Final Report to the American Orthotic and Prosthetic Association's (AOPA) Center for Orthotics and Prosthetics Learning and Outcomes/Evidence-Based Practice (COPL)

Project Title:

Exploiting lower limb orthotic constraint of movement as a strategy for neuromuscular recalibration

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Report Outline:

- 1.) Introduction
- 2.) Purpose
- 3.) Rationale
- 4.) Methods
 - a. Subject Recruitment, Inclusion and Exclusion
 - b. Protocol
 - i. Constraint of movement via custom AFO-footwear combination (AFO-FC)
 - ii. Fit and alignment of the AFO-FC to each subject's lower limb
 - iii. Protocol to elicit neuromuscular responses to constraint of movement
 - a. Screening to identify lower limb dominance
 - b. Establishing resting threshold for each muscle as baseline
 - c. Establishing steady state comfortable walking speed
 - d. Optimizing constraint duration to elicit neuromuscular adaptive responses (neuromuscular recalibration)
 - e. Optimizing washout to minimize carry over effects
 - c. Electromyography (EMG)
 - i. Selection and preparation of sites for surface EMG electrode application
 - d. Joint Kinematics
 - e. Kinetics to Derive Gait Cycle Duration
 - f. Subject Exertion
- 5.) Results
 - a. Subject Data
 - b. Neuromuscular (EMG) Activation Duration
 - c. Neuromuscular (EMG) Activation Effort
 - d. Kinematics of Ankle, Knee and Hip Joints
 - e. Gait Cycle Duration and Phases
 - f. Cardiovascular and Perceived Exertion Responses
- 6.) Conclusion
 - a. Neuromuscular (EMG) Activation Responses to Constraint of Motion
 - b. Kinematic Responses to Constraint of Motion
 - c. Gait Cycle Duration and Phase Responses to Constraint of Motion
 - d. Cardiovascular and Perceived Exertion Responses to Constraint of Motion
- 7.) Future Work
- 8.) References

1.) Introduction

The project began with creation of the constraining device (i.e., AFO and footwear system). This process consumed more time than originally anticipated. The first iteration of AFO involved common thermoplastic and metal hybrid design (i.e., bivalve shank shells with double adjustable ankle joints, stirrup inserts and molded foot plate). The design was relatively heavy and did not sufficiently limit ankle motion. Because the investigation targeted neuromuscular responses to novel lower limb orthotic motion constraint, we needed to improve the orthosis design and to achieve greater lower limb motion control. As a result, we created a unique modular and relatively lightweight carbon composite AFO-footwear combination with adjustable range of motion linear bearing. The creation of the linear bearing also required more time than originally planned. The outcome of the AFO-footwear combination was successful in that a wide variety of subjects could be fit with improved constraint of ankle motion and accuracy in ankle range of motion settings.

The next significant task was to establish an effective protocol to elicit neuromuscular responses to constraint of lower limb movement. A number of changes to the originally proposed protocol were implemented to minimize confounds that would otherwise possibly complicate neuromuscular response data. The final report describes the significant milestones of the research project and summarizes the major findings.

As the principal investigator and on behalf of the investigator team, we are grateful to the AOPA COPL for the funding of the investigation that enabled us to advance the project and for providing a no-cost extension to allow us the extra time to establish and implement the research protocol. The extension of time allowed the investigators to refine the research protocol and to recruit, screen and select appropriate subjects for participation. Because the investigation employs a perturbation to subjects over a moderate duration (i.e., mechanical lower limb constraint for 15 minutes), we discovered many challenges with the substantial data array collected for each of the subjects. Because of the extensive data array generated by each subject's participation in the extensive protocol, we continue our efforts to process and analyze the data.

In order to provide a representative overview of the successes and accomplishments of the project, we will focus on one subject's responses to all major variables measured in the protocol. The reason for this approach is that we implemented several changes to the original protocol. For example, we piloted the original protocol and discovered the need to increase the duration of walking during each condition (i.e., control and constraint) in order to explore the trajectory of neuromuscular behavior (i.e., detect a ceiling effect). To minimize carryover of adaptive responses between each of the conditions (i.e., control and constraint), and to minimize any confounding of subject behavioral responses to each condition, we evaluated the original protocol. We found that the original protocol would have confounded subjects' neuromuscular responses by producing a carryover effect. As such, the protocol was changed to offer "washout" periods between each condition that minimized carry over effects.

The changes in the protocol (i.e., increase from three minutes to 15 minutes of each constraint condition following the control condition, the addition of washout period between each condition notably increased the amount of time for subject participation as well as increased the amount of data acquired for each subject. The substantial increase in data has required significant time for processing and analysis. As such, we have processed and analyzed a large portion of data for five subjects. Because the data is not complete, we will present a full spectrum of analysis focusing in many instances on one subject's representative data.

This report will provide an overview and summary of subjects who participated in a protocol by walking at their self-selected comfortable speed while undergoing a variety of imposed conditions (i.e., walking with and without constraint of the ankle joint of the dominant lower limb) in order to explore their movement responses. The motivation of the research is to lay the groundwork (i.e., foundation knowledge) that will help orthotists/prosthetists and related health care professionals to better understand adaptive responses (i.e., recalibration of the neuromuscular system) in response to constraint of movement and to exploit these neuromuscular responses as a strategy for neurological rehabilitation. Because this research effort is preliminary (i.e., investigating responses of able bodied subjects), the hope is that future clinical investigations targeting persons with central nervous system (CNS) disorders (i.e., stroke survivors) will be implemented based upon the knowledge learned from this investigation. We hope that persons with CNS disorders such as stroke survivors will benefit from targeted clinical trials utilizing lower limb orthotic constraint of movement in order to enhance and/or augment existing neuromuscular rehabilitation approaches.

2.) Purpose

To examine whether a novel constraint of lower limb movement will elicit changes in neuromuscular behavior (i.e. recalibration) that produces increases in muscle activation.

3.) Rationale

Walking may be considered a task specific activity. When walking at steady state, the coordinated behavior of gait is a task involving rhythmic, repeated and generally consistent movement patterns regulated by CNS. Demands may be imposed upon the CNS when walking with imposed constraint of lower limb joint motion (as a perturbation) over repeated gait cycles. The CNS response to demands may be elicited as deviations in movement patterns and muscle activity (possibly based on error feedback) as "motor calibration". The research investigated an approach to measure orthotic treatment during walking as a strategy for motor recalibration.

To create a sufficient perturbation to the CNS, we targeted constraint of the ankle joint complex via a lower limb orthosis. The ankle joint complex and its structures (i.e., nervous, muscular, skeletal, etc.) largely contribute to a person's ability to progress and propel the body forward during gait (Farris, 2011). As such, perturbing the ankle joint complex of subjects via a mechanical joint motion constraint (i.e., lower limb orthosis and footwear combination) while persons walk at a steady state for a moderate duration is an optimal approach to challenge the subject's central nervous system as a strategy to elicit and evaluate adaptive movement responses (i.e., neuromuscular recalibration behavior).

4.) Methods

a. Subject Recruitment, Inclusion and Exclusion:

The no-cost extension of time provided by AOPA for the project allowed the investigators to recruit a larger sample size of subjects and for valuable data to be acquired. The study was conducted with Georgia Tech Institutional Review Board (IRB) approval and informed consent of all subjects. A total of 34 persons were contacted as potential candidates for participation in the study (Figure 1). These individuals responded to electronic advertisement (i.e., targeted email sent to the Georgia Tech School of Biomedical Engineering and the School of Applied Physiology students, staff and faculty). The email included an attached cover letter that explained the purpose of the study, the remuneration for participation (i.e., payment of an hourly rate), the inclusion criteria, as well as information to contact the principal investigator. Eighteen individuals were excluded because they did not meet the inclusion

criteria (based upon their responses to the questionnaire). As a result, 16 healthy subjects with no history of lower limb neuromuscular or skeletal disorders and with no limitation in their walking ability were selected for participation in the protocol. Two of the selected subjects were excluded (one failed the motor screening tests to identify the dominant side lower limb and one did not return for participation in the full data collection protocol). Fourteen subjects participated in the full protocol and their data was collected. One subject's data was incomplete because of an error in instrument preparation. As a result, a full data set was collected for 13 subjects. Of the 13 subjects, five subjects' data has been processed and analyzed however in four of the five subject's data; the data set is incomplete whereby portions of data are missing due to data collection challenges (i.e., intermittent instrument failure) which is not uncommon in moderate duration protocols such as the protocol implemented. As a result, a portion of five subjects' data is presented for this report and the full data of one representative subject is fully presented. We plan to continue processing and analysis of the remaining subject data.





b. Protocol

The research team worked diligently to establish an effective protocol that: a.) optimized each subject's safety, b.) minimized the duration of their participation, and c.) optimized the utilization of research

resources in order to measure subject responses to constraint of lower limb movement. After earlier pilot trials, we learned that changes in the original protocol were necessary in order to rigorously address the purpose of the research (i.e., to examine whether intimate constraint of lower limb motion during steady state walking will elicit changes in neuromuscular behavior. We undertook a rigorous approach in order to engage good science that controls for confounding variables that otherwise could influence the data and that focuses on addressing the research hypotheses.

As a result, we implemented changes to the original protocol (i.e., expanded the number and type of motor tasks to screen subjects for lower limb dominance, increased the duration in which subjects walked with and without lower limb constraint, added a washout period between each constraint condition during the walking trails). These changes were submitted to the Georgia Tech Institutional Review Board (IRB) for review and approval. The changes were deemed appropriate and safe and thus were approved by the IRB. We then implemented the updated protocol for each of the subjects that met the inclusion criteria (i.e., according to the procedures outlined to select the 14 subjects described in **Figure 1**).

i. Constraint of movement via custom AFO-footwear combination (AFO-FC)

Constraint of lower limb movement was achieved via a custom adjustable articulated AFO-footwear combination (AFO-FC) (Figure 2). The AFO consisted of carbon fiber shank and foot shells that contained an adjustable tibial plate and three adjustable foot straps. The tibial plate and foot straps were designed to effectively create an intimate fit to each subject's lower limb dimension, thereby assisting in constraint of ankle motion. An overlapping carbon fiber and steel hinge joint in combination with a custom linear bearing further enhanced the control of subject's constraint of ankle motion. Clamps mounted at the superior and inferior aspects of the linear bearing provided customized range of motion stops. The linear bearing was load tested in isolation from the AFO at the Georgia Tech School of Physics Machine Shop. A compressive load of 90.7 kg (200 lbs.) was applied to the linear bearing. Appropriate load tolerance was observed in which minimal deformation of the bearing was observed. Because the load tolerance of the linear bearing is increased when installed to the AFO carbon fiber foot and shank shells, the AFO-FC has a load tolerance of at least and perhaps greater than 90.7 kg (200 lbs.). We decided to establish a maximum threshold of 79.5 kg (175 lbs.) body weight as a conservative ceiling for subject use. As such, subjects with body weight up to but not exceeding 79.5 kg (175 lbs.) were considered for inclusion in the protocol. Individuals with body weight exceeding 79.5 kg (175 lbs.) were excluded from the study.

The footwear portion of the AFO-FC consisted of a rocker profile with 3/8" heel to sole difference. The heel consisted of multidensity rubber foam, the midfoot was constructed of cork and foam, and the forefoot consisted of a rocker bar, and the distal forefoot contained an exterior sole fenestration and toe ramp. The purpose of the footwear combination was to enable subjects to roll over the constrained ankle-foot complex during stance phase in order to minimize gait deviations which may otherwise confound neuromuscular responses to constraint of ankle motion. Ankle constraint was effectively achieved via the combination of adjustable anterior shank plate, dorsal ankle strap, heel strap, customized padding around the perimeter of each subject's foot within the foot shell in addition to the motion control provided by the linear bearing stop clamps. The AFO-FC allowed fitting of a range of lower limb dimensions (foot size ranging from men's shoe size 5 to 11).

All subjects were fit with the same type of shoe (Apis Footwear, El Monte, CA) on both feet (for control condition) and on the unconstrained left foot only for the constraint condition (in order to minimize alterations in gait performance, which may occur due to different shoe designs and wear patterns).

Similar to the right footwear combination, the left shoe also contained a 3/8" heel to sole difference. (Figure 2).



А



С

D

Figure 2. AFO-Footwear Combination.

A custom AFO-footwear combination was fit to each subject's right lower limb to constrain ankle motion as each subject walked at their self-selected comfortable speed. In addition, subjects were eac fit with the same type of shoe on the left foot to minimize alterations in gait due to variability in shoe designs. The images above illustrate the AFO-FC as the subject walked overground during initial contact (Figure A), midstance (Figure B), terminal stance (Figure C). In the actual protocol, subjects walked over a split belt treadmill in a gait lab while fully instrumented (i.e., wearing wireless EMG, reflective markers and safety harness). Figure D highlights the engagement of the forefoot rocker bar, forefoot sole fenestration and forefoot ramp during terminal stance.

ii. Fit and alignment of the AFO-FC to each subject's lower limb

The fit and alignment of the AFO-FC was established to be comfortable and to mimic mid-midstance (the neutral midstance alignment). These objectives were successfully and reliably attained through a multistep fitting and "tuning" procedure. First, the AFO-FC was pre-fit to each subject to establish an intimate and comfortable fit. This was achieved by adjusting the tibial plate to match the angle of the tibial crest with the addition or removal of modular foam wedges. Because the exterior surface of the proximal tibial crest varies only slightly (range between 110-120°), modular foam wedges can be added or removed to match the external anatomical contour of the proximal anterior tibia. This region of the lower limb is also tolerant to high loads which allows for a relatively snug yet comfortable fit to be achieved. Earlier piloting that involved construction of anterior tibial plates constructed of a variety of thermoplastic and foam materials in a variety of geometrical shapes provided us the informatio to create the final modular tibial plate design which was successful. The dorsal foot strap and heel strap were adjusted to patient tolerance and the inclusion of a crescent foam interface pad enhanced subject comfort while maintaining intimacy of fit. A forefoot strap distal to the metatarsophangeal joints maintained position and seating of the forefoot to the footplate. Persons with small dimension feet were fit with various sizes of foam padding (closed cell polyethylene foam) that was installed around the perimeter of the subject's foot. Intimacy and snugness of fit was customized according to each subject's feedback regarding comfort. The goal of the pre-fitting procedure was to produce an AFO-FC that was comfortable for each subject and which established an intimate fit. All subjects underwent fit and alignment of the AFO-FC by the same individual (i.e., the principal investigator [CH]).

After intimate and comfortable fit of the AFO-FC was achieved, the AFO-FC was then aligned so that the range of subject's lower limb motion was restricted by the linear bearing set in mid-midstance. Midmidstance of the lower limb was achieved when the subject maintained relaxed free standing position where the ground reaction force vector (in the sagittal plane) was positioned through the knee joint (with knee slightly flexed), where the shank was leaning 8 to 11° anterior, and the ground reaction force vector was positioned approximately through the midlength of the foot (depending upon toe out angle) (Owen E, 2010). To reliably achieve this alignment, the subject's knee joint center (in the sagittal plane) is located when the knee is held in terminal extension. A positon that is half the distance between adductor tubercle and medial tibial plateau (in the coronal plane) and which is 60% posterior to the anterior patella (in the sagittal plane) utilizing a biased protractor knee pivot gauge (Otto Bock 647H465-500-08.02/03-MD). This procedure has been purported to reliably locate the knee joint axis in terminal knee extension (Otto Bock Technical Manual, Bedard G, 2007). The knee center along the lateral aspect of the subject's limb is marked with a felt tip pen. With the subject wearing the right AFO-FC and left shoe, the individual is instructed to stand with right foot on a force platform that projects (via a laser beam) the ground reaction force vector (LASAR Posutre, Otto Bock, Duederstat, Germany). The subject is positioned so the laser beam projects along the subject's exterior right lower limb in the sagittal plane. During this time, the subject is instructed to stand in relaxed posture maintaining natural toe out angle. Once the laser beam is positioned through the subject's knee axis, the stop clamps of the linear bearing are fixed and the ankle joint of the AFO is then held in mid-midstance alignment (Figure 3).



Figure 3. Alignment of the AFO-FC to hold the subjecct's right lower limb in mid-midstance.

Red laser represents the ground reaction force vector projected from the LASAR posture (Otto Bock, Duderstad, Germany) over the subject's exterior right lower limb while the subject stands with right foot on loading platform in the sagittal plane while maintaining relaxed free standing that mimics mid-midstance alignment.

iii. Protocol to elicit neuromuscular responses to constraint of movement

A series of protocols were established to: a.) screen subjects in order to confirm lower limb dominance, b.) to establish baseline resting threshold of each muscle, c.) to confirm each subject's comfortable steady state walking speed, d.) to optimize neuromuscular responses to constraint of movement while d.) minimizing carryover effects between constraint conditions.

a.) Screening to identify lower limb dominance

Subjects that met all of the inclusion criteria from the initial screening questionnaire were selected to participate in the study. Each subject participated in a motor task protocol to determine the dominant lower limb. The protocol consisted of subjects performing three trials of three specific functional tasks [a.) ball kick, b.) stair ascent, c.) balance recovery. The leg that initiated the movement of the task for the majority of trials was identified as the dominant lower limb. The procedures were adapted from established methods to identify lower limb dominance (Schneiders, et al., 2010; Lin, et al., 2009).

b.) Establishing resting threshold for each muscle as baseline

In order to establish a minimum muscle behavior threshold, each subject participated in a sitting and standing protocol prior to participating in the walking protocol. The protocol involved the subject resting quietly while sitting upright in a chair. Each subject was instructed to dorsiflex both ankles simultaneously three times followed by standing and performing a heel rise three times followed by performing a squat (i.e., hips and knee flexed and ankles dorsiflexed). During the protocol, raw EMG was collected for each muscle. The protocol was repeated for each condition (i.e., control, Plantarflexion stop/Dorsiflexion stop, Plantarflexion free/Dorsiflexion stop, Plantarflexion free). In order to identify a resting threshold value as baseline for each muscle for each condition, we examined the raw EMG and imposed a 10 Hz high pass filter. The resting threshold for each muscle for each condition (i.e., control, Plantarflexion stop/Dorsiflexion stop/Dorsiflexion stop, Plantarflexion stop, Plantarflexion free). In sidentified as the lowest EMG signal amplitude attained specific to each condition (i.e., control, Plantarflexion stop/Dorsiflexion stop, Plantarflexion free).

c.) Establishing steady state comfortable walking speed

Each subject's comfortable walking speed was determined during an initial appointment that followed the limb dominance motor task screening and initial fitting of the AFO-FC. To determine each subject's comfortable walking speed, individuals were fit with the shoes utilized in the investigation on both feet (i.e., same style of shoes noted in **Figure 2**) which was the control condition. Subjects were then fit with a safety harness and asked to walk on a split belt treadmill with both belts tied to the same speed. Initially a slow speed (i.e., 0.85 m/s) was imposed. Subjects were allowed to acclimate to the initial speed before the speed was increased. Prior to increasing the speed of both split belt treadmills, subjects were asked to rate the speed as "faster" or "slower" or "same" as their comfortable walking speed. If the speed was deemed "slower", then it was increased approximately 0.05 m/s. If the speed was deemed "faster" by the subject, then it was later slowed. Subjects were instructed that comfortable walking speed was defined as the speed in which an individual would walk comfortably for 15 minutes on level terrain.

The same procedures were repeated for each subject walking with a left shoe (utilized in the investigation) and with right ankle constraint. Right ankle constraint consisted of the subject wearing the right AFO-FC with the constraint set in the plantarflexion stop/dorsiflexion stop (PSDS) condition. The PSDS constraint condition was selected because it produced the greatest restriction in lower limb motion and was likely to cause subjects to select the slowest comfortable walking speed than the other partial motion constraint conditions.

The comfortable walking speed that each subject achieved in the PSDS constraint condition was the speed imposed for all of the conditions in the full walking protocol for that subject. Thus, the comfortable walking speed was established for each subject when they walked with the AFO-FC set in the PSDS condition. The mean comfortable walking speed of the 14 subjects assessed when walking without constraint of lower limb motion was 1.17 m/s compared to 1.08 m/s (when walking with lower limb constraint of motion. As a result, there was a moderate decrease (7.69%) in comfortable walking speed due to constraint of ankle motion.

d.) Optimizing constraint duration to elicit neuromuscular adaptive responses (neuromuscular recalibration)

Pilot protocols were enacted with a small sample of subjects (n=2) in order to determine the optimal duration of constraint. Initial piloting that involved subjects walking at steady state for 10 minutes provided evidence that some of the constrained lower limb muscles on the right lower limb (i.e., the limb fit with the AFO-FC) appeared to display a trend of increasing EMG activation in the last two to three minutes of the protocol. As such, the constraint duration was increased from 10 minutes to 15 minutes. Although the increase in constraint duration for each condition substantially increased the time of the overall protocol for subject participation, we felt it would allow a richer data array and thus a better opportunity to explore the neuromuscular behavior to longer term constraint.

e.) Optimizing washout to minimize carry over effects

The original protocol did not account for possible carry over effects of adaptive responses acquired by subjects from one constraint condition and which may potentially influence the next constraint condition. To minimize carry over adaptive responses, from a constraint condition, we implemented a pilot protocol. The protocol involved subjects (n=2) that each walked at their comfortable speed with the same constraint (i.e., PSDS). As washout, a seated rest period was sandwiched between the first and second constraint condition. A different washout (i.e., walking without constraint) was sandwiched between the second and third constraint conditions. We then examined neuromuscular responses of each subject following the washout periods. It was discovered that the neuromuscular behavior following the washout period involving seated rest was very similar to the neuromuscular behavior following the washout period constraint conditions within approximately six minutes. As a result, we instituted a six minute washout period in which each subject sat in a chair and relaxed between each constraint condition in the final full protocol.

In summary, earlier pilot testing of portions of the protocol (constraint duration as well as the type and duration of washout) revealed that the optimal protocol would involve walking at pre-determined comfortable speed without constraint for 10 minutes (habituation to treadmill and laboratory apparatus). Subjects then walked at their pre-determined comfortable speed for 15 minutes while wearing unilateral right lower limb constraint (order of constraint conditions was randomized). The three constraint conditions consisted of: plantarflexion stop/dorsiflexion stop [PSDS], plantarflexion stop/dorsiflexion free [PSDF], and plantarflexion free/dorsiflexion stop [PFDS]. Between each constraint condition, the subject sat in a chair and rested for 6 minutes in order to extinguish any previously adapted behaviors (i.e., washout period). The full protocol incorporating optimum conditions (Control and Constraint) and optimal washout periods between conditions is outlined in **Figure 4**.



Figure 4. Full Protocol Incorporating Optimum Conditions (Control and Constraint) and Optimal Washout Periods Between Conditions

c. Electromyography (EMG)

A 32 channel Wireless EMG (Noraxon Telemyo 2400R G2, Noraxon USA, Inc., Scottsdale, AZ) was utilized to record muscle behavior of 14 lower limb muscles [i.e., right and left tibialis anterior (TA), medial gastrocnemius (MG), lateral gastrocnemius (LG), soleus (Sol), vastus medialis (VM), rectus femoris (RF) and biceps femoris(BF)]. The electrodes contained a pre-amplifier that imposed a 1st order high pass filter of the raw EMG signals at 10 Hz +/- 10% cutoff frequency. All channels also had an 8th order Butterworth/Bessels anti aliasing high pass filter set at 500 Hz +/- 2% cutoff frequency. We attempted to collect EMG data for gluteus maximus but were unsuccessful due to excessively noisy signal data. The 14 muscles were selected because as a sum, they play a notable role in producing motion of the ankle, knee

and hip joints during gait. As a result, it was likely that targeting these muscles for measurement would reveal behavioral changes in response to constraint of lower limb movement.

The EMG system sampled data at 1500 Hz which was downsampled to 1080 Hz as EMG data was transferred into the Vicon data station. The acquired EMG data was offset by 100 ms to adjust for a delay in sampling between the EMG system and Vicon data station.

i. Selection and preparation of sites for surface EMG electrode application

In accordance with the standards for EMG for non-invasive assessment of muscles (SENIAM), the same investigator (CH) identified the optimal surface electrode site for each muscle and then prepared the skin for installation of surface electrodes (Stegeman DF; DeLuca, 1997). In accord with the procedures by Perotto, the apex of each muscle belly was identified as the approximate midlength between the proximal and distal aspect (Perotto, et al. 2005). The optimal electrode location was marked with felt tip pen. The skin was then prepared accordingly: the site was vigorously cleaned with 70% rubbing alcohol, hair was shaved with a disposable single blade disposable razor, skin was abraded with fine grit (i.e., 80 grit) sand paper. Skin preparation procedure was completed by wiping the area clean with disposable towel and water (to remove any remaining debris). After the skin was dry, a pair of silver/silver chloride adhesive removable electrodes (Ambu Blue offset sEMG sensor electrodes, Danlee Medical Products, Inc., Syracuse, NY) were installed to the skin adjacent to each other while parallel to the muscle fiber orientation of the muscle and maintaining a 2.0 cm interelectrode separation. A ground electrode was placed over the bony part of the proximal anteromedial tibia of the left (unconstrained) lower limb of each subject.

d. Joint Kinematics

Vicon motion capture system recorded gait and movement events of each subject's pelvis and lower limbs via a lower body reflective marker set in which subject's movement events were recorded by six cameras each with infrared light detection. Motion events were sampled at 120 Hz. A total of 16 lower body reflective markers were placed at the following anatomical sites of each subject: left and right posterior superior iliac spine, anterior superior iliac spine, lateral distal thigh, knee joint, lateral shank, lateral malleolus, heel and 2nd metatarsophalangeal joint. The reflective markers created detectable coordinates upon each subject's lower body. Reflected infrared light emitted from the six cameras was then captured as raw coordinate data. The raw coordinate data was processed (filtered). Custom computer code utilizing Matlab (Matlab Mathworks, Natick, MA) was utilized to further process and analyze coordinate data to quantify the ankle, knee and hip joint excursions of both lower limbs of each subject.

e. Kinetics to Derive Gait Cycle Duration

Force plates (AMTI, Watertown, MA) underneath each of two custom treadmills mounted in parallel to create a split belt treadmill system recorded forces and moments of each step of subjects as they walked. Data was collected at 1080 Hz and transferred to the Vicon workstation for synchronization with EMG and kinematics data.

f. Subject Exertion

Each subject's cardiovascular exertion was examined by recording heart rate data and the subject's rating of perceived exertion. The subject's resting heart rate was recorded prior to the walking trials. During the walking trials for each condition, the subject's heart rate was recorded at minutes 1, 3, 5, 7, 9, 11, and 13. During each of the heart rate recordings in the walking protocol, the subject was asked to rate their perceived exertion. The rating of perceived exertion is loosely correlated to heart rate data (correlation coefficient approximately r=0.5) (Borg, 1982). We recorded each subject's RPE as an additional supportive variable of subject exertion.

5.) Results

a. Subject Data

	Subject	Gender	Age	Height	Mass	Shoe Size	Self-Selected Walking
			(years)	(cm)	(kg)	(US men's)	Speed (m/s)
	SO	Male	19	167.0	68.7	8	0.90
	DM	Male	25	173.3	65.3	8	0.95
	TN	Female	25	177.7	77.3	9.5	0.95
	SM	Female	22	164.5	56.6	6	1.14
	GC	Female	24	166	62.5	5	1.06
Mean			23.0	169.7	66.1	8.1	1.0
SD			2.5	5.6	7.7	0.9	0.1

Table 1. Subject Data.

Summary of anthropomorphic and related data for five representative subjects.

b. Neuromuscular (EMG) Activation Duration

There are a plethora of methods to process muscle activation behavior. A common approach is to compute the root mean square from the raw EMG signal data. The limitation of this approach is that the activation duration is not clearly expressed. In order to more clearly express each subject's activation duration as a response to constraint of movement during the constraint protocol, a more rigorous approach was undertaken. The approach involved processing the raw EMG signal data into an expression of mean activation duration as a relative percent of the subject's mean gait cycle duration.

The procedure to process the raw EMG data involved a number of steps. First, the resting threshold (in mV) of each muscle was computed from raw muscle EMG signal data collected on the same day, but during a non-walking protocol administered prior to the subject's walking protocol.

For each muscle, the EMG resting threshold value (computed as the lowest amplitude of the raw signal for the particular muscle that was high pass filtered at 10 Hz) from data collected during the non walking protocol. The resting threshold value would later be used as the minimum criteria value to determine when the processed EMG signal data was deemed active or "ON" for each of the 15 minute walking trials (i.e., when the subject walked with and without constraint of lower limb movement at comfortable speed). Processed EMG amplitude peaks that exceeded resting threshold for \geq 50 ms during any time series of the 15 minute walking trials were identified as muscle activation (i.e., muscle defined as "ON").

The processing of representative raw muscle EMG signal data of one subject (GC) is presented in **Figure xx** to clarify how we derived muscle activation duration. In this example, the processed EMG signal data for the subject's left medial gastrocnemius muscle is presented during the ninth minute of walking at comfortable speed during the control condition (no constraint). A multiple step processing procedure was enacted to achieve the neuromuscular activation duration for the targeted muscle. First, raw EMG signal data was collected for each leg of the subject for 30 seconds of each minute for a total of 15 minutes conditions (i.e., control and constraint). Then, the raw EMG signal data for each muscle was processed via a 10 Hz high pass filter (to minimize signal noise created by movement related artifact), de-meaned (to adjust for voltage offset), band pass filtered with cutoffs at 20 Hz and 500 Hz (to minimize physiological artifact), full wave rectified (to convert the sine waves to only positive values), and smoothed with a 50 ms forward and reverse sliding window (to capture the optimal physiological muscle activation).



Figure 5. Computing Neuromuscular (EMG) Activation Duration.

The raw EMG signal data was collected and then processed (filtered, de-meaned, rectified and smoothed). The processed EMG signal data was then analyzed to compute the mean duration of muscle activation (i.e., mean duration muscle is "ON"). The mean duration of muscle activation was "normalized" as the mean duration expressed as a percentage of the mean gait cycle duration. In the above figure, the mean gait cycle duration for the 30 second trail is equal to 1.2 seconds (which represents the average duration for the 26.5 gait cycles during 30 seconds of walking at comfortable speed). The expanded box at the top of the figure denotes a single gait cycle with one activation duration representing 16.7% of the gait cycle duration.

Figures 6-19. Neuromuscular (EMG) Activation Duration in Response to Each Condition (Control and Constraint) (See Multiple Graphs on Next Pages)

The graphs on the following pages depict mean activation duration expressed as a percentage of mean gait cycle duration for 14 leg muscles (Tibialis Anterior [TA], Medial Gastrocnemius [MG], Lateral Gastrocnemius [LG], Soleus [Sol], Vastus Medialis [VM], Rectus Femoris [RF], Biceps Femoris [BF]) of each leg (right and left) of one subject (GC). The subject walked continuously for 15 minutes at self-selected comfortable speed (1.06 m/s) during imposed conditions (control [no constraint], and three constraint conditions: plantarflexion free/dorsiflexion stop (PFDS), plantarflexion stop/dorsiflexion free (PSDF), and plantar flexion stop/dorsiflexion stop (PSDS). During the constraint conditions, the subject utilized the AFO on the right lower limb (which is labeled as the constrained side). We also collected raw EMG data for subject's gluteus maximus, however excessive noise was captured in the signal data. Attempts in filtering the noisy EMG signal data were unsuccessful because no clear activation or quiescent period could be identified. This rendered the EMG signal data for gluteus maximus muscle of right and left lower limbs as unusable.





























c. Neuromuscular (EMG) Activation Effort

Muscle activation effort was computed as the integrated EMG divided by the mean activation duration as a percentage of the mean gait cycle duration. This value provided a relative quantification of each subject's effort to produce muscle contraction during the time when the muscle was activated or "ON".

We determined the mean muscular activation effort in order to express the "intensity" of muscle activation. This expression is an approximation of the contractile strength of the muscle during the period when the muscle is active. Graphs of mean muscular activation effort are expressed as the mean integrated EMG signal during the activation period divided by the percentage of mean gait cycle duration for 14 leg muscles (Tibialis Anterior [TA], Medial Gastrocnemius [MG], Lateral Gastrocnemius [LG], Soleus [Sol], Vastus Medialis [VM], Rectus Femoris [RF], Biceps Femoris [BF]) of each leg (right and left) of subject GC. The subject walked continuously for 15 minutes at self-selected comfortable speed

(1.06 m/s) during imposed conditions (control [no constraint], and three constraint conditions: plantarflexion free/dorsiflexion stop (PFDS), plantarflexion stop/dorsiflexion free (PSDF), and plantar flexion stop/dorsiflexion stop (PSDS). During the constraint conditions, the subject utilized the AFO on the right lower limb (which is labeled as the constrained side).

We attempted to collect EMG data for subject's gluteus maximus, however there was excessive noise in the signal data. We attempted to filter the noise in the EMG signal data for the gluteus maximus muscles, however this was unsuccessful because the magnitude of noise in the signal data was excessive. This rendered the collected EMG data for the gluteus maximus as unusable because no clear periods of activation or quiescent were recognized.































d. Kinematics of Ankle, Knee and Hip Joints

i. Kinematics – Ankle

Kinematics data for the excursion of subject GC's right (constrained side) and left (unconstrained side) ankle joint are presented as the mean<u>+</u>SD by gait cycle (0-100%). Kinematics data was processed and analyzed for each leg (right and left) when the subject walked continuously for 15 minutes at self-selected comfortable speed (1.06 m/s) during imposed conditions (control [no constraint], and three constraint conditions: plantarflexion free/dorsiflexion stop (PFDS), plantarflexion stop/dorsiflexion free (PSDF), and plantar flexion stop/dorsiflexion stop (PSDS). During the constraint conditions, the subject utilized the AFO-FC on the right lower limb.



Figures 33-41. Ankle Joint Kinematics for Subject GC in Response to Control and Constraint Conditions (PSDS, PFDS, PSDF) (See Graphs on This Page and the Following Pages).



ii. Kinematics – Knee

Kinematics data for the excursion of subject GC's right (constrained side) and left (unconstrained side) knee joint are presented as the mean<u>+</u>SD by gait cycle (0-100%). Kinematics data was processed and analyzed for each leg (right and left) when the subject walked continuously for 15 minutes at self-selected comfortable speed (1.06 m/s) during imposed conditions (control [no constraint], and three constraint conditions: plantarflexion free/dorsiflexion stop (PFDS), plantarflexion stop/dorsiflexion free (PSDF), and plantar flexion stop/dorsiflexion stop (PSDS). During the constraint conditions, the subject utilized the AFO on the right lower limb.



Figures 42-49. Knee Joint Kinematics for Subject GC in Response to Control and Constraint Conditions (PSDS, PFDS, PSDF) (See Graphs Below and on the Next Pages).



iii. Kinematics – Hip

Kinematics data for the excursion of subject GC's right (constrained side) and left (unconstrained side) hip joint are presented as the mean<u>+</u>SD by gait cycle (0-100%). Kinematics data was processed and analyzed for each leg (right and left) when the subject walked continuously for 15 minutes at self-selected comfortable speed (1.06 m/s) during imposed conditions (control [no constraint], and three constraint conditions: plantarflexion free/dorsiflexion stop (PFDS), plantarflexion stop/dorsiflexion free (PSDF), and plantar flexion stop/dorsiflexion stop (PSDS). During the constraint conditions, the subject utilized the AFO on the right lower limb.



Figures 50-57. Hip Joint Kinematics for Subject GC in Response to Control and Constraint Conditions (PSDS, PFDS, PSDF) (See Graphs Below and on the Next Pages).



e. Gait Cycle Duration and Phases

The gait cycle duration as well as durations for stance and swing are presented as mean <u>(SD)</u> for subject GC when the subject walked continuously for 15 minutes at self-selected comfortable speed (1.06 m/s) during imposed conditions (control [no constraint], and three constraint conditions: plantarflexion free/dorsiflexion stop (PFDS), plantarflexion stop/dorsiflexion free (PSDF), and plantar flexion stop/dorsiflexion stop (PSDS). During the constraint conditions, the subject utilized the AFO-FC on the right lower limb.

Condition	Left	Right	Left	Right	Left	Right
	Stance	Stance	Swing	Swing	Gait Cycle	Gait Cycle
	Duration	Duration	Duration	Duration	Duration	Duration
	(% GC)	(% GC)	(% GC)	(% GC)	(sec)	(sec)
Control	63.11 (1.08)	63.06 (0.65)	36.89 (1.08)	36.94 (0.65)	1.26 (0.02)	1.10 (0.01)
PSDS	66.24 (2.80)	63.58 (0.68)	33.76 (2.80)	36.42 (0.68)	1.09 (0.03)	1.09 (0.01)
PSDF	69.23 (4.27)	63.67 (0.78)	30.77 (4.27)	36.33 (0.78)	1.10 (0.04)	1.09 (0.01)
PFDS	67.36 (3.16)	62.53 (2.34)	32.64 (3.16)	37.48 (2.34)	1.13 (0.05)	1.10 (0.02)

Table 2. Gait cycle duration, percentage stance phase and percentage swing phase subject GC walking for each condition.

Condition	Left	Right	Left	Right	Left	Right
	Stance	Stance	Swing	Swing	Gait Cycle	Gait Cycle
	Duration	Duration	Duration	Duration	Duration	Duration
	(% control)					
PSDS	104.96	100.82	91.51	98.59	86.51	99.09
PSDF	109.70	100.97	83.41	98.35	87.30	99.09
PFDS	106.73	99.16	88.50	101.46	89.68	100

Table 3. Gait cycle duration, stance phase, swing phase as percent of control for subject GC walking for each condition.

f. Cardiovascular and Perceived Exertion Responses

The heart rate responses (Figure 58 and Figure 59) and perceived exertion (Table 4 and Figure 60) of subject GC to each condition (Control and Constraint) during the walking protocol are presented on the following pages.



Figure 58. Heart rate responses of subject GC to control and constraint conditions while walking at comfortable speed for 15 minutes.



Figure 59. Mean heart rate responses of subject GC to control and constraint conditions while walking at comfortable speed for 15 minutes.

Control	PSDS	PSDF	PFDS
11 (0.82)	13 (0.69)	13 (0.49)	12 (0.69)
"light"	"somewhat hard"	"somewhat hard"	Between "light" and
			"somewhat hard"

Table 4. Mean (Standard Deviation) and definition of rating of perceived exertion.

-

Data is reported by subject GC in response to control and constraint conditions while walking at comfortable speed for 15 minutes.

```
6
  no exertion at all
   extremely light
7.
8
9
   very light
10
11
   light
12
13 somewhat hard
14
15 hard (heavy)
16
17 very hard
18
19 extremely hard
20 maximal exertion
```

Figure 60. Rating of Perceived Exertion (Borg Scale).

6.) Conclusion

a. Neuromuscular (EMG) Activation Responses to Constraint of Motion

Figure 61. Data trends of mean neuromuscular (EMG) activation duration for 14 muscles of subject GC in response to constraint of lower limb motion while walking for 15 minutes at comfortable speed. Increase = overall mean activation duration is greater than control, Decrease = mean activation duration is less than control, NC = mean activation duration is no different than control, Variable = mean activation duration is sometimes greater than, less than and no different than control.

Muscle	PSDS	PFDS	PSDF
Right Tibialis Anterior	Decrease	Decrease	Decrease
Left Tibialis Anterior	NC	NC	NC
Right Medial Gastroc.	Variable	Variable	Variable
Left Medial Gastroc.	Decrease	Decrease	Decrease
Right Lateral Gastroc.	Increase	Increase	Increase
Left Lateral Gastroc.	NC	NC	NC
Right Soleus	NC	NC	NC
Left Soleus	NC	NC	NC
Right Vastus Medialis	Increase	Increase	Increase
Left Vastus Medialis	NC	NC	NC
Right Rectus Femoris	Increase	Decrease	Decrease
Left Rectus Femoris	Increase	Decrease	Decrease
Right Biceps Femoris	Decrease	Decrease	Decrease
Left Biceps Femoris	NC	NC	NC

Figure 62. Data trends of mean neuromuscular (EMG) activation effort for 14 muscles of subject GC in response to constraint of lower limb motion while walking for 15 minutes at comfortable speed. Increase = overall mean activation effort is greater than control, Decrease = mean activation effort is less than control, NC = mean activation effort is no different than control, Variable = mean activation effort is sometimes greater than, less than and no different than control.

Muscle	PSDS	PFDS	PSDF	
Right Tibialis Anterior	Decrease	Decrease	Decrease	
Left Tibialis Anterior	Increase	NC	NC	
Right Medial Gastroc.	Variable	ariable Variable		
Left Medial Gastroc.	Decrease	Variable	Decrease	
Right Lateral Gastroc.	Increase	Increase	Increase	
Left Lateral Gastroc.	NC	NC	NC	
Right Soleus	NC NC		NC	
Left Soleus	NC	NC	NC	
Right Vastus Medialis	Increase	Increase	Increase	
Left Vastus Medialis	NC	Decrease	NC	
Right Rectus Femoris	Increase	Decrease	Increase	
Left Rectus Femoris	Increase	Decrease	NC	
Right Biceps Femoris	Decrease	Variable	Decrease	
Left Biceps Femoris	Variable	Variable	Variable	

Based upon the trends in the data regarding neuromuscular (EMG) activation duration and activation effort to constraint of motion, we re-examined the three original hypotheses (Ho1, Ho2, and Ho3) that were proposed for the investigation and review the evidence to support or deny the statements.

Ho1: Normal healthy subjects walking at constant speed with <u>imposed constraint dorsiflexion and</u> <u>plantarflexion</u> of the dominant lower limb <u>will exhibit greater surface EMG burst activity</u> (tibialis anterior and medial gastrocnemius) during stance phase <u>compared to free ankle (control) condition</u> due to motor calibration in response to restricted ankle motion.

Decision: Reject the hypothesis.

According to the data trends for mean neuromuscular (EMG) activation duration and mean effort for the PSDS condition, the hypothesis is rejected. This is because the trend for constrained side EMG responses by the right tibialis anterior and right medial gastrocnemius muscles to PSDS condition were either variable or decreased.

Ho2: Normal healthy subjects walking at constant speed with imposed constraint of plantarflexion of the dominant lower limb will exhibit greater surface EMG burst activity of medial gastrocnemius during stance phase compared to free ankle condition (control) due to motor calibration in response to restricted ankle plantarflexion motion.

Decision: There is unclear evidence to reject or support the hypothesis.

According to the data trends for mean neuromuscular (EMG) activation duration and mean effort for the PSDS and PSDF conditions, the right medial gastrocnemius muscle response by the subject was variable.

Ho3: Normal healthy subjects walking at constant speed <u>with imposed constraint</u> of <u>dorsiflexion</u> of the dominant lower limb <u>will exhibit greater surface EMG burst activity</u> of <u>tibialis anterior</u> during stance phase <u>compared to free ankle condition (control)</u> due to motor calibration in response to restricted ankle dorsiflexion motion.

Decision: Reject the hypothesis.

According to the data trends for the mean neuromsucualr (EMG) activation duration and mean effort for the PSDS and PFDS conditions of subject GC, the right tibialis anterior muscle response by the subject was to decrease activation behavior.

Further Analysis of Neuromuscular (EMG) Activation Behavior Data

If we examine the data trends for muscle activation behavior (duration and effort) beyond the three original focused hypotheses, there are interesting trends which warrant further examination. The constrained side lateral gastrocnemius and vastus medialis muscles exhibit strong and consistent elevated activation behavior in response to full constraint of ankle motion (PSDS) as well as partial constraint of ankle motion (PSDF, PFDS). Further, full constraint of ankle motion (PSDS) consistently increased muscle activation behavior for the rectus femoris on both the constrained and unconstrained lower limbs in addition to the unconstrained limb tibialis anterior. As such, the neuromuscular (EMG) response to constraint of combined dorsiflexion and plantarflexion motion of the dominant lower limb

appears to influence a greater number of muscles compared to the neuromuscular (EMG) responses to partial constraint of ankle motion (i.e., either plantarflexion constraint or dorsiflexion constraint).

The data also suggests that there may be a graded response to ankle constraint of motion by specific muscles located not only at the ankle (lateral gastrocnemius) but also muscles beyond the ankle (i.e., muscles that control the knee such as the vastus medialis). Because the data represents the neuromuscular responses of a single subject, we will need to confirm these results through analysis of a greater number of subjects. Overall, the preliminary results of neuromuscular (EMG) activation behavior in response to constraint of ankle motion remain promising.

b. Kinematic Responses to Constraint of Motion

Review of the joint kinematics data for subject GC's left and right ankle, knee and hip joints in response to constraint of right ankle joint motion reveals interesting trends.

i. Strategies at the Ankle Joint in Response to Constraint of Motion

In response to ankle constraint, the subject's preserved contralateral (left) ankle joint motion behavior and decreased ipsilateral (right) ankle motion behavior. Specifically, the left (unconstrained) ankle maintained near normal movement behavior. Conversely, the right (constrained) ankle exhibited reduced movement behavior that was specific to the ankle constraint. The most notable reductions in ankle motion appeared when ankle plantarflexion was constrained.

Preliminary explanations for the preservation of contralateral ankle joint motion may be due to the influence of the rocker profile in combination with the ankle motion constraint alignment being held in relation to mid-midstance. Constraining the ankle in mid-midstance alignment may allow the individual to sufficiently roll over the foot during stance phase thereby limiting compensations (i.e, deviations from the normal movement pattern).

ii. Strategies at the Knee Joint in Response to Constraint of Motion

In response to constraint of right ankle joint motion via each of the three types of constraint (PSDS, PFDS, PSDF) while the subject walked at comfortable speed, the response strategy from subject GC at the knee on the ipsilateral side was generally to increase knee flexion throughout stance phase. In the partial constraint condition in which plantarflexion motion was constrained and dorsiflexion motion was free, the subject's response strategy was to increase knee flexion throughout the entire gait cycle. Overall, it appears that constraint of ankle joint motion influences stance phase knee motion, which is enhanced when dorsiflexion motion at the ankle is retained while ankle plantarflexion motion is constrained.

iii. Strategies at the Hip Joint in Response to Constraint of Motion

At the hip joint, the subject's motion strategy in response to constraint of motion was a general increase in flexion through stance phase during the free plantarflexion/dorsiflexion stop condition. During the plantarflexion stop/dorsiflexion stop condition, the subject produced less hip joint flexion and as such exhibited a slightly stiffer hip during stance phase. Cardiovascular responses to constraint of movement reveal increased heart rate. Most likely due to increased exertion due to compensation/adaptation behavior which requires energy to enact. This preliminary finding is consistent with other published research (need reference here).

c. Gait Cycle Duration and Phase Responses to Constraint of Motion

The most notable and consistent response the subject elicited to constraint of ankle motion was to increase the contralateral stance phase duration. In all of the constraint conditions, the subject spent greater time on the contralateral leg during stance. The greatest time was spent on the contralateral leg in response to PSDF (approximately 110% control), followed by PFDS (approximately 107% of control) and PSDS (approximately 105% of control). Interestingly, the greatest amount of ankle motion constraint appeared to elicit the shortest duration of contralateral stance phase duration asymmetry. This may be related to the performance of the AFO-FC alignment and the performance of the rocker profile in minimizing the temporal gait compensation.

d. Cardiovascular and Perceived Exertion Responses to Constraint of Motion

As was generally expected, the subject's exertion increased with the duration of walking in conjunction with the magnitude of ankle joint motion constraint. The subject elicited the highest average heart rate in response to the PSDS condition. In response to partial constraint of ankle motion, the subject displayed a higher heart rate for PFDS compared to PSDF condition. These unique responses may also relate to the performance of the rocker profile and alignment of the AFO-FC.

7.) Future Work

We aim to continue processing and analysis of the remaining subject data. Further statistical analysis will be performed after a larger pool of subject data is analyzed for general trends in neuromuscular and movement responses to constraint of movement. We are not yet clear as how best to analyze the current data set and we require further trend data to decide the optimal statistical analysis approach. The trend analysis of neuromuscular (EMG), joint kinematics, temporal gait data and cardiovascular exertion of one subject reveals promising preliminary results that constraint of ankle motion elicits adaptive changes in specific muscles (not only muscles at the ankle but also the hip). Other muscles that we originally estimated would have had increased in muscle activation behavior were not supported by data to behave accordingly. If the trends we discovered for one subject are similar for the larger sample of subjects, then that information could support future investigation such as a clinical trial involving constraint of lower limb movement for motor recalibration aimed at targeting persons with central nervous system disorder (i.e., hemiparetic stroke survivors).

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