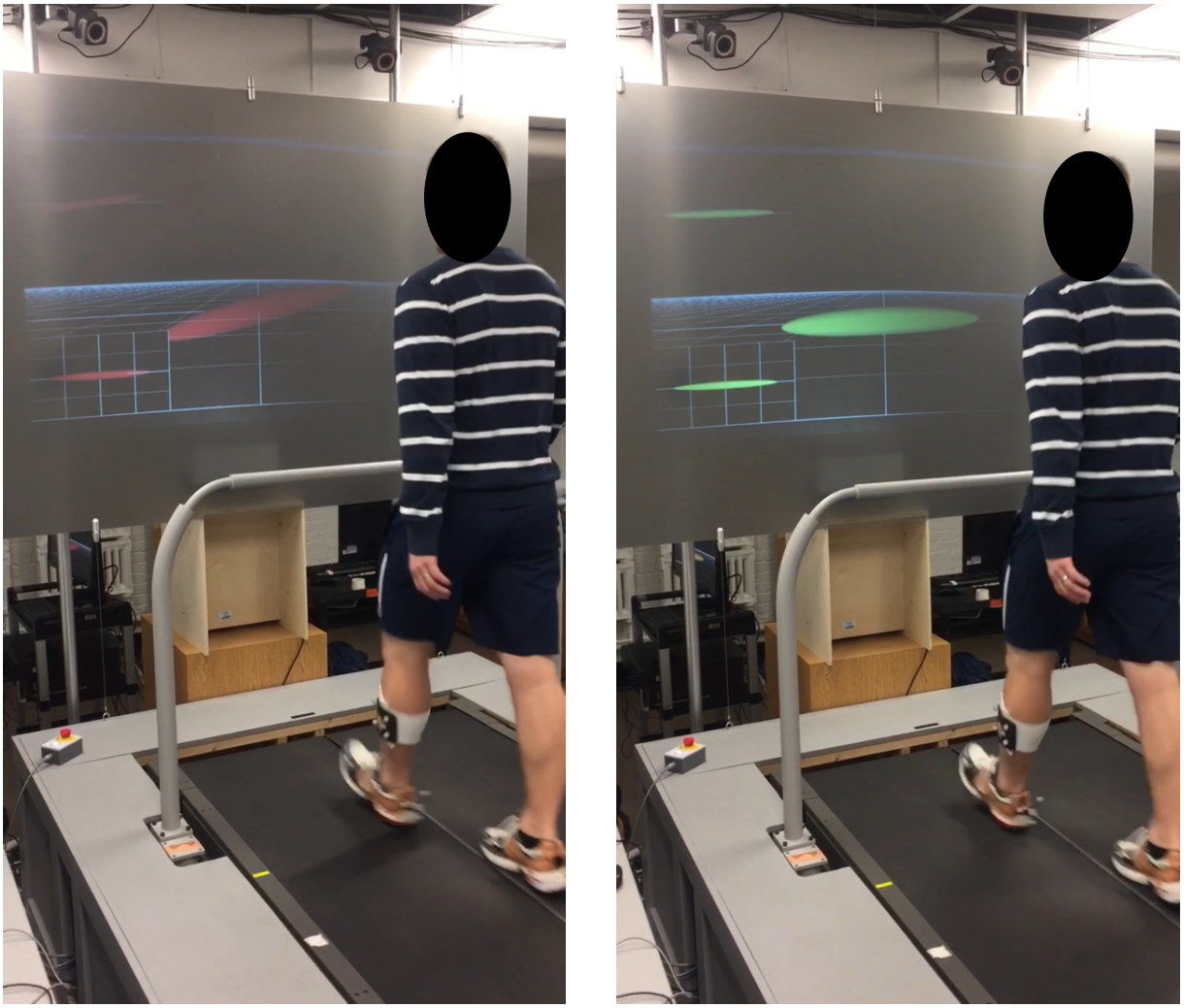
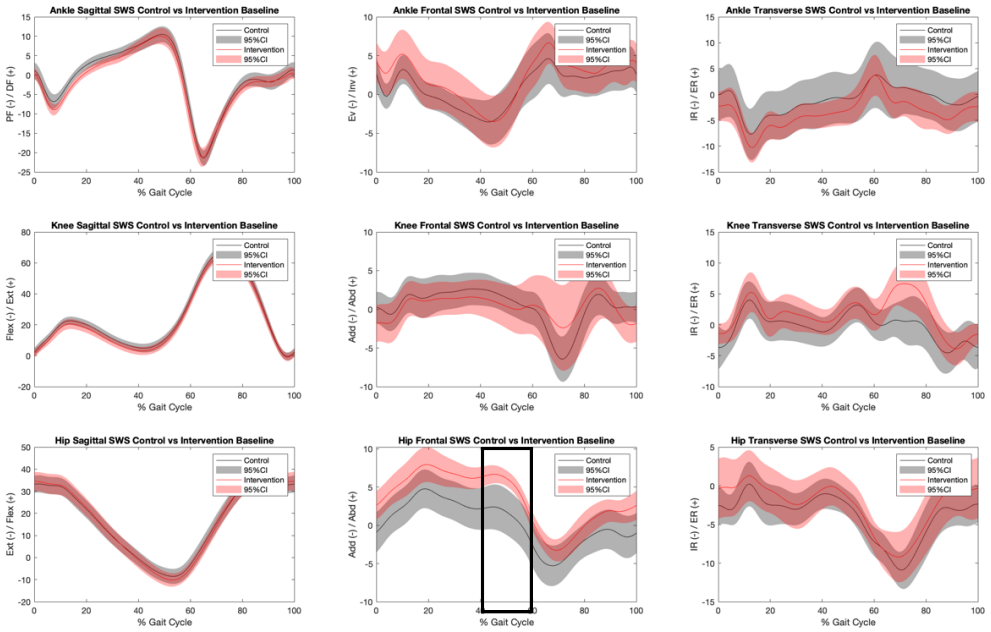


Figure 2.3 Kinematics for the no biofeedback and biofeedback groups at baseline (a) and follow-up (b).

a)



b)

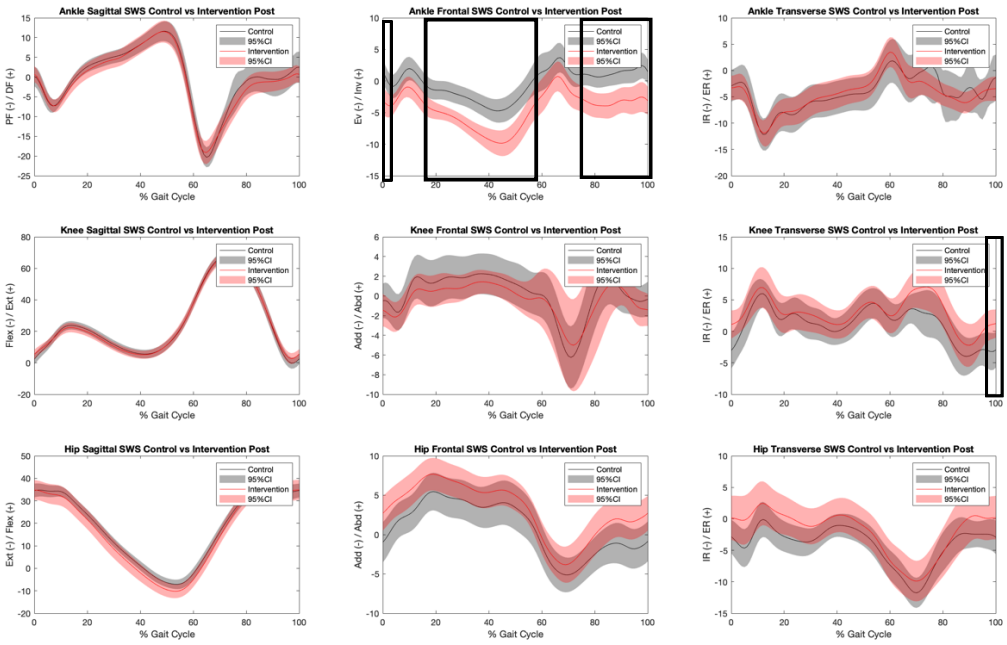
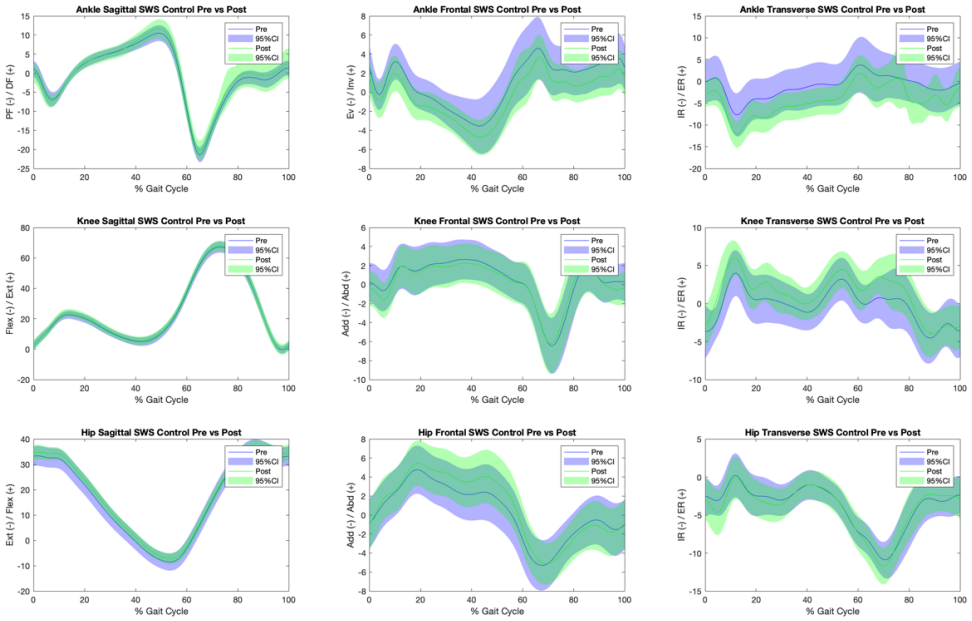


Figure 2.4 Kinematics for the no biofeedback (a) and biofeedback groups (b) for the baseline and follow-up comparisons.

a)



b)

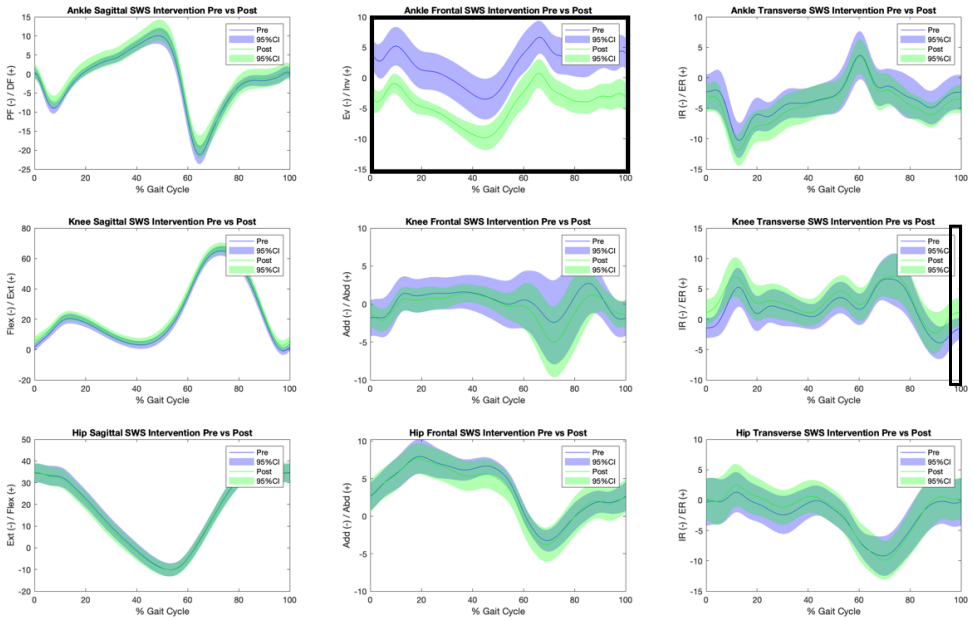
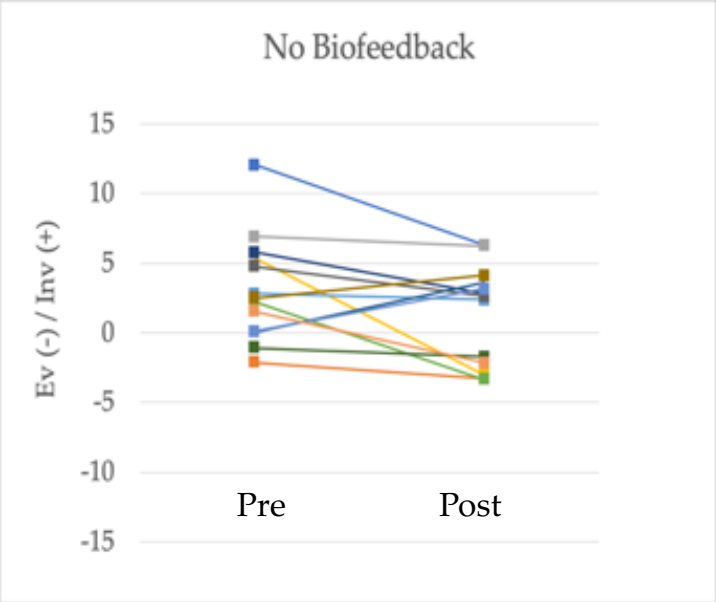
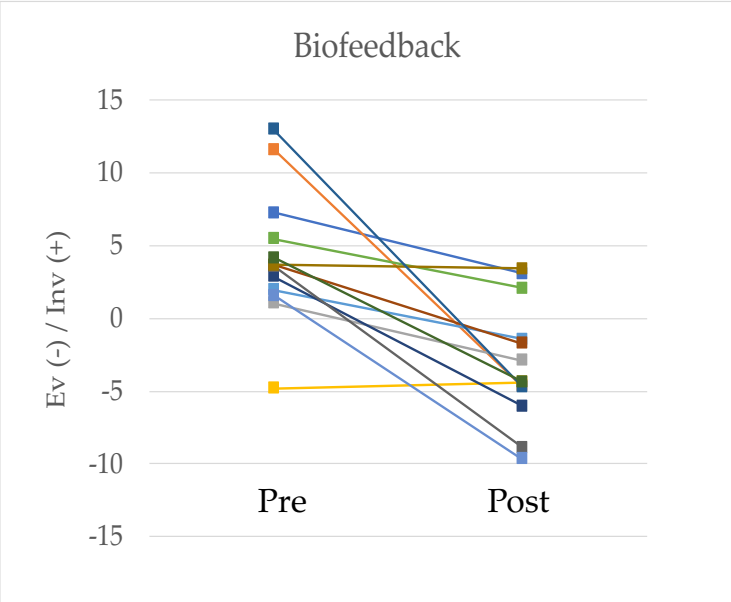


Figure 2.5 Ankle frontal plane angle at initial contact for the biofeedback and no biofeedback groups at baseline and follow-up.



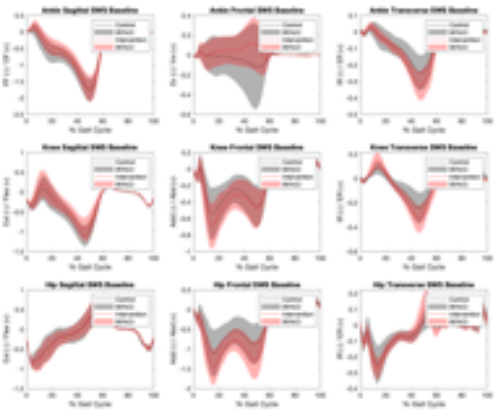
Pre: 2.6±4.2º
Post: 1.6±3.5º
g = 0.3



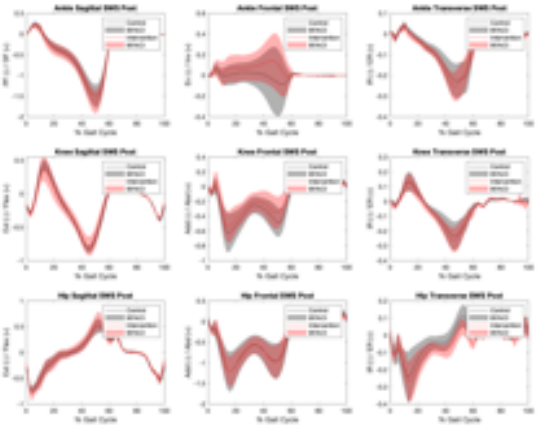
Pre: 4.2±4.6º
Post: -3.1±4.1º
g = 1.6

Figure 2.6 Kinetics for the no biofeedback and biofeedback group comparisons at baseline (a) and follow-up (b). EMG for the no biofeedback (c) and biofeedback groups (d) for the baseline and follow-up comparisons.

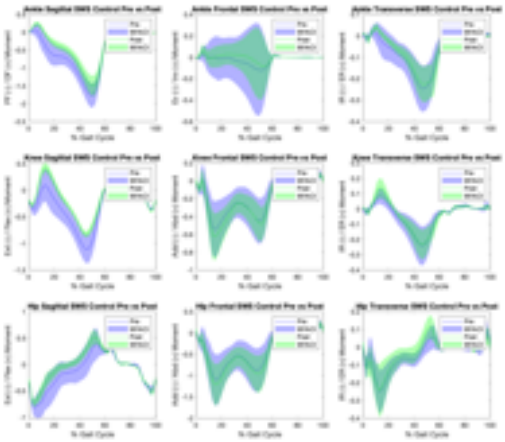
a)



b)



c)



d)

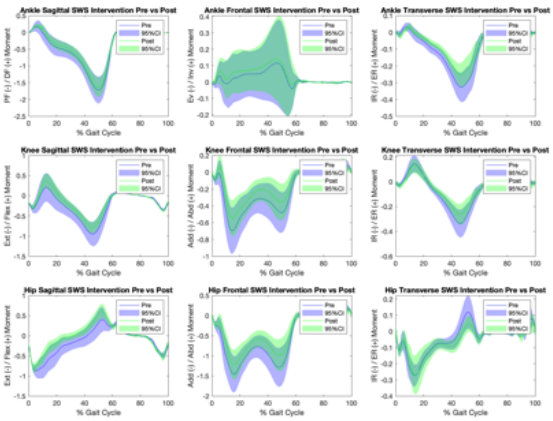
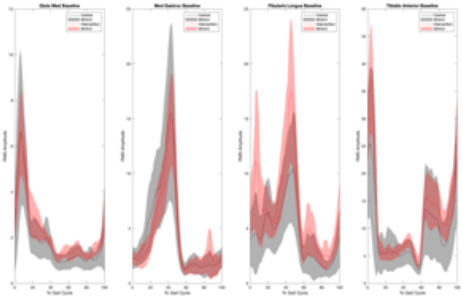
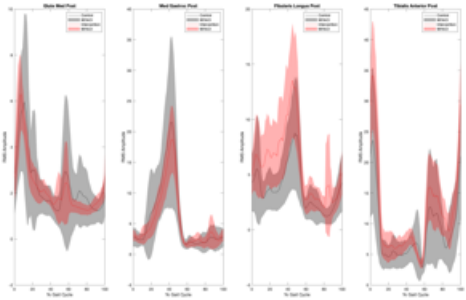


Figure 2.7 EMG for the no biofeedback and biofeedback group comparisons at baseline (a) and follow-up (b). EMG for the no biofeedback (c) and biofeedback groups (d) for the baseline and follow-up comparisons.

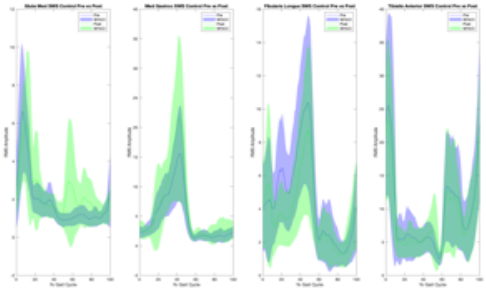
a)



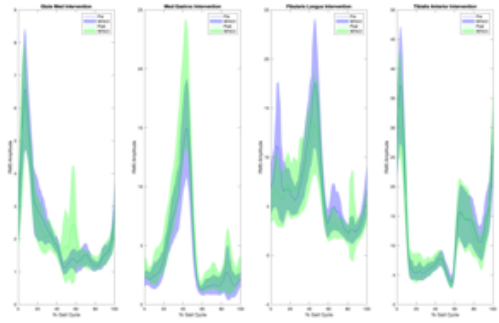
b)



c)



d)



SECTION II: MANUSCRIPT III

MIII: Effects of Gait Biofeedback and Impairment Based Rehabilitation on Clinical Measures in Individuals with Chronic Ankle Instability

ABSTRACT

Context: Individuals with chronic ankle instability (CAI) have decreased dorsiflexion range of motion (ROM), ankle eversion strength, and postural control. An impairment-based rehabilitation may be used to identify and treat patient-specific deficits in ROM, strength, balance, and functional activities.
Objective: To analyze the effects of 4-weeks of visual gait biofeedback and impairment-based rehabilitation compared to impairment-based rehabilitation alone on ROM, strength, and balance in individuals with CAI.
Design: Randomized controlled trial
Patients or Other Participants: Twenty-seven (14 no biofeedback (NBF), 13 gait biofeedback (GBF)) individuals with CAI participated.
Interventions: Both groups received 8 supervised sessions of impairment-based rehabilitation. The GBF group received visual biofeedback to reduce ankle inversion angle at initial contact (IC) during walking. The NBF group walked without biofeedback for the same amount of time.
Main Outcome Measures: Ankle ROM (dorsiflexion, plantarflexion, inversion, eversion), strength measures for ankle (dorsiflexion, plantarflexion, inversion, eversion), toes (flexion: 1st toe, toes 2-5), and hip (extension, abduction), and static balance (single leg balance: eyes open, eyes closed) and dynamic balance (Star Excursion Balance Test composite score) were assessed.
Results: The GBF group significantly increased in plantarflexion ROM (pre: 74.1 ±6.9º, post: 82.2±7.4º) compared to the NBF group (pre: 72.3±7.8º, post: 72.3±10.0º). Greater strength improvements (N/kg) were found in the GBF group for ankle inversion (GBF: pre: 2.3±0.6, post: 3.4±0.7; NBF: pre: 2.6±0.4, post 3.1±0.5), 1st toe flexion (GBF: pre: 1.1±0.3, post: 2.1±0.3; NBF: pre: 1.2±0.3, post 1.8±0.4), and hip abduction (GBF: pre: 1.9±0.5, post: 2.7±0.5; NBF: 2.3±0.5, 2.5±0.5) compared to the NBF group. There were no significant differences between the groups for balance measures.
Conclusion: Impairment-based rehabilitation in combination with visual GBF resulted in greater improvements in strength and ROM compared to the NBF group. This combination of visual GBF and impairment-based rehabilitation is recommended for individuals with CAI.

Word Count: 296

Introduction

Lateral ankle sprains (LAS) are among the most common musculoskeletal injuries in active populations[4,12,41,44] and have an estimated recurrence rate of 70%.[48] While LAS are prevalent and have high recurrence rates, unfortunately, many individuals perceive LAS to be an insignificant injury. One study showed that 55% of individuals with an LAS did not seek care from a healthcare professional after their initial injury.[37] Lack of care could contribute to the decreased neuromuscular function, poor postural control, and altered movement patterns seen in individuals with a history of LAS.[8,11,17] Lack of treatment may also result in long-term consequences such as decreased physical activity across the lifespan,[33] decreased quality of life,[3] and an earlier onset of ankle osteoarthritis.[23] Following a LAS, 40% of individuals develop a condition known as chronic ankle instability (CAI) and have lasting problems associated with their ankle injury.[11]

Several impairments, such as decreased range of motion (ROM), strength, postural control, and alterations during functional activities have been reported for individuals with CAI.[2,13,17,21,26,32,46] Individuals with CAI have been reported to have decreased dorsiflexion ROM which may negatively impact postural control and functional activities such as gait and landing mechanics.[9,16,30–32] Joint mobilizations and mobilizations with movement have been used to restore dorsiflexion ROM.[6,22,29,34]

Decreased ankle and hip strength have been identified in individuals with CAI in recent studies.[2,7,13,35,36,46] At the ankle, individuals with CAI have decreased eversion strength.[2,13,46] Donnelly et al.[13] showed that although eversion strength deficits exist, those with CAI used similar muscle activity measured by EMG which indicated that the

muscle activity did not translate to equivalent force production when compared to the healthy controls. Deficits in hip external rotation strength have also been associated with decreased performance on the Star Excursion Balance Test (SEBT).[36] In addition, decreased hip extension strength has been associated with an increased risk for sustaining a lateral ankle sprain in soccer athletes.[7] When strength training is incorporated into rehabilitation programs, individuals with CAI have shown to improve strength measures for the areas that were addressed.[15,27] Individuals with CAI have also demonstrated poor postural control when compared to ankle sprain copers and healthy controls.[10,42,45] This is concerning because postural control plays an important role in activities of daily living as well as higher level activities. Balance training programs have typically resulted in improvements in both static and dynamic postural control outcomes.[6,38]

Several studies have focused in just one area such as ROM, balance, or strength for the protocol and appear to make improvements in those specific domains.[1,6,27] For example, Cruz-Díaz et al.[6] evaluated the effects of 3-weeks of joint mobilizations for increasing ankle dorsiflexion ROM compared to a placebo and control group. The group that received the joint mobilizations had significant improvements in ankle dorsiflexion ROM, postural control, and self-reported instability while the other groups did not change.[6] Anguish and Sandrey[1] compared the effects of 2 4-week balance training protocols using a hop-to-stabilization balance program and a single-limb balance program. Both balance programs resulted in equal improvements in dynamic postural control.[1] Hall et al.[27] compared 6-weeks of strengthening exercises using resistance bands for one group and proprioceptive neuromuscular facilitation patterns for the other group. Both of the groups had improved ankle strength after completion of rehabilitation.[27]

It is clear that approaches targeted at specific areas of impairment improve the outcome of interest, however, taking a global approach using impairment-based rehabilitation may result in greater treatment effects and should be considered when treating individuals with CAI. Impairment-based rehabilitation focuses on identifying the individual patient's deficits and treating them based on their current state rather than treating all CAI patients with a common rehabilitation protocol. This approach better reflects how clinicians would normally treat an injured individual, but is not typically how rehabilitation protocols have been implemented in research.

Donovan et al.[14,15] assessed the effects of 4-weeks (12 sessions) of impairment-based rehabilitation with or without destabilization devices on ROM, balance, strength, and walking gait biomechanics for individuals with CAI. The intervention group wore the destabilization devices during rehabilitation exercises and during treadmill walking. There were no differences between the groups for self-reported function, ROM, strength, or balance, however, both groups demonstrated large improvements in their self-reported function questionnaires.[15] More importantly, however, were the findings that overall, the impairment-based rehabilitation improved patient-reported outcomes, strength, ROM, and dynamic balance more so than studies that performed specific interventions in an isolated manner.[15]

Our previous paper analyzed the effects of the biofeedback on gait mechanics and patient reported outcomes (M2). The purpose of this study was to evaluate the effects of 4-weeks of visual gait biofeedback and impairment-based rehabilitation on strength, ROM, and balance measures. We hypothesized that the biofeedback group and the no biofeedback group would both improve in ankle all strength measures, sagittal plane

ROM, and the composite score for SEBT, however, there would not be greater improvements in the GBF group.

Methods

Study Design

We performed a single-blinded randomized controlled trial to assess differences in clinical measures and patient-reported outcomes between a visual biofeedback group (GBF) and a no biofeedback (NBF) group. Our independent variables were group (GBF vs. NBF) and time (baseline vs. follow-up). Strength, balance, and ROM were assessed at baseline and follow-up.

Participants

Twenty-seven physically active individuals with CAI volunteered for this study and were part of a larger randomized controlled trial. Demographic information was reported in the prior manuscript (M2). CAI inclusion criteria followed recommendations of the International Ankle Consortium.[24] Succinctly, all participants had a history of at least 1 significant lateral ankle sprain at least 1 year prior to study enrollment, decreased self-reported function (Foot and Ankle Ability Measure (FAAM) Sport $\geq$85%), and feelings of instability or "giving way" (Identification of Functional Ankle Instability (IdFAI) >10).

Exclusion criteria consisted history of lower extremity fracture or surgery, ankle sprain within past 6 weeks, conditions known to affect gait, pregnancy, and currently receiving physical therapy. Study approval was granted by the university's Institutional Review. Participants gave consent prior to participation.

Instrumentation

Static balance was assessed using a pressure mat (Tekscan MatScan™ Pressure Mat, Tekscan Inc., Boston, MA, USA) and dynamic balance was measured using the Star Excursion Balance Test (SEBT) in the anterior, posteromedial and posterolateral directions.[28] Standard 8" and 12" plastic goniometers were used for ankle ROM measures. Strength was assessed using a handheld dynamometer (MicroFET2, Hoggan Scientific, Salt Lake City, UT, USA).

Procedures

Baseline & Follow-up Gait Assessment

Clinical assessments consisted of descriptive foot and ankle measures (FPI, AHI), ROM, balance, and strength. Passive ankle ROM was assessed using a plastic goniometer to measure dorsiflexion, plantarflexion, inversion, and eversion.[20] Weight bearing dorsiflexion (cm) was also assessed for ROM.[20]

Static and dynamic balance were assessed using single limb balance and the SEBT respectively. Single limb balance was performed on the Tekscan Pressure Mat while the participants stood with their arms across their chest and the contralateral limb bent and lifted from the ground. The participants were asked to stand as still as possible for the duration of the test. Participants performed 3 10-second trials with their eyes open, and 3 10-second trials with their eyes closed. The center of pressure velocity was analyzed. The participants performed the SEBT in 3 directions (anterior, posteromedial, posterolateral). Participants were given 3 practice trials in each direction prior to data collection using the testing procedures described by Gribble et al.[25] Three trials were collected for each direction. The average reach distance in each direction was then

normalized to leg length. A composite score was calculated by combining the average score for each direction.

Strength was assessed using methods of Fraser et al.[20] for ankle dorsiflexion, plantarflexion, inversion, and eversion, as well as for isolated 1st toe flexion, and toes 2-5 flexion. Hip abduction was assessed with the participant in the side lying position by placing the dynamometer 5 cm above the lateral malleolus and having the participant actively abduct their hip.[43] Hip extension was measured with the patient in the prone position and the knee flexed to 90º with the dynamometer placed on the posterior aspect of the distal thigh.[43] Three 5-second maximal voluntary isometric contractions were performed for each position. Participants were given adequate time to rest between each trial until they self-reported they felt ready to perform the next trial. The average of the strength measures for each position were normalized to the participant's body mass (N/kg).

After baseline data collection, participants were randomly assigned to treatment groups (GBF or NBF). A random-number generator was used to determine the randomization sequence for participants by a separate investigator (J.H.). Assignments were placed in sealed envelopes to ensure concealed allocations. The supervising clinician (A.F.D., A.H.J.) for the impairment-based rehabilitation was blinded to the gait biofeedback intervention status. The patient was not blinded to the GBF intervention, but was asked not to discuss group allocation with the impairment-based rehabilitation clinician.

Individuals began impairment-based rehabilitation sessions within 1-week after the baseline assessment. Follow-up assessments occurred 1-3 days after completion of the last rehabilitation session.

Impairment-Based Rehabilitation Protocol

The impairment-based rehabilitation protocol has been explained in detail in our prior manuscript (M2). Briefly, all participants began received 8 supervised sessions (2x/week) of impairment-based rehabilitation (Appendix C) adopted from Donovan et al.[15] Participants were evaluated by the supervising clinician during the initial rehabilitation session to determine the appropriate starting point for each exercise category. During each session thereafter, the participant was re-evaluated and progressed as considered appropriate by the supervising clinician to maximize the training stimulus received.

The supervising clinician performed a clinical assessment to determine if there were any arthrokinematic and osteokinematic restrictions. When restrictions were present, the clinician provided appropriate joint mobilizations (Maitland grade II and III) and prescribed stretching. Foot exercises included the short foot exercise, great toe extension, extension of toes 2-5, and toe extension and splay.[18] Heel raises, forefoot raises, 4-way manual resistance, D1/D2 PNF patterns, and heel/toe walks were performed for ankle strengthening. Quadruped, clamshells with resistance band, 4-way hip with resistance band, and seated internal/external rotation with resistance band were used to increase hip strength. For balance, participants performed single leg balance for time, reaching tasks, and hop to stabilization.[38] Participants completed functional exercises

consisting of lunges, forward and lateral step-ups and step-downs on a 30-cm box, and dot jumping drills.[15]

Participants were also given a home exercise plan (HEP) which has been explained in detail in M2 and appendix C.

Visual Biofeedback Intervention

The visual GBF intervention was extensively described in the prior manuscript (M2). Briefly, the visual GBF intervention goal was to reduce frontal plane ankle inversion at initial contact. The goal was to decrease ankle inversion at initial contact as much as possible by the end of the 8th training session. Participants were given feedback for the duration of the training session during the first 4 sessions. For the last 4 sessions, participants received intermittent feedback time that decreased for each following session. The maximum walking time was 20-minutes. The NBF group walked on the treadmill without biofeedback or instruction for the same amount of time for each session as the GBF group.

Statistical Analysis

Strength, balance, and ROM outcome measures at the post-rehabilitation time point were analyzed using an analysis of covariance (ANCOVA) with the baseline scores as the model covariate to compare between the GBF and NBF groups at the follow-up time point. All statistical analyses were analyzed using Statistical Package for Social Sciences (SPSS) version 24.0 (SPSS, Inc., Chicago, IL). The a priori level of significance was set at $p \leq 0.05$. Hedge's *g* effect sizes were calculated to determine the magnitude of difference between the groups at the post-rehabilitation time point. The effect sizes were interpreted as large (≥ 0.80), moderate (0.50-0.79), small (0.20-0.49), or trivial (≤ 0.19).[5]

Positive effect sizes indicate that the GBF group improved more than the NBF group at follow-up. Percent change scores with associated 95% confidence intervals were calculated to compare strength, balance, and ROM outcomes for each group from pre- to post-rehabilitation. The percent change scores were determined to be significant when the confidence intervals did not cross zero. Positive percent change scores indicate an increase from baseline to follow-up and negative percent change scores indicate a decrease from baseline to follow-up.

Results

There were statistically significant improvements in the GBF group at post-rehabilitation while accounting for baseline scores for ankle inversion ($p=0.049$, $g=0.68$), hip abduction ($p=0.047$, $g=0.86$), and 1st toe flexion ($p=0.025$, $g=0.87$) strength, and for plantarflexion ROM ($p=0.002$, $g=1.27$) compared to the NBF group when controlling for baseline scores (Table 1). There were no statistically significant differences at post-rehabilitation between the groups when accounting for baseline scores for any other measures. Based on percent change scores, in the NBF group, strength measures of plantarflexion, inversion, 1st toe flexion, and flexion of toes 2-5 increased and for balance the area and velocity with eyes closed improved (Table 1). In the GBF group, all strength measures increased except hip extension, plantarflexion ROM increased, and for balance the area and velocity in the eyes closed condition improved based on percent change scores from baseline to follow up (Table 1). There were no other significant differences in either group for strength, balance, and ROM from baseline to follow-up.

Discussion

Both groups improved for many of the strength and ROM measures at the follow-up time point based on percent change calculations, however, the primary findings of this study were the significantly greater improvements in plantarflexion ROM as well as several lower extremity strength measures in the GBF group compared to the NBF group. This is contrary to our original hypothesis that both groups would improve equally for strength and balance. Our results differ from those of Donovan et al.[15] that found no significantly greater improvements in the destabilization device group compared to the no device group for strength, balance, or ROM. The findings of our study are unique because we identified that the visual biofeedback gait training intervention had a significant and meaningful impact on strength measures of ankle inversion, 1st toe flexion, and hip abduction as well as plantarflexion ROM. The GBF group adapted a new gait pattern which resulted in a less inverted foot position throughout the entire gait cycle (M2). The substantial change in ankle position during walking gait (M2) may have contributed to the additional improvements in strength in several areas. The impairment-based rehabilitation program improved many of the outcome measures in both groups, however, the addition of gait training may be beneficial for added improvements in strength.

Both the GBF and NBF groups showed improvements in all strength measures which is consistent with previous investigations involving strength-training programs.[15,27,40] Our results in combination with prior research studies, demonstrate that improvements in strength outcomes can be made in as little as 4-weeks with 8 to 12 supervised rehabilitation sessions.[15,40] The GBF group had larger meaningful

improvements than the NBF group in ankle inversion (47.8% vs 19.2% increase), 1st toe flexion (90.9% vs 50% increase), and hip abduction strength (42.1% vs 8.7%) which may be the result of the changed movement patterns during walking (M2). The NBF group in our study had improvements in strength measures similar to those of Donovan et al.[15] and Powden et al.[40] with the exception of ankle eversion strength (Table 2). Powden et al.[40] performed a 4-week multimodal intervention that used balance training, ankle strengthening, and joint mobilizations for individuals with CAI. All participants performed the same rehabilitation exercises and were progressed at a standardized rate and there were no control or sham groups.[40]

The GBF group in our study had greater percent increase in all toe, ankle, and hip strength measures compared to the NBF group. In addition, the GBF group had greater percent increase in strength for ankle inversion and eversion compared to Donovan et al.[15] and in all ankle and hip strength measures compared Powden et al.[40] (Table 2). In our study, individuals likely had greater improvements in strength than Powden et al.[40] because our rehabilitation protocol was customized to each individual as opposed to all participants completing the same exercise regimen. Gait training using visual biofeedback in addition to impairment-based rehabilitation is recommended for greater improvements in lower extremity strength.

Deficits in ankle dorsiflexion ROM have been previously reported for individuals with CAI.[39] Both groups increased by 4-5º for dorsiflexion ROM, but there were not greater improvements in the GBF group. We identified a greater increase in plantarflexion ROM in the GBF group (8º increase) at follow-up compared to the NBF group. The NBF group did not change in plantarflexion ROM at follow-up compared to

baseline. When considering the total ROM in the sagittal plane, the joint excursion at follow up was greater in the GBF group compared to the NBF group (95º and 83º respectively). Fraser et al.[19] reported the total rearfoot sagittal excursion in healthy individuals to be 83.7º and 84.1º in individuals with CAI during a single session assessment. Increased plantarflexion at the time of initial contact during functional movement has been linked to an increased risk of sustaining a lateral ankle sprain,[47] however, it is unclear if the increase in passive plantarflexion ROM found in our GBF group is unsafe for individuals with CAI.

The groups were not significantly different at the follow-up time point for any of the balance measures The results for both static and dynamic balance in our study are similar to those of Donovan et al.[15] The negative percent change values reported in table 1 for the static balance measures indicate an improvement for the area and velocity outcome measures. For static single leg balance, the greatest improvements were seen in the eyes closed condition, which is not surprising as this task is increasingly more difficult than single leg balance with eyes open and there was more room for improvement through rehabilitation. Participants performed a variety of balancing exercises with eyes open and closed throughout the impairment-based rehabilitation. For the SEBT, both groups showed 5-7% increase in the composite score for reach distance. Donovan et al.[15] found similar results with the device and no-device groups increasing the SEBT composite score by 3-5% respectively. Our results were not directly comparable to those of Powden et al.[40] as they reported scores for each direction as opposed to a composite score, however, they found increased reach distances in all directions (anterior, posteromedial, posterolateral) after 4-weeks of a multimodal

rehabilitation program. Impairment-based rehabilitation and multimodal rehabilitation programs improve balance measures after 4-weeks.

Our study had a few limitations. Our statistical analysis focused on comparing group differences in outcome measures at follow-up and we did not test for a significant time main effect because we used the baseline scores as the covariate in our statistical model. We calculated percent change scores from baseline to follow up and the associated confidence intervals. Where confidence intervals did not cross zero, there was a significant improvement at follow-up compared to baseline. Over time, both groups appear to improve for the majority of the strength and ROM outcome measures (Table 1). In addition, physically active young adults participated in this study so the external validity of this study is limited to this population. We did not include a true control group and therefore we are unable to make comparisons from the impairment-based rehabilitation to the natural changes in CAI individuals over a 4-week period.

After 8-sessions of impairment-based rehabilitation, both groups (GBF, NBF) improved in strength, balance, and ROM. The GBF group had greater improvements at follow-up compared to the NBF group when controlling for baseline scores for ankle inversion, 1st toe flexion, and hip abduction strength. In addition, the GBF group had greater increases in plantarflexion ROM. Both groups also improved in static and dynamic balance after 4-weeks of impairment-based rehabilitation, but there were no significant differences between the groups. Impairment-based rehabilitation in addition to gait training with visual biofeedback resulted in greater improvements in strength and ROM.

References:

1. Anguish B, Sandrey MA. Two 4-Week Balance-Training Programs for Chronic Ankle Instability. *J Athl Train*. 2018;53(7):662-671. doi:10.4085/1062-6050-555-16.

2. Arnold BL, Linens SW, de la Motte SJ, Ross SE. Concentric Evertor Strength Differences and Functional Ankle Instability: A Meta-Analysis. *J Athl Train*. 2009;44(6):653-662. doi:10.4085/1062-6050-44.6.653.

3. Arnold BL, Wright CJ, Ross SE. Functional Ankle Instability and Health-Related Quality of Life. *J Athl Train*. 2011;46(6):634-641. doi:10.4085/1062-6050-46.6.634.

4. Clifton DR, Koldenhoven RM, Hertel J, Onate JA, Dompier TP, Kerr ZY. Epidemiological Patterns of Ankle Sprains in Youth, High School, and College Football. *Am J Sports Med*. October 2016:0363546516667914. doi:10.1177/0363546516667914.

5. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. Routledge; 1988.

6. Cruz-Díaz D, Lomas Vega R, Osuna-Pérez MC, Hita-Contreras F, Martínez-Amat A. Effects of joint mobilization on chronic ankle instability: a randomized controlled trial. *Disabil Rehabil*. 2015;37(7):601-610. doi:10.3109/09638288.2014.935877.

7. De Ridder R, Witvrouw E, Dolphens M, Roosen P, Van Ginckel A. Hip Strength as an Intrinsic Risk Factor for Lateral Ankle Sprains in Youth Soccer Players: A 3-Season Prospective Study. *Am J Sports Med*. 2017;45(2):410-416. doi:10.1177/0363546516672650.

8. Delahunt E, Monaghan K, Caulfield B. Altered Neuromuscular Control and Ankle Joint Kinematics During Walking in Subjects With Functional Instability of the Ankle Joint. *Am J Sports Med*. 2006;34(12):1970-1976.

9. Denegar CR, Hertel J, Fonseca J. The Effect of Lateral Ankle Sprain on Dorsiflexion Range of Motion, Posterior Talar Glide, and Joint Laxity. *J Orthop Sports Phys Ther*. 2002;32(4):166-173. doi:10.2519/jospt.2002.32.4.166.

10. Doherty C, Bleakley C, Hertel J, et al. Inter-joint coordination strategies during unilateral stance following first-time, acute lateral ankle sprain: A brief report. *Clin Biomech*. 2015;30(6):636-639. doi:10.1016/j.clinbiomech.2015.04.012.

11. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Recovery From a First-Time Lateral Ankle Sprain and the Predictors of Chronic Ankle Instability A Prospective Cohort Analysis. *Am J Sports Med*. 2016;44(4):995-1003.

12. Doherty C, Delahunt E, Caulfield B, Hertel J, Ryan J, Bleakley C. The Incidence and Prevalence of Ankle Sprain Injury: A Systematic Review and Meta-Analysis of Prospective Epidemiological Studies. *Sports Med*. 2014;44(1):123-140. doi:10.1007/s40279-013-0102-5.

13. Donnelly L, Donovan L, Hart JM, Hertel J. Eversion Strength and Surface Electromyography Measures With and Without Chronic Ankle Instability Measured in 2 Positions. *Foot Ankle Int*. 2017;38(7):769-778. doi:10.1177/1071100717701231.

14. Donovan L, Hart JM, Saliba S, et al. Effects of ankle destabilization devices and rehabilitation on gait biomechanics in chronic ankle instability patients: A randomized controlled trial. *Phys Ther Sport*. 2016;21:46-56. doi:10.1016/j.ptsp.2016.02.006.

15. Donovan L, Hart JM, Saliba SA, et al. Rehabilitation for Chronic Ankle Instability With or Without Destabilization Devices: A Randomized Controlled Trial. *J Athl Train*. 2016;51(3):233-251. doi:10.4085/1062-6050-51.3.09.

16. Drewes LK, McKeon PO, Casey Kerrigan D, Hertel J. Dorsiflexion deficit during jogging with chronic ankle instability. *J Sci Med Sport*. 2009;12(6):685-687. doi:10.1016/j.jsams.2008.07.003.

17. Evans T, Hertel J, Sebastianelli W. Bilateral Deficits in Postural Control following Lateral Ankle Sprain. *Foot Ankle Int*. 2004;25(11):833-839. doi:10.1177/107110070402501114.

18. Fraser JJ, Hertel J. Effects of a 4-Week Intrinsic Foot Muscle Exercise Program on Motor Function: A Preliminary Randomized Control Trial. *J Sport Rehabil*. January 2018:1-32. doi:10.1123/jsr.2017-0150.

19. Fraser JJ, Koldenhoven RM, Jaffri AH, et al. Foot impairments contribute to functional limitation in individuals with ankle sprain and chronic ankle instability. *Knee Surg Sports Traumatol Arthrosc*. July 2018:1-11. doi:10.1007/s00167-018-5028-x.

20. Fraser JJ, Koldenhoven RM, Saliba SA, Hertel J. RELIABILITY OF ANKLE-FOOT MORPHOLOGY, MOBILITY, STRENGTH, AND MOTOR PERFORMANCE MEASURES. *Int J Sports Phys Ther*. 2017;12(7):1134-1149.

21. Fu ASN, Hui-Chan CWY. Ankle Joint Proprioception and Postural Control in Basketball Players with Bilateral Ankle Sprains. *Am J Sports Med*. 2005;33(8):1174-1182. doi:10.1177/0363546504271976.

22. Gilbreath JP, Gaven SL, Van Lunen BL, Hoch MC. The effects of Mobilization with Movement on dorsiflexion range of motion, dynamic balance, and self-reported function in individuals with chronic ankle instability. *Man Ther*. 2014;19(2):152-157. doi:10.1016/j.math.2013.10.001.

23. Golditz T, Steib S, Pfeifer K, et al. Functional ankle instability as a risk factor for osteoarthritis: using T2-mapping to analyze early cartilage degeneration in the ankle joint of young athletes. *Osteoarthr Cartil OARS Osteoarthr Res Soc*. 2014;22(10):1377-1385. doi:10.1016/j.joca.2014.04.029.

24. Gribble PA, Delahunt E, Bleakley C, et al. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Br J Sports Med*. 2014;48(13):1014-1018.

25. Gribble PA, Hertel J, Denegar CR, Buckley WE. The Effects of Fatigue and Chronic Ankle Instability on Dynamic Postural Control. *J Athl Train*. 2004;39(4):321-329.

26. Gribble PA, Hertel J, Plisky P. Using the Star Excursion Balance Test to Assess Dynamic Postural-Control Deficits and Outcomes in Lower Extremity Injury: A Literature and Systematic Review. *J Athl Train*. 2012;47(3):339-357.

27. Hall EA, Docherty CL, Simon J, Kingma JJ, Klossner JC. Strength-Training Protocols to Improve Deficits in Participants With Chronic Ankle Instability: A Randomized Controlled Trial. *J Athl Train*. 2014;50(1):36-44. doi:10.4085/1062-6050-49.3.71.

28. Hertel J, Braham RA, Hale SA, Olmsted-Kramer LC. Simplifying the Star Excursion Balance Test: Analyses of Subjects With and Without Chronic Ankle Instability. *J Orthop Sports Phys Ther*. 2006;36(3):131-137. doi:10.2519/jospt.2006.36.3.131.

29. Hoch MC, Andreatta RD, Mullineaux DR, et al. Two-week joint mobilization intervention improves self-reported function, range of motion, and dynamic balance in those with chronic ankle instability. *J Orthop Res*. 2012;30(11):1798-1804. doi:10.1002/jor.22150.

30. Hoch MC, Farwell KE, Gaven SL, Weinhandl JT. Weight-Bearing Dorsiflexion Range of Motion and Landing Biomechanics in Individuals With Chronic Ankle Instability. *J Athl Train*. 2015;50(8):833-839. doi:10.4085/1062-6050-50.5.07.

31. Hoch MC, McKeon PO. Joint mobilization improves spatiotemporal postural control and range of motion in those with chronic ankle instability. *J Orthop Res*. 2011;29(3):326-332. doi:10.1002/jor.21256.

32. Hoch MC, Staton GS, Medina McKeon JM, Mattacola CG, McKeon PO. Dorsiflexion and dynamic postural control deficits are present in those with chronic ankle instability. *J Sci Med Sport*. 2012;15(6):574-579. doi:10.1016/j.jsams.2012.02.009.

33. Hubbard-Turner T, Turner MJ. Physical Activity Levels in College Students With Chronic Ankle Instability. *J Athl Train*. April 2015. doi:10.4085/1062-6050-50.3.05.

34. Kosik KB, Gribble PA. The Effect of Joint Mobilization on Dynamic Postural Control in Patients With Chronic Ankle Instability: A Critically Appraised Topic. *J Sport Rehabil*. 2018;27(1):103-108. doi:10.1123/jsr.2016-0074.

35. McCann RS, Bolding BA, Terada M, Kosik KB, Crossett ID, Gribble PA. Isometric Hip Strength and Dynamic Stability of Individuals With Chronic Ankle Instability. *J Athl Train*. 2018;53(7):672-678. doi:10.4085/1062-6050-238-17.

36. McCann RS, Crossett ID, Terada M, Kosik KB, Bolding BA, Gribble PA. Hip strength and star excursion balance test deficits of patients with chronic ankle instability. *J Sci Med Sport*. 2017;20(11):992-996. doi:10.1016/j.jsams.2017.05.005.

37. McKay GD, Goldie PA, Payne WR, Oakes BW. Ankle injuries in basketball: injury rate and risk factors. *Br J Sports Med*. 2001;35(2):103-108.

38. Mckeon PO, Ingersoll CD, Kerrigan DC, Saliba E, Bennett BC, Hertel J. Balance Training Improves Function and Postural Control in Those with Chronic Ankle Instability. *Med Sci Sports Exerc*. 2008;40(10):1810-1819. doi:10.1249/MSS.0b013e31817e0f92.

39. Plante JE, Wikstrom EA. Differences in clinician-oriented outcomes among controls, copers, and chronic ankle instability groups. *Phys Ther Sport*. 2013;14(4):221-226. doi:10.1016/j.ptsp.2012.09.005.

40. Powden CJ, Hoch JM, Jamali BE, Hoch MC. A 4-Week Multimodal Intervention for Individuals With Chronic Ankle Instability: Examination of Disease-Oriented and Patient-Oriented Outcomes. *J Athl Train*. December 2018. doi:10.4085/1062-6050-344-17.

41. Roos KG, Kerr ZY, Mauntel TC, Djoko A, Dompier TP, Wickstrom EA. The Epidemiology of Lateral Ligament Complex Ankle Sprains in National Collegiate Athletic Association Sports. *Am J Sports Med*. August 2016:0363546516660980. doi:10.1177/0363546516660980.

42. Terada M, Beard M, Carey S, et al. Nonlinear Dynamic Measures for Evaluating Postural Control in Individuals With and Without Chronic Ankle Instability. *Motor Control*. October 2018:1-19. doi:10.1123/mc.2017-0001.

43. Thorborg K, Petersen J, Magnusson SP, Hölmich P. Clinical assessment of hip strength using a hand-held dynamometer is reliable. *Scand J Med Sci Sports*. 2010;20(3):493-501. doi:10.1111/j.1600-0838.2009.00958.x.

44. Waterman BR. The Epidemiology of Ankle Sprains in the United States. *J Bone Jt Surg Am*. 2010;92(13):2279. doi:10.2106/JBJS.I.01537.

45. Wikstrom EA, Fournier KA, McKeon PO. Postural control differs between those with and without chronic ankle instability. *Gait Posture*. 2010;32(1):82-86. doi:10.1016/j.gaitpost.2010.03.015.

46. Willems T, Witvrouw E, Verstuyft J, Vaes P, De Clercq D. Proprioception and Muscle Strength in Subjects With a History of Ankle Sprains and Chronic Instability. *J Athl Train*. 2002;37(4):487-493.

47. Wright IC, Neptune RR, van den Bogert AJ, Nigg BM. The influence of foot positioning on ankle sprains. *J Biomech*. 2000;33(5):513-519. doi:10.1016/S0021-9290(99)00218-3.

48. Yeung MS, Chan KM, So CH, Yuan WY. An epidemiological survey on ankle sprain. *Br J Sports Med*. 1994;28(2):112-116.

TABLES:

Table 3.1 Results for strength, ROM, and balance for the no biofeedback and biofeedback groups (means±SD) and between group Hedges *g* effect sizes. Positive effect sizes indicate greater improvements in the biofeedback group. Positive percent change indicates an increase and negative percent change indicates a decrease. † indicates 95% confidence interval does not cross zero.

	No Biofeedback Group			Biofeedback Group			Group Main Effect *P* Value	Between Group Hedges *g* Effect Size
Variable	Pre-rehabilitation	Post-rehabilitation	% change at follow-up (95% CI)	Pre-rehabilitation	Post-rehabilitation	% change at follow-up (95% CI)		
Strength (N/kg)								
1st Toe Flexion	1.2±0.3	1.8±0.4	50.0 (23.7, 76.3)†	1.1±0.3	2.1±0.3	90.9 (59.0, 122.9)†	**0.025**	0.87
2-5 Toe Flexion	1.3±0.3	1.7±0.4	30.8 (8.2, 53.3)†	1.2±0.4	2.0±0.4	66.7 (31.4, 101.9)†	0.071	0.72
Dorsiflexion	3.6±0.6	3.8±0.6	5.6 (-7.1, 18.2)	2.9±0.9	3.6±0.4	24.1 (1.9, 46.4)†	0.112	0.37
Plantarflexion	6.5±1.4	7.8±1.4	20.0 (2.4, 37.6)†	6.6±1.6	8.5±1.1	28.8 (9.5, 48.0)†	0.169	0.55
Inversion	2.6±0.4	3.1±0.5	19.2 (5.3, 33.2)†	2.3±0.6	3.4±0.7	47.8 (21.1, 74.5)†	**0.049**	0.68
Eversion	2.5±0.5	3.9±3.0	56.0 (-8.9, 120.9)	2.0±0.7	3.3±0.5	65.0 (30.8, 99.2)†	0.716	0.13
Hip Abduction	2.3±0.5	2.5±0.5	8.7 (-8.1, 25.5)	1.9±0.5	2.7±0.5	42.1 (17.2, 67.0)†	**0.047**	0.86
Hip Extension	3.8±0.7	4.0±0.8	5.3 (-9.7, 20.3)	3.7±0.8	4.2±0.7	13.5 (-3.3, 30.4)	0.419	0.32
ROM								
Weightbearing								
Dorsiflexion (cm)	11.7±3.1	13.9±3.7	18.8 (-4.5, 42.2)	10.6±3.9	12.7±4.2	19.8 (-12.4,52.0)	0.961	0.02
Dorsiflexion (º)	7.8±8.2	11.6±7.2	48.7 (-46.2, 143.8)	8.7±9.9	13.8±12.0	58.6 (-64.9, 182.1)	0.516	0.24
Plantarflexion (º)	72.3±7.8	72.3±10.0	0.0 (-9.2, 9.2)	74.1±6.9	81.4±5.7	9.8 (2.9, 16.8)†	**0.003**	0.92
Inversion (º)	31.6±9.7	34.4±9.9	8.9 (-15.1, 32.9)	34.7±13.3	31.0±11.3	-10.7 (-36.4, 15.0)	0.341	0.36
Eversion (º)	14.0±8.4	13.0±3.9	-7.1 (-39.8,25.5)	9.6±5.9	13.7±8.3	42.7 (-24.2,109.7)	0.616	0.19
Balance								
Static Balance								
Eyes Open								
Area (cm^2)	4.0±2.1	3.8±2.7	-5.0 (-48.9,38.9)	4.6±3.9	3.4±1.3	-26.1 (-63.5, 11.3)	0.606	0.23
Velocity (cm/s)	3.3±1.0	3.1±1.2	-6.1 (-30.25, 18.1)	3.2±1.2	2.6±0.6	-18.5 (-38.2, 0.7)	0.208	0.54
Eyes Closed								
Area (cm^2)	17.6±6.9	13.0±4.7	-26.1 (-46.8, -5.5)†	20.4±9.7	12.9±7.1	-36.8 (-61.8, -11.8)†	0.606	0.19
Velocity (cm/s)	8.7±2.2	6.9±1.7	-20.7 (-35.4, -6.0)†	8.5±2.9	6.6±2.1	-22.4 (-42.0, -2.7)†	0.690	0.20
Dynamic Balance								
SEBT Composite Score (%)	71.7±8.2	79.2±5.6	7.5 (-0.3, 15.3)	72.6±7.6	77.8±5.5	5.2 (-2.2, 12.6)	0.292	0.41

Table 3.2 Percent change for pre- to post-rehabilitation strength measures for various 4-week rehabilitation programs including strengthening exercises.

	IBR and Biofeedback	IBR and no Biofeedback	IBR and destabilization device (Donovan et al.)	IRB and no destabilization device (Donovan et al.)	Multimodal Rehabilitation (Powden et al.)
Dorsiflexion	24.1%	5.6%	22.2%	13.0%	9.8%
Plantarflexion	28.8%	20.0%	22.3%	12.3%	21.8%
Inversion	47.8%	19.2%	29.5%	30.3%	20.3%
Eversion (neutral)	65.0%	56.0%	30.4%	21.7%	22.1%
Hip Abduction	42.1%	8.7%	-	-	8.9%
Hip Extension	13.5%	5.3%	-	-	10.8%

Abbreviation: Impairment-based rehabilitation (IBR)

SECTION III: APPENDICES

APPENDIX A

The Problem

Lateral ankle sprains are a common musculoskeletal injury in athletic populations as well as the general public. Following an initial lateral ankle sprain (LAS), many individuals do not seek care from a medical professional. Lack of care could contribute to the decreased neuromuscular function, poor postural control, and altered gait patterns seen in individuals with a history of LAS.[4,10] Following an initial LAS, 40% of individuals develop chronic ankle instability (CAI)[15] which involves feelings of instability or "giving way, decreased self-reported function, and recurrent sprains. Individuals with CAI have been shown to have deficits in range of motion, sensorimotor control, proprioception, postural control, and strength.[38]

Several studies have focused in just one area such as ROM, balance, or strength for the protocol and appear to make improvements in those specific domains.[1,6,36] For example, Cruz-Díaz et al.[6] evaluated the effects of 3-weeks of joint mobilizations for increasing ankle dorsiflexion ROM compared to a placebo and control group. The group that received the joint mobilizations had significant improvements in ankle dorsiflexion ROM, postural control, and self-reported instability while the other groups did not change.[6] Anguish and Sandrey[1] compared the effects of 2 4-week balance training protocols using a hop-to-stabilization balance program and a single-limb balance program. Both balance programs resulted in equal improvements in dynamic postural control.[1] Hall et al.[36] compared 6-weeks of strengthening exercises using resistance bands

for one group and proprioceptive neuromuscular facilitation patterns for the other group. Both of the groups had improved ankle strength after completion of rehabilitation.[36]

Focusing treatment in only one of the areas of where deficits lie may not actually improve the patient's overall condition. Impairment-based rehabilitation takes a more clinically applicable approach and uses an "asses, treat, re-assess" protocol to target patient-specific deficits.[21] An impairment-based rehabilitation program has previously shown to improve range of motion, balance, strength, and patient reported outcomes associated with CAI.[20,21] Thus, taking a global treatment approach using impairment-based rehabilitation to intervene where deficits are observed is necessary.

During walking gait, CAI patients demonstrate alterations in neuromuscular control, plantar pressure, kinematics, and spatial-temporal measures compared to healthy controls.[10,10,27,30,44,50] Over time this may present a larger problem as walking is a primary form of locomotion and a common daily activity. During walking, individuals with CAI may be at risk for subsequent ankle sprains due to the inverted position of the foot and ankle during terminal swing and at initial contact (IC).[4] Several factors may contribute to the compromised foot position during gait including altered muscle function, laxity of the lateral ankle ligaments, and decreased proprioception.[38,50,52,77] Individuals with CAI have been shown to be 6-7º more inverted prior to IC during walking than their healthy counterparts.[10] While it is important to understand how individuals with CAI compare to an uninjured control, it has been suggested that comparing to a group with the same initial injury that has learned to successfully cope may be more appropriate approach when considering potential treatment techniques.[73] Copers are individuals who have had

a lateral ankle sprain but have learned to cope with the injury and return to pre-injury levels of function.[73]

Traditionally, gait deficits have been targeted with strength or balance training but these interventions have not been successful at correcting gait mechanics. Likewise, Davis and Futrell note that strength training without neuromuscular reeducation rarely translates to changes in movement patterns.[4] Simple forms of feedback such as holding a mirror in front of a treadmill or using audio cues have been shown to change gait.[4,18] These are techniques that could be implemented in the clinic setting and used to correct altered gait patterns. It has become apparent that in order to change gait mechanics, we need to perform specific gait training.

With the advancements in technology, it is now possible to provide real-time visual feedback to participants through computer monitors or projector screens that reflect the motion of the subject. A study by Noehren et al.[18] looked at the effects of real-time gait retraining on hip kinematics in patients with patellofemoral pain and found that pain and function in participants were improved following gait retraining. The participants completed 8 sessions over 2 weeks and walked on a treadmill while their hip adduction angle of the involved limb was displayed on a monitor throughout the stance phase. They were given instruction to keep their superimposed hip angle within the shaded area (indicating $\pm$1SD of mean of healthy individuals). They used intermittent feedback which has been shown to have better long-term effects than subjects who receive continuous immediate feedback.[18] During the first 4 sessions participants received 100% continuous immediate feedback and then had faded feedback for the remaining sessions.[18] Runners were able to decrease their hip adduction, internal rotation,

and contralateral pelvic drop following the retraining and were able to maintain changes at the 1-month follow up visit.[18] Focusing treatment to adopt a safer movement pattern by reducing the ankle inversion angle during walking may translate to improvements in self-reported function and reduced feelings of instability during activities of daily living.

To our knowledge, only two published studies have used audio or visual cues to provide feedback during walking gait.[7,19] Donovan et al[7] used auditory biofeedback to alert participants when too much force was placed under the lateral aspect of the foot. Participants were instructed to walk in a way that would not trigger the audible cue.[7] When walking in the auditory feedback condition, the participants with CAI demonstrated large decreases in peak pressure and pressure time integral in the lateral midfoot and forefoot and increases in the hallux.[7] More recently, Torp et al.[19] used a shoe mounted laser to provide visual biofeedback during walking. Individuals with CAI were instructed to alter their gait pattern so that the laser projected on the wall in front of them did not rotate to the right or left of a vertical target. When participants received the external biofeedback, they were able to shift the location of COP medially by 1-2 mm and reduce peak pressure forces on the lateral aspect of the mid- and forefoot.[19] Both of these studies showed that individuals with CAI could alter their gait while feedback was provided during a single intervention session, however, it is unknown how gait training using these techniques impact gait biomechanics after several intervention sessions and after the biofeedback is removed.

For individuals with CAI, it may be beneficial to provide visual feedback to teach safer foot and ankle positioning around the timing of IC. When the foot contacts the ground in an increasingly inverted position, an ankle sprain could potentially occur.

Therefore, addressing the position of the ankle at IC could be beneficial in adapting less risky motor patterns ultimately reducing the risk of subsequent ankle sprains.

Specific Aim #1: to simultaneously compare gait kinematics, kinetics, and sEMG during treadmill walking at three speeds (preferred walking speed (PWS), 120% of PWS (120WS), and a standardized walking speed (SWS)) between individuals with CAI and copers.

Hypothesis #1: The CAI group would have a more inverted foot position during walking gait than the coper group. Gait would be impacted spatiotemporally by the faster walking speeds and that group differences would become larger as walking speed increased and became more challenging.

Specific Aim#2: To evaluate the effects of 4-weeks of a visual gait biofeedback intervention and impairment-based rehabilitation on gait biomechanics and PROs between biofeedback and no biofeedback groups

Hypothesis#2: The biofeedback group would have a reduced ankle inversion angle at IC that would also translate to a less inverted position throughout the remainder of the stride cycle. In addition, the no biofeedback group would not significantly change their gait kinematics from baseline to follow-up time points. Lastly, we hypothesized that both groups would have equal improvements in patient-reported outcomes after completing rehabilitation.

Specific Aim#3: To evaluate the effects of 4-weeks of audiovisual gait training and impairment-based rehabilitation on strength, ROM, and balance between biofeedback and no biofeedback groups

Hypothesis#3: The biofeedback group and the no biofeedback group would have the same improvements for strength, balance, and ROM.

ASSUMPTIONS

- Participants will be honest when answering all questions related to inclusion and exclusion criteria
- Participants will perform to the best of their ability during baseline and follow-up assessments
- Participants will walk as normally as possible during gait assessment
- Participants will give their best effort during the rehabilitation and gait biofeedback sessions (if allocated to the biofeedback group)
- Measurement tools will accurately collect the data

DELIMITATIONS

- Participants were limited by our inclusion and exclusion criteria
- All were between 18-30 years of age
- All were physically active
- Participants were recruited from the university and the surrounding community area
- Participants were not currently seeking physical therapy or medical
- Gait assessments were performed wearing standard laboratory shoes and walked at a standardized speed

LIMITATIONS

Study 1

The speed at which individuals walked may have been impacted by lack of exposure to a split belt treadmill. The study was originally powered to identify differences between the groups for ankle inversion kinematics and did not account for the kinetic and EMG variables.

Study 2

The study was powered to identify pre- to post-intervention differences for ankle inversion angle at initial contact (the primary dependent variable) and not for kinetic or sEMG measures. Our study had primarily female participants, however, this is reflective of the higher incidence rate of ankle sprains in females compared to males.

Study 3

Our statistical analysis focused on comparing group differences in outcome measures at follow-up and we did not test for a significant time main effect because we used the baseline scores as the covariate in our statistical model. We instead calculated percent change scores from baseline to follow up and the associated confidence intervals. We did not include a true control group and therefore we are unable to make comparisons from the impairment-based rehabilitation to the natural changes in CAI individuals over a 4-week period.

SIGNIFICANCE OF THE STUDY

This project will help clinicians in determining appropriate treatment strategies for individuals with CAI in addition to what is already utilized. There is a large gap in the literature regarding gait training in this population. This project is innovative and will help to advance the athletic training profession by determining if gait training in addition to impairment-based rehabilitation is effective at addressing common gait deficits or if impairment-based rehabilitation alone may be useful. This project will also aim to test the theory that "to change gait we need to train gait." Many manuscripts conclude that gait training should be considered as a possible treatment for the deficits in gait for individuals with CAI,[7,8,15,22] however, there are only published results from two studies utilizing gait training in this population.[7,8] Lastly, this study will allow for the investigation of whether it is possible to alter the foot position at IC. If we can change the position of the rearfoot at IC, we could potentially develop a simpler gait training tool that would be easily accessible to clinicians who are treating these individuals regularly.

APPENDIX B

Literature Review

The purpose of this literature review is to: 1. Review the epidemiology and etiology of lateral ankle sprains, 2. Define copers and chronic ankle instability and discuss characteristics associated with each condition, 3. Describe impairment-based rehabilitation, and 4. Examine how alterations in gait have been previously addressed.

1.) Epidemiology and Etiology of Lateral Ankle Sprains

Lateral ankle sprains (LAS) are among the most common musculoskeletal injuries in active populations[4,15,59,64] and have an estimated recurrence rate of 70%.[74] Individuals between the ages of 15-19 have been noted to have the highest occurrence of an ankle sprain injury.[64] In collegiate athletes, LAS was the most common injury reported and comprised 7.3% of all injuries in a study using data from the National Collegiate Athletic Association Injury Surveillance Program.[59] Ankle sprains are also common among other active populations such as military recruits.[65] Females have been shown to have a higher incidence of ankle sprains (13.6 vs. 6.94 per 1,000 exposures)[15] compared to their male counter parts.

While LAS are prevalent and have high recurrence rates, unfortunately, many individuals perceive LAS to be an insignificant injury. One study showed that 55% of individuals with an LAS did not seek care from a healthcare professional after their initial injury.[50] Lack of care could contribute to the decreased neuromuscular function, poor postural control, and altered gait patterns seen in individuals with a history of LAS.[3,9] Lack of treatment may also result in long-term consequences such as decreased physical activity across the lifespan,[42] decreased quality of life,[122] and an earlier onset of ankle

osteoarthritis.[30] Following a LAS, 40% of individuals develop a condition known as chronic ankle instability (CAI) and have lasting problems associated with their ankle injury.[14] In contrast, some individuals will fully recover after a LAS and return to normal pre-injury activity levels with no ongoing instability. These individuals are called copers.[66] While these are two groups used to classify individuals with a history of a LAS, it is also important to understand that some individuals may not be distinctly classified as being a coper or having CAI, but fall somewhere on the spectrum in between these two groups.

Copers

Copers are defined as individuals with a history of previous LAS who do not experience symptoms of instability or recurrent injury after an ankle sprain.[66] Wikstrom and Brown[66] conducted a systematic review to determine the discrepancies and common standards for inclusion and exclusion criteria of copers in the CAI literature. An additional purpose of the study was to make recommendations for inclusion and exclusion criteria, operationally define, and provide important reporting criteria for inclusion of copers in future studies.[66] The recommended components for defining copers were 1) an initial LAS, 2) lack of symptoms associated with CAI such as "giving way" or instability and 3) no LAS, disability, or giving way episodes within the last the last 12 months.[66] Traditionally, individuals with CAI have been compared with uninjured healthy control participants, however, this may not be the best comparison group. Copers may be a more appropriate comparison group, especially when considering recommendations for rehabilitation or treatment, because they have been exposed to the same initial injury but have not developed instability or have recurrent sprains.

Chronic Ankle Instability

CAI is a condition with which individuals have residual symptoms such as pain or weakness, feelings of instability, and decreased self-reported function due to their ankle injury.[31] Individuals with CAI have demonstrated deficits with dorsiflexion range of motion, eversion strength, and postural control.[41] In addition to these deficits, there are alterations that have been reported during functional activities which are discussed below. This condition encompasses both mechanical and functional deficiencies of the ankle joint.[34] The International Ankle Consortium has published guidelines for the classification of CAI which were developed as a standard for defining this condition for researchers and clinicians.[31] The following inclusion and exclusion criteria help to identify patients that meet the requirements for a heterogeneous sample of individuals with CAI. Standardizing the minimum criteria for inclusion and exclusion ensures that the participants classified as having CAI remains consistent across studies.

The consortium recommends the following as inclusion criteria for CAI: 1) a history of at least one significant ankle sprain that occurred at least 12-months prior to study enrollment that was associated with inflammatory symptoms and created at least one interrupted day of desired physical activity 2) the previously injured ankle joint has feelings of 'giving way' or 'instability' 3) and decreased self-reported ankle or foot function.[31] Several questionnaires are considered to be acceptable for inclusion using the following cut-off points: for the Identification of functional ankle instability (IdFAI) questionnaire a score of >11, a Foot and Ankle Ability Measure (FAAM) ADL scale <90% and FAAM Sport scale <80%.[31] The Ankle Instability Instrument, Cumberland

Ankle Instability Tool, and the Foot and Ankle Outcome Score are also acceptable questionnaires to be used.[31]

In addition to the recommended inclusion criteria, the consortium has a set of standard exclusion criteria in which they have endorsed. The following criteria should be excluded: 1) history of surgery or fracture to either lower extremity and 2) acute injury to the structures of other joints in the lower extremity within the previous 3 months that impacted joint integrity and function that resulted in at least 1 day of interrupted physical activity.[31]

Characteristics of CAI

Several impairments, such as decreases in range of motion (ROM), strength, postural control, and functional activities have been reported for individuals with CAI.[1,16,23,27,32,38,69] Individuals with CAI have been reported to have decreased dorsiflexion ROM which negatively impacts postural control as well as several functional activities such as gait and landing mechanics.[10,21,36–38] The lack of dorsiflexion ROM has been associated with an anterior positional fault of the fibula that may prevent the ankle from reaching a more ideal closed-packed position.[40,68] Joint mobilizations and mobilizations with movement have traditionally been used to address this impairment.[5,28,35,46]

Decreased ankle and hip strength have also been identified in individuals with CAI in recent studies.[1,8,16,48,49,69] At the ankle, individuals with CAI tend to have decreased eversion strength.[1,16,69] Donnelly et al.[16] showed that although eversion strength deficits exist, those with CAI used similar muscle activity measured by EMG which indicated that the muscle activity did not translate to equivalent force production when compared to the healthy controls. Deficits in hip external rotation strength have

also been associated with decreased performance on the Star Excursion Balance Test (SEBT).[49] Decreased hip extension strength has also been associated with an increased risk factor for sustaining a lateral ankle sprain in a prospective study of youth soccer athletes.[8] Rehabilitation programs should consider implementing strengthening exercises for the ankle and hip to improve strength as well as to facilitate improvements in functional tasks that rely on proper muscle function in the lower extremity.

Individuals with CAI have demonstrated poor postural control when compared to ankle sprain copers and uninjured individuals.[11,62,67] This is concerning because postural control is an important component of activities of daily living as well as higher level activities. Balance training programs have typically resulted in improvements in both static and dynamic postural control outcomes.[5,51] Targeted approaches used in research studies seem to improve the outcome of interest, however, taking a multimodal approach may result in greater treatment effects and should be considered when treating individuals with CAI.

2.) Gait alterations associated with ankle sprain & CAI

Gait is a common area of study likely due to its importance during various activities of daily living and recreational activities. In general, following an injury, individuals will alter their movement patterns to avoid pain or potential reinjury. Many studies have been conducted to better understand the effects of LAS on walking and running gait biomechanics. Individuals with CAI have demonstrated differences in kinematic, kinetic, and muscle activity measures compared to individuals free from LAS.

Kinematics

During walking, individuals with a history of ankle sprain demonstrate kinematic alterations in both sagittal[3,13,61] and frontal[7,9,54] planes when compared to their healthy counterparts or their uninjured limb. A recent systematic review summarized that during walking, individuals with CAI had a more inverted rearfoot and ankle position and had increased plantarflexion during various portions of the gait cycle.[53]

In the frontal plane, those with CAI have demonstrated a more inverted ankle or foot position during various portions of the stride cycle.[12,22,54,57] At initial contact, participants with CAI have been shown to be approximately 6-7º more inverted than a healthy control group.[54] These individuals were not only more inverted, but were inverting at a faster rate (0.5 rad/s) while the healthy control individuals were actually everting (0.1 rad/s) their ankle.[54] In another study, individuals with functional ankle instability were about 3-4º more inverted around the timing of initial contact than a healthy control group while walking barefoot on a treadmill.[9] A similar study by Drewes et al.[22] found comparable results with the CAI group exhibiting 2º of increased inversion throughout the entire gait cycle. In addition, they found that individuals with CAI patients had less consistent movement patterns during terminal swing portion of the gait cycle which could put the ankle at increased risk for injury.[22] Increased knee sagittal-ankle frontal plane joint coupling variability has also been identified during the gait cycle (51-66%, 81-88%).[47] Excessive inversion at initial contact and increased variability throughout the stride cycle may further subject individuals to recurrent LAS.[9,22,54,57]

In contrast, Herb et al.[33] found a decrease in shank-rearfoot stride-stride variability CAI subjects during late stance, toe off and early swing phase during walking gait.[33] One potential explanation for a less variable position may be that individuals with

CAI attempt to create a stable position for the ankle in preparation for contact with the ground but this may not be a beneficial coping strategy.[33] A more rigid system that cannot adapt properly to external changes may contribute to the chronic instability that CAI subjects incur.[33]

One study has reported individuals with CAI to have a more everted ankle position when using a rigid foot model.[7] This study also identified that CAI participants were more inverted by an average of 9 º from 87-98% of the stance phase when considering the medial forefoot in relation to the midfoot.[7] The authors speculated that these conflicting results could be due to a compensation mechanism to overcome an unstable feeling, however, these results are yet to be reproduced by any studies.[7]

In the sagittal plane, individuals with CAI have been shown to walk with less dorsiflexion (3º) from mid to late stance (42-51% gait cycle) compared to a healthy control group.[3] This altered ankle position during gait has the potential to be problematic because dorsiflexion allows the ankle to achieve the closed-packed position in which the ankle joint is most stable. Impaired dorsiflexion range of motion could contribute to recurrent sprains affecting individuals with CAI as increased plantarflexion may increase the changes of suffering an inversion ankle sprain.[72]

Currently only two studies describe the gait differences between ankle sprain copers and individuals with ankle instability.[12,71] One study identified that the functional ankle instability group had about 3º more forefoot inversion just after initial contact when compared to a healthy group, but there were no differences when compared to the copers.[71] The other study identified an increase in ankle inversion during the toe off phase of gait in the CAI group compared to the copers.[12] At the same time point,

individuals with CAI had decreased hip extension and increased knee flexion.[12] At initial contact, individuals with CAI demonstrated increased hip flexion, but no other differences at the ankle or knee were identified during this time point.[12]

Kinetics

Kinetics have not been as extensively studied as kinematics for gait analysis in individuals with CAI. Individuals with CAI have been found to have increased lateral plantar pressure during walking which is likely related to their inverted foot position described in several studies.[39,45,55] Hopkins et al.[39] identified a lateral deviation in the center of pressure at initial contact and from 25-90% of the stance phase for individuals with CAI. Furthermore, a similar study using pressure insoles identified a more lateral location of (COP) throughout the entire stance phase, increased peak pressure, and increased pressure-time integral in the lateral forefoot in the CAI group.[45] In a follow-up study, the authors also found that individuals with CAI had a more variable location of COP during the loading response which may be associated with a more variable foot position at the time of initial contact.[44] Another study examined the pronation-supination index which indicates where the pressure is located in relation to the midline of the foot.[55] The researchers performed the gait analysis using a pressure mat and found an increase in adduction-supination of the foot during mid-stance suggesting a more supinated foot position during walking.[55]

Only one study has examined kinetics at the proximal joints in addition to the ankle. Monaghan et al.[54] did not identify any significant differences in kinetics at the hip or knee joints in the sagittal, frontal, or transverse planes between the individuals with CAI and the healthy controls. They identified an evertor moment at the ankle in the CAI

group when the control group exhibited an invertor moment. Although the methods and outcome measures varied between the studies, it is evident that there are alterations in the kinetics of individuals with CAI. The more inverted and plantarflexed foot position during walking in addition to the lateral plantar pressures may put the ankle in a compromised position during a simple every day task.

Surface Electromyography

CAI subjects have demonstrated altered neuromuscular control when compared to healthy controls.[9,24,39,45] Fibularis muscle activation has been a popular area of study for these individuals likely due to the role the muscle plays in everting the ankle while in an open chain position and pronating the foot during the stance phase. Several studies have identified increased fibularis activity around initial contact, during stance, and at toe off.[9,39,45] It has been suggested that increased fibularis longus activation is a strategy used by those with ankle instability to counteract the supinated position of the foot during the stance phase.[9]

Earlier time of activation in various lower extremity muscles has been identified in CAI.[24] They tested the tibialis anterior, fibularis longus, lateral gastrocnemius, rectus femoris, biceps femoris, and gluteus medius and identified the onset of activation was earlier (but not always significant) in all muscle groups tested.[24] In addition to being activated earlier, the fibularis longus muscle was activated for significantly more time throughout the cycle which may be a coping strategy used by those with CAI, but it may have consequences as well.[24] In addition, individuals with CAI have demonstrated a more consistent amplitude for the fibularis muscle suggesting a more constrained motor pattern.[44] By activating the muscle earlier in the gait cycle and with decreased variability

from stride to stride, individuals may have a decreased ability to use the muscle for pronation during the weight baring phase of walking. This may also lead to an early onset for muscle fatigue during higher level activities.

Santilli et al.[60] also studied activation patterns of the fibularis longus during gait in those with unilateral functional ankle instability and compared results to the contralateral uninjured limb rather than a control group. They found a decrease in fibularis longus activation time which is contradictory to Delahunt et al.[9], Feger et al.[24] and Hopkins et al.[39] but may be due to the differences in methodology and subjects tested.

Alterations have also been examined for the more proximal musculature of the lower extremities. Individuals with CAI have demonstrated increased gluteus medius activation amplitude during the late stance and early swing phase of walking gait[45] as well as increased variability in sEMG amplitude.[43] Kautzky et al.[43] studied muscle recruitment variability during walking for the anterior tibialis, fibularis longus, lateral gastrocnemius, rectus femoris, biceps femoris, and gluteus medius. There was decreased activation amplitude variability for the tibialis anterior, fibularis longus, and biceps femoris and increased activation amplitude variability for the rectus femoris.[43] Prior to initial contact, the CAI group had more variability in gluteus medius activation amplitudes.[43] There are not currently any studies that assess the differences in muscle activation between copers and individuals with CAI.

3.) Impairment-Based Rehabilitation

Research studies commonly target only one area in their rehabilitation protocols, however, taking a global approach may have a greater impact on the overall treatment

effects. Focusing treatment in only one of the areas of where deficits lie may not actually improve the patient's condition overall. Impairment-based rehabilitation uses an "assess, treat, re-assess" approach to target deficits and has previously shown to improve patient reported outcomes associated with CAI.[19,20] Thus, taking a comprehensive treatment approach using impairment-based rehabilitation to intervene where deficits are observed is essential.

A variety of rehabilitation techniques have been used to address specific impairments in individuals with CAI. Many rehabilitation protocols focus on a specific domain and use the same protocol for all research participants involved. While many show improvements in the targeted area of interest, it is important to address all of the impairments that are present. Additionally, not all individuals present with the same impairments. For example, one individual may have a lack in dorsiflexion range of motion and would benefit from routine stretching and possibly joint mobilizations, while another individual may not have this problem and would not need treatment in this area.

Impairment-based rehabilitation is a way to identify the individual's deficits and treat them based on their current state rather than treating them the same as all others who also have CAI. This approach better reflects how clinicians would typically treat an injured individual, but is not typically how rehabilitation protocols are implemented on the research side of things. While impairment-based rehabilitation is not as common in research yet, few studies have shown improvements in CAI and in individuals with patellofemoral pain (PFP).[18,19,29]

Donovan et al.[18,19] performed 4-weeks (12 sessions) of impairment-based rehabilitation for individuals with CAI. In addition to impairment-based rehabilitation,

they incorporated destabilization devices for the intervention group to determine if there was added benefit from the devices for ROM, balance, strength, and walking gait biomechanics.[18,19] The intervention group wore the destabilization devices during rehabilitation exercises and during treadmill walking. There were no differences between the groups for self-reported function, ROM, strength, or balance, however, both groups demonstrated large improvements in their self-reported function questionnaires.[19] Therefore, there were not additional treatment effects from wearing the destabilization devices compared to not wearing the destabilization devices.[19] More importantly however, were the findings that overall, impairment-based rehabilitation improved patient-reported outcomes, strength, ROM, and dynamic balance more so than studies that performed specific interventions in an isolated manner.[19]

For the gait parameters, the device group increased their dorsiflexion during mid-late stance and had lower sEMG amplitude for the fibularis longus muscle during early stance and mid-swing compared to their baseline values. While there were improvements in sagittal plane motion for the destabilization device group, there were no improvements for frontal plane ankle kinematics for either group.[18] It is apparent that rehabilitation alone, without specified gait training, is unable to improve frontal plane kinematics during walking.

Glaviano et al.[29] also studied the effects impairment-based rehabilitation in patellofemoral pain participants on subjective function, pain, strength, ROM and physical activity levels. In addition to impairment-based rehabilitation, the intervention group received patterned electrical neuromuscular stimulation (PENS) and the control group received a sham treatment. Both groups significantly improved in subjective function,

pain, strength, and ROM at post rehabilitation compared to their baseline scores.[29] The PENS group had improved levels of current pain at both 6- and 12-months post rehabilitation compared to their baseline scores, but did not improve in clinical measures more than the sham treatment group.[29] The authors of this study also compared their results to those using more isolated intervention strategies and found that with impairment-based rehabilitation there were greater improvements in subjective function and pain 1 year post rehabilitation, strength measures at the knee and hip at post rehabilitation.[29] Therefore, it appears that a comprehensive impairment-based rehabilitation protocol may be advantageous for increasing the overall treatment effect for individuals with CAI and patellofemoral pain.

4.) Addressing Gait Alterations in CAI

It has been established that individuals with CAI demonstrate altered biomechanics during walking. Gait training has been suggested by several researchers as a way to address both hip and ankle alterations with hopes to reduce the risk of recurrent ankle sprains.[73] Traditionally, gait deficits have been targeted with strength or balance training but these interventions have not been successful at correcting frontal plane kinematics.[52,58] Likewise, Davis and Futrell[6] have noted that strength training without neuromuscular reeducation rarely translates to changes in movement patterns.

Few studies have been conducted in individuals with CAI that have focused on improving gait biomechanics.[17,19,25,63] Auditory and external visual cues have been used as forms of real-time biofeedback.[17,63] For the study using auditory feedback, individuals walked on a treadmill wearing a sensor on the lateral aspect of the shoe that detected the amount of pressure under that portion of the foot.[17] When participants placed too much

pressure on the lateral portion of the foot, they received an auditory cue indicating the pressure was above the set threshold.[17] While wearing the auditory feedback device, individuals with CAI were able to decrease their lateral plantar pressure and also increased the fibularis longus muscle activity.[17]

In another study, Torp et al.[63] used a shoe mounted laser to provide visual feedback during walking. Individuals with CAI were instructed to alter their walking so that the laser vertically aligned with a piece of tape on the wall in front of them and did not rotate to the right or left. When participants received the external biofeedback, they were able to shift the location of COP medially by 1-2 mm and reduce peak pressure forces on the lateral aspect of the mid- and forefoot.[63] Both of these studies showed that individuals with CAI could alter their gait while feedback was provided, however, it is unknown how gait training using these techniques would be impacted after several sessions of biofeedback.

Other gait training studies have not used modes of biofeedback, but rather used devices while walking to challenge individuals with CAI.[19,25,26] Donovan et al.[19] used destabilization devices that place the foot into a plantarflexed and inverted position to challenge the ankle position during activity. Participants also underwent 4-weeks of impairment based rehabilitation.[19] They wore the destabilization devices during rehabilitation exercises and during treadmill walking to determine if the devices were capable of improving ankle, knee, and hip kinematics, kinetics, as well as lower leg sEMG measures when compared to a no device group.[19] The key findings from this study showed that the device group increased in dorsiflexion during mid-late stance, but frontal plane motion was not improved for either group.[19] In addition, they identified a decrease

in fibularis brevis muscle activity following 4-weeks of rehabilitation during walking in the device group. [19]

A novel gait training device designed for users to resist a medial directed force from resistance bands placed at the lower leg during walking has been tested in individuals with CAI during a single session and after 5 gait training sessions.[25,26] Gait mechanics were examined during walking using the device[26] and while walking without the device after the 5 gait training sessions were completed.[25] While participants walked against resistance from the novel gait training device, they exhibited a shift in medial plantar pressure and increased muscle activity for the fibularis longus and the gluteus medius muscles.[26] Although the authors found differences while wearing the device, it was also important to understand the impact of the gait training once the stimulus has been removed. In their follow up study, patients underwent 5 gait training sessions using the device. Similar results to the original study were found after the gait training sessions.[25] They again found a medial shift in the location of COP from 10% of stance through toe-off that was likely related the increases in fibularis longus muscle activity throughout various portions of stance and increased gluteus medius muscle activity during late stance.[25] In addition to the overall improvements with gait mechanics, individuals also had improved self-reported function following the gait training sessions compared to their baseline measures.[25]

With the advancements in technology, it is now possible to provide real-time visual feedback to participants through computer monitors or projector screens that reflect the real-time motion of the subject. A study by Noehren et al.[56] looked at the effects of real-time gait retraining on hip kinematics in patients with patellofemoral pain

and found that pain and function in participants were improved following gait retraining. The participants completed 8 sessions over 2 weeks and ran on a treadmill while their hip adduction angle of the involved limb was displayed on a monitor throughout the stance phase.[56] They were given instruction to keep their superimposed hip angle within the shaded area (indicating mean$\pm$1 SD of mean of healthy individuals).[56] They used intermittent feedback which has been shown to have better long-term effects than subjects who receive continuous immediate feedback.[56] During the first 4 sessions participants received 100% continuous immediate feedback and then had progressively reduced intermittent feedback for the remaining 4 sessions (Figure 2).[56] Runners were able to decrease their hip adduction, internal rotation, and contralateral pelvic drop following the retraining and were able to maintain changes at the 1-month follow up visit.[56] Similar concepts could be adapted to address the altered kinematics in individuals with CAI.

For individuals with CAI, it may be beneficial to provide visual feedback about the ankle inversion angle at IC to train individuals to walk with a safer foot position. When the foot contacts the ground in an increasingly inverted position, an ankle sprain could potentially occur. Therefore, addressing the position of the ankle at IC could be beneficial in adapting less risky motor patterns ultimately reducing the risk of subsequent ankle sprains.

Weinstein[72] previously defined motor learning as "a set of internal processes associated with practice or experience leading to a relatively permanent change in the capability for responding." These processes are thought to be "complex central nervous system phenomena whereby sensory and motor information is organized and integrated."

Because traditional rehabilitation techniques have not successfully addressed the altered mechanics during walking, it appears that gait training using biofeedback focused on reducing ankle inversion would be appropriate.

Conclusion

In summary, LAS are a common injury that may or may not result in CAI. Individuals who develop CAI have a range of deficits in ROM, strength, balance, and during functional tasks.[19] When rehabilitation is implemented there are generally improvements for the measure of interest, however, taking a multimodal global approach may improve the overall treatment effects.[20] During walking, individuals with CAI have demonstrated a more inverted foot position and lateral forces under the foot.[53] Gait training has been suggested to improve gait mechanics, however no studies have specifically targeted and measured the frontal plane ankle motion during or after gait training. Framing rehabilitation and gait training efforts to resemble results seen in LAS copers may be beneficial. Reducing ankle inversion for CAI individuals should be done by using targeted gait training strategies. Improvements in frontal plane ankle gait mechanics could ultimately reduce the risk of recurrent sprains.

APPENDIX C

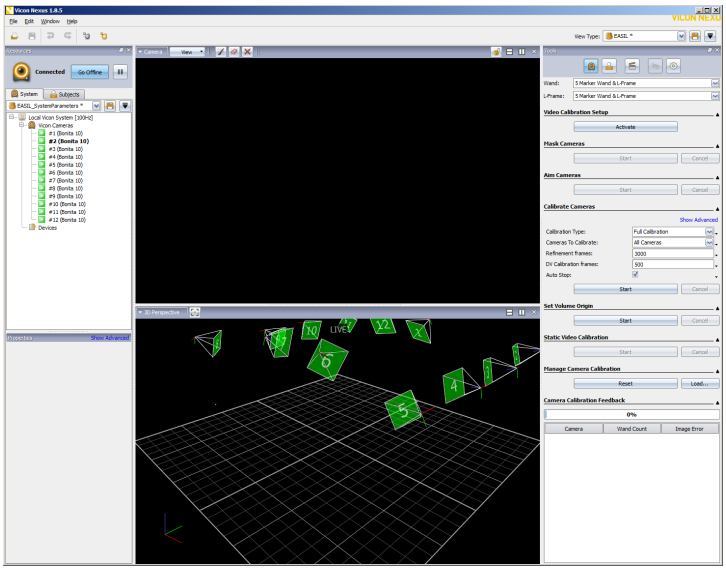
Additional Methods

Table C1

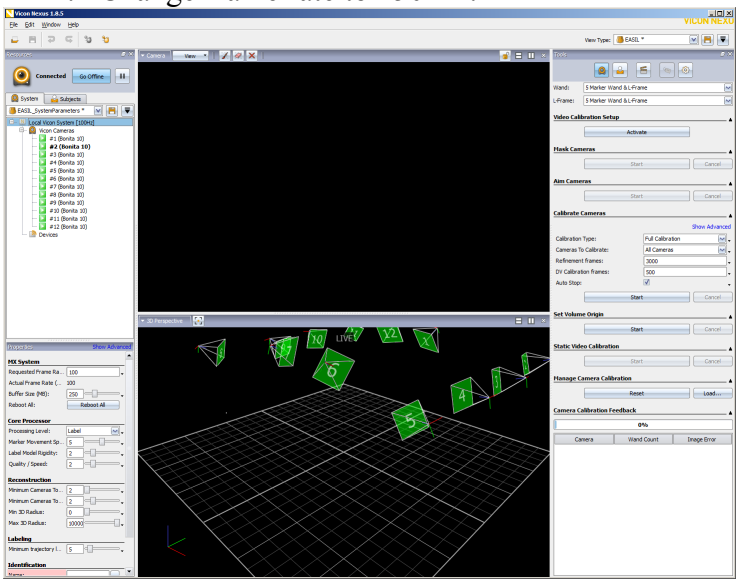
1. **Questionnaires**
    a. Foot and Ankle Ability Measure
        i. Activities of Daily Living
        ii. Sport Subscale
    b. Identification of Functional Ankle Instability
    c. Tampa Scale of Kinesiophobia
    d. International Physical Activity Questionnaire
    e. Patient Specific Functional Scale
    f. Global Rating of Change Score
    g. Ankle history questions
        i. Total number of ankle sprains
        ii. Time since first sprain
        iii. Time since last sprain
2. **Descriptive Measures**
    a. Age
    b. Height
    c. Mass
3. **Gait Assessment**

Vicon and MotionMonitor Setup Using the Cluster Markers

1. Turn on computer and open Vicon Nexus
    a. Make sure all cameras are green
    b. If any cameras are not green, unplug and reinsert corresponding camera cable



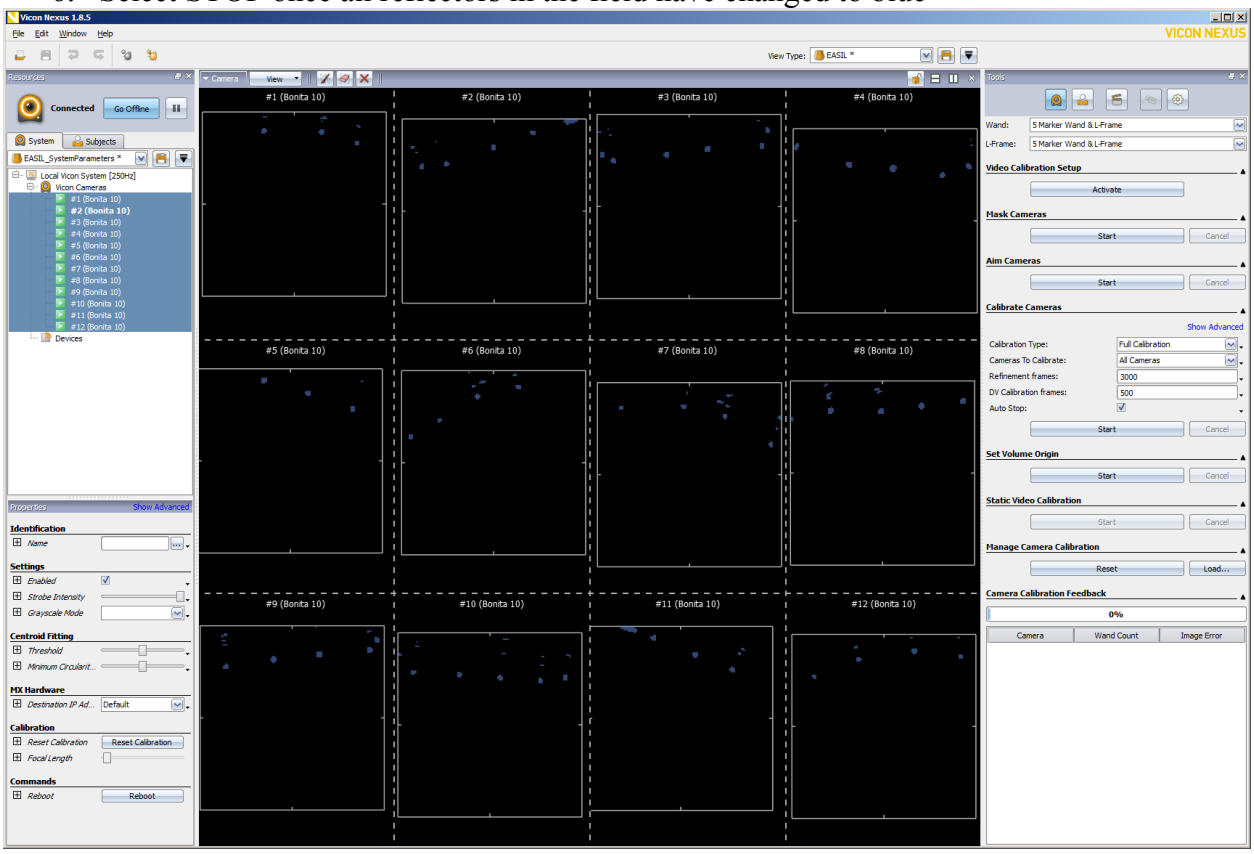
2. Change frame rate to 250 Hz.



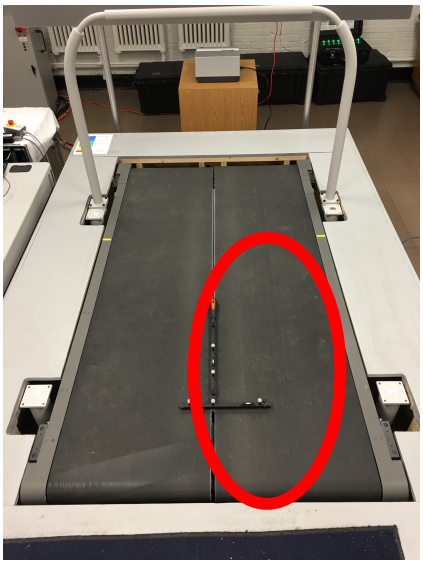
3. Select all cameras and change view to camera view
4. Remove all markers from the field

a. If an unknown marker is in the field, try to locate it before masking cameras

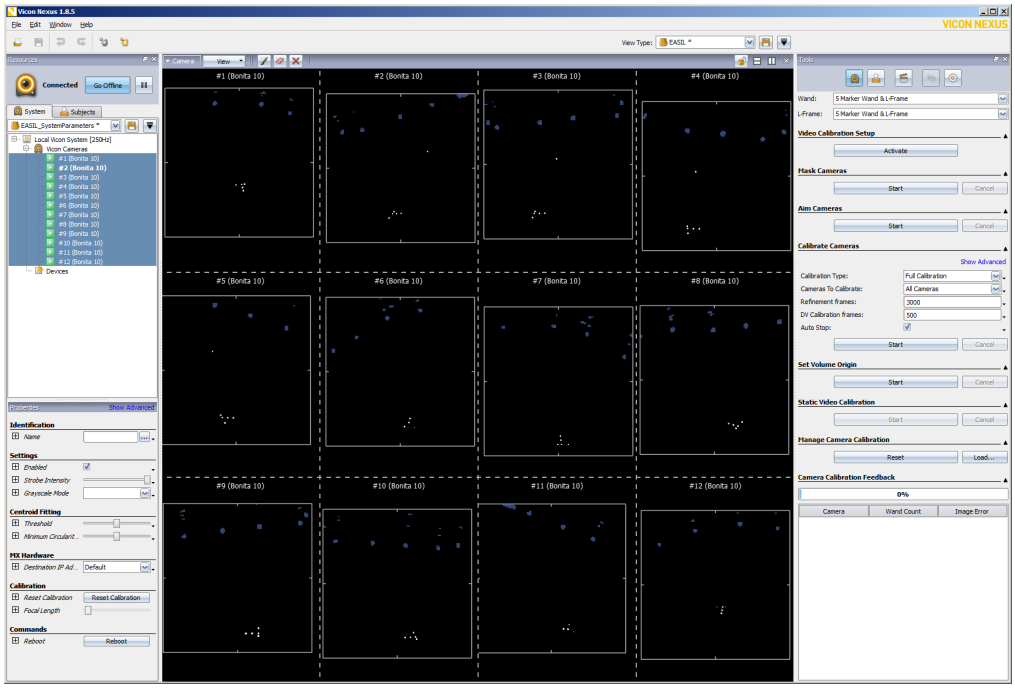
5. Mask cameras
6. Select STOP once all reflectors in the field have changed to blue



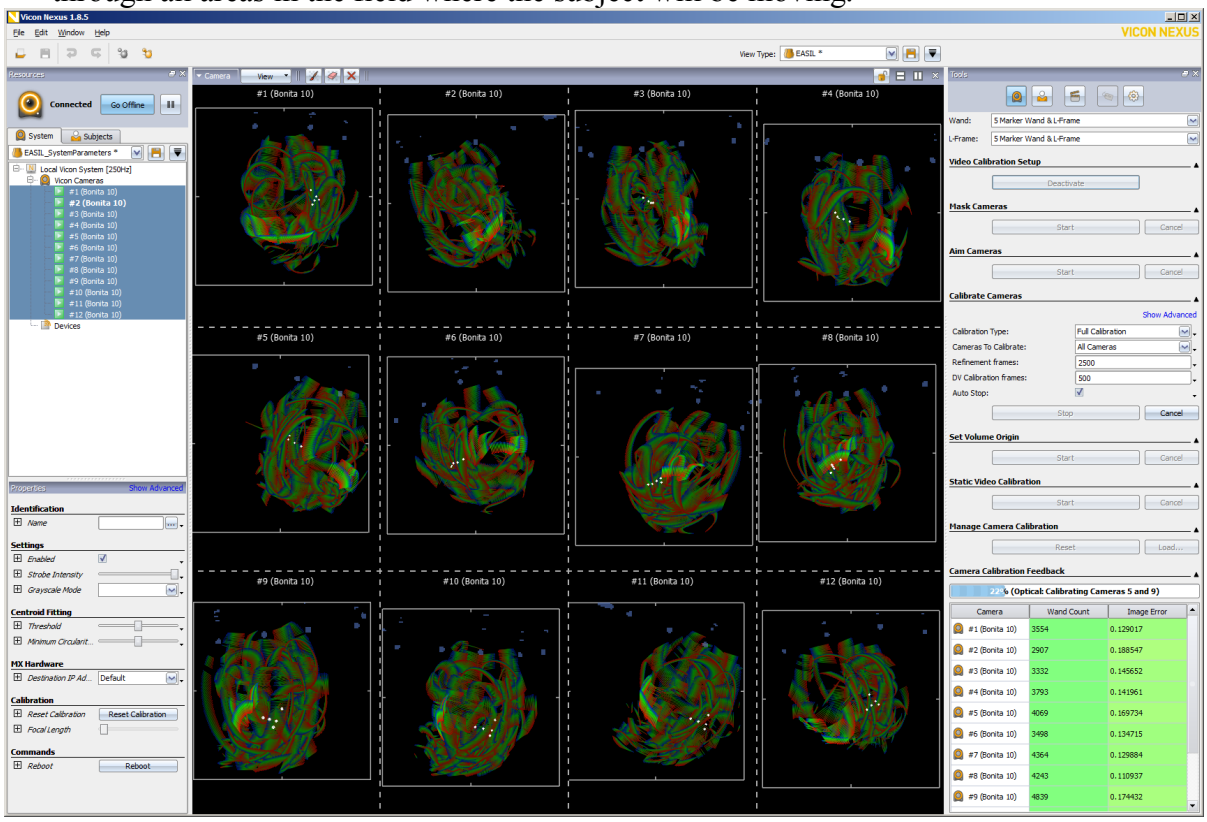
7. Place the L-shaped wand in the field at the edge of the force plates



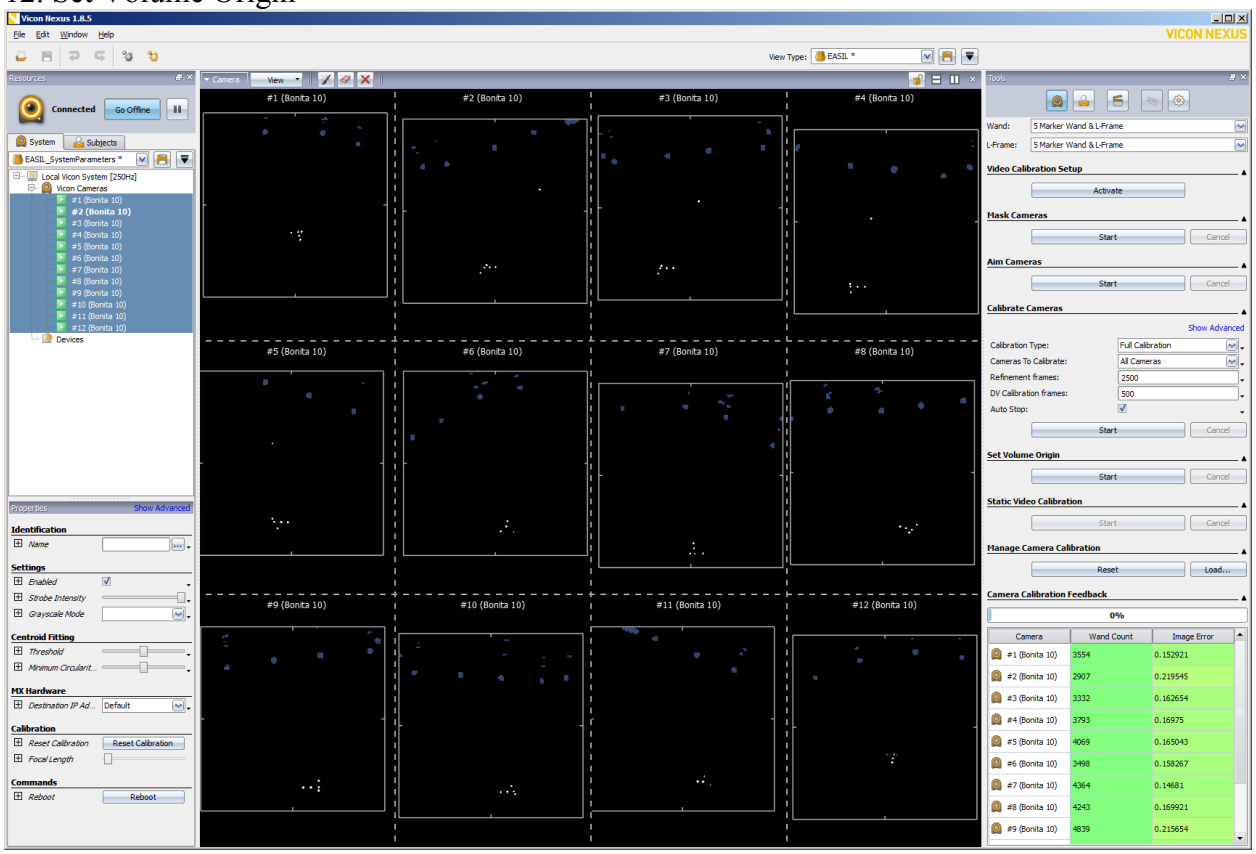
8. Aim Cameras



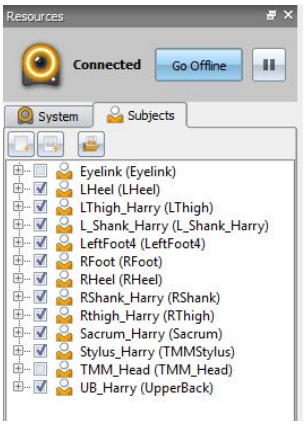
9. Calibrate cameras using 2500 refinement frames. Make sure to move the wand through all areas in the field where the subject will be moving.



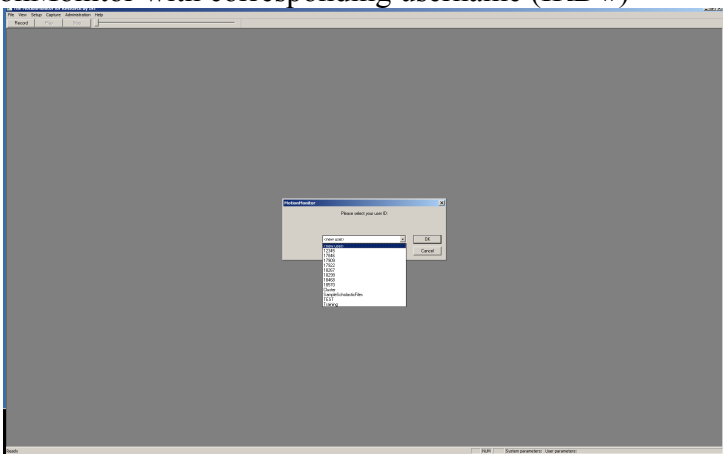
10. Check Image Error for any error greater than 0.25 – this may require recalibration
11. Replace the wand in the field (see picture in Step 7)
12. Set Volume Origin



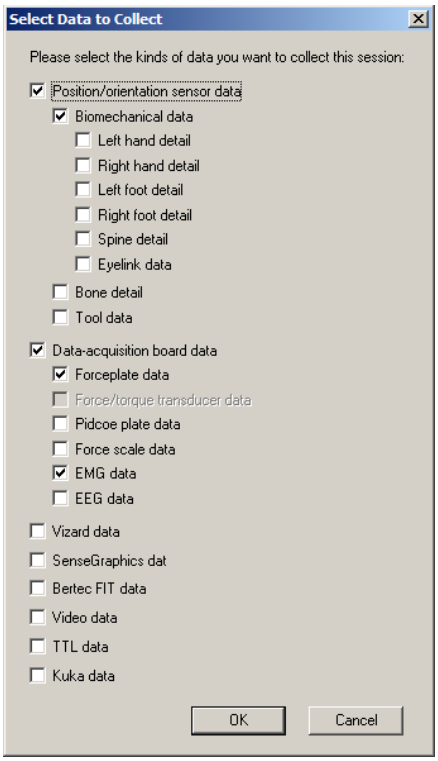
13. Select "Subjects' tab to verify cluster files have loaded.
    a. Select the appropriate subject markers. (Uncheck Eyelink and TMM_Head)
    b. Press Control-R and markers on participant will be recognized to create model.



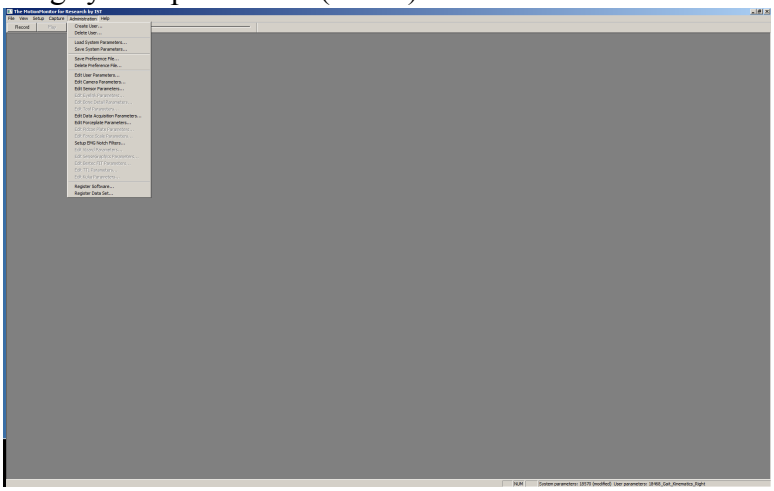
14. Open MotionMonitor with corresponding username (IRB #)



15. Select data to collect: Make sure Position/orientation sensor data, Biomechanical data, Data-acquisition data, forceplate data, and EMG data are checked.

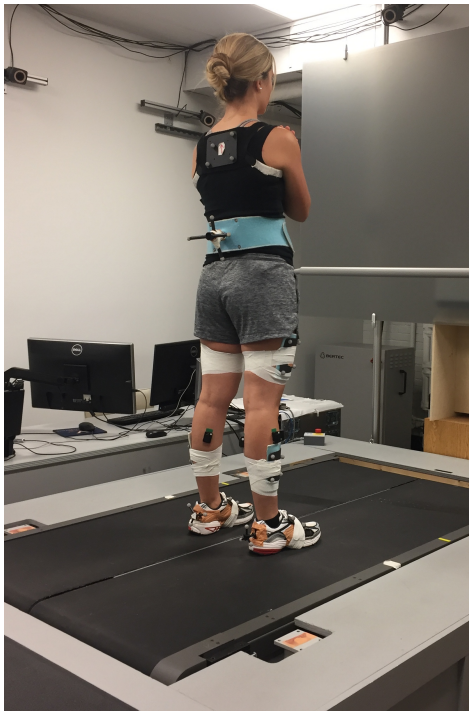


16. Go to the top menu and select Administration and Load System Parameters. Load corresponding system parameters (IRB #).



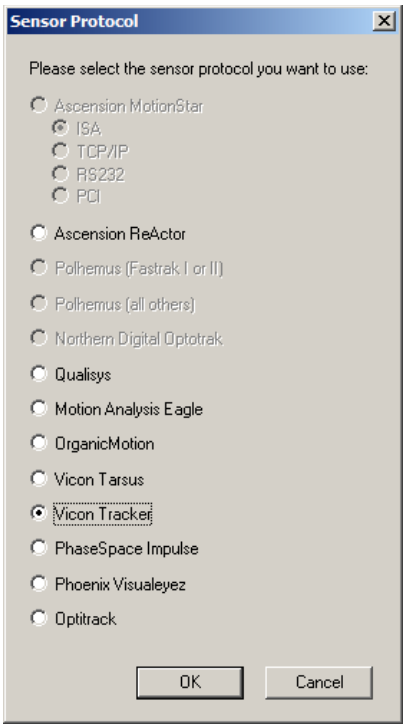
17. Go to the top menu and select File and Preference File. Load appropriate preference file.
18. Subject should enter the field (stand on the treadmill) with all clusters attached and the stylus placed within the view of the cameras.

a. Press Control-R to refresh the view of the markers in Vicon

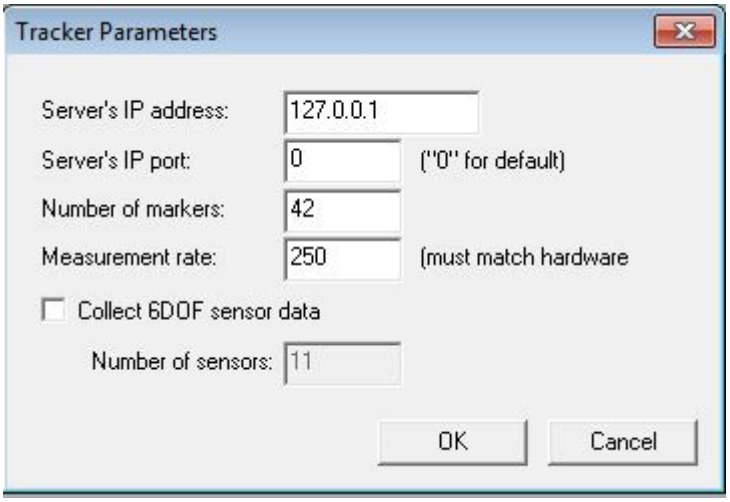


19. Go to the top menu and select Administration then select Edit Sensor Parameters.

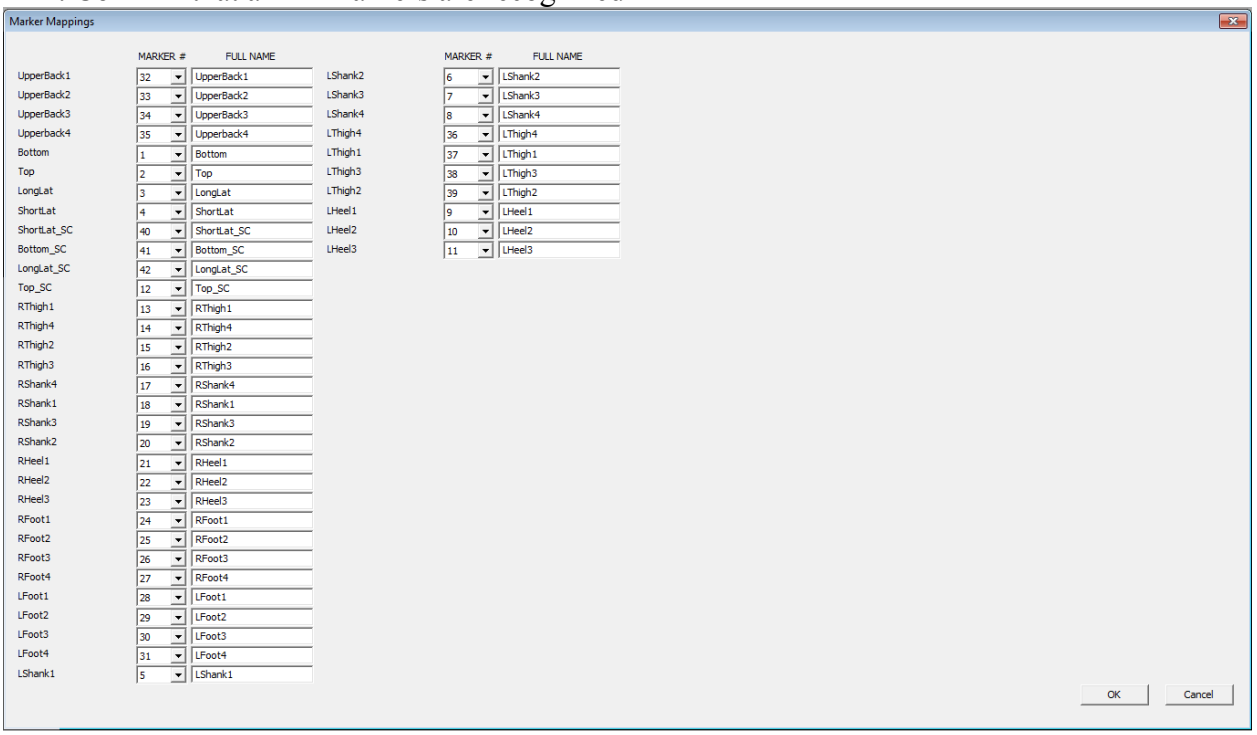
20. Select Vicon Tracker

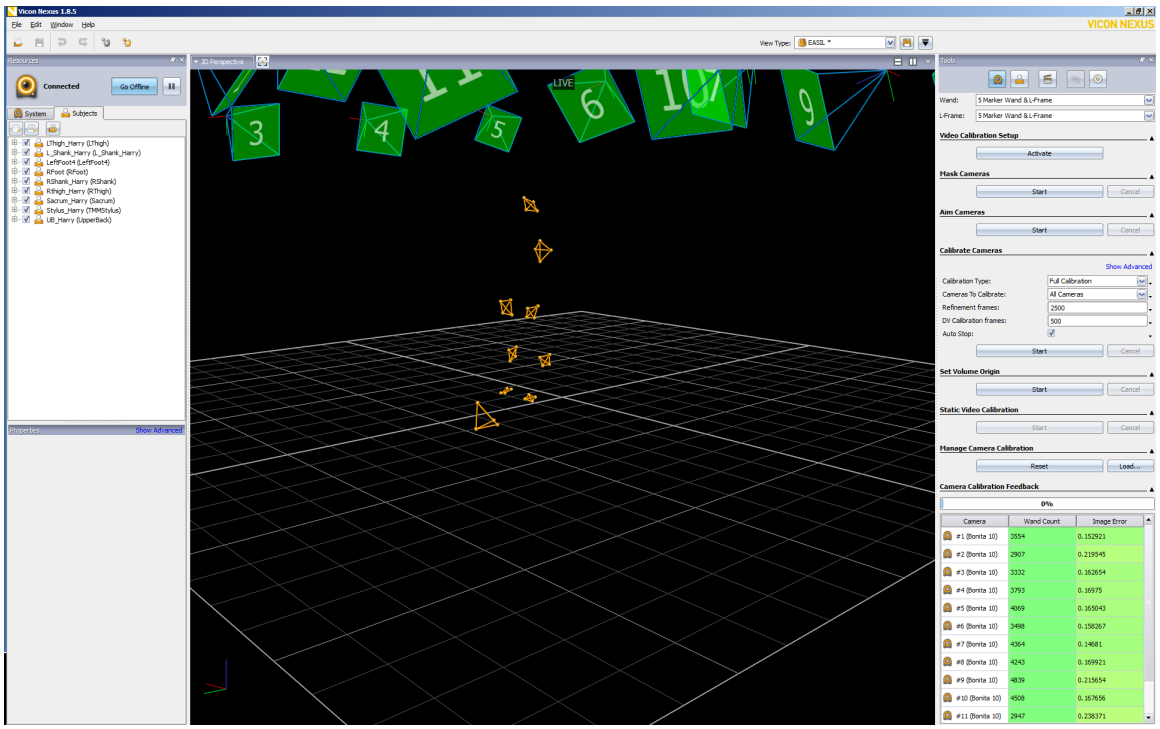


21. Confirm that number of markers = 42 and measurement rate = 250Hz

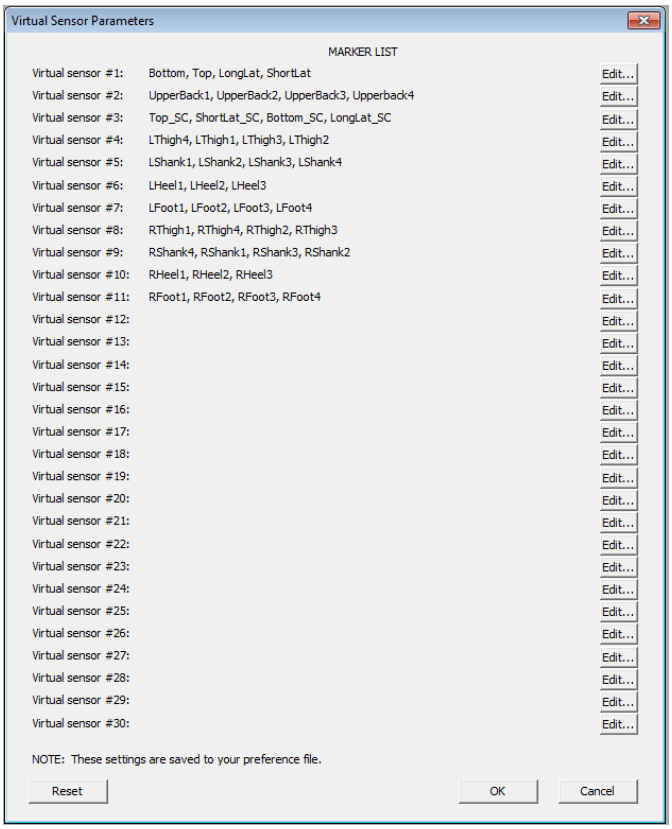


22. Confirm that all 42 markers are recognized

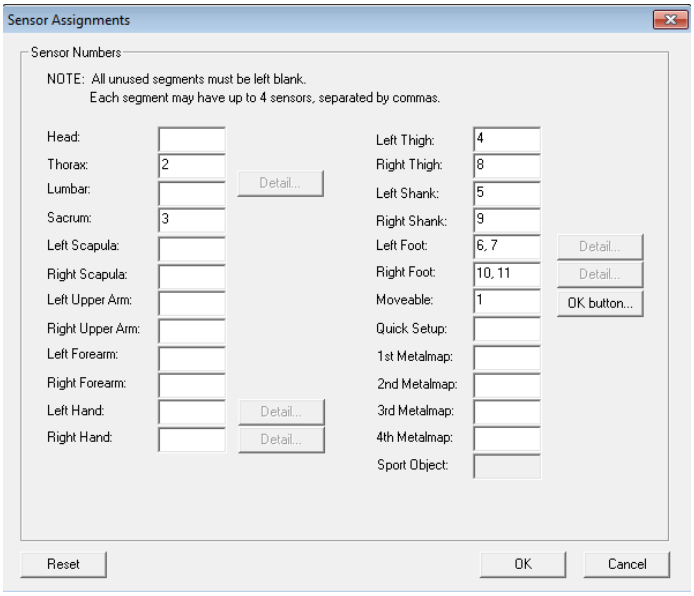




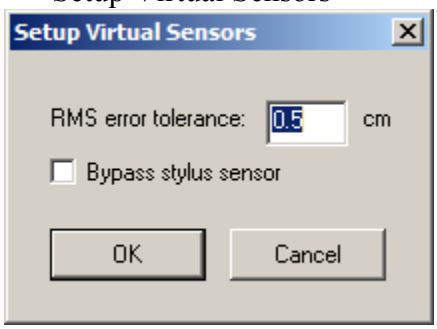
23. Confirm all clusters are assigned to appropriate virtual sensor.



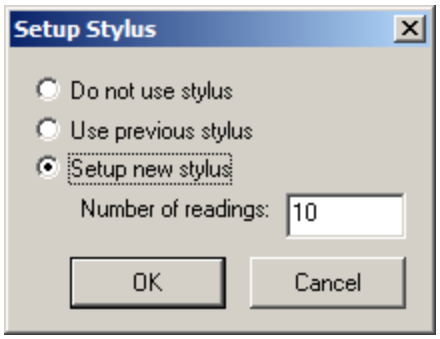
24. Go to the top menu and select setup and Edit Sensor Assignments. Sensor assignments listed should match assignments in virtual sensor parameters (see previous step).



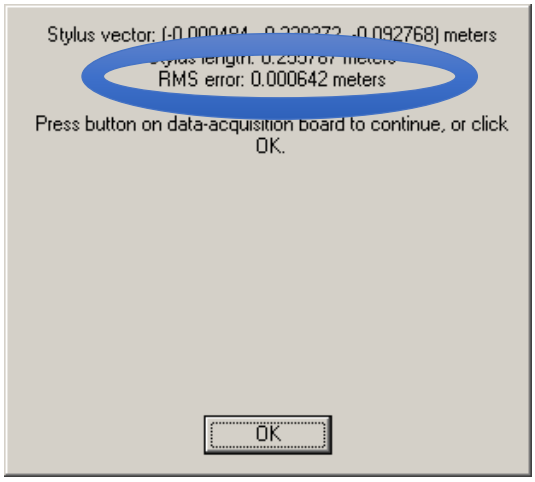
25. Ask the subject to stand still with hands crossed on the shoulders
26. Go to Vicon Nexus window and press Control-R
27. Return to MotionMonitor window and go to the top menu and select Setup and Setup Virtual Sensors



28. If you DO NOT receive an error, continue to step 30. If you DO receive an error, go back to step 20.
    a. Be sure to double check which subject sensors are marked in Vicon
29. Ask Subject to step onto the mat behind the treadmill.
30. Select Setup and Select Data to Collect. **Uncheck EMG data.**
31. Select Setup and Setup Stylus. Setup a new stylus with 10 readings.



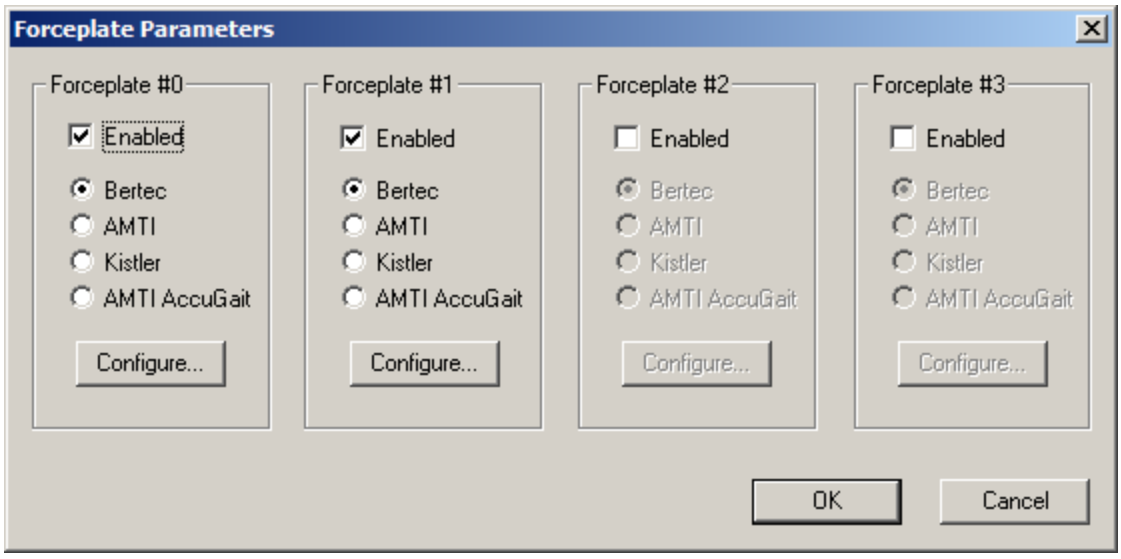
32. Calibrate stylus.
    a. RMS error should be less than 0.001



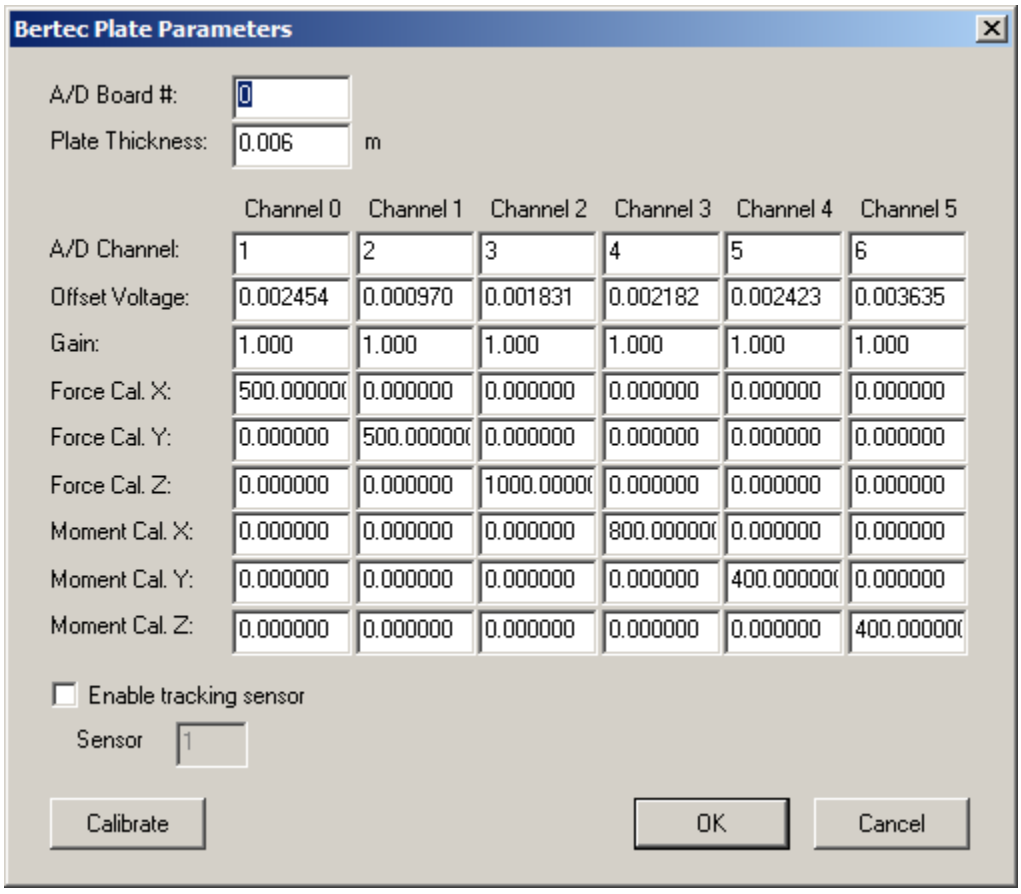
33. Remove all weight from forceplates. Zero the forceplates on the hardware.

34. Go to Administration and Edit Forceplate Parameters.

35. Select Configure for Forceplate #0

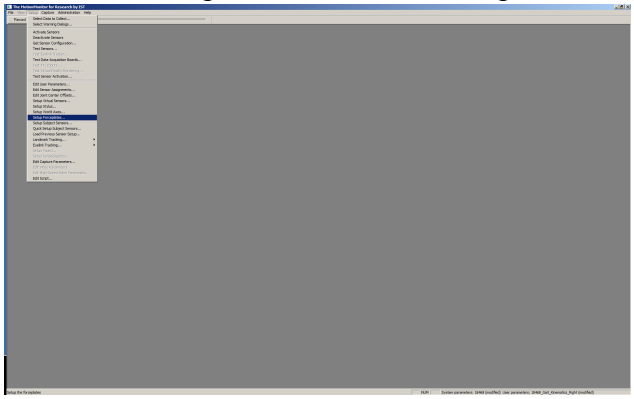


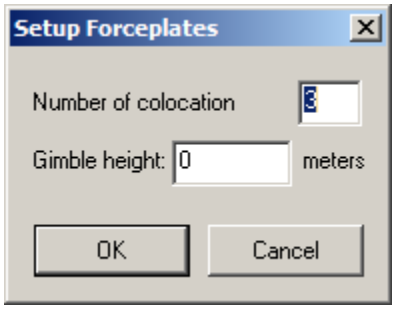
36. Select Calibrate



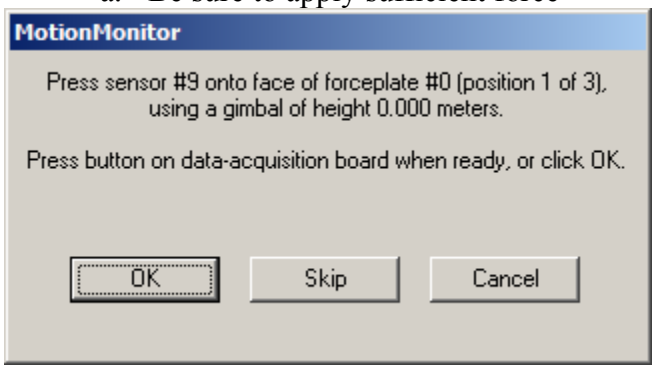
37. Select OK and repeat steps for Forceplate #1

38. Go to the top menu and select Setup and Setup Forceplates

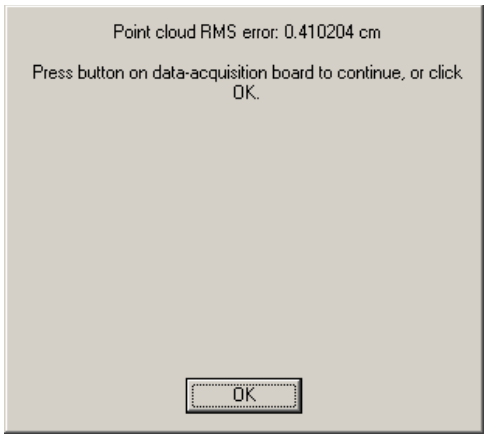




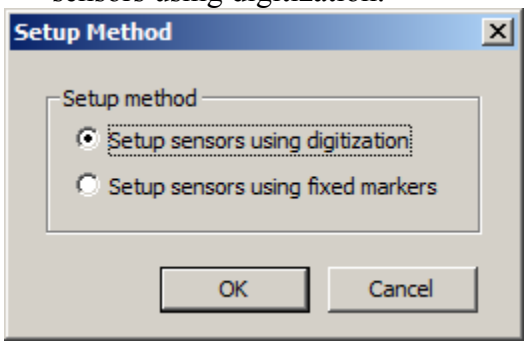
39. Using the stylus, press into the forceplate at three non-linear locations.
    a. Be sure to apply sufficient force

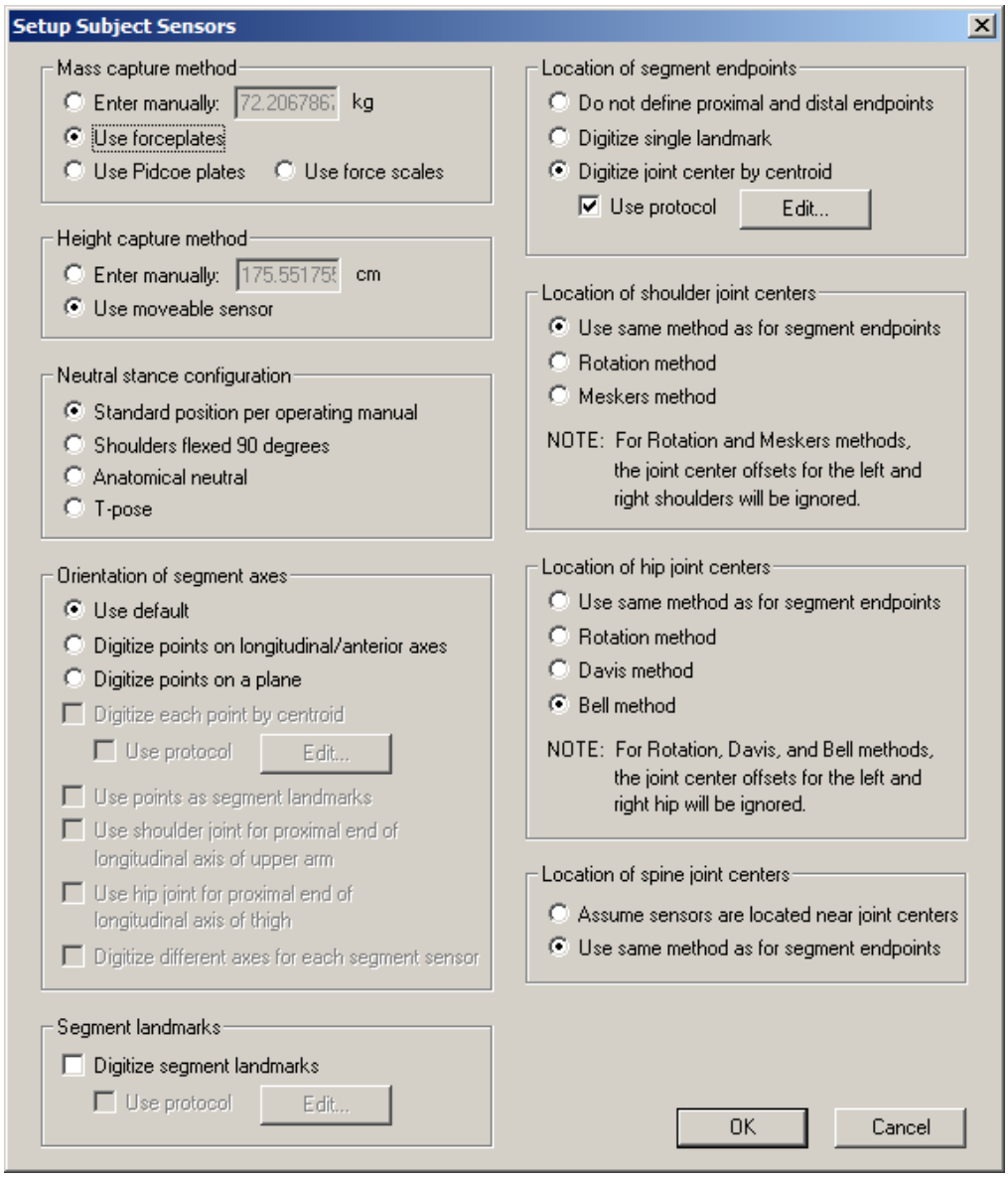


40. RMS error should be less than 1 cm. If it is greater than 1.0, repeat steps 34-40.

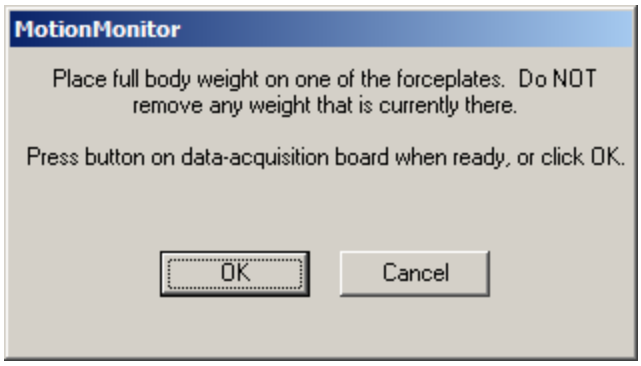


41. Go to the top menu and select Setup and Setup Subject Sensors. Select setup sensors using digitization.

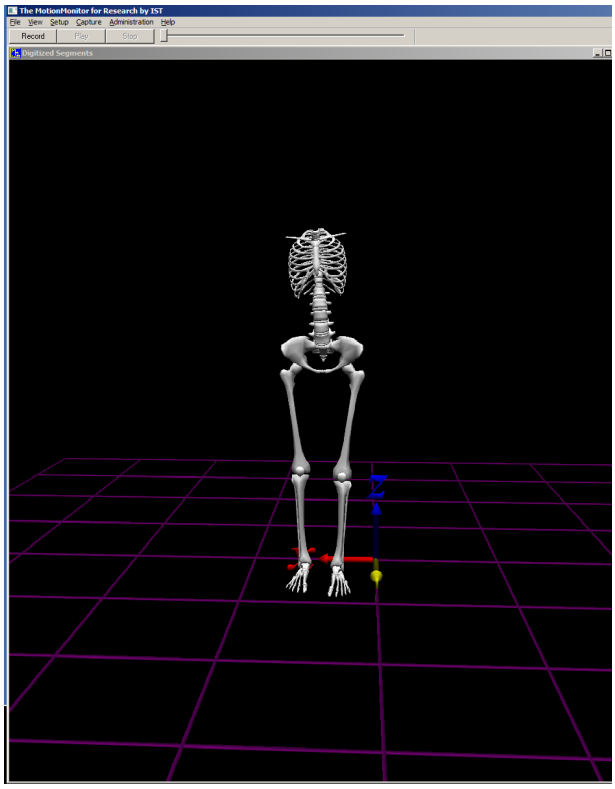




42. With below image on screen, ask subject to step onto **ONE** of the forceplates (one treadmill belt) with both feet. Once subject is in place, click "OK" to record body weight.



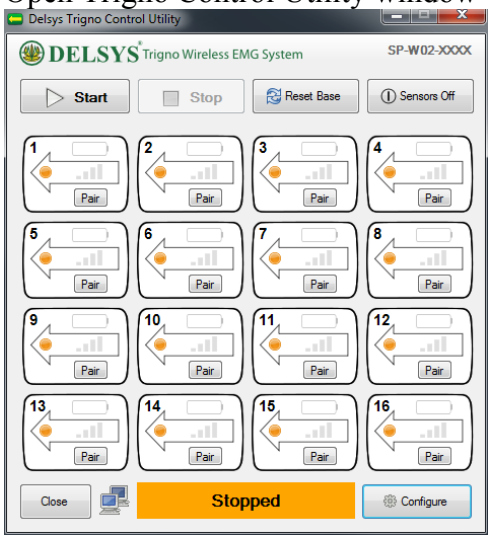
43. Place the tip of the stylus on top of the subject's head when prompted by MotionMonitor. Make sure height and weight are accurate (around what you would expect). Hold still with stylus to don sensors.
44. Point out the following landmarks on the subject in the following order (hitting Control-R on Vicon Nexus screen as appropriate):
    a. Left ASIS
    b. Right ASIS (hold still to get final hip reading)
    c. C7/T1
    d. T12/L1
    e. L5/S1
    f. Left Lateral Knee Joint Line
    g. Left Medial Knee Joint Line
    h. Left Lateral Malleolus
    i. Left Medial Malleolus
    j. Left Tip of 2nd Phalanx
    k. Right Lateral Knee Joint Line
    l. Right Medial Knee Joint Line
    m. Right Lateral Malleolus
    n. Right Medial Malleolus
    o. Right Tip of 2nd Phalanx
45. If skeleton looks appropriate, continue with collection. If anything does not look right, re-digitize the skeleton (redo steps 42-45).



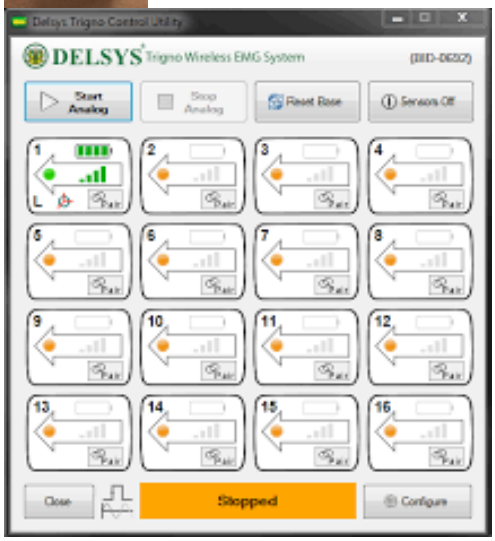
46. Go to the top menu and select Setup and Select Data to Collect**. Recheck EMG Data.**

Electromyography Set Up for Trigno Wireless System

1. Open Trigno Control Utility window



2. Turn electrodes on (green light illuminates)



3. Set up the subject
    a. Shave
    b. Abrade
    c. Cleanse
    d. Place electrodes over muscle belly
4. Collect maximal voluntary isometric contraction by Selecting Record on the **MotionMonitor** window (DO NOT press START on the Control Utility Window)

Coper Data Collection Sheet

Weight: _____(kg) **Test Limb:**_____

Height:_____(cm) **Age:**_____

TSK & IPAQ Questionnaires ☐

Surface EMG Setup

☐ Shave, Abrade, Cleanse area

☐ Manual test to check electrode placement

Quiet standing trial

☐ 10-s quiet standing in neutral

Walking

	Speed (m/s)	Trial 1	Trial 2
Preferred WS			
120% PWS			
Standardized	1.34		

Running

	Speed (m/s)	Trial 1	Trial 2
Preferred RS			
120% PRS			
Standardized	2.68		

Speed order collected (1, 2, 3):

Preferred: ☐ **120% PWS:** ☐ **Standardized:** ☐

Drop Vertical Jump

☐ 5 trials collected

Notes:

CAI Gait Assessment

Weight: _____ **Test Limb:_____**

Height:_____

Surface EMG Setup

- ☐ Shave, Abrade, Cleanse area
- ☐ Manual test to check electrode placement

Quiet standing trial

- ☐ 10-s quiet standing in neutral

Walking

	Speed (m/s)	Trial 1	Trial 2
Preferred WS			
120% PWS			
Standardized	1.34		

Running

	Speed (m/s)	Trial 1	Trial 2
Preferred RS			
120% PRS			
Standardized	2.68		

Speed order collected (1, 2, 3):

Preferred: ☐ **120% PWS:** ☐ **Standardized:** ☐

Drop Vertical Jump

- ☐ 5 trials collected

Fitbit assignment: _____

Walking Speed Randomization Order

ID number	Order
01	PWS, 120% PWS, Standard
02	120%, Standard, PWS
03	Standard, PWS, 120%
04	PWS, 120% PWS, Standard
05	120%, Standard, PWS
06	Standard, PWS, 120%
07	PWS, 120% PWS, Standard
08	120%, Standard, PWS
09	Standard, PWS, 120%
10	PWS, 120% PWS, Standard
11	120%, Standard, PWS
12	Standard, PWS, 120%
13	PWS, 120% PWS, Standard
14	120%, Standard, PWS
15	Standard, PWS, 120%
16	PWS, 120% PWS, Standard
17	120%, Standard, PWS
18	Standard, PWS, 120%
19	PWS, 120% PWS, Standard
20	120%, Standard, PWS
21	Standard, PWS, 120%
22	PWS, 120% PWS, Standard
23	120%, Standard, PWS
24	Standard, PWS, 120%
25	PWS, 120% PWS, Standard
26	120%, Standard, PWS
27	Standard, PWS, 120%

Gait Speeds (m/s)				
PWS	120%		PRS	120%
0.5	0.6		**2.1**	2.52
0.6	0.72		**2.2**	2.64
0.7	0.84		**2.3**	2.76
0.8	0.96		**2.4**	2.88
0.9	1.08		**2.5**	3
1	1.2		**2.6**	3.12
1.1	1.32		**2.7**	3.24
1.2	1.44		**2.8**	3.36
1.3	1.56		**2.9**	3.48
1.4	1.68		**3**	3.6
1.5	1.8		**3.1**	3.72
1.6	1.92		**3.2**	3.84
1.7	2.04		**3.3**	3.96
1.8	2.16		**3.4**	4.08
1.9	2.28		**3.5**	4.2
2	2.4		**3.6**	4.32

4. **Clinical Assessment**

Assessor Initials:_____ Test Limb:_____

Pre- Post-Rehabilitation Data Collection Form

Foot Morphology

Arch Height Index	Unloaded		Loaded	
	RT	LT	RT	LT
Total Foot Length (cm)				
Truncated Foot Length (cm)				
Foot Width (mm)				
Dorsal Arch Height (50% foot length, cm)				

Intrinsic Foot Muscle Test

RT	RT

Satisfactory: **Neutral navicular height without over-activity of the extrinsics** consistent throughout the 30-sec trial

Fair: unsteadiness of the neutral navicular height and/or over-activity of the extrinsics are **inconsistently** observed during the 30-sec

Poor: unsteadiness of the neutral navicular height and/or over-activity of the extrinsics are **consistently** observed during the 30-sec

	FACTOR	PLANE	SCORE 1 Date_____ Comment_____	
			Left (-2 to +2)	Right (-2 to +2)
Rearfoot	Talar head palpation	*Transverse*		
Rearfoot	Curves above and below lateral malleoli.	*Frontal/ trans*		
Rearfoot	Inversion/eversion of the calcaneus	*Frontal*		
Forefoot	Bulge in the region of the TNJ	*Transverse*		
Forefoot	Congruence of the medial longitudinal arch	*Sagittal*		
Forefoot	Abd/adduction of forefoot on rearfoot (too-many-toes).	*Transverse*		
	TOTAL			

-12 – -5	-4 – -1	0-5	6-9	10+
Highly Supinated	Supinated	Normal	Pronated	Highly Pronated

Range of Motion

	1	2	3
Ankle DF (º)			
Ankle PF (º)			
Ankle Inv (º)			
Ankle Ev (º)			

Weight bearing dorsiflexion (cm) ☐

Balance

Static Balance (Tekscan)

☐ 3 10s trials: Single limb balance, eyes open

☐ 3 10s trials: Single limb balance, eyes closed

Dynamic Balance

Star Excursion Balance Test

Anterior (cm)	**1**	
	2	
	3	
Posteromedial (cm)	**1**	
	2	
	3	
Posterolateral (cm)	**1**	
	2	
	3	

Leg length (cm – affected limb) ☐

Ultrasound	
Intrinsic foot (AH, FDB, QP, FHB)	
Peroneus Longus	

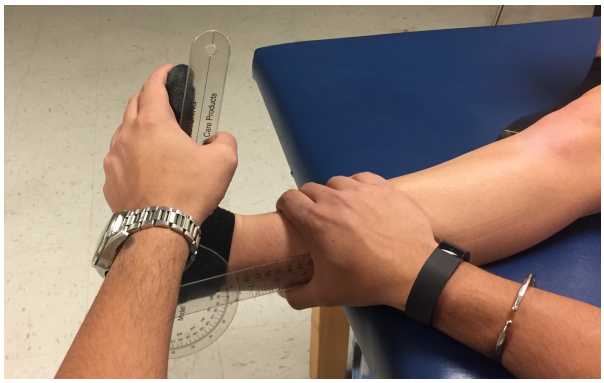
Strength

	1	2	3
Ankle DF			
Ankle PF			
Ankle Inv			
Ankle Ev			
Hip Ext			
Hip ABD			
2-5 Toe Flex			

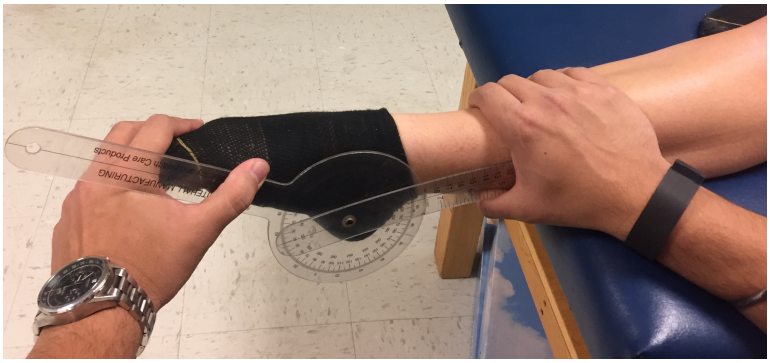
a. Ankle Range of Motion

i. Weight bearing dorsiflexion

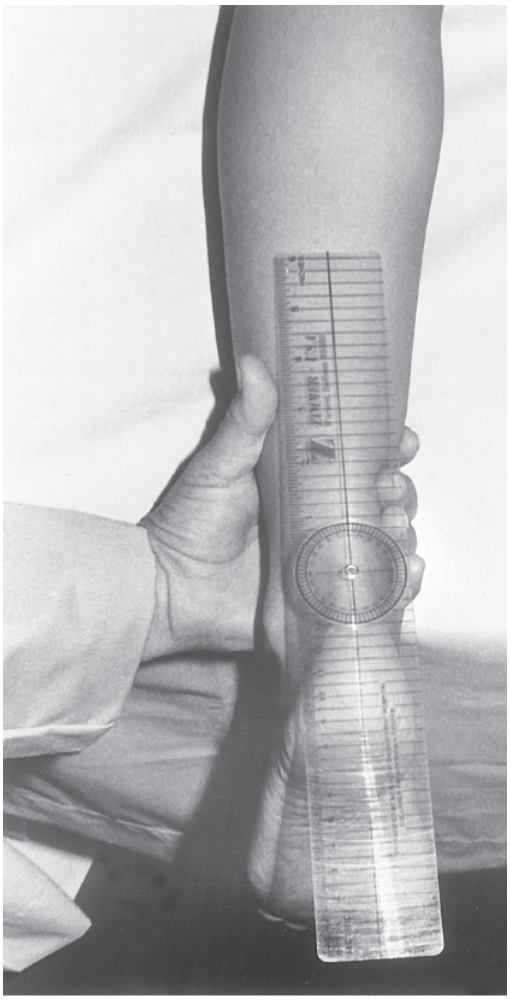
ii. Dorsiflexion



iii. Plantarflexion



iv. Inversion/Eversion



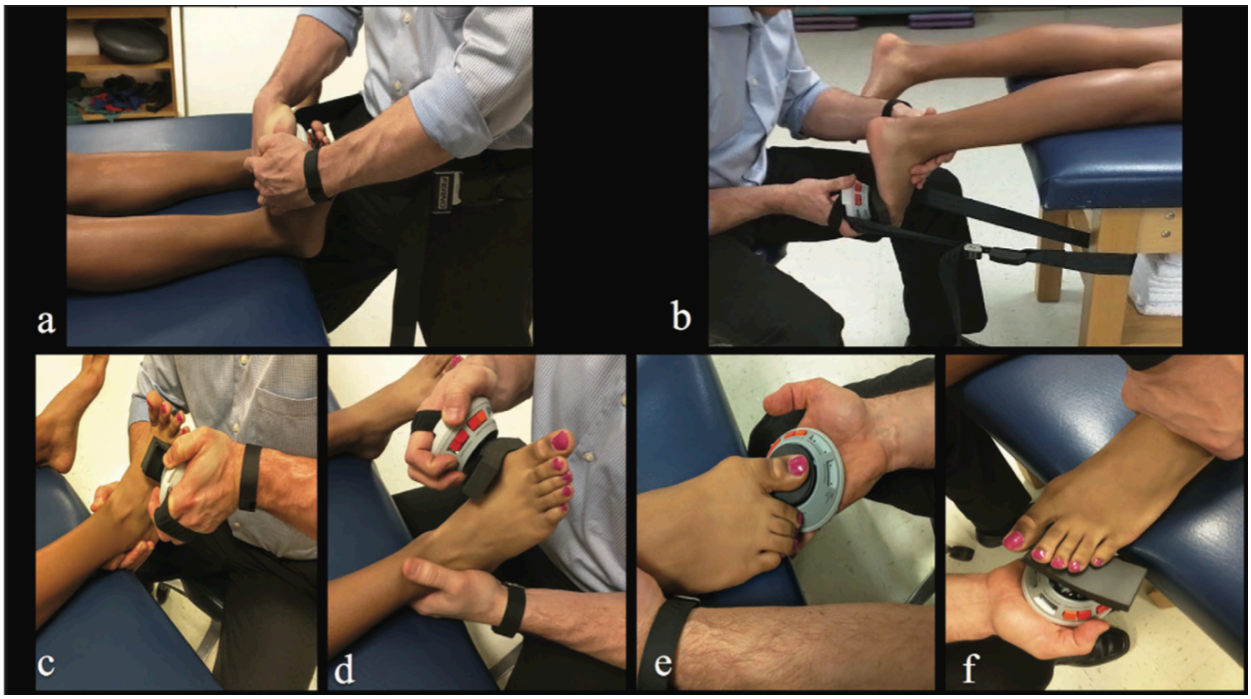
b. Balance
    i. Static
        1. Single limb balance with eyes open and closed

    ii. Dynamic
        1. Star Excursion Balance Test Directions

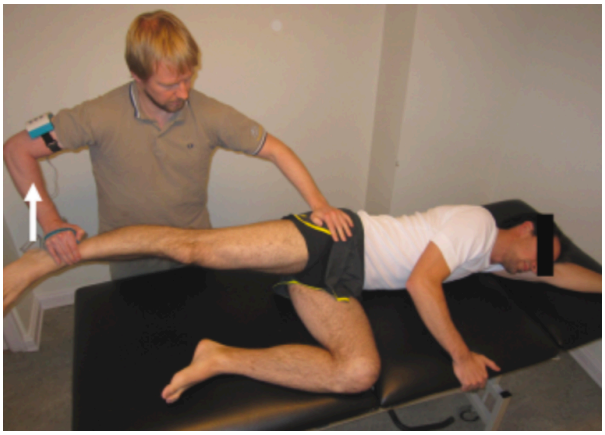


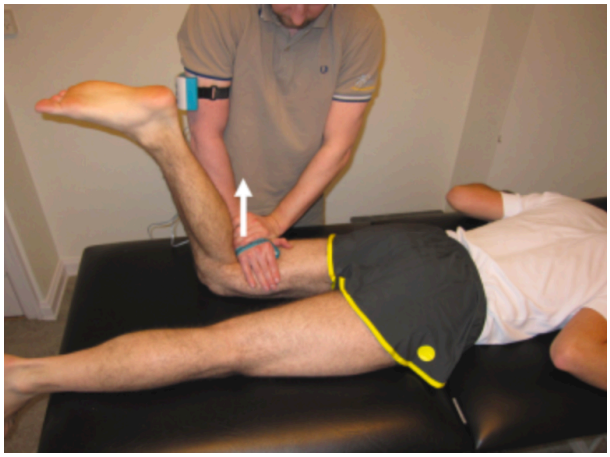
c. Strength

i. Ankle and toe strength using methods from Fraser et al. 2017



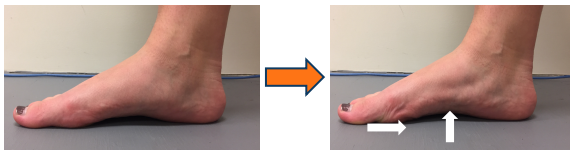
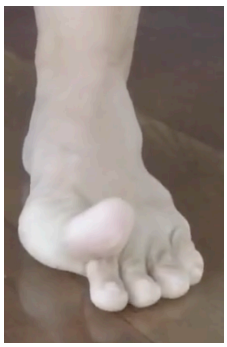
ii. Hip strength using methods from Thornborg et al. 2010





5. **Impairment-Based Rehabilitation Program**

Impairment Based Rehab Guide

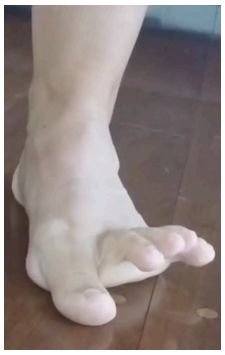
Name	Description	Photo
Intrinsic Foot Muscle Exercises		
Short Foot Exercise	Patient starts in seated or standing position with foot flat on the ground. They are asked to raise their arch up without curling their toes (bring first metatarsal head backward toward calcaneus). Progression: seated, bipedal standing, single limb stance Goal is 50 repetitions	
1st Toe Extension	Patient starts in seated or standing position with foot flat on the ground. They are asked to extend their 1st toe while keeping toes 2-5 on the ground.	

Progression: seated, bipedal standing, single limb stance

Goal is 50 repetitions

Toes 2-5 Extension

Patient starts in seated or standing position with foot flat on the ground. They are asked to extend their toes 2-5 while keeping 1st toe on the ground.

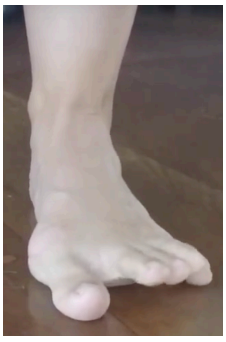


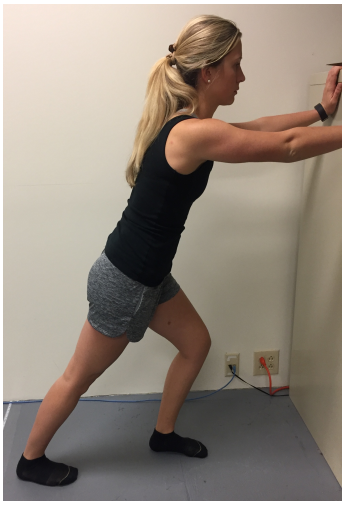
Progression: seated, bipedal standing, single limb stance

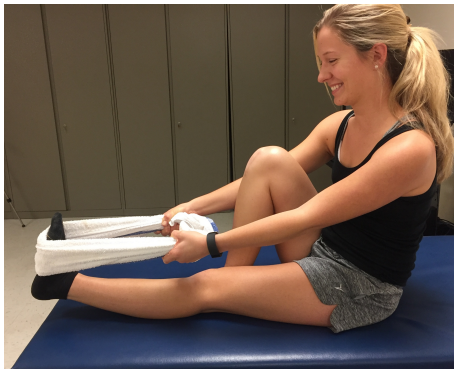
Goal is 50 repetitions

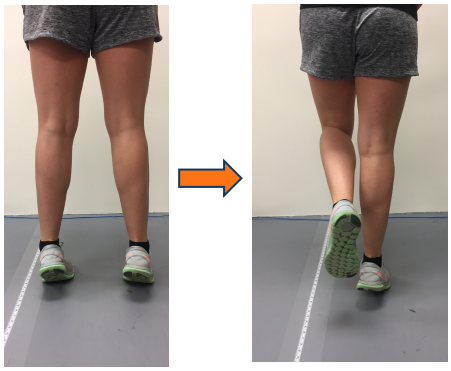
Toe Extension & Splay

Patient starts in seated or standing position with foot flat on the ground. They are asked to extend all toes, then abduct ("splay"), and then slowly lower toes starting with 1 & 5, then 2-4.



	Progression: seated, bipedal standing, single limb stance Goal is 50 repetitions	
Stretches		
Standing straight knee dorsiflexion	Patient stands, places hands on wall, stretches back leg with knee straight. Goal is 3x30 seconds	
Standing bent knee dorsiflexion	Patient stands, places hands on wall, stretches back leg with knee bent. Goal is 3x30 seconds	

Seated towel stretches	Patient sits with one leg bent and other leg straight, use towel to pull foot into dorsiflexion. Repeat with stretching leg in bent position. Goal is 3x30 seconds	

Ankle Exercises		
Double legged/Single legged heel raise	Patient stands on ground with one or both feet and is asked to raise up onto their toes bringing their heel off of the ground. Goal is 3x10. Then progress.	

Double legged/Single legged forefoot raise

Patient stands on ground with one or both feet and is asked to raise up their toes keeping their heel on the ground.

Goal is 3x10. Then progress.

4-way manual resistance

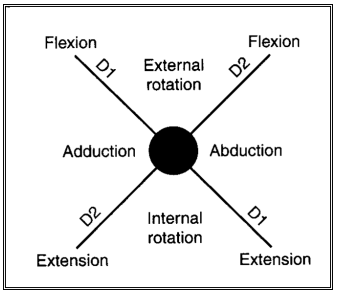
Patient sits with leg straight on the table. Clinician resists them through the full range of motion in the following directions: dorsiflexion, inversion, eversion, plantar flexion

Progression: concentric contraction to eccentric contractions

Increase resistance if exercise is not challenging enough.

D1/D2 PNF

Patients will move ankle in diagonal D1 and D2 patterns against manual resistance.



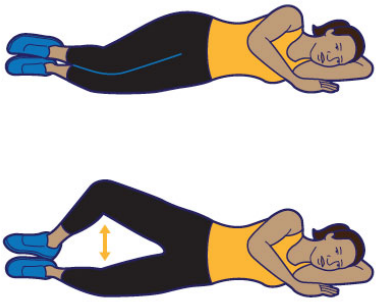
Increase resistance if exercise is not challenging enough.

Heel/toe walks

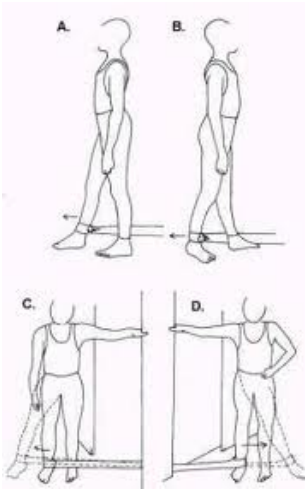
Patient walks with their feet in 4 positions: on their toes, on their heels for 10m lap.

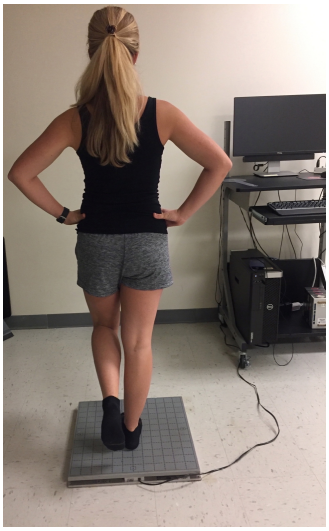
Increase laps as needed.

Hip Exercises

Quadraped: arm extension/leg extension	Patient starts in position on hands and knees. The patient then simultaneously will extend one arm and the opposite leg. Then they will repeat on the opposite side. Progression: arm/leg only, both arm and leg Proper form is more important than high reps. Goal is 3x10.	
Clamshells with theraband	Patient starts in side-lying position with knees and hips flexed. Ask patient to rotate leg upward then return to start position. Progression: Place the theraband around their mid-thigh, increase resistance (color)	

	Progress when they can complete 3x10.
4-way hip with theraband	Patient stands on their “healthy” limb and uses ankle sprain limb to perform hip motions. Place appropriate theraband around lower leg. Patient completes the following motions at the hip: flexion, abduction, extension, and adduction.
	Progression: increase theraband resistance color, have patient stand further from anchor
	Progress when they can complete 3x10.
Internal/External rotation on BOSU with theraband	Patient sits on BOSU ball with erect posture. Place the appropriate theraband around the lower leg. Have patient internally and externally rotate the hip.



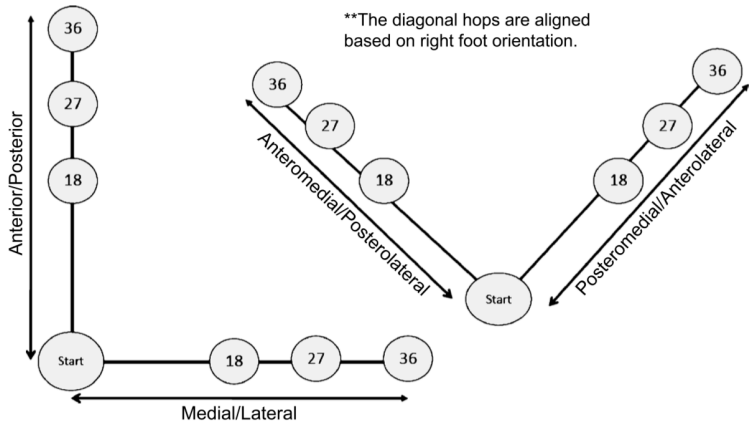
	Progression: increase theraband resistance color, have patient sit further from anchor Progress when they can complete 3x10.	
	Balance	
Single leg balance	Patient position: stand with 1 on ground, arms crossed in front of their chest, lift the uninvolved limb to about 30º of hip flexion and 45º of knee flexion, and stand as still as possible. Progression eyes: open to closed Progression surface: firm, foam, DynaDisc	

	Progress if patient can complete 3x30 seconds error free.	
Reach tasks (Star Excursion Balance Test)	Patient stands with hands on hips, on the test limb at the edge of the tape measure. The patient reaches as far as they can in the designated direction. Patient is instructed to reach in specific directions. They must control their motion, tap as far as they can, and return to the start position. Pick 3 different directions for each visit.	  
	Progression surface: firm, foam, DynaDisc	

Progress when they can complete 2x10.

Hop to stabilization

Patients will perform 10 hops in each of 4 directions: medial to lateral, anterior to posterior, anteromedial to posterolateral, and anterolateral to posteromedial.

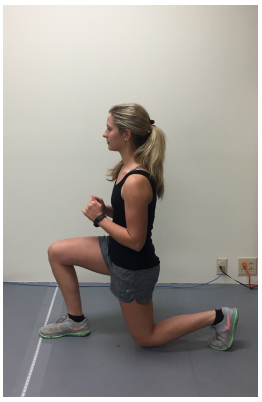


Targets will be placed at a set distance away.

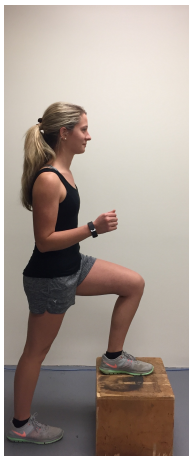
Progression: 18 inch, 27 inch, 36 inch.

Progression surface: firm, foam, DynaDisc

Add reach in opposite direction of hop for increased difficulty.

	Progress after 10 error- free hops.	
	Functional Exercises	
Lunges	Patient will lunge forward and will progress by surface type. Hands will remain on their hips. Errors include taking hands off of hips, lost balance during descent or ascent, unable to reach 90º/90º position, or excessively alter the trunk lean during any phase of the lunge. Progression surface: firm, foam, DynaDisc Progress after 10 error-free lunges.	

Forward step-ups and step-downs (30 cm box)	Step up: patient will stand behind box and step up in forward direction with the involved limb Step down: patient will stand on top of box and step down in forward direction with the involved limb Progression surface: firm, foam, DynaDisc Increase difficulty as needed. Goal is 3x10
Lateral step-ups and step-downs (30 cm box)	Step up: patient will stand next to box and step up to the side with the involved limb Step down: patient will stand on top of box and step down to the side with the involved limb Progression surface: firm, foam, DynaDisc


	Increase difficulty as needed. Goal is 3x10.
Dot jumping drill	Dots (targets) will be placed apart by 24 inches. Participants will jump from dot to dot as fast as possible while remaining comfortable. Hop directions include: medial to lateral, anterior to posterior, figure of 8 randomized jumps. (Change direction of figure 8 as necessary) Phase 1: double legged jumps Phase 2: single legged jumps Phase 3: progress duration of single legged jumps by 15 seconds after completing 3 successful trials at previous duration Goal is 3x30 seconds comfortably

Impairment Based Rehabilitation

Sync & charge Fitbit ☐

Did you forget to wear your Fitbit at all since last session? If so, how long? _____

_____

Home exercise compliance

How many days did you complete your home exercises program since last session? _____

_____

Intrinsic Foot Exercises Progression if needed

Exercise	**Reps**	**Duration (minutes)**
Short foot exercise		
1st toe extension		
2-5 toe extension		
Extend & splay		

Range of Motion

Arthrokinematic restrictions? If yes, list joints: _____

Joint Mobilization Type/Grade	**Sets**	**Duration (minutes)**	**Grade Mob.**

Stretching exercises: 3x30 seconds each selected

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

Ankle Strength Progression if needed

Exercise (circle appropriate)	**Sets**	**Repetitions**
Double legged/Single legged heel raises		

Double legged/Single legged forefoot raises		
3-way manual resistance		
D1/D2 PNF		
Heel/toe walking		

Hip Strength Progression if needed

Exercise (circle appropriate)	**Sets**	**Repetitions**	**Resistance**
Quadraped: arm extension/leg extension			
Clamshells with theraband			
4-way hip with theraband			
Internal/External rotation on BOSU: No resistance/Theraband			
Band walking			

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		
3. Eyes Open Single leg balance on Dynadisc™		
Eyes Closed Progression		
1. Eyes Closed Single leg balance		
2. Eyes Closed Single leg balance on a foam		
3. Eyes Closed Single leg balance on Dynadisc™		

Reach Tasks (circle appropriate phase) Goal 2x10 each direction	**Sets**	**Duration (seconds)**

1. Completing the exercise standing on firm surface		
2. Completing the exercise standing on foam surface		
3. Completing the exercise standing on Dynadisc™		

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	
1. 18-inch hop with arm assistance while jumping onto a foam pad	
2. 18-inch hop with hands on hips while jumping onto a foam pad	
3. 27-inch hop with arm assistance while jumping onto a foam pad	
4. 27-inch hop with hands on hips while jumping onto a foam pad	
5. 36-inch hop with arm assistance while jumping onto a foam pad	
6. 36-inch hop with hands on hips while jumping onto a foam pad	

Functional Exercises

Lunges (circle appropriate phase) **Goal is 2x10 each leg**	**Sets**	**Repetitions**
1. Complete lunges on firm surface		
2. Complete lunges with foam beneath stance leg and lunge on top another foam pad		
3. Complete lunges with Dynadisc™ beneath stance leg and lunge on top another Dynadisc™		

Forward Step-ups and Step-downs (circle appropriate phase) Goal is 3x10	**Sets**	**Repetitions**
1. Step on and off of a box		

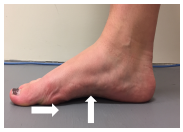
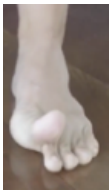
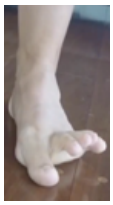
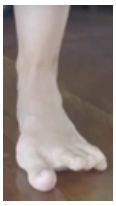
2. Step on and off of a box with foam pad		
3. Step on and off of a box with Dynadisc™		

Dot Jumping Drill at 24-inches (circle appropriate phase) Goal is 3x30 seconds	**Sets**	**Repetitions**
1. Double legged lateral to medial hops, double legged anterior to posterior jumps, double legged figure 8 jumps		
2. Single legged lateral to medial hops, single legged anterior to posterior jumps, single legged figure 8 jumps		

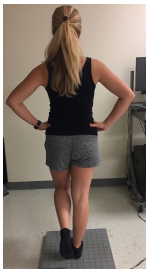
NOTES:

Ankle Home Exercise Plan

Intrinsic Foot Exercises
Perform 50 repetitions of each exercise 1x/day

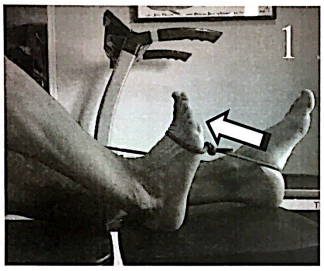
Calf Stretching
With heel in contact with the ground, perform with knee straight for 30 seconds and knee bent for 30 seconds, 3x/day

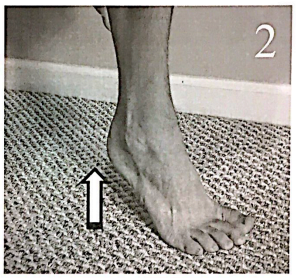
Balancing
Stand on affected limb, place hands on hips and maintain balance 30 seconds, 3x/day

Resisted toe raises

With a resistance band/tube wrapped around your foot, extend your foot slowly over 2 secs to the end of the motion. Slowly return your foot to starting position over a 4 sec count. Perform 30 times, 3 times a day.



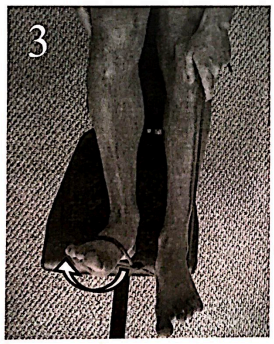
Resisted heel raises

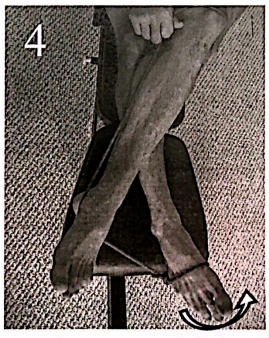


While standing on one foot (and touching a wall for balance), slowly lift your heel over 2 secs to the end of the motion. Slowly return your foot to starting position over a 4 sec count. Perform 30 times, 3 times a day.

Resisted eversion

With a resistance band/tube wrapped around your foot, rotate your foot outboard slowly over 2 secs to the end of the motion. Slowly return your foot to starting position over a 4 sec count. Perform 30 times, 3 times a day.





Resisted inversion

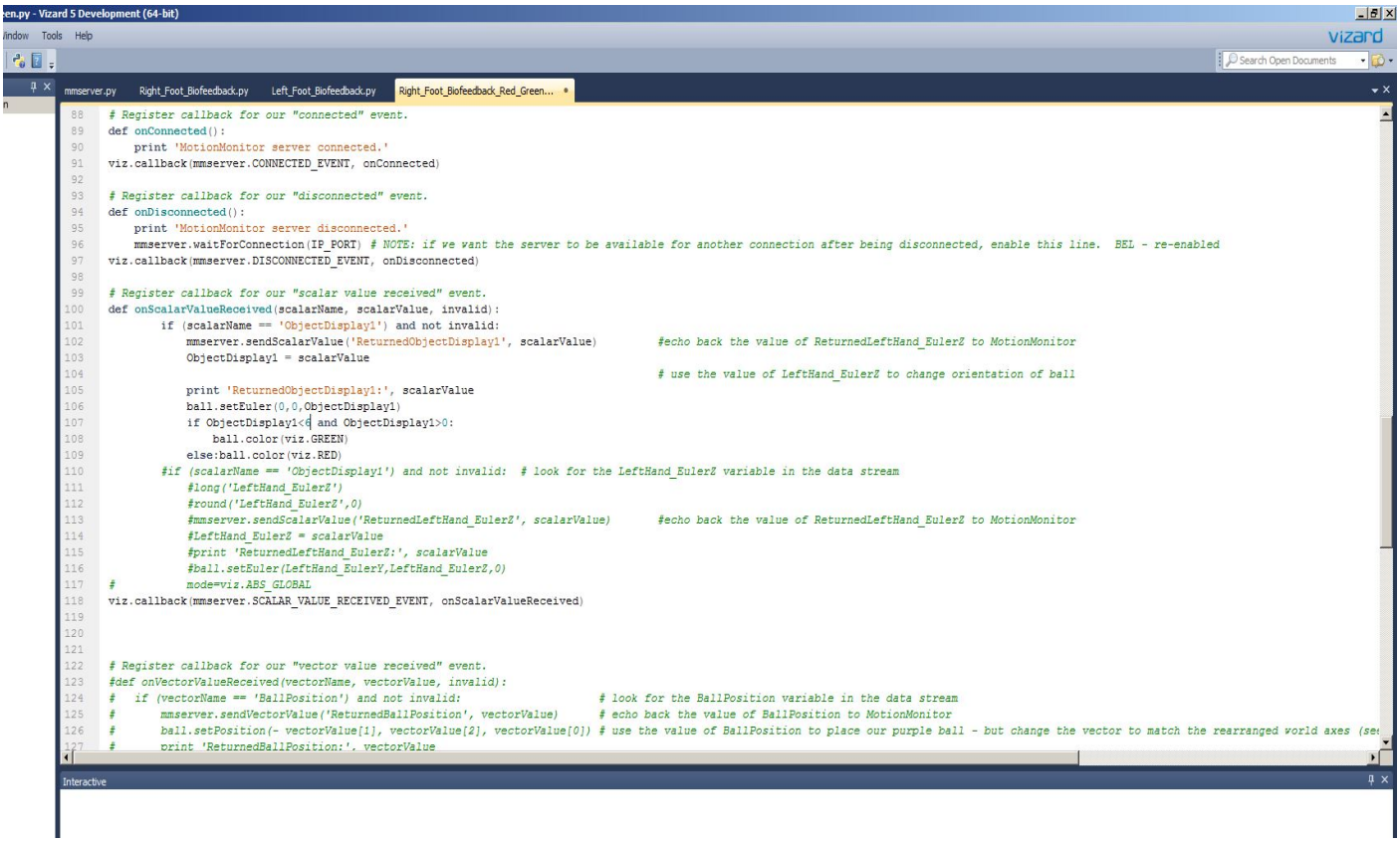
With a resistance band/tube wrapped around your foot, rotate your foot inboard slowly over 2 secs to the end of the motion. Slowly return your foot to starting position over a 4 sec count. Perform 30 times, 3 times a day.

6. Visual Biofeedback

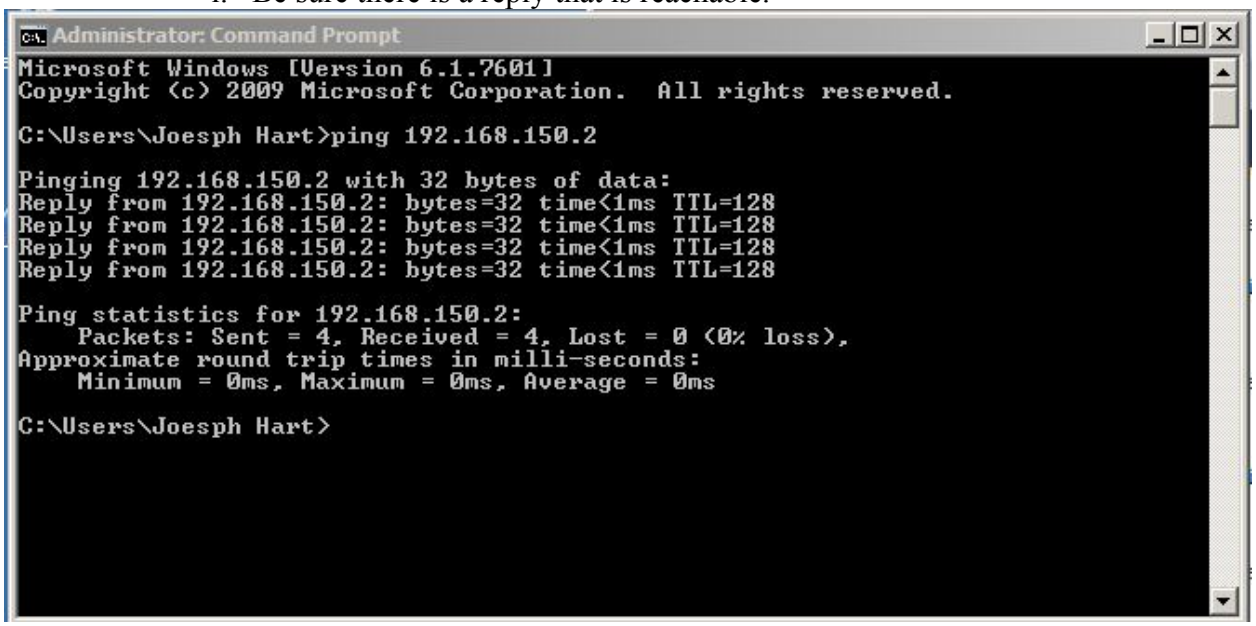
Biofeedback & MM Computer Set Up

1. Turn on computer and open Vizard

2. Turn on projector
3. On Vizard Computer go to File and Select Open
    a. Select mmserver.py
    b. Repeat step 2 and open
        i. Right_Foot_Biofeedback_Red_Green.py



4. Open Network and Sharing Center
    a. Change adapter settings
        i. Select LAN A
        ii. Double click on Internet Protocol Version 4 (TCP/IPv4)
            1. Enter the following information
                a. IP address: 192.168.150.1
                b. Subnet mask: 255.255.255.0
                c. *Note the IP address on the MM computer should read 192.168.150.2*
            2. Press OK
        iii. Press OK on LAN A properties
        iv. Close Network and Sharing Center
5. Open Command Prompt (located in computer start menu)
    a. Type: ping 192.168.150.2
    b. Press enter
        i. Be sure there is a reply that is reachable.

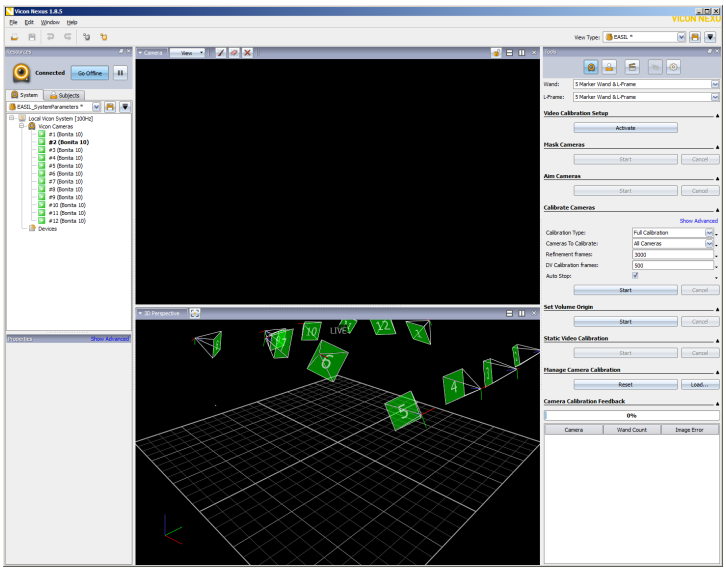


6. Repeat step 3 on Motion Monitor computer
    a. Open Command Prompt (located in computer start menu)
        i. Type: ping **192.168.150.1**
        ii. Press enter
    b. Be sure there is a reply that is reachable.

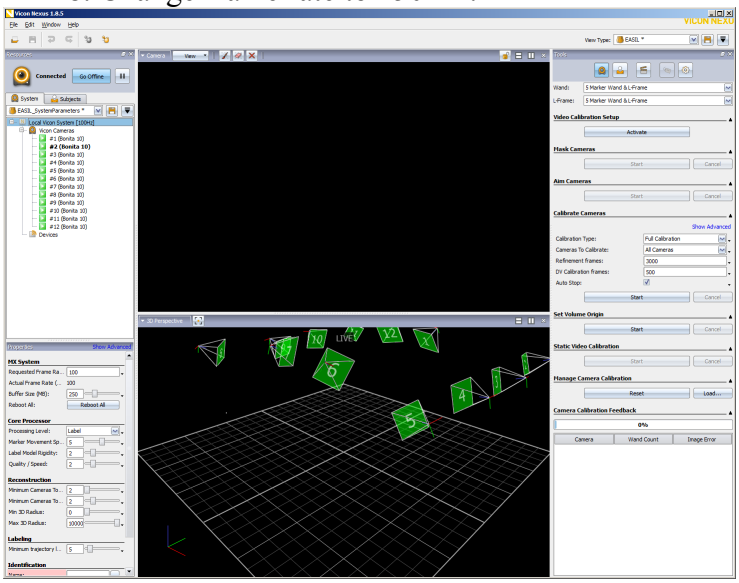
Vicon and MotionMonitor Setup Using the Cluster Markers

47. Turn on computer and open Vicon Nexus

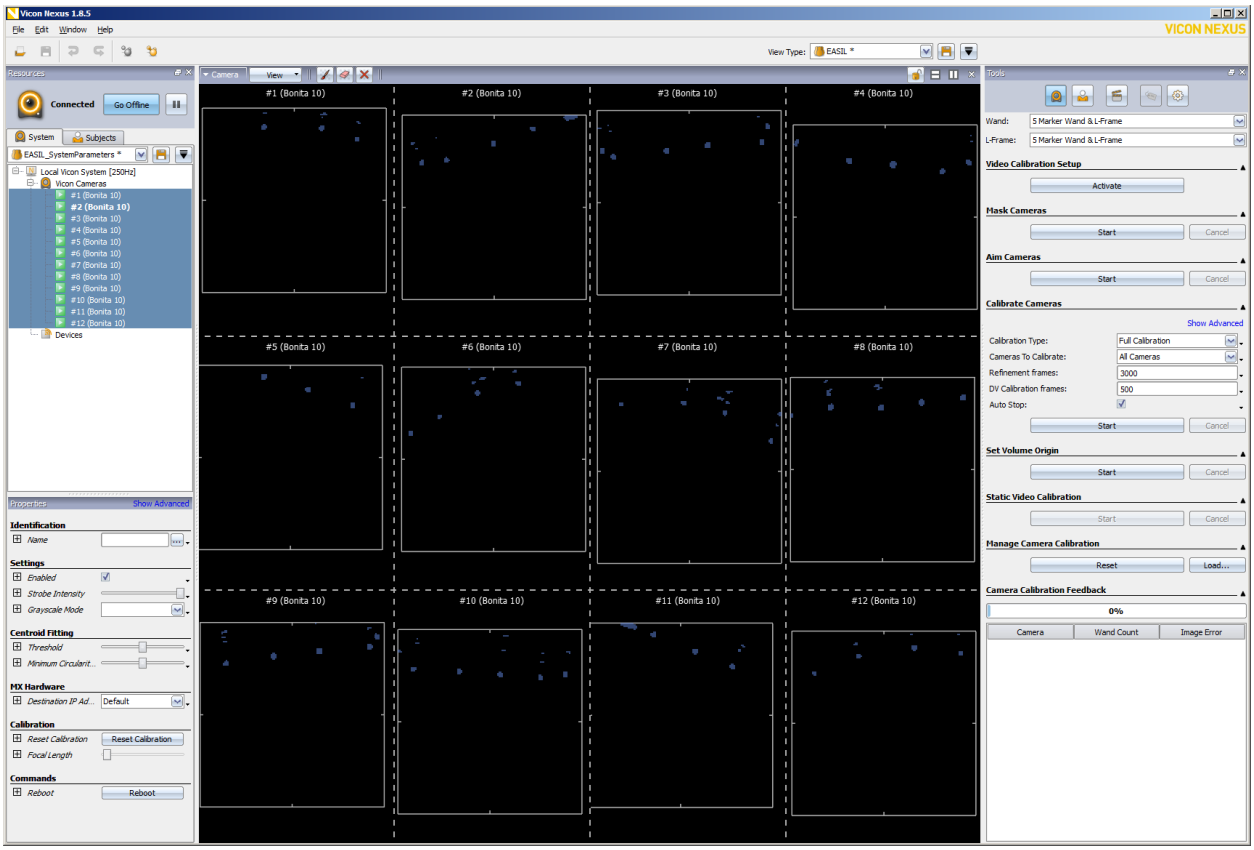
a. Make sure all cameras are green
b. If any cameras are not green, unplug and reinsert corresponding camera cable



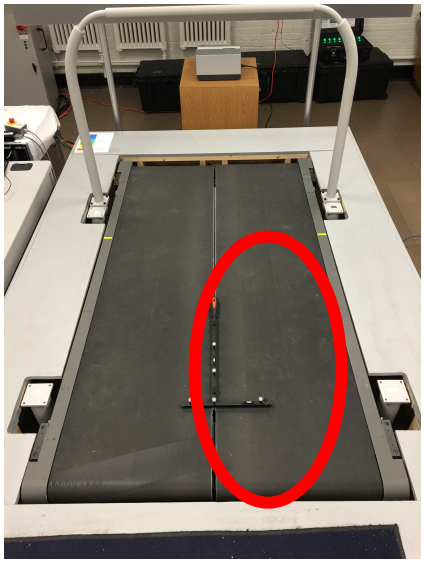
48. Change frame rate to 250 Hz.



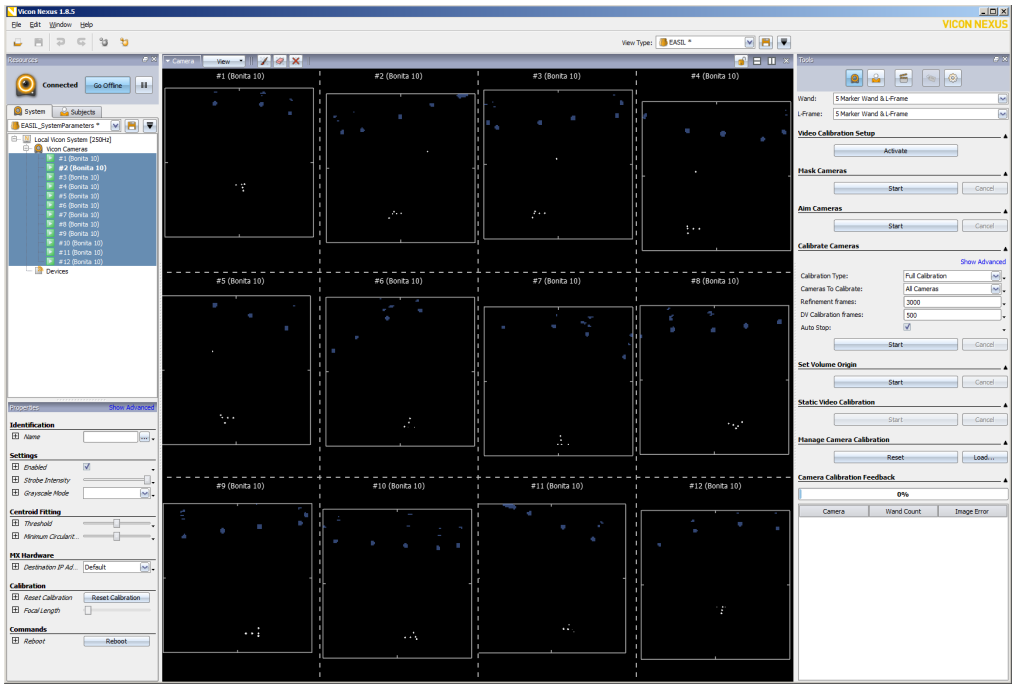
49. Select all cameras and change view to camera view
50. Remove all markers from the field
    a. If an unknown marker is in the field, try to locate it before masking cameras
51. Mask cameras
52. Select STOP once all reflectors in the field have changed to blue



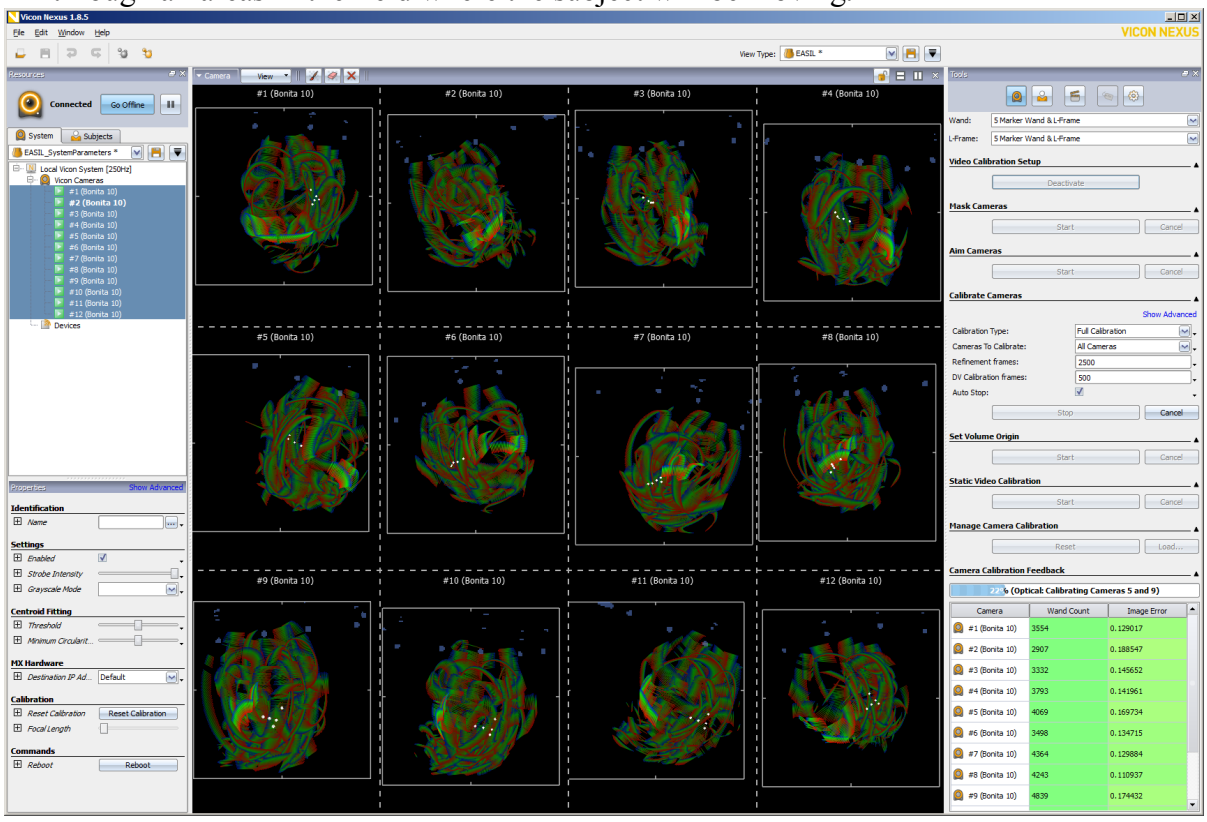
53. Place the L-shaped wand in the field at the edge of the force plates



54. Aim Cameras

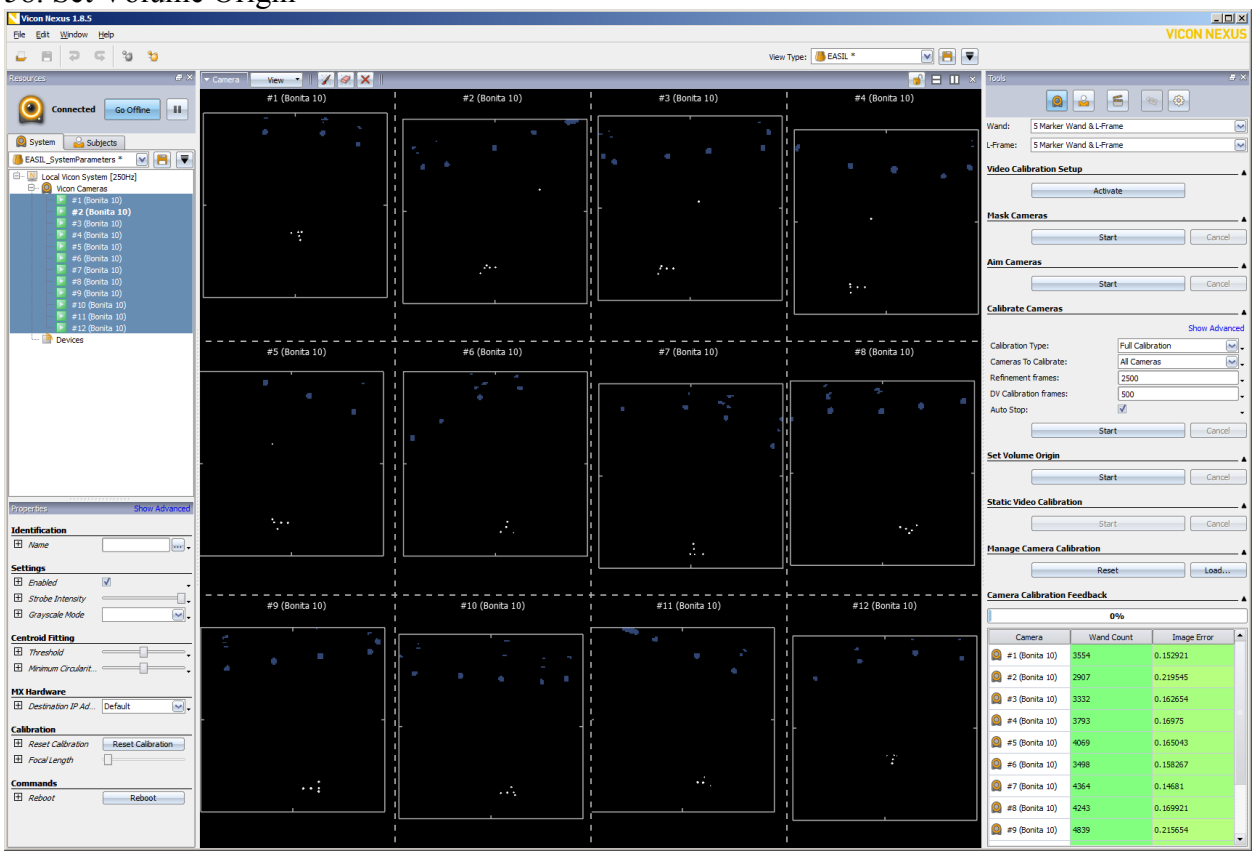


55. Calibrate cameras using 2500 refinement frames. Make sure to move the wand through all areas in the field where the subject will be moving.

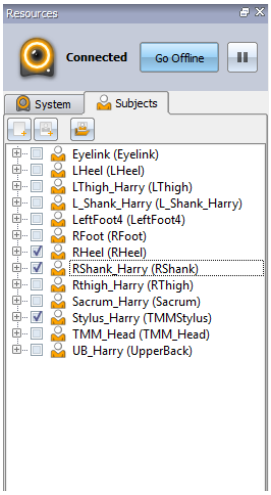


56. Check Image Error for any error greater than 0.25 – this may require recalibration
57. Replace the wand in the field (see picture in Step 7)

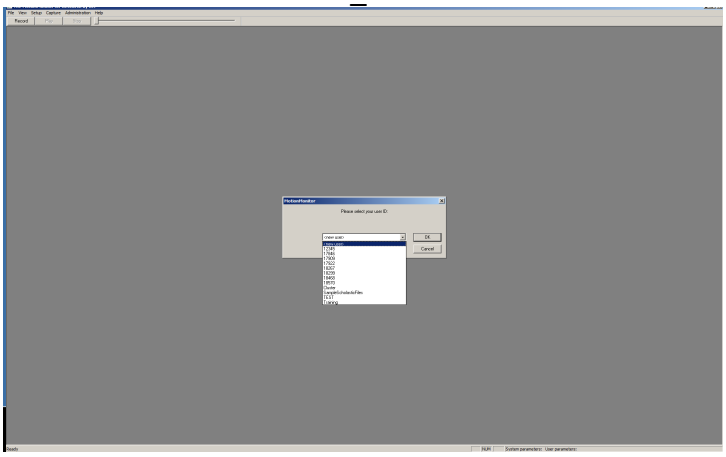
58. Set Volume Origin



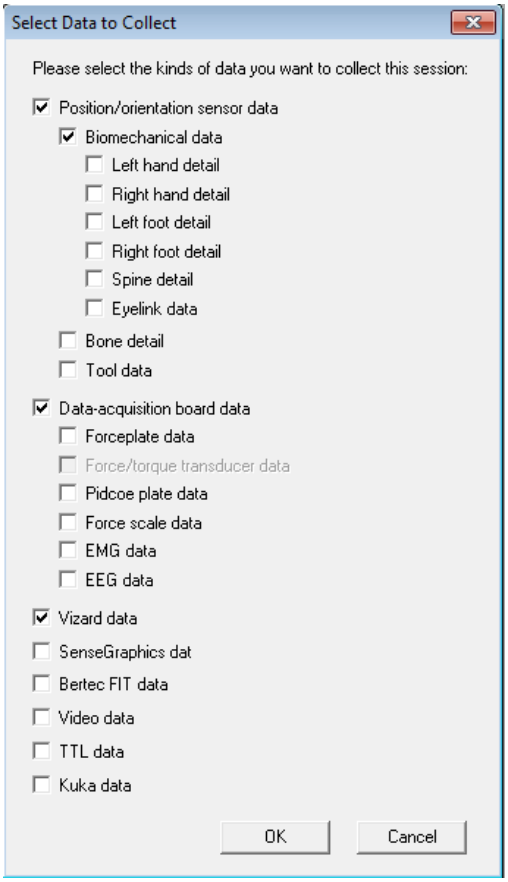
59. Select “Subjects’ tab to verify cluster files have loaded.
    a. Select the appropriate subject markers. (**Only Stylus and R/L heel & shank)**
    b. Press Control-R and markers on participant will be recognized to create model.



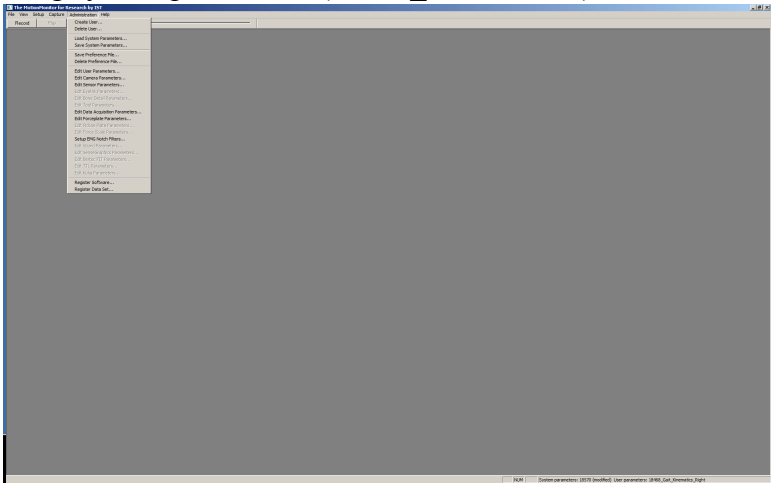
60. Open MotionMonitor user with **20446_Intervention**



61. Select data to collect: Make sure Position/orientation sensor data, Biomechanical data, Data-acquisition, and Vizard are checked



62. Go to the top menu and select Administration and Load System Parameters. Load corresponding system parameters (20446_Intervention).

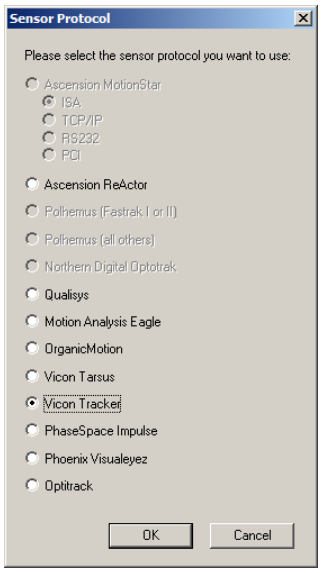


63. Go to the top menu and select File and Preference File. Load appropriate preference file.
    a. 20446_Left_GaitTraining

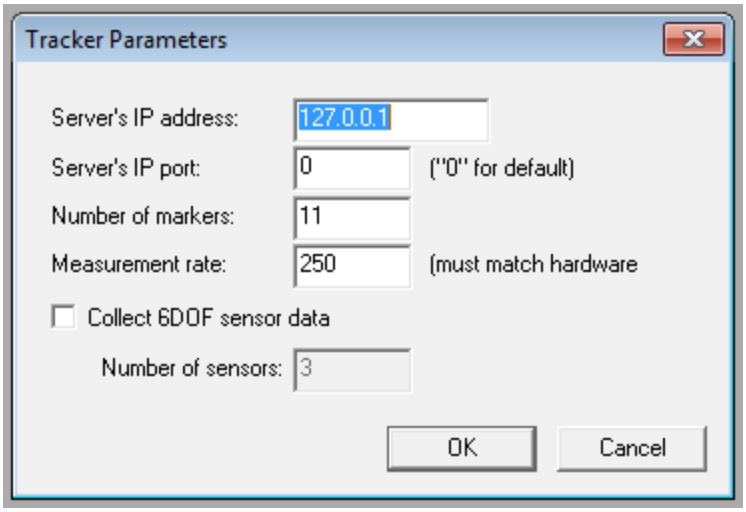
b. 20446_Right_GaitTraining

64. Subject should enter the field (stand on the treadmill) with all clusters (shank and heel) attached and the stylus placed within the view of the cameras.
    a. Press Control-R to refresh the view of the markers in Vicon

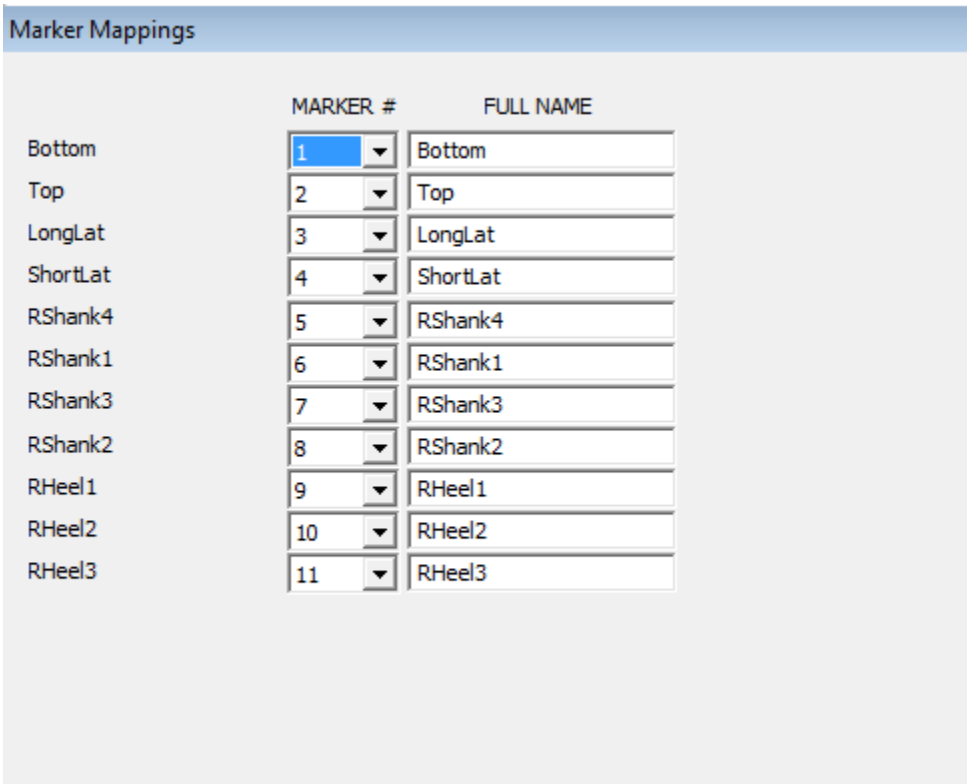
65. Go to the top menu and select Administration then select Edit Sensor Parameters.
    a. Select Vicon Tracker



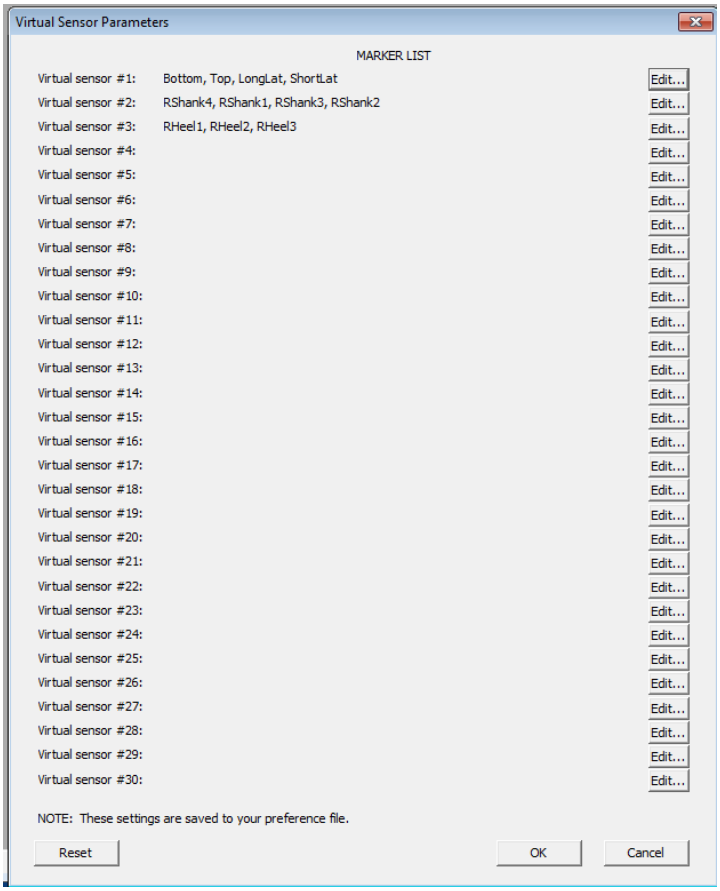
66. Confirm that number of markers = 11 and measurement rate = 250Hz



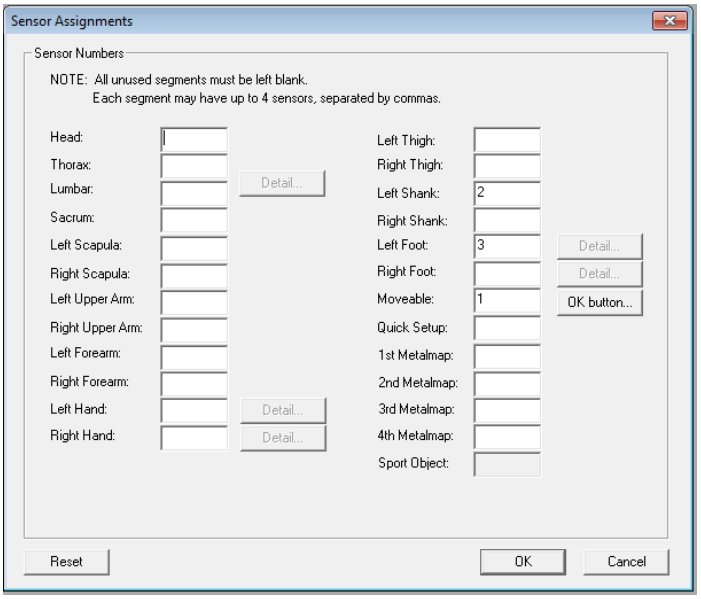
67. Confirm that all 11 markers are recognized



68. Confirm all clusters are assigned to appropriate virtual sensor.

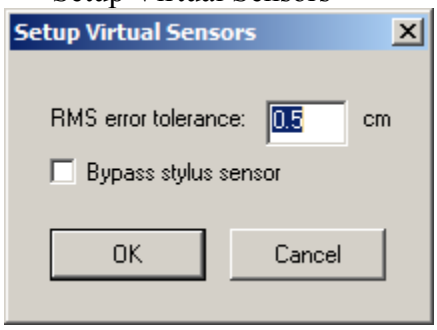


69. Go to the top menu and select setup and Edit Sensor Assignments. Sensor assignments listed should match assignments in virtual sensor parameters (see previous step).



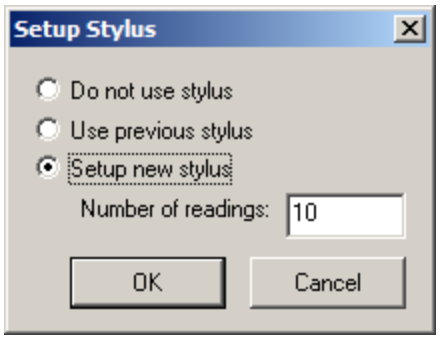
70. Ask the subject to stand still with hands crossed on the shoulders

71. Go to Vicon Nexus window and press Control-R
72. Return to MotionMonitor window and go to the top menu and select Setup and Setup Virtual Sensors

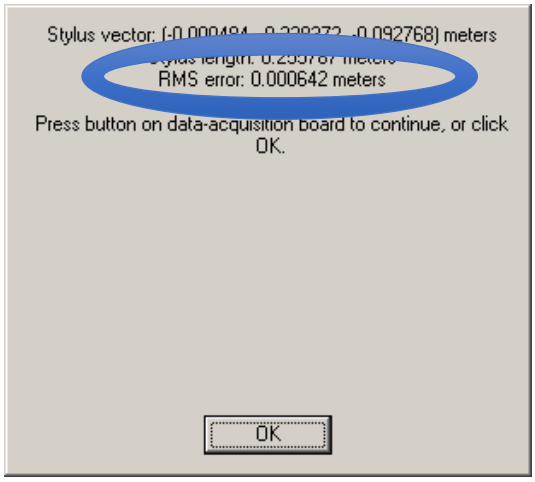


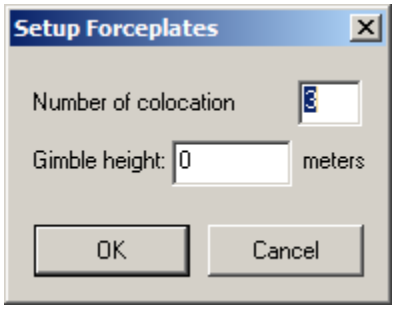
73. If you DO NOT receive an error, continue to step 28. If you DO receive an error, go back to step 21.
    a. Be sure to double check which subject sensors are marked in Vicon
74. Ask Subject to step onto the mat behind the treadmill.

75. Select Setup and Setup Stylus. Setup a new stylus with 10 readings.

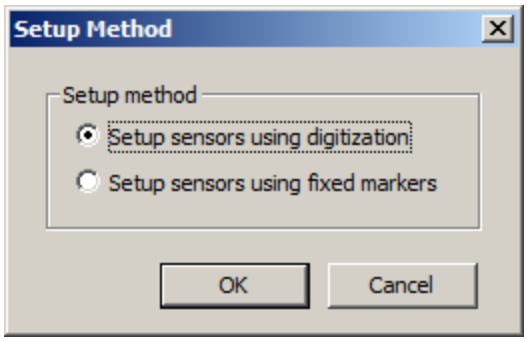


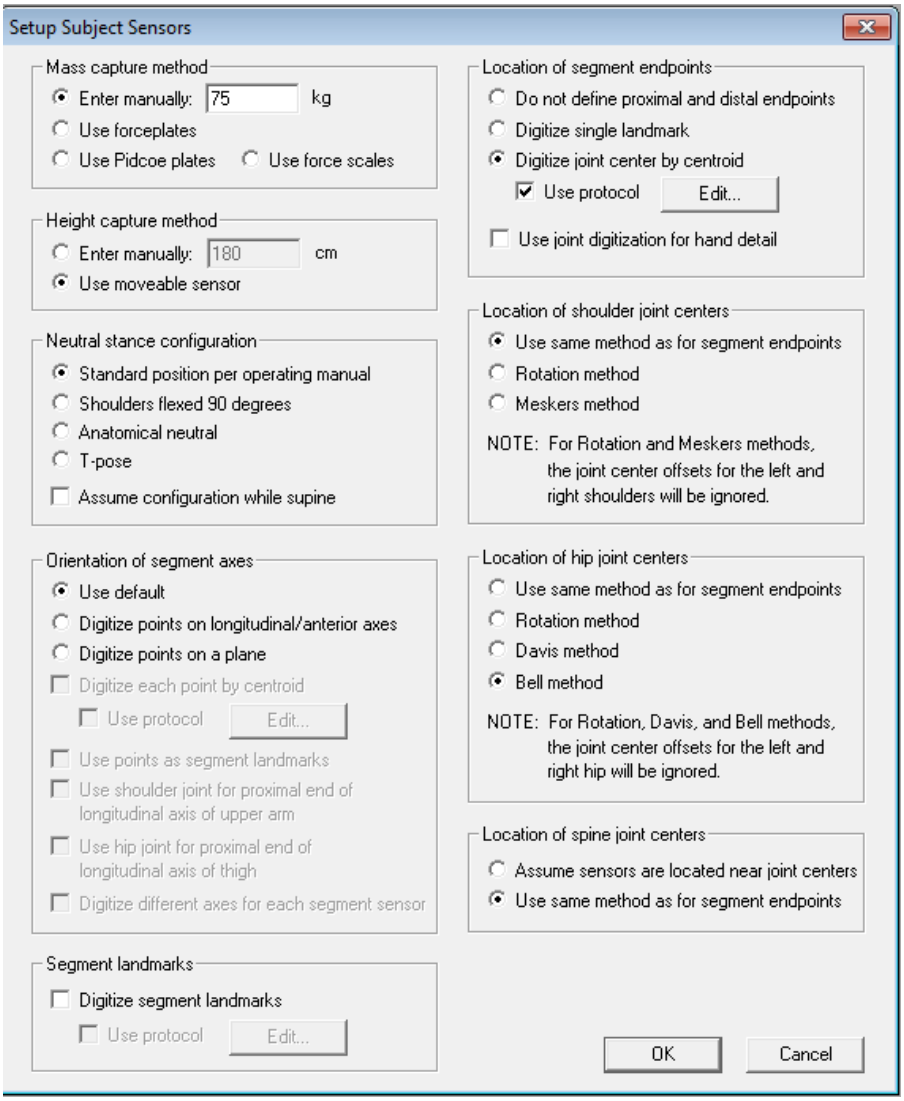
76. Calibrate stylus.
    a. RMS error should be less than 0.001



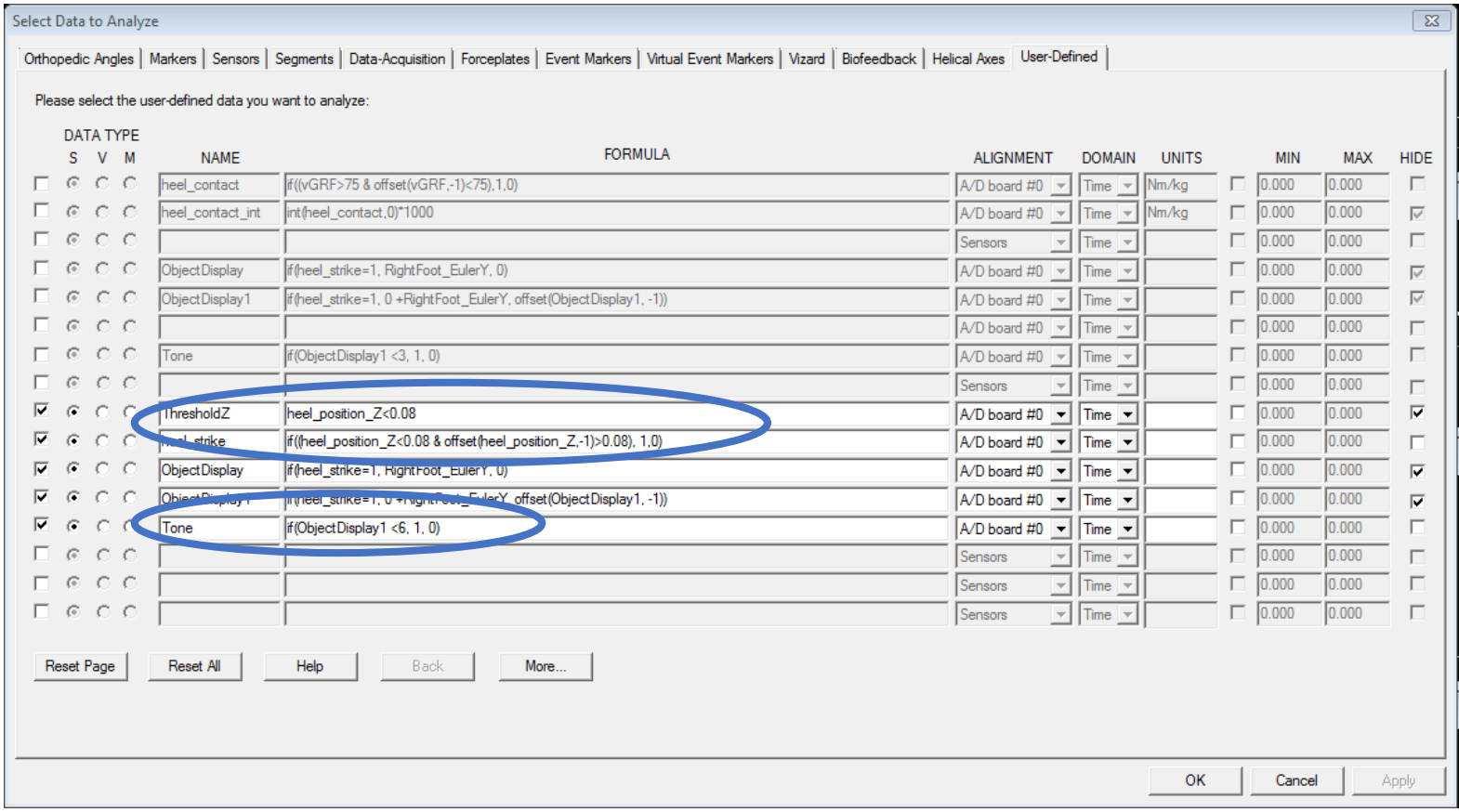


77. Go to the top menu and select Setup and Setup Subject Sensors. Select setup sensors using digitization. (Enter mass manually)


Setup Method
Setup method
Setup sensors using digitization
Setup sensors using fixed markers
OK
Cancel


Setup Subject Sensors
Mass capture method
Enter manually: 75 kg
Use forceplates
Use Pidcoe plates
Use force scales
Height capture method
Enter manually: 180 cm
Use moveable sensor
Neutral stance configuration
Standard position per operating manual
Shoulders flexed 90 degrees
Anatomical neutral
T-pose
Assume configuration while supine
Orientation of segment axes
Use default
Digitize points on longitudinal/anterior axes
Digitize points on a plane
Digitize each point by centroid
Use protocol
Edit...
Use points as segment landmarks
Use shoulder joint for proximal end of longitudinal axis of upper arm
Use hip joint for proximal end of longitudinal axis of thigh
Digitize different axes for each segment sensor
Segment landmarks
Digitize segment landmarks
Use protocol
Edit...
Location of segment endpoints
Do not define proximal and distal endpoints
Digitize single landmark
Digitize joint center by centroid
Use protocol
Edit...
Use joint digitization for hand detail
Location of shoulder joint centers
Use same method as for segment endpoints
Rotation method
Meskers method
NOTE: For Rotation and Meskers methods, the joint center offsets for the left and right shoulders will be ignored.
Location of hip joint centers
Use same method as for segment endpoints
Rotation method
Davis method
Bell method
NOTE: For Rotation, Davis, and Bell methods, the joint center offsets for the left and right hip will be ignored.
Location of spine joint centers
Assume sensors are located near joint centers
Use same method as for segment endpoints
OK
Cancel

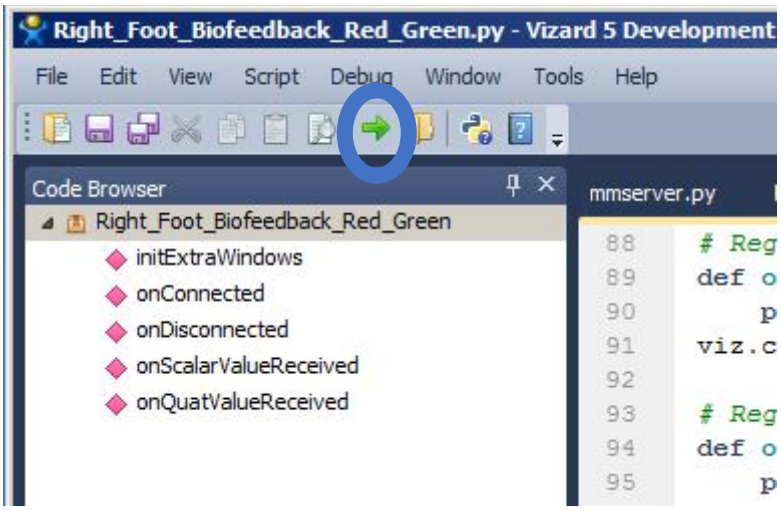
78. Place the tip of the stylus on top of the subject's head when prompted by MotionMonitor. Make sure height and weight are accurate (around what you would expect). Hold still with stylus to don sensors.
79. Point out the following landmarks on the subject in the following order (hitting Control-R on Vicon Nexus screen as appropriate): *Example is for Right Limb*
    a. Right Lateral Knee Joint Line
    b. Right Medial Knee Joint Line
    c. Right Lateral Malleolus
    d. Right Medial Malleolus
    e. Right Tip of 2nd Phalanx
80. If skeleton looks appropriate, continue with collection. If anything does not look right, re-digitize the skeleton.
81. Once subject is set up select File, New
82. Record a quiet standing trial and record the Euler_Y and heel_position_Z
83. Record a short walking trial
    a. Identify average Euler_Y value at heel_strike and use to determine gait training threshold
    b. Select Analyze → Real Time… → User-Defined
        i. TresholdZ input quiet standing value
        ii. Inversion threshold
            1. In tone, select threshold for EulerY where highlighted
                a. if(ObjectDisplay1 <6, 1, 0)



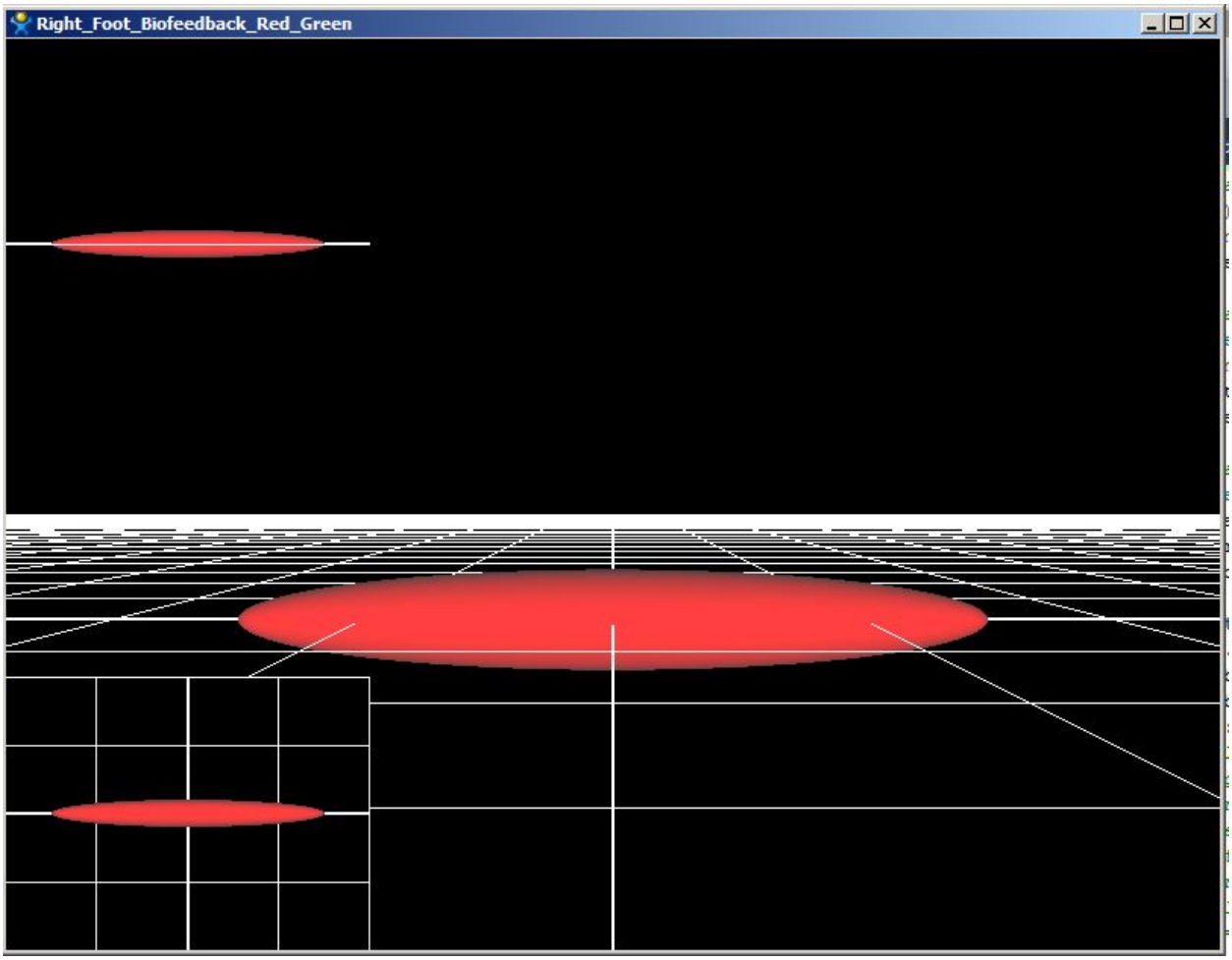
2. On the **Vizard** computer, **on line 107** set threshold for green (match ObjectDisplay1 threshold on MM computer)

```
98
99  # Register callback for our "scalar value received" event.
100 def onScalarValueReceived(scalarName, scalarValue, invalid):
101         if (scalarName == 'ObjectDisplay1') and not invalid:
102             mmserver.sendScalarValue('ReturnedObjectDisplay1', scalarValue)
103             ObjectDisplay1 = scalarValue
104
105             print 'ReturnedObjectDisplay1:', scalarValue
106             ball.setEuler(0,0,ObjectDisplay1)
107             if ObjectDisplay1<6 and ObjectDisplay1>0:
108                 ball.color(viz.GREEN)
109             else:ball.color(viz.RED)
110         #if (scalarName == 'ObjectDisplay1') and not invalid:  # look for th
111             #long('LeftHand_EulerZ')
112             #round('LeftHand_EulerZ',0)
113             #mmserver.sendScalarValue('ReturnedLeftHand_EulerZ', scalarValue
114             #LeftHand_EulerZ = scalarValue
115             #print 'ReturnedLeftHand_EulerZ:', scalarValue
116             #ball.setEuler(LeftHand_EulerY,LeftHand_EulerZ,0)
117 #           mode=viz.ABS_GLOBAL
118 viz.callback(mmserver.SCALAR_VALUE_RECEIVED_EVENT, onScalarValueReceived)
119
```

84. When you are ready to provide feedback to subject, select **run** on the Vizard computer



85. A window with the biofeedback will appear. *Shape will not move until you are running Biofeedback in Motion Monitor.*

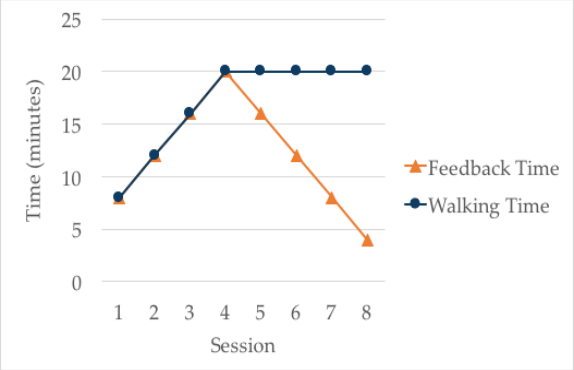


86. On the **Motion Monitor computer** close the previous walking and quiet standing trials

87. Select File → New
88. Go to Interact → Biofeedback
    a. Press OK to begin biofeedback
    b. Press STOP when you are done with intervention. **DO NOT PRESS DONE**

Gait Training Schedule

Session 1: 8 minutes
Session 2: 12 minutes
Session 3: 16 minutes
Session 4: 20 minutes
Session 5-8: 20 minutes



Degrees of Inversion Displacement	Total Change in degrees									
	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
1	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
2	0.2	0.4	0.6	0.8	1	1.2	1.4	1.6	1.8	2
3	0.3	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3
4	0.4	0.8	1.2	1.6	2	2.4	2.8	3.2	3.6	4
5	0.5	1	1.5	2	2.5	3	3.5	4	4.5	5
6	0.6	1.2	1.8	2.4	3	3.6	4.2	4.8	5.4	6
7	0.7	1.4	2.1	2.8	3.5	4.2	4.9	5.6	6.3	7
8	0.8	1.6	2.4	3.2	4	4.8	5.6	6.4	7.2	8
9	0.9	1.8	2.7	3.6	4.5	5.4	6.3	7.2	8.1	9
10	1	2	3	4	5	6	7	8	9	10

Gait Training Data Sheet

Group

☐ Intervention
☐ Control

Time: _____

Intervention Protocol

Neutral Stance

	Degrees (º)		Degrees (º)
Y-position At IC		Z-position At IC	

	% difference	Degrees (º)
Intervention Threshold		

☐ Set threshold in preference file **Object Display**
☐ Set threshold in Vizard for **green and red**

Walking

	Speed (m/s)	Time
Preferred WS		
120% PWS		

Time	Time (min)
Biofeedback	
No biofeedback	
Total	

Progression for next visit:

☐ Majority of steps performed without error
☐ Can maintain ≥ 10 consecutive strides without error
☐ Self-report success at current threshold

Decrease threshold if: majority of steps performed with error, cannot maintain ≥10 strides without error, self-report difficulty at current threshold

NOTES:

Subject ID:_____

No Biofeedback - Gait Log

Visit #	Date	Preferred Speed	Time	120% PS	Time	Total Time
1						
2						
3						
4						
5						
6						
7						
8						

Table C2

PROTOCOL

Background

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

INSTRUCTIONS

- This should include a referenced systematic evidenced-based review when possible.
- If this study involves qualitative research explain the major constructs of your study.
- Do not state in this section what you plan to do in this study. This information should be entered later under "What will be done in this protocol?"
- Do not include the bibliography in this section.
- For studies submitted under the Expedited review criteria, this section need not be more than a few paragraphs.
- For those studies where data will be analyzed collaboratively by multiple sites doing a similar study for which there is no common protocol (Collaborative Site Analysis Study) include a description of the common scientific goals/ procedures/data points.
- If this is a FIVE YEAR UPDATE make sure the information throughout the protocol includes the most current information.

Answer/Response:

Lateral ankle sprains are a common musculoskeletal injury in athletic populations as well as the general public. Following an initial lateral ankle sprain (LAS), many individuals do not seek care from a medical professional. Lack of care could contribute to the decreased neuromuscular function, poor postural control, and altered gait patterns seen in individuals with a history of LAS.[1,3] Lack of treatment may also result in long-term consequences such as decreased physical activity across the lifespan, decreased quality of life, and an earlier onset of ankle osteoarthritis. Following an initial LAS, 40% of individuals develop chronic ankle instability (CAI).[5] This condition involves feelings of instability or "giving way, decreased self-reported function, and recurrent sprains. Deficits in individuals with CAI have been linked to range of motion, sensorimotor control, proprioception, postural control, and strength.[9] Research studies commonly target only one area in their rehabilitation protocols. Focusing treatment in only one of the areas of where deficits lie may not actually improve the patient's condition overall. Impairment-based rehabilitation uses an "asses, treat, re-assess" approach to target deficits and has previously shown to improve patient reported outcomes associated with CAI.[7,8] ***Thus, taking a global treatment approach using impairment-based rehabilitation to intervene where deficits are observed is essential.***

During walking gait, CAI patients demonstrate alterations in neuromuscular control, plantar pressure, kinematics, and spatial-temporal measures. Over time this may represent a larger problem as walking is the primary form of locomotion and is a common daily activity.

During walking, individuals with CAI may be at risk for subsequent ankle sprains due to position of the foot and ankle during terminal swing and at initial contact (IC) leading into the loading response.[1] Several factors may contribute to the compromised foot position during gait including altered distal and proximal muscle function, laxity of the lateral ankle ligaments, and decreased proprioception.[10] ***Individuals with CAI have been shown to be 6-7º more inverted prior to IC during walking.***[3] ***When the ankle is inverted during the swing phase, it is in an open packed position which may leave the joint susceptible to inversion ankle injuries.*** This inverted foot position may also translate to the more lateral pressures under the foot in those with CAI during gait.[10]

Gait retraining has been suggested as a way to address ankle alterations with hopes to reduce the risks of recurrent ankle sprains.[4,10,14]

Individuals take approximately 1,000 steps per limb per mile during walking. Over the course of several miles the total number of steps taken increases rapidly. As walking is a relatively simple task, it may be helpful to address deficits in this area for individuals with CAI. Traditionally, gait deficits have been targeted with strength or balance training but these interventions have not been successful at correcting gait mechanics.[11] Likewise, Davis and Futrell note that ***strength training without neuromuscular reeducation rarely translates to changes in movement patterns***.[2]

Weinstein previously defined motor learning as "a set of internal processes associated with practice or experience leading to a relatively permanent change in the capability for responding.[13] These processes are thought to be "complex central nervous system phenomena whereby sensory and motor information is organized and integrated." More clinically applicable interventions have also used simple forms of feedback such as holding a mirror in front of a treadmill or using audio cues. ***It has become apparent that in order to change gait mechanics, we need to perform specific gait training.***

With the advancements in technology, it is now possible to provide real-time visual feedback to participants through computer monitors or projector screens that reflect the motion of the subject. A study by Noehren et al.[12] looked at the effects of real-time gait retraining on hip kinematics in patients with patellofemoral pain and found that pain and function in participants were improved following gait retraining. The participants completed 8 sessions over 2 weeks and walked on a treadmill while their hip adduction angle of the involved limb was displayed on a monitor throughout the stance phase. They were given instruction to keep their superimposed hip angle within the shaded area (indicating $\pm$1SD of mean of healthy individuals). They used intermittent feedback which has been shown to have better long-term effects than subjects who receive continuous immediate feedback.[12] During the first 4 sessions participants received 100% continuous immediate feedback and then had faded feedback for the remaining sessions (Figure 2).[12] Runners were able to decrease their hip adduction, internal rotation, and contralateral pelvic drop following the retraining and were able to maintain changes at the 1-month follow up visit.[12]

Gait training with the use of feedback has not been extensively studied in individuals with CAI. Only one published study has used audio cues to provide feedback during walking gait.[6] Auditory biofeedback devices were worn in the shoes to alert participants when too much force was placed on the sensor which was placed under the lateral aspect of the foot while surface electromyography and plantar pressure were simultaneously recorded. Participants were instructed to walk in a way that would not trigger the audible cue. When walking in the auditory feedback condition, the participants demonstrated large and significant decreases in peak pressure and pressure time integral in the lateral midfoot and forefoot and increases in the hallux.[6] Donovan et al. [6] speculated that this shift in pressure may be due increased amplitudes of the peroneus longus and medial gastrocnemius muscles.

For individuals with CAI, it may be beneficial to provide visual feedback in addition to impairment based rehabilitation to teach safer ankle positioning around IC. When the foot contacts the ground in an increasingly inverted position, an ankle sprain could potentially occur. Therefore, addressing the position of the ankle at IC could be beneficial in adapting less risky motor patterns ultimately reducing the risk of subsequent ankle sprains.

Objectives/Hypothesis

INSTRUCTIONS:
If this study involves biomedical research clearly state the objectives and hypotheses and clearly define the primary and any secondary outcome measures. If this study involves qualitative research clearly state your research hypothesis or question.

This section should not include information already included in other sections such as background information or information from the procedures section.

Answer/Response:

Specific Aim #1: ***To assess differences in walking gait biomechanics between individuals with CAI and lateral ankle sprain copers at preferred, fast, and standardized walking speeds.***

Hypothesis#1: Individuals with CAI will have more inverted foot position throughout the gait cycle. Inversion changes will be greater at faster walking speeds.

Specific Aim#2: ***To assess if impairment-based rehabilitation with visual feedback gait training is more effective than rehabilitation without gait training at improving the ankle inversion angle at IC during walking in CAI patients.***

Hypothesis#2: Impairment-based rehabilitation utilizing visual biofeedback gait training will lead to a more everted rearfoot angle at IC compared to rehabilitation without gait training in CAI patients.

Specific Aim#3: ***To assess if impairment-based rehabilitation with visual feedback gait training is more effective than rehabilitation without gait training at improving patient-reported outcomes in CAI patients.***

Hypothesis#3: Impairment-based rehabilitation utilizing visual biofeedback gait training will lead to greater improvements in patient-reported outcomes compared to rehabilitation without gait training in CAI patients.

Specific Aim #4: To assess if impairment-based rehabilitation with visual feedback gait training is more effective than rehabilitation without gait training for intrinsic foot muscle strength, cross section (CSA), and foot morphology in CAI patients.

Hypothesis#4: Impairment-based rehabilitation utilizing visual biofeedback gait training will lead to greater improvements in strength, CSA and thickness measures of foot intrinsic muscles compared to rehabilitation without gait training in CAI patients.

Specific Aim #5: To assess if impairment-based rehabilitation with visual feedback gait training is more effective than rehabilitation without gait training at maintaining improvements at 6 and 12 months after study completion.

Hypothesis#5: Impairment-based rehabilitation utilizing visual biofeedback gait training will lead to greater improvements in patient-reported outcomes compared to rehabilitation without gait training in CAI patients at the 6 and 12 month follow up (via email).

Specific Aim #6: To assess if impairment-based rehabilitation with visual feedback gait training affects gluteal muscle activation during standardized, self-selected, and fast walking gait for gluteus medius and maximus activity ratios and preferential activation ratios through ultrasound imaging.

Hypothesis #6: Impairment-based rehabilitation with visual feedback during gait training will lead to increased gluteus maximus and medius activity ratios, and increased preferential activation of the gluteus medius muscle during stance phases of gait compared to rehabilitation without gait training in CAI patients, and will present more similarly to the coper group.

Study Design: Biomedical

1. Will controls be used?

Answer/Response:

Yes

►IF YES, explain the kind of controls to be used.

Answer/Response:

Lateral ankle sprain copers (history of 1 sprain) will serve as a control for the baseline visit.

For aims 2-4, a control group of CAI participants will be used

2. What is the study design?

Example: case series, case control study, cohort study, randomized control study, single-blind, double-blind, met-analysis, systematic reviews, other. You may also view the IRB-HSR Learning Shot on this topic to help you answer this question. (http://www.virginia.edu/vpr/irb/learningshots/Writing_protocol_June09/player.html

Answer/Response:

Aim 1: descriptive laboratory

Aims 2-4: single blinded randomized controlled trial

3. **Does the study involve a placebo?**

   Answer/Response:

   No

   ►IF YES, provide a justification for the use of a placebo

   Answer/Response:

Human Participants

Ages: __18-30__
Sex: _**Any**___
Race: _**Any**___

Subjects- see below

> **INSTRUCTIONS:** For question 1-4 below insert an exact #. Ranges or OPEN is not allowed. This # should be the maximum # you expect to need to enroll (i.e. sign consent) If you are only collecting specimens the number of participants should equate to the # of specimens you need. If you are collecting only data from a chart review the number should designate the number of subjects whose medical records you plan to review. Age/ Sex/Race criteria should designate the demographics of participants from whom you will obtain the specimen/data.

1. **Provide target # of subjects (at all sites) needed to complete protocol.**

   > **INSTRUCTIONS:** If this is NOT a database protocol, this number should be the same as the number of subjects needed to obtain statistically significant results.

   Answer/Response: 80

   Aim 1: 20 total

   Aims 2-4: 60 total

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.**

   Answer/Response:

   Up to 15% attrition rate has been accounted for in the sample size calculation of all aims. Screen failure/dropouts/withdrawal rates are not expected to be high, but we estimate for up to 20 total.

3. **How many subjects will be enrolled at all sites?**

   > **INSTRUCTIONS:** This number must be the same or higher than the # from question # 1 in order to account for the # of screen failures, dropouts, withdrawals described in question # 2.

   Answer/Response: **100 total**

   Aim 1: 20 total

   Aims 2-4: 60 total

   Dropouts/withdrawals/screen fail: 20

4. How many subjects will sign a consent form under this UVa protocol?

INSTRUCTIONS: If the protocol does not have a consent form- the number listed here should reflect such things as the number of subjects from whom specimens will be obtained, the number of charts to be reviewed etc.

Answer/Response:
Up to 100

Inclusion/Exclusion Criteria

INSTRUCTIONS:

- The inclusion and exclusion criteria should be written in bullet format.
- *This item applicable if the study will require consent (verbal or written).* Unless there is a scientific reason for not recruiting a certain type of vulnerable population(e.g. not enrolling fetuses, neonates or children in a study regarding Alzheimer's) list the following vulnerable populations under either Inclusion or Exclusion criteria below: pregnant women, fetuses, neonates, children, prisoners, cognitively impaired, educational or economically disadvantage, non- English speaking subjects .
- If you will not enroll subjects who do not speak English because certain procedures cannot be carried out if the subject does not speak English (e.g. a survey is not validated in other languages) insert the following as an Inclusion Criteria: Willingness and ability to comply with scheduled visits and study procedures.
- If this is a collection of only retrospective* specimens or data, the inclusion criteria must include a start and stop date for when specimens/ data will be collected.
- The stop date must be prior to the version date of this protocol.
- *Retrospective: all specimens are in a lab at the time this protocol is approved by the IRB. All data exists in medical records or records from previous studies at the time this protocol is approved by the IRB.

1. List the criteria for inclusion

Answer/Response:

Coper

1) ≥1 Ankle Sprain (>12 months prior)
2) Physically active (>1.5 hr/week)
3) Either
   - ➢ Scores ≤ 10 on Identification of Functional Ankle Instability (IdFAI)

   OR
   - ➢ (a) Answers "no" to question "Do you frequently roll your ankle or feel like it gives way?" AND (b) Answers "never" or "Once a year" for the following questions: "During activities of daily life how often does your ankle feel unstable?", "During sport or recreational activity how often does your ankle feel unstable?"
4) 99 Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL)
5) 97 FAAM Sport

CAI

1) ≥1 Ankle Sprain (>12 months prior)
2) Physically active (>1.5 hr/week)
3) 10 on Identification of Functional Ankle Instability (IdFAI)
4) ≤ 90 Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL)
5) ≤ 85 FAAM Sport

2. List the criteria for exclusion

Answer/Response:

Coper & CAI

1) -Hx of LE fracture
2) -Hx of LE surgery
3) -Hx of ankle sprain within last 6 weeks
4) -Participating in physical therapy for ankle
5) -Multiple Sclerosis
6) -Marfan's Syndrome
7) -Lumbosacral Radiculopathy
8) -Ehlers-Danlos Syndrome
9) -Diabetes Mellitus

-Pregnant (self-reported)
-Unable to provide informed consent

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

Answer/Response: none

Statistical Considerations

1. Is stratification/randomization involved?

Answer/Response:

Yes

►IF YES, describe the stratification/ randomization scheme.

INSTRUCTIONS:
The stratification factors and/or the randomization plan should be identified. If there is no randomization component or important patient characteristics that will be used in treatment allocation or data analysis, a statement to this effect should be included.

Stratification factors: These are pretreatment patient characteristics which could be balanced across treatment arms by design or may be used to determine starting dose or treatment allocation.

If randomization is going to be used, the details of the randomization plan should be described.

The description should include:
--the method and timing of randomization
--the type of randomization scheme that will be used in the study

--whether or not the randomization masked/blinded/if so, then to whom is it masked/blinded
--who has access to the randomization scheme

Answer/Response:
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 randomization will be completed following the baseline testing. The investigator who supervises the rehabilitation program will 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 Answer/Response:
_____ UVa Investigational Drug Service (IDS)
__X___ Other: Specify Answer/Response: A UVA faculty member will generate the randomization scheme prior to any participant enrollments. A disinterested third party member will have access to the scheme and reveal to the clinician performing the intervention part of the study.

2. What are the statistical considerations for the protocol?

The objectives section and the statistical section should correspond, and any objective for which analysis is unfeasible should be deleted. Also, the estimates and non-statistical assumptions of the statistical section should be supported by discussion in the background section.

The answer to this question should include:
--Study Design/Endpoints
--Recap of study objectives and endpoint definitions. An assessment of how study objectives will be assessed by identifying & defining which endpoints will be used to assess each component of the study objectives.
--The study design should include contingencies for early stopping, interim analyses, stratification factors (If applicable), and any characteristics to be incorporated in analyses.
--The power/precision of the study to address the major study endpoint(s), the assumptions involved in the determination of power/precision.
--If statistical hypothesis testing is included then specify the null and alternative hypotheses, the test statistic, and the type I and II error rates
--If precision of an estimate, then provide a definition for precision
--If other, then specify

Answer/Response:
Aims 1 & 2: For the dependent variables degrees of inversion-eversion and dorsiflexion-plantar flexion motion during gait, group means will be calculated across all 100 points of the gait cycle. Statistical parametric mapping (SPM) repeated measures ANOVAs will be used to compare group differences and post-hoc 1-dimentional SPM t-tests will be

used when p<0.05. For Aim 1, a 2x3 (group by speed) SPM ANOVA will be used. For aim 2, a 2x2 (group by time) SPM ANOVA will be used.

Aims 3-5: For primary dependent variables (FAAM-ADL and Sport measures, intrinsic foot strength, CSA, and foot morphology) 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 Coper 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 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).

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

Include the anticipated accrual rate, the accrual goal for the study, including accrual goals by strata if appropriate, adjustments for drop-outs etc. and study duration.

Answer/Response:

Aim 1:
An a priori sample size estimate was performed based on previously published data[4] estimating a group difference of 2º for ankle inversion/eversion at toe-off between CAI and coper participants during walking. The variability was approximately 2º. To find statistically significant differences at an alpha level (Type I error) of 0.05 and power $(1-\beta)$ of 0.8, with an 15% of data lost due to attrition, we will collect up to 20 subjects per group. Note that 20 CAI participants from aims 2-4 will be matched to the copers.

Aims 2-5:
An a priori sample size estimate was performed based on previously published data[3] estimating a group difference of 3.5º for ankle inversion/eversion at IC between control and functional ankle instability participants during walking. Assuming a variability of approximately 4.6º, we estimated that 25 subjects per group would be needed to find statistically significant differences at an alpha level (Type I error) of 0.05 and power $(1-\beta)$ of 0.8. We estimate up to 15% of data will be lost due to attrition and will collect up to 30 subjects per group. Therefore, we will enroll up to 60 participants in this study.

4. What is your plan for primary variable analysis?

Include a sketch of the analysis to assess primary study objectives.

Answer/Response:
We will do SPM ANOVAs to determine any significant differences in gait biomechanics.

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?

Include the following: --A sketch of the analysis to assess secondary study objectives. --For phase III studies, the power/precision of the study to address the secondary objective(s).

Answer/Response:
We will do an analysis of variance to determine any significant differences in strength, ROM, and balance measures between the control and experimental group.

6. Have you been working with a statistician in designing this protocol?
Answer/Response:
No

IF YES, what is their name?
Answer/Response:

7. Will data from multiple sites be combined during analysis?
Answer/Response:

INSTRUCTIONS: IF YES, answer the following questions

No

7(a). Does the study involve randomization?

Answer/Response:

IF YES, will randomization be done at each site or among sites?
Answer/Response:

7(b). Has the sample size calculation considered the variation among sites?
Answer/Response:

7(c). When combining the data from multiple sites to assess the study results, is the effect of the treatment to be tested (or the association to be tested) assumed to be the same across sites or vary among sites? What is the modelling strategy?

Answer/Response:

7(d). Is there a common protocol used in all sites?

Answer/Response:

IF NO, how will differences among sites, such as those related to the implementation, inclusion criteria, patient characteristics, or other sites characteristics, be considered to assess the study results?

Answer/Response:

Study Procedures-Biomedical Research

1. What will be done in this protocol?

INSTRUCTIONS:
This should include everything that will be done as part of this protocol. Do not repeat information that is included in other sections such as Background or Hypothesis sections.
This section should include an indication of which research interventions if any offer a prospect for direct benefit and which interventions (invasive measurements, collection of blood, tissue, data, surveys, etc.) are being done solely to answer a research question and generate generalizable knowledge. If the interventions done solely for research purposes are associated with greater than minimal risk they need to be justified. Describe and justify any control and experimental arm and include method, dose, and duration of drug administration. Reference any claim of clinical equipoise if applicable.

If you are obtaining specimens or data, provide information regarding the type of specimen/data, amount of specimen needed and how the specimen/data will be obtained and what analysis will be done with the specimen/data.

Special note for studies with waiver of consent/waiver of documentation of consent: Include a statement regarding how subjects will be recruited. For other studies this information is captured in Recruitment does not need to be duplicated in this section.

Answer/Response:
Interested participants will sign consent and the following will be completed for screening purposes: Foot and Ankle Ability Measure (FAAM-ADL and Sport), and Identification of foot and ankle instability (IdFAI).

Each CAI subject will complete two testing sessions (1 pre and 1 post intervention) and a 4- week rehabilitation program (with or without biofeedback intervention). Each coper subject will complete only the self-reported function forms and the first testing session (can be completed on same day if participant prefers).

The first testing session (following enrollment/screening) will consist of an evaluation of walking gait including gluteal muscle imaging, an evaluation of jumping, foot alignment, intrinsic foot muscle imaging, range of motion, laxity, strength, and balance. After the first testing session, the CAI subjects only will return to the lab to start the 4-week rehabilitation protocol a minimum of 7 days 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 receiving biofeedback about their ankle position during walking. The rehabilitation sessions will be supervised by a Certified Athletic Trainer and/or Physical Therapist. After 4 weeks, each group will be asked to return to the lab to complete the 2nd testing day. At this time, both groups will fill out self-reported function questionnaires and have their walking gait with gluteal muscle imaging, jumping gait, foot alignment, intrinsic foot muscles, range of motion, laxity, strength and balance re-evaluated. The 2nd session will be completed by the same investigator as the 1st testing session

Session 1

Self-reported Function: Questionnaires will be administered to each subject. This will be completed on the first visit after informed consent has been received and will be completed again on the second visit after 4 weeks.

1. International Physical Activity Questionnaire (IPAQ)- self-report of physical activity over the course of a typical week and the time spent doing activity.

2. Foot and Ankle Ability Measure (FAAM) Activities of daily living and FAAM sport subscale - region-specific outcome questionnaires that requires subjects to assess their perceived ability in both activities of daily living and sports.

3. Identification of foot and ankle instability (IdFAI)- A questionnaire that provides specific information about their ankle instability

4. Tampa Scale of Kinesiophobia (TSK) – a questionnaire that provides

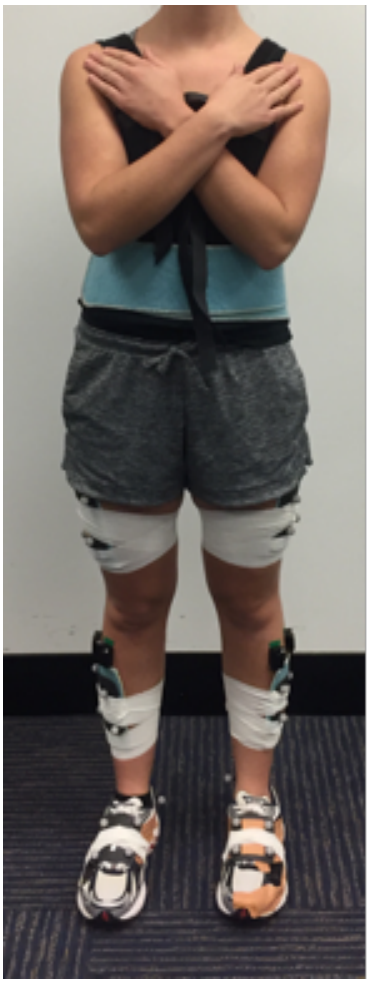
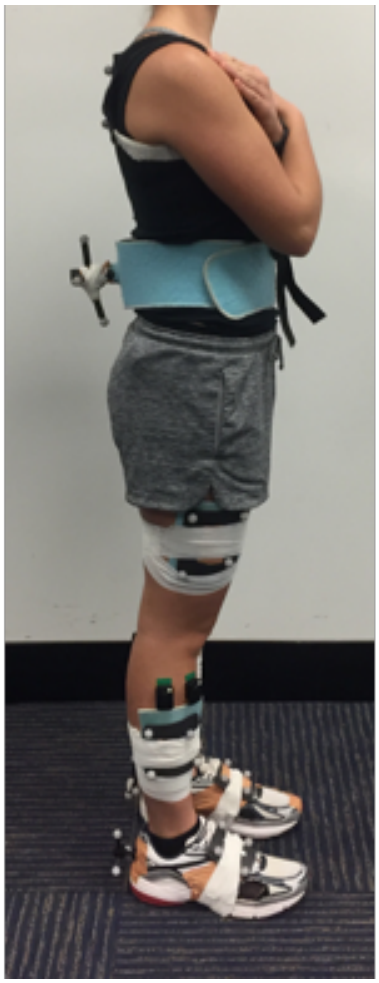
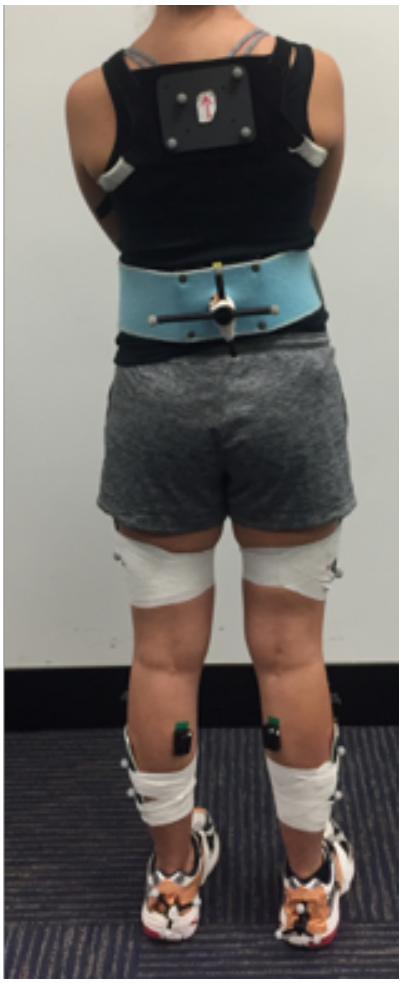
information about fear of movement patterns (avoidance or altered movements)

5. Visual analog scale (VAS) – assessment of ankle pain

6. Global Rating of Change – provides information about how participant feels after completing study compared to before the study

7. Patient Specific Functional Scale – used to quantify activity limitation and measure functional outcome for patients with any orthopaedic condition

1. **Walking/Jumping Gait Analysis:** Participants will wear standard laboratory shoes (Brooks) during motion analysis. Three-dimensional joint kinematics of the ankle will be measured using the Vicon motion analysis system controlled by Motion Monitor software. A forceplate embedded in the treadmill will be used to collect ground reaction forces for determination of initial contact and terminal stance during walking trials. A total of 10 clusters of markers (38 markers) will be placed on the upper back, lower back, lateral mid-thigh, lateral mid-shank, posterior calcaneus, and the foot. Electromygraphy (EMG) of lower extremity musculature (medial gastrocnemius, fibularis longus, anterior tibialis, and gluteus medius) will also be collected synchronously using wireless surface EMG electrodes. Additionally, subjects will wear an ultrasound transducer housed in a custom foam block and belt on the hip of their affected, and control-matched, limb. Participant setup can be seen in image below. An example of the ultrasound setup is included in a separate image below. Once sensor set-up is complete, the participant will be instructed to walk on the treadmill at their preferred walking speed (PWS) for 5 minutes. Once the subject is familiar with the treadmill and has completed the 5-minute warm-up, we will collect 60 seconds of walking at the PWS, a fast (120% of PWS), and standardized (3.0mph) walking speeds. After walking trials, we will collect 60 seconds of jogging at the preferred jogging speed (PJS), a fast (120% of PJS), and standardized (6.0mph) walking speeds. At this time, the ultrasound transducer will be removed. Then 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.

2. **Foot alignment:** Each participant will have their foot alignment evaluated using the Jaktool arch height index. Participants will be required to sit then stand facing forward while the investigator measures these alignments. A visual inspection of the foot (foot posture index) will be done with participants facing forward and then backward. These tests are widely used in assessing people with lower extremity pathologies.

3. **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, and weight bearing dorsiflexion. We will also analyze hip flexion, extension, abduction and adduction.

4. **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.

5. **Strength:** Ankle dorsiflexion, plantar flexion, inversion, eversion, plantar flexion, eversion, and hip flexion, extension, and abduction will be measured using a hand-held dynamometer (Microfet2). Three 5-second maximum voluntary

isometric contraction (MVIC) trials will be completed for each motion.

6. **Balance Testing**: Each subject will complete the Star excursion balance test (SEBT), and static balance testing

    a. 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.

    b. Static 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.

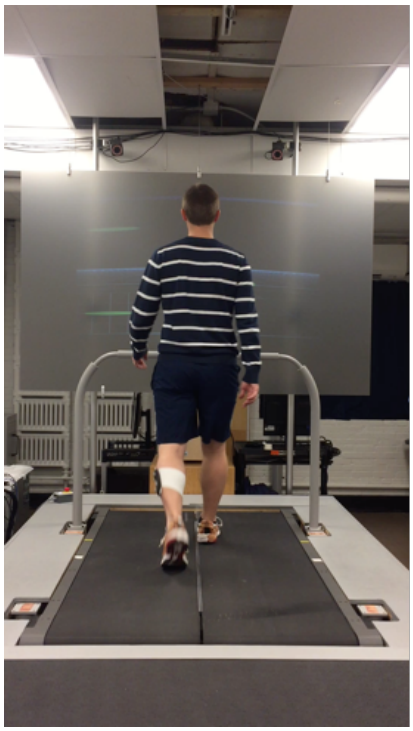
7. **Ultrasound Imaging (Seimens Accuson Freestyle):** Water-soluble ultrasound gel will be placed on the bottom of the foot. The ultrasound probe will be placed on the skin over the gelled area. This will display underlying muscles on ultrasound computer screen.

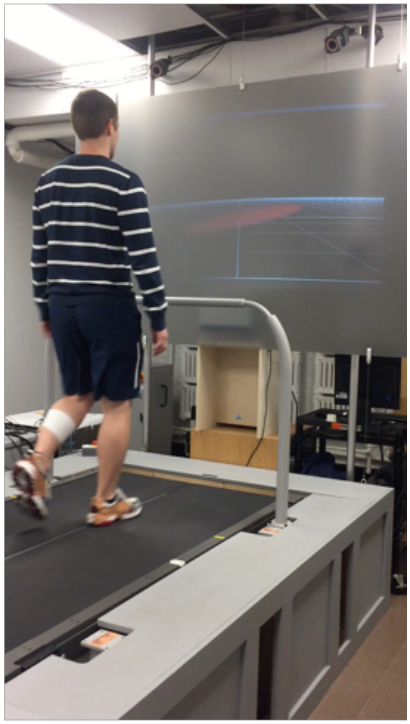
8. **Physical Activity (CAI only):** each CAI participant will receive a Fitbit to wear for the duration of their rehabilitation and return upon completion. The Fitbit will allow us to count the number of steps taken by each participant.

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 7 days after completing their first test day. Subjects will be asked to complete 8 rehabilitation sessions (2x week) over a 4 week period. Subjects must complete 7 rehabilitation sessions in order to be included in the analysis. The investigator for each of the rehabilitation sessions will be a certified Athletic Trainer (ATC) and/or Physical Therapist (PT) and blinded to intervention group status. A separate ATC or PT not involved in the rehabilitation portion of the project will conduct all walking and jogging after rehabilitation is completed for the visit. Only this clinician will know the status of feedback or no feedback and will not discuss this with the person providing rehabilitation. Each rehabilitation session will last approximately 1 hour. Rehabilitation does not need to be completed by the same ATC or PT, but each ATC/PT 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. These methods have been previously employed at the University of Virginia. Lastly, the experimental group will receive feedback during walking about their ankle position. Feedback for the intervention group will be based off of information the computer receives about the foot position when contacting the ground. When the shape is red, the participant is too inverted (bad foot position). When the shape is green, the participant is in a good foot position. See image below for example of projection for feedback.





Session 2

After completing the 4 weeks of rehabilitation, the CAI subjects will return to our lab within 72 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.

Follow Up Emails (6- and 12-months post rehab)
After study completion, participants will receive an email at 6 and 12 months. The email will include a link to a Qualtrics survey and will include the following questionnaires: International Physical Activity Questionnaire (IPAQ), Identification of foot and ankle instability (IdFAI), Foot and Ankle Ability Measure (FAAM-ADL & sport subscale), Tampa Scale of Kinesiophobia (TSK), Global Rating of Change (GROC), and VAS for current pain, best pain, and worst pain over past 6-months. We will also ask questions about ankle health.

2. **If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.**

Example: If the subject will be taking an investigational drug, will they need to be put back on an approved drug when they have completed the study? If yes, explain how this will be accomplished and who will cover the cost. If the subject has a device implanted will it be removed? Again- who will cover the cost of the removal?
Instructions: Answer NA if this study does not involve a study treatment.

Answer/Response:

NA

(Unapproved Device being used but not evaluated)

INSTRUCTIONS: This section is to provide the IRB with information about the safety of a device that is being USED, but not evaluated in this study for safety and efficacy. The device may have FDA approval and is being used for a non-approved indication OR the device may not have FDA approval [these are typically known as Research Use Only (RUO) Devices]. Again the RUO Device is only being USED and NOT being evaluated for safety and efficacy in this study. The information below will be used by the IRB to make a minimal risk determination regarding this protocol.

1. **List name of device(s) being used in an unapproved manner in this protocol**.

Per the statute: Federal Food, Drug, and Cosmetic Act Sec 201.h [21USC321]
DEVICE: (h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical

action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Answer/Response:
1. Ultrasound Transducer
2. Custom foam block and belt

2. **Do you confirm the device is only being USED and NOT being evaluated in this study?**
   Answer/Response: Yes

3. **Is the device a Research Use Only (RUO) device?**
   IF YES, submit the manufactures brochure/information regarding the RUO with other documents at the time of pre-review.
   IMPORTANT: The RUO designation is made by the FDA.
   The package insert MUST stipulate that this is a RUO device.
   Answer/Response: NO

   ►If the device is a RUO device, do you agree to use the device according to instructions in the manufacturers brochure?
   Answer/Response:

   ►If the device is NOT a RUO device, is the device currently approved for any indication?
   Answer/Response:

   ►If the device is currently approved list the indication:
   INSTRUCTIONS: Also submit the Manufacturer's Brochure
   Answer/Response:

   ►If the device is currently approved, do you confirm that results will not be used in clinical care of the subject (e.g. will not be used for diagnosis or treatment?)
   Answer/Response:

4. **In how many humans has this device been used previously as it is being used in this study?**
   Answer/Response: None

5. **Describe pertinent human data that is available regarding the safety of this device as you are using it in this protocol.**
   Answer/Response: None available at this time.

6. **If this protocol will be used in children, describe any previous use of this device with children of a similar age range as it is being used in this study.**
   Answer/Response: No

7. **What steps will be taken to minimize risk?**
   Answer/Response: The ultrasound device is non-invasive and will be placed on the participant while they are awake and aware, so the participant will be able to say if the foam block and/or belt is uncomfortable.

8. **Would you consider the use of this device to be minimal risk? Why or why not?**

Minimal Risk: probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. 45CFR46.102

Answer/Response: Yes, the ultrasound device is non-invasive and the foam block and belt will be adjusted to the comfort of the participant.

Bibliography

INSTRUCTIONS: Provide a current bibliography supporting the hypothesis, background and methodology including references to papers and abstracts that have resulted from previous work by the investigator and references to the work of others.

1. Delahunt E, Monaghan K, Caulfield B. Altered Neuromuscular Control and Ankle Joint Kinematics During Walking in Subjects With Functional Instability of the Ankle Joint. *Am J Sports Med*. 2006;34(12):1970-1976.

2. Chinn L, Dicharry J, Hertel J. Ankle kinematics of individuals with chronic ankle instability while walking and jogging on a treadmill in shoes. *Phys Ther Sport*. 2013;14(4):232-239. doi:10.1016/j.ptsp.2012.10.001.

3. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Recovery From a First-Time Lateral Ankle Sprain and the Predictors of Chronic Ankle Instability A Prospective Cohort Analysis. *Am J Sports Med*. 2016;44(4):995-1003.

4. Hertel J. Functional anatomy, pathomechanics, and pathophysiology of lateral ankle instability. *J Athl Train*. 2002;37(4):364.

5. Donovan L, Hart JM, Saliba SA, et al. Rehabilitation for Chronic Ankle Instability With or Without Destabilization Devices: A Randomized Controlled Trial. *J Athl Train*. 2016;51(3):233-251. doi:10.4085/1062-6050-51.3.09.

6. Donovan L, Hertel J. A new paradigm for rehabilitation of patients with chronic ankle instability. *Phys Sportsmed*. 2012;40(4):41-51. doi:10.3810/psm.2012.11.1987.

7. Koldenhoven RM, Feger MA, Fraser JJ, Saliba S, Hertel J. Surface electromyography and plantar pressure during walking in young adults with chronic ankle instability. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(4):1060-1070.

8. Yen S-C, Chui KK, Corkery MB, Allen EA, Cloonan CM. Hip-ankle coordination during gait in individuals with chronic ankle instability. *Gait Posture*. 2017;53:193-200. doi:10.1016/j.gaitpost.2017.02.001.

9. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Locomotive biomechanics in persons with chronic ankle instability and lateral ankle sprain copers. *J Sci Med Sport*. 2016;19(7):524-530. doi:10.1016/j.jsams.2015.07.010.

10. McKeon PO, Paolini G, Ingersoll CD, et al. Effects of balance training on gait parameters in patients with chronic ankle instability: a randomized controlled trial. *Clin Rehabil*. 2009;23(7):609-621. doi:10.1177/0269215509102954.

11. Davis IS, Futrell E. Gait Retraining: Altering the Fingerprint of Gait. *Phys Med Rehabil Clin N Am*. 2016;27(1):339-355. doi:10.1016/j.pmr.2015.09.002.

12. Winstein C. Knowledge of results and motor learning--implications for physical therapy. *Phys Ther*. 1991;71(2):140-149.

13. Noehren B, Scholz J, Davis I. The effect of real-time gait retraining on hip kinematics, pain and function in subjects with patellofemoral pain syndrome. *Br J Sports Med*. 2011;45(9):691-696. doi:10.1136/bjsm.2009.069112.

14. Donovan L, Feger MA, Hart JM, Saliba S, Park J, Hertel J. Effects of an auditory biofeedback device on plantar pressure in patients with chronic ankle instability. *Gait Posture*. 2016;44:29-36. doi:10.1016/j.gaitpost.2015.10.013.

DATA SECURITY PLAN

Version Date: **01/29/18**

IRB-HSR # 20446: Effects of gait biofeedback and impairment-based rehabilitation in individuals with chronic ankle instability

General Information

You should consult with ISPRO during the development phase of this protocol if your protocol will involve highly technical issues such as the creation of a website to collect data, software application development, the use of a smart phone app, or if you plan to store identifiable data ONTO an individual use device such as a tablet/laptop/camera. Otherwise submit the protocol and this Data Security Plan to the IRB-HSR for pre-review. The IRB-HSR will notify the study team and ISPRO if ISPRO approval is required. .

ISPRO CONTACT INFORMATION:

UVa Office of Information Security, Policy & Records Office (ISPRO)

www.virginia.edu/ispro

Email: IT-Security@Virginia.edu

Glossary of terms located at end of document.

Completion Instructions

1. Read questions carefully and answer questions as indicated.
2. For questions, contact ISPRO IT-Security@Virginia.edu

3. Use the following instructions to provide the server name. **INSTRUCTIONS:**

- You may locate the server/drive name and path by taking the following steps :
  - In Windows under computer, right click on the Drive icon (e.g. F). Then click on Properties. The server/drive name and path will appear at the very top of the box.
  - If you need additional assistance contact your department computer support or system administrator for assistance.

Submission Instructions

The IRB-HSR will submit the protocol to ISPRO after the pre-review is completed if their review is required.

DATA COLLECTION

1A. Will any HIPAA identifiers be <u>collected</u> or <u>received</u> by the UVa study team?

INSTRUCTIONS:

- Answer YES if you are collecting, recording or receiving any of these items for a potential subject, an enrolled subject, a subject's relative, household member or employer.
- Answer YES even if you are recording any item below temporarily while the information is being collected.
- Keep in mind that the information below includes data collected via photographs, video, audiotapes, and systems like IVRS (Interactive Voice Response System)
- If you answer NO to all items it means you would never be able to go back and obtain any additional information about an individual.

YES	NO	HIPAA Identifier
☒	☐	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- *Must be checked if you are collecting SS# for compensation.*
☐	☒	7. Medical Record number
☐	☒	8. Health plan beneficiary numbers
☐	☒	9. Account numbers (e.g. bank numbers, credit card numbers, hospital bill account number)
☐	☒	10. Certificate/license numbers (e.g. passport number, driver's license number, medical board license number)
☐	☒	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

INSTRUCTIONS:

If you checked NO to all HIPAA Identifiers above your data is considered to be MODERATELY SENSITIVE.

Follow requirements for handling moderately sensitive data in the Privacy Plan of the protocol.

Do not answer any additional questions. No review by ISPRO is required.

If you checked YES to any item above, continue to question 1B.

1B. Check ALL applicable items below to describe HOW DATA will be COLLECTED:

►IMPORTANT: If you check any of the items 1B(1) through 1B(3) below and you will be collecting HIPAA identifiers with the information, the protocol may require review and approval by ISPRO. The IRB-HSR office staff will notify ISPRO if their review is required.

1B(1). ☒

Collection of data ONTO* an individual-use device (examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer, camera, video or audio recorder)

*ONTO means the data will reside on OR will be stored on the device even if temporarily.

Do not check this box if the device will simply be used to access a server.

IF CHECKED:

Describe the individual use device: (e.g., smart phone) **Fit bit**

LIST all HIPAA identifiers to be collected: **none**

AND COMPLETE APPENDIX 1B(1) below.

1B(2.) ☒

Collection of data via web-based format or cloud storage (e.g., UVaBox, UVa-Collab or other cloud service OR online consent, online surveys)

DO NOT check if data will be collected directly to a server/drive managed by the sponsor or CRO (use item 1B(5) below if server managed by sponsor or CRO).

IF CHECKED:

List the web address (URL): **Qualtrics (General)**

LIST all HIPAA identifiers to be collected: **none**

AND COMPLETE APPENDIX 1B(2) below.

1B(3). ☐

Collection of data directly to a server at UVa NOT listed under 1B(4) below.

IF CHECKED:

List the name of the server (e.g. name.virginia.edu\project name):

LIST all HIPAA identifiers to be collected:

AND COMPLETE APPENDIX 1B(3) below.

►IMPORTANT: If you check any of the items 1B(1) through 1B(3) above and you will be collecting HIPAA identifiers with the information, the protocol may require review and approval by ISPRO. The IRB-HSR office staff will notify ISPRO if their review is required.

1B(4). ☒

Collection of data directly to one or more of the UVa servers checked below.

IF CHECKED,

LIST all HIPAA identifiers to be collected onto this device: **name, email, telephone number**

AND COMPLETE APPENDIX 1B(4) below

☐ domatlas.eservices.virginia.edu
☐ dom-titan.eservices.virginia.edu
☐ Elson1.studenthealth.virginia.edu

☐ EPIC
☒ es3.eservices.virginia.edu
☐ gcrcserver.itc.virginia.edu
☐ \\HSCS-ss7
☐ \\HSCS-ss8
☐ \\HSCS-ss9
☐ \\HSCS-ss10
☐ \\HSCS-ss11
☐ \\HSCS-ss12
☐ \\HSCS-ss13
☐ \\hscs-share1\
☐ \\hscs-share2\
☐ \\hscs-share3\
☐ hstsdatalab.hscs.virginia.edu
☐ hstsdsmpogapp.hscs.virginia.edu
☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
☐ musicvpn01.med.virginia.edu
☐ Oncore (oncore.med.virginia.edu)
☐ School of Nursing SECURE NETf
☐ Redcap-int.hscs.virginia.edu

☐ \\radshare\
☐ upgusers.hscs.virginia.edu

1B(5). ☐

Collection of data directly to a server/drive managed by the sponsor or CRO. Data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA.

IF CHECKED:

List the name of the server (e.g. remote.sponsor.com\project name): _____

LIST all HIPAA identifiers to be collected onto this server: _____

AND COMPLETE APPENDIX 1B(5) below

1B(6). ☒ Paper -

IF CHECKED:

List ALL the HIPAA identifiers to be stored in paper file(s): **Name, address and SSN**

Remember: Initials are considered a HIPAA identifier!

►If health information with HIPAA identifiers are stored in a paper file, where will the paper files be housed?

☒ Signed consent forms or documentation regarding obtaining verbal consent will be stored in a *secure area with limited access.*

☐ Case report forms will be stored in a *secure area with limited access.*

☐ Questionnaires/surveys will be stored in a *secure area with limited access.*

☒ Other - *Specify* **Name, address, and SS# are needed for subject payments and will be signed by PI, then submitted for payment.**

NOTE: "*in a secure area with limited access*" means access to data is limited to study personnel only and there must be two forms of security. Example: 1) in a locked office in a building with swipe locks when unattended or 2) in a locked file cabinet in a locked room when unattended or 3) study personnel present in room at all times located in a building with swipe locks or a room with a lock,

DATA STORAGE

1C. Will any data be <u>stored electronically (e.g. during data analysis and/or beyond)</u> ?

Yes ☒ No ☐ *IF NO, skip to item 1C(1)b.*

1C(1)►IF YES, will it include storage of any health information or other sensitive data?

Yes ☒ No ☐

1C(1)a If YES, check the HIPAA identifiers in the table below that will be kept with highly sensitive data in the same location (e.g. on the same electronic drive,server or file).

YES	NO	HIPAA Identifier
☒	☐	1. Name
☐	☐	2. Postal address information, other than town or city, state, and zip code (e.g. street name or GPS)
☐	☐	3. Telephone numbers
☐	☐	4. Fax numbers
☒	☐	5. Electronic mail addresses
☐	☐	6. Social Security number- *Must be checked if you are collecting SS# for compensation.*
☐	☐	7. Medical Record number
☐	☐	8. Health plan beneficiary numbers
☐	☐	9. Account numbers (e.g. bank numbers, credit card numbers, hospital bill account number)
☐	☐	10. Certificate/license numbers (e.g. passport number, driver's license number, medical board license number)
☐	☐	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

INSTRUCTIONS: If you checked YES to any HIPAA Identifier above your data is considered to be HIGHLY SENSITIVE.

Follow requirements for handling Highly Sensitive data in the Privacy Plan of the protocol.

1C(1)b. Will you store any of the following HIPAA identifiers electronically in a different location from the data?

YES	NO	HIPAA Identifier
☒	☐	Social Security number- *Must be checked if you are collecting SSN for compensation.*
☐	☒	Account numbers (e.g. bank numbers, credit card numbers, hospital bill account number)
☐	☒	Certificate/license numbers (e.g. passport number, driver's license number, medical board license number)

IF YOU CHECKED YES to any Identifier above:
List the name of the server (e.g. name.virginia.edu\project name):**on paper**

INSTRUCTIONS: If you checked YES to any HIPAA Identifier above your data is considered to be HIGHLY SENSITIVE. Follow requirements for handling Highly Sensitive data in the Privacy Plan of the protocol.

1C(2). WHERE will the data be stored long term (e.g. during data analysis and beyond) by you (UVa) and/or the sponsor?

☒ Data will be stored in the same location to which it was collected or transferred as noted in 1B *(Skip to Transferring Data)*

You may check 1C(2) above and also add a new place where data will be stored that was not a location where it was collected. For example, you may have checked 1B(2) for collection of data, and plan to store it both in same location as 1B(2) as well as store on HSCS server. So you could check 1C(2) above and just fill out 1C(1)d below.

If you did not answer the option above, check an applicable option below.

1C(2)a. ☐

*ONTO** an individual-use device (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer)*

**ONTO means the data will reside or be stored on the device even if temporarily. Do not check this box if the device will simply be used to access a server.*

IF CHECKED:

Describe the individual use device: (e.g., smart phone)

LIST all HIPAA identifiers to be stored:

AND COMPLETE APPENDIX 1C(2)a below

ISPRO approval mayl be required. The IRB-HSR staff will send the protocol and Data Security Plan to ISPRO after pre-review is completed if ISPRO approval is required.

1C(2)b. ☐

Web-based or cloud storage (e.g., UVaBox, UVa-Collab or other cloud service)

IF CHECKED:

LIST the web address (URL):

LIST all HIPAA identifiers to be stored:

AND COMPLETE APPENDIX 1C (2)b below.

ISPRO approval may be required. The IRB-HSR staff will send the protocol and Data Security Plan to ISPRO after pre-review is completed if ISPRO approval is required.

1C (2)c. ☐

On a server at UVa NOT listed under 1C(2)d below.

IF CHECKED:

List the name of the server/drive (e.g. name.virginia.edu\project name):

_____

*LIST all HIPAA identifiers to be stored:*_____

AND COMPLETE APPENDIX 1C2(c) below.

ISPRO approval may be required. The IRB-HSR staff will send the protocol and Data Security Plan to ISPRO after pre-review is completed if ISPRO approval is required.

1C(2)d. ☐

Directly to one or more of the UVa servers listed below.

IF CHECKED:

*LIST all HIPAA identifiers to be stored:*_____

AND COMPLETE APPENDIX 1C(2)d.

☐ domatlas.eservices.virginia.edu
☐ dom-titan.eservices.virginia.edu

- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☐ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
- ☐ musicvpn01.med.virginia.edu
- ☐ Oncore (oncore.med.virginia.edu)
- ☐ School of Nursing SECURE NETf
- ☐ Redcap-int.hscs.virginia.edu

- ☐ \\radshare\
- ☐ upgusers.hscs.virginia.edu

1C(2)e. ☐

A server/drive managed by the sponsor or CRO. The data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) onto a server/drive that is configured to store data regulated by HIPAA.

IF CHECKED:

List the name of the server (e.g. remote.sponsor.com\project name): _____

LIST all HIPAA identifiers to be stored: _____

AND COMPLETE APPENDIX 1C(2)e.

DATA TRANSFER

1E(1) Will you be sharing/transferring data outside of UVa? Yes ☐ No ☒

If YES, Will any of the following HIPAA identifiers be shared/transported with the data outside of UVa?

Limited Data Set criteria per HIPAA under 164.514(e)

☐Yes ☐ No	1. Name
☐Yes ☐ No	2. Postal address information, other than town or city, state, and zip code
☐Yes ☐ No	3. Telephone numbers
☐Yes ☐ No	4. Fax numbers
☐Yes ☐ No	5. Electronic mail addresses
☐Yes ☐ No	6. Social Security number
☐Yes ☐ No	7. Medical Record number
☐Yes ☐ No	8. Health plan beneficiary numbers
☐Yes ☐ No	9. Account numbers
☐Yes ☐ No	10. Certificate/license numbers
☐Yes ☐ No	11. Vehicle identifiers and serial numbers, including license plate numbers
☐Yes ☐ No	12. Device identifiers and serial numbers
☐Yes ☐ No	13. Web Universal Resource Locators (URLs)
☐Yes ☐ No	14. Internet Protocol (IP) address numbers
☐Yes ☐ No	15. Biometric identifiers, including finger and voice prints
☐Yes ☐ No	16. Full face photographic images and any comparable images

1E(2).If you checked YES to any item above have you obtained written HIPAA authorization to share the data with the specific group outside of UVa?

Yes ☐ No ☐

If NO, NOTE: No data collected without consent/HIPAA authorization or collected under verbal consent/HIPAA authorization may be shared outside of UVa with any of the HIPAA identifiers checked above unless the IRB has approved the disclosure and tracking the disclosure in EPIC is performed by the study team.

1E(3). How will the data be shared/transported?

☐ **Paper forms**

If shipped outside of UVa must be shipped with tracking (FedEx, UPS, certified mail etc.)

Messenger mail not allowed if you have answered YES to any item above

☐ **Email:**

Not allowed if you have answered YES to any item above unless *the data will only be sent to and from an individual with a *HS in their email address*

☐ **Secure Email:**

Not allowed if you have answered YES to any item above UNLESS you use the HSC Mail System and follow the steps listed at:

https://www.hsts.virginia.edu/services/it-security/how-tos/encrypted-email

☐ **FAX:**

Not allowed unless receiving fax machine is in a restricted-access location, the intended recipient is clearly indicated, and that recipient has been alerted to the pending transmission and is available to pick it up immediately. Also verify FAX numbers before faxing and use FAX cover sheet with a confidentiality statement.

☐ **Devices such as flash-drive/ CD etc.:**

Not allowed if you have answered YES to any item in 1E(1) unless you written approval from a VP/ Dean. The request for their written approval should be obtained using the Highly Sensitive Data Storage Request Form. You may also contact the UVa Office of Information, Security, Policy and Records Management at IT-Security@Virginia.edu for assistance in completing this form.

☐ **Web Based Data Entry (e.g. website, database, registry): NOT Encrypted and Password Protected;**

Not allowed if you have answered YES to any item 1E(1).

☐ **Web Based Data Entry (e.g. website, database, registry): Encrypted and Password Protected;**

If checked, do you confirm that you have verified with host site that the data will be sent and stored in an encrypted fashion (e.g. via Secure FX, Secure FTP, HTTPS, PGP)? Yes ☐ No ☐

IF CHECKED COMPLETE DATA SECURITY PLAN APPENDIX 1B(5) if not already completed.

INSTRUCTIONS: Do not complete the questions below if the only data being shared/transported are being sent with specimens. See Specimens Section

1E(4) If sharing data with anyone outside of UVa do you confirm that you will obtain a contract/ material transfer agreement with them via the School of Medicine Grants and Contracts Office or the Office of Sponsored Programs (OSP) ospnoa@virginia.edu**?**
Yes ☐ No ☐

1E(5) Will any data be sent outside of UVa to any person at another institution other than the sponsor or the FDA (e.g. researcher outside of UVa)?

Yes ☐ No ☐

INSTRUCTIONS:

If NO, skip questions 1E(5))a-d below

1E(5)a. What will be shared?

*List the data to be shared, including any HIPAA identifiers:*_____

1E(5)b. Who will the data be shared with?

_____

1E(5)c. What will they do with the data?

_____

1E(5)d. Will information be sent back to UVa? Yes ☐ No ☒

If yes, *LIST the data to be sent back, including any HIPAA identifiers:*_____

If yes, ***how it will sent back (see the list under 1E(3) for possible methods)*****?**

_____

END OF FORM- COMPLETE THE APPENDIX SECTIONS THAT FOLLOW ONLY IF APPLICABLE.

Data Security Plan: APPENDIX 1B(1)

1B(1). Collection of data *ONTO** an individual-use device (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer, camera, audio or video recorder)*

- What kind of device is it (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer, camera, audio or video recorder)* **Fit bit**

- Who manages / supports the device (e.g., Health Systems Computing Services (HS/CS), local computer support partner (LSP), self)? LSP

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

- Will the data be transferred elsewhere? Yes ☒ No ☐

- INSTRUCTIONS:
- *If NO, you must complete Appendix 1C(2)a below and if you will store health information with any of the identifiers check in the table 1A on page 2 you must also complete and have signed a* ***Highly Sensitive Data Storage Request form available at:*** www.virginia.edu/informationsecurity/highlysensitivedata/approvalform.doc
- *If YES, answer the following four questions*

1. Will the data be transferred in an encrypted secure manner such as the use of SFTP or HTTPS? Yes ☐ No ☒

Describe transfer method:

- All data is deidentified from the beginning of participation. Subjects are provided a FitBit and it is assigned to their subject number, not any identifiable information. The FitBit will be synced each week via Bluetooth with the FitBit Connect Application. Data will be exported from the FitBit website each week with activity levels for each participant.

2. How long will the data remain on the individual-use device before being transferred? Data will be transferred each week from the device to the Connect app. All data will be transferred prior to subject dismissal.

3. Please provide the location the data are transferred to: Data are transferred via Bluetooth to the FitBit Connect Application and then exported as excel or .csv files.

4. After the information is transferred elsewhere will you securely delete all data from the website/server? Yes ☒ No ☐

INSTRUCTIONS: For computers not using Windows 8 or newer, download and use the Secure Delete Program from ITS. If using Windows 8 or newer, click on Secure Delete when deleting a file. For Macintosh computers, select "Secure Empty Trash" from the Finder menu.

- Will anyone other than study team members have access to data on the device? Yes ☐ No ☒ If yes, describe: _____

- Are any backups made of the information on the device? Yes ☒ No ☐
  - If yes, explain how backups are made and where they are stored: Computer automatically backs up data to UVA servers.

- Does the owner of the device (e.g. phone service provider/ app developer) have any rights to use or access data either individually or in aggregate? Yes ☐ No ☒

Data Security Plan: APPENDIX 1B(1) continued

- Are you doing any audio or videotaping (recording)? Yes ☐ No ☒ N/A ☐
  - If yes, have you completed the Taping/Photography section in the protocol? Yes ☐ No ☐ N/A ☐

- If you are using an individual use device such as a camera or video recorder do you confirm the photos will not include the full face. Yes ☐ No ☐ N/A ☒

- If you are using a video or audio recorder, do you confirm the data will not include HIPAA identifiers? Yes ☐ No ☐ N/A ☒

END OF APPENDIX 1B(1)

Data Security Plan: APPENDIX 1B(2)

1B(2.) Collection of data via web-based or cloud storage (e.g. UVaCollab, UVaBox, or online consent, online surveys or any cloud service)

- Provide the name of the website or cloud storage (e.g.,URL): **UVA Qualtrics**

NOTE: No research data of any kind may be stored in a non-UVa licensed cloud provider such as Dropbox, Google Drive, SkyDrive, Survey Monkey etc.
INSTRUCTIONS: (e.g., https://name1.name2.org/mystudy/login.html)
The URL is in the address bar of your web browser (e.g., Internet Explorer (IE), Firefox, Chrome)
If you need additional assistance contact your department computer support or system administrator for assistance in answering this question.

- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS),ITS, third party)? **UVA ITS**
  - List how you contact this support (e.g., name, email, phone number): ____
- What kind of device will be used to connect to this website/server? (*examples include non-UVA desktop computer, smart phone app, drive, tablet, laptop,*)? **Desktop/laptop/phone, etc**

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group, self)? **self**
  - List how you contact this support (e.g., name, email, phone number): **self (each participant will access the Qualtrics survey on their own computer**

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

- Will the data be transferred elsewhere? Yes ☐ No ☒
  If yes, answer the following four questions.

1. Will the data be transferred in an **encrypted** secure manner such as the use of SFTP or HTTPS? Yes ☐ No ☐

1a. Describe the transfer method: _____

2. How long will the data remain on the website/server before being transferred?_____

3. Please provide the location the data are transferred to:_____

Data Security Plan: APPENDIX 1B(2) continued

4. After information is transferred elsewhere will all the data be **securely** delete from the website/server? Yes ☐ No ☐

- **NOTE: Securely** deleted means the data are overwritten with zeros and ones and then deleted. You may need to check with the website/server administrator about their deletion method.

- Will anyone other than study team members have access to data on the server/website? Yes ☐ No ☒
  - If yes, describe: _____

- Are any backups made of the information on the secure server/website? Yes ☐ No ☒
  If yes, explain how backups are made and where they are stored: _____

- Do the owners of the website/server have any rights to use or access data either individually or in aggregate? Yes ☐ No ☒
  If yes, please explain: _____

- If the website/server is not hosted at UVa, is there a Business Associates Agreement (BAA) with the provider of the non-UVa website? Yes ☐ No ☐ N/A ☒

END OF APPENDIX 1B(2)

Data Security Plan: APPENDIX 1B(3)

1B(3). To a UVa server NOT listed under 1B(4) below.

- Provide the name of the server/drive:
- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS),ITS, your department, third party)?
- List how you contact this support (e.g., name, email, phone number):
- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop,*?
- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)?
- List how you contact this support (e.g., name, email, phone number):

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1B(3)

Data Security Plan: APPENDIX 1B(4)

1B(4). Directly to one or more of the UVa servers listed below.

- ☐ domatlas.eservices.virginia.edu
- ☐ dom-titan.eservices.virginia.edu
- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☒ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
- ☐ musicvpn01.med.virginia.edu
- ☐ Oncore (oncore.med.virginia.edu)
- ☐ School of Nursing SECURE NETf
- ☐ Redcap-int.hscs.virginia.edu

- ☐ \\radshare\
- ☐ upgusers.hscs.virginia.edu

- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop)* **Desktop computer**

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? **HSCS**

- List how you contact this support (e.g., name, email, phone number): **HS Help Desk (434) 924-5334**

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1B(4)

Data Security Plan: APPENDIX 1B(5)

1B(5).

Directly to a server/drive managed by the sponsor or CRO. Data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA.

- Provide the name of the server/drive: _____

- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop,)*)? _____

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group, self)? _____

- List how you contact this support (e.g., name, Email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1B(5)

Data Security Plan: APPENDIX 1C(2)a

1C(2)a. Storage of data *ONTO** an individual-use device (*examples include desktop computer, smart phone app, flash (thumb) drive, external hard drive, tablet, laptop, CD, C drive of your computer)*)

> **INSTRUCTIONS:** *If you will store health information with any of the identifiers checked in the table 1C(1)a (around page 5) you must also complete and have signed a* ***Highly Sensitive Data Storage Request form available at:*** www.virginia.edu/informationsecurity/highlysensitivedata/approvalform.doc

- What kind of device is it (e.g. desktop computer, smart phone app, flash (thumb) drive, tablet, laptop, CD, C drive of your computer) _____
- Who manages / supports the device (e.g., Health Systems Computing Services (HS/CS), local computer support partner (LSP), self)? _____

> **INSTRUCTIONS:** If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

- Will anyone other than study team members have access to data on the device? Yes ☐ No ☐ If yes, describe: _____
- Are any backups made of the information on the device? Yes ☐ No ☐
  - If yes, explain how backups are made and where they are stored: _____
- Does the owner of the device (e.g. phone service provider/ app developer) have any rights to use or access data either individually or in aggregate? Yes ☐ No ☐
- Are you storing audio- or video-recordings or pictures? Yes ☐ No ☐ N/A ☐
  - If yes, have you completed the Taping/Photography section in the protocol? Yes ☐ No ☐ N/A ☐
- If you are storing pictures or video recordings, do you confirm they will not include the full face? Yes ☐ No ☐ N/A ☐

- If you are storing audio- or video-recordings or pictures, do you confirm the data will not include HIPAA identifiers? Yes ☐ No ☐ N/A ☐

END OF APPENDIX 1C(2)a

Data Security Plan: APPENDIX 1C(2)b

1C(2)b. Storage of data on web-based or cloud storage (e.g., UVaBox, UVaCollab, online surveys or any cloud service)

- Provide the name of the website or cloud storage (e.g., URL): _____

NOTE: Not allowed if you have answered YES to any HIPAA identifier

(the use of a unique subject ID (e.g. Subject # 1) is acceptable).

NOTE: No research data of any kind may be stored in a non-UVa licensed cloud provider such as Dropbox, Google Drive, SkyDrive, Survey Monkey etc.

INSTRUCTIONS: (e.g., https://name1.name2.org/mystudy/login.html)
The URL is in the address bar of your web browser (e.g., Internet Explorer (IE), Firefox, Chrome)
If you need additional assistance contact your department computer support or system administrator for assistance in answering this question.

- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS), ITS, third party)? _____
- List how you contact this support (e.g., name, email, phone number): _____
- What kind of device will be used to connect to this server/website? (*examples include desktop computer, smart phone app, tablet, laptop,*)? _____
- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group, self)? _____
- List how you contact this support (e.g., name, Email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of

Information Security, Policy & Records Office (ISPRO) webpage:

http://www.virginia.edu/informationsecurity/device-requirements.html

Data Security Plan: APPENDIX 1C(2)b continued

- Will anyone other than study team members have access to data on the server/drive? Yes ☐ No ☐
  - If yes, please describe: _____

- Are any backups made of the information on the secure server/drive? Yes ☐ No ☐
  If yes, explain how backups are made and where they are stored: _____

- Do the owners of the website/server have any rights to use or access data either individually or in aggregate? Yes ☐ No ☐
  If yes, please explain: _____

- If the website/server is not hosted at UVa, is there a Business Associates Agreement (BAA) with the provider of the non-UVa website? Yes ☐ No ☐ N/A ☐

END OF APPENDIX 1C(2)b

Data Security Plan: APPENDIX 1C(2)c

1C(2)c. To a UVa server NOT listed in 1C(2)d below.

- Provide the name of the server/drive: _____
- Who manages / supports this server or website (e.g., Health Systems Computing Services (HS/CS), ITS, third party)? _____
  - List how you contact this support (e.g., name, email, phone number): _____
- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop)*? _____
- Who manages / supports this individual-use device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? _____
  - List how to contact this support (e.g., name, Email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1C(2)c

Data Security Plan: APPENDIX 1C(2)d

1C(2)d. Directly to one or more of the UVa servers listed below.

- ☐ domatlas.eservices.virginia.edu
- ☐ dom-titan.eservices.virginia.edu
- ☐ Elson1.studenthealth.virginia.edu
- ☐ EPIC
- ☐ es3.eservices.virginia.edu
- ☐ gcrcserver.itc.virginia.edu
- ☐ \\HSCS-ss7
- ☐ \\HSCS-ss8
- ☐ \\HSCS-ss9
- ☐ \\HSCS-ss10
- ☐ \\HSCS-ss11
- ☐ \\HSCS-ss12
- ☐ \\HSCS-ss13
- ☐ \\hscs-share1\
- ☐ \\hscs-share2\
- ☐ \\hscs-share3\
- ☐ hstsdatalab.hscs.virginia.edu
- ☐ hstsdsmpogapp.hscs.virginia.edu
- ☐ Ivy Secure Computing Platform/ Ivy Secure Cloud/Ivy Cloud
- ☐ musicvpn01.med.virginia.edu
- ☐ Oncore (oncore.med.virginia.edu)
- ☐ School of Nursing SECURE NETf
- ☐ Redcap-int.hscs.virginia.edu

- ☐ \\radshare\
- ☐ upgusers.hscs.virginia.edu

- What kind of device will be used to connect to this server/drive? (*examples include desktop computer, smart phone app, tablet, laptop.)* _____

- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), self)? _____

  - List how to contact this support (e.g., name, email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1C(2)d

Data Security Plan: APPENDIX 1C(2)e

1C(2)e. Directly to a server/drive managed by the sponsor or CRO. Data must be sent and stored in an encrypted fashion (e.g. must be shared and stored via Secure FX, Secure FTP, HTTPS, PGP) and the server/drive is configured to store data regulated by HIPAA.

- Provide the name of the server/drive: _____
- Who manages / supports this server or website? _____
- List how you contact this support (e.g., name, email, phone number): _____
- What kind of device will be used to connect to this server/drive? _____ (*examples include desktop computer, smart phone app, tablet, laptop,)*)?
- Who manages / supports this device (e.g., Health Systems Computing Services (HS/CS), local computer support person (LSP), departmental technology support group,, self)? _____
- List how to contact this support (e.g., name, email, phone number): _____

INSTRUCTIONS: If the device is managed/support by *self* you must follow both the setup and maintenance security standards described on the UVa Office of Information Security, Policy & Records Office (ISPRO) webpage: http://www.virginia.edu/informationsecurity/device-requirements.html

END OF APPENDIX 1C(2)e

Data Security Plan Glossary:

Data Collected or Received: Where you put any kind of data recorded or gathered from another source for purposes of research. The data can come from any source, electronic, paper or voice. You may be sent these individual data points by paper, subject/patient interview or electronically. You may be manually extracting these data points from EPIC. You may be collecting these data with devices (camera, heart monitor, etc.)

Data Stored Long Term (Data storage) is different from data collected as it implies a longer-term non-volatile storage. It may be the same location as collected, (such as paper or HSCS server) or it may be a new location (computer drive or paper). It is where it is located for further analysis, manipulation, and access.

Highly Sensitive Data: includes personal information that can lead to identity theft if exposed and/or health information that reveals an individual's health condition and/or history of health services use. Electronic data storage policy: http://uvapolicy.virginia.edu/policy/IRM-015
Three HIPAA-identifiers are considered highly sensitive data by themselves (without being connected to PHI). These are #7-Social Security Number, #10-Account numbers, if it's a financial account number such as credit card or bank card number and #11 – Certificate/license number if it's a passport number, driver's license number, board license number, etc.). If these are in a file or on paper without any personal health information (PHI) it is still highly sensitive data (HSD).

Moderately Sensitive Data: includes information that is not highly sensitive nor is intentionally made public. So this category includes most of the data and information we work with. All research data that is not intentionally made public (e.g., published) is considered moderately sensitive data (MSD).

Individual Use Device: any kind of technology that has persistent memory. Flash memory, solid state drives, traditional hard drives, SD cards, USB thumb drives (sticks) allow for data to be kept long term. This means that any smartphones, laptops, tablets, biometric fitness devices and digital cameras and MP3 recorders (digital audio) qualify as individual use devices that could store potential data and must be protected.

Web based or Cloud storage: generally implies a storage server where a web browser is the main way to login and manipulate files. Sometimes a smartphone app is created to interface to these cloud storage containers. Examples include UVaBox, Box.com Google Drive, Google Docs, DropBox. Use of any Google Drive, Doc, Email, etc. for any UVa data or files is against UVa data protection policies.

Consent of an Adult to Be in a Research Study

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
Sponsor:	**1)** The Curry School of Education at the University of Virginia **2)** The Mid-Atlantic Athletic Trainers' Association 3) The National Athletic Trainers' Association

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

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

Who is funding this study?

This study has received grant funding from the Curry School of Education, the Mid-Atlantic Athletic Trainers' Association, and the National Athletic Trainers' Association for participant payments and supplies for study.

Why is this research being done?

The purpose of this study is to see if rehabilitation and receiving information while you are walking, will improve ankle function for people who have chronic ankle instability (CAI). This study will also compare how people with CAI walk compared to people who are copers (people who sprained their ankle and recovered fully).

People with CAI have symptoms from an ankle sprain that last more than one year. The symptoms include feeling like you may roll your ankle, having repeated ankle sprains, or feel like your ankle is loose. This study could help clinicians provide better exercises to help people with CAI and see how they walk differently from people with no ankle instability.

You are being asked to be in the study because you have CAI or are a coper and are physically active (do physical activity for at least 30 minutes per day, three days per week). People with CAI have a history of repetitive ankle sprains, and/or have feelings of

ankle "giving way" and prolonged symptoms, and are not seeking therapy or treatment for your ankle condition.

Up to ***100*** people will be in this study at UVA.

What will happen if you are in the study?

If you agree to be in this study, you will sign this consent form before any study related procedures take place. All procedures are done for research purposes and will take place at the UVA Memorial Gymnasium.

SCREENING

Before you can start in the study, there will be a screening period **(Visit 1)**. We will ask you some questions during this time to make sure you are eligible and it is safe for you to participate. These include the following:

Ankle Questionnaires:

2. Questions about your general health as it relates to your ankle injury
3. A questionnaire asking about your current physical activity level
4. Questionnaires asking about your ankle function
5. A questionnaire asking about how you feel when you move

If these items show you are eligible, you will return within **7 days** to begin the study.

STUDY PROCEDURES

Coper study procedures include ONLY screening and baseline visit. CAI study procedures will include screening and multiple visits.

BASELINE STUDY PROCEDURES Visit 2 (will take about 2 hours to complete):

Walking and Jogging Testing:

6. You will have sensors attached to your skin that will passively record how you move and how your muscles turn on during walking and jogging.
7. You will have ultrasound with a belt put on your hip for images of your hip muscles while you are moving
8. With the sensors and ultrasound on, you will walk for up to 15 minutes and jog for up to 5 minutes on a treadmill.

Jumping Testing:

- With the same sensors on, you will jump up to 15 times off a 30cm box
- Without the sensors on, you will do a timed jump test

Foot Alignment:

- You will have your foot alignment measured.
- You will be asked to so sit and to stand upright for visual inspection and measurement.

Range of motion:

- Your ankle and hip 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, turning your foot outward, pulling your leg

forward, pushing your leg backward, pushing your leg outward, and pulling your leg inward.

Ankle Laxity:

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

Ankle and Hip Strength:

- You will have your ankle and hip 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, pulling your leg forward, pushing your leg backward, and pushing your leg outward.

Balance Testing

- You will complete 2 different tasks that will determine how well you balance. The tasks are:
    - **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.
    - **Static Balance Test:** (eyes opened and eyes closed) while standing on a force plate for 10 seconds

Muscle Imaging

- You will have images of your foot muscles taken using ultrasound imaging
- You will be asked to lie on a table and relax while images are taken

This is the end of procedures for coper participants.

CAI Participants will continue with the following procedures:

Physical Activity

- You will be given a FitBit pedometer that will count how many steps you take each day
- You will wear the FitBit for the duration of your rehabilitation and return it when you're done participating

You will be asked to return to the lab within 7 days to begin the 8 rehabilitation sessions.

VISITS 3 TO 10 (REHABILITATION TREATMENT SESSIONS 1 TO 8)

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to any one of the groups (**Group 1** and **Group 2**). You cannot choose to which group you are assigned.

Group 1:

Group will be asked to complete 4 weeks of treatment for their ankle instability. You will be asked to complete 2 sessions per week for a total of 8 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 walking,

you will get feedback about how you are walking. The feedback will appear on a screen in front of the treadmill.

Group 2:
Group 2 will be asked to complete 4 weeks of treatment that will treat their ankle instability. You will be asked to complete 2 sessions per week for a total of 8 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 this study, you will be asked to fill out some questionnaires. These questionnaires ask about:

4. how you are feeling
5. your lifestyle habits
6. daily activities
7. how your ankle instability affects your lifestyle

FOLLOW UP:

VISIT 11 Both groups 1 and 2 will return to the lab approximately 48 to 96 hours after their final rehab session. You will complete the same testing as you did on the first day. This will take no longer than 1.5 hours.

Email follow up
You will be contacted at 6 months and 12 months after you complete the follow-up testing. You will complete the same questionnaires from previous visits and answer questions about your current ankle health.

Study Schedule

	Visit 1 (Screening)	**Visit 2 (Baseline)**	**Visits 3-10 (Rehab)***	**Visit 11 (Follow-up)***	**Email Follow-up***
Study Week	-1	0	1-4	5	6 and 12 months
Informed Consent	X				
Review study eligibility	X				
Ankle Questionnaires	X			X	X
Walking, jogging, jumping, strength, ROM, balance testing		X	X	X	
Muscle images		X		X	

*CAI participants only

WHAT ARE YOUR RESPONSIBILITIES IN THE STUDY?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must be completely truthful about your ankle health history.
- Follow all instructions given.
- Attend all rehab sessions.
- You should tell the study investigator or staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study investigator or study staff as soon as possible if you have to take any new injuries.

How long will this study take?

Your participation in this study will require ***2 or 11*** of study visits over ***4-5 week*** period of time depending on if you are a CAI or a Coper participant. Each visit will last about **1-1.5** hours. Study visits 2 and 11 will last up to **2** hours. Email follow ups for CAI participants will be sent 6 and 12 months after the follow-up visit and will take about **30 minutes** to complete.

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

The rehabilitation sessions will use common measure normally used during physical therapy and rehabilitation. 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?

Risks and side effects related to the intervention and rehabilitation:

Likely

2. Mild soreness of muscles involved with exercises

Rare but serious

3. Tripping or falling during: walking or jogging on treadmill, jumping or balance exercises
4. Ankle sprain due to participation in 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?

You may or may not benefit from being in this study. Possible benefits for CAI participants include: decreased symptoms associated with ankle instability and better overall movement from the rehab sessions**.** 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 may include the following as determined by your care provider:

- Seeking formal physical therapy for your ankle
- Wearing a brace or ankle tape during normal activity

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?

If you are a CAI participant, you will be paid $100 for finishing this study by check.

You should get your:

1) first payment of $30 about 4-6 weeks after your initial visit.
2) second payment of $70 4-6 weeks after finishing the study.

If you are a coper participant, you will be paid $20 for finishing this study by check. You should get your payment of $20 about 4-6 weeks after your study visit.

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 investigatory is concerned about your health
b) Your ankle instability gets worse
c) The side effects of the treatment are too dangerous for you
d) You do not follow your study team's instructions

If you decide to stop being in the study, we will ask you to: ***notify your study team you are no longer willing to participate.***

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. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

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
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- 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.
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. 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 or complete the "Leaving the Study Early" part of this form and return it to the researchers. 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.

A copy of this consent form will be put in your medical record. (This is not the same as the record of this research study.) This means that everyone who is allowed to see your medical records will be able to find out that you are in this study. This is done so your regular doctors will know what you receive as part of this study. If you have other health problems during the study, they will be able to treat you properly.

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

Principal Investigator: Jay Hertel
University of Virginia
210 Emmet St South
Charlottesville, VA 22904

Telephone: (434)243-8673

What if you have a concern about this study?

You may also report a concern about this 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

To be completed by participant if 18 years of age or older.

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

Signature of Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

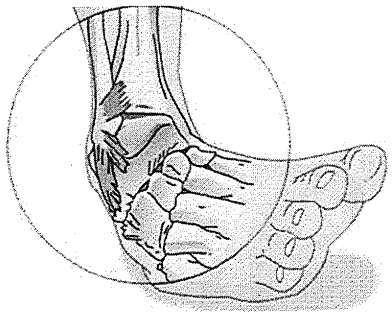
I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):
☐ Subject

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

Have you sprained your ankle?

The Exercise and Sport Injury Laboratory is seeking Adults (ages 18-30) with a previous ankle sprain for participation in a research study.



- The purpose of this research study is to compare individuals with history of one ankle sprain (>12 months prior) who have fully recovered to individuals who have ankle instability.
- This study will require:
  - 1 screening visit (15 minutes)
  - 1 laboratory session (lasting about 1-hour)

  All visits will be at the University of Virginia.
- You will be paid **$20** for participation in this study.

For more information, please contact:

Rachel Rolfe
rmk7ye@virginia.edu

Or call the Exercise and Sport Injury Laboratory:
434-924-6184

IRB-HSR: *20446* ***Principle Investigator:*** Jay Hertel, PhD

IRB-HSR APPROVAL DATE: 28SEP2018

Rachel Rolfe rmk7ye@virginia.edu 434-924-6184
Rachel Rolfe rmk7ye@virginia.edu 434-924-6184
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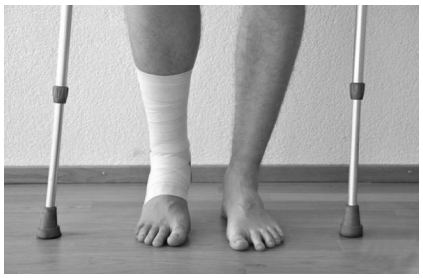
Rachel Rolfe rmk7ye@virginia.edu 434-924-6184

DO YOU HAVE ANKLE INSTABILITY?

The Exercise and Sport Injury Laboratory is seeking Adults (age 18-30) with a previous ankle sprain AND instability for participation in a research study.



- The purpose of this research study is to investigate the effects of 4-weeks of rehabilitation on the way people walk.
- This study will require:
  - 1 screening visit
  - 2 laboratory sessions
  - 8 rehabilitation sessions

  All visits will be at the University of Virginia, and each visit will last about 1-hour.
- You will be paid **$100** for completing this study.

For more information, please contact:

Rachel Rolfe
rmk7ye@virginia.edu

Or call the Exercise and Sport Injury Laboratory:
434-924-6184

IRB-HSR: *20446* ***Principle Investigator:*** Jay Hertel, PhD

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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

Tampa Scale for Kinesiophobia
(Miller , Kori and Todd 1991)

1 = strongly disagree
2 = disagree
3 = agree
4 = strongly agree

1. I'm afraid that I might injury myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren't taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't think it's actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

Table C7

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ days per week

No vigorous physical activities ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ hours per day _____ minutes per day

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ days per week

No moderate physical activities ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ hours per day _____ minutes per day

Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

No walking ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day** Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. Duringthe**last7days**,howmuchtimedidyouspend**sitting**ona**weekday**?

_____ **hours per day**

_____ **minutes per day** Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Table C8

The Patient-Specific Functional Scale

This useful questionnaire can be used to quantify activity limitation and measure functional outcome for patients with any orthopaedic condition.

Clinician to read and fill in below: Complete at the end of the history and prior to physical examination.

Initial Assessment:

I am going to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your _____ problem. Today, are there any activities that you are unable to do or having difficulty with because of your _____ problem? (Clinician: show scale to patient and have the patient rate each activity).

Follow-up Assessments:

When I assessed you on (state previous assessment date), you told me that you had difficulty with (read all activities from list at a time). Today, do you still have difficulty with: (read and have patient score each item in the list)?

Patient-specific activity scoring scheme (Point to one number):

0 1 2 3 4 5 6 7 8 9 10

Unable to perform activity

Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	Initial					
1.						
2.						
3.						
4.						
5.						
Additional						
Additional						

Total score = sum of the activity scores/number of activities
Minimum detectable change (90%CI) for average score = 2 points
Minimum detectable change (90%CI) for single activity score = 3 points

PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

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Table C9

Global Rating of Change

Please rate the overall condition of your injured body part or region from the **time that you began treatment until now**. (Select only one)

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

APPENDIX D
ADDITIONAL RESULTS

Table D1. Descriptive statistics for Coper and CAI groups

Group Statistics

	Group_1_is_CAI	N	Mean	Std. Deviation
Weight_kg	Coper	17	66.1665	11.29362
	CAI	17	66.9306	14.34948
Height_cm	Coper	17	168.2124	6.03552
	CAI	17	167.4871	9.07051
Age_y	Coper	17	20.47	1.908
	CAI	17	21.53	3.430
Pre_IdFAI	Coper	17	10.65	3.587
	CAI	17	20.18	3.557
Pre_FAAM_ADL_Raw	Coper	17	83.94	.243
	CAI	17	72.35	8.170
Pre_FAAM_ADL_Percent	Coper	17	99.9299720	.288732887
	CAI	17	86.1344538	9.72573490
Pre_FAAM_Sport_Raw	Coper	17	27.71	.470
	CAI	17	19.24	4.855
Pre_FAAM_Sport_Percent	Coper	17	98.9495798	1.67738649
	CAI	17	68.6974790	17.3375023
Pre_IPAQ_Total_MET	Coper	17	5014.29	2210.013
	CAI	17	5133.94	3327.227
Pre_TSK	Coper	17	30.76	3.615
	CAI	17	35.00	6.052
Test_Limb_Times_Sprained	Coper	17	1.29	.588
	CAI	17	3.47	1.068
Test_Limb_Time_Since_First_Sprain	Coper	17	70.59	42.135
	CAI	17	98.12	52.002
Test_Limb_Time_Most_Recent_Sprain	Coper	17	63.18	45.750
	CAI	17	18.06	27.408
Preferred_Walking_Speed	Coper	17	.8882	.12690
	CAI	17	1.0441	.15399
120_Walking_Speed	Coper	17	1.0659	.15228
	CAI	17	1.2494	.19002

Independent Samples Test

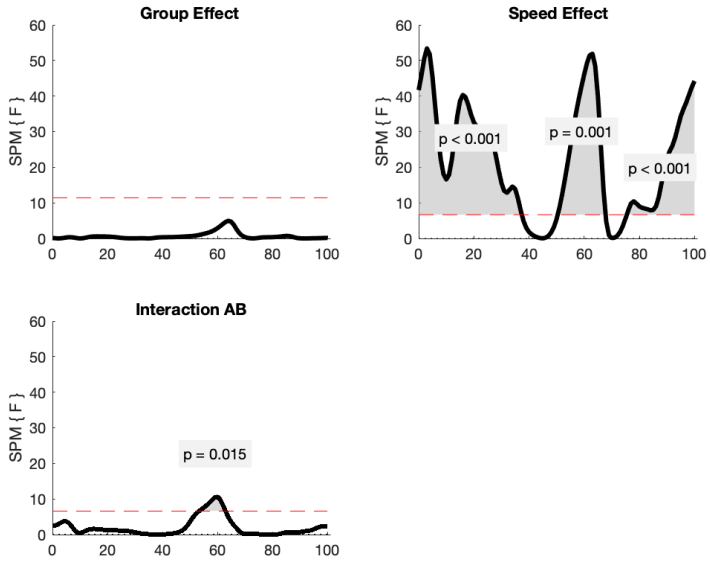
		t-test for Equality of Means		
		df	Sig. (2-tailed)	Mean Difference
Weight_kg	Equal variances assumed	32	.864	-.76412
	Equal variances not assumed	30.325	.864	-.76412
Height_cm	Equal variances assumed	32	.785	.72529
	Equal variances not assumed	27.846	.786	.72529
Age_y	Equal variances assumed	32	.274	-1.059
	Equal variances not assumed	25.035	.277	-1.059
Pre_IdFAI	Equal variances assumed	32	.000	-9.529
	Equal variances not assumed	31.998	.000	-9.529
Pre_FAAM_ADL_Raw	Equal variances assumed	32	.000	11.588
	Equal variances not assumed	16.028	.000	11.588
Pre_FAAM_ADL_Percent	Equal variances assumed	32	.000	13.7955182
	Equal variances not assumed	16.028	.000	13.7955182
Pre_FAAM_Sport_Raw	Equal variances assumed	32	.000	8.471
	Equal variances not assumed	16.300	.000	8.471
Pre_FAAM_Sport_Percent	Equal variances assumed	32	.000	30.2521008
	Equal variances not assumed	16.300	.000	30.2521008
Pre_IPAQ_Total_MET	Equal variances assumed	32	.902	-119.647
	Equal variances not assumed	27.818	.903	-119.647
Pre_TSK	Equal variances assumed	32	.019	-4.235
	Equal variances not assumed	26.127	.020	-4.235

Independent Samples Test

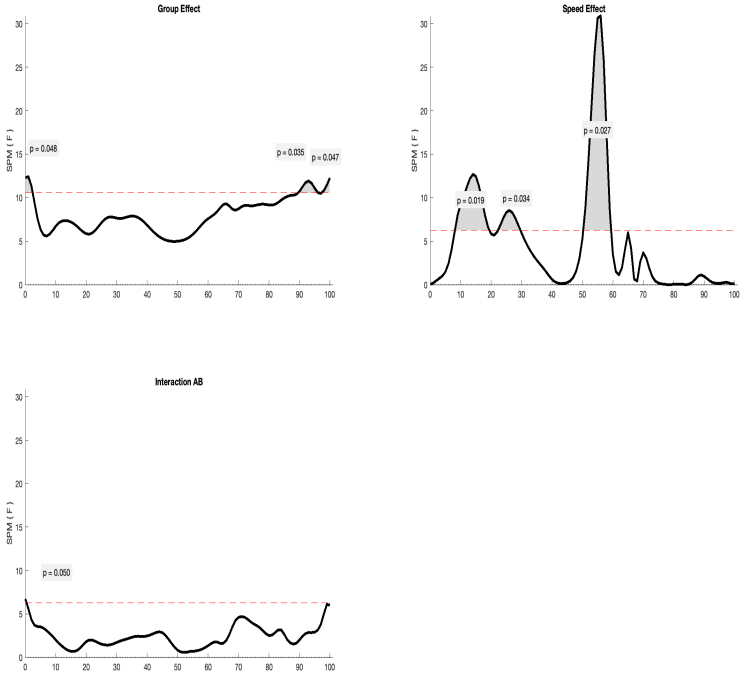
		Levene's Test for Equality of Variances		t-test for Equality ..
		F	Sig.	t
Test_Limb_Times_Sprained	Equal variances assumed	5.809	.022	-7.363
	Equal variances not assumed			-7.363
Test_Limb_Time_Since_First_Sprain	Equal variances assumed	2.417	.130	-1.696
	Equal variances not assumed			-1.696
Test_Limb_Time_Most_Recent_Sprain	Equal variances assumed	4.594	.040	3.488
	Equal variances not assumed			3.488
Preferred_Walking_Speed	Equal variances assumed	.294	.592	-3.221
	Equal variances not assumed			-3.221
120_Walking_Speed	Equal variances assumed	.339	.565	-3.108
	Equal variances not assumed			-3.108

Figure D1. SPM Results for CAI vs. Coper at 3 walking speeds.
M1: Results

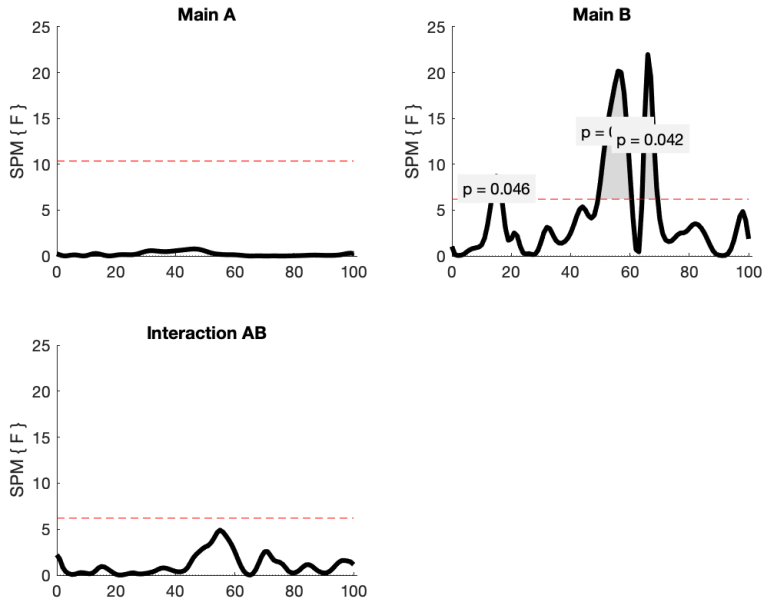
ANOVA – Ankle Sagittal



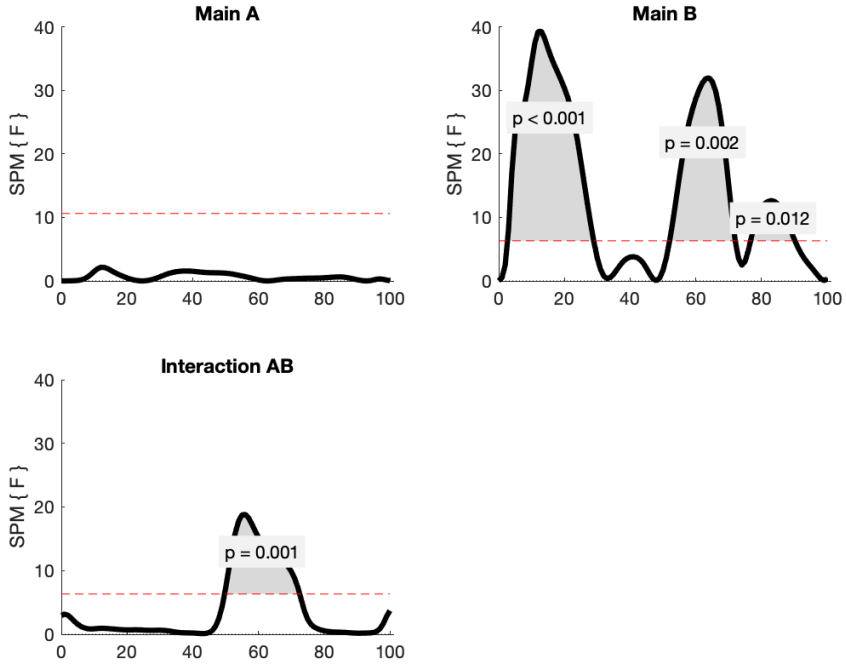
ANOVA - Ankle Frontal



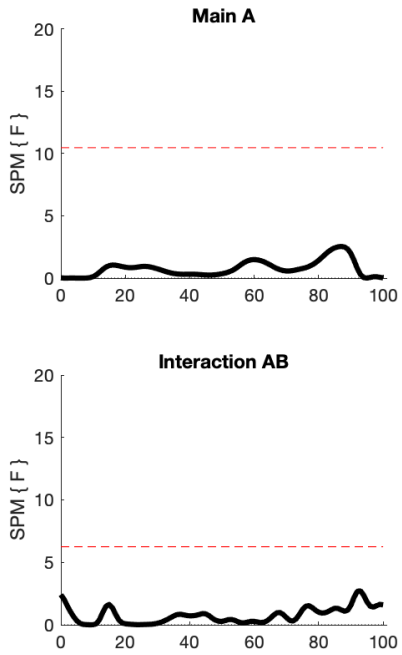
ANOVA - Ankle Transverse



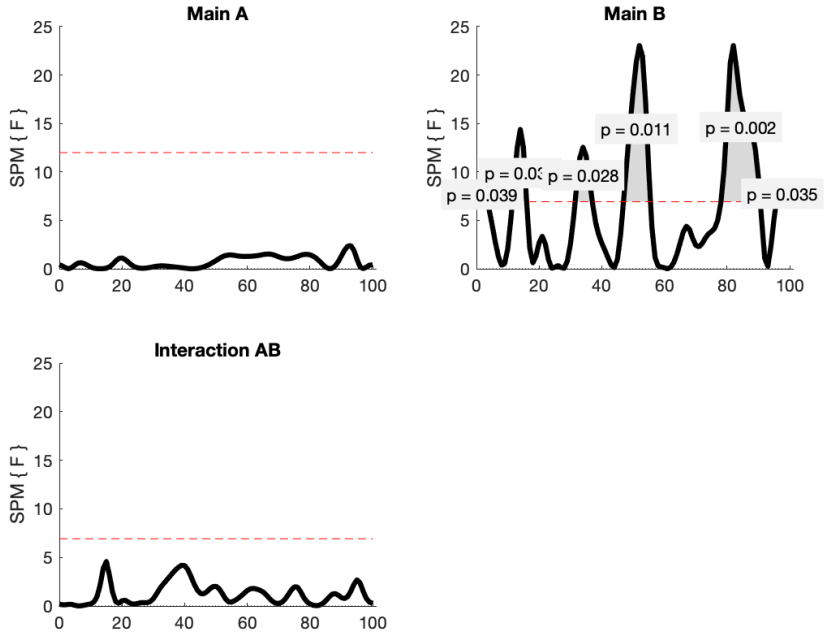
ANOVA – Knee Sagittal



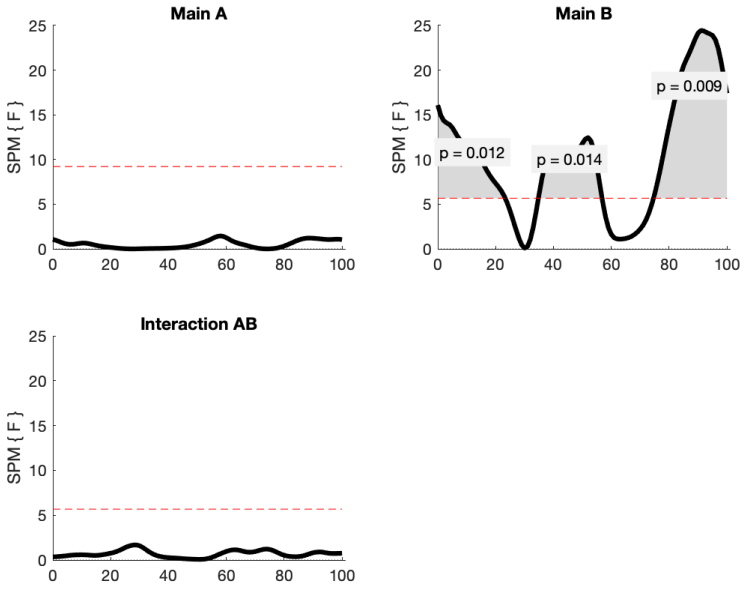
ANOVA Knee Frontal



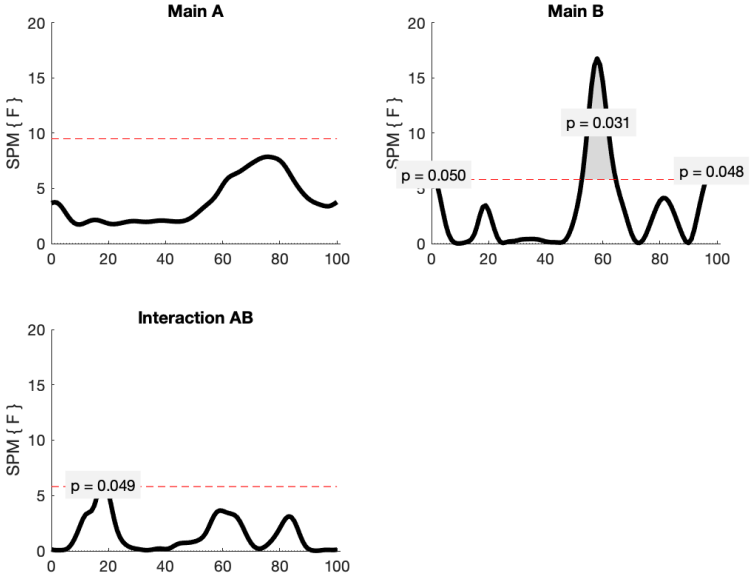
ANOVA Knee Transverse



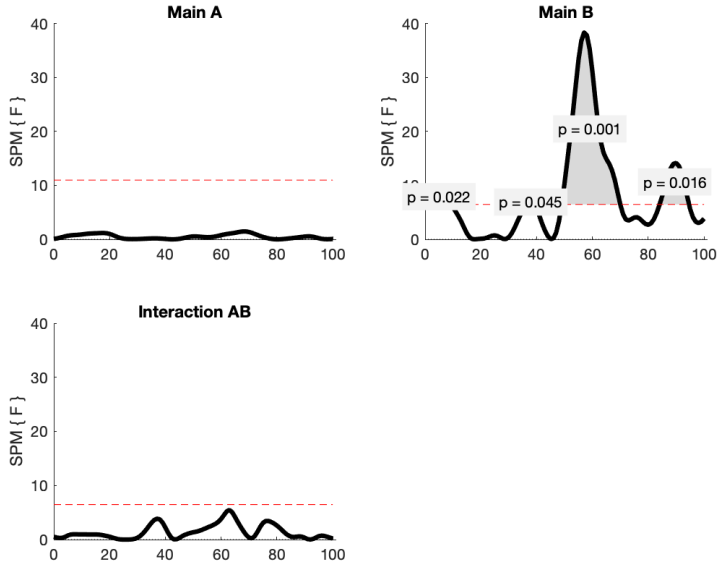
ANOVA - Hip Sagittal



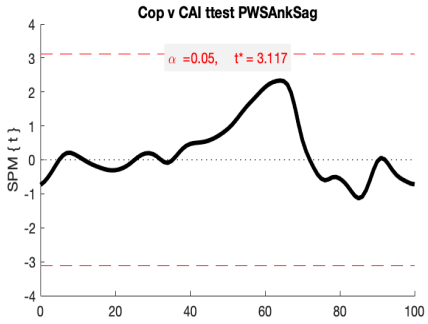
ANOVA – Hip Frontal

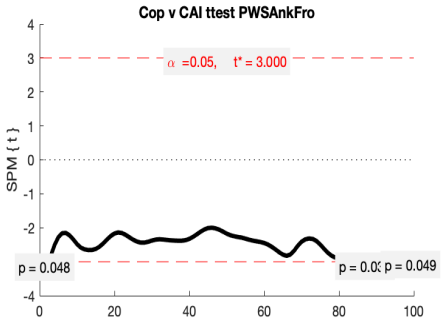


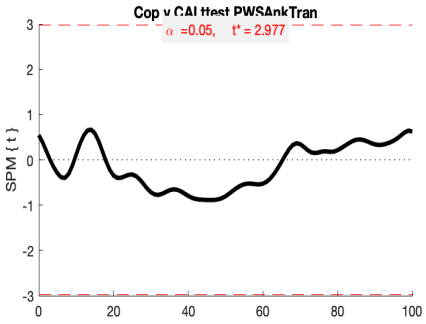
ANOVA – Hip Transverse

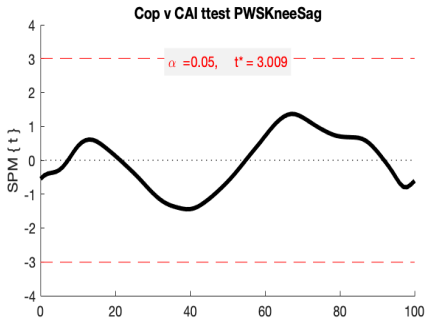


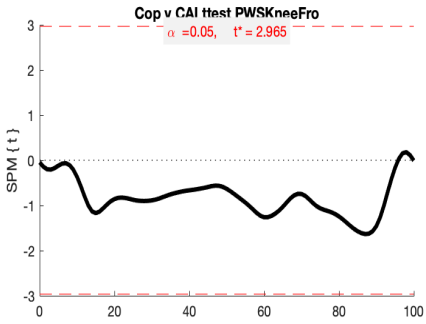
T-test Group Differences at PWS

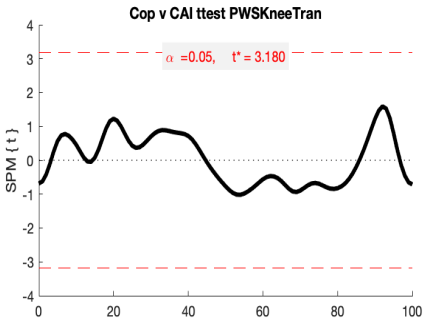


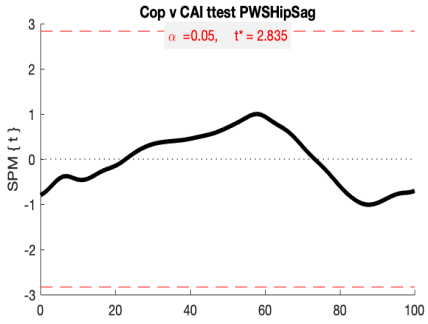


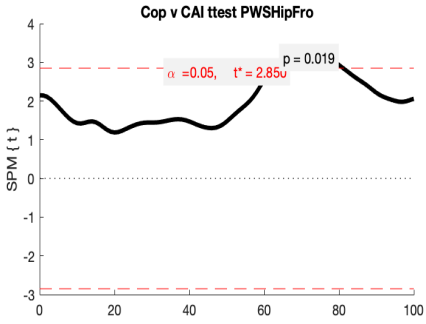


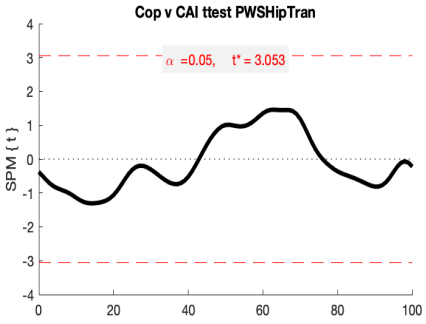




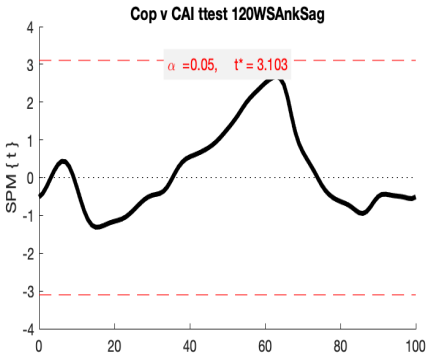


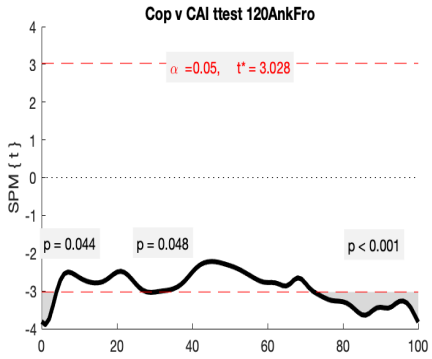


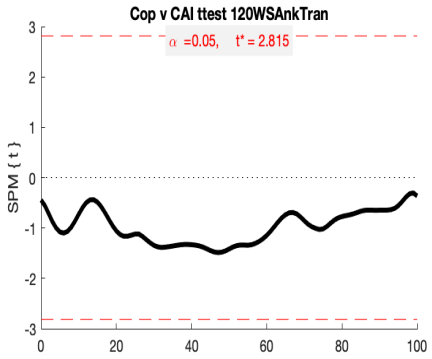


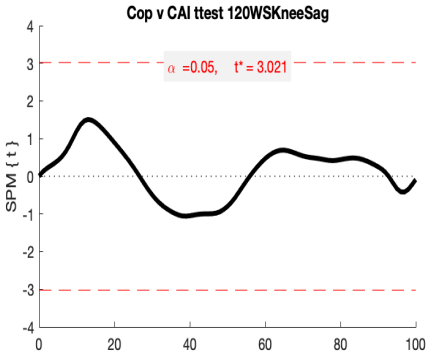


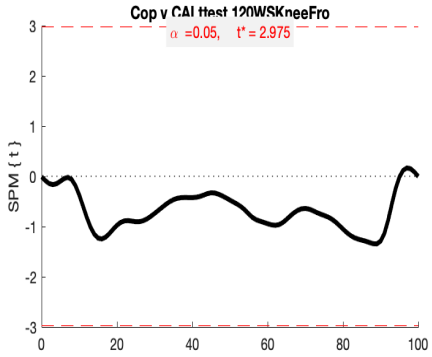
T-test Group Differences at 120WS

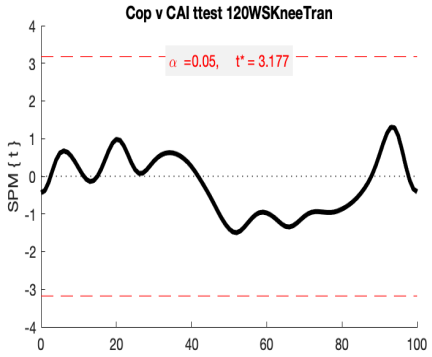


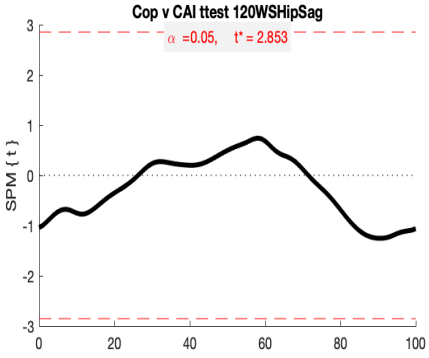


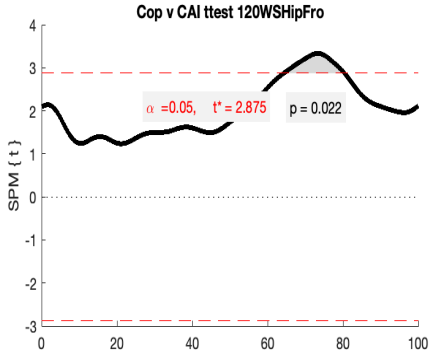


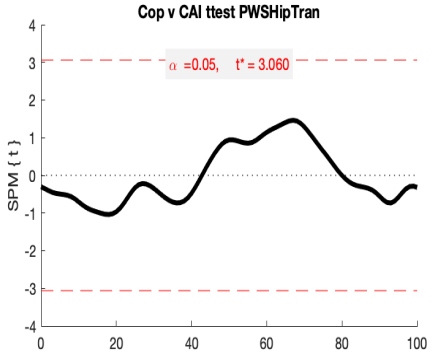




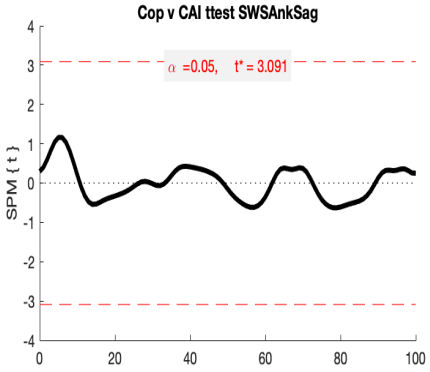


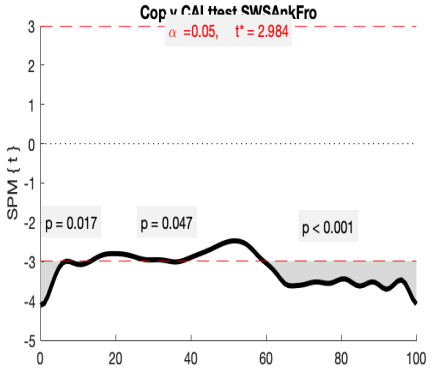


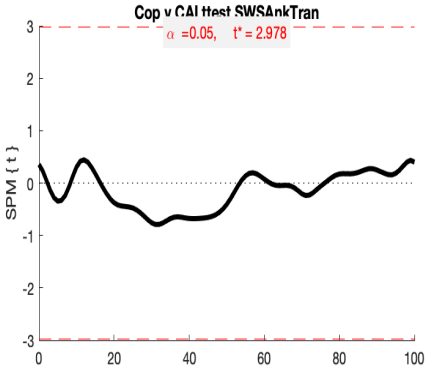


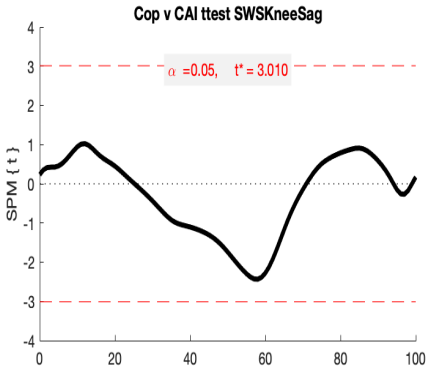


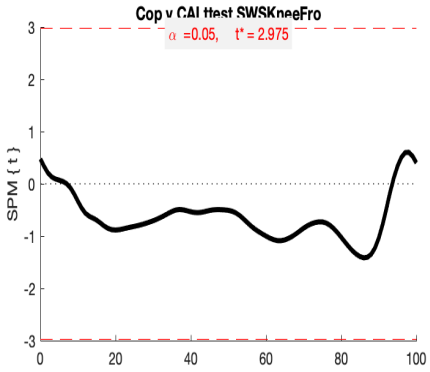
T-test Group Differences at SWS

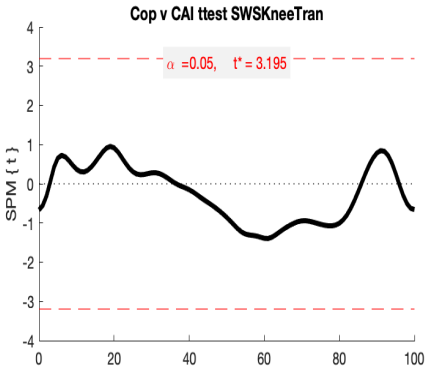


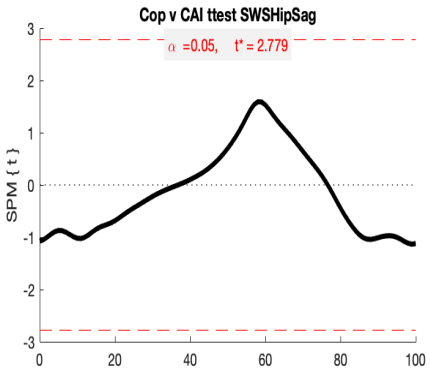


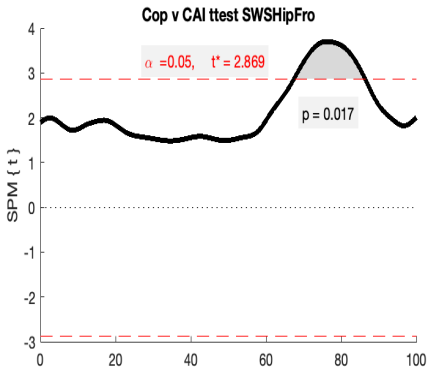


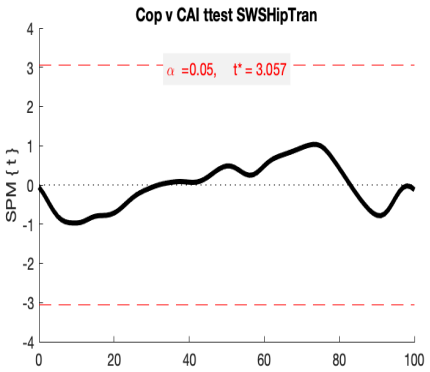




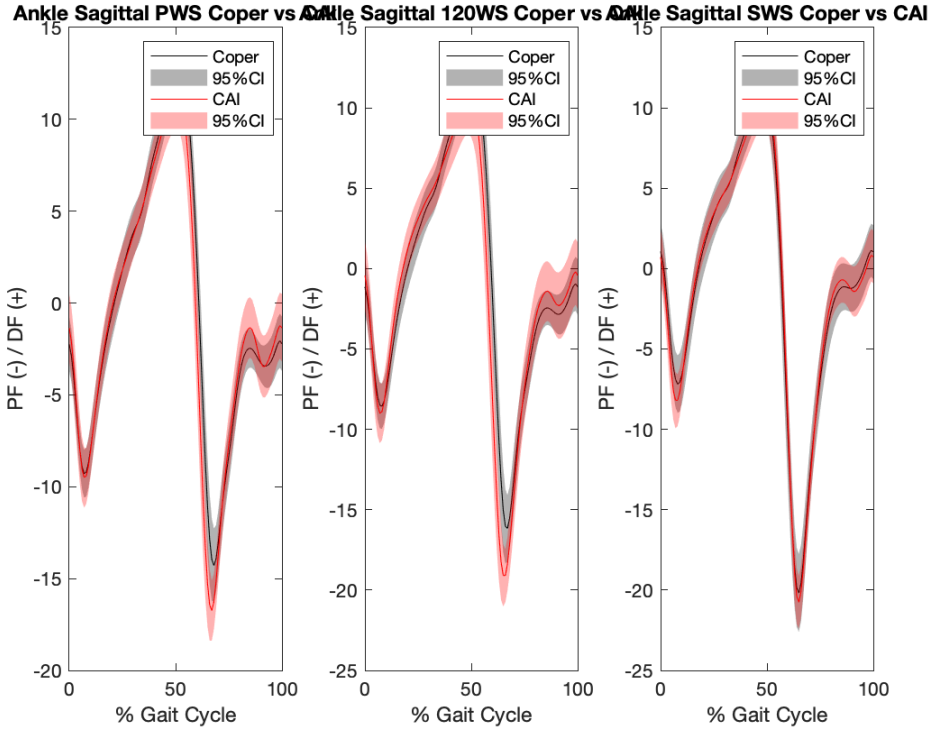




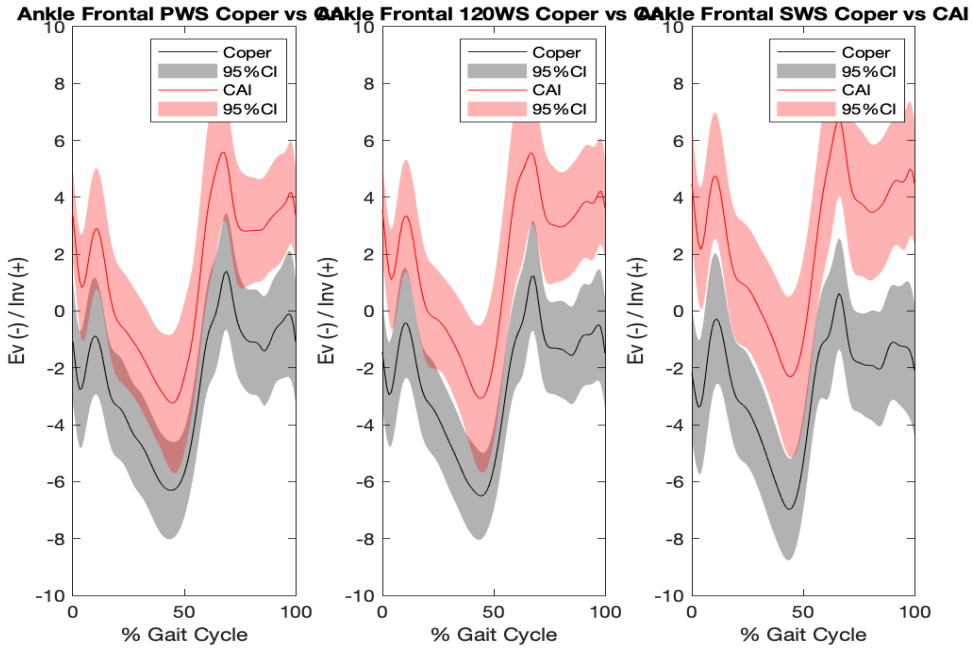




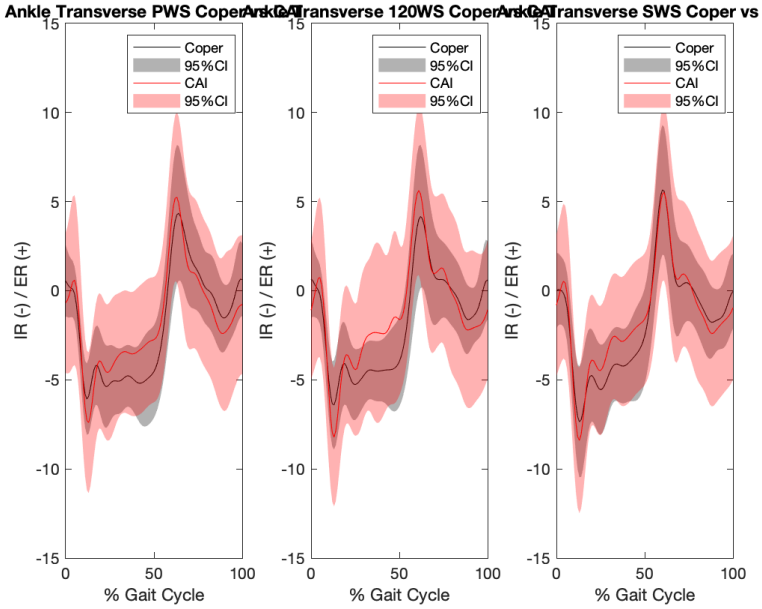
T-test Group Differences
Ankle Sagittal



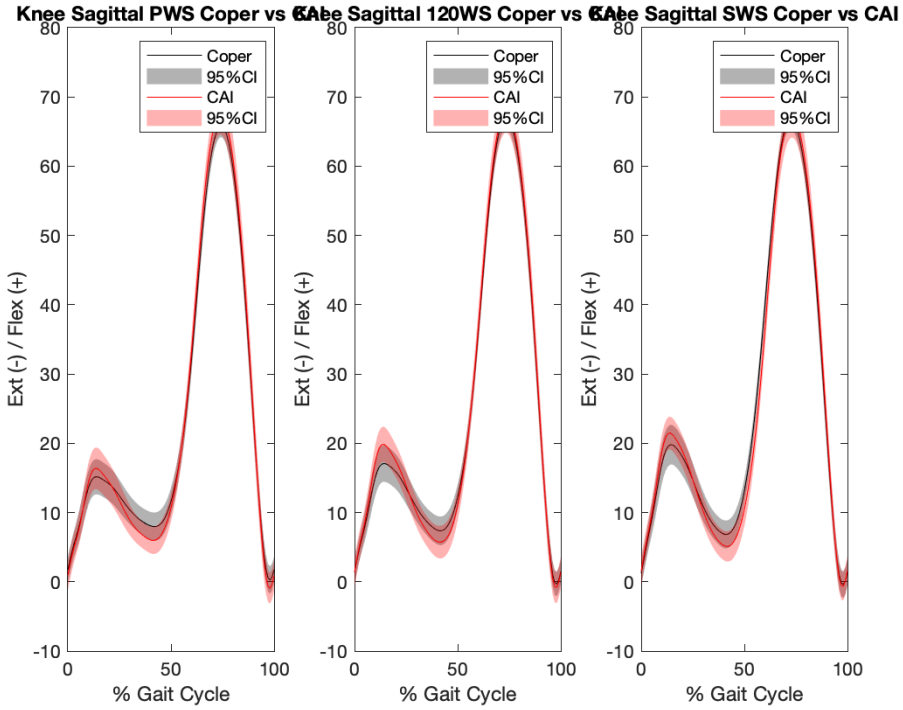
T-test Group Differences
Ankle Frontal



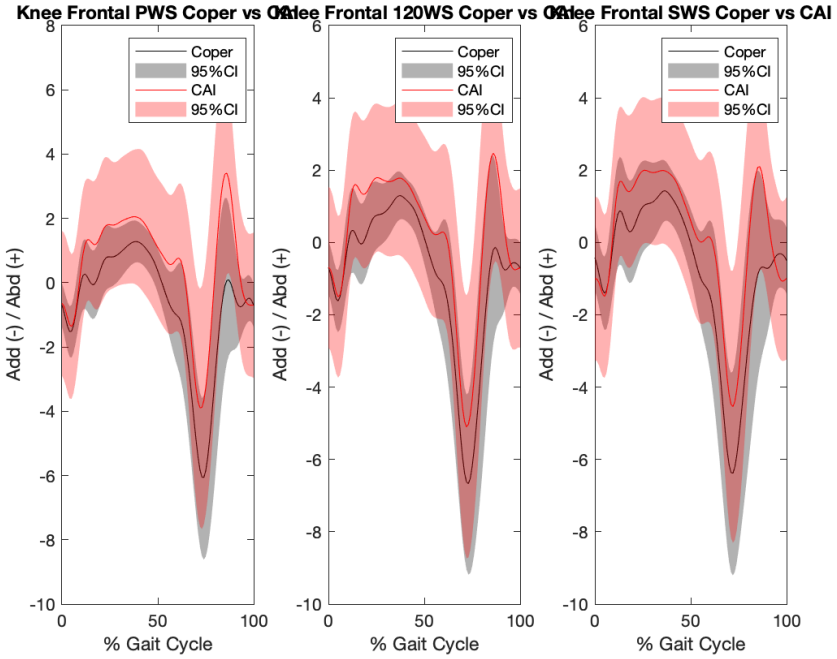
T-test Group Differences
Ankle Transverse



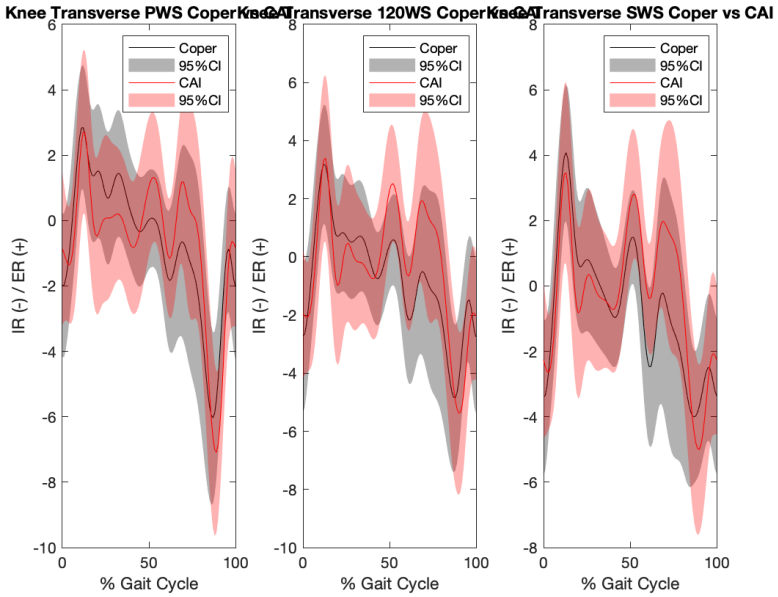
T-test Group Differences
Knee Sagittal



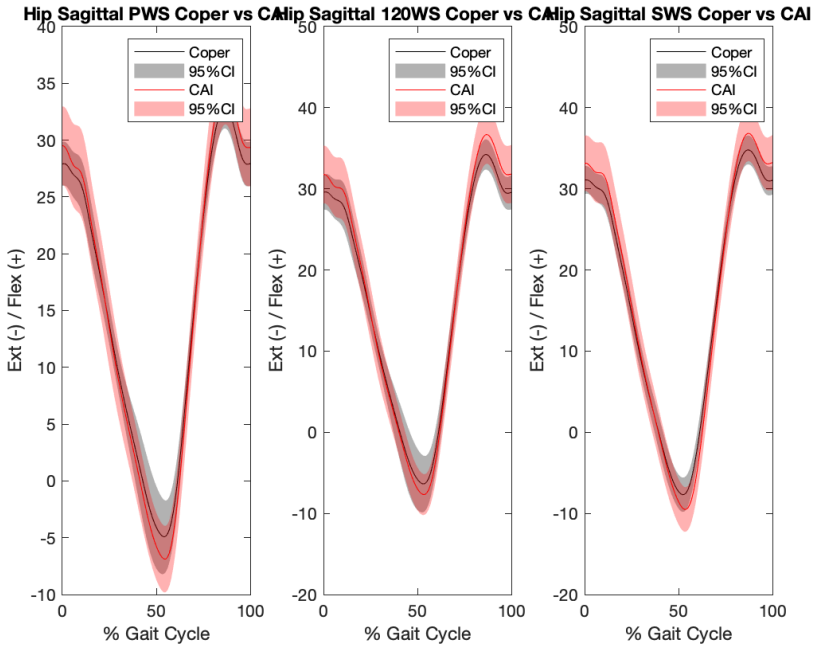
T-test Group Differences
Knee Frontal



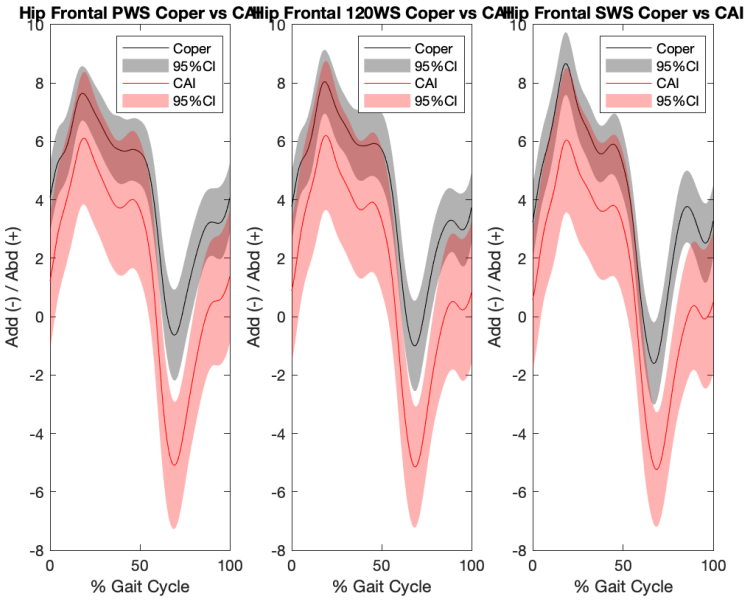
T-test Group Differences
Knee Transverse



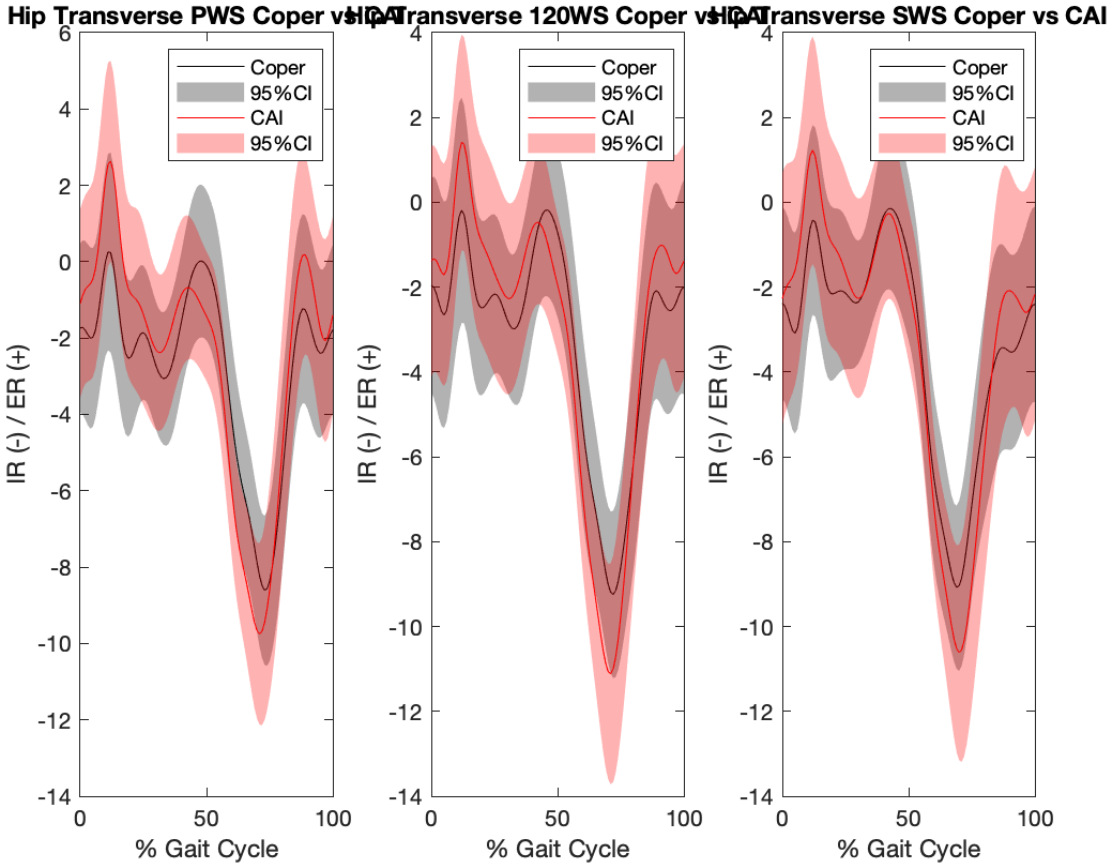
T-test Group Differences
Hip Sagittal



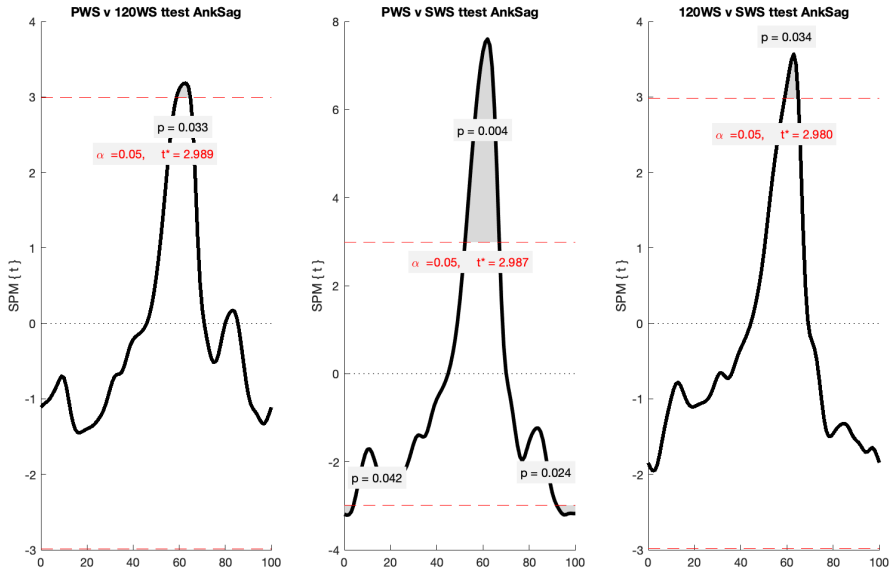
T-test Group Differences
Hip Frontal

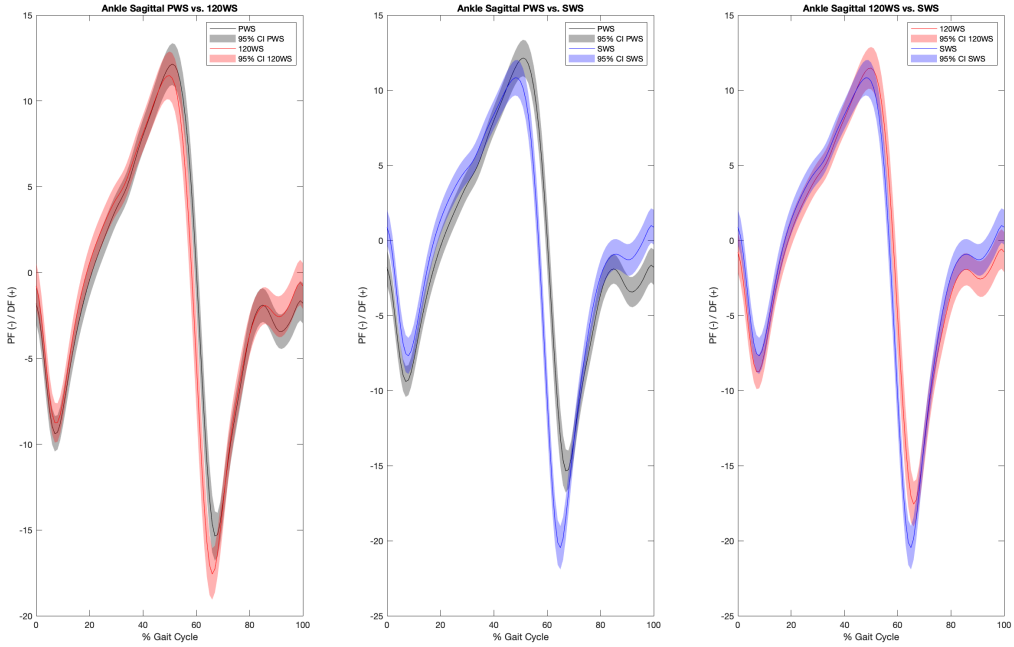


T-test Group Differences
Hip Transverse

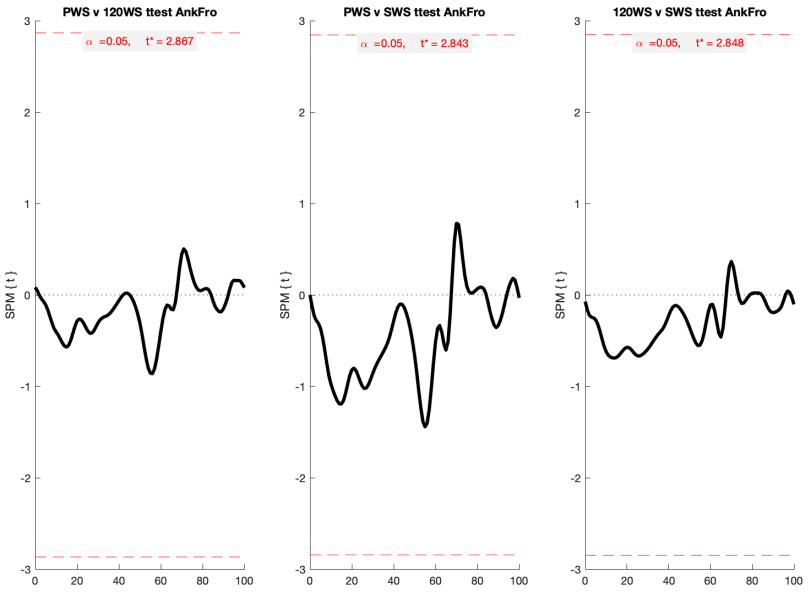


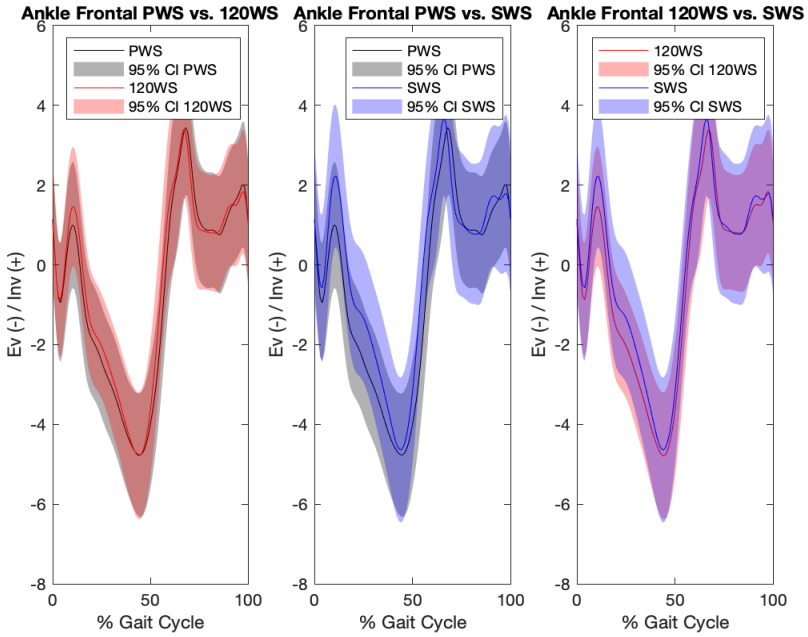
T-test Speed Differences
Ankle Sagittal



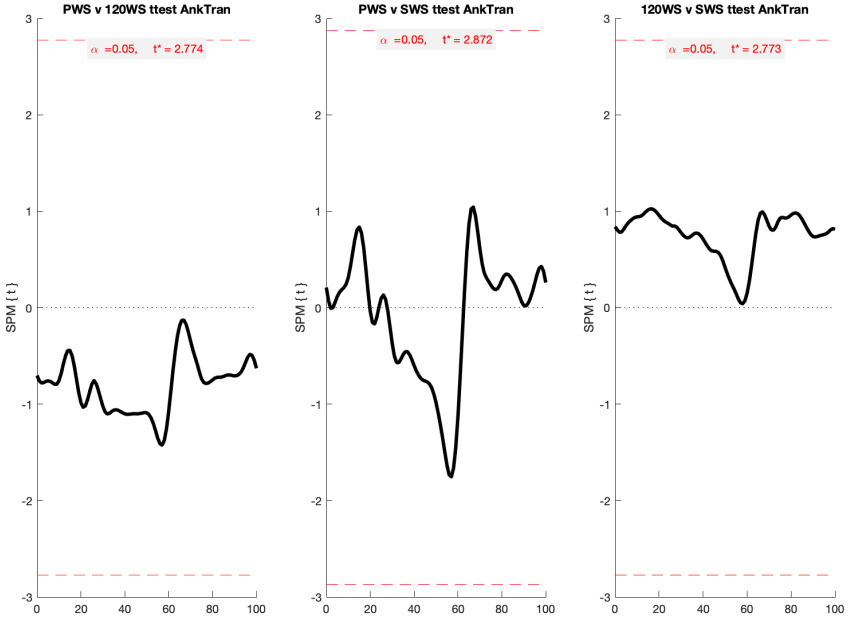


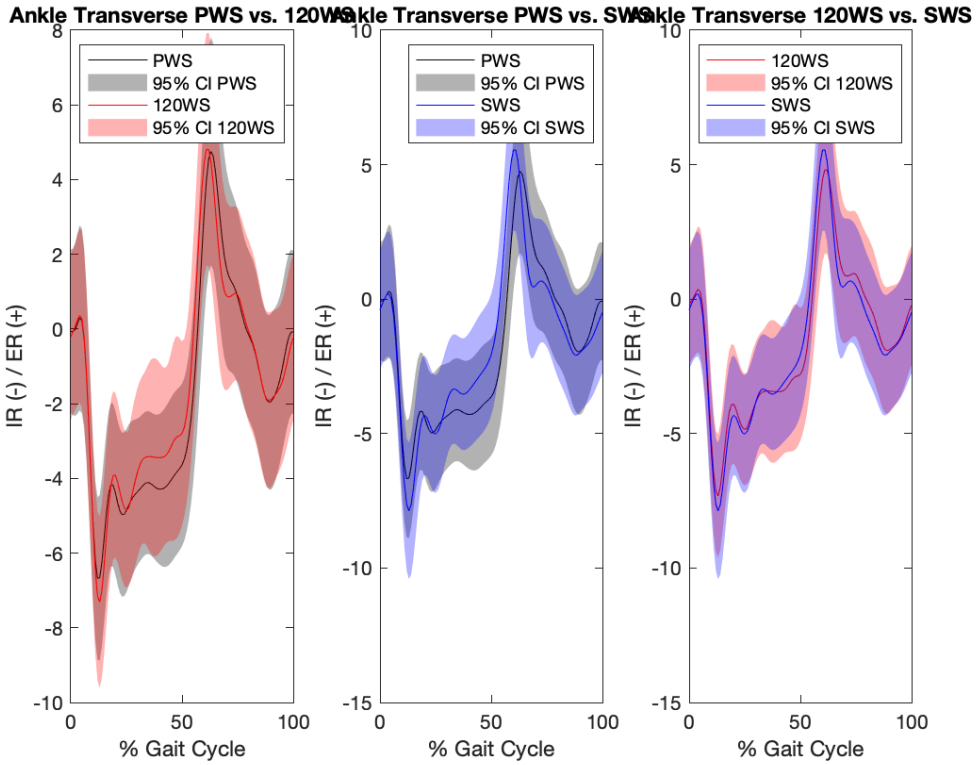
T-test Speed Differences
Ankle Frontal



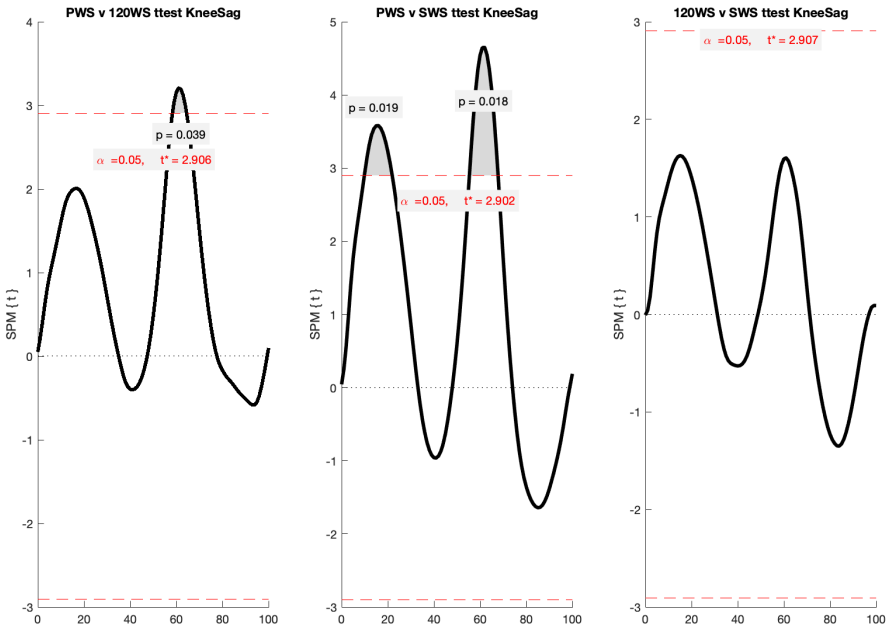


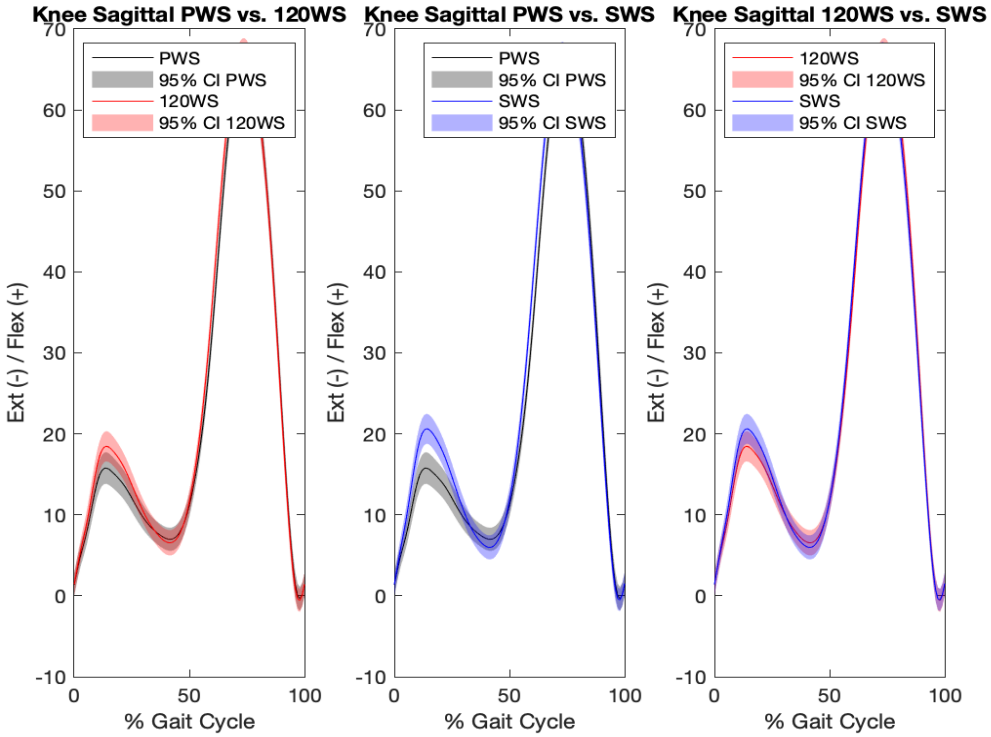
T-test Speed Differences
Ankle Transverse



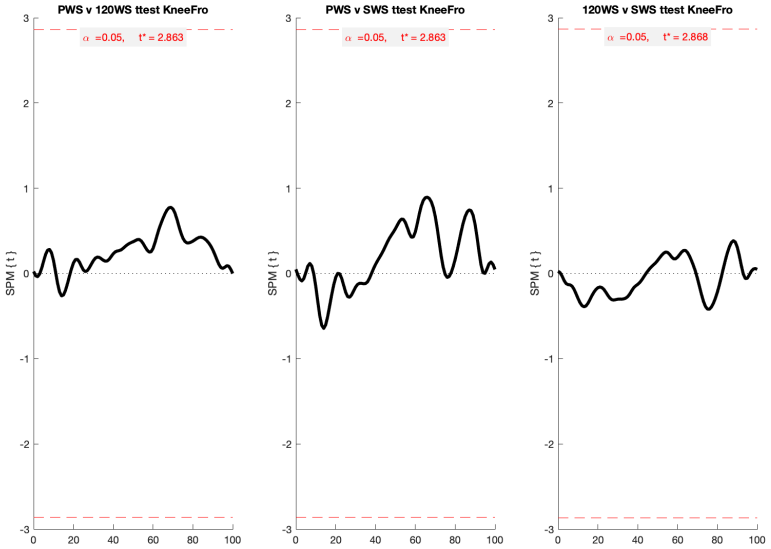


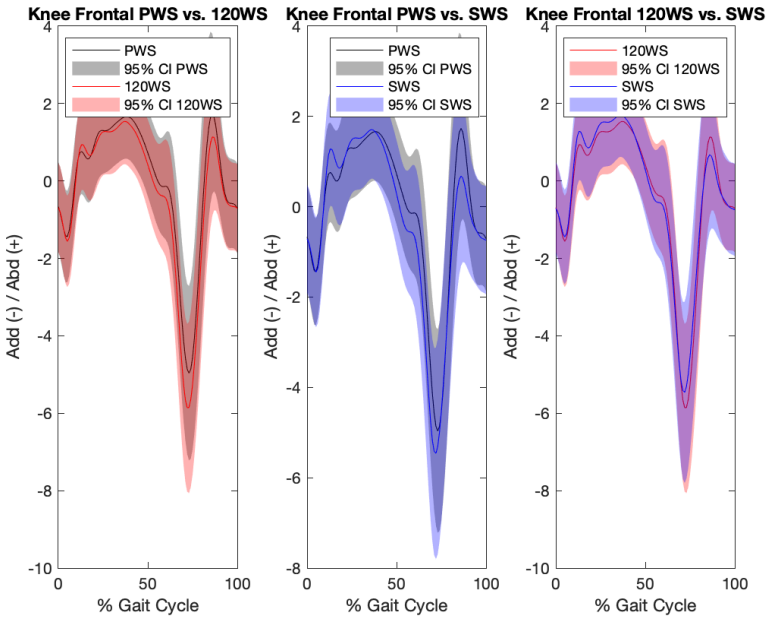
T-test Speed Differences
Knee Sagittal



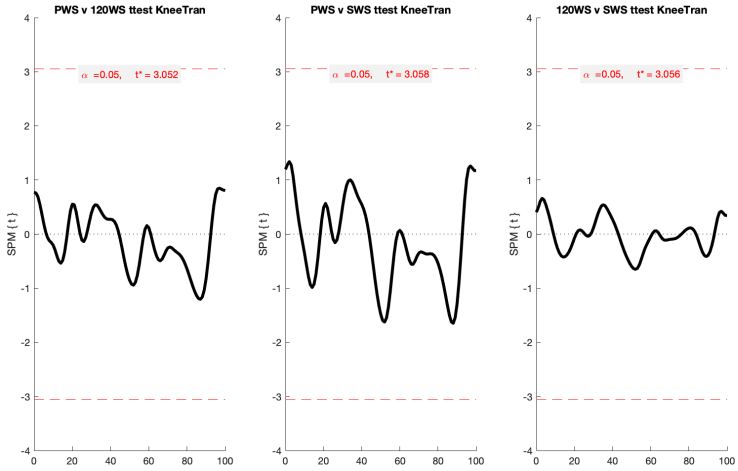


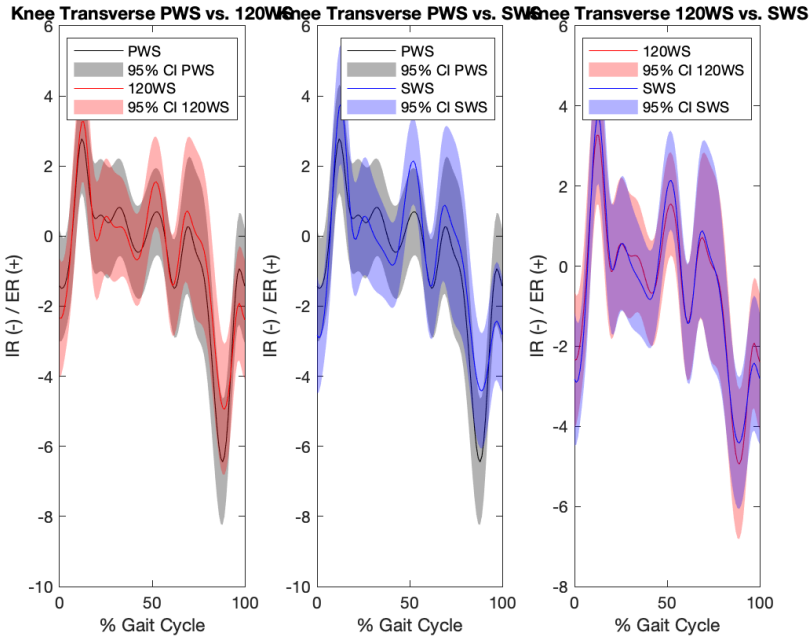
T-test Speed Differences
Knee Frontal



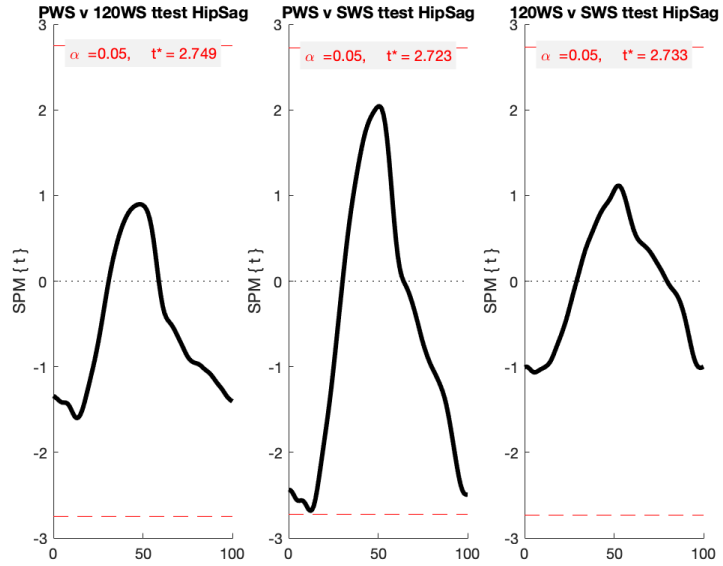


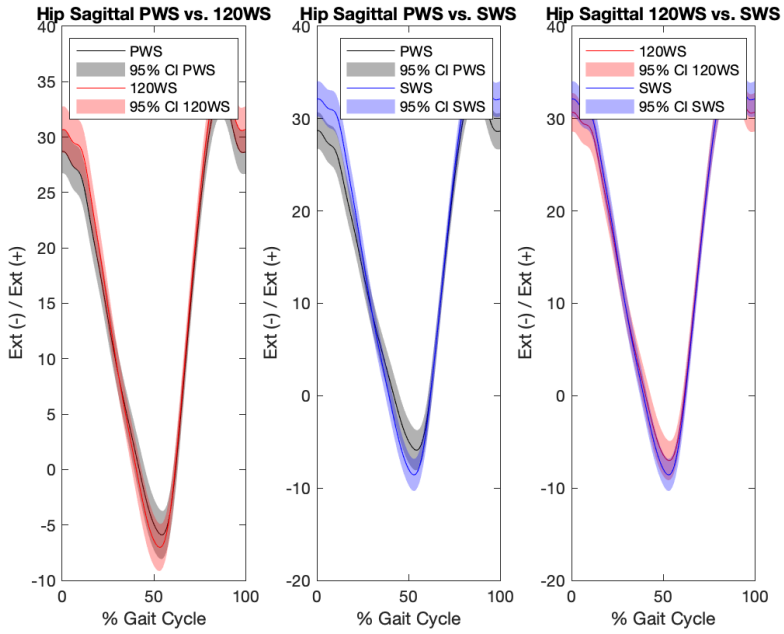
T-test Speed Differences
Knee Transverse



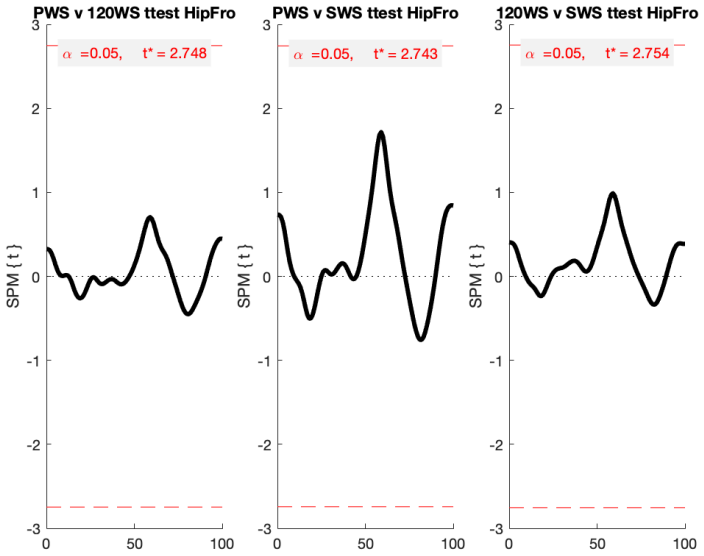


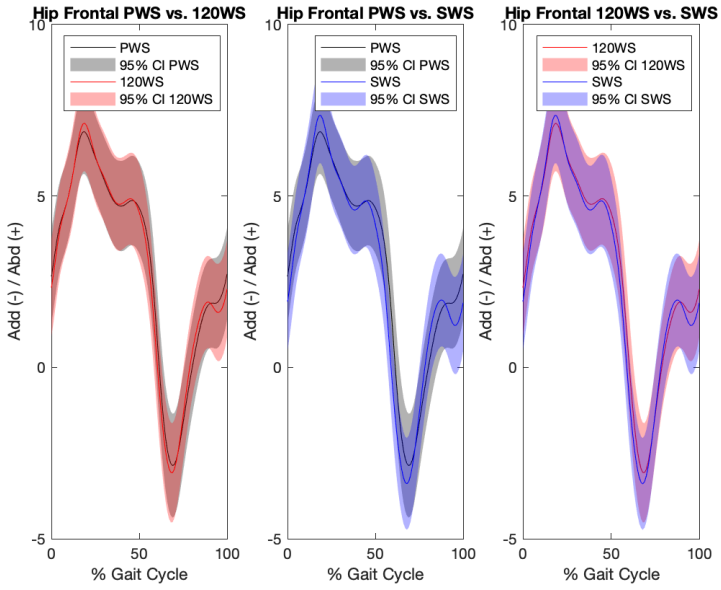
T-test Speed Differences
Hip Sagittal



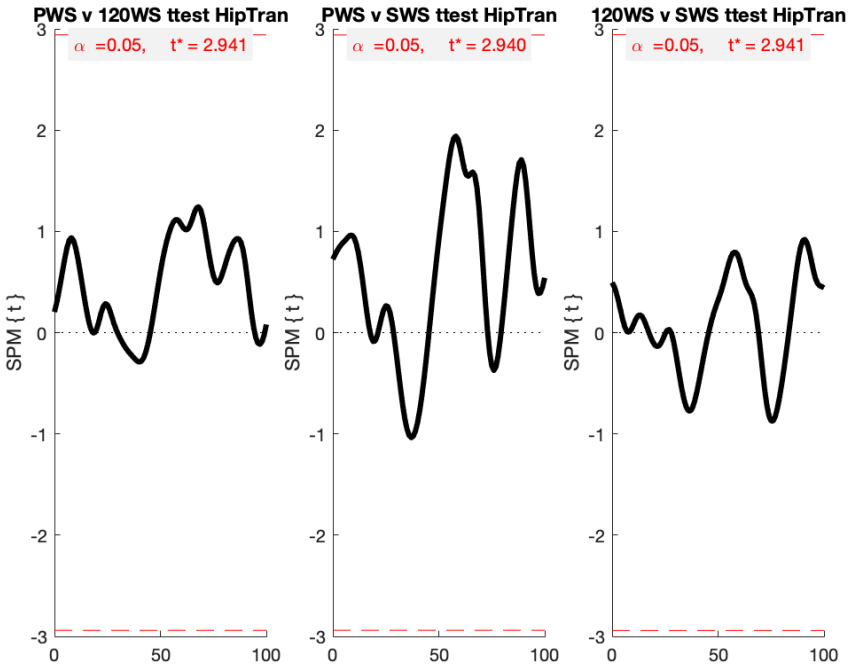


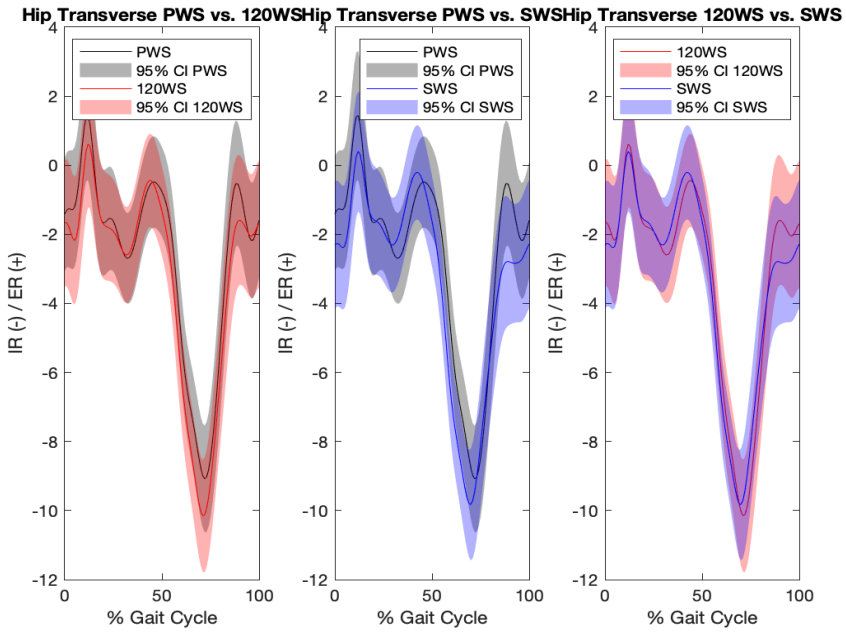
T-test Speed Differences
Hip Frontal



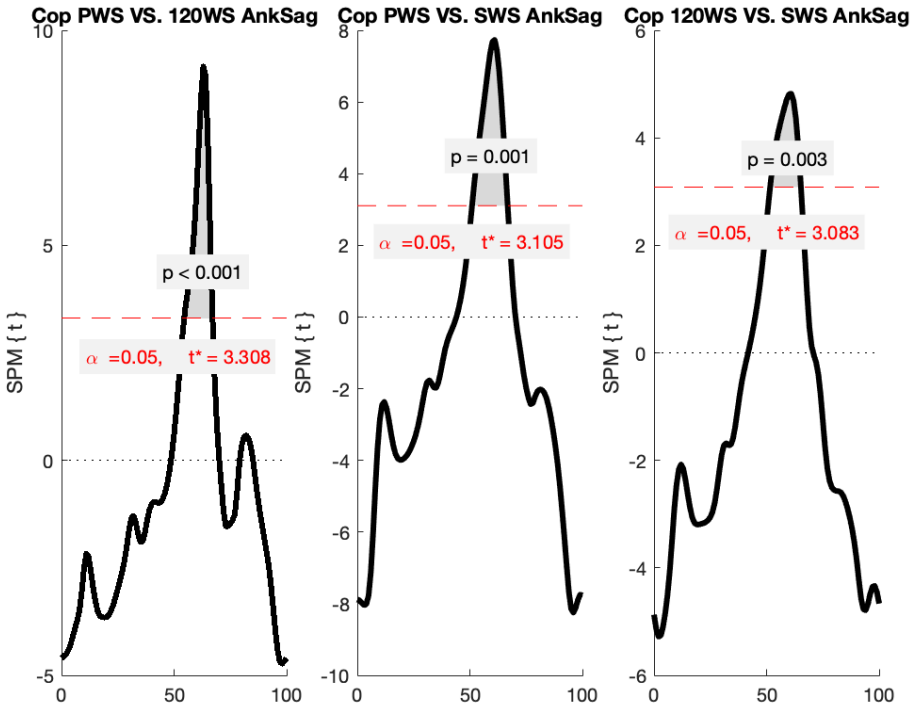


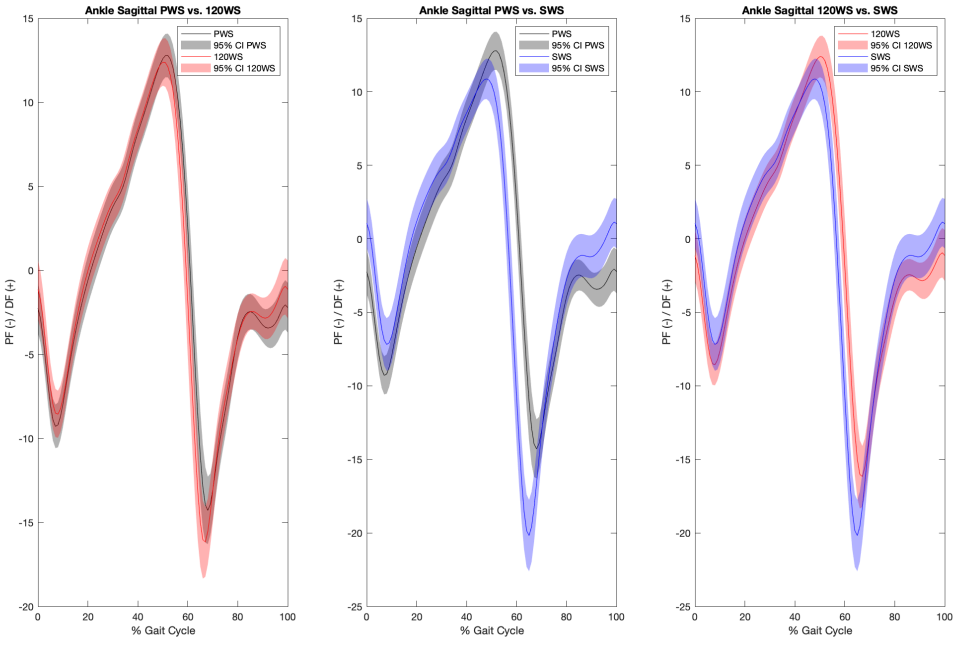
T-test Speed Differences
Hip Transverse



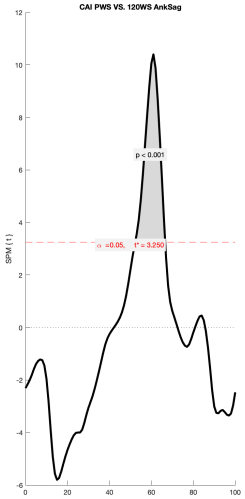


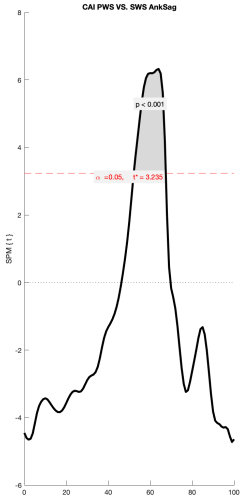
T-test Speed Differences
Coper Ankle Sagittal

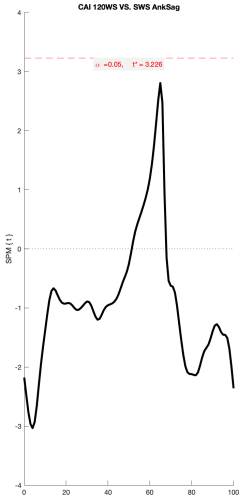


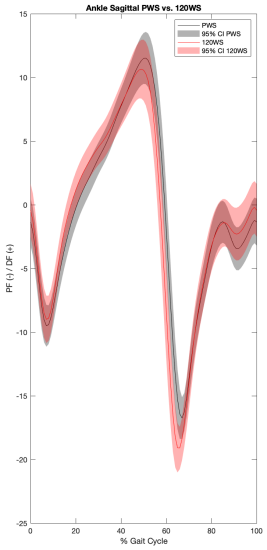


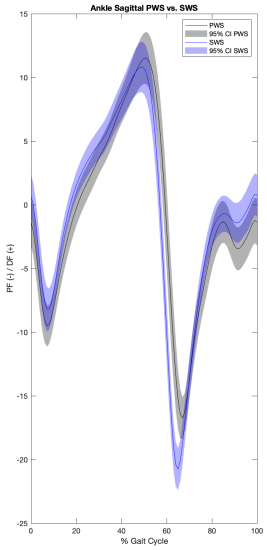
T-test Speed Differences
CAI Ankle Sagittal

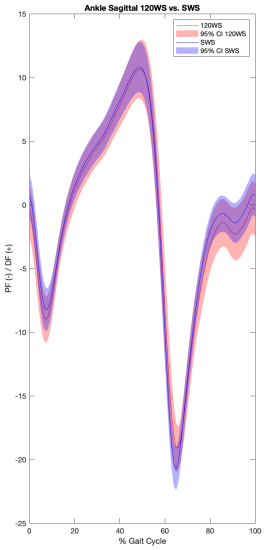




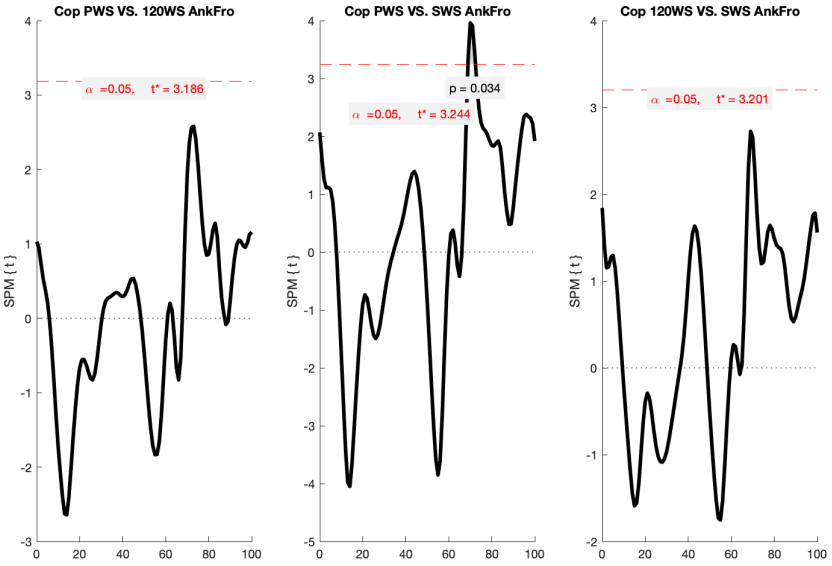


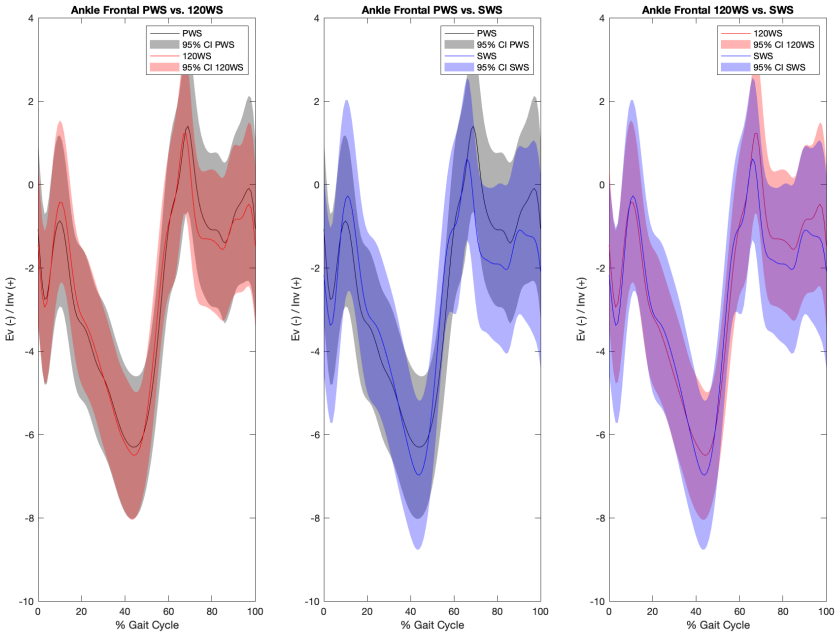




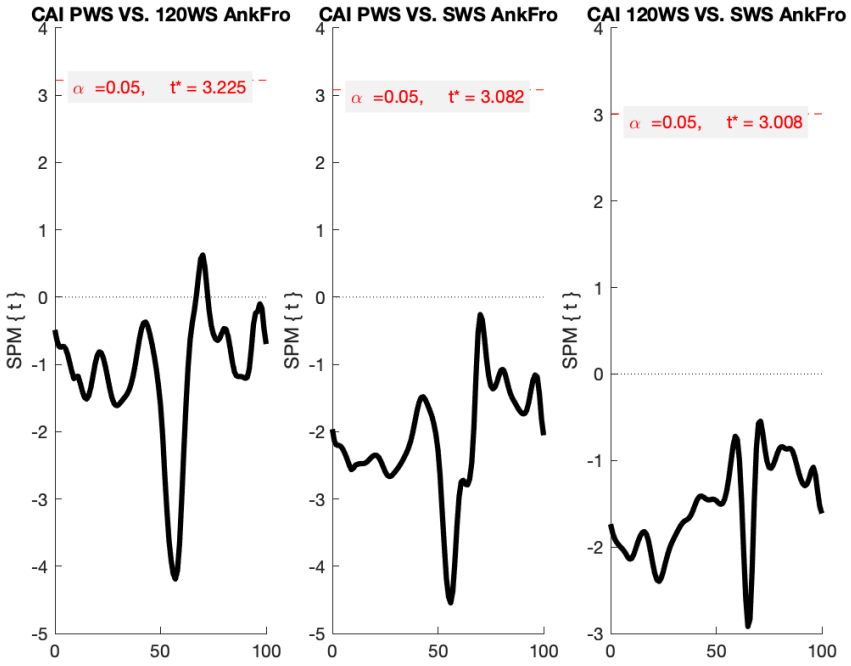


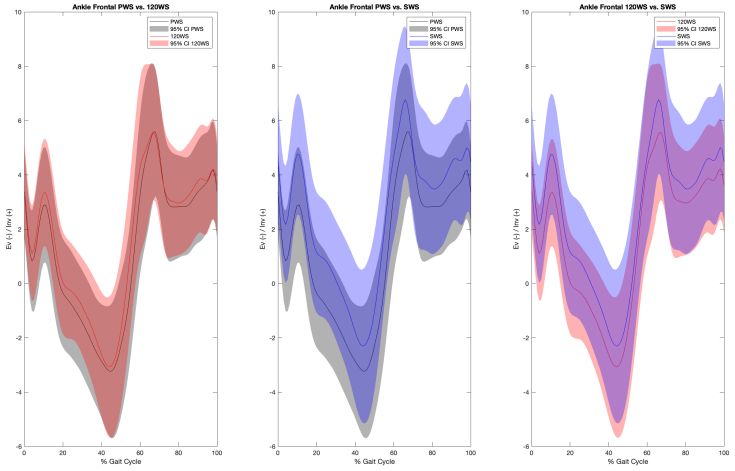
T-test Speed Differences
Coper Ankle Frontal



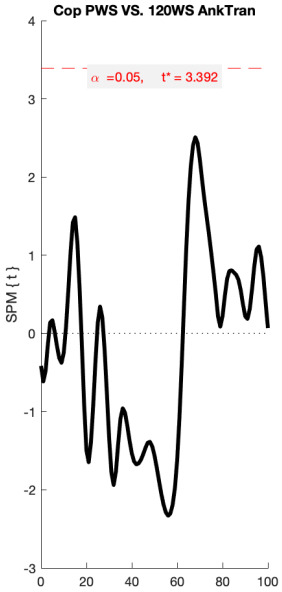


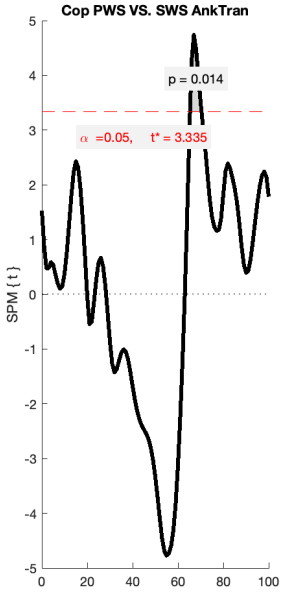
T-test Speed Differences
CAI Ankle Frontal

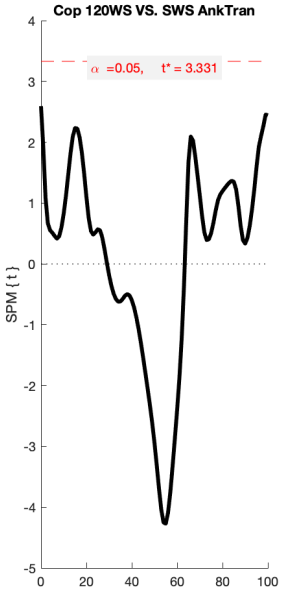


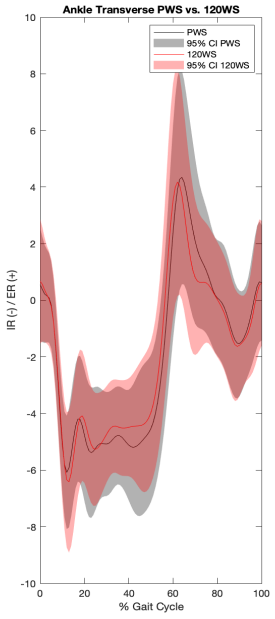


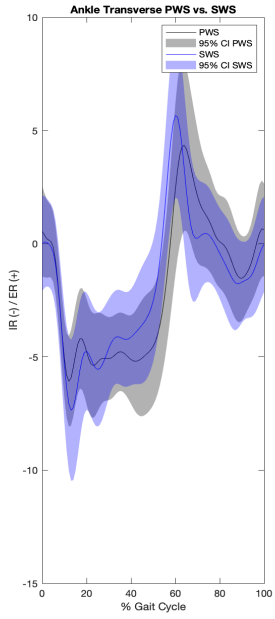
T-test Speed Differences
Coper Ankle Transverse

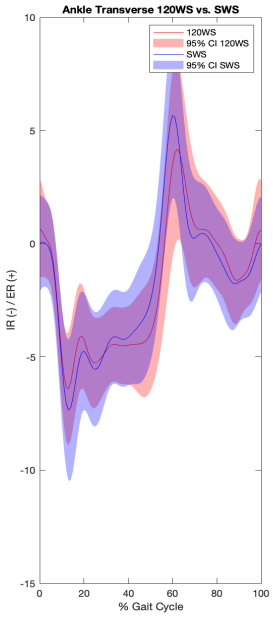




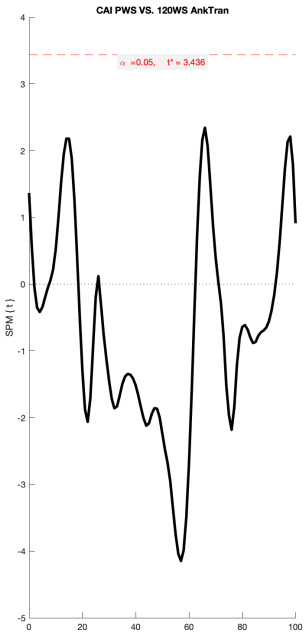


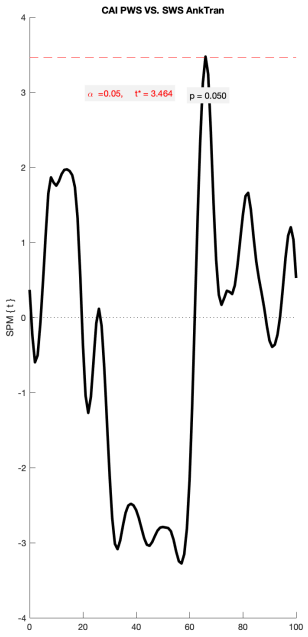


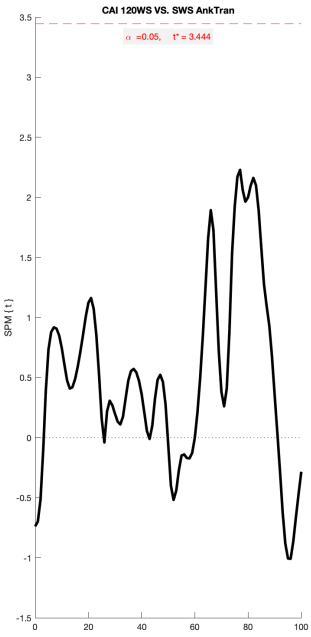


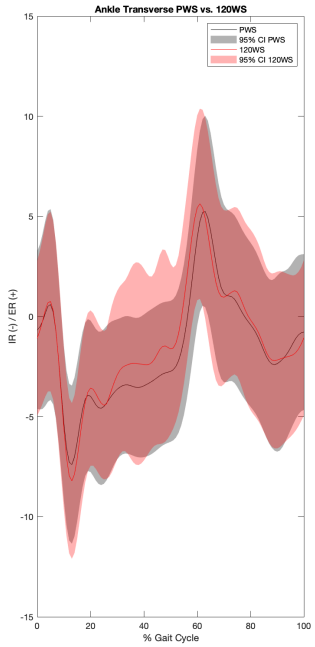


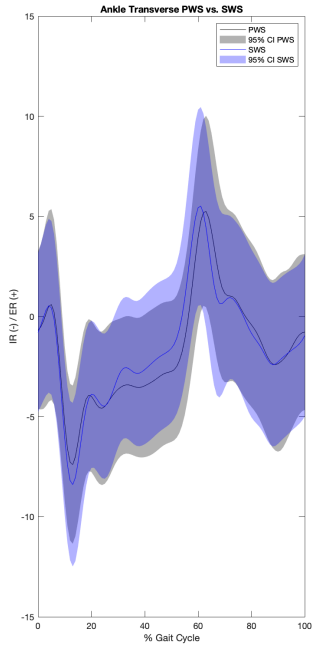
T-test Speed Differences
CAI Ankle Transverse

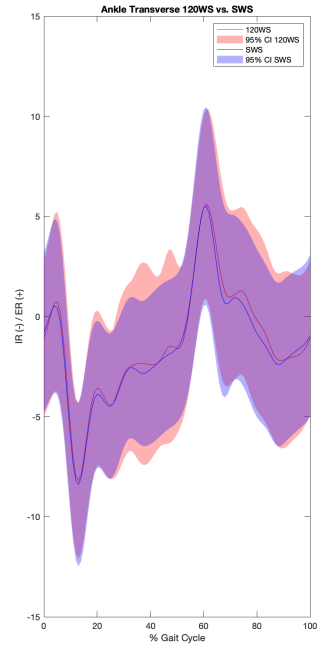




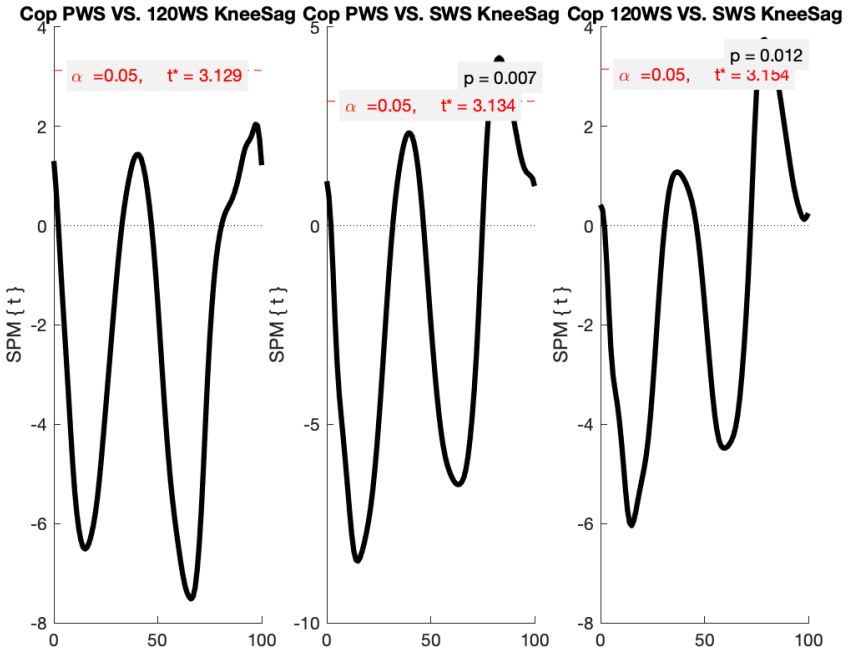


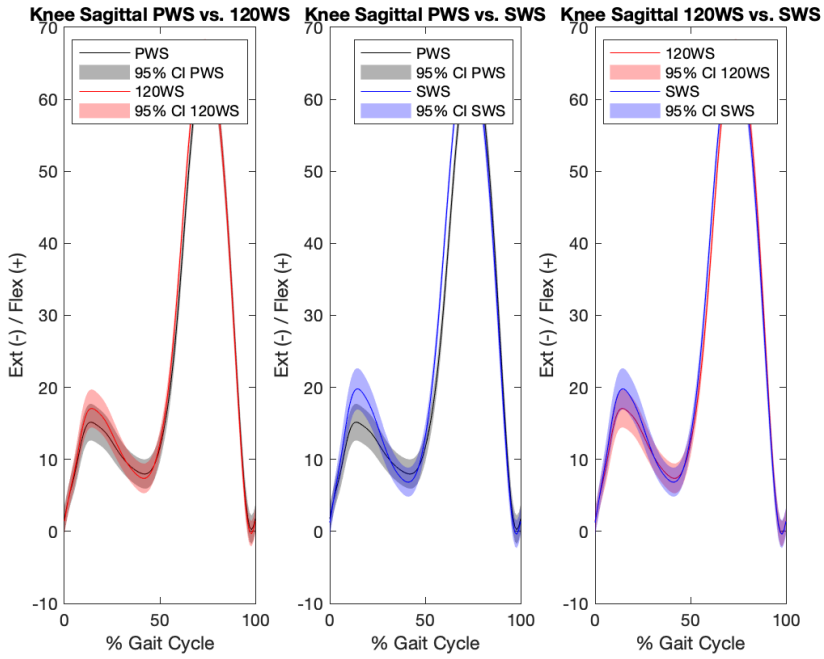




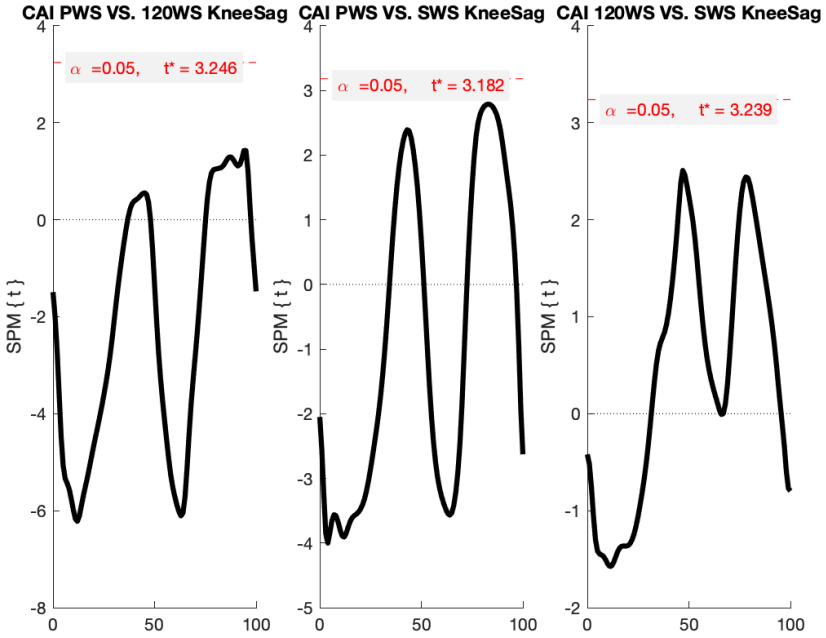


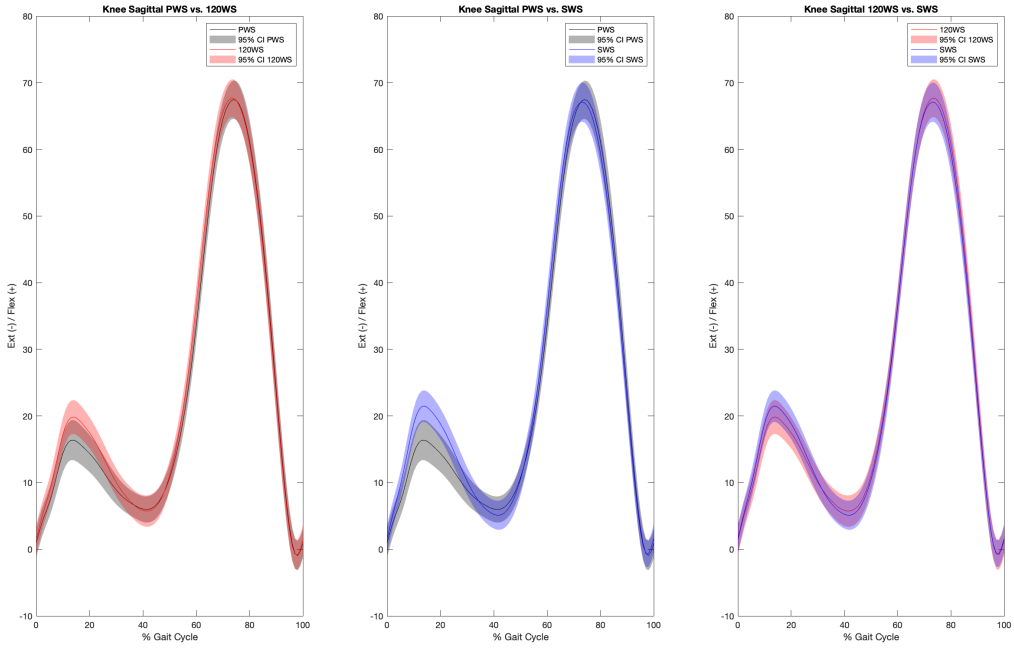
T-test Speed Differences
Coper Knee Sagittal



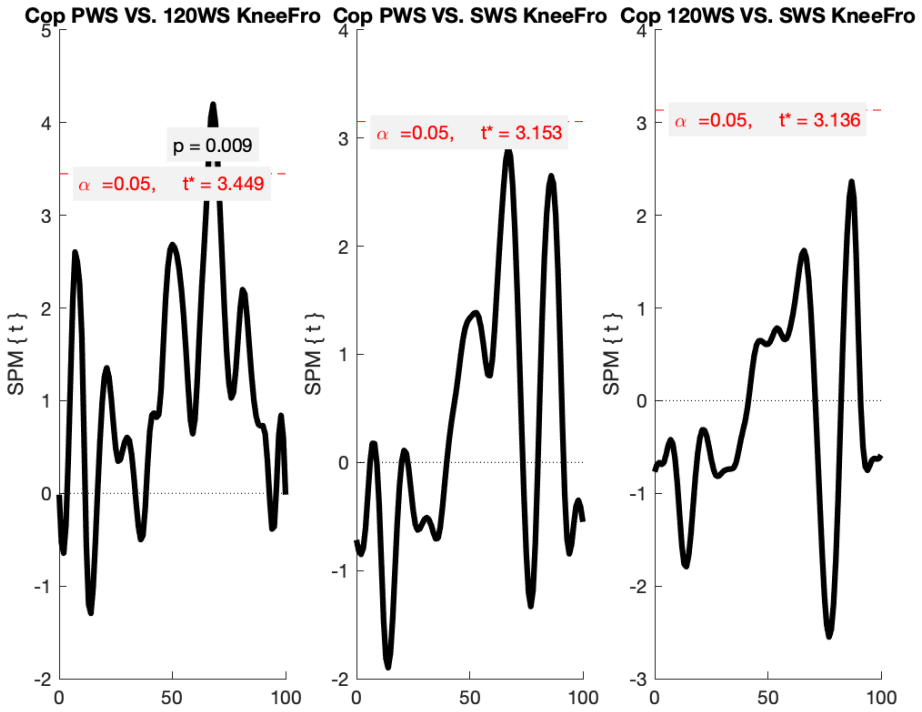


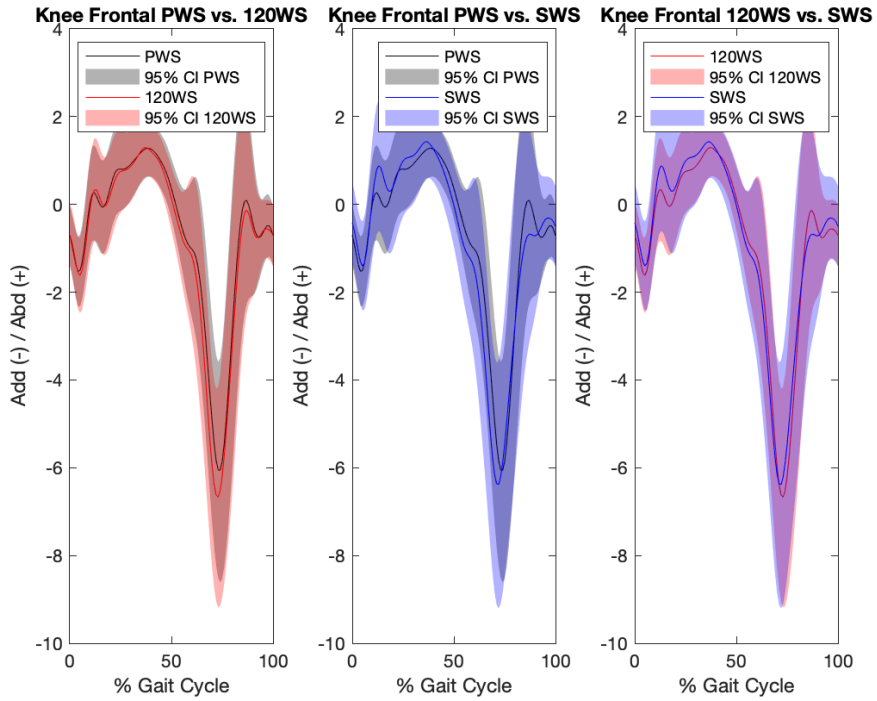
T-test Speed Differences
CAI Knee Sagittal



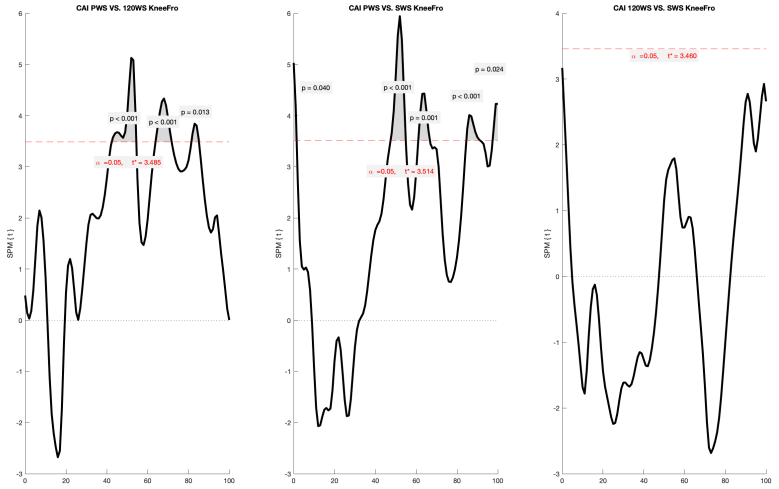


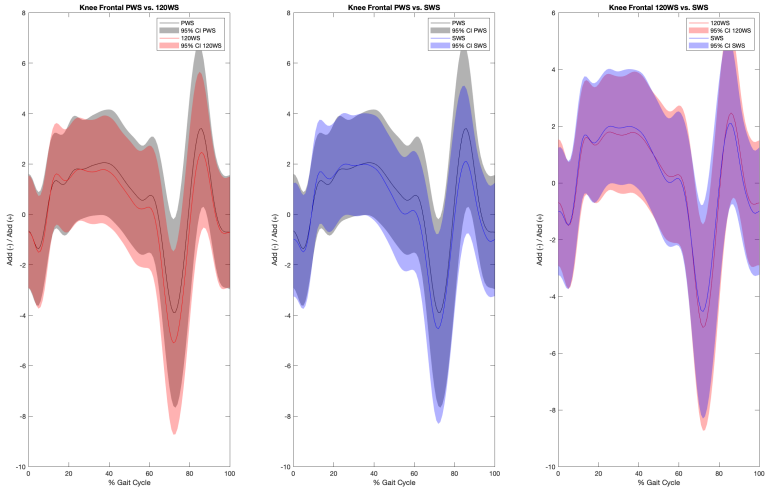
T-test Speed Differences
Coper Knee Frontal



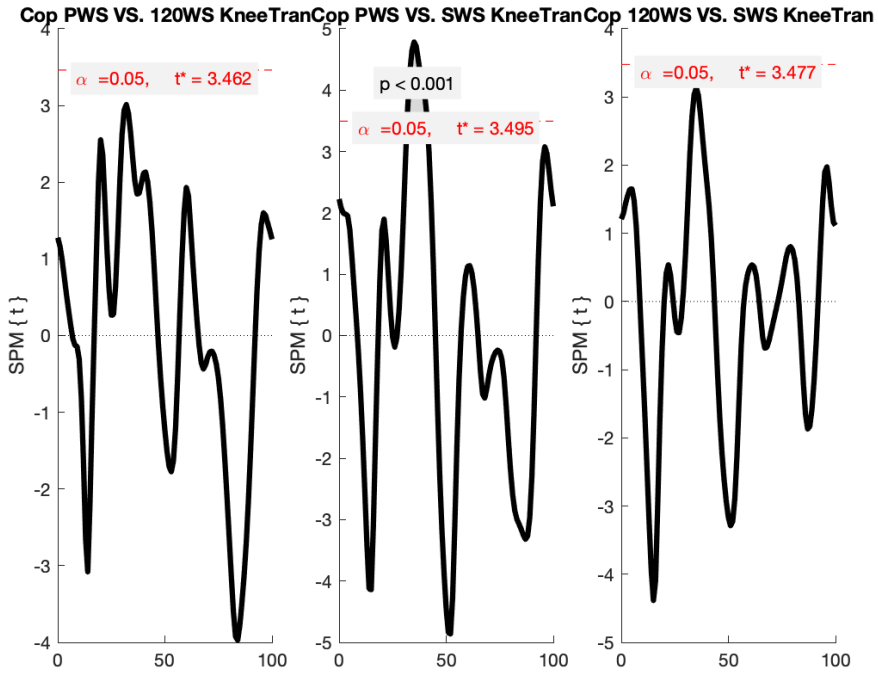


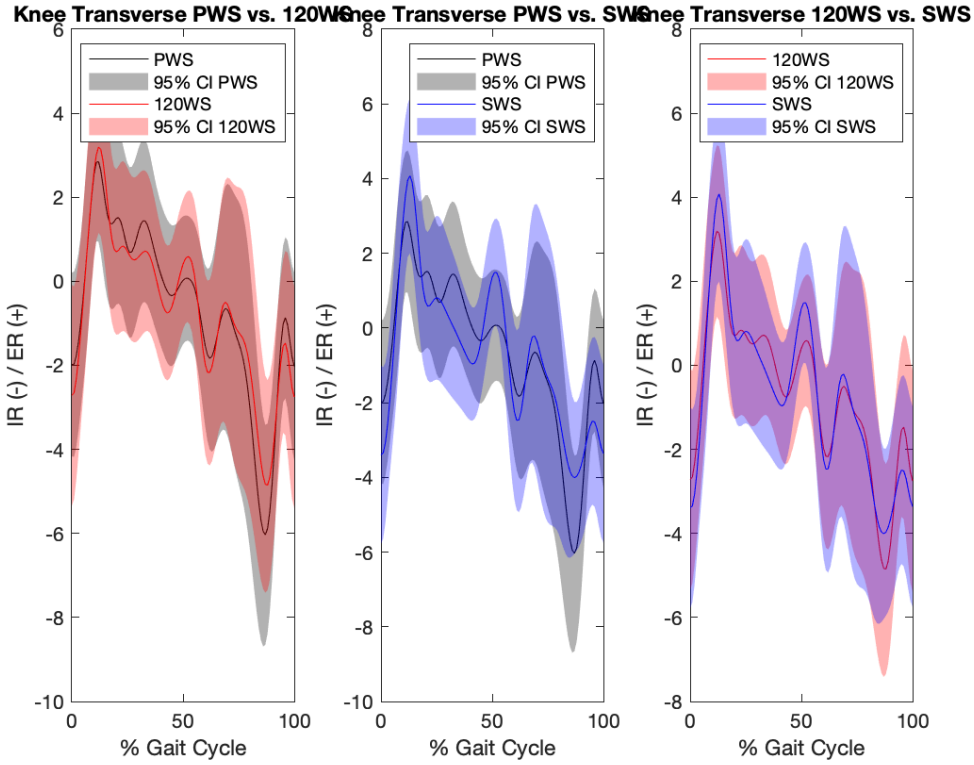
T-test Speed Differences
CAI Knee Frontal



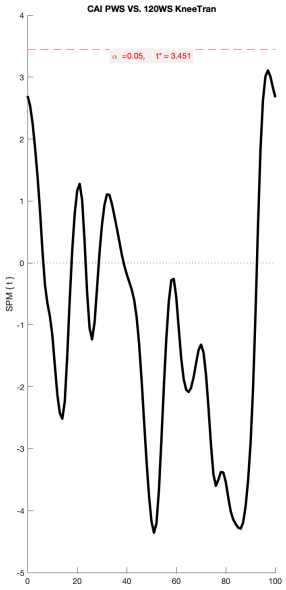


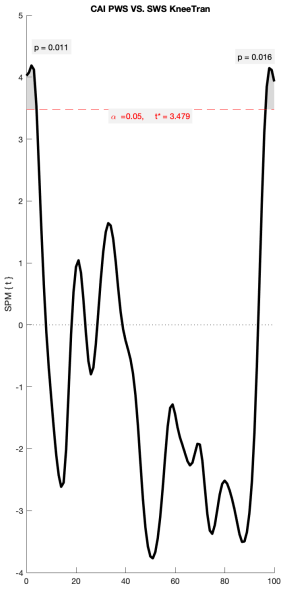
T-test Speed Differences
Coper Knee Transverse

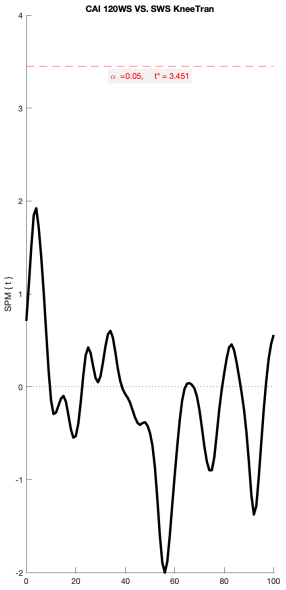


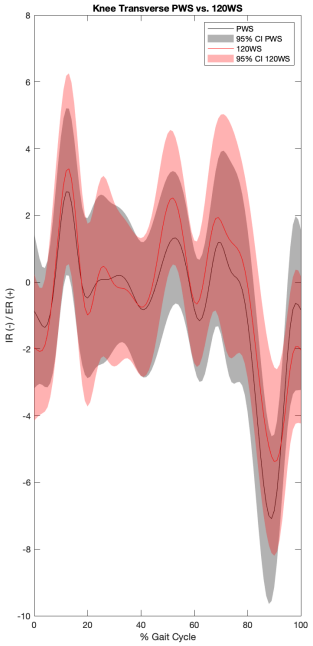


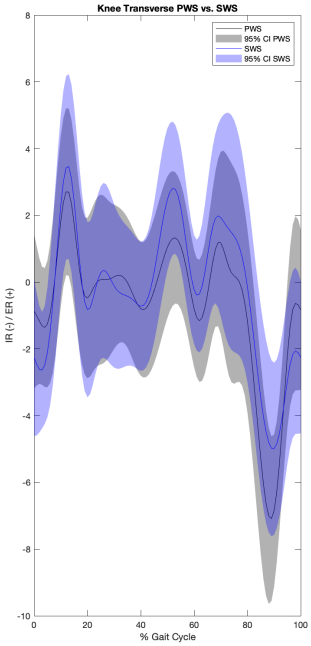
T-test Speed Differences
CAI Knee Transverse

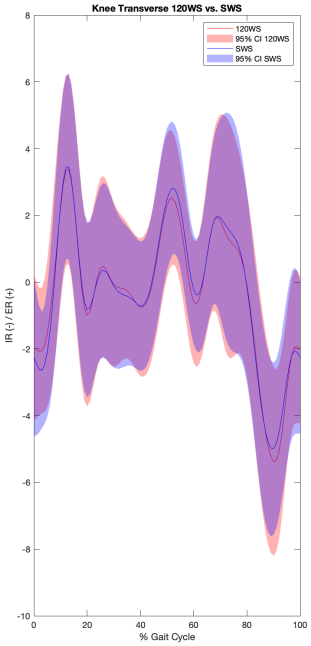




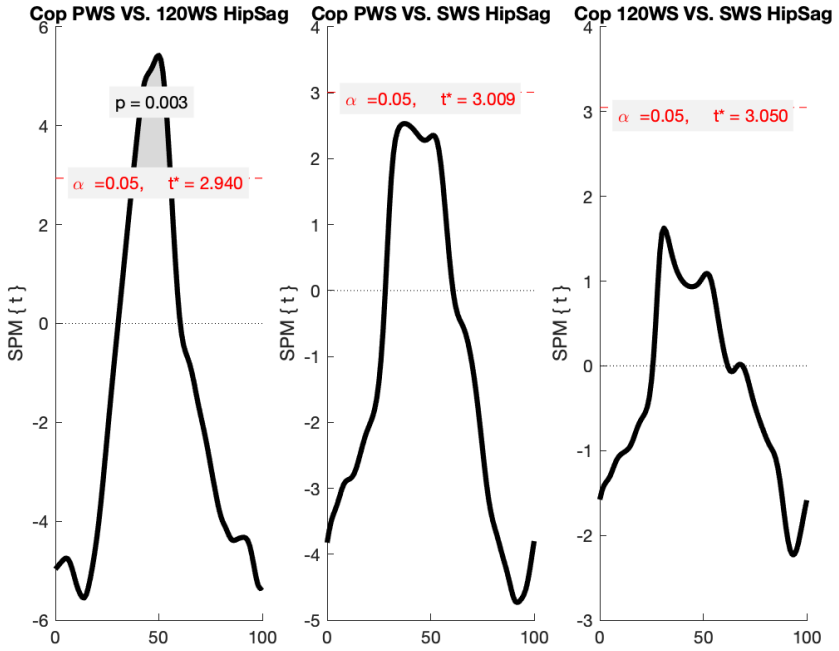


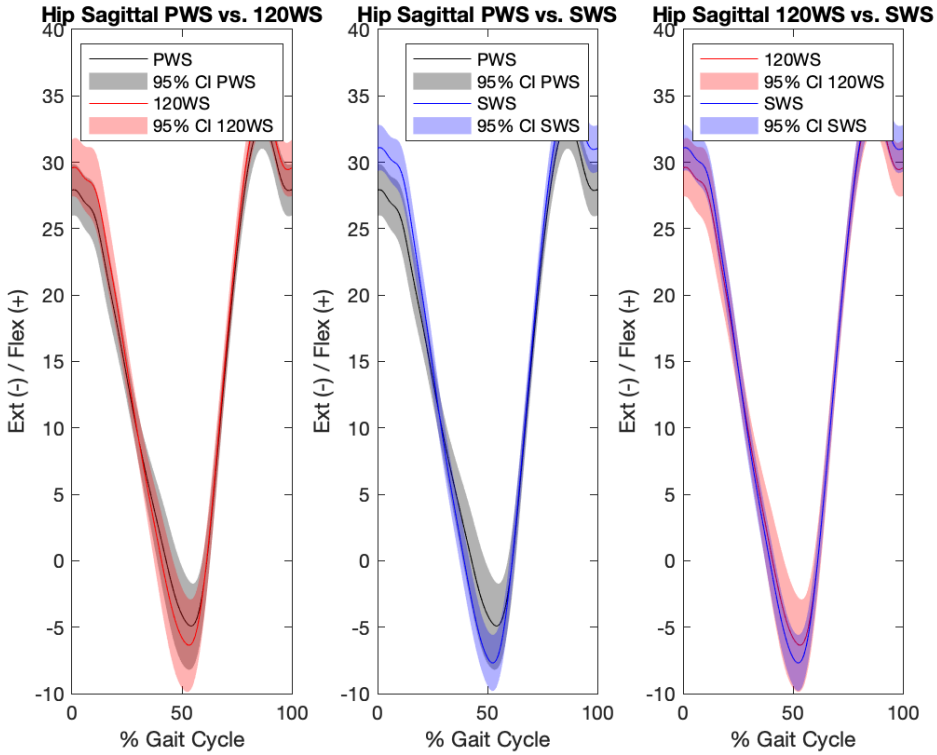




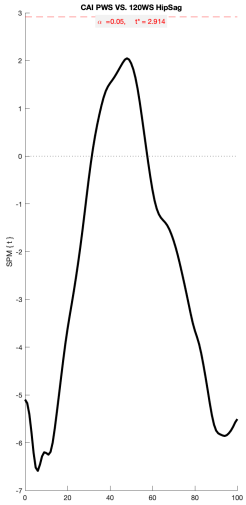


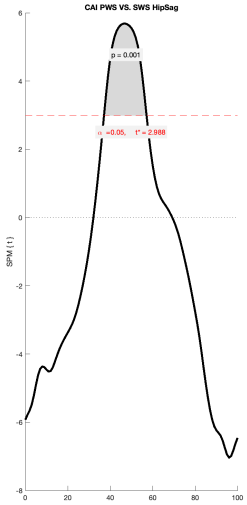
T-test Speed Differences
Coper Hip Sagittal

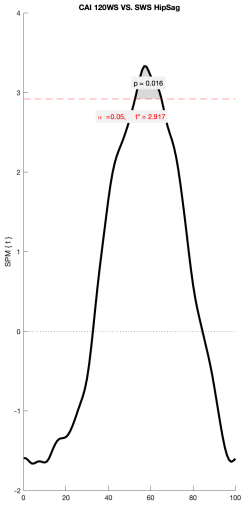


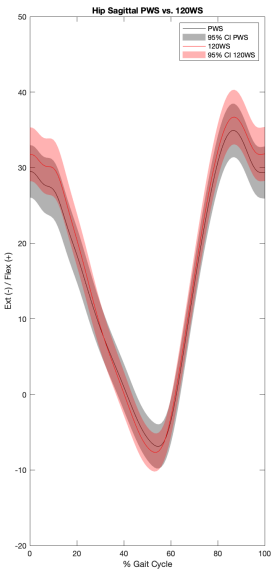


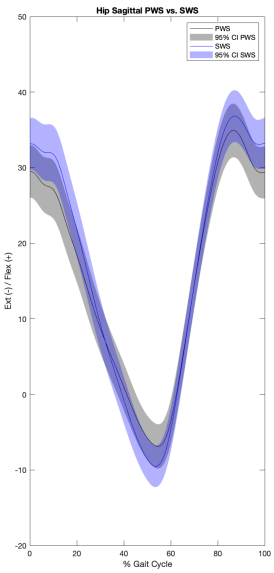
T-test Speed Differences
CAI Hip Sagittal

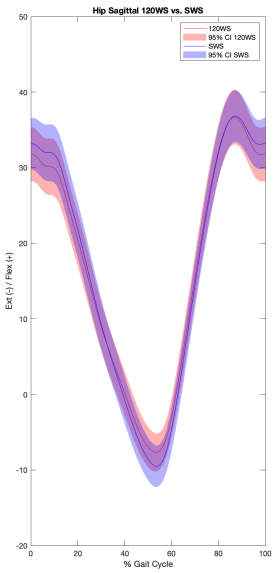




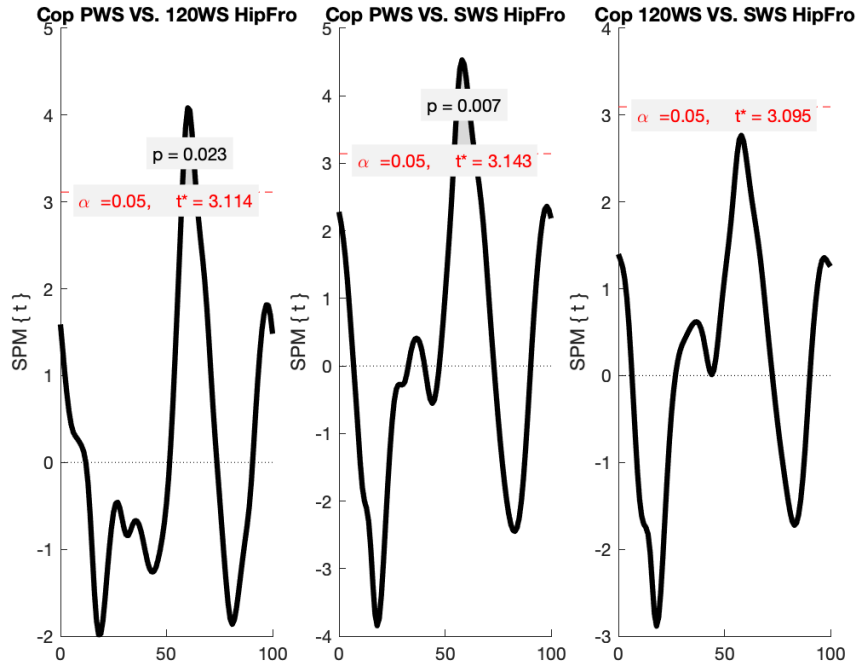


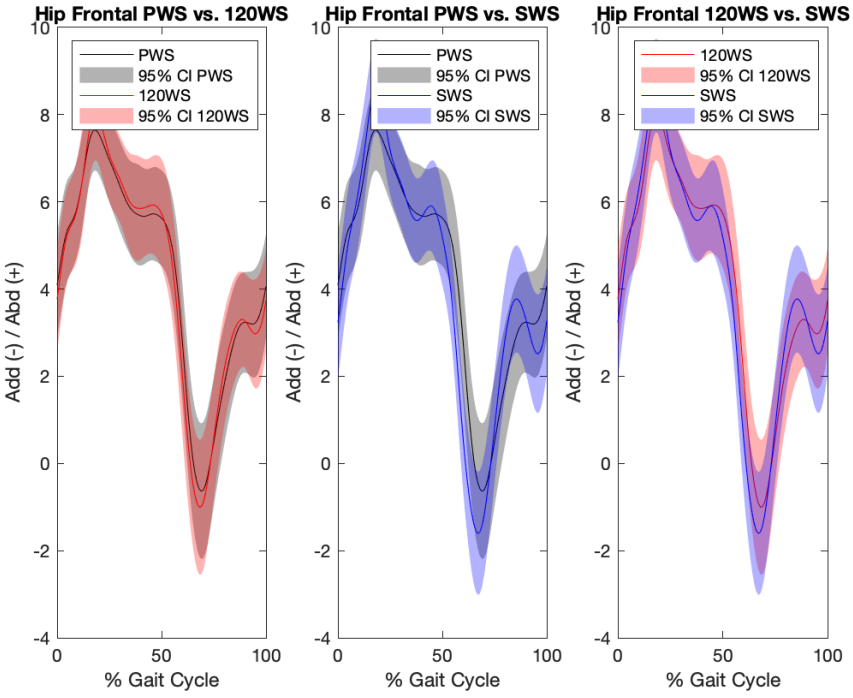




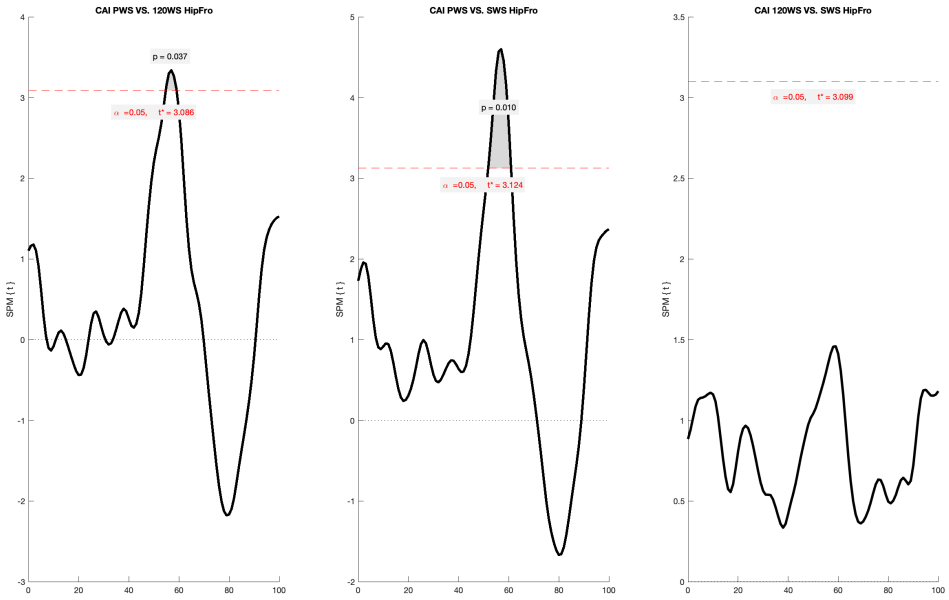


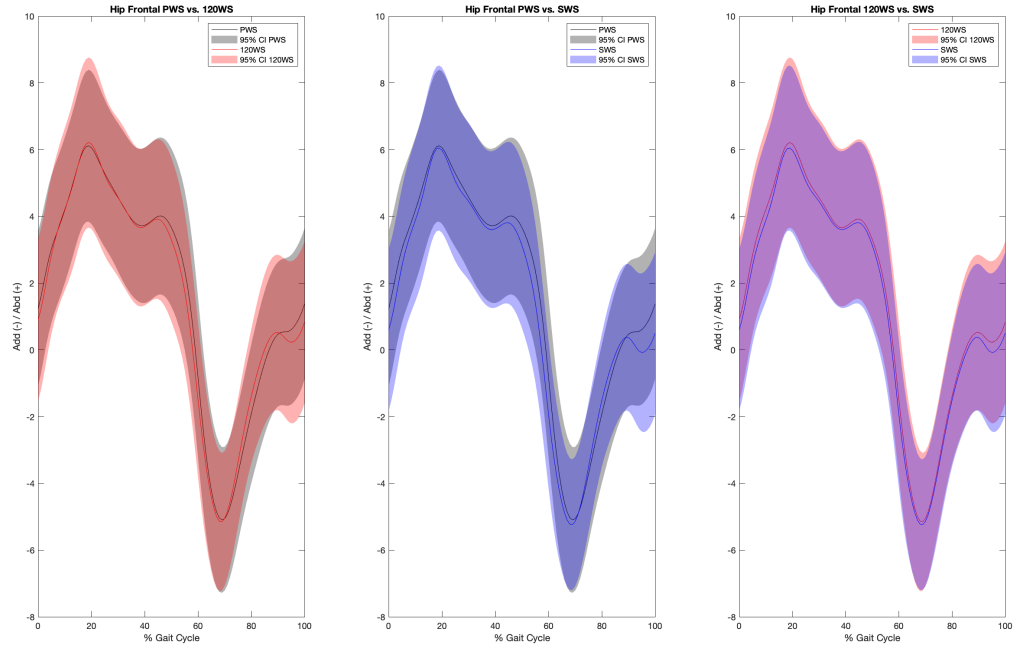
T-test Speed Differences
Coper Hip Frontal



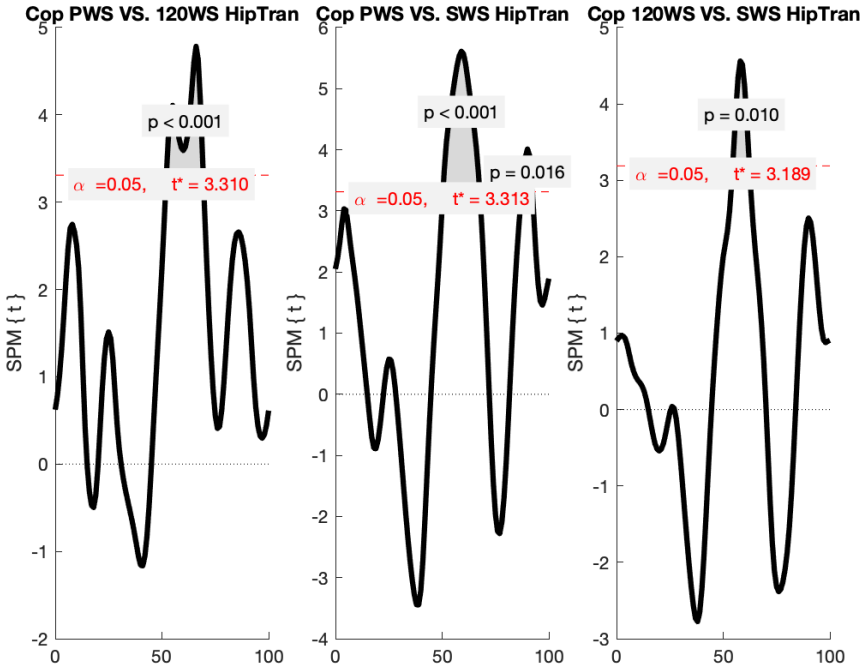


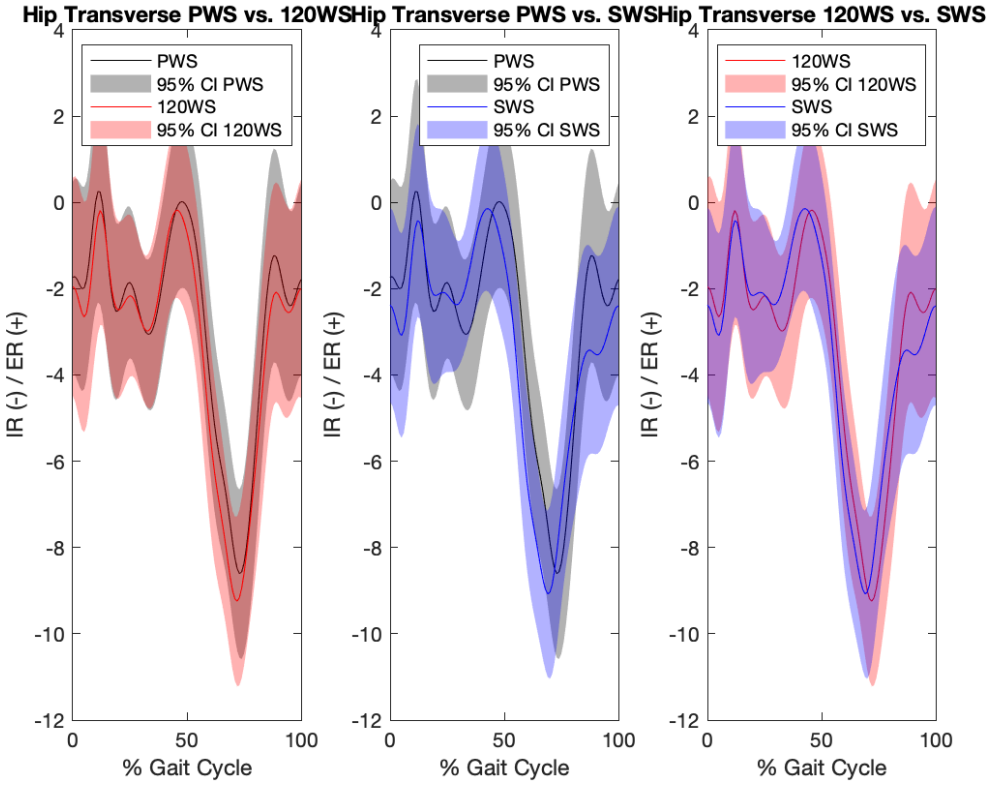
T-test Speed Differences
CAI Hip Frontal



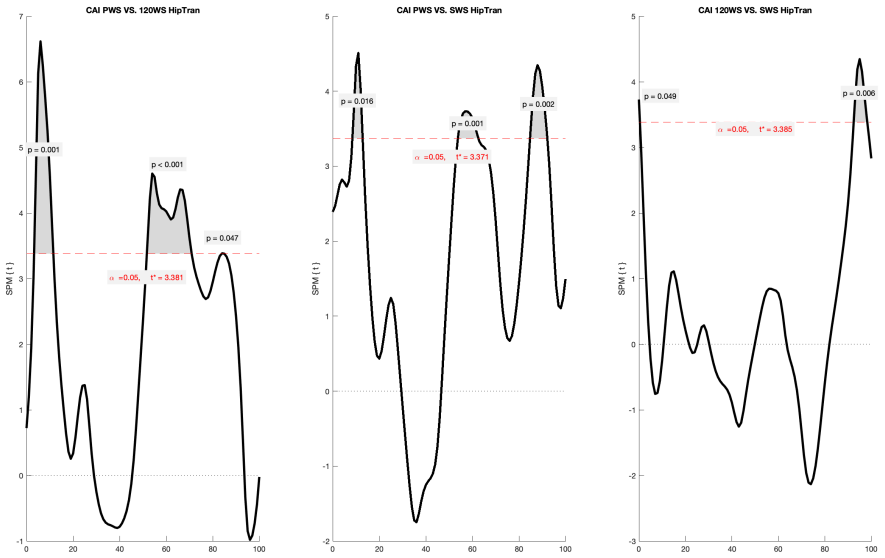


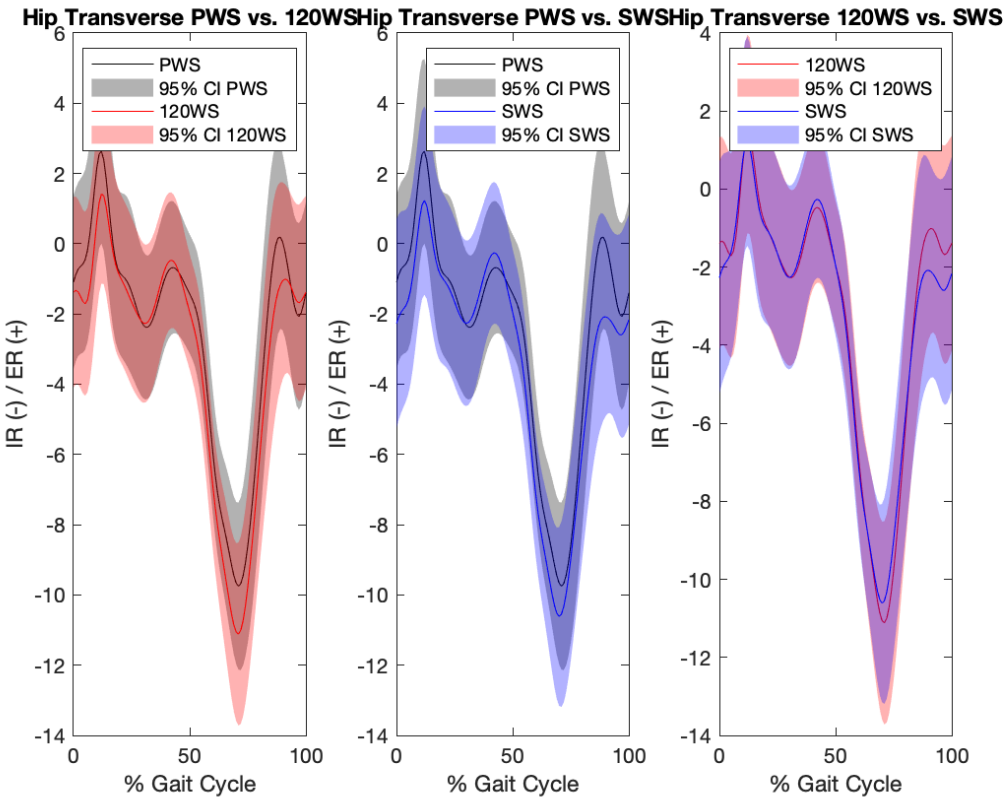
T-test Speed Differences
Coper Hip Transverse





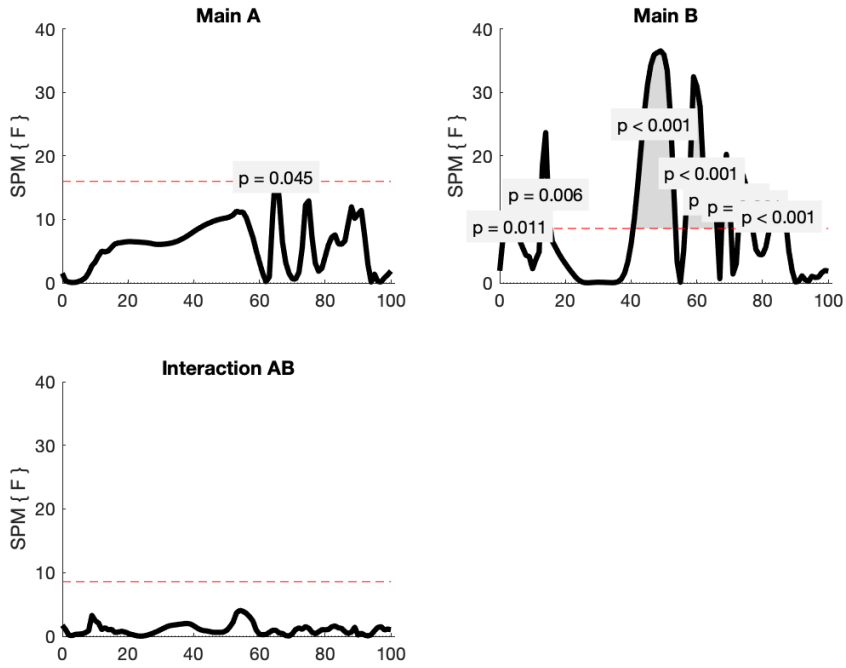
T-test Speed Differences
CAI Hip Transverse



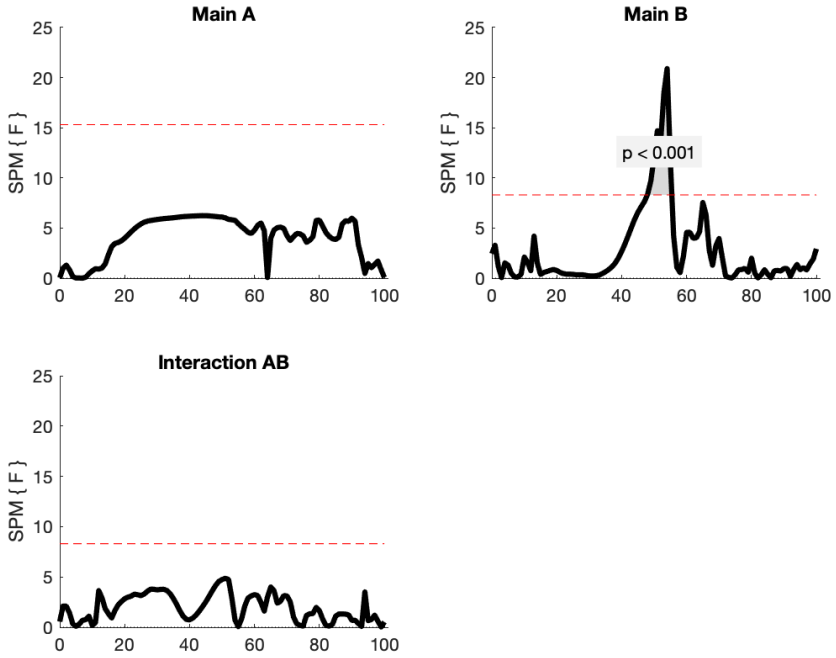


M1: Results

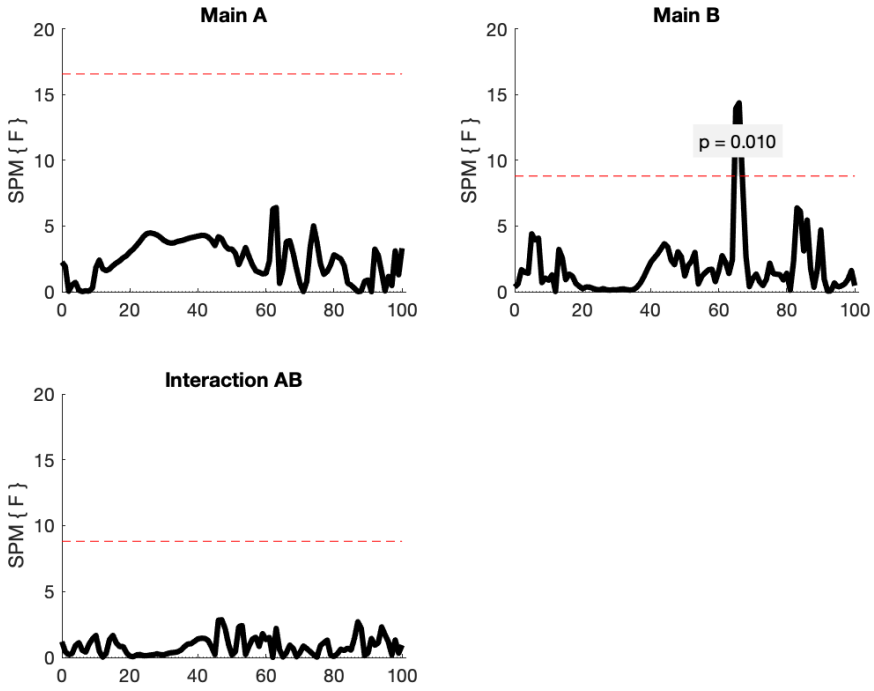
ANOVA – Ankle Sagittal



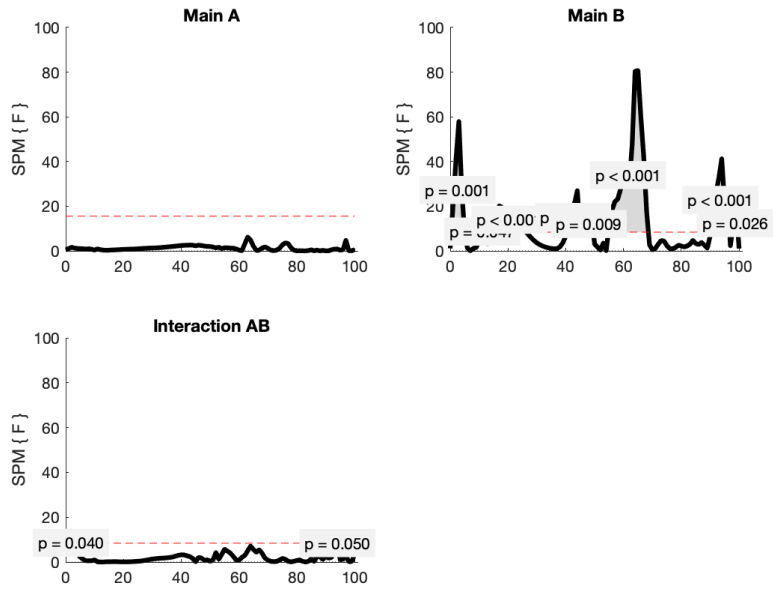
ANOVA - Ankle Frontal



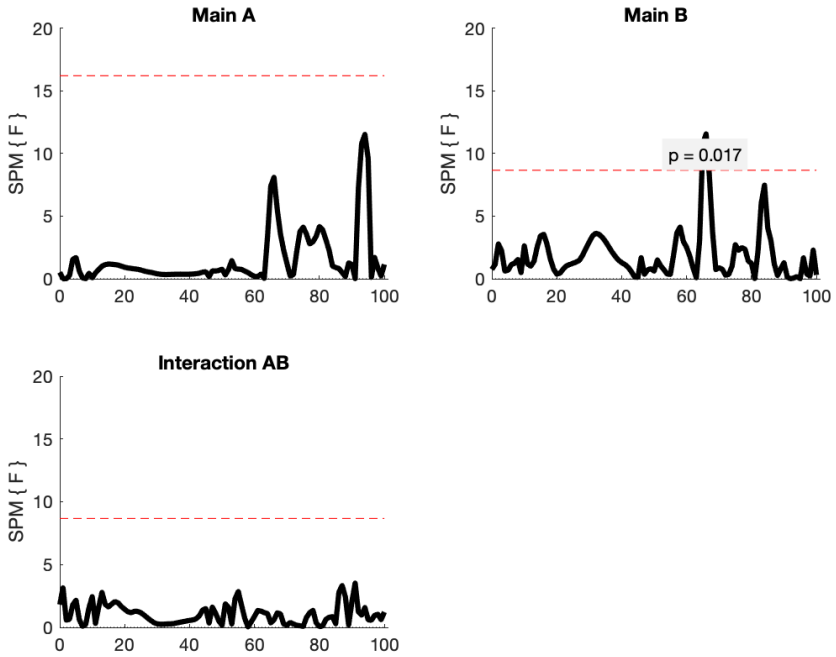
ANOVA - Ankle Transverse



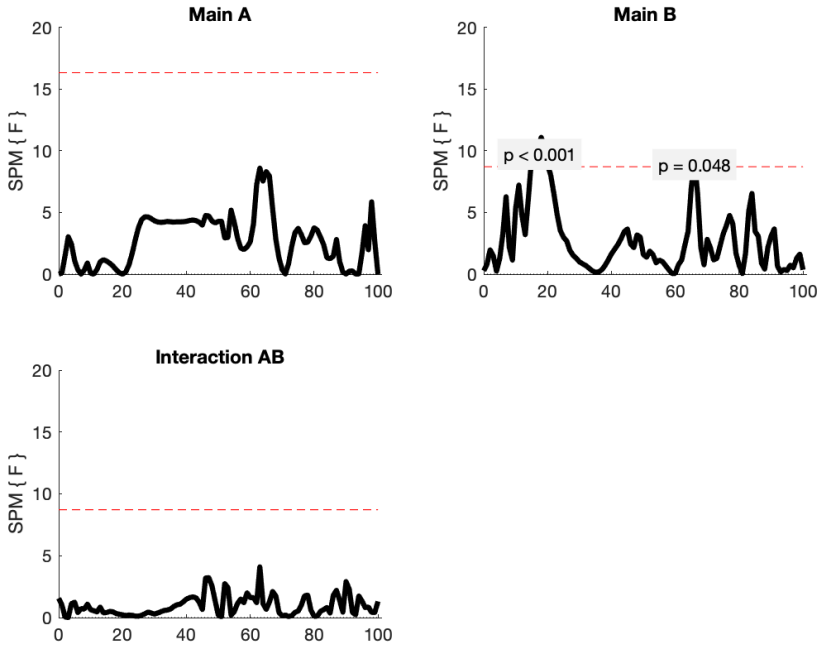
ANOVA – Knee Sagittal



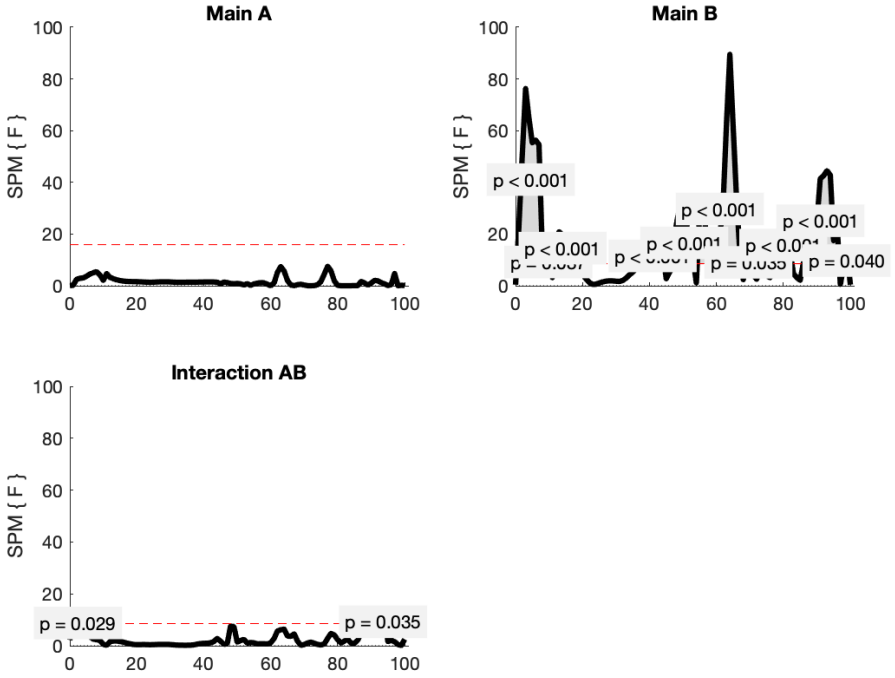
ANOVA Knee Frontal



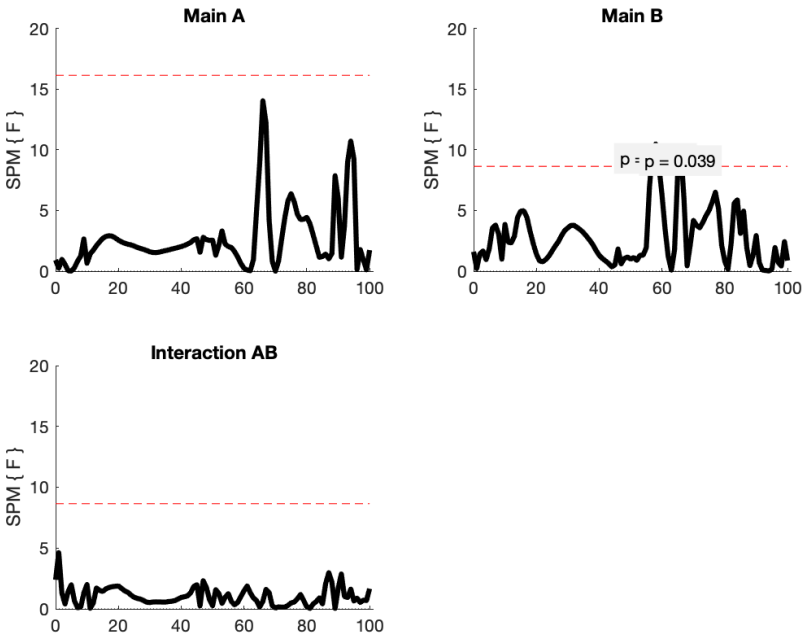
ANOVA Knee Transverse



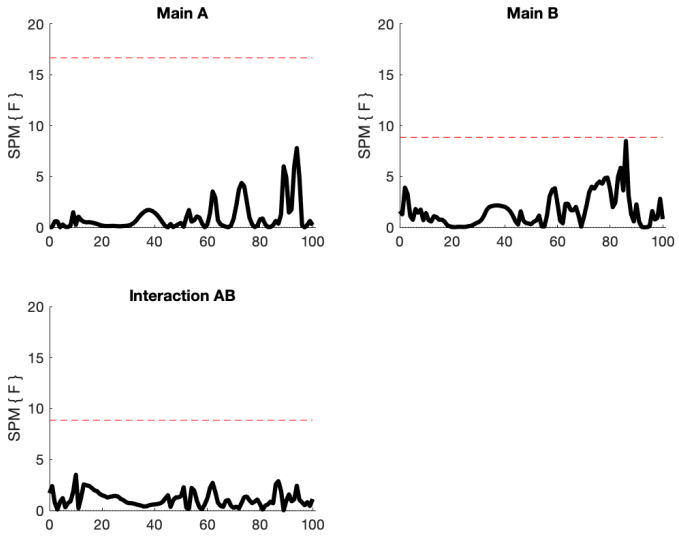
ANOVA - Hip Sagittal



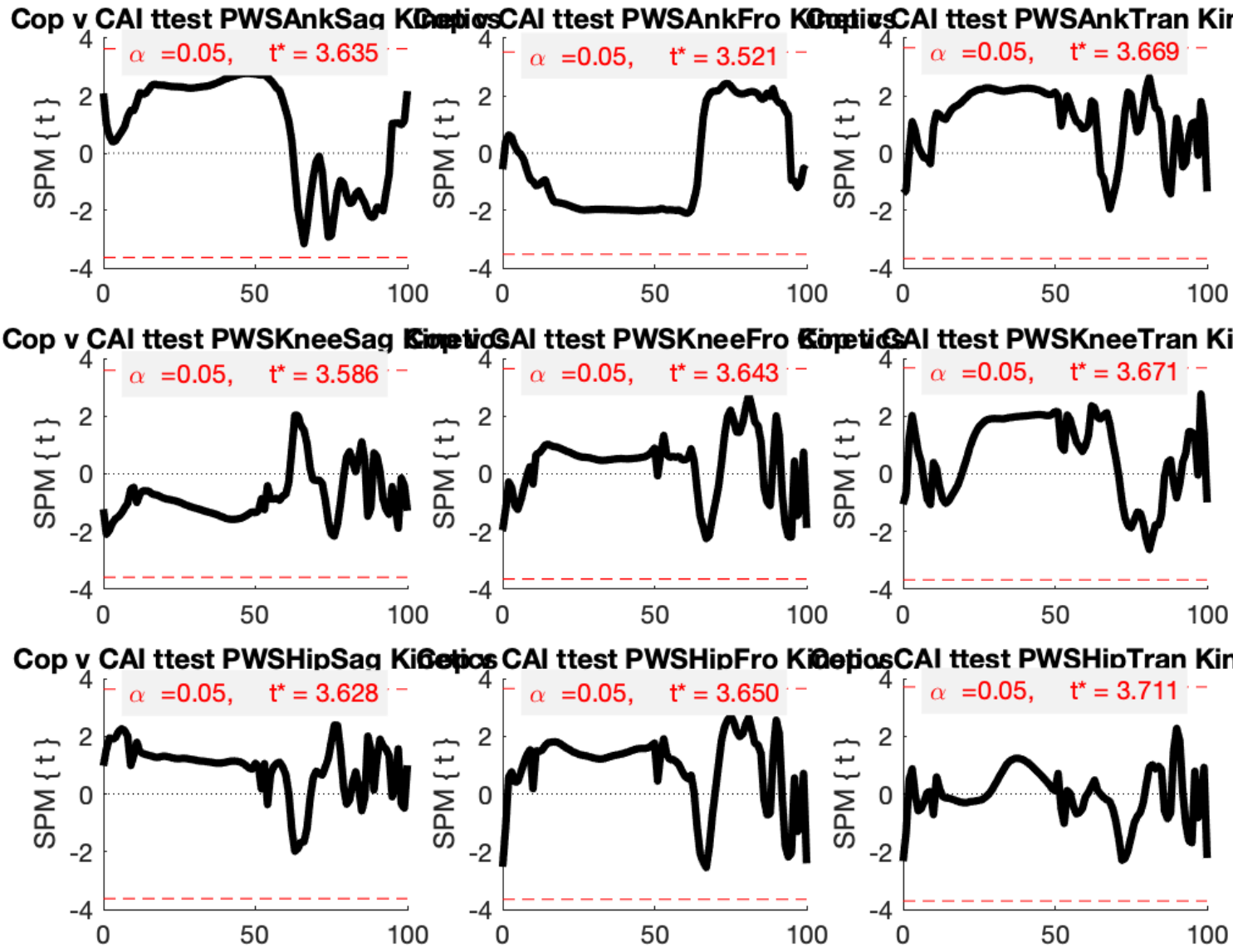
ANOVA – Hip Frontal



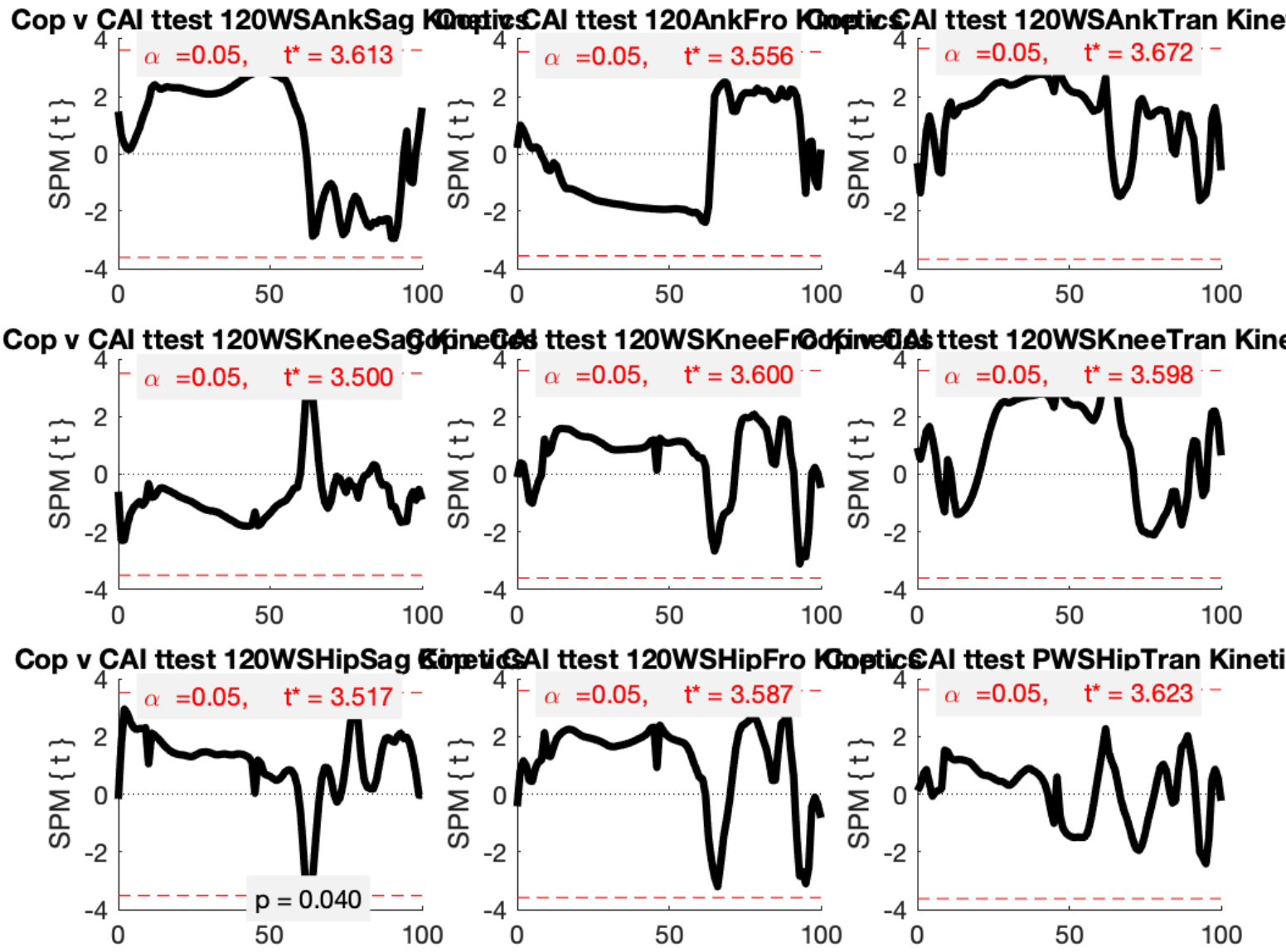
ANOVA – Hip Transverse



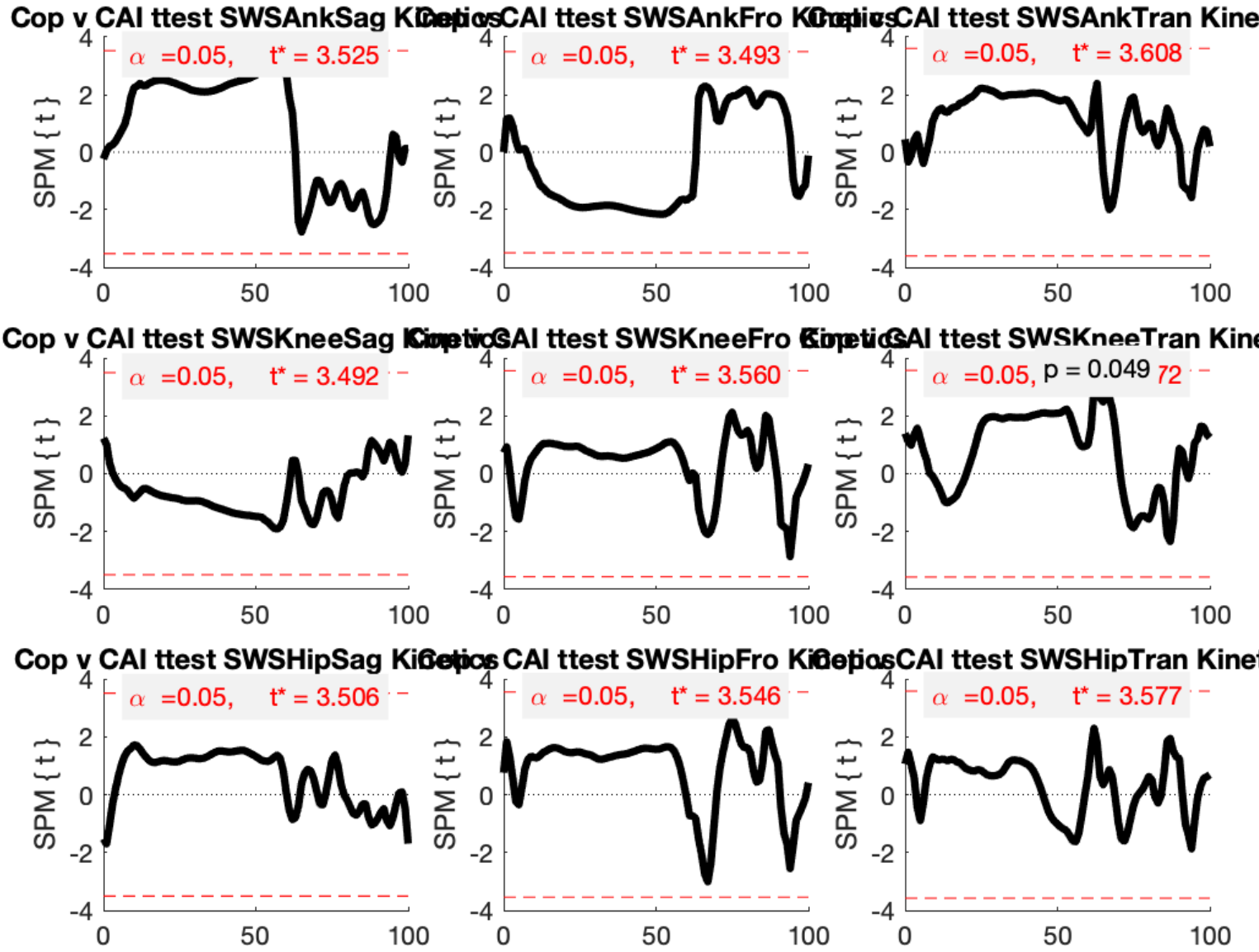
T-test Group Differences at PWS



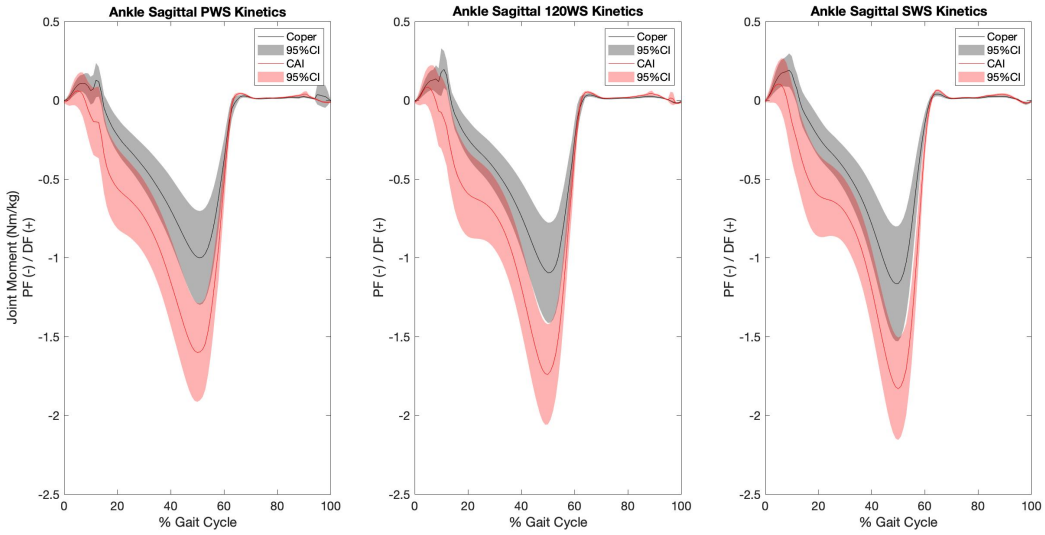
T-test Group Differences at 120WS



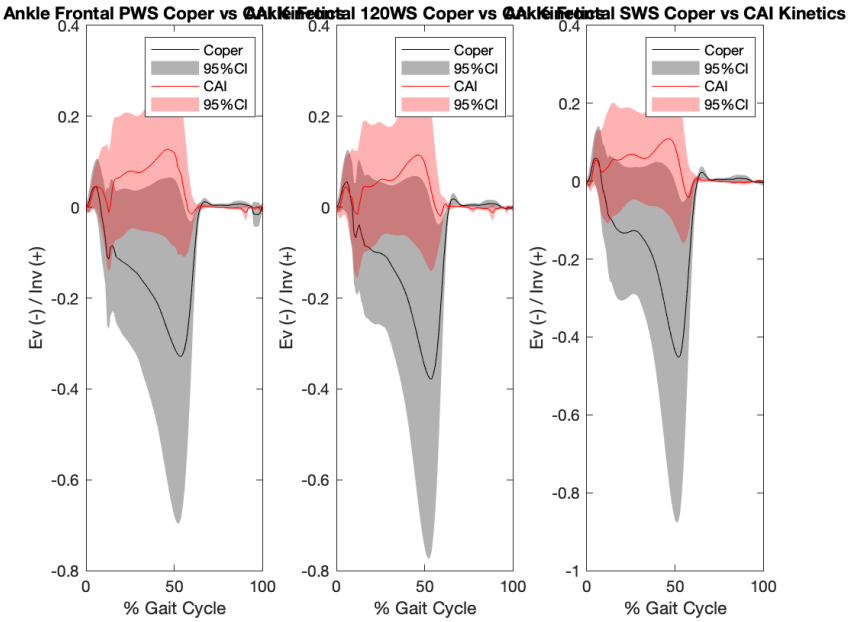
T-test Group Differences at SWS



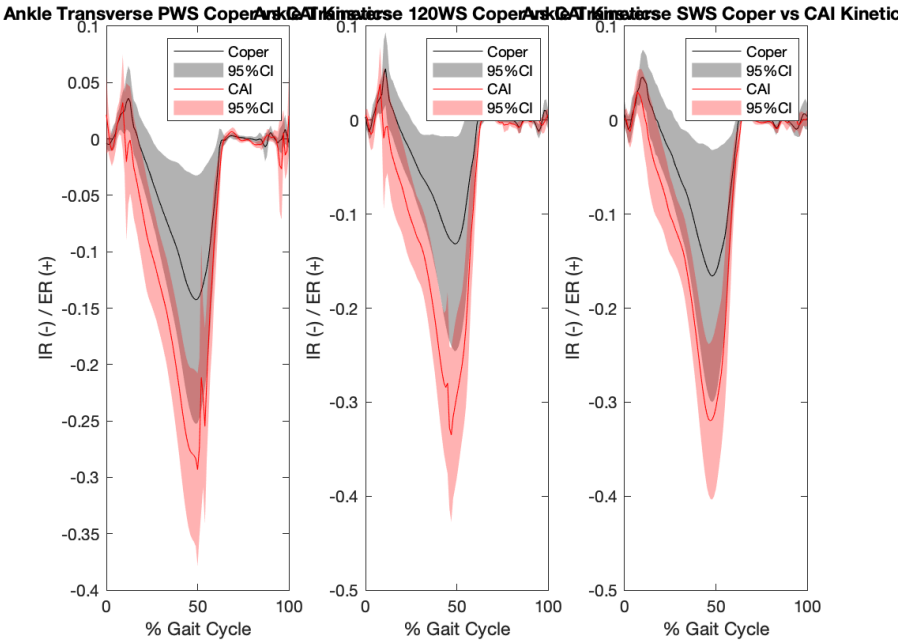
T-test Group Differences
Ankle Sagittal



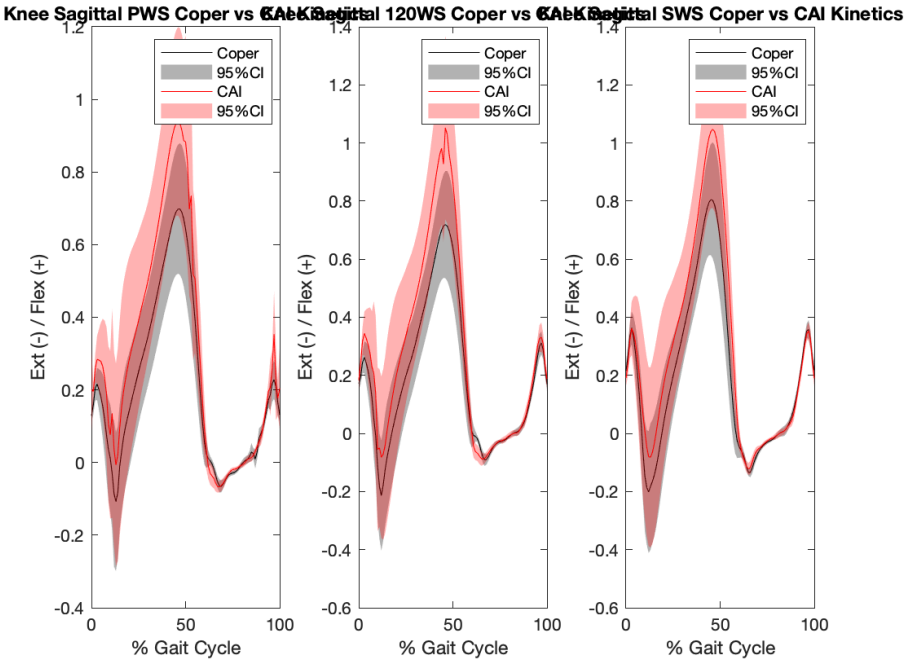
T-test Group Differences
Ankle Frontal



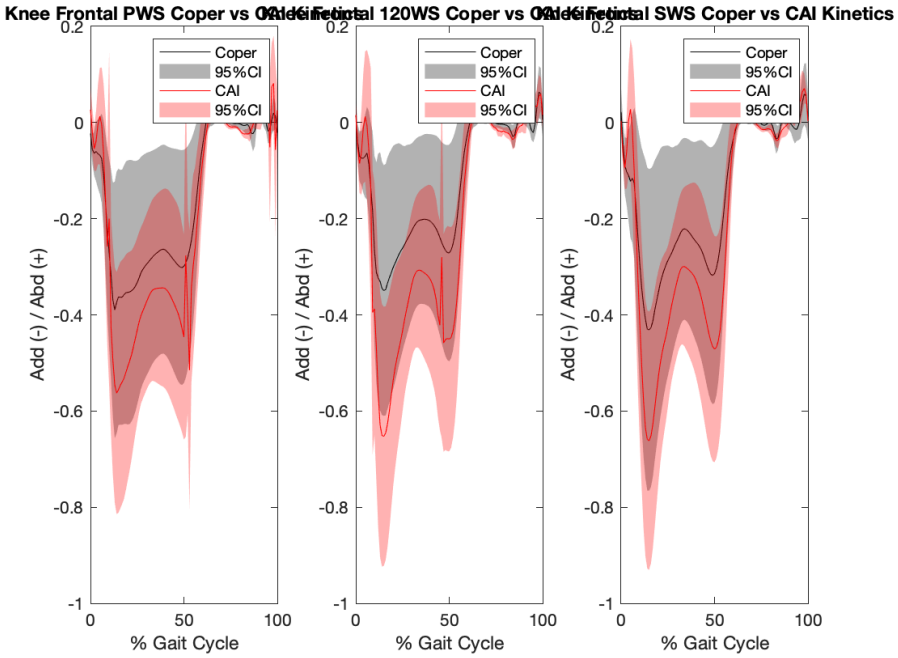
T-test Group Differences
Ankle Transverse



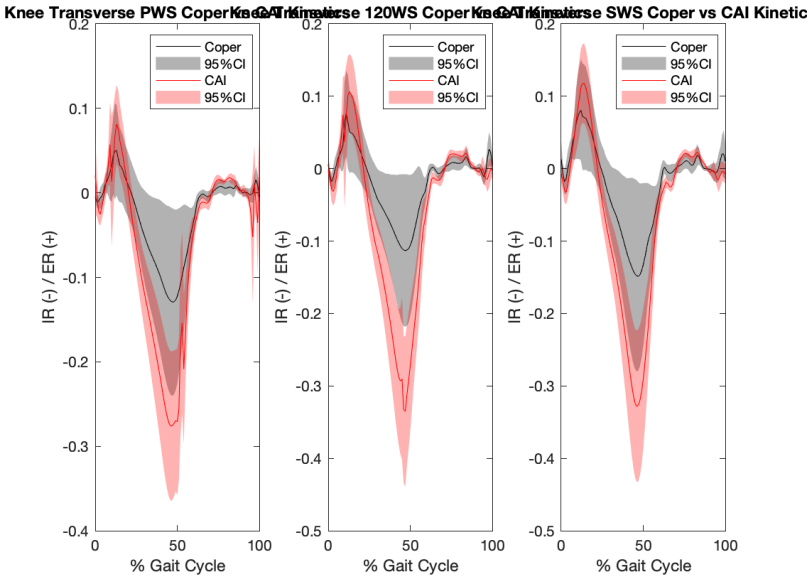
T-test Group Differences
Knee Sagittal



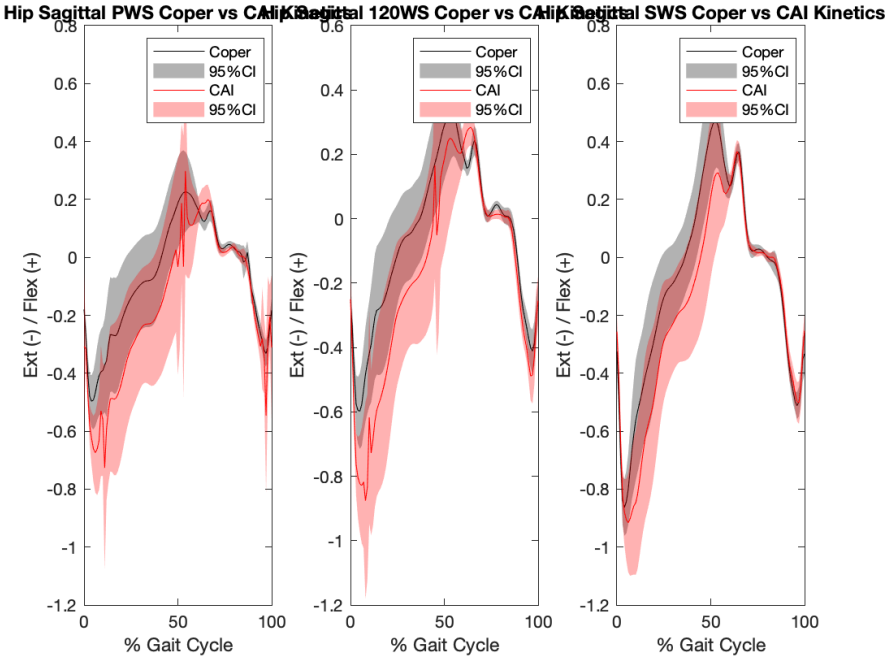
T-test Group Differences
Knee Frontal



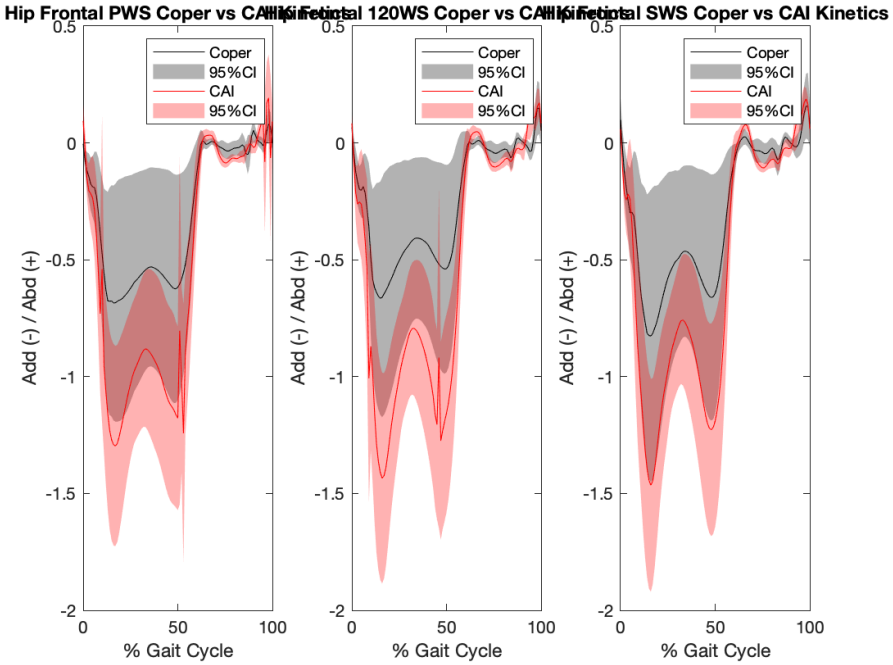
T-test Group Differences
Knee Transverse



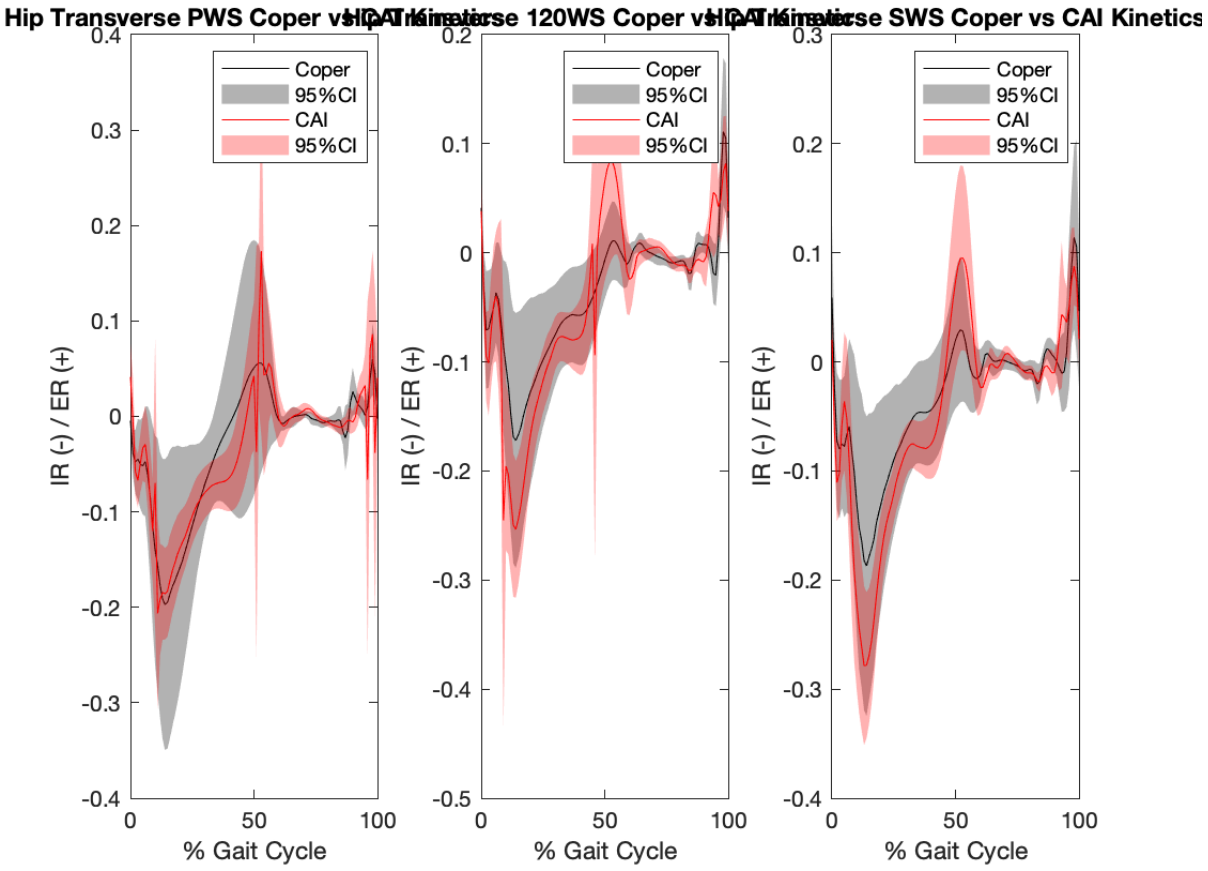
T-test Group Differences
Hip Sagittal



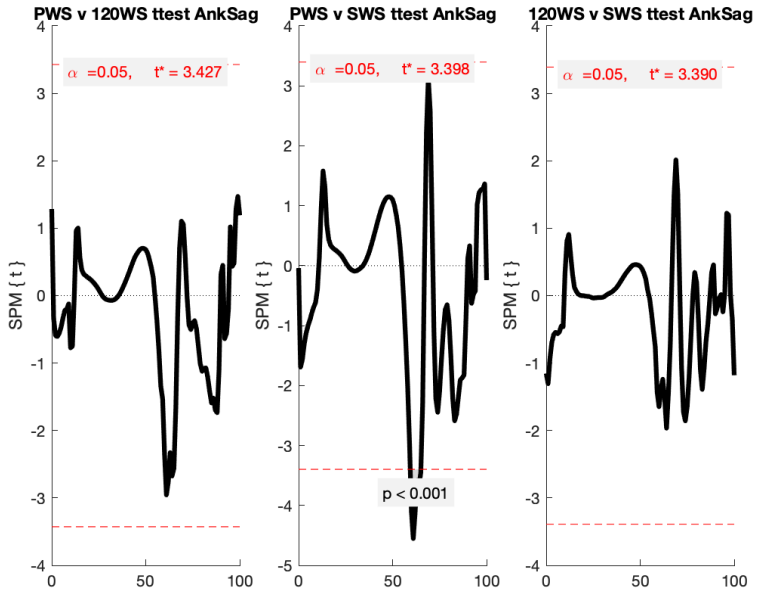
T-test Group Differences
Hip Frontal

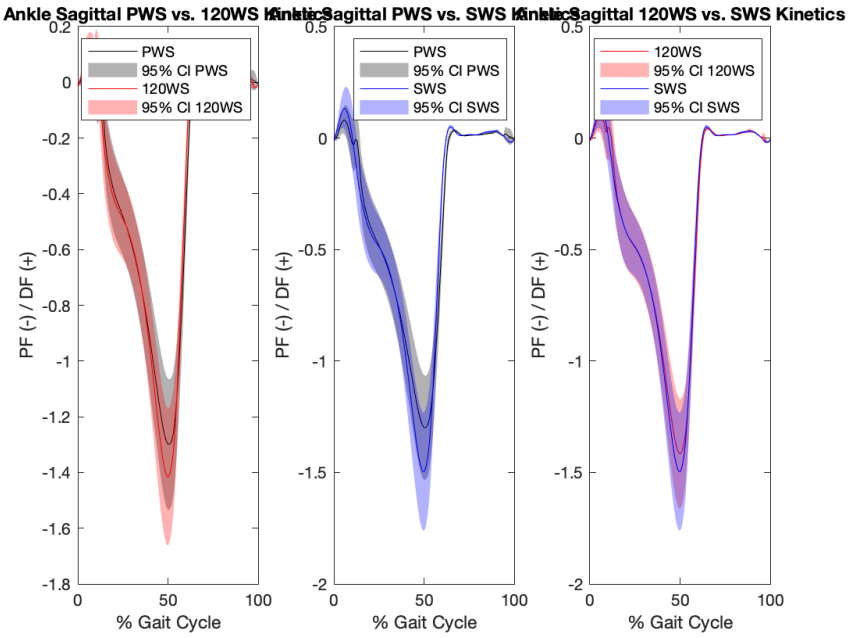


T-test Group Differences
Hip Transverse

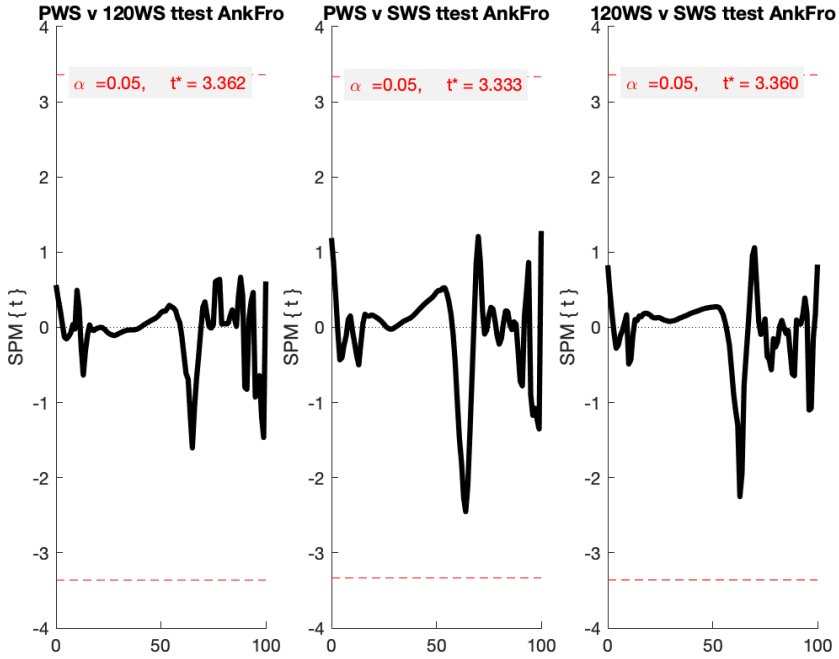


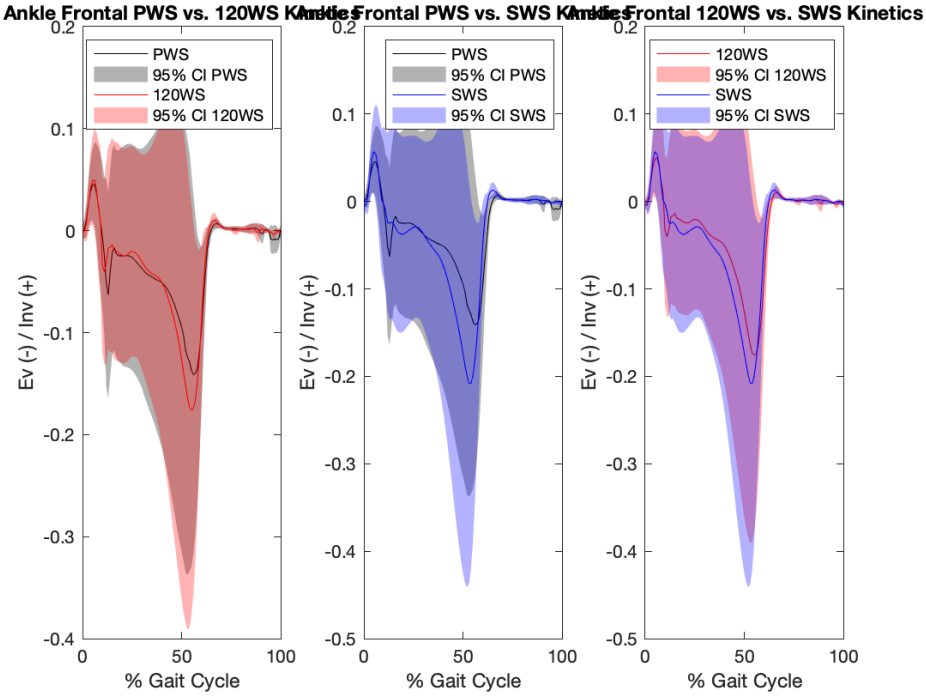
T-test Speed Differences
Ankle Sagittal



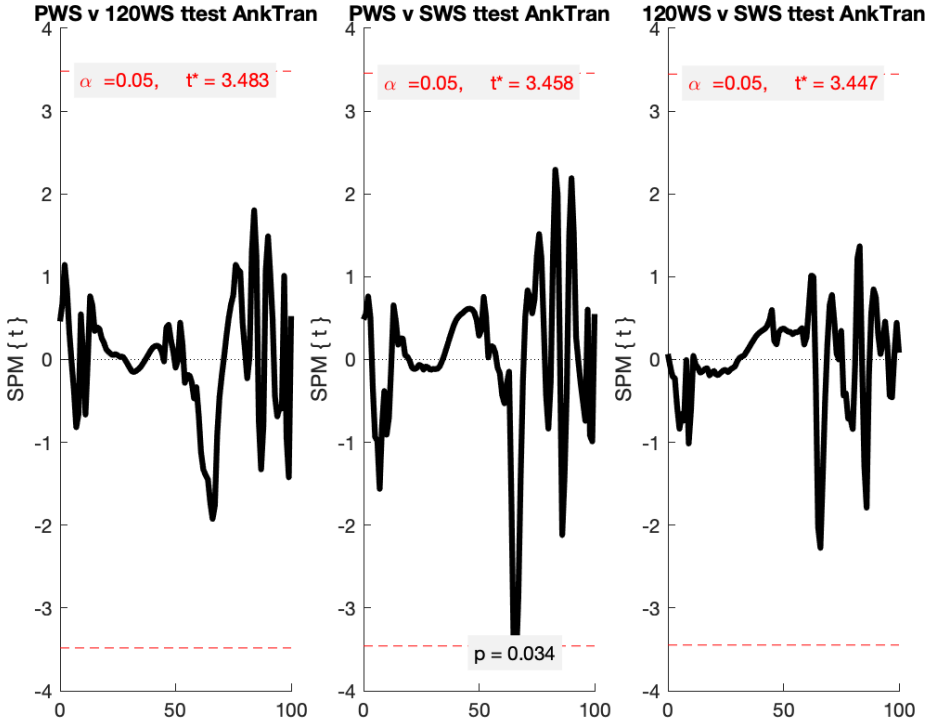


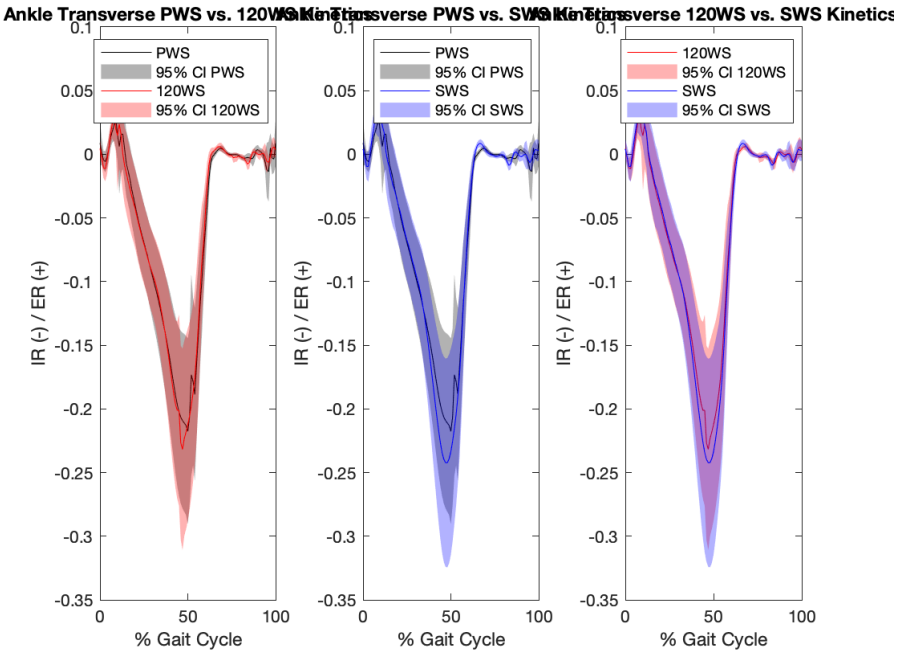
T-test Speed Differences
Ankle Frontal



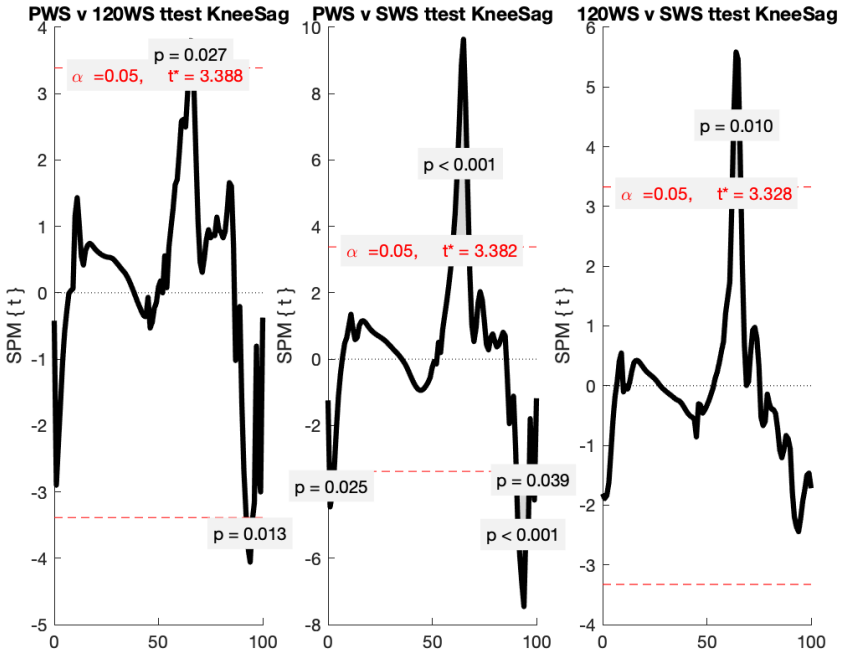


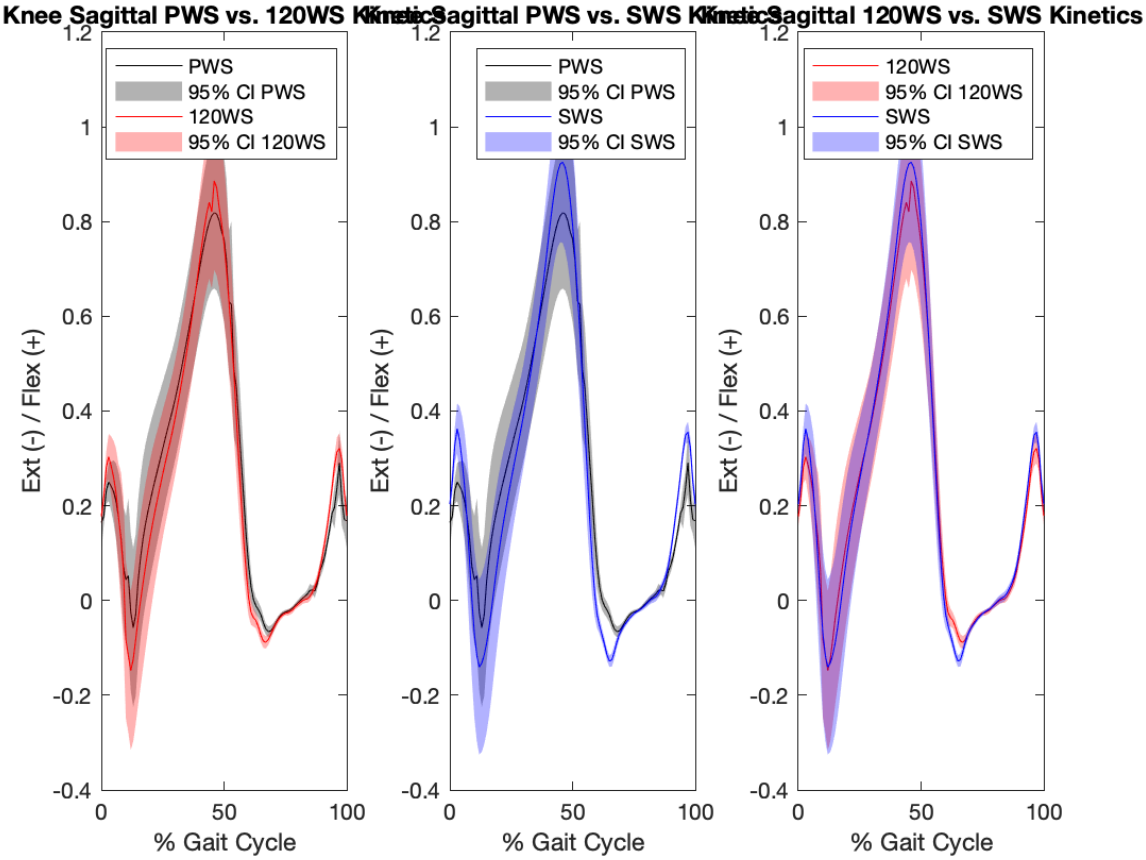
T-test Speed Differences
Ankle Transverse



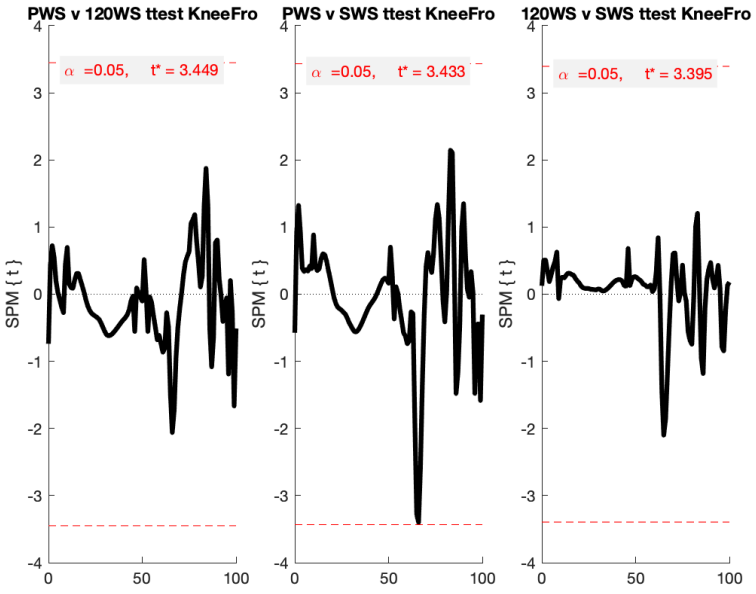


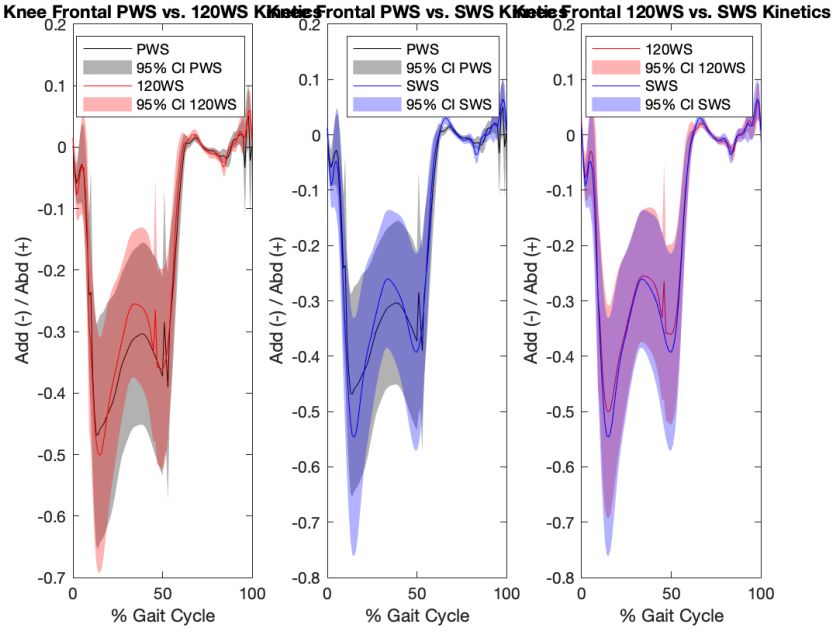
T-test Speed Differences
Knee Sagittal



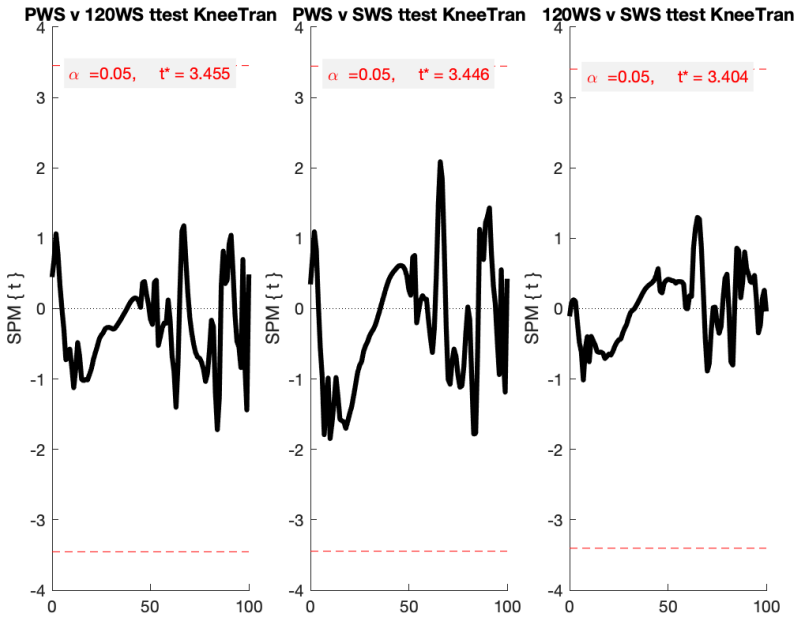


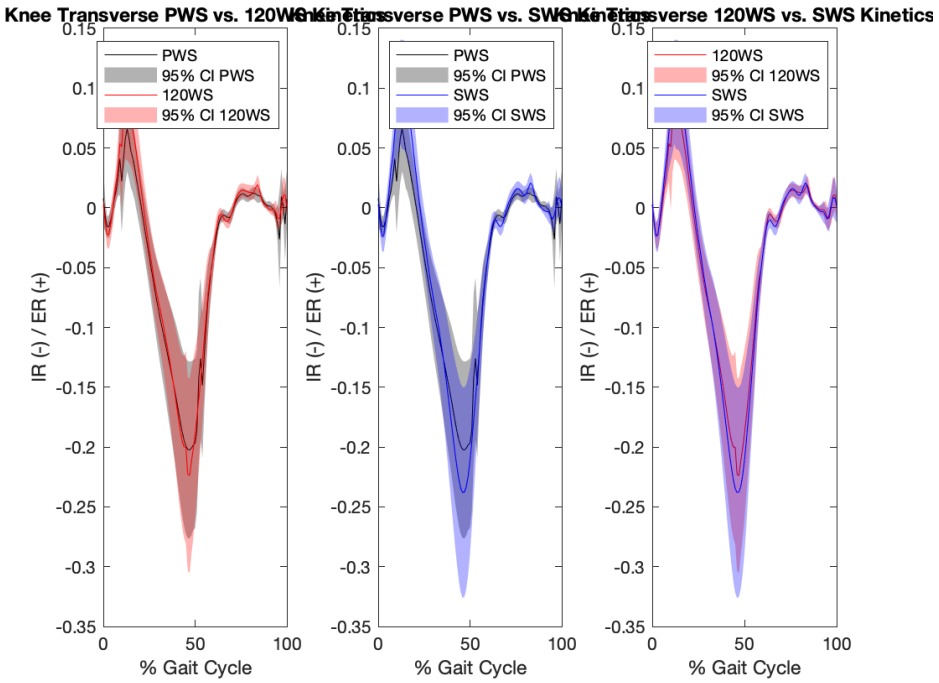
T-test Speed Differences
Knee Frontal



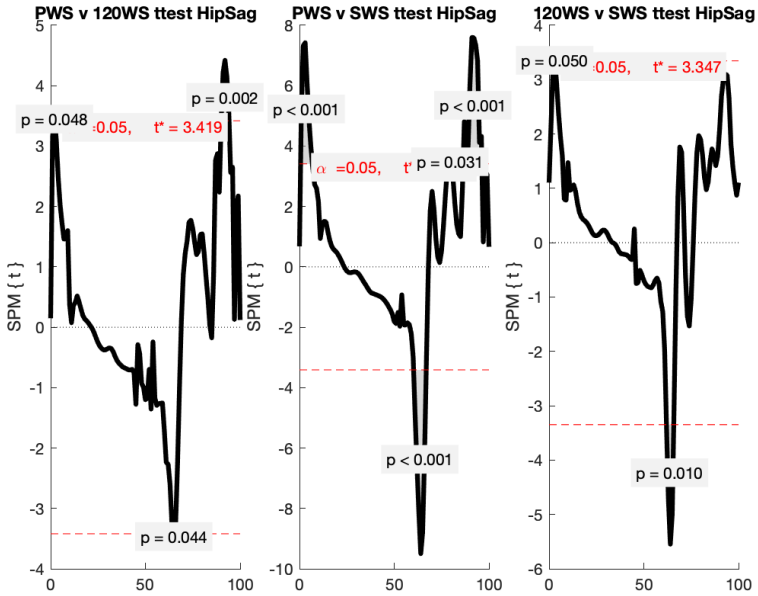


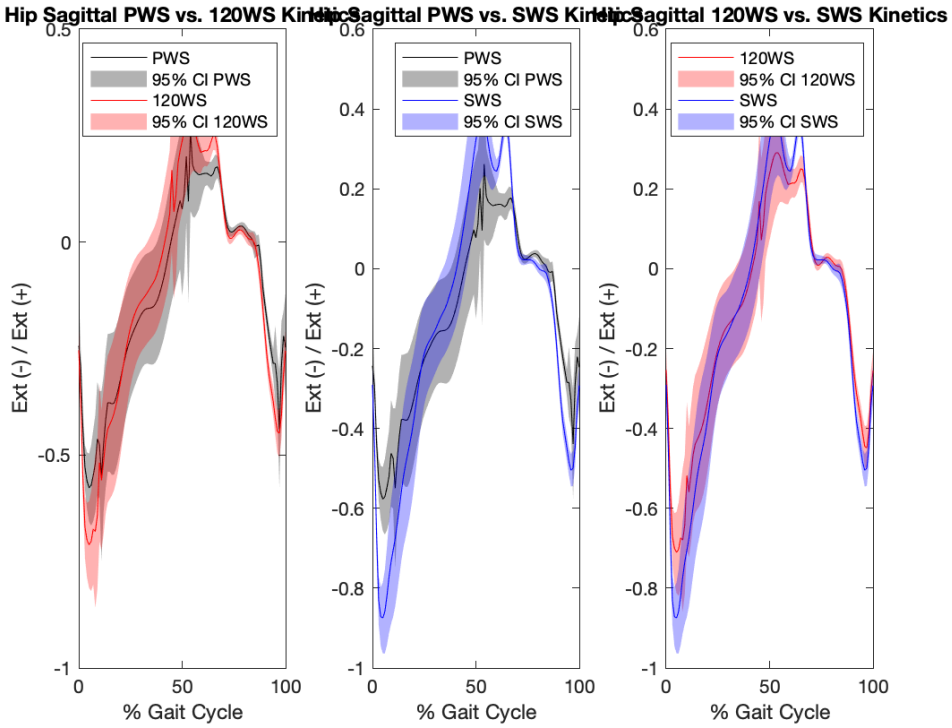
T-test Speed Differences
Knee Transverse



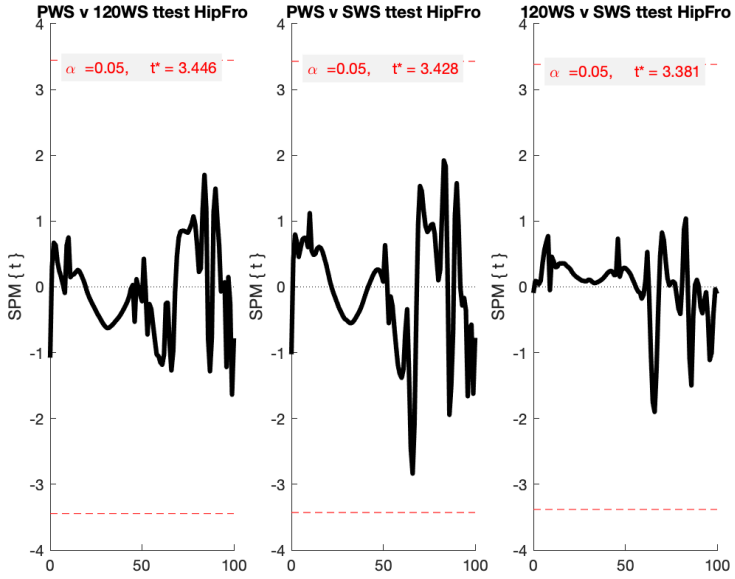


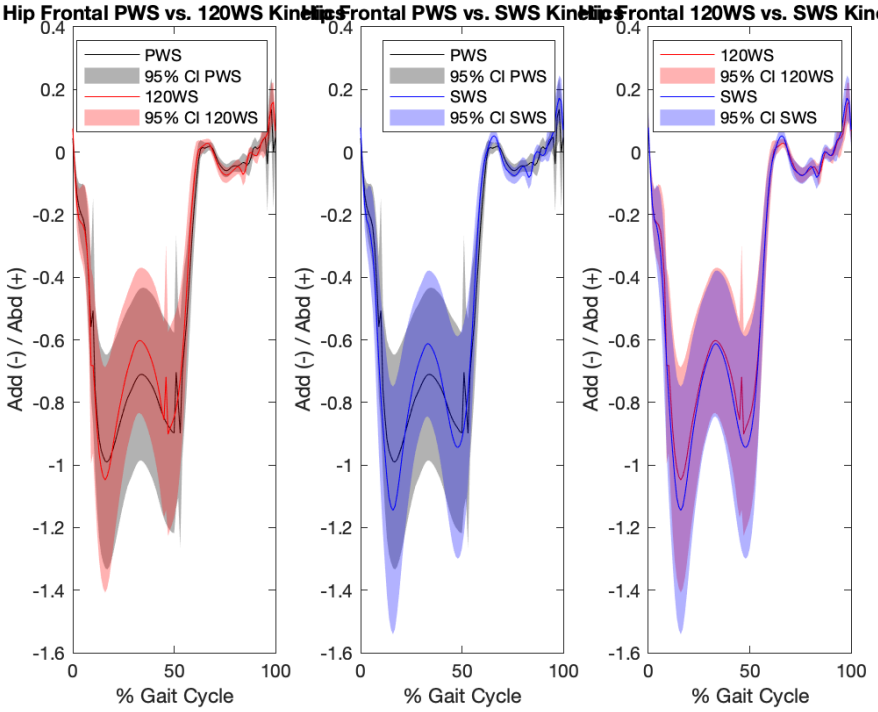
T-test Speed Differences
Hip Sagittal



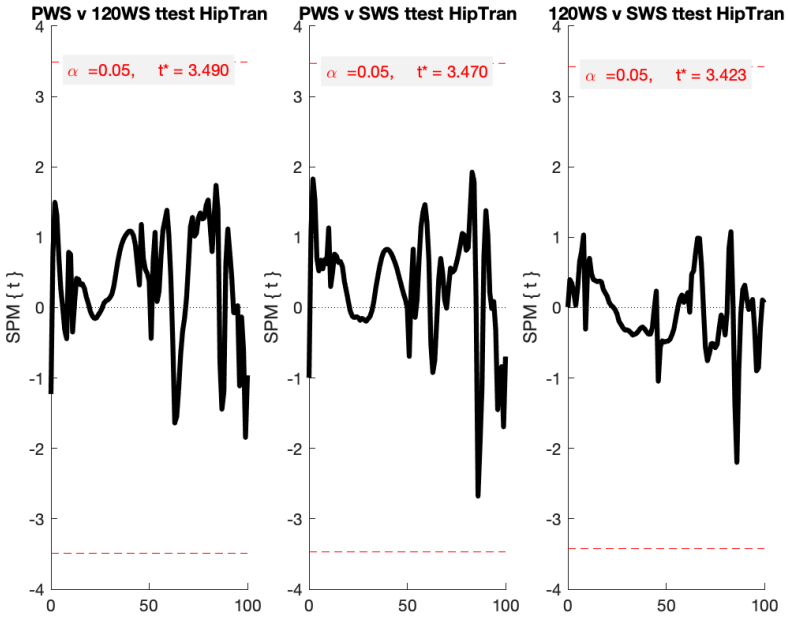


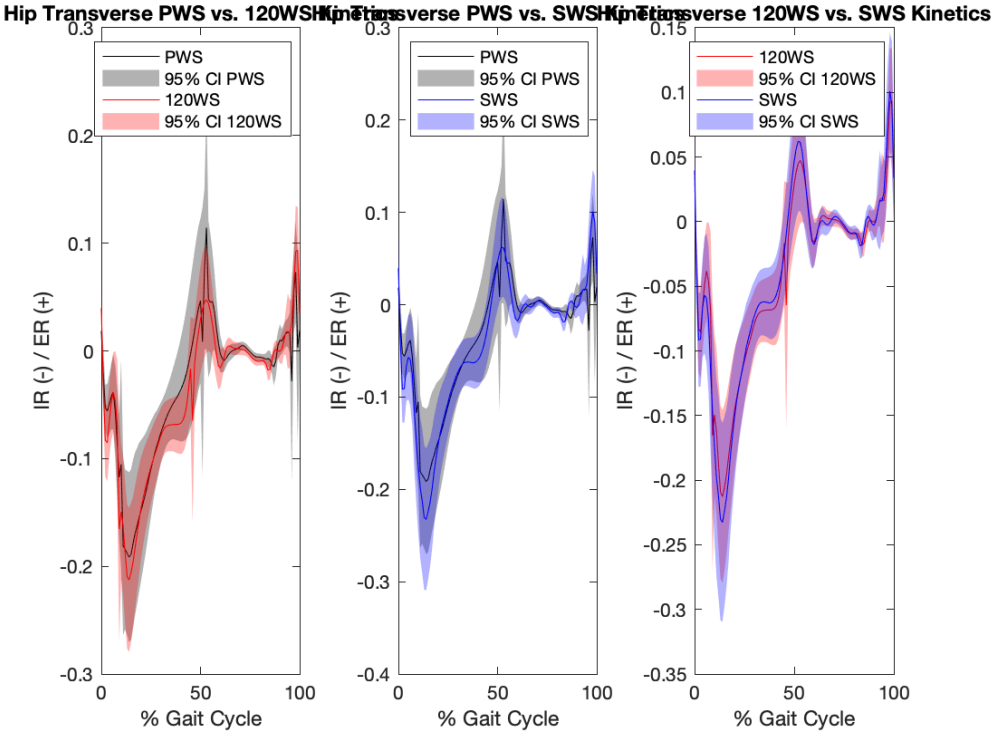
T-test Speed Differences
Hip Frontal



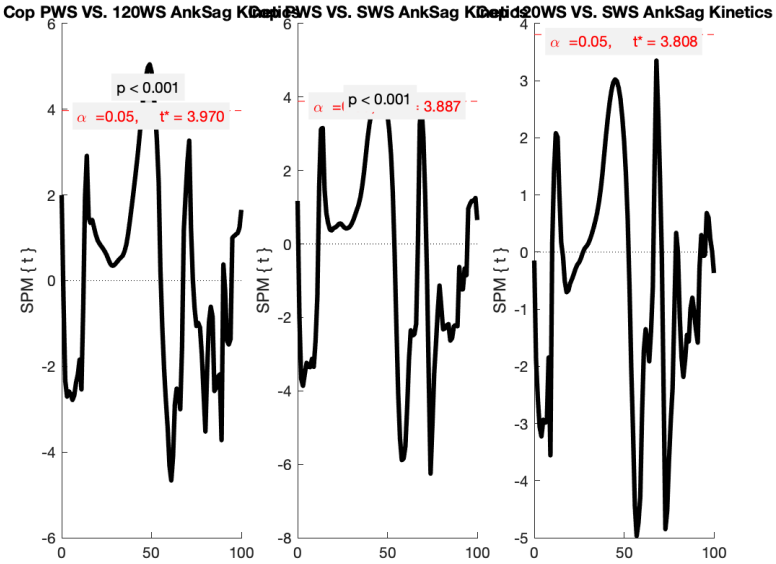


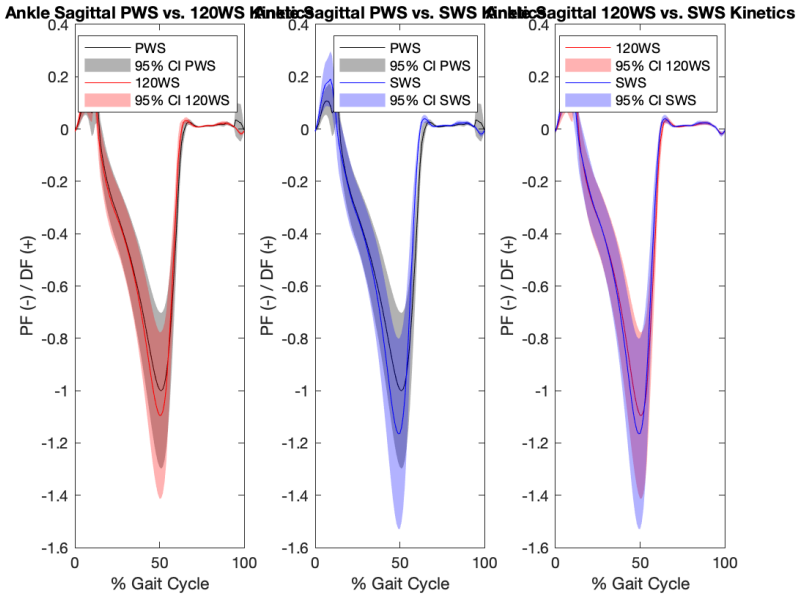
T-test Speed Differences
Hip Transverse



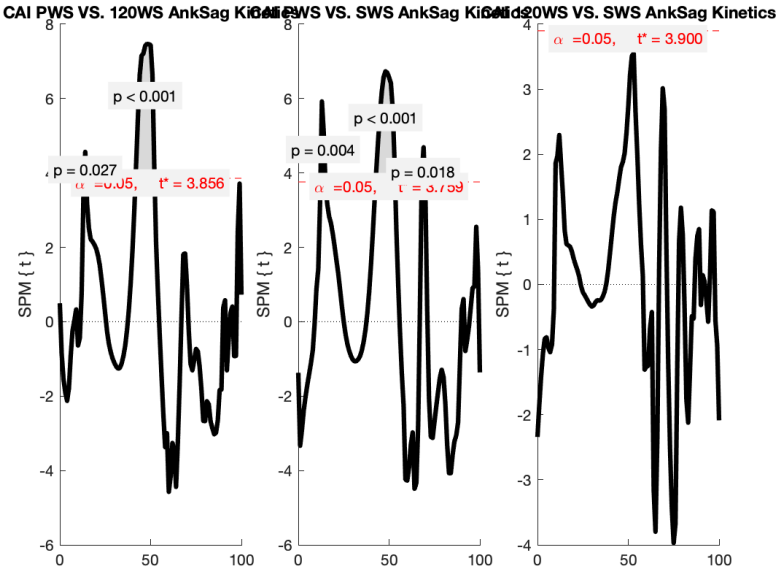


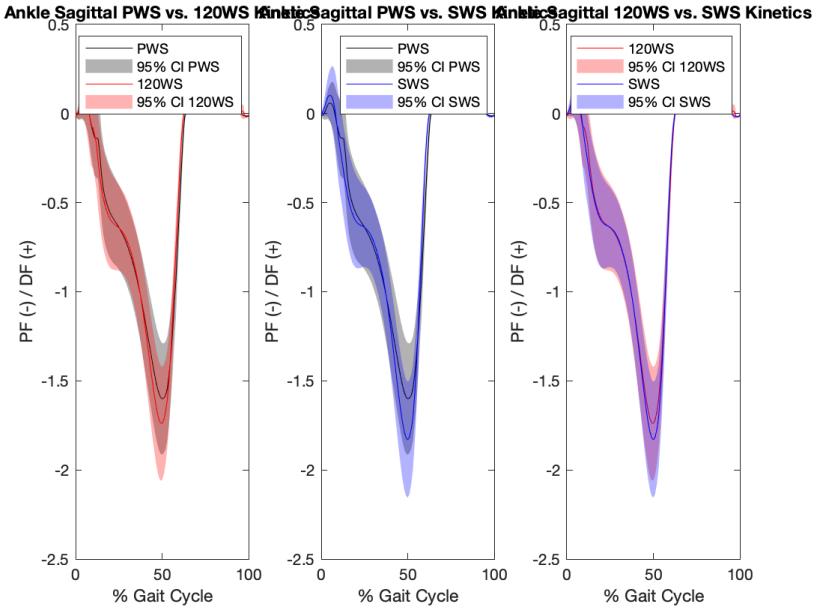
T-test Speed Differences
Coper Ankle Sagittal



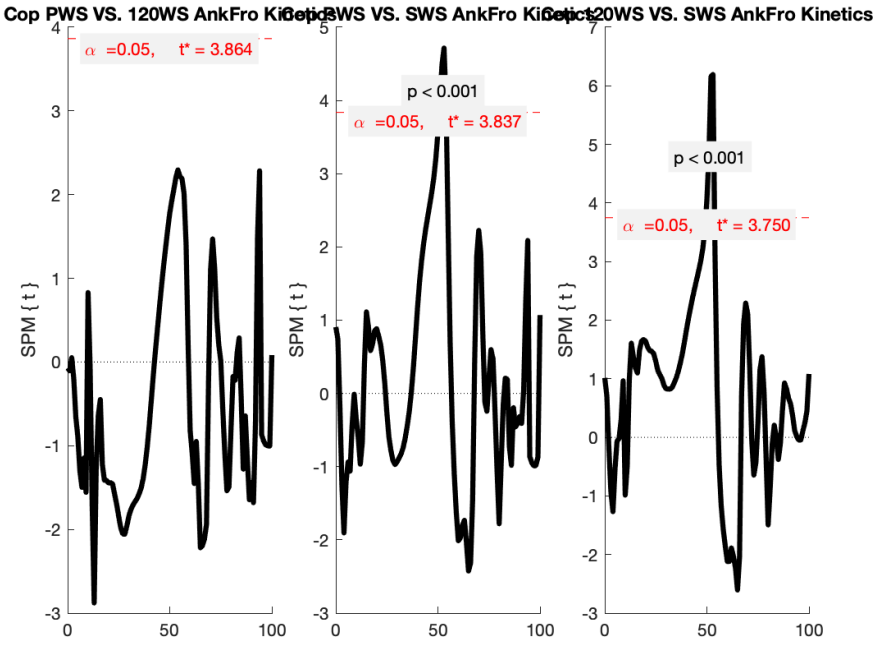


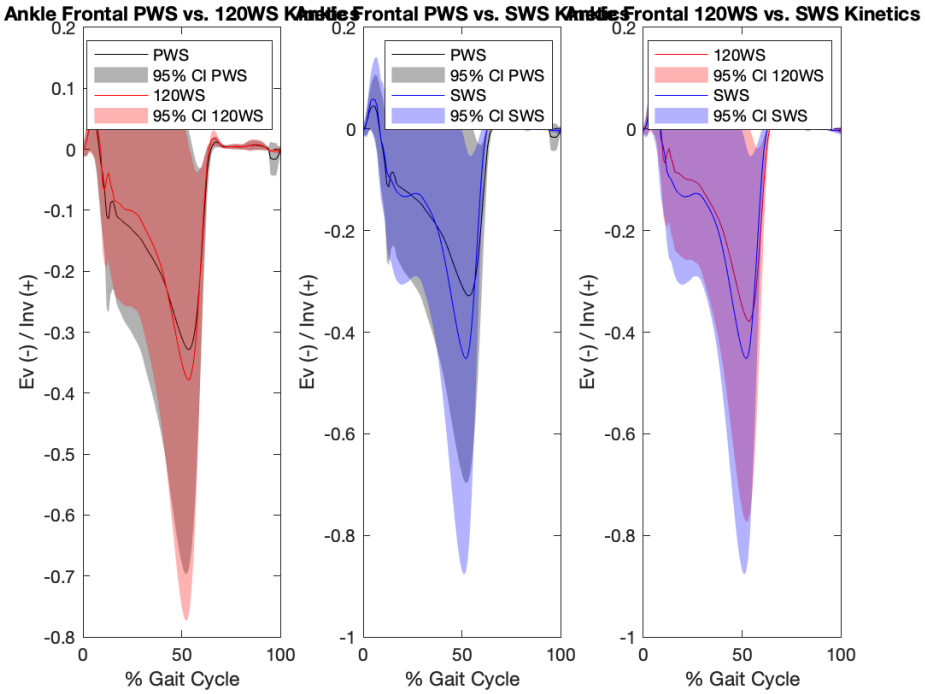
T-test Speed Differences
CAI Ankle Sagittal



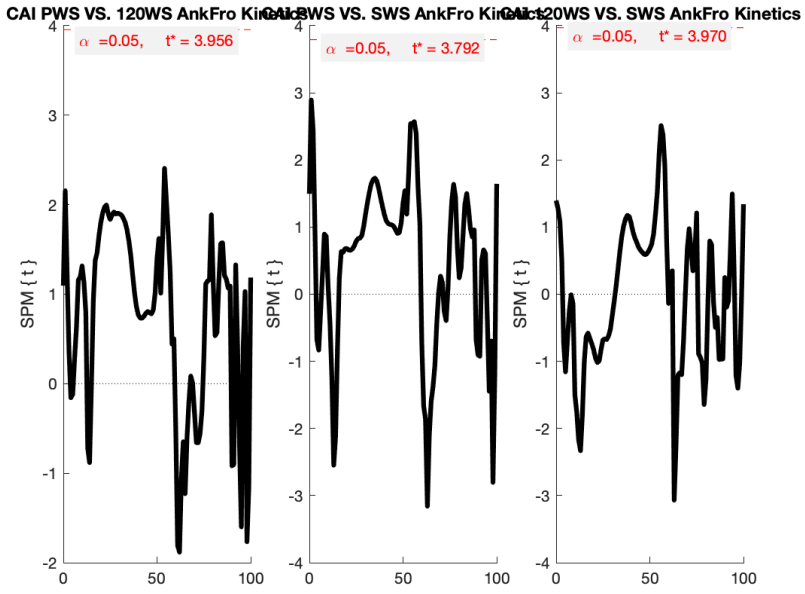


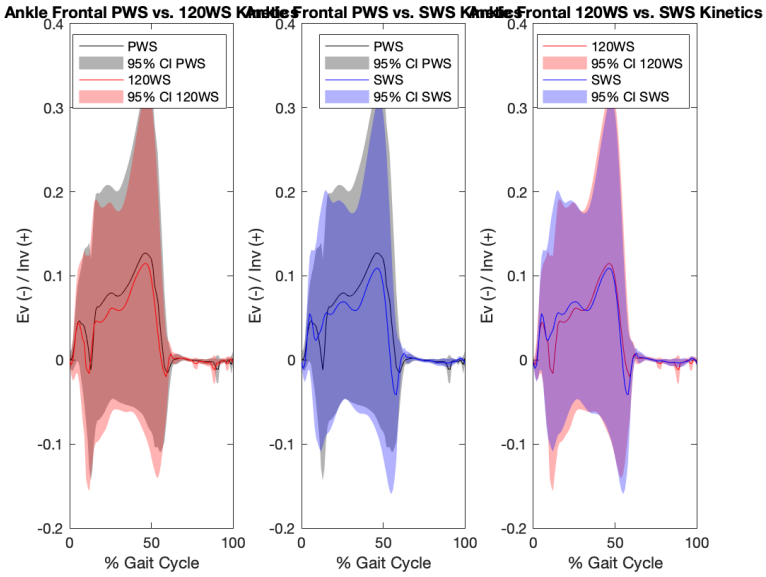
T-test Speed Differences
Coper Ankle Frontal



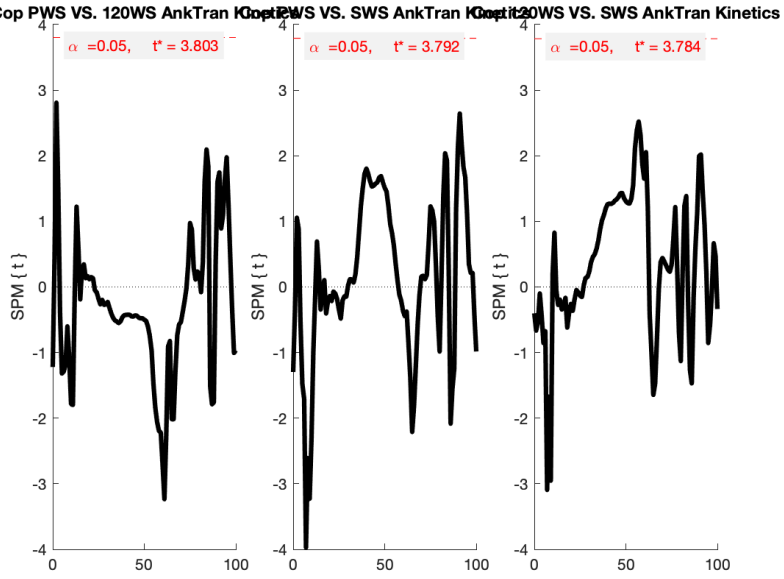


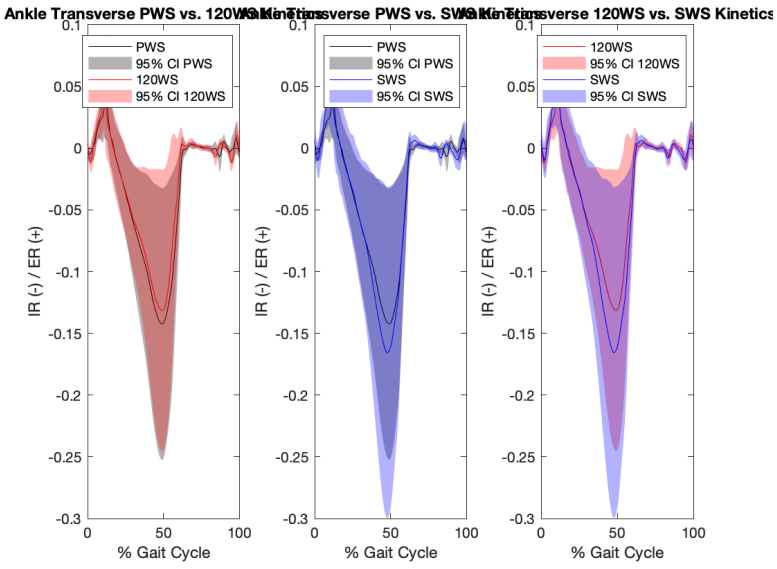
T-test Speed Differences
CAI Ankle Frontal



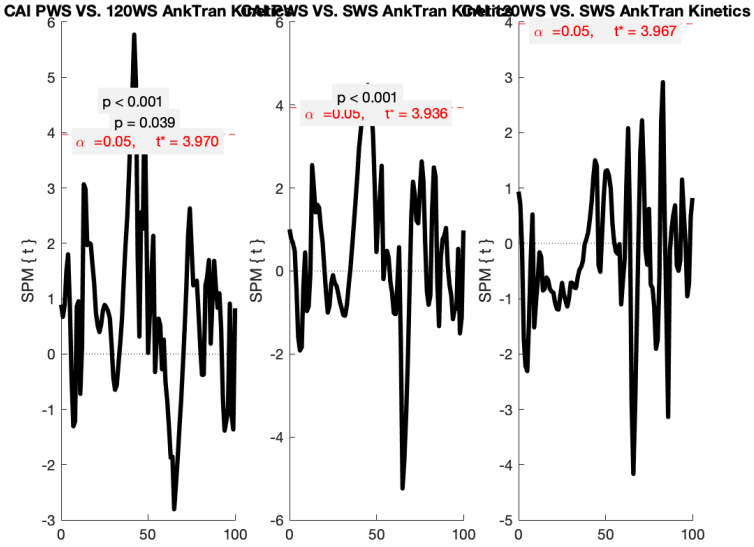


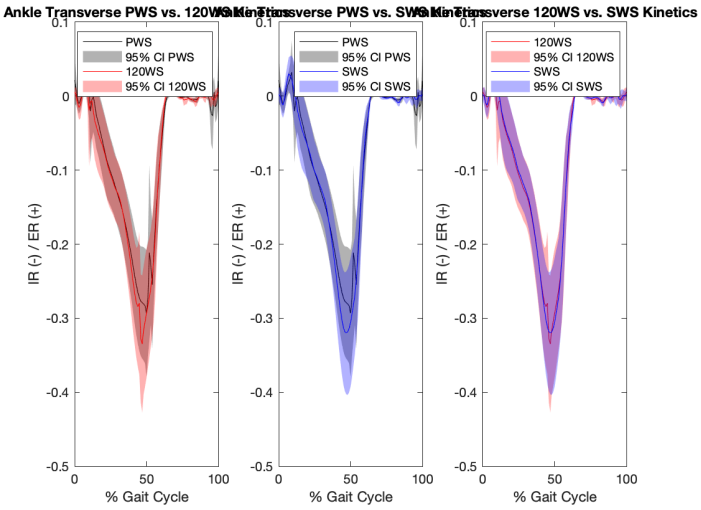
T-test Speed Differences
Coper Ankle Transverse



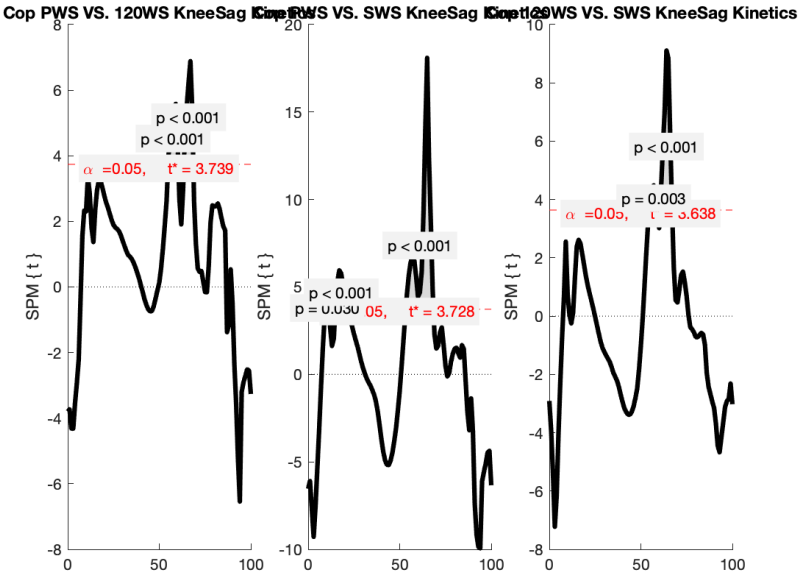


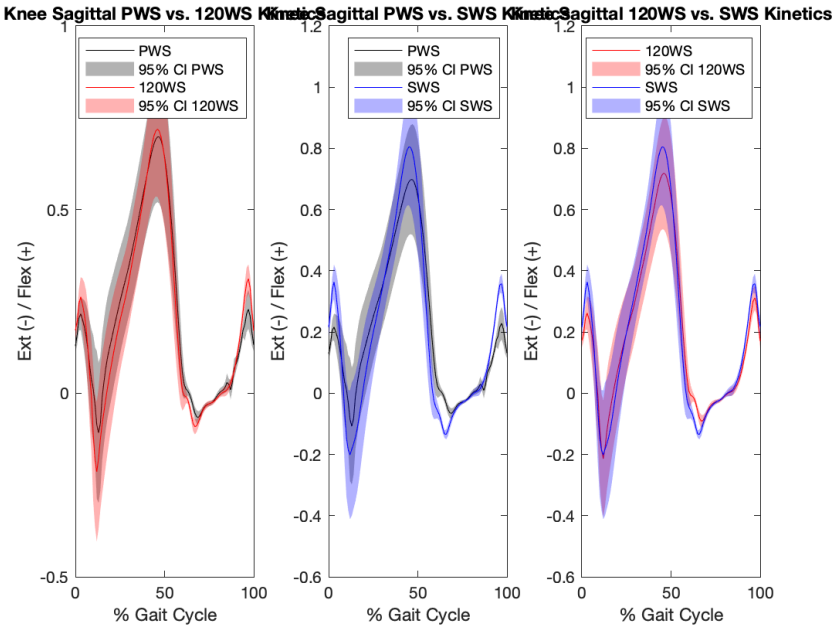
T-test Speed Differences
CAI Ankle Transverse



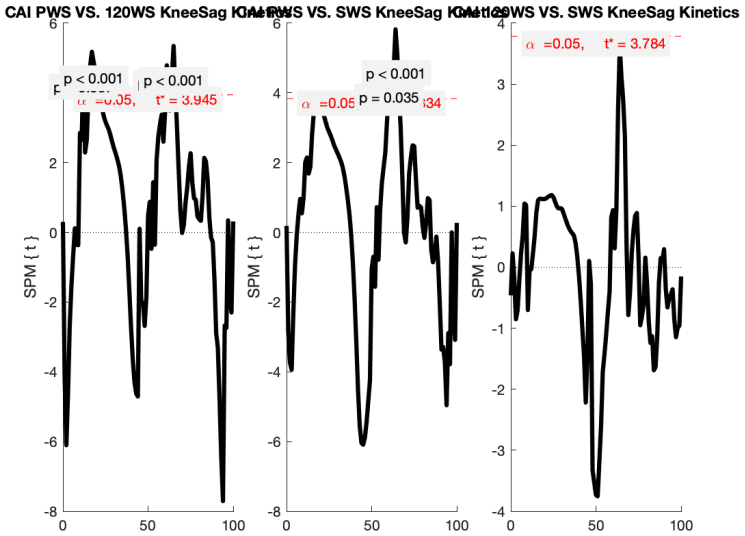


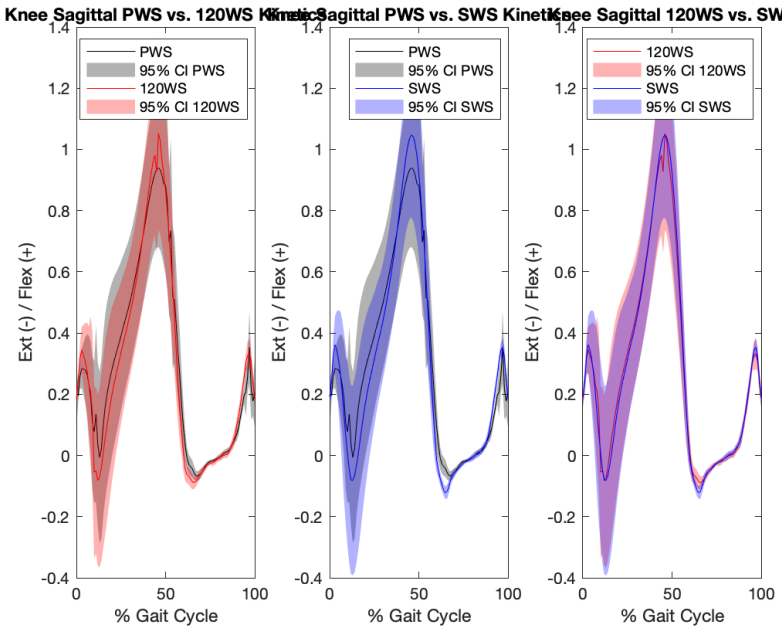
T-test Speed Differences
Coper Knee Sagittal



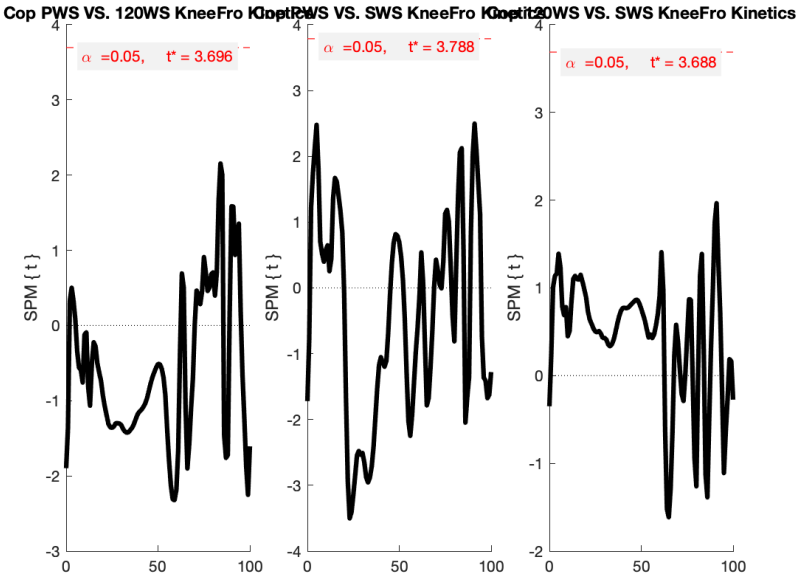


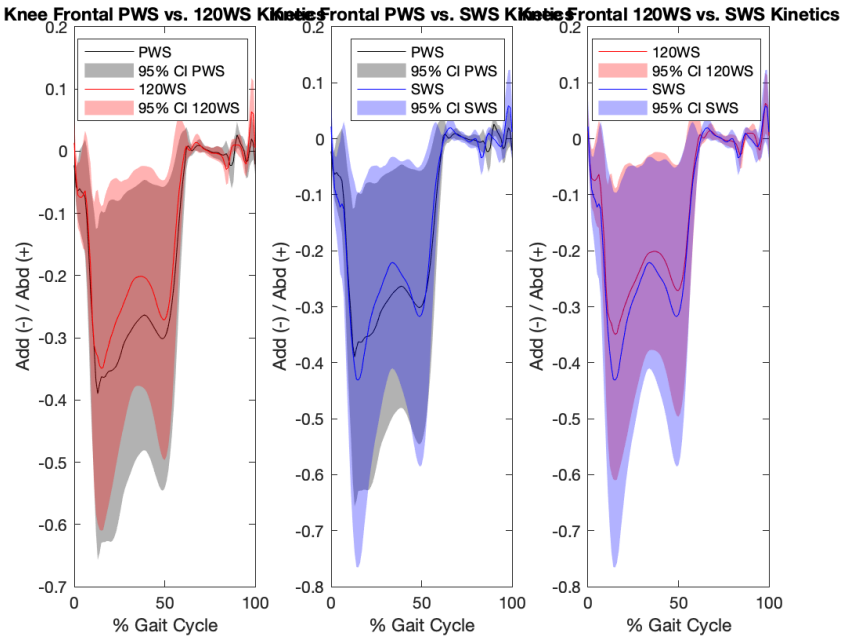
T-test Speed Differences
CAI Knee Sagittal



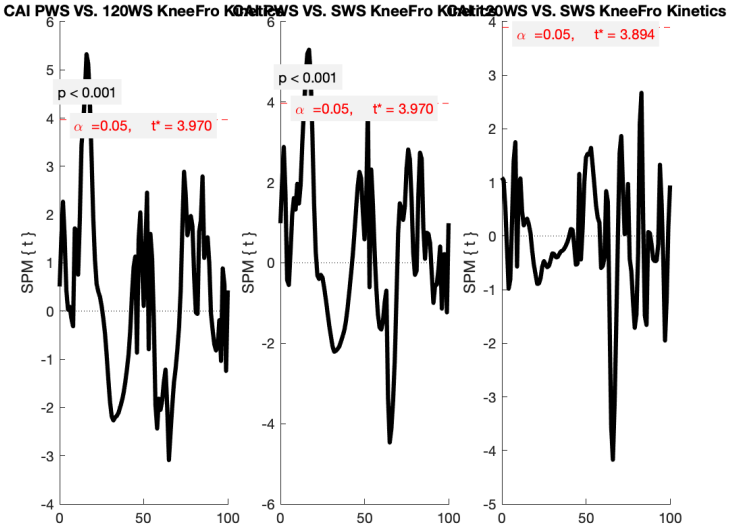


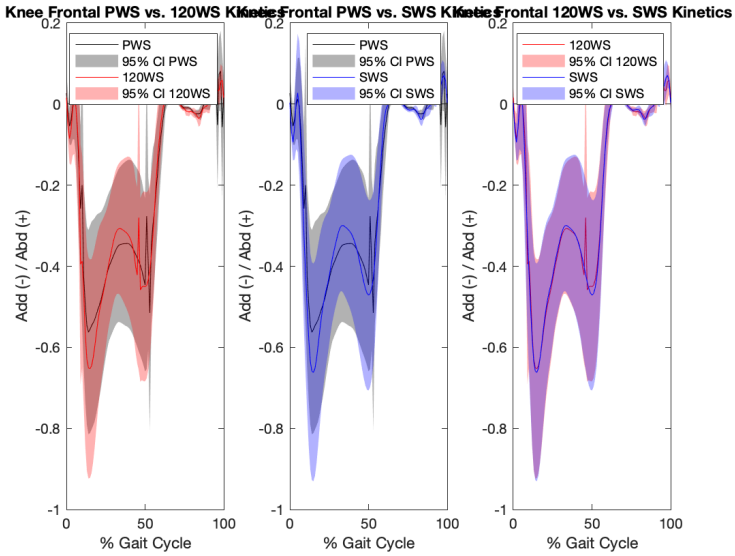
T-test Speed Differences
Coper Knee Frontal



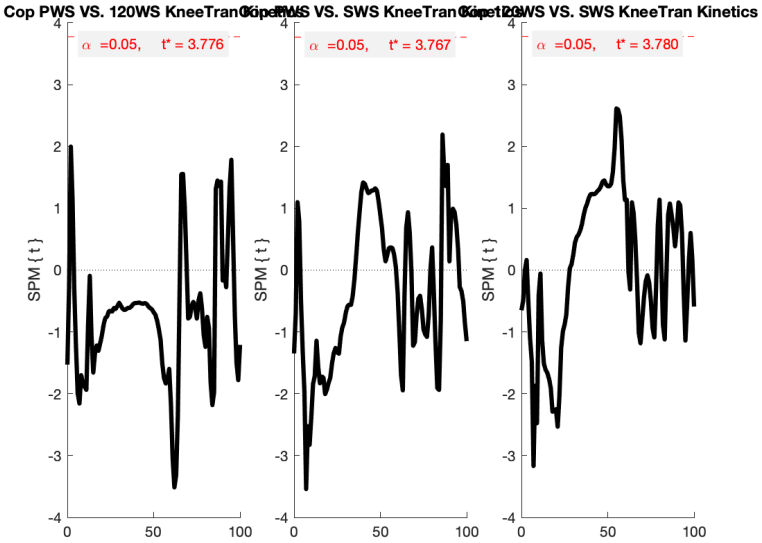


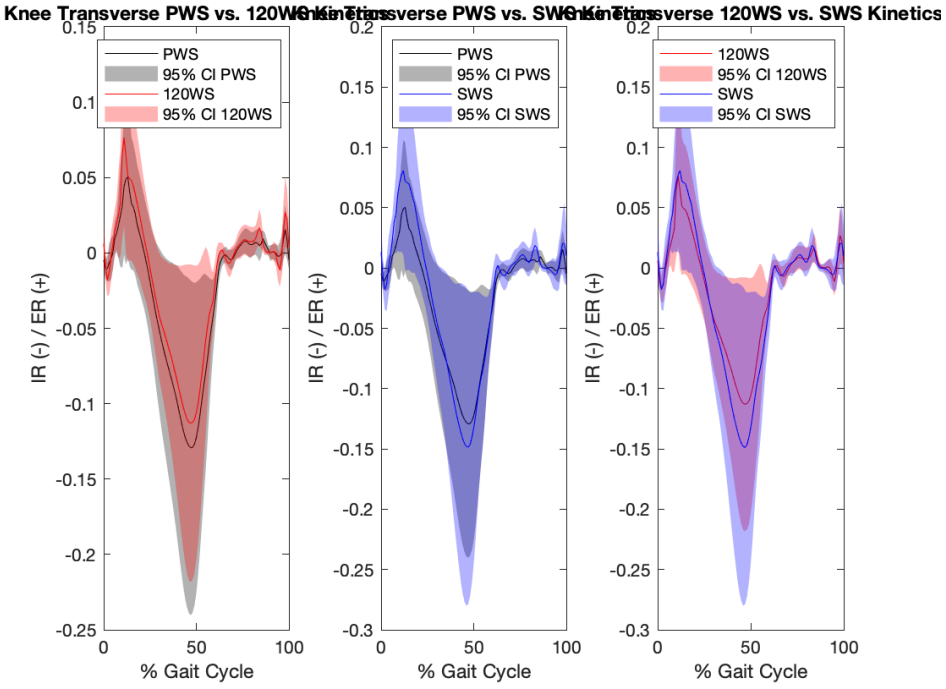
T-test Speed Differences
CAI Knee Frontal



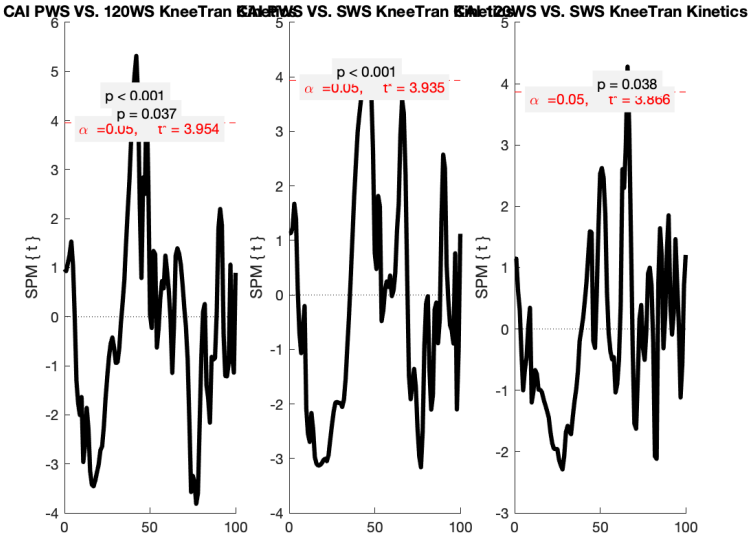


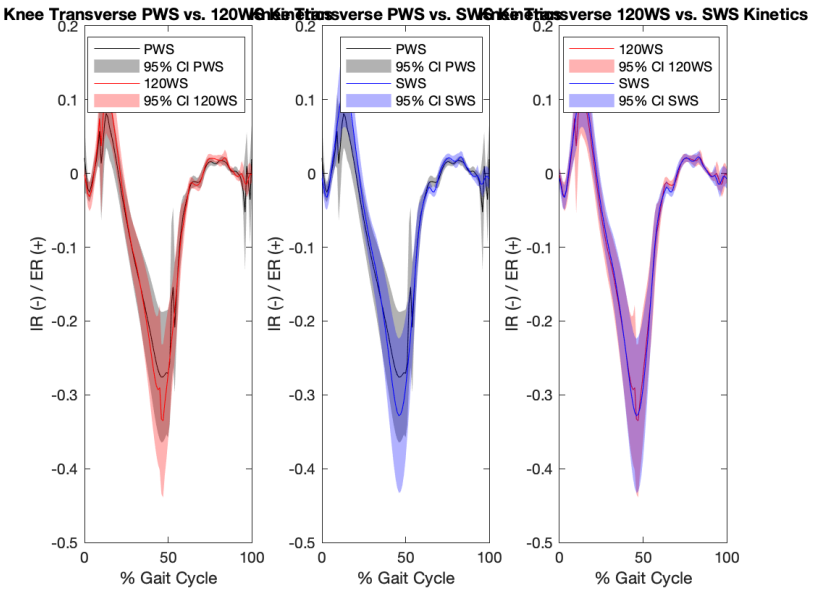
T-test Speed Differences
Coper Knee Transverse



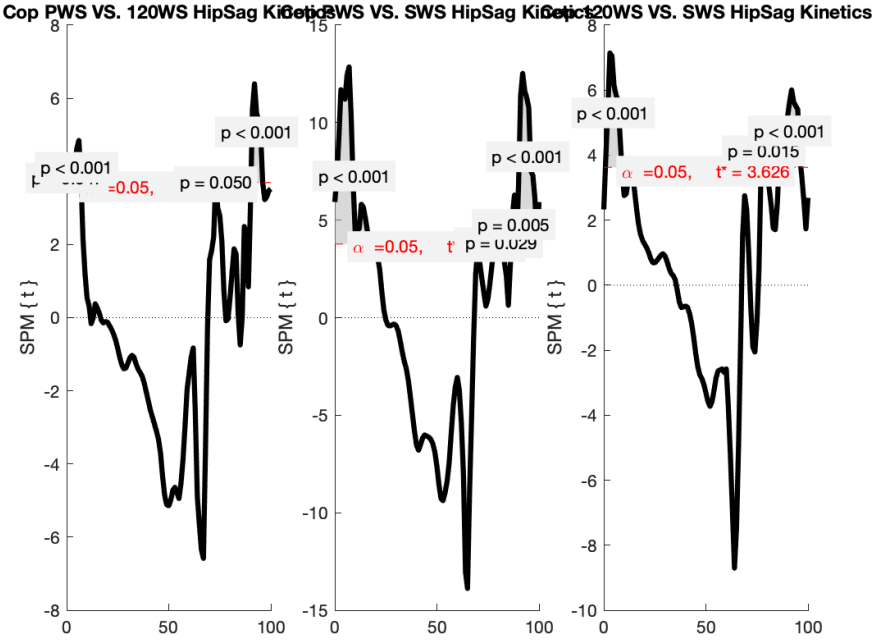


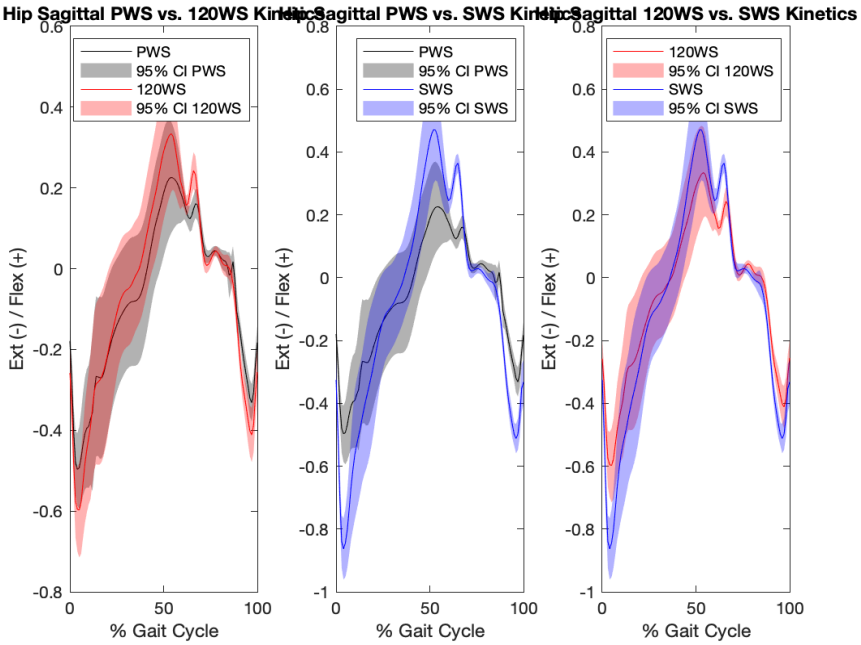
T-test Speed Differences
CAI Knee Transverse



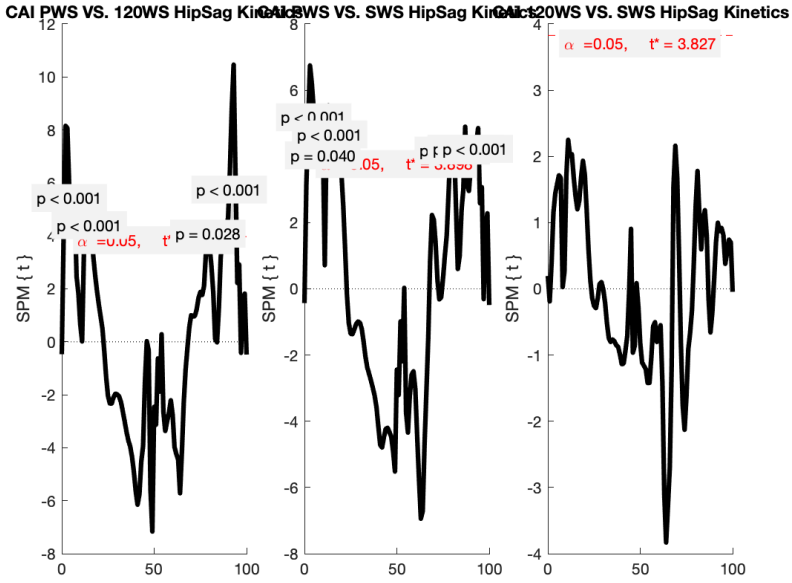


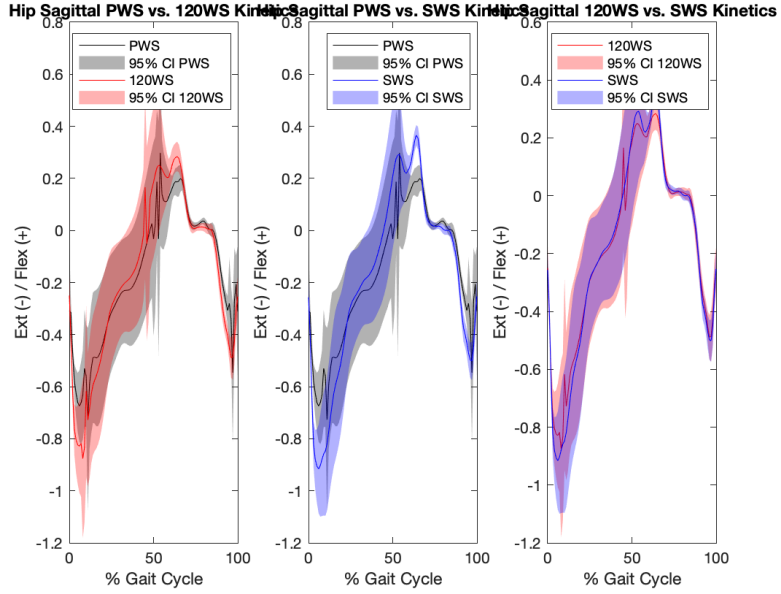
T-test Speed Differences
Coper Hip Sagittal



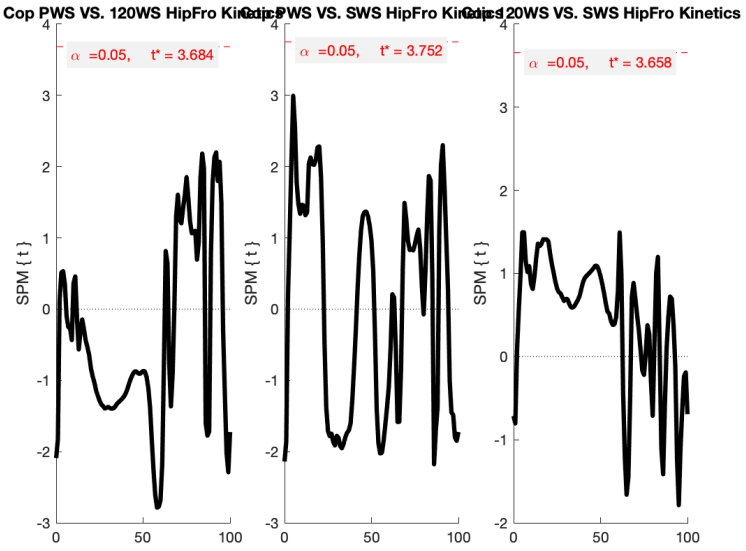


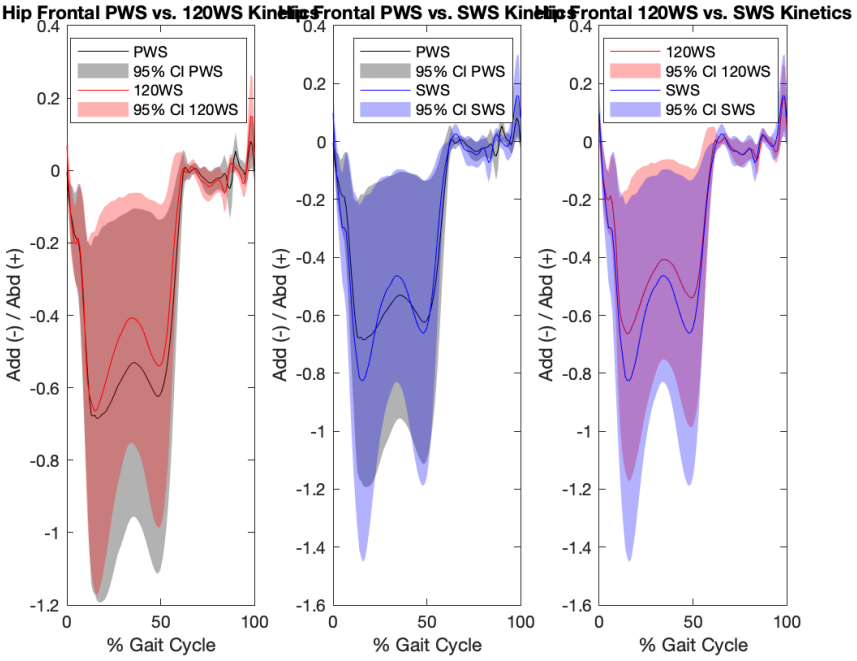
T-test Speed Differences
CAI Hip Sagittal



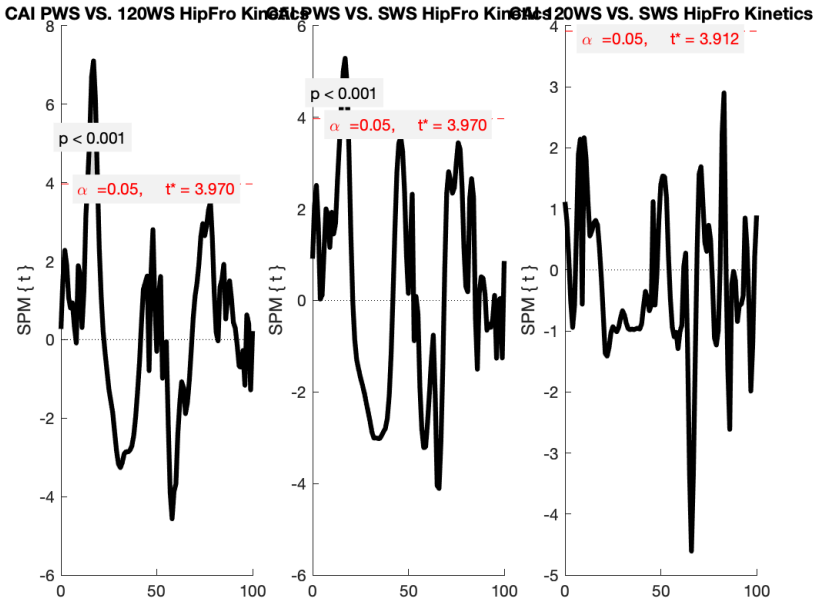


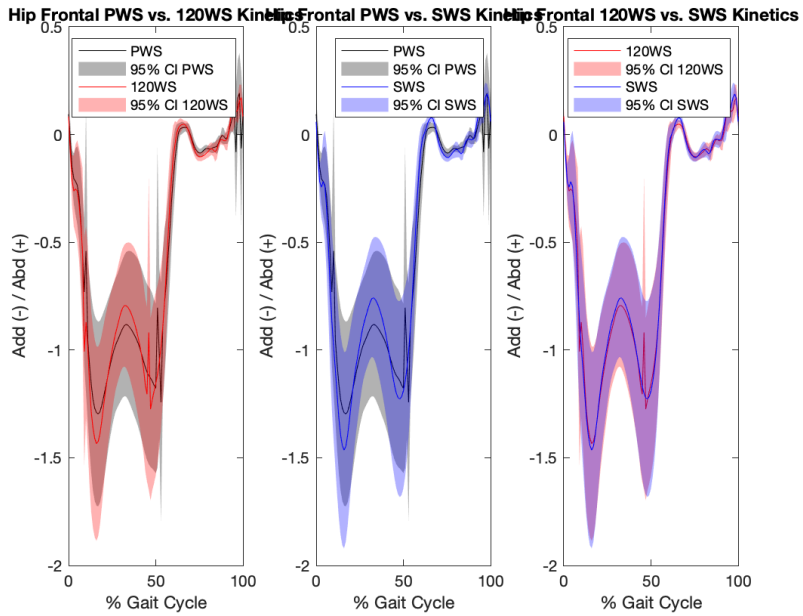
T-test Speed Differences
Coper Hip Frontal



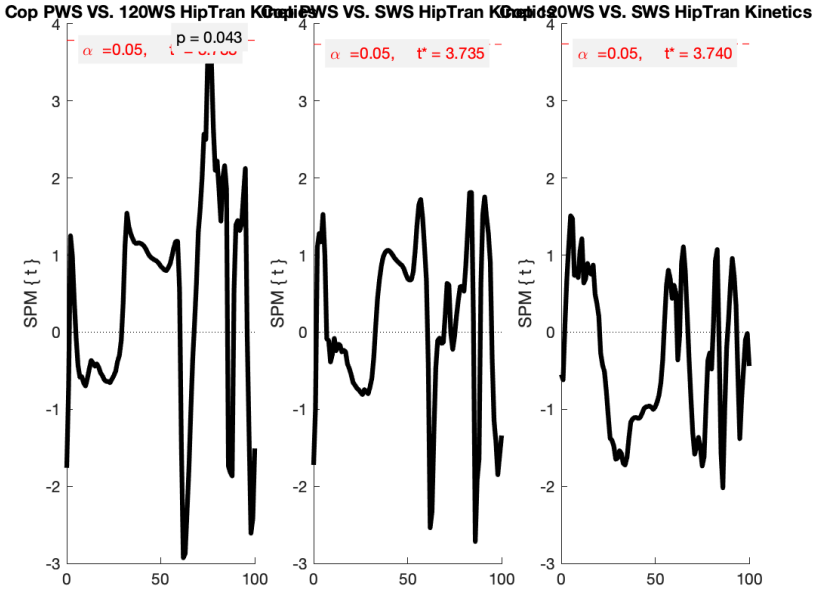


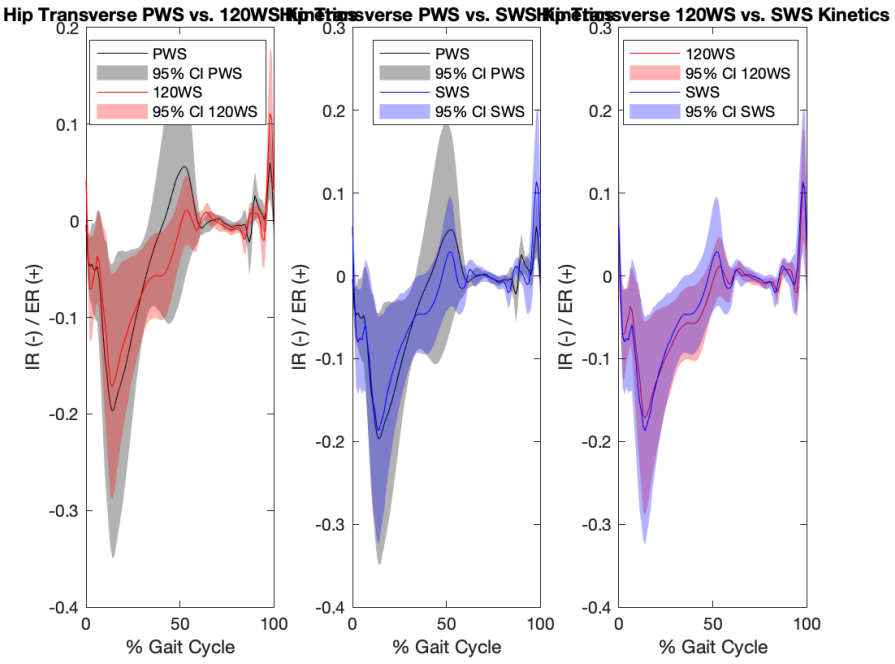
T-test Speed Differences
CAI Hip Frontal



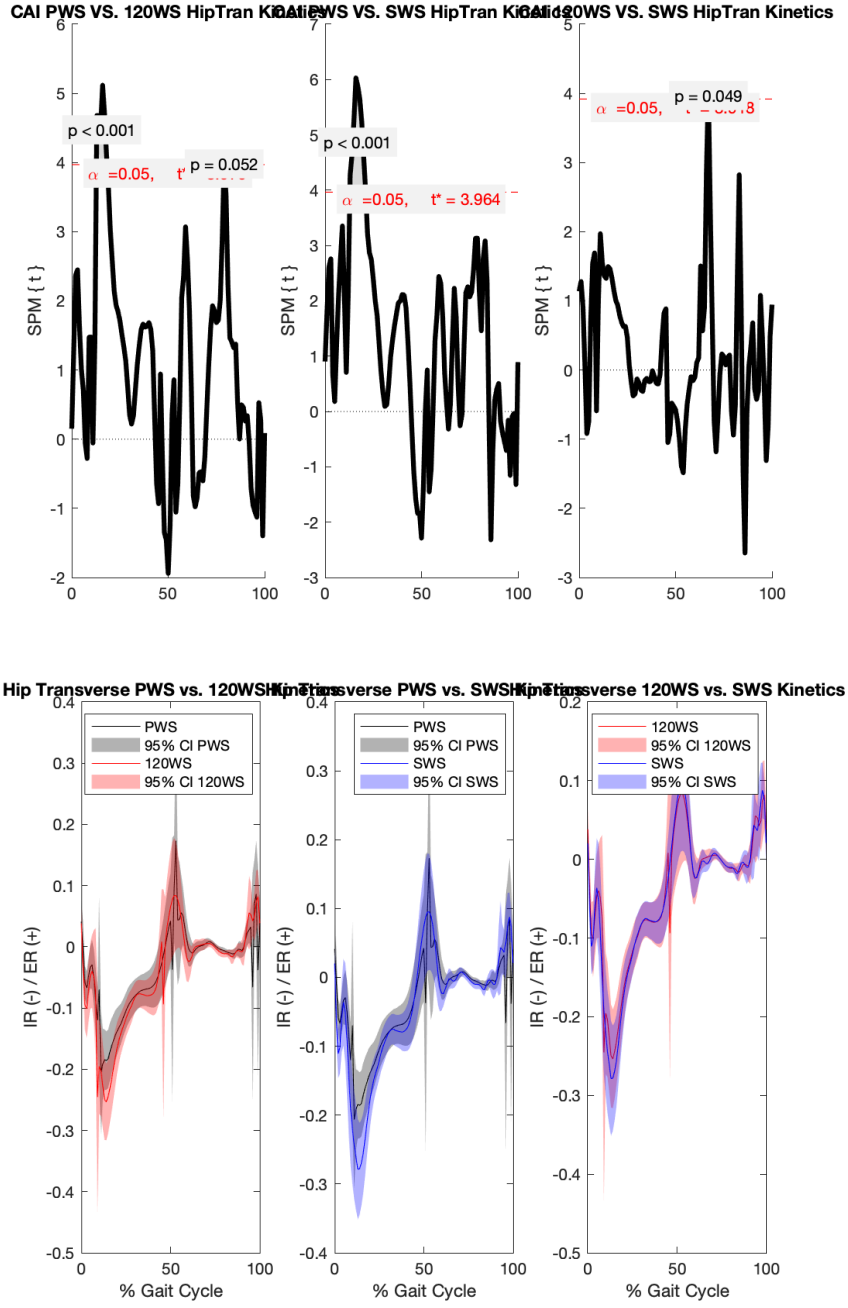


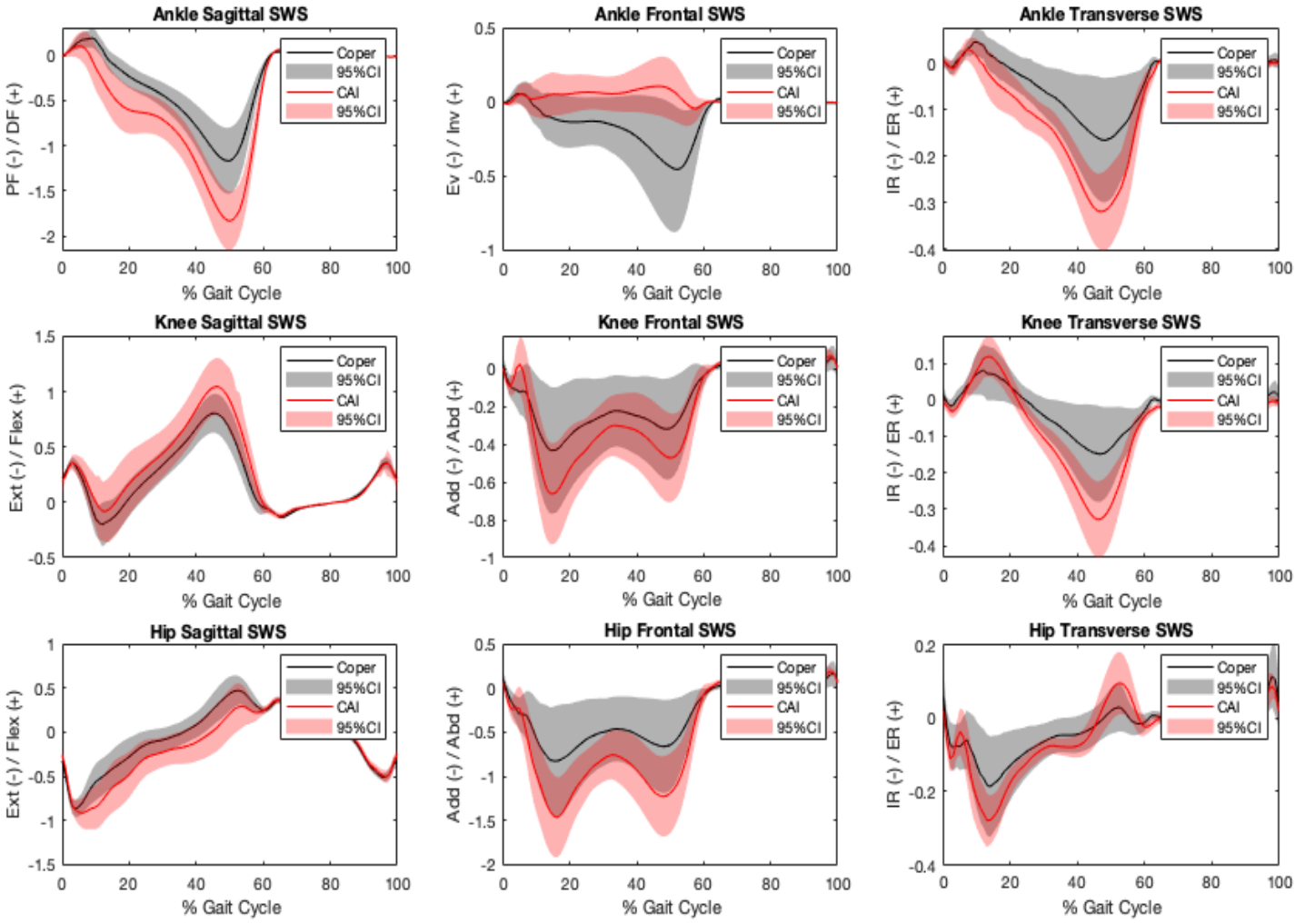
T-test Speed Differences
Coper Hip Transverse





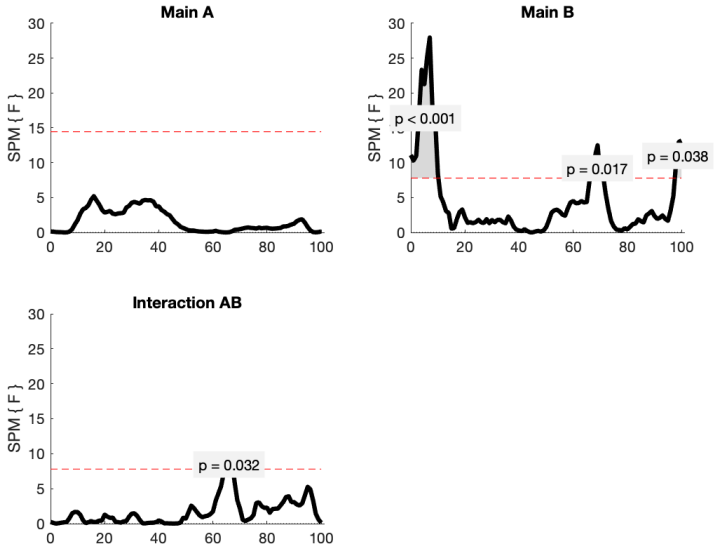
T-test Speed Differences
CAI Hip Transverse



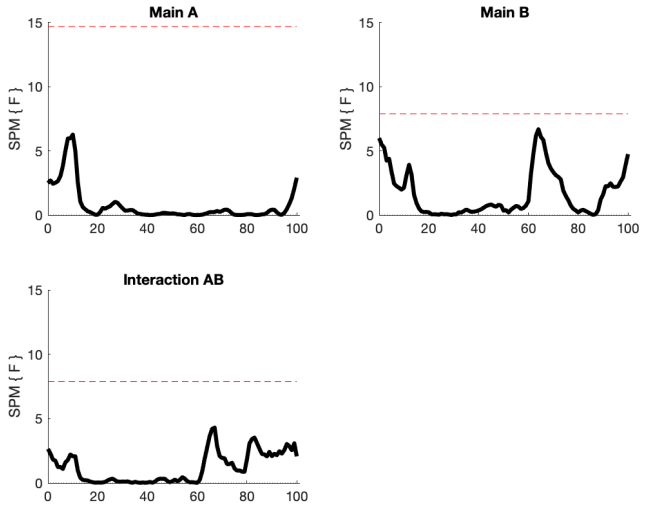

Ankle Sagittal SWS
PF (-) / DF (+)
Ankle Frontal SWS
Ev (-) / Inv (+)
Ankle Transverse SWS
IR (-) / ER (+)
Knee Sagittal SWS
Ext (-) / Flex (+)
Knee Frontal SWS
Add (-) / Abd (+)
Knee Transverse SWS
IR (-) / ER (+)
Hip Sagittal SWS
Ext (-) / Flex (+)
Hip Frontal SWS
Add (-) / Abd (+)
Hip Transverse SWS
IR (-) / ER (+)
% Gait Cycle
Coper
95%CI
CAI
95%CI

M1: Results

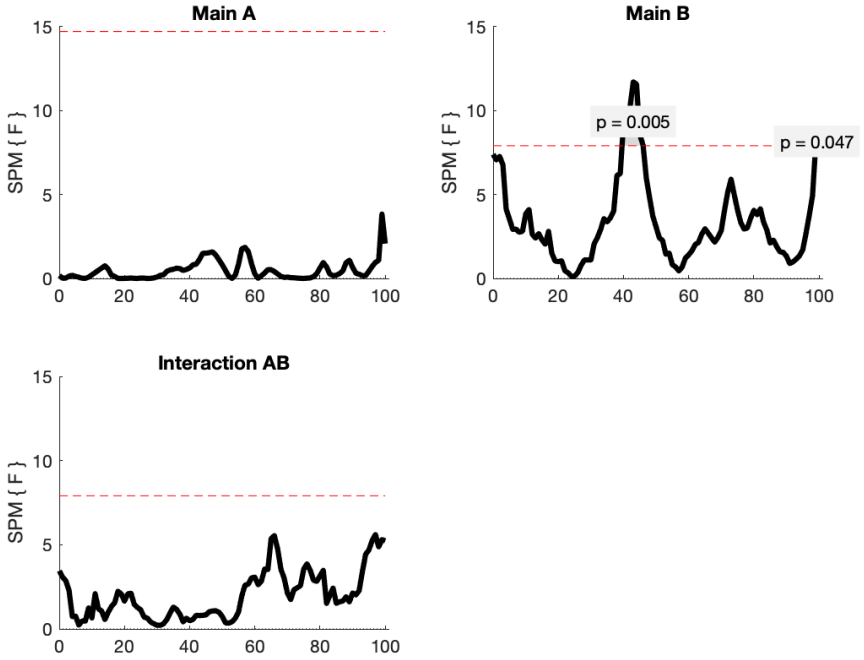
ANOVA – Gluteus Medius



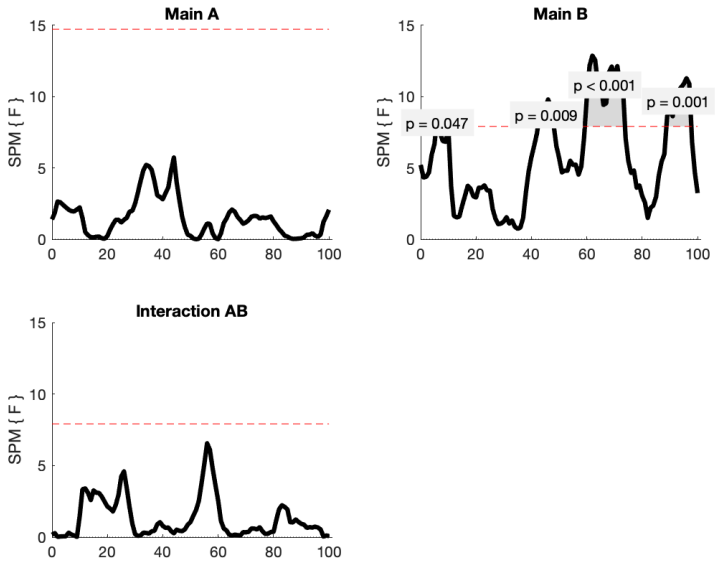
ANOVA - Medial Gastroc



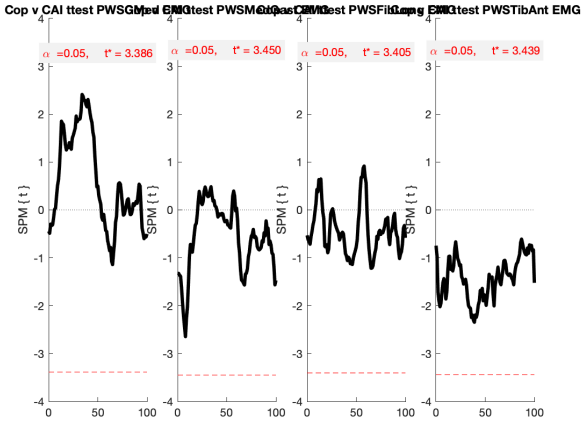
ANOVA - Fibularis Longus



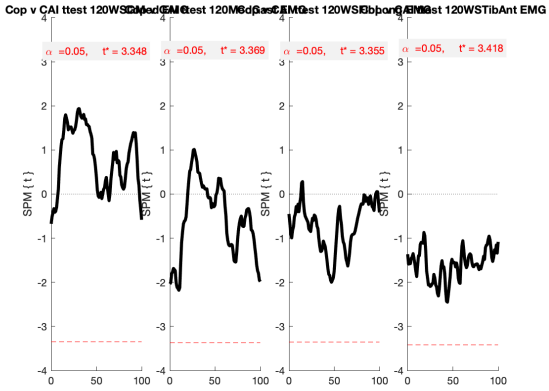
ANOVA – Tibialis Anterior



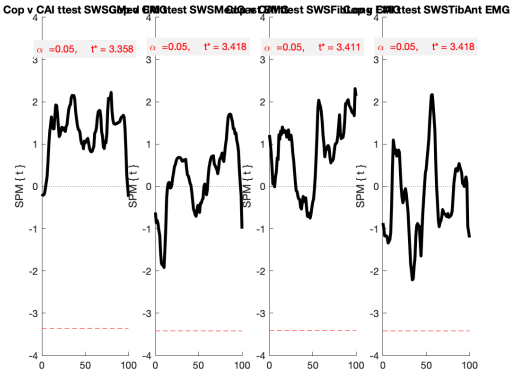
T-test Group Differences at PWS



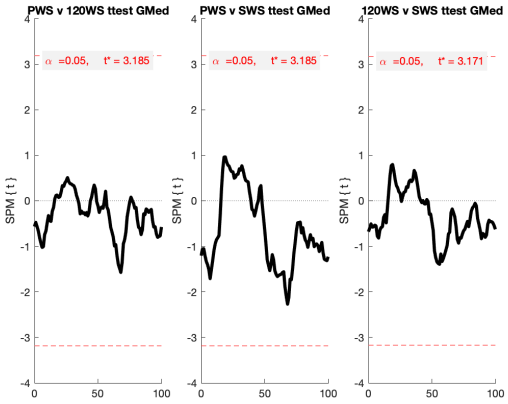
T-test Group Differences at 120WS

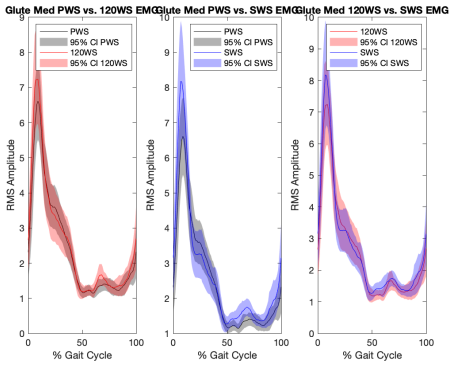


T-test Group Differences at SWS

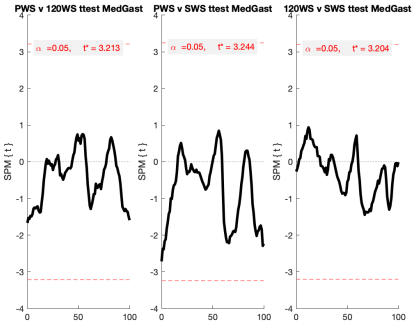


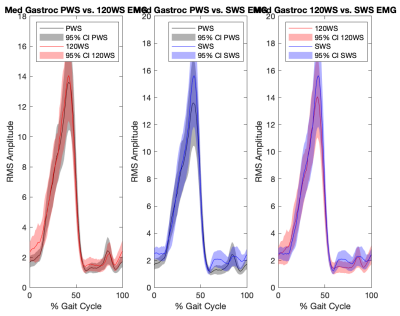
T-test Speed Differences
Gluteus Medius



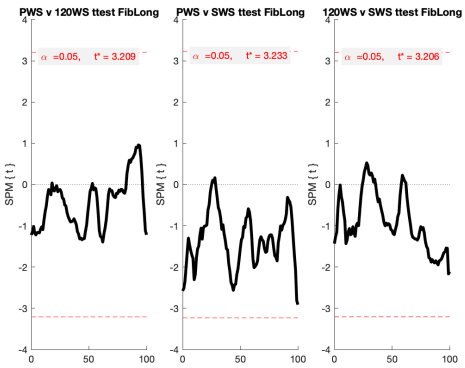


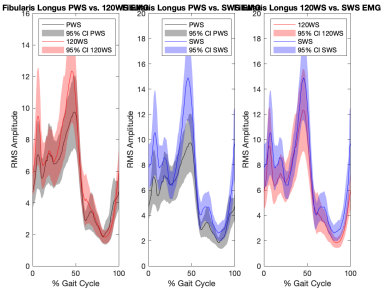
T-test Speed Differences
Medial Gastroc



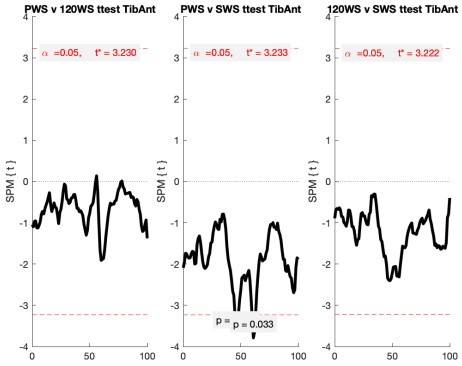


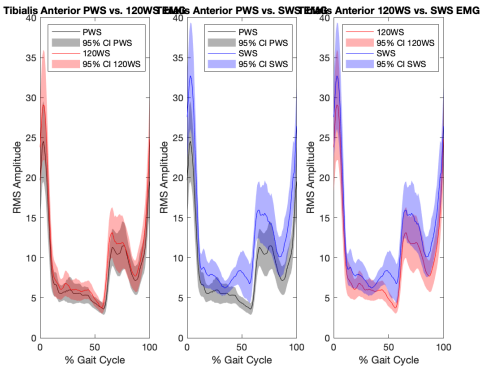
T-test Speed Differences
Fibularis Longus



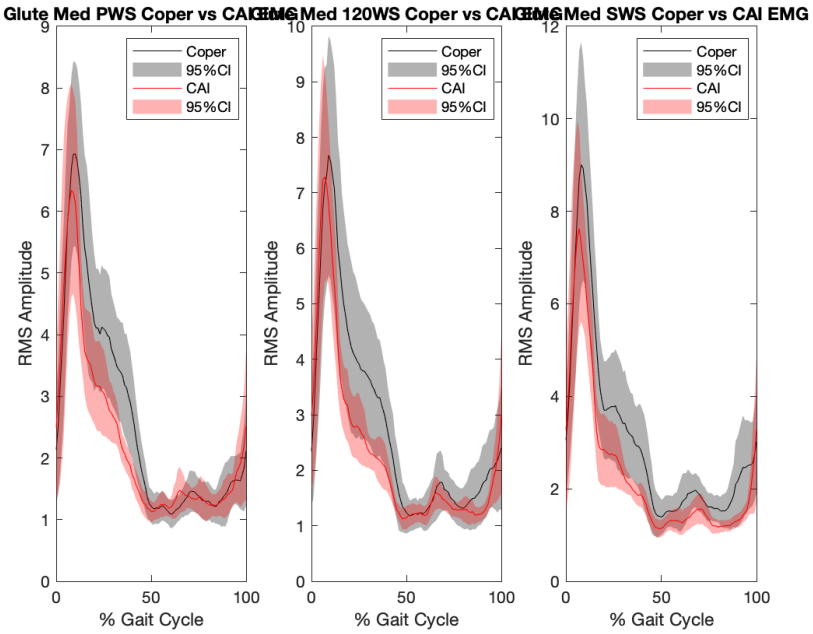


T-test Speed Differences
Tibialis Anterior

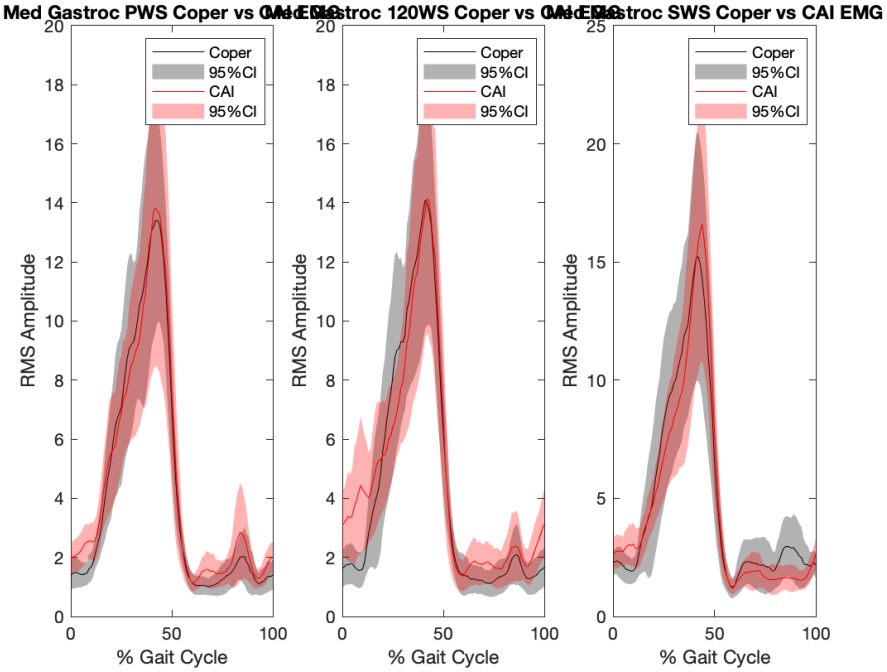




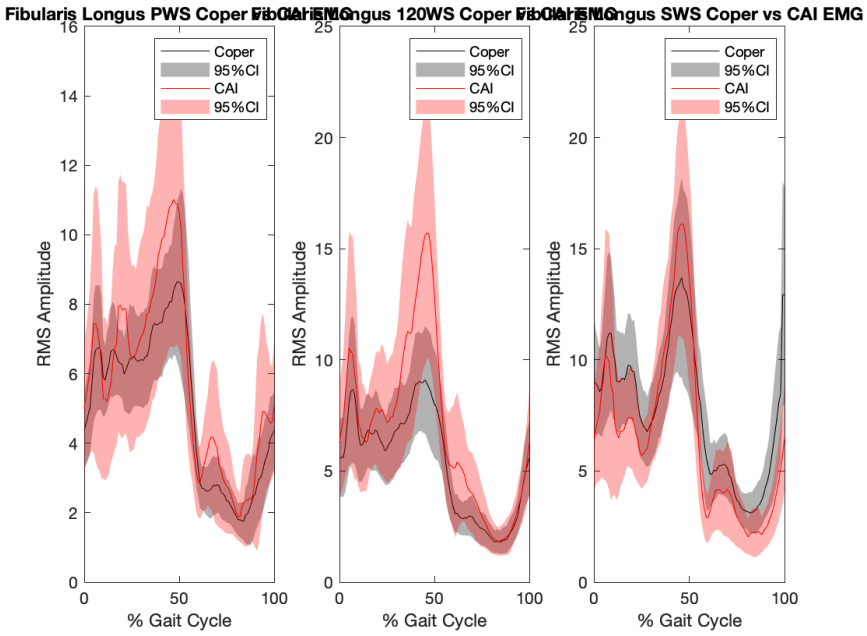
Group Comparisons
Gluteus Medius



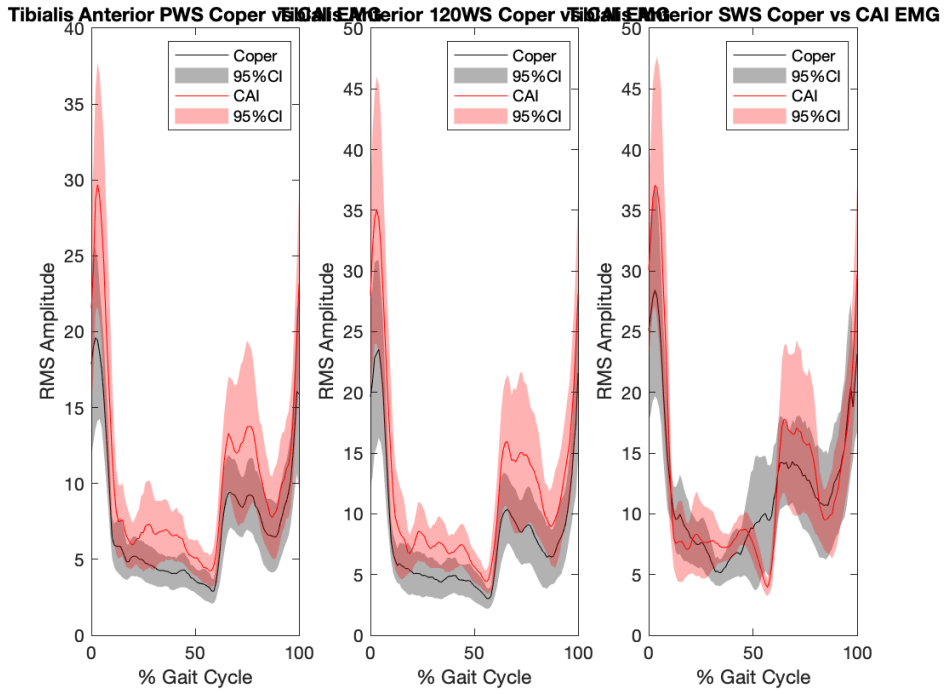
T-test Speed Differences
Medial Gastroc



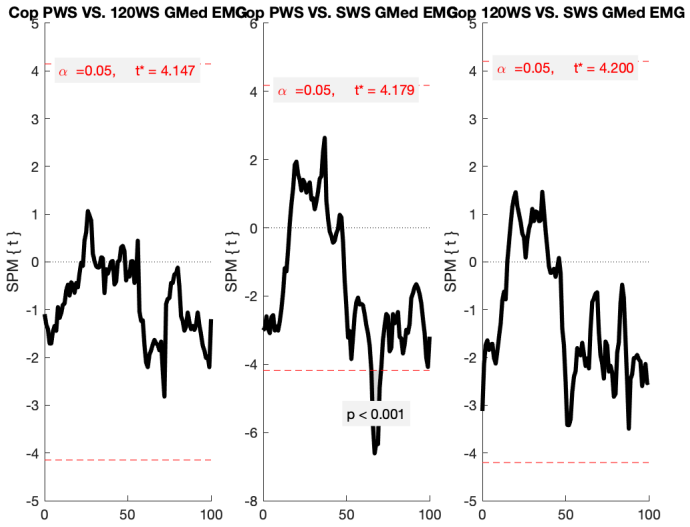
T-test Speed Differences
Fibularis Longus

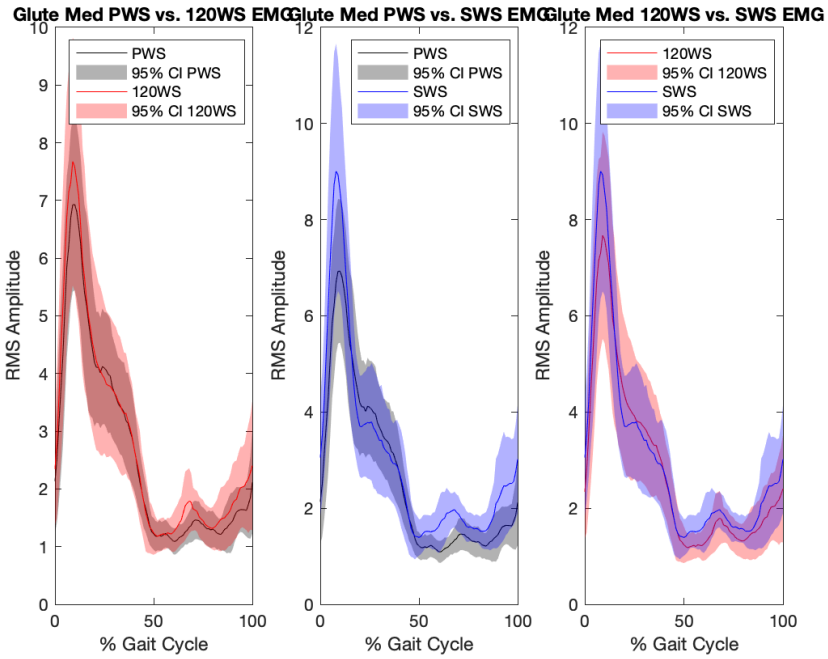


T-test Speed Differences
Tibialis Anterior

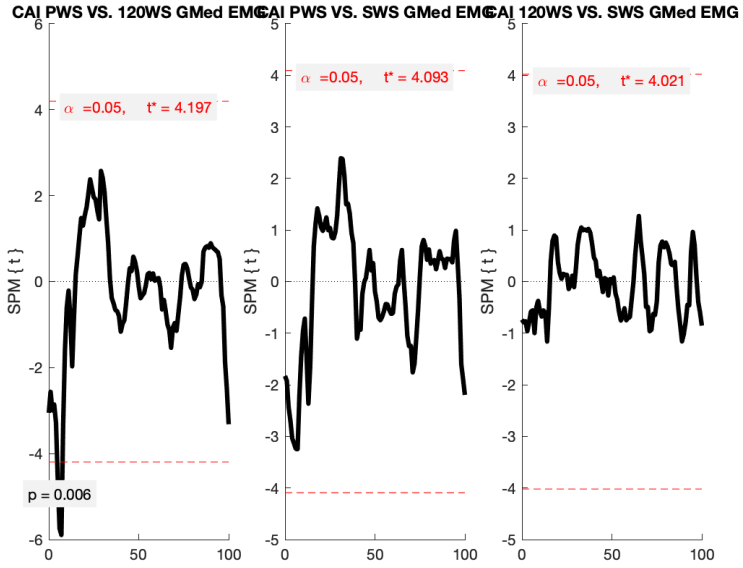


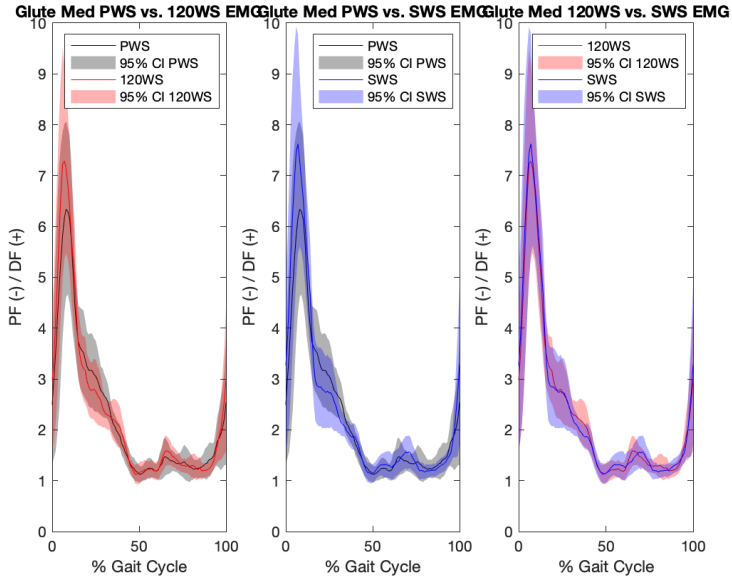
T-test Speed Differences
Coper Gluteus Medius



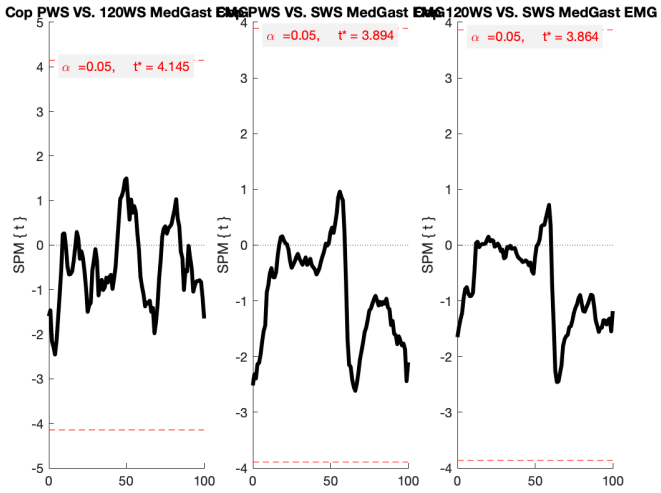


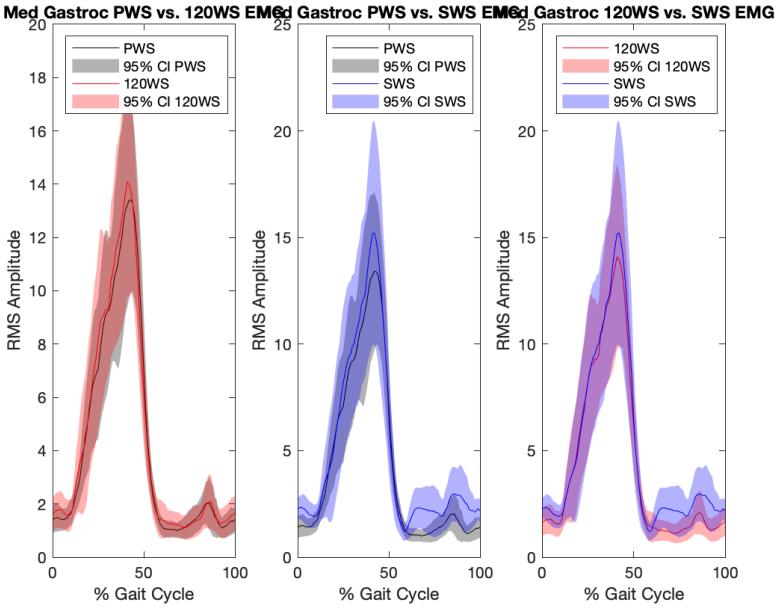
T-test Speed Differences
CAI Gluteus Medius



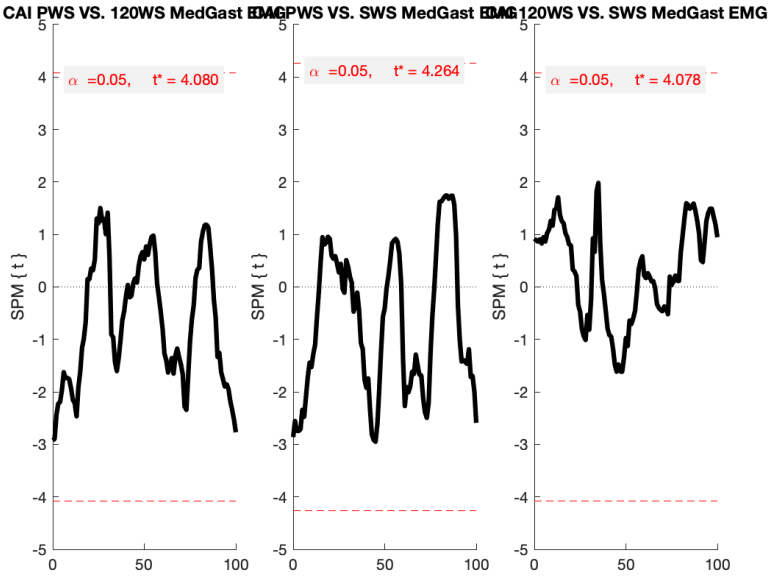


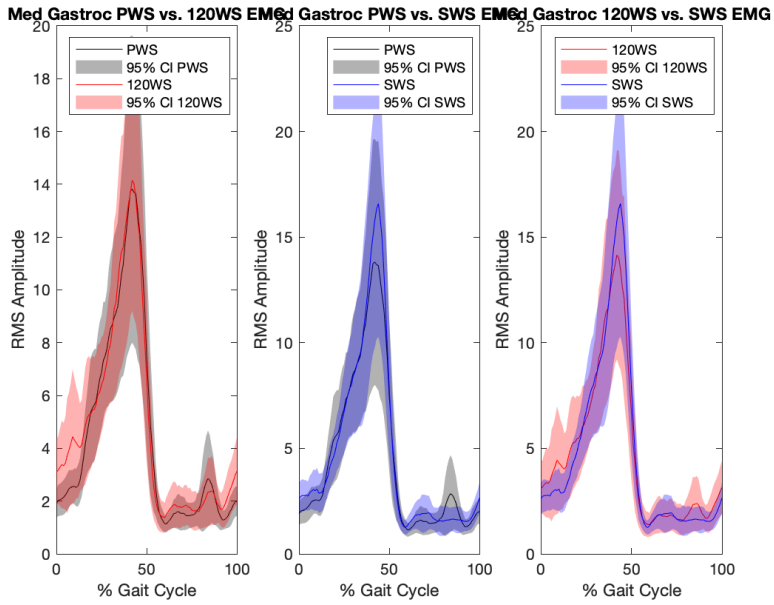
T-test Speed Differences
Coper Medial Gastroc



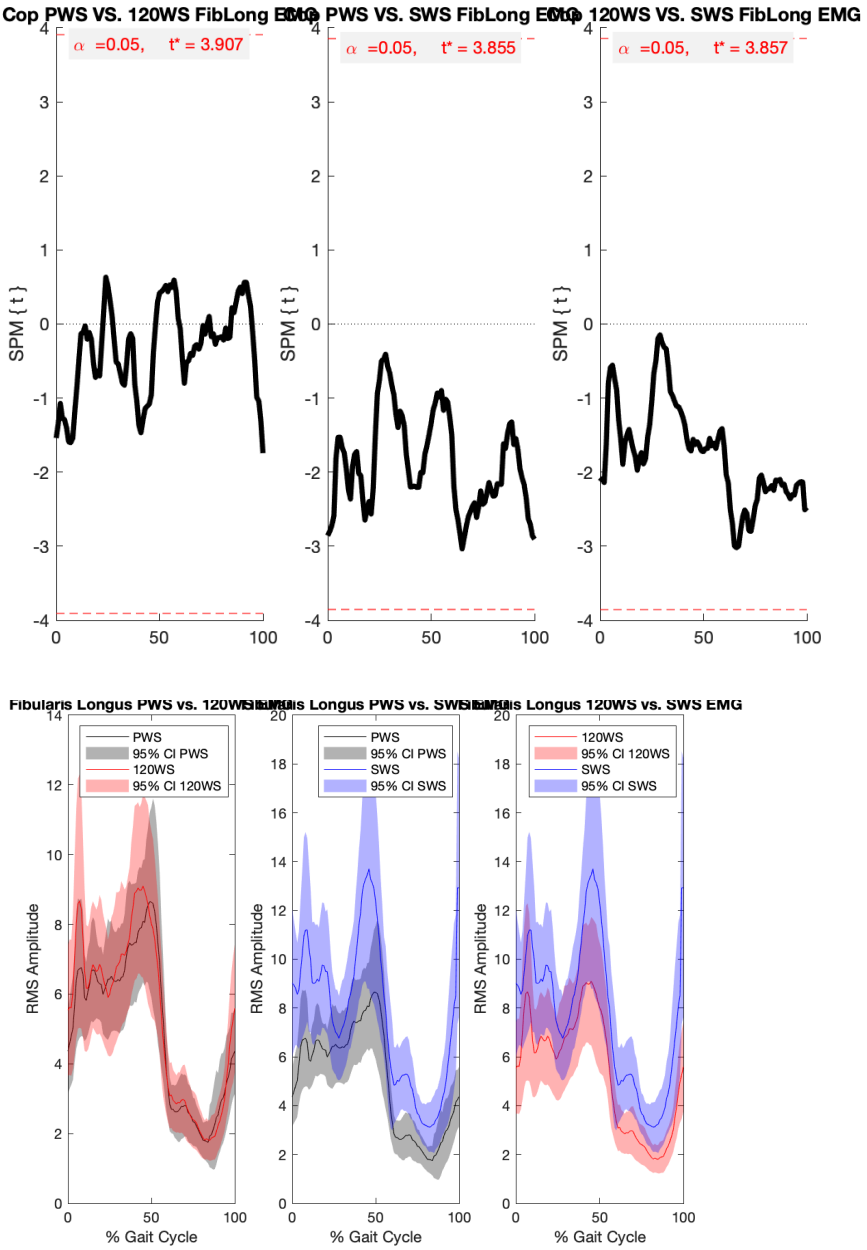


T-test Speed Differences
CAI Medial Gastroc

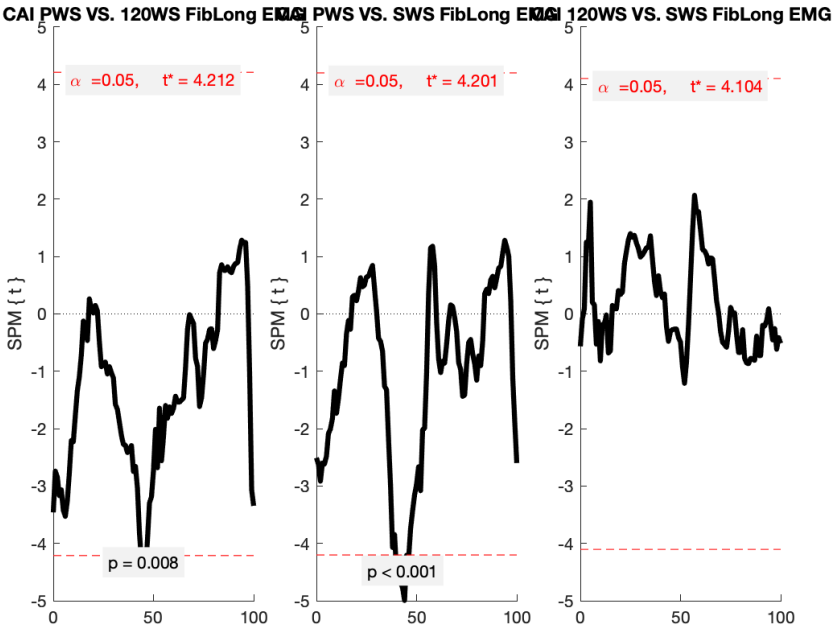


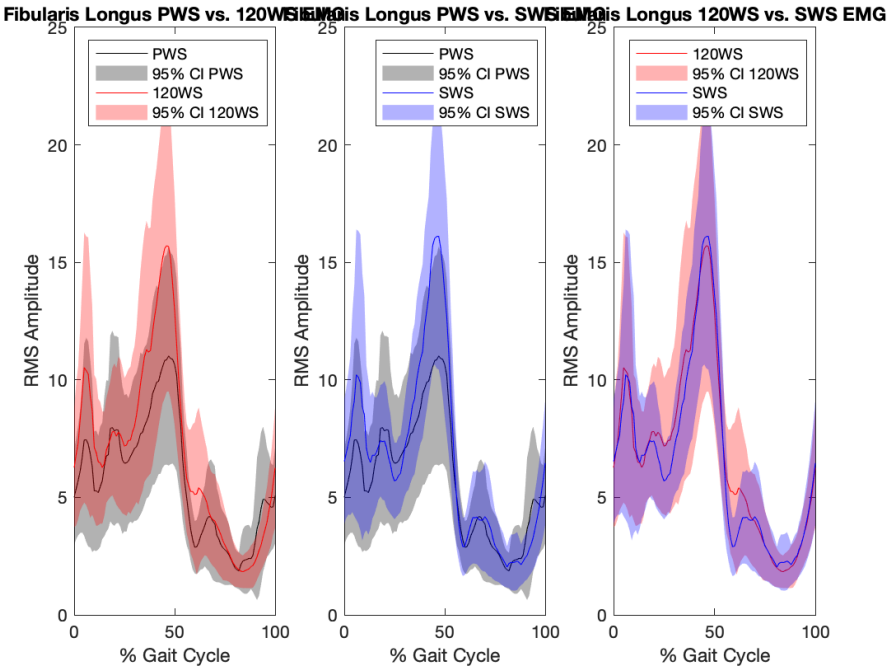


T-test Speed Differences
Coper Fibularis Longus

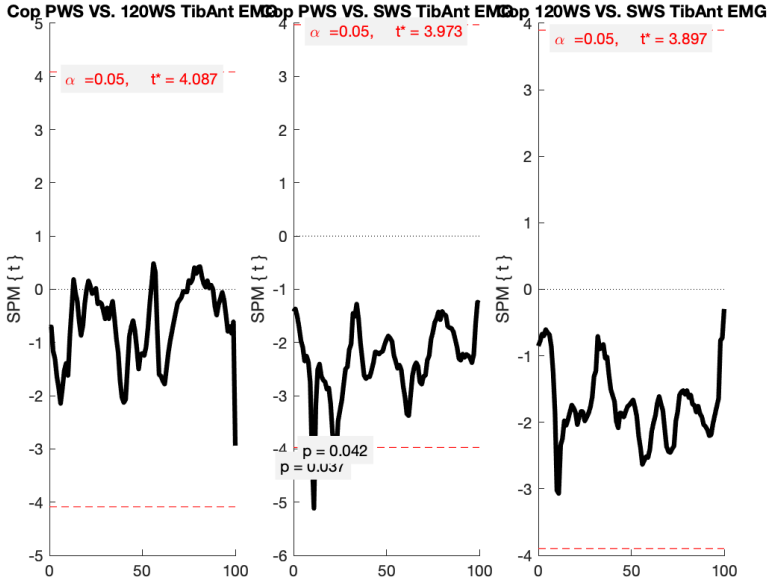


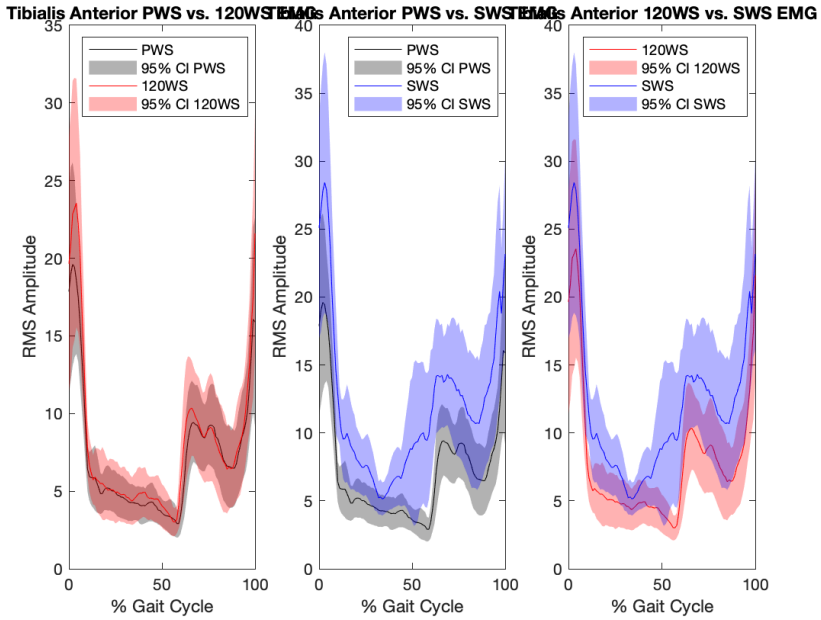
T-test Speed Differences
CAI Fibularis Longus



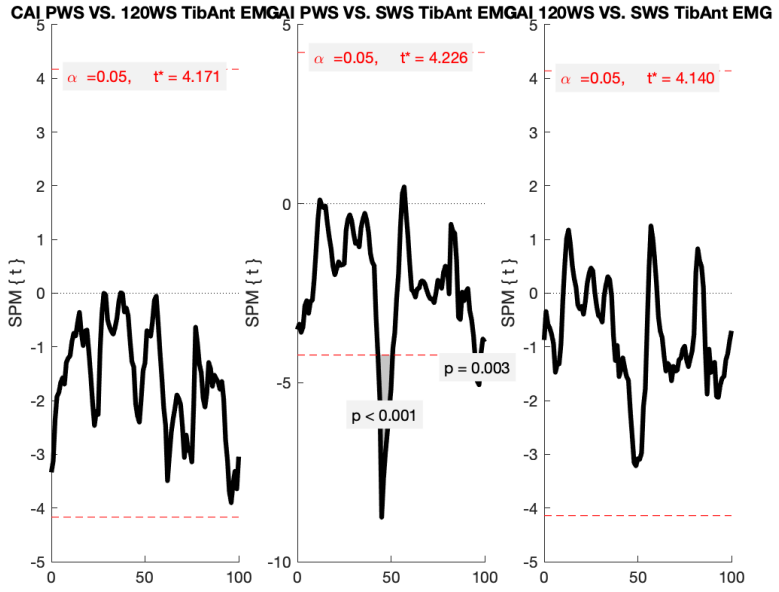


T-test Speed Differences
Coper Tibialis Anterior





T-test Speed Differences
CAI Tibialis Anterior



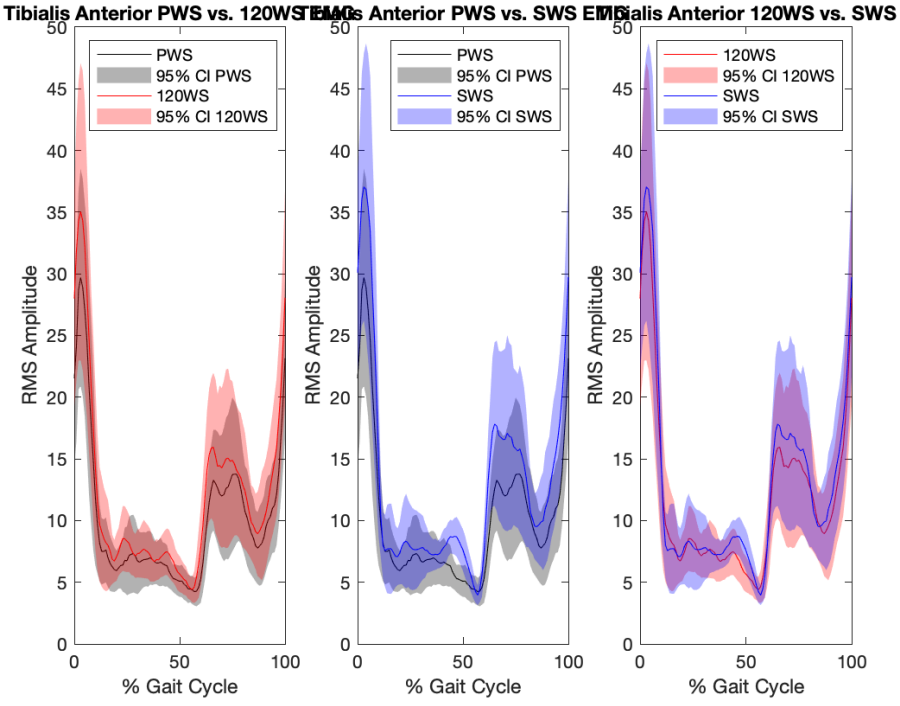


Table D2. Results tables for Manuscript 2

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Intervention	13

Descriptive Statistics

Dependent Variable: Post_FAAM_ADL_Percent

Group	Mean	Std. Deviation	N
Control	92.0068027	5.68882782	14
Intervention	97.0695971	2.25957402	13
Total	94.4444444	5.01828160	27

Tests of Between-Subjects Effects

Dependent Variable: Post_FAAM_ADL_Percent

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	1053.506	1	1053.506	73.688
	Error	354.700	24.810	14.297[a]	
Pre_FAAM_ADL_Percent	Hypothesis	155.559	1	155.559	11.437
	Error	326.425	24	13.601[b]	
Group	Hypothesis	91.532	1	91.532	6.730
	Error	326.425	24	13.601[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_FAAM_ADL_Percent

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.748	73.688	1.000
	Error				
Pre_FAAM_ADL_Percent	Hypothesis	.002	.323	11.437	.900
	Error				
Group	Hypothesis	.016	.219	6.730	.702
	Error				

a. .009 MS(Group) + .991 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

	Variance Component		
Source	Var(Group)	Var(Error)	Quadratic Term
Intercept	.113	1.000	Intercept
Pre_FAAM_ADL_Percent	.000	1.000	Pre_FAAM_ADL_Percent
Group	12.621	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_FAAM_ADL_Percent

Mean	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound
94.515[a]	.710	93.049	95.981

a. Covariates appearing in the model are evaluated at the following values: Pre_FAAM_ADL_Percent = 87.654320987654320.

2. Group

Dependent Variable: Post_FAAM_ADL_Percent

Group	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	92.611[a]	1.002	90.543	94.678
Intervention	96.419[a]	1.041	94.271	98.567

a. Covariates appearing in the model are evaluated at the following values: Pre_FAAM_ADL_Percent = 87.654320987654320.

Descriptive Statistics

Dependent Variable: Post_FAAM_Sport_Percent

Group	Mean	Std. Deviation	N
Control	80.1020408	11.8628251	14
Intervention	86.2637363	8.35619574	13
Total	83.0687831	10.6034835	27

Tests of Between-Subjects Effects

Dependent Variable: Post_FAAM_Sport_Percent

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	8017.534	1	8017.534	69.200
	Error	2698.026	23.287	115.861[a]	
Pre_FAAM_Sport_Percent	Hypothesis	16.417	1	16.417	.149
	Error	2650.941	24	110.456[b]	
Group	Hypothesis	221.270	1	221.270	2.003
	Error	2650.941	24	110.456[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_FAAM_Sport_Percent

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.748	69.200	1.000
	Error				
Pre_FAAM_Sport_Percent	Hypothesis	.703	.006	.149	.066
	Error				
Group	Hypothesis	.170	.077	2.003	.274
	Error				

a. .049 MS(Group) + .951 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component		
	Var(Group)	Var(Error)	Quadratic Term
Intercept	.632	1.000	Intercept
Pre_FAAM_Sport_Percent	.000	1.000	Pre_FAAM_Sport_Percent
Group	12.950	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_FAAM_Sport_Percent

Mean	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound
83.177 [a]	2.024	79.000	87.354

a. Covariates appearing in the model are evaluated at the following values: Pre_FAAM_Sport_Percent = 67.195767195767190.

2. Group

Dependent Variable: Post_FAAM_Sport_Percent

Group	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	80.254 [a]	2.836	74.400	86.108
Intervention	86.100 [a]	2.946	80.020	92.180

a. Covariates appearing in the model are evaluated at the following values: Pre_FAAM_Sport_Percent = 67.195767195767190.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Intervention	13

Descriptive Statistics

Dependent Variable: Post_IdFAI

Group	Mean	Std. Deviation	N
Control	20.93	3.474	14
Intervention	19.15	4.562	13
Total	20.07	4.057	27

Tests of Between-Subjects Effects

Dependent Variable: Post_IdFAI

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	146.323	1	146.323	9.437	.005
	Error	387.586	24.998	15.505 [a]		
Pre_IdFAI	Hypothesis	38.765	1	38.765	2.529	.125
	Error	367.856	24	15.327 [b]		
Group	Hypothesis	21.109	1	21.109	1.377	.252
	Error	367.856	24	15.327 [b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_IdFAI

Source		Partial Eta Squared	Noncent. Parameter	Observed Power [c]
Intercept	Hypothesis	.274	9.437	.839
	Error			
Pre_IdFAI	Hypothesis	.095	2.529	.333
	Error			
Group	Hypothesis	.054	1.377	.203
	Error			

a. .031 MS(Group) + .969 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.414	1.000	Intercept
Pre_IdFAI	.000	1.000	Pre_IdFAI
Group	13.481	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_IdFAI

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
20.041 [a]	.754	18.485	21.597

a. Covariates appearing in the model are evaluated at the following values: Pre_IdFAI = 21.78.

2. Group

Dependent Variable: Post_IdFAI

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	20.926 [a]	1.046	18.767	23.086
Intervention	19.156 [a]	1.086	16.915	21.398

a. Covariates appearing in the model are evaluated at the following values: Pre_IdFAI = 21.78.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Intervention	13

Descriptive Statistics

Dependent Variable: Post_TSK

Group	Mean	Std. Deviation	N
Control	34.93	5.784	14
Intervention	29.69	3.706	13
Total	32.41	5.493	27

Tests of Between-Subjects Effects

Dependent Variable: Post_TSK

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	88.325	1	88.325	5.535	.029
	Error	312.608	19.588	15.959[a]		
Pre_TSK	Hypothesis	263.337	1	263.337	18.790	.000
	Error	336.361	24	14.015[b]		
Group	Hypothesis	94.533	1	94.533	6.745	.016
	Error	336.361	24	14.015[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_TSK

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.220	5.535	.609
	Error			
Pre_TSK	Hypothesis	.439	18.790	.986
	Error			
Group	Hypothesis	.219	6.745	.703
	Error			

a. .024 MS(Group) + .976 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.310	1.000	Intercept
Pre_TSK	.000	1.000	Pre_TSK
Group	12.839	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_TSK

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
32.336[a]	.721	30.848	33.824

a. Covariates appearing in the model are evaluated at the following values: Pre_TSK = 34.30.

2. Group

Dependent Variable: Post_TSK

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	34.255[a]	1.013	32.165	36.345
Intervention	30.418[a]	1.052	28.247	32.588

a. Covariates appearing in the model are evaluated at the following values: Pre_TSK = 34.30.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Intervention	13

Descriptive Statistics

Dependent Variable: Post_IPAQ_Total_MET

Group	Mean	Std. Deviation	N
Control	4846.107	1972.8310	14
Intervention	5239.077	2578.5687	13
Total	5035.315	2248.2981	27

Tests of Between-Subjects Effects

Dependent Variable: Post_IPAQ_Total_MET

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	69862027.2	1	69862027.2	21.524	.000
	Error	80604164.0	24.833	3245795.5 [a]		
Pre_IPAQ_Total_MET	Hypothesis	29062388.6	1	29062388.6	6.884	.015
	Error	101322620	24	4221775.8 [b]		
Group	Hypothesis	311456.985	1	311456.985	.074	.788
	Error	101322620	24	4221775.8 [b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_IPAQ_Total_MET

Source		Partial Eta Squared	Noncent. Parameter	Observed Power [c]
Intercept	Hypothesis	.464	21.524	.994
	Error			
Pre_IPAQ_Total_MET	Hypothesis	.223	6.884	.711
	Error			
Group	Hypothesis	.003	.074	.058
	Error			

a. .250 MS(Group) + .750 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	3.341	1.000	Intercept
Pre_IPAQ_Total_MET	.000	1.000	Pre_IPAQ_Total_MET
Group	13.384	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_IPAQ_Total_MET

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
5039.310 [a]	395.700	4222.625	5855.994

a. Covariates appearing in the model are evaluated at the following values: Pre_IPAQ_Total_MET = 4970.56.

2. Group

Dependent Variable: Post_IPAQ_Total_MET

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	4931.442 [a]	550.103	3796.085	6066.799
Intervention	5147.178 [a]	570.946	3968.804	6325.551

a. Covariates appearing in the model are evaluated at the following values: Pre_IPAQ_Total_MET = 4970.56.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Intervention	13

Descriptive Statistics

Dependent Variable: V5_GROC

Group	Mean	Std. Deviation	N
Control	2.36	1.985	14
Intervention	3.54	1.198	13
Total	2.93	1.730	27

Tests of Between-Subjects Effects

Dependent Variable: V5_GROC

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	234.296	1	234.296	24.907	.126
	Error	9.407	1	9.407[a]		
GROC_Pre	Hypothesis	.000	0	.	.	.
	Error	.	.	.[b]		
Group	Hypothesis	9.407	1	9.407	3.436	.076
	Error	68.445	25	2.738[c]		

Tests of Between-Subjects Effects

Dependent Variable: V5_GROC

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[d]
Intercept	Hypothesis	.961	24.907	.305
	Error			
GROC_Pre	Hypothesis	.	.	.
	Error			
Group	Hypothesis	.121	3.436	.430
	Error			

a. MS(Group)

b. Cannot compute the appropriate error term using Satterthwaite's method.

c. MS(Error)

d. Computed using alpha = .05

Page

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	13.481	1.000	Intercept
GROC_Pre	.000	.000	
Group	13.481	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: V5_GROC

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
2.948[a]	.319	2.292	3.604

a. Covariates appearing in the model are evaluated at the following values: GROC_Pre = .0000.

2. Group

Dependent Variable: V5_GROC

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	2.357[a]	.442	1.446	3.268
Intervention	3.538[a]	.459	2.593	4.484

a. Covariates appearing in the model are evaluated at the following values: GROC_Pre = .0000.

Group * Change_FAAM_ADL Crosstabulation

Count

		Change_FAAM_ADL						
		-2.38	-1.19	.00	1.19	2.38	4.76	5.95
Group	Control	0	1	2	0	2	1	1
	Intervention	1	0	1	3	0	2	0
Total		1	1	3	3	2	3	1

Group * Change_FAAM_ADL Crosstabulation

Count

		Change_FAAM_ADL						
		7.14	8.33	10.71	11.90	15.48	16.67	27.38
Group	Control	2	1	1	2	0	1	0
	Intervention	1	1	1	0	2	0	1
Total		3	2	2	2	2	1	1

Group * Change_FAAM_Sport Crosstabulation

Count

		Change_FAAM_Sport						
		-17.86	-7.14	-3.57	.00	3.57	10.71	14.29
Group	Control	1	1	2	0	1	0	2
	Intervention	0	0	1	1	2	2	2
Total		1	1	3	1	3	2	4

Group * Change_FAAM_Sport Crosstabulation

Count

		Change_FAAM_Sport						
		17.86	21.43	25.00	32.14	39.29	50.00	57.14
Group	Control	0	2	2	2	0	0	1
	Intervention	1	1	0	1	1	1	0
Total		1	3	2	3	1	1	1

Group * Change_TSK Crosstabulation

Count

		Change_TSK						
		-9.00	-8.00	-7.00	-6.00	-5.00	-4.00	-3.00
Group	Control	0	0	0	0	2	2	0
	Intervention	1	2	1	1	0	1	1
Total		1	2	1	1	2	3	1

Group * Change_TSK Crosstabulation

Count

		Change_TSK						
		-2.00	-1.00	.00	1.00	2.00	3.00	5.00
Group	Control	2	3	2	1	1	0	1
	Intervention	3	0	0	0	2	1	0
Total		5	3	2	1	3	1	1

Group * V5_GROC Crosstabulation

Count

		V5_GROC						
		-1	0	1	2	3	4	5
Group	Control	1	1	4	2	1	2	3
	Intervention	0	0	1	1	4	4	3
Total		1	1	5	3	5	6	6

Group * Post_GROC Crosstabulation

Count

		Post_GROC						
		1	2	3	4	5	6	7
Group	Control	2	1	4	2	1	2	2
	Intervention	0	0	1	0	6	4	2
Total		2	1	5	2	7	6	4

Results for change in ankle inversion angle at initial contact (IC). Good is representative of the ankle angle at IC at the follow-up visit being within the upper limit of the 95% confidence interval for coper group from M1. Bad is representative of the ankle angle at IC at the follow-up visit being greater than value of the upper limit of the 95% confidence interval for coper group from M1.

NBF Group

	Improve TSK $\leq$ 5	Improve TSK $\geq$ 6	OR	UL	LL	p-value
Change IC Good	5	0	1.72	0.03	99.99	0.792
Change IC Bad	9	0				

	GROC $\leq$ 3	GROC $\geq$ 4	OR	UL	LL	p-value
Change IC Good	3	2	0.53	0.058	4.90	0.579
Change IC Bad	4	5				

GBF Group

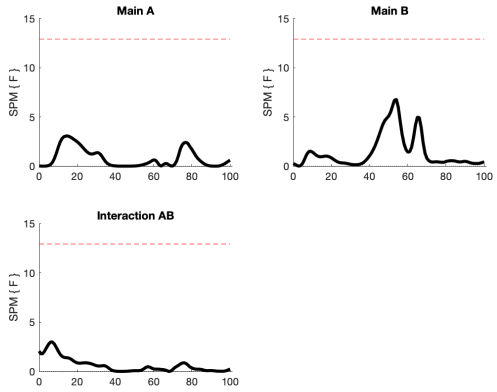
	Improve TSK $\leq$ 5	Improve TSK $\geq$ 6	OR	UL	LL	p-value
Change IC Good	7	3	0.21	0.01	3.37	0.273
Change IC Bad	1	2				

	GROC $\leq$ 3	GROC $\geq$ 4	OR	UL	LL	p-value
Change IC Good	0	10	12.6	0.39	411.13	0.154
Change IC Bad	1	2				

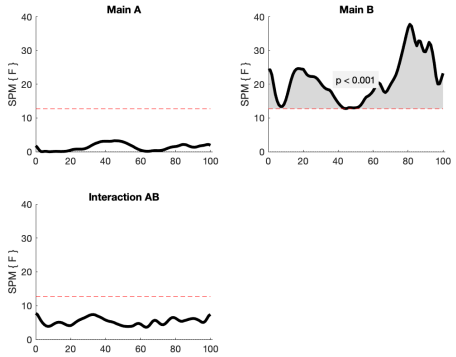
Figure D2. Manuscript 2 SPM Results for the biofeedback and no biofeedback groups.

ANOVA

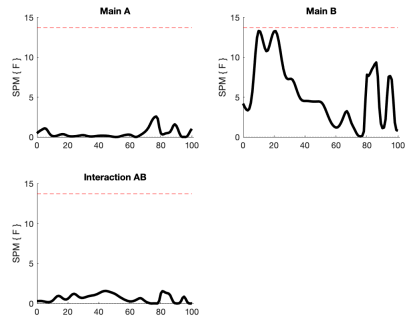
Ankle Sagittal



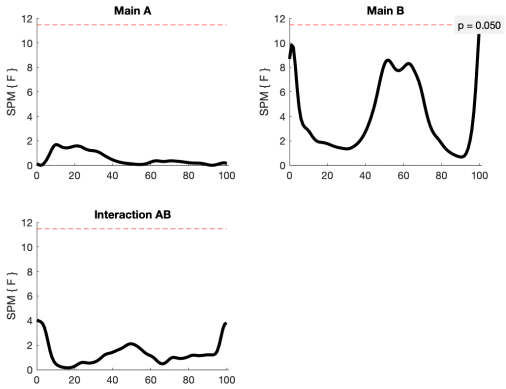
Ankle Frontal



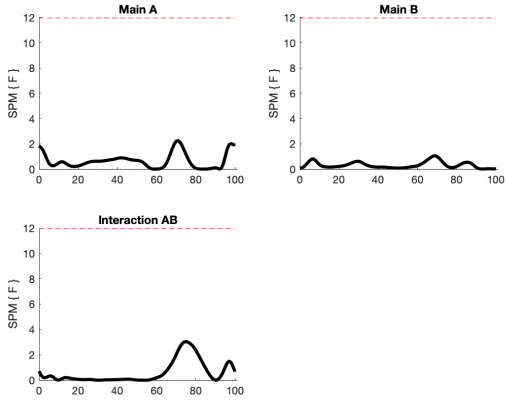
Ankle Transverse



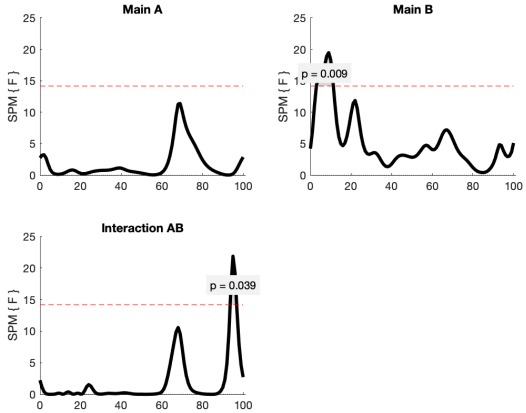
Knee Sagittal



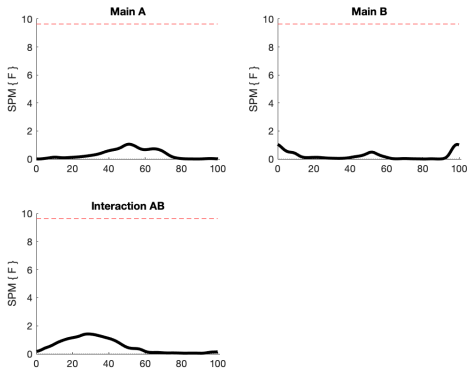
Knee Frontal



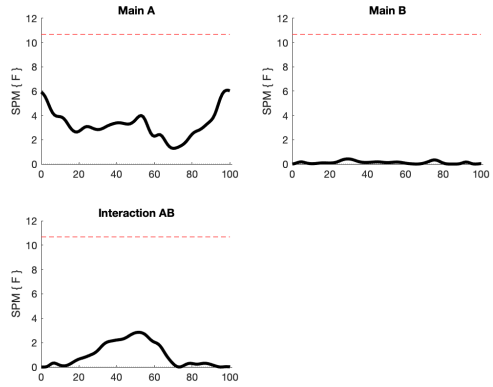
Knee Transverse



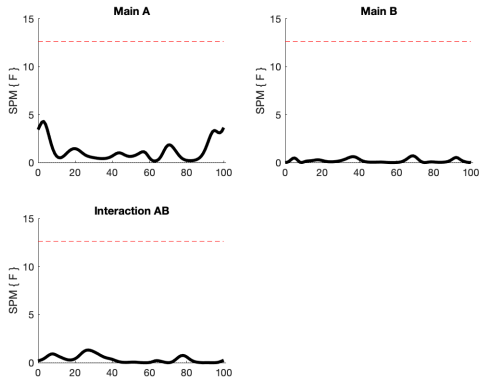
Hip Sagittal



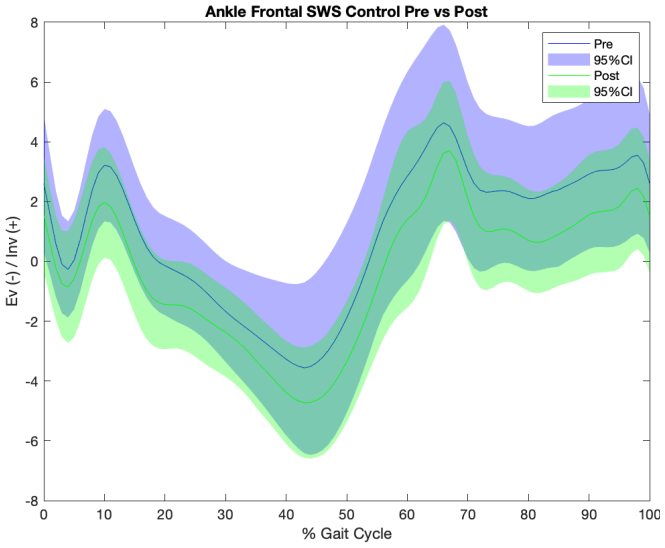
Hip Frontal

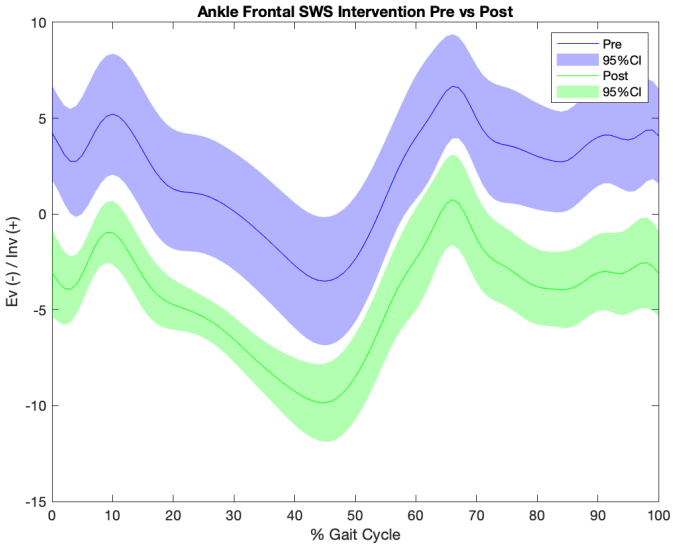


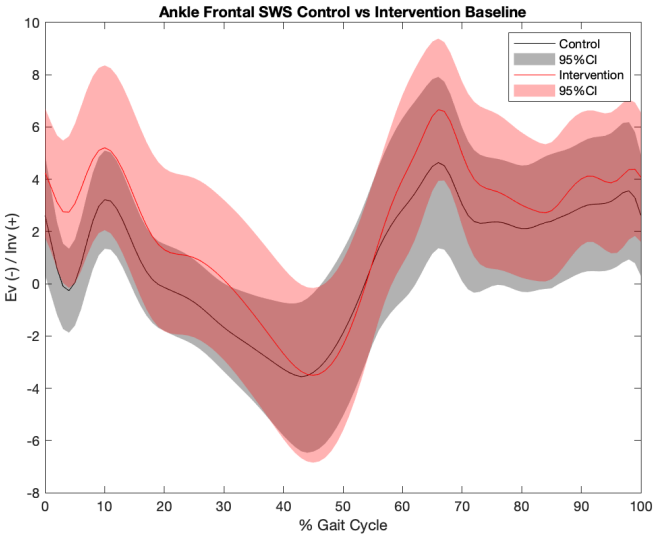
Hip Transverse

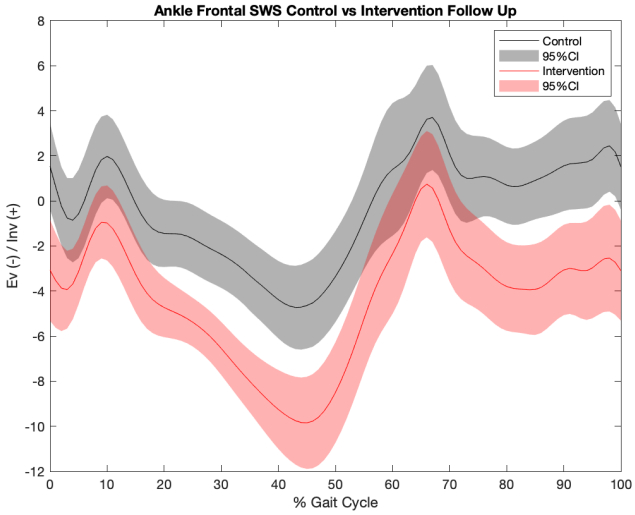


Ankle Frontal

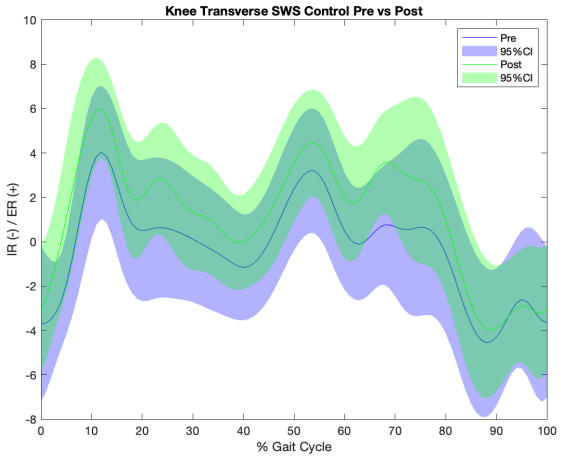


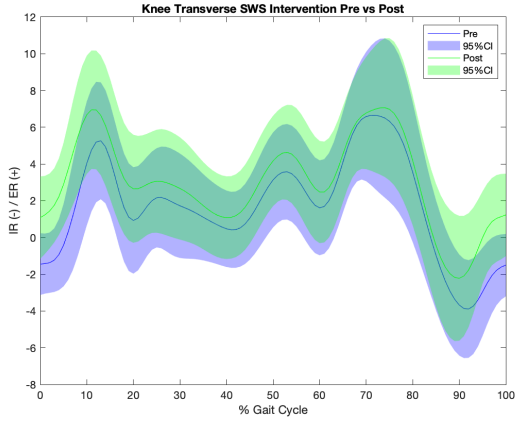


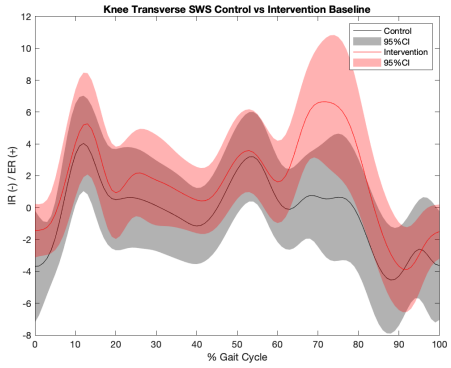


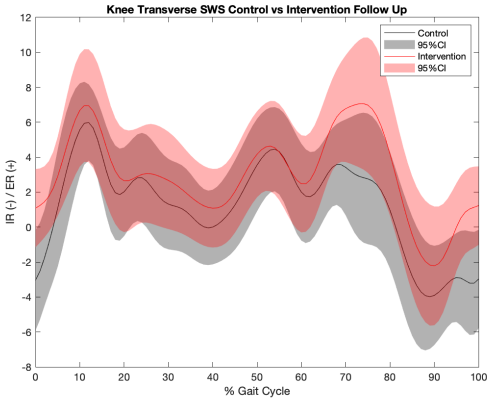


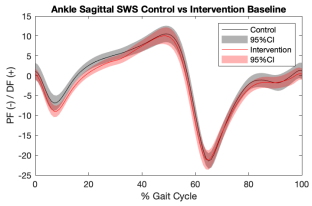
Knee Transverse (ANOVA – Interaction during swing)

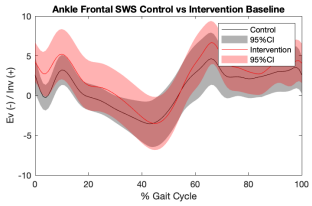


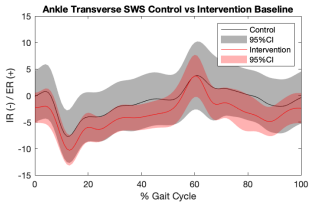


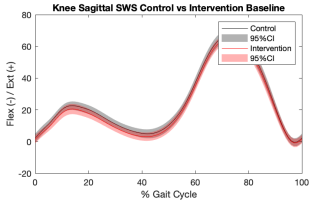


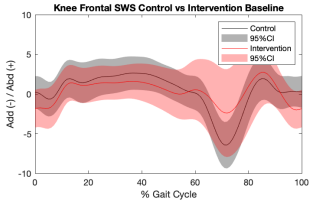


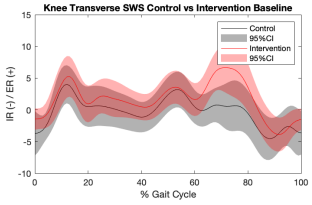

Ankle Sagittal SWS Control vs Intervention Baseline
PF (-) / DF (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

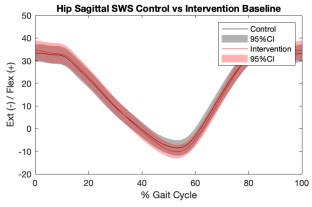

Ankle Frontal SWS Control vs Intervention Baseline
Ev (-) / Inv (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

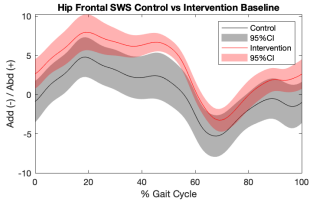

Ankle Transverse SWS Control vs Intervention Baseline
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

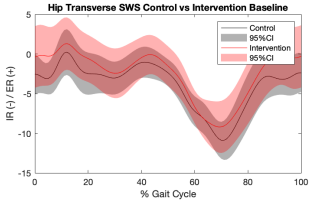

Knee Sagittal SWS Control vs Intervention Baseline
Flex (-) / Ext (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

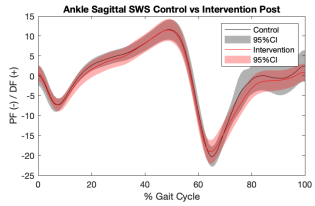

Knee Frontal SWS Control vs Intervention Baseline
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

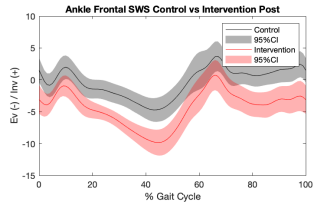

Knee Transverse SWS Control vs Intervention Baseline
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

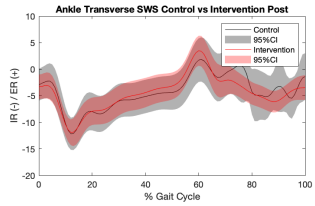

Hip Sagittal SWS Control vs Intervention Baseline
Ext (-) / Flex (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

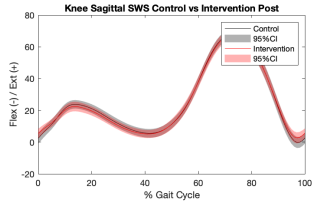

Hip Frontal SWS Control vs Intervention Baseline
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

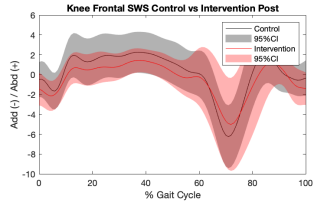

Hip Transverse SWS Control vs Intervention Baseline
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

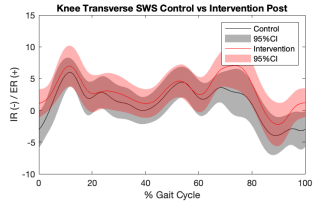

Ankle Sagittal SWS Control vs Intervention Post
PF (-) / DF (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

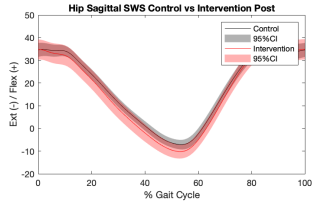

Ankle Frontal SWS Control vs Intervention Post
Ev (-) / Inv (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

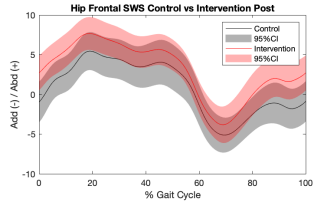

Ankle Transverse SWS Control vs Intervention Post
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

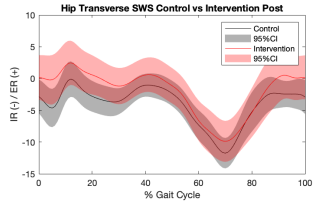

Knee Sagittal SWS Control vs Intervention Post
Flex (-) / Ext (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

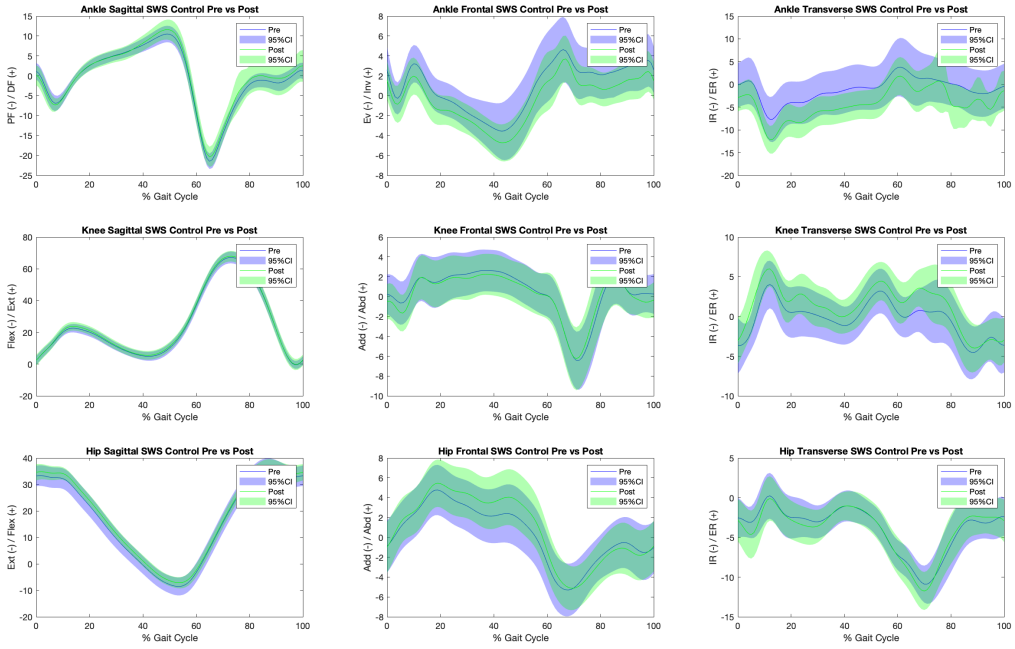

Knee Frontal SWS Control vs Intervention Post
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

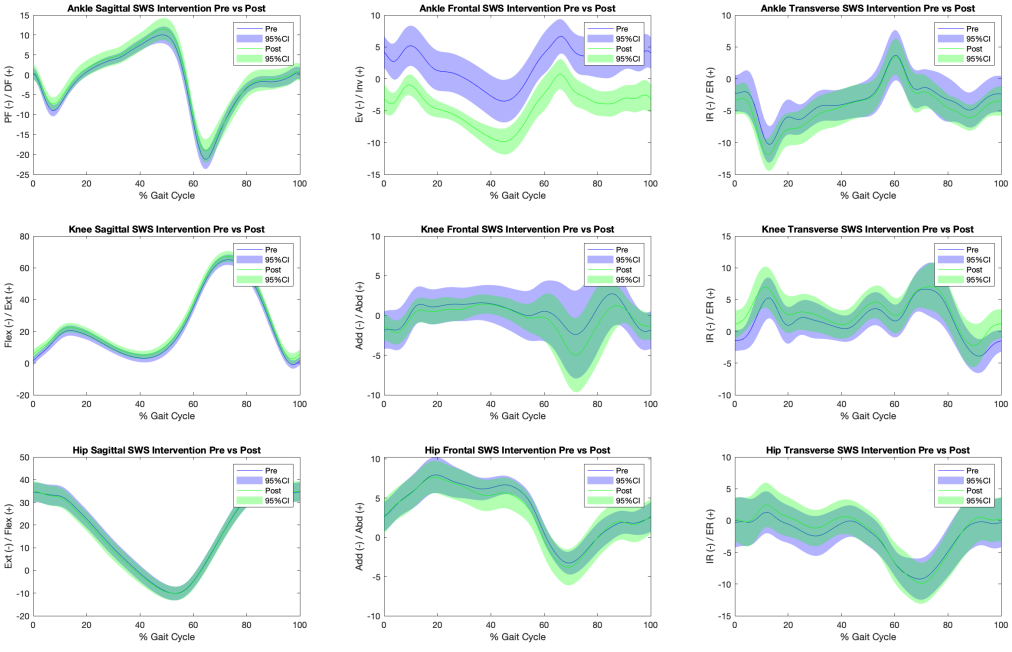

Knee Transverse SWS Control vs Intervention Post
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Hip Sagittal SWS Control vs Intervention Post
Ext (-) / Flex (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Hip Frontal SWS Control vs Intervention Post
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Hip Transverse SWS Control vs Intervention Post
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

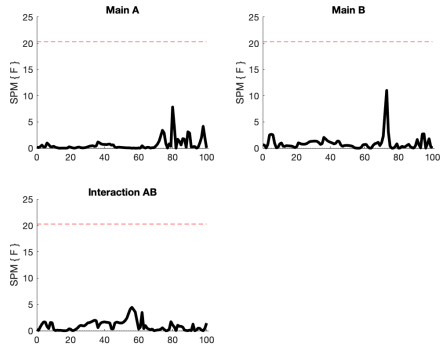

Ankle Sagittal SWS Control Pre vs Post
PF (-) / DF (+)
Ankle Frontal SWS Control Pre vs Post
Ev (-) / Inv (+)
Ankle Transverse SWS Control Pre vs Post
IR (-) / ER (+)
Knee Sagittal SWS Control Pre vs Post
Flex (-) / Ext (+)
Knee Frontal SWS Control Pre vs Post
Add (-) / Abd (+)
Knee Transverse SWS Control Pre vs Post
IR (-) / ER (+)
Hip Sagittal SWS Control Pre vs Post
Ext (-) / Flex (+)
Hip Frontal SWS Control Pre vs Post
Add (-) / Abd (+)
Hip Transverse SWS Control Pre vs Post
IR (-) / ER (+)
% Gait Cycle
Pre
95%CI
Post
95%CI


Ankle Sagittal SWS Intervention Pre vs Post
PF (-) / DF (+)
Ankle Frontal SWS Intervention Pre vs Post
Ev (-) / Inv (+)
Ankle Transverse SWS Intervention Pre vs Post
IR (-) / ER (+)
Knee Sagittal SWS Intervention Pre vs Post
Flex (-) / Ext (+)
Knee Frontal SWS Intervention Pre vs Post
Add (-) / Abd (+)
Knee Transverse SWS Intervention Pre vs Post
IR (-) / ER (+)
Hip Sagittal SWS Intervention Pre vs Post
Ext (-) / Flex (+)
Hip Frontal SWS Intervention Pre vs Post
Add (-) / Abd (+)
Hip Transverse SWS Intervention Pre vs Post
IR (-) / ER (+)
% Gait Cycle
Pre
95%CI
Post
95%CI

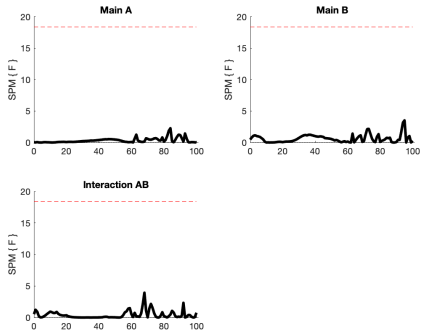
Kinetics

(**No differences for any joints any planes)**

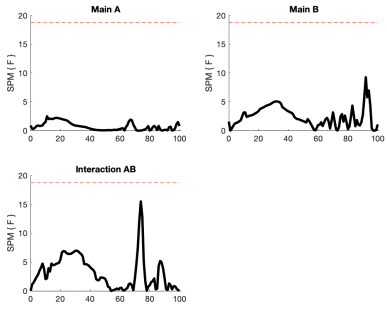
Ankle Sagittal kinetics



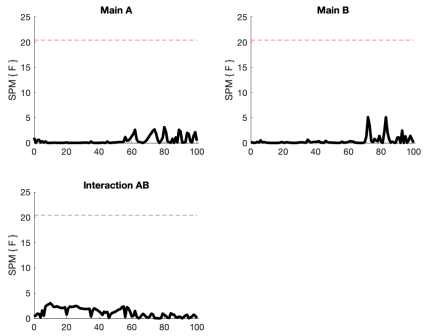
Ankle Frontal kinetics



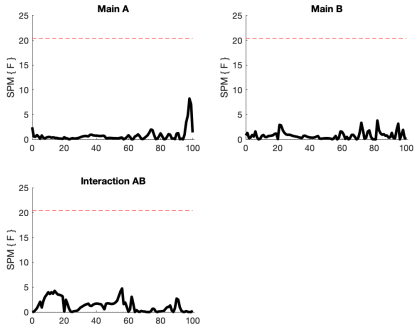
Ankle Transverse kinetics



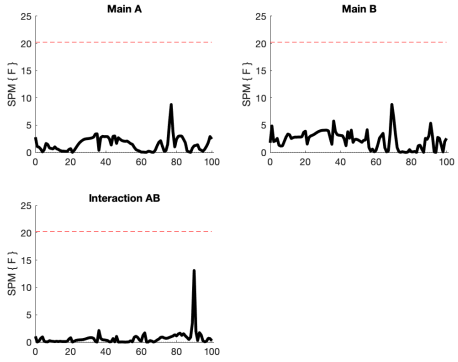
Knee sagittal kinetics



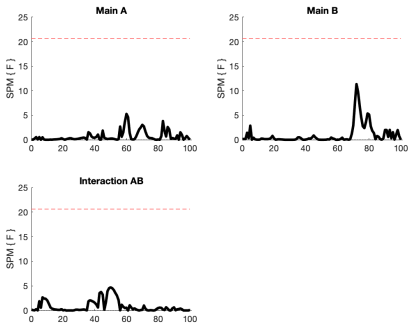
Knee frontal kinetics



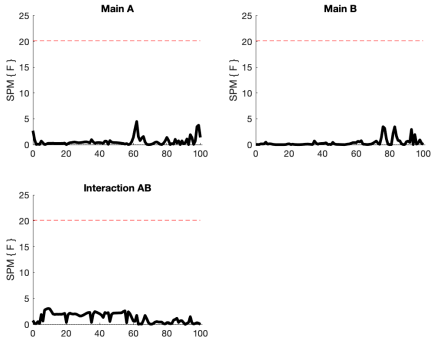
Knee transverse kinetics



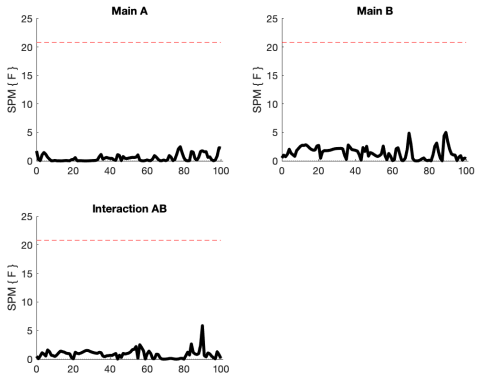
Hip Sagittal kinetics

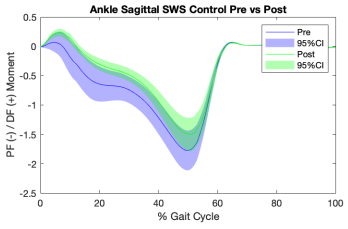


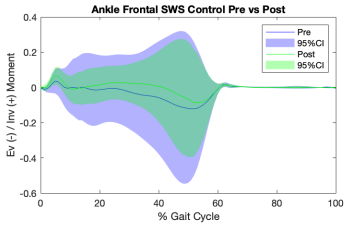
Hip frontal kinetics

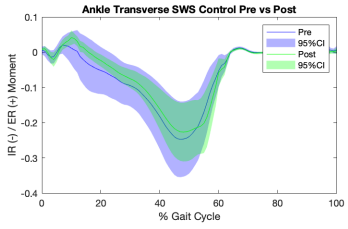


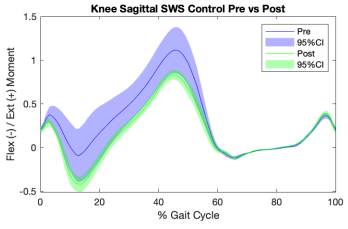
Hip transverse kinetics

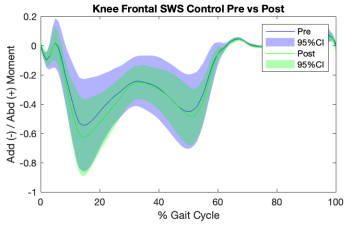



Ankle Sagittal SWS Control Pre vs Post
PF (-) / DF (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Ankle Frontal SWS Control Pre vs Post
Ev (-) / Inv (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Ankle Transverse SWS Control Pre vs Post
IR (-) / ER (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Knee Sagittal SWS Control Pre vs Post
Flex (-) / Ext (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Knee Frontal SWS Control Pre vs Post
Add (-) / Abd (+) Moment
% Gait Cycle
Pre
95%CI
Post
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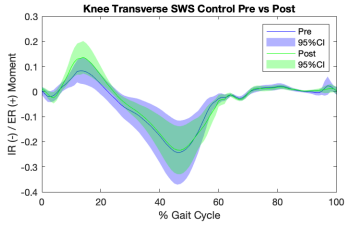
Knee Transverse SWS Control Pre vs Post
IR (-) / ER (+) Moment
% Gait Cycle
Pre
95%CI
Post
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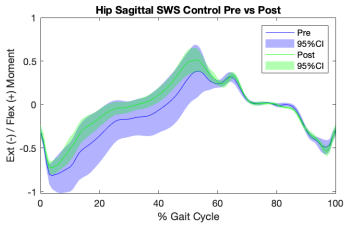
Hip Sagittal SWS Control Pre vs Post
Ext (-) / Flex (+) Moment
% Gait Cycle
Pre
95%CI
Post
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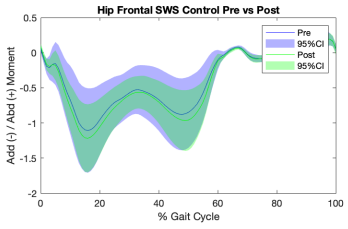
Hip Frontal SWS Control Pre vs Post
Add (-) / Abd (+) Moment
% Gait Cycle
Pre
95%CI
Post
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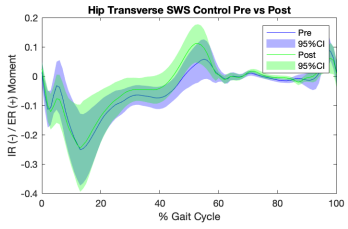
Hip Transverse SWS Control Pre vs Post
IR (-) / ER (+) Moment
% Gait Cycle
Pre
95%CI
Post
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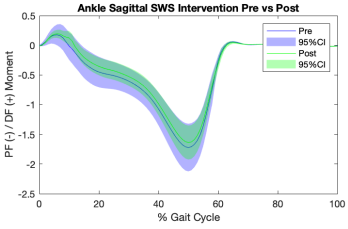
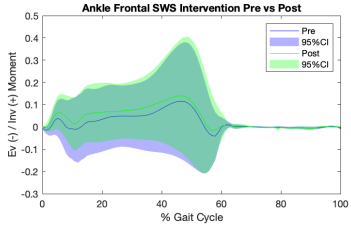

Ankle Sagittal SWS Intervention Pre vs Post
PF (-) / DF (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Ankle Frontal SWS Intervention Pre vs Post
Ev (-) / Inv (+) Moment
% Gait Cycle
Pre
95%CI
Post
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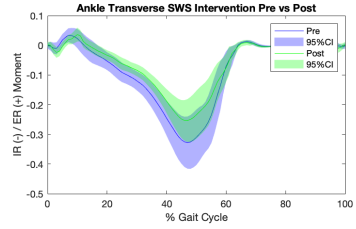
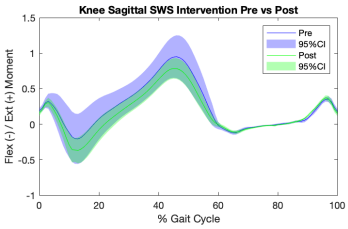
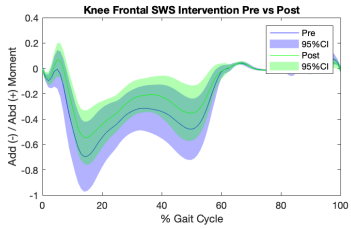
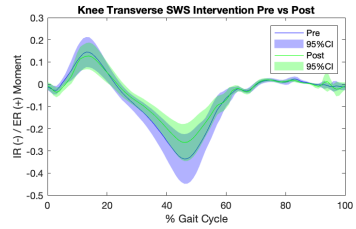
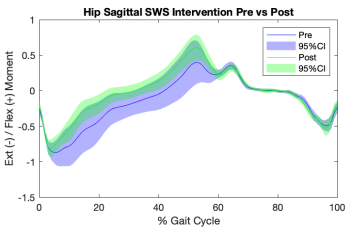

Ankle Transverse SWS Intervention Pre vs Post
IR (-) / ER (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Knee Sagittal SWS Intervention Pre vs Post
Flex (-) / Ext (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Knee Frontal SWS Intervention Pre vs Post
Add (-) / Abd (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Knee Transverse SWS Intervention Pre vs Post
IR (-) / ER (+) Moment
% Gait Cycle
Pre
95%CI
Post
95%CI


Hip Sagittal SWS Intervention Pre vs Post
Ext (-) / Flex (+) Moment
% Gait Cycle
Pre
95%CI
Post
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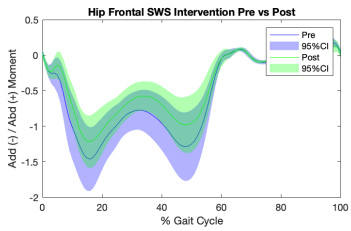
Hip Frontal SWS Intervention Pre vs Post
Add (-) / Abd (+) Moment
% Gait Cycle
Pre
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Post
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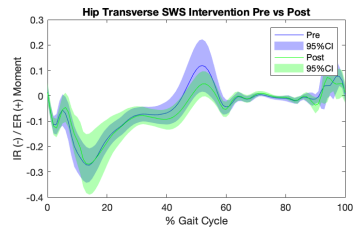
Hip Transverse SWS Intervention Pre vs Post
IR (-) / ER (+) Moment
% Gait Cycle
Pre
95%CI
Post
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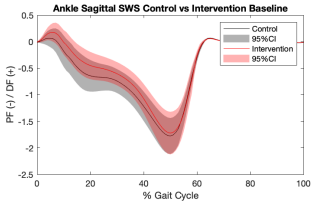
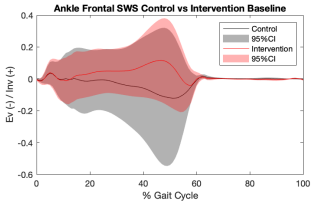
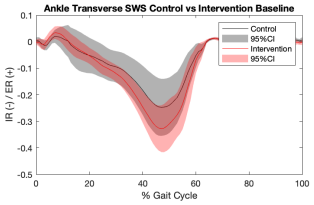
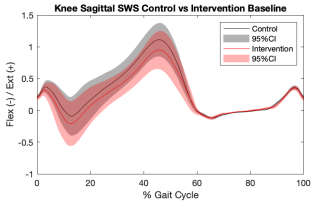
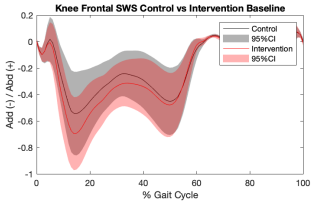

Ankle Sagittal SWS Control vs Intervention Baseline
PF (-) / DF (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Ankle Frontal SWS Control vs Intervention Baseline
Ev (-) / Inv (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Ankle Transverse SWS Control vs Intervention Baseline
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Knee Sagittal SWS Control vs Intervention Baseline
Flex (-) / Ext (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Knee Frontal SWS Control vs Intervention Baseline
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
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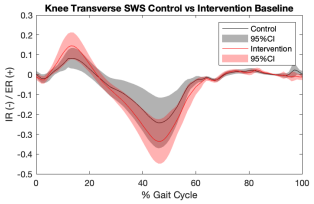
Knee Transverse SWS Control vs Intervention Baseline
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
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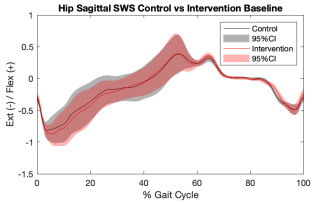
Hip Sagittal SWS Control vs Intervention Baseline
Ext (-) / Flex (+)
% Gait Cycle
Control
95%CI
Intervention
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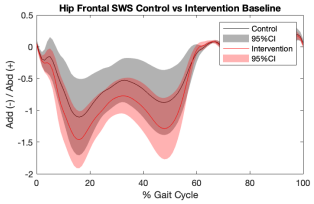
Hip Frontal SWS Control vs Intervention Baseline
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
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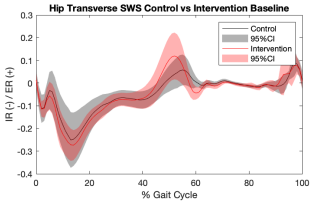
Hip Transverse SWS Control vs Intervention Baseline
IR (-) / ER (+)
% Gait Cycle
Control
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Intervention
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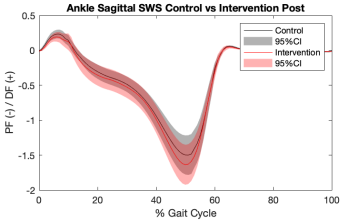
Ankle Sagittal SWS Control vs Intervention Post
PF (-) / DF (+)
% Gait Cycle
Control
95%CI
Intervention
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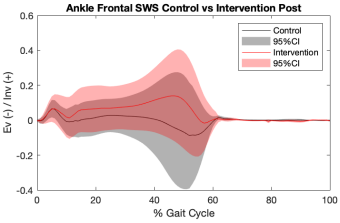
Ankle Frontal SWS Control vs Intervention Post
Ev (-) / Inv (+)
% Gait Cycle
Control
95%CI
Intervention
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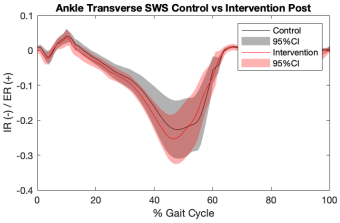
Ankle Transverse SWS Control vs Intervention Post
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
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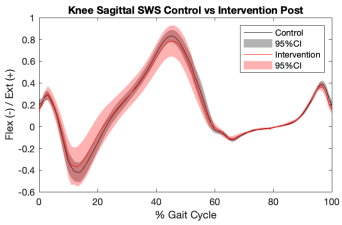
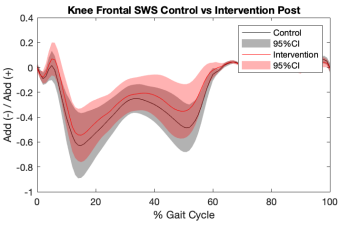

Knee Sagittal SWS Control vs Intervention Post
Flex (-) / Ext (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI


Knee Frontal SWS Control vs Intervention Post
Add (-) / Abd (+)
% Gait Cycle
Control
95%CI
Intervention
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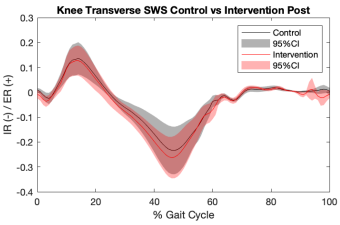
Knee Transverse SWS Control vs Intervention Post
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
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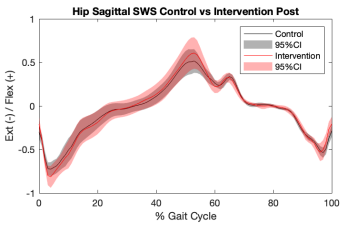
Hip Sagittal SWS Control vs Intervention Post
Ext (-) / Flex (+)
% Gait Cycle
Control
95%CI
Intervention
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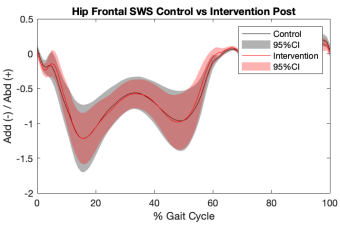
Hip Frontal SWS Control vs Intervention Post
Add (-) / Abd (+)
% Gait Cycle
Control
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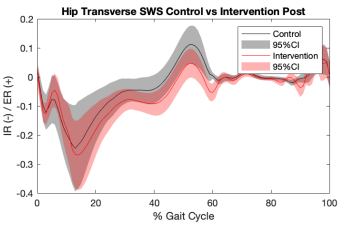
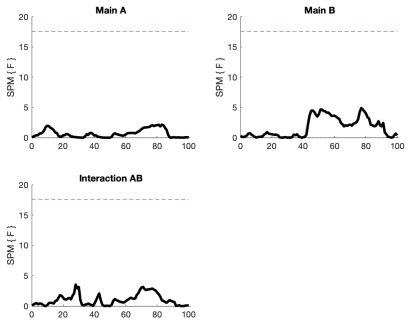
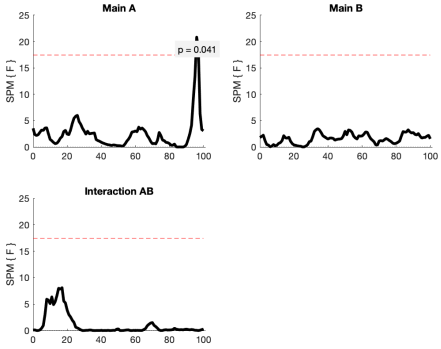

Hip Transverse SWS Control vs Intervention Post
IR (-) / ER (+)
% Gait Cycle
Control
95%CI
Intervention
95%CI

EMG

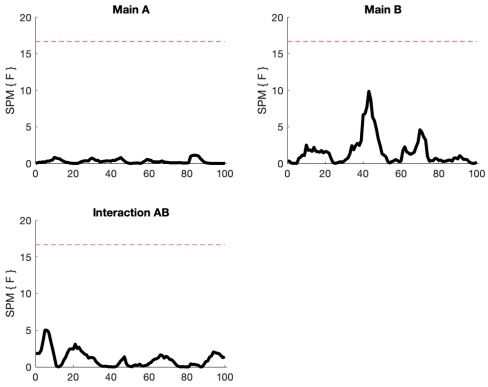
Glute Med



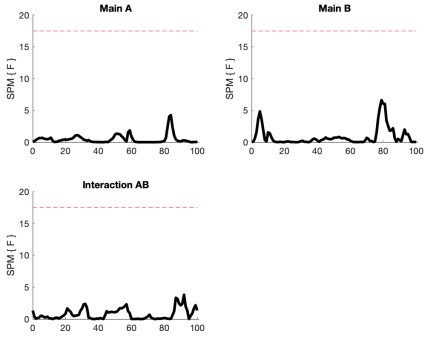
Medial Gastroc

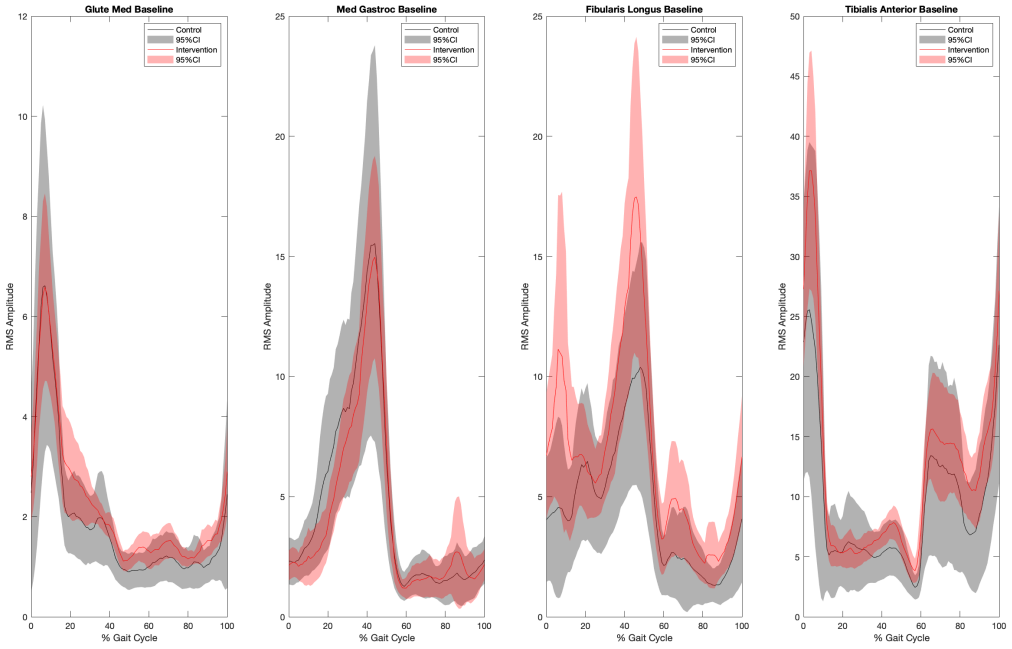


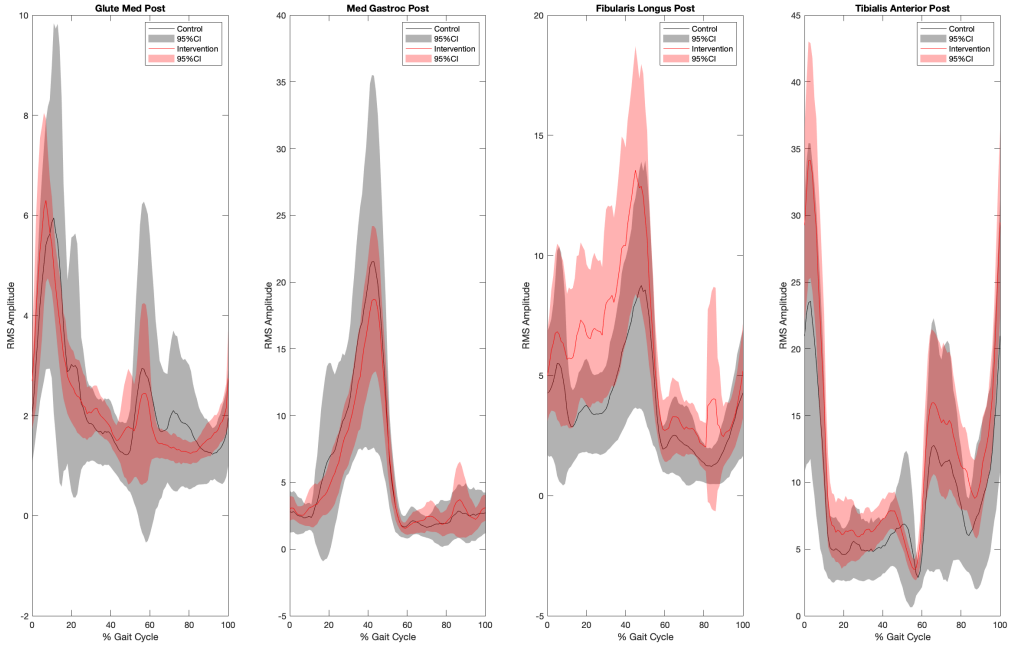
Fibularis Longus

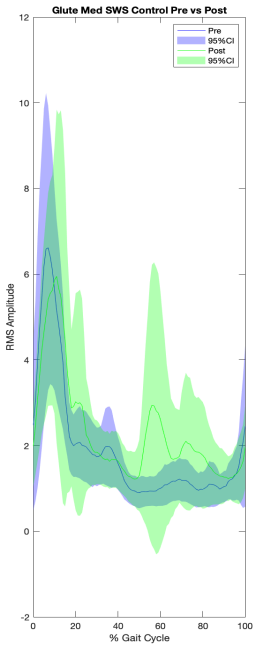


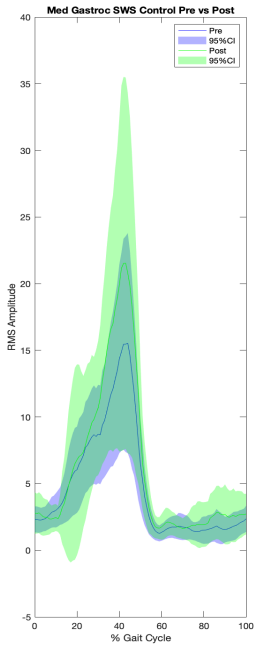
Peroneus Longus

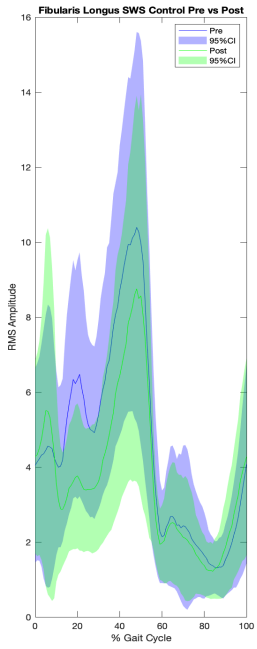


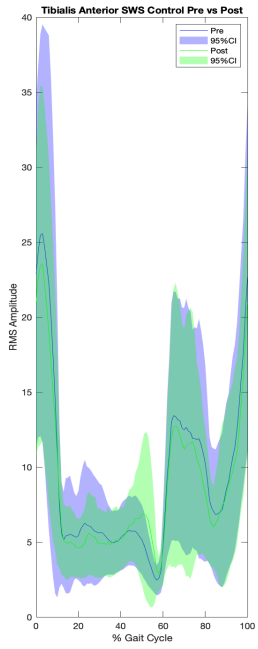

Glute Med Baseline
Med Gastroc Baseline
Fibularis Longus Baseline
Tibialis Anterior Baseline
Control
95%CI
Intervention
95%CI
RMS Amplitude
% Gait Cycle

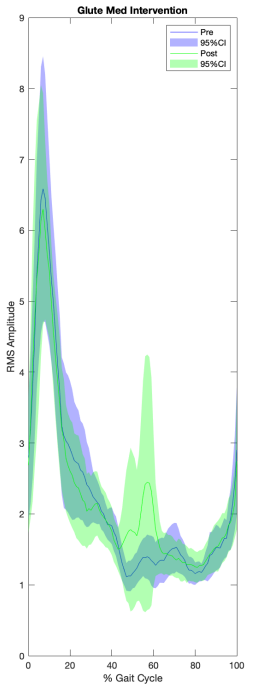

Glute Med Post
Med Gastroc Post
Fibularis Longus Post
Tibialis Anterior Post
Control
95%CI
Intervention
95%CI
RMS Amplitude
% Gait Cycle

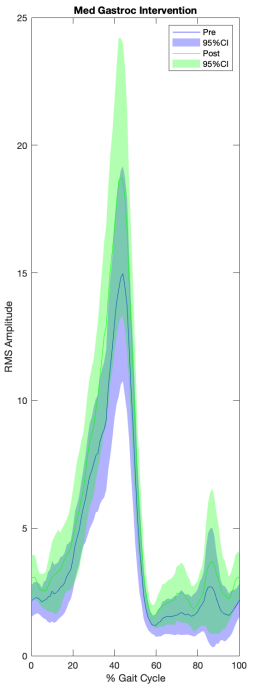

Glute Med SWS Control Pre vs Post
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle

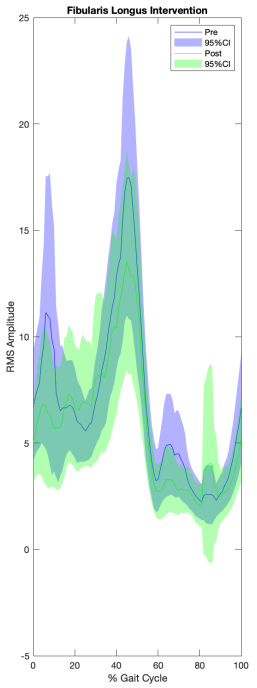

Med Gastroc SWS Control Pre vs Post
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle


Fibularis Longus SWS Control Pre vs Post
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle


Tibialis Anterior SWS Control Pre vs Post
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle


Glute Med Intervention
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle


Med Gastroc Intervention
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle


Fibularis Longus Intervention
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle

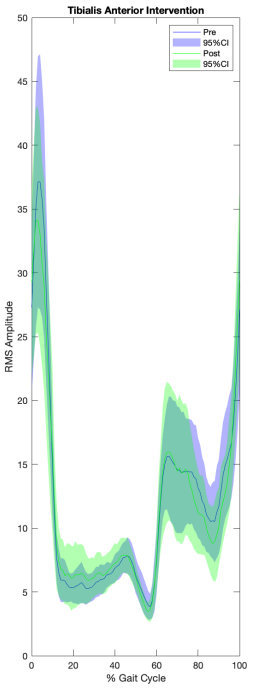

Tibialis Anterior Intervention
Pre
95%CI
Post
95%CI
RMS Amplitude
% Gait Cycle

Table D3. Additional results for Manuscript 3 balance, strength, and ROM

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Gait_Training	13

Descriptive Statistics

Dependent Variable: Post_SEBT_Composite

Group	Mean	Std. Deviation	N
Control	79.2862625	5.27762803	14
Gait_Training	77.4579287	5.48908096	13
Total	78.4059536	5.35719051	27

Tests of Between-Subjects Effects

Dependent Variable: Post_SEBT_Composite

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	559.987	1	559.987	31.848	.000
	Error	430.605	24.490	17.583[a]		
Pre_SEBT_Composite	Hypothesis	302.341	1	302.341	17.223	.000
	Error	421.313	24	17.555[b]		
Group	Hypothesis	20.337	1	20.337	1.158	.292
	Error	421.313	24	17.555[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_SEBT_Composite

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.565	31.848	1.000
	Error			
Pre_SEBT_Composite	Hypothesis	.418	17.223	.978
	Error			
Group	Hypothesis	.046	1.158	.179
	Error			

a. .010 MS(Group) + .990 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

	Variance Component		
Source	Var(Group)	Var(Error)	Quadratic Term
Intercept	.137	1.000	Intercept
Pre_SEBT_Composite	.000	1.000	Pre_SEBT_Composite
Group	13.479	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_SEBT_Composite

Mean	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound
78.374[a]	.807	76.708	80.039

a. Covariates appearing in the model are evaluated at the following values: Pre_SEBT_Composite = 72.172239536893100.

2. Group

Dependent Variable: Post_SEBT_Composite

Group	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	79.242[a]	1.120	76.931	81.554
Gait_Training	77.505[a]	1.162	75.107	79.904

a. Covariates appearing in the model are evaluated at the following values: Pre_SEBT_Composite = 72.172239536893100.

Descriptive Statistics

Dependent Variable: Post_Open_Area_A

Group	Mean	Std. Deviation	N
Control	3.76500000	2.70497092	12
Gait_Training	3.39027778	1.27780546	12
Total	3.57763889	2.07771509	24

Tests of Between-Subjects Effects

Dependent Variable: Post_Open_Area_A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	51.775	1	51.775	15.802	.001
	Error	58.017	17.707	3.276[a]		
Pre_Open_Area	Hypothesis	11.412	1	11.412	2.754	.112
	Error	87.034	21	4.144[b]		
Group	Hypothesis	1.485	1	1.485	.358	.556
	Error	87.034	21	4.144[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_Open_Area_A

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.472	15.802	.963
	Error			
Pre_Open_Area	Hypothesis	.116	2.754	.354
	Error			
Group	Hypothesis	.017	.358	.088
	Error			

a. .326 MS(Group) + .674 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	3.886	1.000	Intercept
Pre_Open_Area	.000	1.000	Pre_Open_Area
Group	11.902	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Open_Area_A

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
3.578 [a]	.416	2.713	4.442

a. Covariates appearing in the model are evaluated at the following values: Pre_Open_Area = 4.308902777777778.

2. Group

Dependent Variable: Post_Open_Area_A

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	3.827 [a]	.589	2.603	5.052
Gait_Training	3.328 [a]	.589	2.103	4.552

a. Covariates appearing in the model are evaluated at the following values: Pre_Open_Area = 4.308902777777778.

Between-Subjects Factors

		Value Label	N
Group	0	Control	12
	1	Gait_Training	12

Descriptive Statistics

Dependent Variable: Post_Closed_Area_A

Group	Mean	Std. Deviation	N
Control	13.0025000	4.68615716	12
Gait_Training	12.9233333	7.10700977	12
Total	12.9629167	5.88736240	24

Tests of Between-Subjects Effects

Dependent Variable: Post_Closed_Area_A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	121.750	1	121.750	5.065	.035
	Error	528.687	21.994	24.038 [a]		
Pre_Closed_Area	Hypothesis	226.891	1	226.891	8.355	.009
	Error	570.275	21	27.156 [b]		
Group	Hypothesis	7.436	1	7.436	.274	.606
	Error	570.275	21	27.156 [b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_Closed_Area_A

Source		Partial Eta Squared	Noncent. Parameter	Observed Power [c]
Intercept	Hypothesis	.187	5.065	.576
	Error			
Pre_Closed_Area	Hypothesis	.285	8.355	.787
	Error			
Group	Hypothesis	.013	.274	.079
	Error			

a. .158 MS(Group) + .842 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	1.844	1.000	Intercept
Pre_Closed_Area	.000	1.000	Pre_Closed_Area
Group	11.660	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Closed_Area_A

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
12.963[a]	1.064	10.751	15.175

a. Covariates appearing in the model are evaluated at the following values: Pre_Closed_Area = 18.994097222222220.

2. Group

Dependent Variable: Post_Closed_Area_A

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	13.528[a]	1.515	10.376	16.679
Gait_Training	12.398[a]	1.515	9.247	15.549

a. Covariates appearing in the model are evaluated at the following values: Pre_Closed_Area = 18.994097222222220.

Between-Subjects Factors

		Value Label	N
Group	0	Control	12
	1	Gait_Training	12

Descriptive Statistics

Dependent Variable: Post_Open_Velocity_A

Group	Mean	Std. Deviation	N
Control	3.11161111	1.22278592	12
Gait_Training	2.66100000	.629430093	12
Total	2.88630556	.978542981	24

Tests of Between-Subjects Effects

Dependent Variable: Post_Open_Velocity_A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	183.647	1	183.647	133.219	.045
	Error	1.507	1.093	1.379[a]		
Pre_Open_Velocity	Hypothesis	.253	1	.253	.258	.616
	Error	20.552	21	.979[b]		
Group	Hypothesis	1.405	1	1.405	1.435	.244
	Error	20.552	21	.979[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_Open_Velocity_A

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.992	133.219	.725
	Error			
Pre_Open_Velocity	Hypothesis	.012	.258	.077
	Error			
Group	Hypothesis	.064	1.435	.208
	Error			

a. .939 MS(Group) + .061 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	10.761	1.000	Intercept
Pre_Open_Velocity	.000	1.000	Pre_Open_Velocity
Group	11.463	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Open_Velocity_A

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
2.886[a]	.202	2.466	3.306

a. Covariates appearing in the model are evaluated at the following values: Pre_Open_Velocity = 8.724152777777777.

2. Group

Dependent Variable: Post_Open_Velocity_A

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	3.134[a]	.289	2.533	3.735
Gait_Training	2.639[a]	.289	2.038	3.240

a. Covariates appearing in the model are evaluated at the following values: Pre_Open_Velocity = 8.724152777777777.

Between-Subjects Factors

		Value Label	N
Group	0	Control	12
	1	Gait_Training	12

Descriptive Statistics

Dependent Variable: Post_Closed_Velocity_A

Group	Mean	Std. Deviation	N
Control	6.95825000	1.73360674	12
Gait_Training	6.64194444	2.08630789	12
Total	6.80009722	1.88286435	24

Tests of Between-Subjects Effects

Dependent Variable: Post_Closed_Velocity_A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	10.309	1	10.309	5.607	.027
	Error	39.523	21.494	1.839[a]		
Pre_Closed_Velocity	Hypothesis	39.654	1	39.654	20.170	.000
	Error	41.285	21	1.966[b]		
Group	Hypothesis	.321	1	.321	.163	.690
	Error	41.285	21	1.966[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_Closed_Velocity_A

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.207	5.607	.618
	Error			
Pre_Closed_Velocity	Hypothesis	.490	20.170	.990
	Error			
Group	Hypothesis	.008	.163	.067
	Error			

a. .077 MS(Group) + .923 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.927	1.000	Intercept
Pre_Closed_Velocity	.000	1.000	Pre_Closed_ Velocity
Group	11.987	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Closed_Velocity_A

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
6.800[a]	.286	6.205	7.395

a. Covariates appearing in the model are evaluated at the following values: Pre_Closed_Velocity = 8.581319444444444.

2. Group

Dependent Variable: Post_Closed_Velocity_A

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	6.916[a]	.405	6.074	7.758
Gait_Training	6.684[a]	.405	5.842	7.526

a. Covariates appearing in the model are evaluated at the following values: Pre_Closed_Velocity = 8.581319444444444.

Between-Subjects Factors

		Value Label	N
Group	0	Control	12
	1	Gait_Training	12

Descriptive Statistics

Dependent Variable: Post_Open_Velocity_A

Group	Mean	Std. Deviation	N
Control	3.11161111	1.22278592	12
Gait_Training	2.66100000	.629430093	12
Total	2.88630556	.978542981	24

Tests of Between-Subjects Effects

Dependent Variable: Post_Open_Velocity_A

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	5.257	1	5.257	6.894	.018
	Error	12.585	16.505	.763[a]		
Pre_Open_Velocity	Hypothesis	5.875	1	5.875	8.263	.009
	Error	14.931	21	.711[b]		
Group	Hypothesis	1.201	1	1.201	1.689	.208
	Error	14.931	21	.711[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_Open_Velocity_A

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.295	6.894	.695
	Error			
Pre_Open_Velocity	Hypothesis	.282	8.263	.783
	Error			
Group	Hypothesis	.074	1.689	.237
	Error			

a. .105 MS(Group) + .895 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	1.262	1.000	Intercept
Pre_Open_Velocity	.000	1.000	Pre_Open_Velocity
Group	12.000	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Open_Velocity_A

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
2.886[a]	.172	2.528	3.244

a. Covariates appearing in the model are evaluated at the following values: Pre_Open_Velocity = 3.164422777777777.

2. Group

Dependent Variable: Post_Open_Velocity_A

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	3.110[a]	.243	2.604	3.616
Gait_Training	2.663[a]	.243	2.156	3.169

a. Covariates appearing in the model are evaluated at the following values: Pre_Open_Velocity = 3.164422777777777.

Strength Measures

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Gait_Training	13

Descriptive Statistics

Dependent Variable: Post_Strength_DF_Avg_Normalized

Group	Mean	Std. Deviation	N
Control	3.81842910	.605173726	14
Gait_Training	3.64914041	.397909920	13
Total	3.73691973	.513443366	27

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_DF_Avg_Normalized

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	10.066	1	10.066	45.159
	Error	5.350	24.000	.223[a]	
Pre_Strength_DF_Avg_Normalized	Hypothesis	1.002	1	1.002	4.250
	Error	5.659	24	.236[b]	
Group	Hypothesis	1.037E-8	1	1.037E-8	.000
	Error	5.659	24	.236[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_DF_Avg_Normalized

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.653	45.159	1.000
	Error				
Pre_Strength_DF_Avg_Normalized	Hypothesis	.050	.150	4.250	.508
	Error				
Group	Hypothesis	1.000	.000	.000	.050
	Error				

a. .055 MS(Group) + .945 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

	Variance Component		
Source	Var(Group)	Var(Error)	Quadratic Term
Intercept	.618	1.000	Intercept
Pre_Strength_DF_Avg_Normalized	.000	1.000	Pre_Strength_DF_Avg_Normalized
Group	11.302	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_DF_Avg_Normalized

Mean	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound
3.737[a]	.094	3.544	3.930

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_DF_Avg_Normalized = 3.258369695886737.

2. Group

Dependent Variable: Post_Strength_DF_Avg_Normalized

Group	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	3.737[a]	.136	3.457	4.017
Gait_Training	3.737[a]	.141	3.445	4.028

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_DF_Avg_Normalized = 3.258369695886737.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Gait_Training	13

Descriptive Statistics

Dependent Variable: Post_Strength_PF_Avg_normalized

Group	Mean	Std. Deviation	N
Control	7.81876641	1.43446776	14
Gait_Training	8.53807775	1.13136088	13
Total	8.16510150	1.32429253	27

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_PF_Avg_normalized

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	44.556	1	44.556	29.045
	Error	35.890	23.396	1.534[a]	
Pre_Strength_PF_Avg_Normalized	Hypothesis	6.981	1	6.981	4.770
	Error	35.128	24	1.464[b]	
Group	Hypothesis	2.941	1	2.941	2.009
	Error	35.128	24	1.464[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_PF_Avg_normalized

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.554	29.045	.999
	Error				
Pre_Strength_PF_Avg_Normalized	Hypothesis	.039	.166	4.770	.554
	Error				
Group	Hypothesis	.169	.077	2.009	.275
	Error				

a. .048 MS(Group) + .952 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.640	1.000	Intercept
Pre_Strength_PF_Avg_Normalized	.000	1.000	Pre_Strength_PF_Avg_Normalized
Group	13.438	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_PF_Avg_normalized

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
8.177[a]	.233	7.696	8.658

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_PF_Avg_Normalized = 6.552155575533559.

2. Group

Dependent Variable: Post_Strength_PF_Avg_normalized

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	7.847[a]	.324	7.179	8.514
Gait_Training	8.508[a]	.336	7.815	9.201

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_PF_Avg_Normalized = 6.552155575533559.

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Inv_Avg

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	2.381	1	2.381	8.446
	Error	5.113	18.137	.282[a]	
Pre_Strength_Inv_Normalized	Hypothesis	3.527	1	3.527	14.271
	Error	5.932	24	.247[b]	
Group	Hypothesis	1.065	1	1.065	4.307
	Error	5.932	24	.247[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Inv_Avg

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.009	.318	8.446	.785
	Error				
Pre_Strength_Inv_Normalized	Hypothesis	.001	.373	14.271	.952
	Error				
Group	Hypothesis	.049	.152	4.307	.513
	Error				

a. .043 MS(Group) + .957 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.547	1.000	Intercept
Pre_Strength_Inv_Normalized	.000	1.000	Pre_Strength_Inv_Normalized
Group	12.867	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_Inv_Avg

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
3.237[a]	.096	3.039	3.435

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_Inv_Normalized = 2.479703869358351.

2. Group

Dependent Variable: Post_Strength_Inv_Avg

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	3.034[a]	.134	2.756	3.311
Gait_Training	3.440[a]	.140	3.152	3.728

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_Inv_Normalized = 2.479703869358351.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Gait_Training	13

Descriptive Statistics

Dependent Variable: Post_Strength_Ev_Avg_Normalized

Group	Mean	Std. Deviation	N
Control	3.98844479	3.00652452	14
Gait_Training	3.31301175	.453998182	13
Total	3.66323629	2.17554617	27

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Ev_Avg_Normalized

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	6.669	1	6.669	1.486
	Error	109.730	24.448	4.488[a]	
Pre_Strength_Ev_Avg_Normalized	Hypothesis	5.038	1	5.038	1.052
	Error	114.945	24	4.789[b]	
Group	Hypothesis	.651	1	.651	.136
	Error	114.945	24	4.789[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Ev_Avg_Normalized

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.234	.057	1.486	.216
	Error				
Pre_Strength_Ev_Avg_Normalized	Hypothesis	.315	.042	1.052	.166
	Error				
Group	Hypothesis	.716	.006	.136	.064
	Error				

a. .073 MS(Group) + .927 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.848	1.000	Intercept
Pre_Strength_Ev_Avg_Normalized	.000	1.000	Pre_Strength_Ev_Avg_Normalized
Group	11.663	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_Ev_Avg_Normalized

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
3.657[a]	.422	2.787	4.527

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_Ev_Avg_Normalized = 2.278005242457588.

2. Group

Dependent Variable: Post_Strength_Ev_Avg_Normalized

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	3.824[a]	.606	2.572	5.076
Gait_Training	3.490[a]	.631	2.188	4.792

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_Ev_Avg_Normalized = 2.278005242457588.

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Hip_Ext_Avg_Normalized

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	4.382	1	4.382	9.988
	Error	10.907	24.860	.439[a]	
Pre_Strength_Hip_Ext_Avg_Normalized	Hypothesis	4.066	1	4.066	9.156
	Error	10.658	24	.444[b]	
Group	Hypothesis	.300	1	.300	.676
	Error	10.658	24	.444[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Hip_Ext_Avg_Normalized

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.004	.287	9.988	.859
	Error				
Pre_Strength_Hip_Ext_Avg_Normalized	Hypothesis	.006	.276	9.156	.827
	Error				
Group	Hypothesis	.419	.027	.676	.124
	Error				

a. .037 MS(Group) + .963 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.497	1.000	Intercept
Pre_Strength_Hip_Ext_Avg_Normalized	.000	1.000	Pre_Strength_Hip_Ext_Avg_Normalized
Group	13.429	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_Hip_Ext_Avg_Normalized

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
4.085[a]	.128	3.820	4.350

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_Hip_Ext_Avg_Normalized = 3.783709111681406.

2. Group

Dependent Variable: Post_Strength_Hip_Ext_Avg_Normalized

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	3.979[a]	.178	3.611	4.347
Gait_Training	4.190[a]	.185	3.808	4.572

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_Hip_Ext_Avg_Normalized = 3.783709111681406.

Descriptive Statistics

Dependent Variable: Post_Strength_Hip_Abd_Avg_Normalized

Group	Mean	Std. Deviation	N
Control	2.51697369	.471806755	14
Gait_Training	2.67072873	.508406372	13
Total	2.59100390	.486545938	27

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Hip_Abd_Avg_Normalized

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	3.336	1	3.336	15.356	.002
	Error	2.849	13.114	.217[a]		
V98	Hypothesis	1.693	1	1.693	9.444	.005
	Error	4.302	24	.179[b]		
Group	Hypothesis	.784	1	.784	4.376	.047
	Error	4.302	24	.179[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_Hip_Abd_Avg_Normalized

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.539	15.356	.951
	Error			
V98	Hypothesis	.282	9.444	.838
	Error			
Group	Hypothesis	.154	4.376	.519
	Error			

a. .063 MS(Group) + .937 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.711	1.000	Intercept
V98	.000	1.000	V98
Group	11.331	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_Hip_Abd_Avg_Normalized

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
2.598[a]	.082	2.430	2.766

a. Covariates appearing in the model are evaluated at the following values: V98 = 2.128396463186053.

2. Group

Dependent Variable: Post_Strength_Hip_Abd_Avg_Normalized

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	2.412[a]	.118	2.168	2.656
Gait_Training	2.784[a]	.123	2.530	3.038

a. Covariates appearing in the model are evaluated at the following values: V98 = 2.128396463186053.

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_2_5_Flex_Avg

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	4.722	1	4.722	26.106
	Error	2.136	11.807	.181[a]	
Pre_Strength_2_5_Flex_Avg_Normalized	Hypothesis	.376	1	.376	2.528
	Error	3.569	24	.149[b]	
Group	Hypothesis	.530	1	.530	3.565
	Error	3.569	24	.149[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_2_5_Flex_Avg

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.689	26.106	.997
	Error				
Pre_Strength_2_5_Flex_Avg_Normalized	Hypothesis	.125	.095	2.528	.333
	Error				
Group	Hypothesis	.071	.129	3.565	.441
	Error				

a. .084 MS(Group) + .916 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	1.119	1.000	Intercept
Pre_Strength_2_5_Flex_Avg_Normalized	.000	1.000	Pre_Strength_2_5_Flex_Avg_Normalized
Group	13.274	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_2_5_Flex_Avg

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
1.845[a]	.074	1.692	1.999

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_2_5_Flex_Avg_Normalized = 1.210373399502117.

2. Group

Dependent Variable: Post_Strength_2_5_Flex_Avg

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	1.704[a]	.103	1.491	1.918
Gait_Training	1.987[a]	.107	1.765	2.208

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_2_5_Flex_Avg_Normalized = 1.210373399502117.

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_1_Toe_Flex_Avg_Normalized

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	5.470	1	5.470	32.438
	Error	1.597	9.470	.169[a]	
Pre_Strength_1_Toe_Flex_Avg_Normalized	Hypothesis	.068	1	.068	.528
	Error	3.076	24	.128[b]	
Group	Hypothesis	.730	1	.730	5.697
	Error	3.076	24	.128[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Strength_1_Toe_Flex_Avg_Normalized

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.774	32.438	.999
	Error				
Pre_Strength_1_Toe_Flex_Avg_Normalized	Hypothesis	.475	.022	.528	.107
	Error				
Group	Hypothesis	.025	.192	5.697	.630
	Error				

a. .067 MS(Group) + .933 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.886	1.000	Intercept
Pre_Strength_1_Toe_Flex_Avg_Normalized	.000	1.000	Pre_Strength_1_Toe_Flex_Avg_Normalized
Group	13.180	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Strength_1_Toe_Flex_Avg_Normalized

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
1.947[a]	.069	1.804	2.089

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_1_Toe_Flex_Avg_Normalized = 1.189958079566235.

2. Group

Dependent Variable: Post_Strength_1_Toe_Flex_Avg_Normalized

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	1.780[a]	.096	1.582	1.979
Gait_Training	2.113[a]	.100	1.907	2.319

a. Covariates appearing in the model are evaluated at the following values: Pre_Strength_1_Toe_Flex_Avg_Normalized = 1.189958079566235.

ROM

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_DF_ROM_Average

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	390.919	1	390.919	18.143
	Error	170.193	7.899	21.547[a]	
Pre_Ankle_DF_Average	Hypothesis	1680.456	1	1680.456	54.649
	Error	737.998	24	30.750[b]	
Group	Hypothesis	13.364	1	13.364	.435
	Error	737.998	24	30.750[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_DF_ROM_Average

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.003	.697	18.143	.959
	Error				
Pre_Ankle_DF_Average	Hypothesis	.000	.695	54.649	1.000
	Error				
Group	Hypothesis	.516	.018	.435	.097
	Error				

a. .529 MS(Group) + .471 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

	Variance Component		
Source	Var(Group)	Var(Error)	Quadratic Term
Intercept	7.115	1.000	Intercept
Pre_Ankle_DF_Average	.000	1.000	Pre_Ankle_DF_Average
Group	13.441	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Ankle_DF_ROM_Average

Mean	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound
12.693[a]	1.068	10.489	14.897

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_DF_Average = 8.271604938271604.

2. Group

Dependent Variable: Post_Ankle_DF_ROM_Average

Group	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	11.988[a]	1.483	8.927	15.049
Gait_Training	13.398[a]	1.539	10.221	16.575

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_DF_Average = 8.271604938271604.

Descriptive Statistics

Dependent Variable: Post_Ankle_PF_ROM_Average

Group	Mean	Std. Deviation	N
Control	72.2857143	9.96734595	14
Gait_Training	82.1794872	7.35302329	13
Total	77.0493827	10.0003007	27

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_PF_ROM_Average

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	66.907	1	66.907	1.499
	Error	1018.445	22.825	44.620 [a]	
Pre_Ankle_PF_Average	Hypothesis	967.648	1	967.648	23.876
	Error	972.680	24	40.528 [b]	
Group	Hypothesis	463.176	1	463.176	11.428
	Error	972.680	24	40.528 [b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_PF_ROM_Average

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power [c]
Intercept	Hypothesis	.233	.062	1.499	.217
	Error				
Pre_Ankle_PF_Average	Hypothesis	.000	.499	23.876	.997
	Error				
Group	Hypothesis	.002	.323	11.428	.900
	Error				

a. .010 MS(Group) + .990 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	.128	1.000	Intercept
Pre_Ankle_PF_Average	.000	1.000	Pre_Ankle_PF_Average
Group	13.263	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Ankle_PF_ROM_Average

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
77.204[a]	1.226	74.674	79.735

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_PF_Average = 73.148148148148140.

2. Group

Dependent Variable: Post_Ankle_PF_ROM_Average

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	73.026[a]	1.708	69.500	76.551
Gait_Training	81.383[a]	1.773	77.723	85.042

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_PF_Average = 73.148148148148140.

Between-Subjects Factors

		Value Label	N
Group	0	Control	14
	1	Gait_Training	13

Descriptive Statistics

Dependent Variable: Post_Ankle_Inv_Average

Group	Mean	Std. Deviation	N
Control	34.4047619	9.97019367	14
Gait_Training	31.0256410	11.3508537	13
Total	32.7777778	10.5890606	27

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_Inv_Average

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	1866.224	1	1866.224	16.677
	Error	2566.358	22.933	111.905[a]	
Pre_Ankle_Inv_Average	Hypothesis	136.827	1	136.827	1.216
	Error	2701.538	24	112.564[b]	
Group	Hypothesis	106.230	1	106.230	.944
	Error	2701.538	24	112.564[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_Inv_Average

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.421	16.677	.974
	Error				
Pre_Ankle_Inv_Average	Hypothesis	.281	.048	1.216	.185
	Error				
Group	Hypothesis	.341	.038	.944	.154
	Error				

Expected Mean Squares[a,b]

	Variance Component		
Source	Var(Group)	Var(Error)	Quadratic Term
Intercept	1.377	1.000	Intercept
Pre_Ankle_Inv_Average	.000	1.000	Pre_Ankle_Inv_Average
Group	13.224	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Ankle_Inv_Average

		95% Confidence Interval	
Mean	Std. Error	Lower Bound	Upper Bound
32.704[a]	2.043	28.486	36.921

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_Inv_Average = 33.074074074074080.

2. Group

Dependent Variable: Post_Ankle_Inv_Average

			95% Confidence Interval	
Group	Mean	Std. Error	Lower Bound	Upper Bound
Control	34.708[a]	2.849	28.828	40.587
Gait_Training	30.699[a]	2.957	24.596	36.803

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_Inv_Average

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_Ev_Average

Source		Type III Sum of Squares	df	Mean Square	F
Intercept	Hypothesis	1008.897	1	1008.897	30.504
	Error	766.699	23.181	33.074[a]	
Pre_Ankle_Ev_Average	Hypothesis	19.660	1	19.660	.467
	Error	1009.862	24	42.078[b]	
Group	Hypothesis	10.877	1	10.877	.258
	Error	1009.862	24	42.078[b]	

Tests of Between-Subjects Effects

Dependent Variable: Post_Ankle_Ev_Average

Source		Sig.	Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.000	.568	30.504	1.000
	Error				
Pre_Ankle_Ev_Average	Hypothesis	.501	.019	.467	.101
	Error				
Group	Hypothesis	.616	.011	.258	.078
	Error				

a. .289 MS(Group) + .711 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares[a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	3.538	1.000	Intercept
Pre_Ankle_Ev_Average	.000	1.000	Pre_Ankle_Ev_Average
Group	12.260	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_Ankle_Ev_Average

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
13.383[a]	1.249	10.804	15.961

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_Ev_Average = 11.864197530864200.

2. Group

Dependent Variable: Post_Ankle_Ev_Average

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	12.717[a]	1.775	9.054	16.380
Gait_Training	14.049[a]	1.845	10.241	17.857

a. Covariates appearing in the model are evaluated at the following values: Pre_Ankle_Ev_Average = 11.864197530864200.

Descriptive Statistics

Dependent Variable: Post_WB_DF_cm

Group	Mean	Std. Deviation	N
Control	13.900	3.6776	14
Gait_Training	12.792	4.2586	13
Total	13.367	3.9307	27

Tests of Between-Subjects Effects

Dependent Variable: Post_WB_DF_cm

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Intercept	Hypothesis	12.903	1	12.903	3.634	.069
	Error	85.251	24.011	3.550[a]		
Pre_WB_DF_cm	Hypothesis	300.123	1	300.123	77.180	.000
	Error	93.326	24	3.889[b]		
Group	Hypothesis	.010	1	.010	.002	.961
	Error	93.326	24	3.889[b]		

Tests of Between-Subjects Effects

Dependent Variable: Post_WB_DF_cm

Source		Partial Eta Squared	Noncent. Parameter	Observed Power[c]
Intercept	Hypothesis	.131	3.634	.448
	Error			
Pre_WB_DF_cm	Hypothesis	.763	77.180	1.000
	Error			
Group	Hypothesis	.000	.002	.050
	Error			

a. .087 MS(Group) + .913 MS(Error)

b. MS(Error)

c. Computed using alpha = .05

Expected Mean Squares [a,b]

Source	Variance Component: Var(Group)	Var(Error)	Quadratic Term
Intercept	1.142	1.000	Intercept
Pre_WB_DF_cm	.000	1.000	Pre_WB_DF_cm
Group	13.095	1.000	
Error	.000	1.000	

a. For each source, the expected mean square equals the sum of the coefficients in the cells times the variance components, plus a quadratic term involving effects in the Quadratic Term cell.

b. Expected Mean Squares are based on the Type III Sums of Squares.

Estimated Marginal Means

1. Grand Mean

Dependent Variable: Post_WB_DF_cm

Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
13.367 [a]	.380	12.584	14.151

a. Covariates appearing in the model are evaluated at the following values: Pre_WB_DF_cm = 11.222.

2. Group

Dependent Variable: Post_WB_DF_cm

Group	Mean	Std. Error	95% Confidence Interval: Lower Bound	Upper Bound
Control	13.348 [a]	.531	12.253	14.444
Gait_Training	13.387 [a]	.551	12.249	14.524

a. Covariates appearing in the model are evaluated at the following values: Pre_WB_DF_cm = 11.222.

APPENDIX E

BIBLIOGRAPHY

1. Arnold BL, Linens SW, de la Motte SJ, Ross SE. Concentric Evertor Strength Differences and Functional Ankle Instability: A Meta-Analysis. *J Athl Train*. 2009;44(6):653-662. doi:10.4085/1062-6050-44.6.653.

2. Arnold BL, Wright CJ, Ross SE. Functional Ankle Instability and Health-Related Quality of Life. *J Athl Train*. 2011;46(6):634-641. doi:10.4085/1062-6050-46.6.634.

3. Chinn L, Dicharry J, Hertel J. Ankle kinematics of individuals with chronic ankle instability while walking and jogging on a treadmill in shoes. *Phys Ther Sport*. 2013;14(4):232-239. doi:10.1016/j.ptsp.2012.10.001.

4. Clifton DR, Koldenhoven RM, Hertel J, Onate JA, Dompier TP, Kerr ZY. Epidemiological Patterns of Ankle Sprains in Youth, High School, and College Football. *Am J Sports Med*. October 2016:0363546516667914. doi:10.1177/0363546516667914.

5. Cruz-Díaz D, Lomas Vega R, Osuna-Pérez MC, Hita-Contreras F, Martínez-Amat A. Effects of joint mobilization on chronic ankle instability: a randomized controlled trial. *Disabil Rehabil*. 2015;37(7):601-610. doi:10.3109/09638288.2014.935877.

6. Davis IS, Futrell E. Gait Retraining: Altering the Fingerprint of Gait. *Phys Med Rehabil Clin N Am*. 2016;27(1):339-355. doi:10.1016/j.pmr.2015.09.002.

7. De Ridder R, Willems T, Vanrenterghem J, Robinson M, Pataky T, Roosen P. Gait kinematics of subjects with ankle instability using a multisegmented foot model. *Med Sci Sports Exerc*. 2013;45(11):2129-2136. doi:10.1249/MSS.0b013e31829991a2.

8. De Ridder R, Witvrouw E, Dolphens M, Roosen P, Van Ginckel A. Hip Strength as an Intrinsic Risk Factor for Lateral Ankle Sprains in Youth Soccer Players: A 3-Season Prospective Study. *Am J Sports Med*. 2017;45(2):410-416. doi:10.1177/0363546516672650.

9. Delahunt E, Monaghan K, Caulfield B. Altered Neuromuscular Control and Ankle Joint Kinematics During Walking in Subjects With Functional Instability of the Ankle Joint. *Am J Sports Med*. 2006;34(12):1970-1976.

10. Denegar CR, Hertel J, Fonseca J. The Effect of Lateral Ankle Sprain on Dorsiflexion Range of Motion, Posterior Talar Glide, and Joint Laxity. *J Orthop Sports Phys Ther*. 2002;32(4):166-173. doi:10.2519/jospt.2002.32.4.166.

11. Doherty C, Bleakley C, Hertel J, et al. Inter-joint coordination strategies during unilateral stance following first-time, acute lateral ankle sprain: A brief report. *Clin Biomech*. 2015;30(6):636-639. doi:10.1016/j.clinbiomech.2015.04.012.

12. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Locomotive biomechanics in persons with chronic ankle instability and lateral ankle sprain copers. *J Sci Med Sport*. 2016;19(7):524-530. doi:10.1016/j.jsams.2015.07.010.

13. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Lower extremity function during gait in participants with first time acute lateral ankle sprain compared to controls. *J Electromyogr Kinesiol*. 2015;25(1):182-192. doi:10.1016/j.jelekin.2014.09.004.

14. Doherty C, Bleakley C, Hertel J, Caulfield B, Ryan J, Delahunt E. Recovery From a First-Time Lateral Ankle Sprain and the Predictors of Chronic Ankle Instability A Prospective Cohort Analysis. *Am J Sports Med*. 2016;44(4):995-1003.

15. Doherty C, Delahunt E, Caulfield B, Hertel J, Ryan J, Bleakley C. The Incidence and Prevalence of Ankle Sprain Injury: A Systematic Review and Meta-Analysis of Prospective Epidemiological Studies. *Sports Med*. 2014;44(1):123-140. doi:10.1007/s40279-013-0102-5.

16. Donnelly L, Donovan L, Hart JM, Hertel J. Eversion Strength and Surface Electromyography Measures With and Without Chronic Ankle Instability Measured in 2 Positions. *Foot Ankle Int*. 2017;38(7):769-778. doi:10.1177/1071100717701231.

17. Donovan L, Feger MA, Hart JM, Saliba S, Park J, Hertel J. Effects of an auditory biofeedback device on plantar pressure in patients with chronic ankle instability. *Gait Posture*. 2016;44:29-36. doi:10.1016/j.gaitpost.2015.10.013.

18. Donovan L, Hart JM, Saliba S, et al. Effects of ankle destabilization devices and rehabilitation on gait biomechanics in chronic ankle instability patients: A randomized controlled trial. *Phys Ther Sport*. 2016;21:46-56. doi:10.1016/j.ptsp.2016.02.006.

19. Donovan L, Hart JM, Saliba SA, et al. Rehabilitation for Chronic Ankle Instability With or Without Destabilization Devices: A Randomized Controlled Trial. *J Athl Train*. 2016;51(3):233-251. doi:10.4085/1062-6050-51.3.09.

20. Donovan L, Hertel J. A new paradigm for rehabilitation of patients with chronic ankle instability. *Phys Sportsmed*. 2012;40(4):41-51. doi:10.3810/psm.2012.11.1987.

21. Drewes LK, McKeon PO, Casey Kerrigan D, Hertel J. Dorsiflexion deficit during jogging with chronic ankle instability. *J Sci Med Sport*. 2009;12(6):685-687. doi:10.1016/j.jsams.2008.07.003.

22. Drewes LK, McKeon PO, Paolini G, et al. Altered ankle kinematics and shank-rear-foot coupling in those with chronic ankle instability. *J Sport Rehabil*. 2009;18(3):375.

23. Evans T, Hertel J, Sebastianelli W. Bilateral Deficits in Postural Control following Lateral Ankle Sprain. *Foot Ankle Int*. 2004;25(11):833-839. doi:10.1177/107110070402501114.

24. Feger M, Donovan L, Hart J, Hertel J. Lower Extremity Muscle Activation in Patients With and Without Chronic Ankle Instability. *J Athl Train*. 2013.

25. Feger MA, Hart JM, Saliba S, Abel MF, Hertel J. Gait training for chronic ankle instability improves neuromechanics during walking. *J Orthop Res*. 2018;36(1):515-524. doi:10.1002/jor.23639.

26. Feger MA, Hertel J. Surface electromyography and plantar pressure changes with novel gait training device in participants with chronic ankle instability. *Clin Biomech*. 2016;37:117-124. doi:10.1016/j.clinbiomech.2016.07.002.

27. Fu ASN, Hui-Chan CWY. Ankle Joint Proprioception and Postural Control in Basketball Players with Bilateral Ankle Sprains. *Am J Sports Med*. 2005;33(8):1174-1182. doi:10.1177/0363546504271976.

28. Gilbreath JP, Gaven SL, Van Lunen BL, Hoch MC. The effects of Mobilization with Movement on dorsiflexion range of motion, dynamic balance, and self-reported function in individuals with chronic ankle instability. *Man Ther*. 2014;19(2):152-157. doi:10.1016/j.math.2013.10.001.

29. Glaviano NR, Marshall AN, Mangum LC, et al. Impairment-Based Rehabilitation With Patterned Electrical Neuromuscular Stimulation and Lower Extremity Function in Individuals With Patellofemoral Pain: A Preliminary Study. *J Athl Train*. February 2019. doi:10.4085/1062-6050-490-17.

30. Golditz T, Steib S, Pfeifer K, et al. Functional ankle instability as a risk factor for osteoarthritis: using T2-mapping to analyze early cartilage degeneration in the ankle joint of young athletes. *Osteoarthr Cartil OARS Osteoarthr Res Soc*. 2014;22(10):1377-1385. doi:10.1016/j.joca.2014.04.029.

31. Gribble PA, Delahunt E, Bleakley C, et al. Selection criteria for patients with chronic ankle instability in controlled research: a position statement of the International Ankle Consortium. *Br J Sports Med*. 2014;48(13):1014-1018.

32. Gribble PA, Hertel J, Plisky P. Using the Star Excursion Balance Test to Assess Dynamic Postural-Control Deficits and Outcomes in Lower Extremity Injury: A Literature and Systematic Review. *J Athl Train*. 2012;47(3):339-357.

33. Herb CC, Chinn L, Dicharry J, McKeon PO, Hart JM, Hertel J. Shank-Rearfoot Joint Coupling with Chronic Ankle Instability. *J Appl Biomech*. 2014;30(3):366-372. doi:10.1123/jab.2013-0085.

34. Hertel J. Functional anatomy, pathomechanics, and pathophysiology of lateral ankle instability. *J Athl Train*. 2002;37(4):364.

35. Hoch MC, Andreatta RD, Mullineaux DR, et al. Two-week joint mobilization intervention improves self-reported function, range of motion, and dynamic balance in those with chronic ankle instability. *J Orthop Res*. 2012;30(11):1798-1804. doi:10.1002/jor.22150.

36. Hoch MC, Farwell KE, Gaven SL, Weinhandl JT. Weight-Bearing Dorsiflexion Range of Motion and Landing Biomechanics in Individuals With Chronic Ankle Instability. *J Athl Train*. 2015;50(8):833-839. doi:10.4085/1062-6050-50.5.07.

37. Hoch MC, McKeon PO. Joint mobilization improves spatiotemporal postural control and range of motion in those with chronic ankle instability. *J Orthop Res*. 2011;29(3):326-332. doi:10.1002/jor.21256.

38. Hoch MC, Staton GS, Medina McKeon JM, Mattacola CG, McKeon PO. Dorsiflexion and dynamic postural control deficits are present in those with chronic ankle instability. *J Sci Med Sport*. 2012;15(6):574-579. doi:10.1016/j.jsams.2012.02.009.

39. Hopkins J, Coglianese M, Glasgow P, Reese S, Seeley MK. Alterations in evertor/invertor muscle activation and center of pressure trajectory in participants with functional ankle instability. *J Electromyogr Kinesiol*. 2012;22(2):280-285.

40. Hubbard TJ, Hertel J. Anterior positional fault of the fibula after sub-acute lateral ankle sprains. *Man Ther*. 2008;13(1):63-67. doi:10.1016/j.math.2006.09.008.

41. Hubbard TJ, Kramer LC, Denegar CR, Hertel J. Contributing factors to chronic ankle instability. *Foot Ankle Int*. 2007;28(3):343–354.

42. Hubbard-Turner T, Turner MJ. Physical Activity Levels in College Students With Chronic Ankle Instability. *J Athl Train*. April 2015. doi:10.4085/1062-6050-50.3.05.

43. Kautzky K, Feger M, Hart J, Hertel J. Surface Electromyography Variability Measures During Walking: Effects Of Chronic Ankle Instability And Prophylactic Bracing. *Athl Train Sports Health Care*. 2015;7(1):14-22.

44. Koldenhoven RM, Feger MA, Fraser JJ, Hertel J. Variability in center of pressure position and muscle activation during walking with chronic ankle instability. *J Electromyogr Kinesiol*. 2018;38:155-161. doi:10.1016/j.jelekin.2017.12.003.

45. Koldenhoven RM, Feger MA, Fraser JJ, Saliba S, Hertel J. Surface electromyography and plantar pressure during walking in young adults with chronic ankle instability. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(4):1060-1070. doi:10.1007/s00167-016-4015-3.

46. Kosik KB, Gribble PA. The Effect of Joint Mobilization on Dynamic Postural Control in Patients With Chronic Ankle Instability: A Critically Appraised Topic. *J Sport Rehabil*. 2018;27(1):103-108. doi:10.1123/jsr.2016-0074.

47. Lilley T, Herb CC, Hart J, Hertel J. Lower extremity joint coupling variability during gait in young adults with and without chronic ankle instability. *Sports Biomech*. 2018;17(2):261-272. doi:10.1080/14763141.2017.1287215.

48. McCann RS, Bolding BA, Terada M, Kosik KB, Crossett ID, Gribble PA. Isometric Hip Strength and Dynamic Stability of Individuals With Chronic Ankle Instability. *J Athl Train*. 2018;53(7):672-678. doi:10.4085/1062-6050-238-17.

49. McCann RS, Crossett ID, Terada M, Kosik KB, Bolding BA, Gribble PA. Hip strength and star excursion balance test deficits of patients with chronic ankle instability. *J Sci Med Sport*. 2017;20(11):992-996. doi:10.1016/j.jsams.2017.05.005.

50. McKay GD, Goldie PA, Payne WR, Oakes BW. Ankle injuries in basketball: injury rate and risk factors. *Br J Sports Med*. 2001;35(2):103-108.

51. Mckeon PO, Ingersoll CD, Kerrigan DC, Saliba E, Bennett BC, Hertel J. Balance Training Improves Function and Postural Control in Those with Chronic Ankle Instability. *Med Sci Sports Exerc*. 2008;40(10):1810-1819. doi:10.1249/MSS.0b013e31817e0f92.

52. McKeon PO, Paolini G, Ingersoll CD, et al. Effects of balance training on gait parameters in patients with chronic ankle instability: a randomized controlled trial. *Clin Rehabil*. 2009;23(7):609-621. doi:10.1177/0269215509102954.

53. Moisan G, Descarreaux M, Cantin V. Effects of chronic ankle instability on kinetics, kinematics and muscle activity during walking and running: A systematic review. *Gait Posture*. 2017;52:381-399. doi:10.1016/j.gaitpost.2016.11.037.

54. Monaghan K, Delahunt E, Caulfield B. Ankle function during gait in patients with chronic ankle instability compared to controls. *Clin Biomech*. 2006;21(2):168-174.

55. Nawata K, Nishihara S, Hayashi I, Teshima R. Plantar pressure distribution during gait in athletes with functional instability of the ankle joint: preliminary report. *J Orthop Sci Off J Jpn Orthop Assoc*. 2005;10(3):298-301. doi:10.1007/s00776-005-0898-4.

56. Noehren B, Scholz J, Davis I. The effect of real-time gait retraining on hip kinematics, pain and function in subjects with patellofemoral pain syndrome. *Br J Sports Med*. 2011;45(9):691-696. doi:10.1136/bjsm.2009.069112.

57. Northeast L, Gautrey CN, Bottoms L, Hughes G, Mitchell ACS, Greenhalgh A. Full gait cycle analysis of lower limb and trunk kinematics and muscle activations during walking in participants with and without ankle instability. *Gait Posture*. 2018;64:114-118. doi:10.1016/j.gaitpost.2018.06.001.

58. O'Driscoll J, Kerin F, Delahunt E. Effect of a 6-week dynamic neuromuscular training programme on ankle joint function: A Case report. *Sports Med Arthrosc Rehabil Ther Technol SMARTT*. 2011;3:13. doi:10.1186/1758-2555-3-13.

59. Roos KG, Kerr ZY, Mauntel TC, Djoko A, Dompier TP, Wickstrom EA. The Epidemiology of Lateral Ligament Complex Ankle Sprains in National Collegiate Athletic Association Sports. *Am J Sports Med*. August 2016:0363546516660980. doi:10.1177/0363546516660980.

60. Santilli V, Frascarelli MA, Paoloni M, et al. Peroneus Longus Muscle Activation Pattern During Gait Cycle in Athletes Affected by Functional Ankle Instability A Surface Electromyographic Study. *Am J Sports Med*. 2005;33(8):1183-1187. doi:10.1177/0363546504274147.

61. Spaulding SJ, Livingston LA, Hartsell HD. The influence of external orthotic support on the adaptive gait characteristics of individuals with chronically unstable ankles. *Gait Posture*. 2003;17(2):152-158.

62. Terada M, Beard M, Carey S, et al. Nonlinear Dynamic Measures for Evaluating Postural Control in Individuals With and Without Chronic Ankle Instability. *Motor Control*. October 2018:1-19. doi:10.1123/mc.2017-0001.

63. Torp DM, Thomas AC, Donovan L. External feedback during walking improves measures of plantar pressure in individuals with chronic ankle instability. *Gait Posture*. 2019;67:236-241. doi:10.1016/j.gaitpost.2018.10.023.

64. Waterman BR. The Epidemiology of Ankle Sprains in the United States. *J Bone Jt Surg Am*. 2010;92(13):2279. doi:10.2106/JBJS.I.01537.

65. Waterman BR, Belmont PJ, Cameron KL, Deberardino TM, Owens BD. Epidemiology of ankle sprain at the United States Military Academy. *Am J Sports Med*. 2010;38(4):797-803. doi:10.1177/0363546509350757.

66. Wikstrom EA, Brown CN. Minimum Reporting Standards for Copers in Chronic Ankle Instability Research. *Sports Med*. 2014;44(2):251-268. doi:10.1007/s40279-013-0111-4.

67. Wikstrom EA, Fournier KA, McKeon PO. Postural control differs between those with and without chronic ankle instability. *Gait Posture*. 2010;32(1):82-86. doi:10.1016/j.gaitpost.2010.03.015.

68. Wikstrom EA, Hubbard TJ. Talar Positional Fault in Persons With Chronic Ankle Instability. *Arch Phys Med Rehabil*. 2010;91(8):1267-1271. doi:10.1016/j.apmr.2010.04.022.

69. Willems T, Witvrouw E, Verstuyft J, Vaes P, De Clercq D. Proprioception and Muscle Strength in Subjects With a History of Ankle Sprains and Chronic Instability. *J Athl Train*. 2002;37(4):487-493.

70. Winstein C. Knowledge of results and motor learning--implications for physical therapy. *Phys Ther*. 1991;71(2):140-149.

71. Wright CJ, Arnold BL, Ross SE, Pidcoe PE. Individuals With Functional Ankle Instability, but not Copers, Have Increased Forefoot Inversion During Walking Gait. *Athl Train Sports Health Care*. 2013;5(5):201-209. doi:10.3928/19425864-20130827-01.

72. Wright IC, Neptune RR, van den Bogert AJ, Nigg BM. The influence of foot positioning on ankle sprains. *J Biomech*. 2000;33(5):513-519. doi:10.1016/S0021-9290(99)00218-3.

73. Yen S-C, Chui KK, Corkery MB, Allen EA, Cloonan CM. Hip-ankle coordination during gait in individuals with chronic ankle instability. *Gait Posture*. 2017;53:193-200. doi:10.1016/j.gaitpost.2017.02.001.

74. Yeung MS, Chan KM, So CH, Yuan WY. An epidemiological survey on ankle sprain. *Br J Sports Med*. 1994;28(2):112-116.