AN EVALUATION OF THE RELATIONSHIP BETWEEN CLINICAL MEASURES OF PLANTAR FLEXOR STRENGTH AND PLANTAR FLEXOR FUNCTION DURING GAIT

by

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ABSTRACT

The plantar flexors play a critical role in gait by aiding in moving the body forward. The function of the plantar flexor muscles, like many other muscle groups, decreases with age, resulting in plantar flexor weakness. Plantar flexor function is also affected by neurological impairment, like stroke. In order to quantify an individual's level of plantar flexor function, the maximum plantar flexion moment during the stance phase of gait can be evaluated via a gait analysis. However, gait analysis software and equipment is expensive and not always clinically-feasible. Instead, clinicians usually evaluate a patient's level of plantar flexor weakness via common clinical tests, such as isometric muscle testing and the single-leg heel rise test. It has not yet been determined if measures of plantar flexor strength from either of these clinical tests are related to plantar flexor function during gait. Thus, the purpose of this study was to determine if there is a relationship between clinical and gait measures of plantar flexor strength and function. To accomplish this purpose, three populations were chosen: young, healthy individuals (n = 15); older, healthy individuals (n = 10); and individuals post-stroke (n = 8). Subjects underwent three different tests: (1) a gait analysis, (2) isometric muscle testing of the plantar flexors, and (3) a single-leg heel rise test. For individuals post-stroke, the single-leg heel rise test was modified (i.e. laying-down and seated versions of the test) as this population could not perform the test standing. The absolute maximum plantar flexion moment during the gait analysis, maximum isometric plantar flexion torque during isometric muscle testing, and total work, average heel rise height, and maximum plantar flexion moment during the single-leg heel rise test were calculated for each subject. Percent differences and positive, one-tailed Pearson correlation analyses were conducted between gait and

clinical measures of plantar flexor function and strength. Maximum plantar flexion moment from the single-leg heel rise test was the clinical measure with the strongest relationship to the absolute maximum plantar flexion moment during gait as the absolute average percent difference between these measures was less than 10% for young and older, healthy individuals. Furthermore, there was nearly a significant correlation ($r = 0.512$, $p = 0.051$) and a significant, moderate correlation ($r = 0.647$, $p = 0.043$) for young and older, healthy individuals, respectively. Significant, moderate correlations to the absolute maximum plantar flexion moment during gait were also found with total work done during the single-leg heel rise test and with maximum isometric plantar flexion torque for older, healthy individuals. This study's findings provide an initial understanding of the relationship between plantar flexor function during gait and plantar flexor strength and, ultimately, lays a foundation for facilitating the clinical evaluation of plantar flexor strength in a manner that relates to plantar flexor function during gait.

Keywords: gait analysis; isometric muscle testing; single-leg heel rise test; young, healthy individuals; older, healthy individuals; individuals post-stroke

DEFINITIONS AND NOMENCLATURE

Table of Definitions

Plantar Flexor Function	For the purpose of this study, the plantar flexion moment during stance in gait is used as a measure of plantar flexor function during gait. The plantar flexion moment quantifies how the plantar flexors eccentrically contract to control forward progression of the shank during stance.
Plantar Flexor Strength	For the purpose of this study, total work and average heel rise height during the single-leg heel rise test and isometric plantar flexion torque are used as measures of plantar flexor strength during these clinical trials.

Table of Abbreviations

M_{SLHR}	Maximum plantar flexion moment calculated from the single-leg heel rise test
M_{GAIT}	Absolute maximum plantar flexion moment during gait
W_{tot_SLHR}	Total work done during the single-leg heel rise test
HR_{avg_SLHR}	Average heel rise height during the single-leg heel rise test
T_{max_ISO}	Maximum isometric plantar flexion torque produced during isometric muscle testing

Chapter 1

INTRODUCTION

Significance

The plantar flexors play a critical role in gait by aiding in moving the body forward [1]. During early-to-mid single-leg stance, the plantar flexors eccentrically contract to control tibia progression over the flat foot [1], [2]. As the tibia advances, the plantar flexors provide ankle stability [1] and a moment is created about the ankle. This moment increases as the ankle moves from 5^{o} plantar flexion to 10^{o} dorsiflexion [1], [3]. Furthermore, the energy stored in the plantar flexors as the tibia rotates over the flat foot is returned during push-off [4], [5] to help initiate swing [3], [6]. Overall, these muscles help with maintaining body support [6], [7], [8] and forward propulsion [1], [4], [6], [9].

The function of the plantar flexor muscles is affected by neurological impairment, like stroke [10], which is the leading cause of long-term disability in the United States [11], [12]. A stroke very commonly results in weakness of the plantar flexors, which decreases the individual's ability to control tibia advancement over the flat foot. Studies have shown that because of this inability to control tibia progression, shortened step length [13], [14] and decreased gait speed [1], [4], [15] are gait deficits commonly seen in individuals post-stroke. These gait deficits reduce the individual's mobility [10] and physical activity levels [10], which may ultimately increase one's risk of having a second stroke [10]. According to the Center for Disease Control and Prevention, nearly 800,000 people suffer from stroke each year in the United States

[16]. It is also estimated that about $34 billion is spent annually on health care services, medication, and missed days of work for these individuals [16]. Thus, it is important that individuals post-stroke regain their previous plantar flexor function to reduce their health care expenses and comorbidities.

Ankle-foot orthoses (AFOs) are commonly prescribed to individuals post-stroke with a goal of assisting weakened ankle muscles and improving an individual's mobility [2], [17]. It is believed that AFOs should be personalized for each individual based on his or her level of plantar flexor weakness in order to effectively enhance mobility [2]. However, in order to facilitate personalized AFO prescription, each individual's level of plantar flexor weakness must be able to be quantified in a clinical setting.

Furthermore, the function of the plantar flexor muscles, like many other muscle groups, decreases with age [18], [19], resulting in plantar flexor weakness and decreased mobility [20]. Studies have shown that the maximum plantar flexion moment during the stance phase of gait, which can be used to quantify plantar flexor function, is lower in older individuals as compared to younger individuals [21], [22]. Studies have also shown that because of this reduced maximum plantar flexion moment, the kinetics at more proximal joints, such as the hip and knee, are altered [21], [22], which is indicative of a compensatory gait strategy. Similar to an individual who has had a stroke, this decrease in plantar flexor function not only changes an individual's gait biomechanics, but also contributes to decreased mobility [23], [24], thus increasing one's chance of being physically inactive [25]. Physical inactivity is a risk factor for premature death and has serious health consequences including obesity, heart disease, and stroke [25]. The economic cost of physical inactivity is estimated to

be between 1.5 and 3% of total direct healthcare costs, which was estimated to be about $75 billion in the United States in 2000 [25], [26]. While older adults are not typically prescribed AFOs until they have extreme plantar flexor weakness, having a clinical measure of plantar flexor weakness that is related to plantar flexor function during gait for individuals with age-related weakness may help optimize interventions that effectively enhance mobility and physical activity for these individuals.

Innovation

Currently, the maximum plantar flexion moment during the stance phase of gait can be calculated via a gait analysis in order to quantify an individual's level of plantar flexor function. However, gait analysis laboratories can cost from $150,000 to $250,000 for optical equipment and software alone [27]. As a result of this high cost, as well as the space needed to setup such equipment, clinicians do not always have access to gait analysis laboratories. Thus, conducting a gait analysis to determine an individual's level of plantar flexor function is not often clinically-feasible.

Instead, an individual's level of plantar flexor weakness is more commonly evaluated through clinical tests, like isometric muscle testing [28] and the single-leg heel rise test [29], [30]. For an isometric muscle test of the plantar flexors, the individual voluntarily contracts their plantar flexors and resists a force applied to the bottom of the foot by a practitioner [31]–[35], or with the use of a computer-controlled dynamometer, like a Kinetic-Communicator (Kin-Com; Chattex Corp, Chattanooga, TN, USA). However, isometric muscle testing of the plantar flexors, both manually and mechanically, has its limitations.

Despite convenience and simplicity, when the test is performed manually, results may be subjective and vary depending on the practitioner's strength [28].

Furthermore, manually applying more force than what the plantar flexors can resist may be challenging in healthy individuals [36], [37] creating a ceiling effect in individuals with normal strength [38]–[40]. When the test is performed mechanically, strength of the plantar flexors is evaluated through torque values using force and moment arms. Since this test is performed in a laying-down or seated position, true strength of the plantar flexors may not be obtained because the plantar flexors are not working in a weight-bearing position [34], [39]. Furthermore, participants may use their entire leg to create a torque during the test, so the plantar flexors are not working in isolation. A study conducted by Fugl-Meyer and colleagues showed that isometric plantar flexor strength decreased by 15% when the knee was in a flexed position as compared to when the knee was in full extension [41], which suggests that measuring plantar flexor strength is dependent on the position in which the individual is placed [35], [41]. Furthermore, this test may not be an indicator of weight-bearing plantar flexor function. Moreover, while historically one of the most common clinical measures of muscle strength [42], isometric muscle testing is a static test and thus may not accurately reflect muscle strength during a dynamic movement, like gait.

As an alternative to isometric muscle testing, the single-leg heel rise test is a dynamic test and was developed to overcome the limitations of the isometric muscle test of the plantar flexors [28], [31], [36], [40]. For the single-leg heel rise test, the individual stands on one leg with his/her knee straight and ankle at 10^{o} dorsiflexion. A linear encoder, which is attached to the calcaneus, measures the displacement of each heel rise until test termination. This test measures plantar flexor strength [28], [36], [43] and records total work and height of each heel rise during the entire test. Total work is a maximal measure that accounts for how long it takes an individual to

displace his/her body weight; thus, total work is an indication of plantar flexor strength [44]. Previous studies have shown that the single-leg heel rise test is reliable in healthy individuals [35], [45], [46], can detect differences between the injured and uninjured leg [46], and outcomes have been shown to be dependent on age, gender, and physical activity [28], [29]. Previous studies have also determined that the criteria for "normal" plantar flexor strength is at least 20 heel rises [28], [43], meaning an individual may have plantar flexor weakness if he/she cannot perform at least 20 heel rises.

To our knowledge, it has not been determined if measures of plantar flexor strength from either of these clinical tests are related to plantar flexor function during gait. Understanding this relationship will bridge the gap in our knowledge of how plantar flexor strength is associated with plantar flexor function during gait. It is important that this relationship be determined as clinicians may not always have access to a gait analysis laboratory; thus, making the evaluation of a patient's plantar flexor function during gait difficult. Identifying if clinical outcome measures can be a surrogate measure of plantar flexor function during gait may enable clinicians to more effectively prescribe AFOs or design rehabilitation programs for individuals with plantar flexor weakness.

Specific Aims and Hypotheses

The purpose of this study was to determine if there is a relationship between clinical and gait measures of plantar flexor strength and function. Identifying which, if any, of these clinical measures of plantar flexor strength provide a surrogate measure for plantar flexor function during gait may facilitate rehabilitation and/or orthotic management for individuals with plantar flexor weakness. To accomplish this purpose,

three populations were chosen: young, healthy individuals; older, healthy individuals; and individuals post-stroke. It was anticipated that these populations would provide a spectrum of plantar flexor function – typical, age-related weakness, and neurological impairment-related weakness – across which the relationship between clinical measures of plantar flexor strength and plantar function during gait could be evaluated.

Aim 1: Determine if maximum plantar flexion moment calculated during the single-leg heel rise test is equivalent to the absolute maximum plantar flexion moment during gait.

Hypothesis 1.1: The maximum plantar flexion moment calculated during the single-leg heel rise test will be within 10% of the absolute maximum plantar flexion moment during gait for young, healthy individuals.

Hypothesis 1.2: The maximum plantar flexion moment calculated during the single-leg heel rise test will be within 10% of the absolute maximum plantar flexion moment during gait for older, healthy individuals.

Hypothesis 1.3: The maximum plantar flexion moment calculated during the single-leg heel rise test will be within 10% of the absolute maximum plantar flexion moment during gait for individuals post-stroke.

Aim 2: Evaluate if total work and average heel rise height during the single-leg heel rise test correlate to absolute maximum plantar flexion moment during gait.

Hypothesis 2.1: Total work and average heel rise height during the single-leg rise test will be correlated to absolute maximum plantar flexion moment during gait for young, healthy individuals.

Hypothesis 2.2: Total work and average heel rise height during the single-leg rise test will be correlated to absolute maximum plantar flexion moment during gait for older, healthy individuals.

Hypothesis 2.3: Total work and average heel rise height during the single-leg rise test will be correlated to absolute maximum plantar flexion moment during gait for individuals post-stroke.

Aim 3: Evaluate if maximum isometric plantar flexor torque correlates to absolute maximum plantar flexion moment during gait.

Hypothesis 3.1: Maximum isometric plantar flexor torque will not be correlated to absolute maximum plantar flexion moment during gait for young, healthy individuals.

Hypothesis 3.2: Maximum isometric plantar flexor torque will not be correlated to absolute maximum plantar flexion moment during gait for older, healthy individuals.

Hypothesis 3.3: Maximum isometric plantar flexor torque will not be correlated to absolute maximum plantar flexion moment during gait for individuals post-stroke.

Chapter 2

METHODS

Subjects

Fifteen young, healthy individuals, 14 older, healthy individuals and 8 individuals post-stroke were recruited to participate in this study. Consent was obtained from all subjects according to the protocols approved by the University of Delaware's Institutional Review Board. Young, healthy individuals were excluded if they had any musculoskeletal disease or injury three months prior to their participation that limited their physical activity. Older, healthy individuals had to be 65 years of age or older and were excluded if they had any musculoskeletal disease or injury three months prior to participation, if they had hip, knee, or ankle joint replacement surgery within the past year, or if they were unable to walk at least a block without stopping or using a walking aid. Individuals post-stroke were excluded if there was evidence of a cerebellar stroke on a clinical MRI, other neurologic conditions in addition to stroke, sensorimotor neglect, an inability to walk outside the home prior to the stroke, a total joint replacement or orthopedic problem in the lower limbs or spine that limit walking, coronary artery bypass graft or myocardial infarction within the past three months, unexplained dizziness in the last six months, or an inability to communicate with investigators.

Testing Procedures Overview

Subjects visited the laboratory at the University of Delaware for one 1.5-hour testing session during which they underwent three different tests: (1) a gait analysis, (2) isometric muscle testing of the plantar flexors, and (3) a single-leg heel rise test. From the gait analysis, the subject's absolute maximum plantar flexion moment was

calculated. From the isometric muscle test, the subject's maximum isometric plantar flexion torque was calculated. Lastly, from the single-leg heel rise test, the subject's absolute maximum plantar flexion moment, total work and average heel rise height were calculated.

Plantar Flexor Function Testing: Gait Analysis

Prior to conducting the gait analysis, each subject's self-selected walking speed was calculated using a 10-meter walk test. The middle six meters of each trial were timed as the first two and last two meters were used to allow for acceleration and deceleration [47], [48]. Each subject completed three trials, which were averaged to determine each subject's self-selected walking speed. Additionally, height, weight and various anthropometric measurements, which include foot length, the distance from the ankle joint center (AJC) to the heel ($d_{AJC\text{-}HEEL}$), and the distance from the second metatarsal head (MH2) to the end of the toe ($d_{MH2\text{-}TOE}$), were recorded. Then, thirty-eight retro-reflective markers were placed on the subject's lower extremities and pelvis using a six degree-of-freedom (DOF) marker set [49], [50]. Once set up, subjects walked at their self-selected speed on a split-belt treadmill (Bertec Corp., Columbus, OH, USA) that was calibrated to optimize center of pressure measurements [51]. A seven-camera motion analysis system (Motion Analysis, Santa Rosa, CA, USA) was used to capture segment kinematics while the force platforms under the treadmill belts captured kinetic data. Kinematic and kinetic data were captured at 240Hz and 1200Hz, respectively. After the data collection, data were processed through Cortex (Motion Analysis Corp., Santa Rosa, CA, USA). Then, to determine each subject's absolute maximum plantar flexion moment during the stance phase of gait, a standard inverse dynamics approach was used in Visual 3D (C-Motion, Inc.,

Gaithersburg, MD, USA). The absolute value of the maximum plantar flexion moment was taken because when the coordinate system at the ankle moves relative to the coordinate system at the knee, plantar flexion is negative. All plantar flexion moments were scaled by each subject's mass. The data of the young and older, healthy subject's dominant leg were analyzed where leg dominance was determined using the Waterloo Footedness Questionnaire [52]. Data from the paretic leg were analyzed for individuals post-stroke.

Plantar Flexor Strength Testing: Isometric Muscle Test

After the gait analysis, young and older, healthy subjects performed isometric muscle testing on their dominant leg using a Kin-Com (Chattex Corp., Chattanooga, TN, USA). Individuals post-stroke performed isometric muscle testing on their paretic leg. In the isometric plantar flexor test, the subject resisted a force applied to the bottom of the foot [35]. Each subject performed this test barefoot, laying supine with their arms across their chest and the knee of the testing leg fully extended (Fig. 1a). Each subject placed his/her ankle into the ankle attachment of the machine and the heel pad was positioned so that the subject's lateral malleolus aligned with the rotational axis of the Kin-Com. The subject's ankle was snuggly strapped into the ankle attachment using Velcro straps across the metatarsals and ankle joint (Fig. 1b). The subject's first metatarsal joint was placed in the middle of the forefoot pad. The ankle attachment was positioned at 10^{o} dorsiflexion using an electric goniometer (Mitutoyo, Aurora, IL, USA), which was calibrated so that 0^{o} was parallel to a horizontal surface.

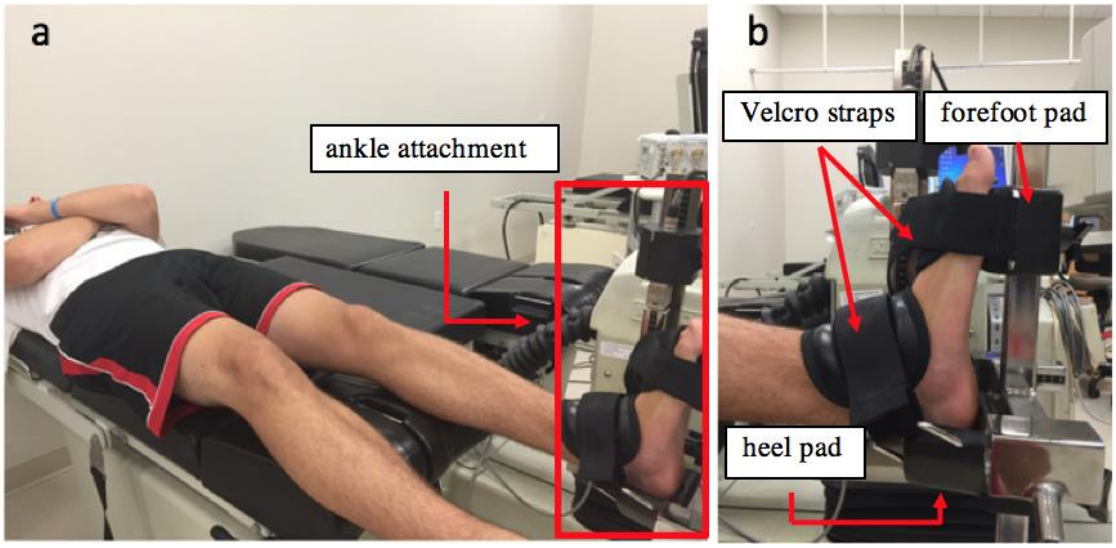

Figure 1 a) The testing position for isometric testing. b) The testing ankle at 10^{o} dorsiflexion.

For the test, the subjects were instructed to push on the forefoot pad at a constant force as if he/she was pushing on a gas pedal. Subjects were given three practice rounds to familiarize themselves with the procedure. For the practice rounds, subjects were asked to exert approximately 50%, 75%, and 100% of their maximum force, respectively. After this familiarization phase, subjects performed at least three trials, each at least three seconds long, pushing at their maximum force. Subjects received verbal encouragement during each trial. A custom LabView program (National Instruments, Austin, TX, USA) recorded and graphed force curves. After each trial, the force over time was inspected to ensure the graph had a plateau at the maximum force with no peaks or valleys. If the force curve did not have a plateau, the trial was repeated.

After three successful trials were captured, data were analyzed in the custom LabView program and the maximum force produced during each trial was determined.

Each trial's maximum force values were then averaged to determine the average maximum force (F_{avg}) for the entire test. To calculate the subject's maximum plantar flexion torque (τ_{max}; Eq. 1), the average maximum force was multiplied by the subject's moment arm ($PF_{moment\ arm}$). Calculating the subject's moment arm required anthropometric measurements of the foot, which were recorded during the gait analysis, and trigonometry (Eq. 2). The specific anthropometric measurements were foot length, the distance from the ankle joint center (AJC) to heel ($d_{AJC\text{-}HEEL}$) and the distance from the second metatarsal head (MH2) to the end of the toe ($d_{MH2\text{-}TOE}$). The force during the isometric muscle test originated at the ankle joint center and through the plantar flexor muscles. The subject pushed his/her forefoot on the forefoot pad, thus the metatarsal joints are the point about which the foot pivots. Moreover, the perpendicular distance from the ankle joint center to the second metatarsal joint was the moment arm.

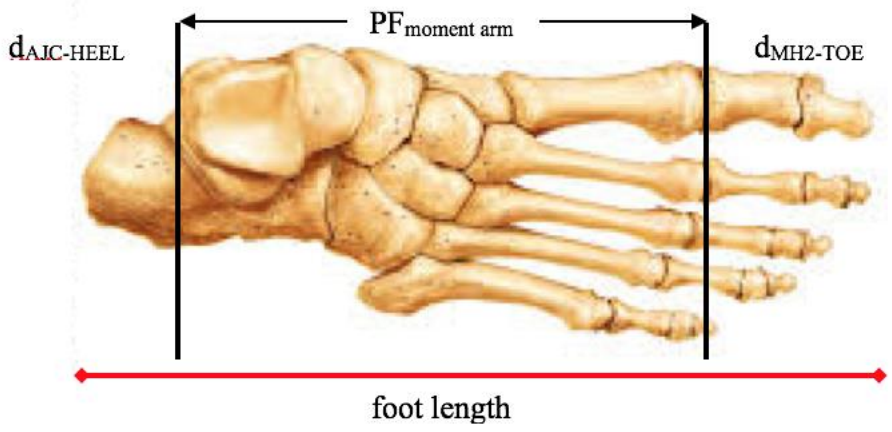

Figure 2 Foot anthropometrics used to calculate the plantar flexor moment arm.

$$\tau_{max} = F_{avg} * PF_{moment\ arm} \quad \text{Eq. 1}$$

$$PF_{moment\ arm} = \left[(foot\ length) - d_{AJC-HEEL} - d_{MH2-TOE}\right] * \cos\theta,$$

$$where\ \theta = 10^{o}\ dorsiflexion \qquad \text{Eq. 2}$$

Plantar Flexor Strength Testing: Single-Leg Heel Test

Young and Older, Healthy Individuals

After isometric muscle testing, subjects performed a standing single-leg heel rise test on their dominant leg using MuscleLab® software (Ergotest Technology, Oslo, Norway). For this test, subjects stood barefoot on an inclined platform that positioned their ankle in 10º dorsiflexion when their shank was vertical (Fig. 3a). A ring, which was attached to a linear encoder, was taped to the back of the subject's calcaneus (Fig. 3b). The linear encoder measured heel rise height throughout the entirety of the test, with a 0.019mm resolution and a 200Hz sampling rate. Before the single-leg heel rise test was conducted, the linear encoder was calibrated for each subject. For this calibration, subjects were asked to perform their highest heel rise, pause, and then return to the resting position with their heel on the platform.

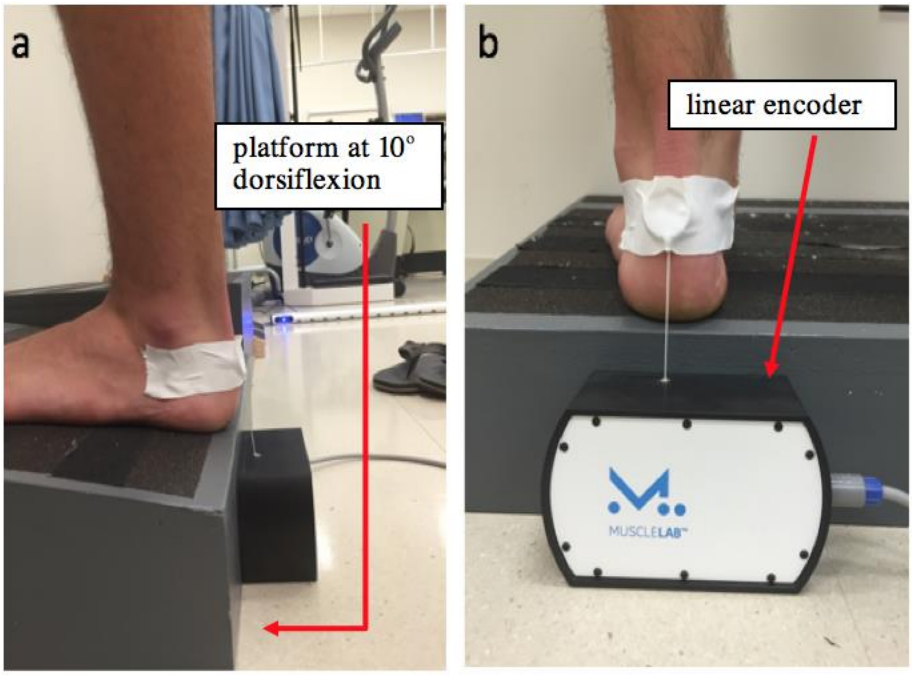

Figure 3 a) Side view of the ankle at 10° dorsiflexion during the single-leg heel rise test. b) The string from the linear encoder taped to the heel during the single-leg heel rise test.

During the single-leg heel rise test, subjects were allowed two fingers of each hand on the wall to assist with balance. Each subject was instructed to do as many heel rises as possible, as high as possible, while keeping his/her knee of the testing leg fully extended for the entirety of the test. A metronome was set to 60 beats/minute and subjects were instructed to perform heel rises every two seconds in sync with the metronome. Essentially, subjects performed 30 heel rises/minute. Subjects received verbal encouragement for the entirety of the test. The test was terminated when the subject flexed his/her knee of the testing leg, used more than two fingers of each hand for balance, when two heel rises were not in sync with the metronome, or if the subject acknowledged he/she could not complete any more heel rises.

Outcome variables, including displacement height of each heel rise, force (time it took the subject to displace his/her body mass), and total work (sum of the force times the heel rise displacement height) were recorded and automatically calculated in the MuscleLab® software. Total work (W_{tot_SLHR}) was calculated in the MuscleLab® software by adding up the force (F) produced at each heel rise multiplied by the heel rise displacement (d; Eq. 3). Since heel rise displacement was measured in centimeters, the product, F*d, had to be divided by 100 as a conversion from centimeters to meters, which enabled the calculation of total work in Joules. Force was calculated automatically in the MusceLab® software by summing the individual's mass (m) multiplied by gravity (g) and the individual's mass (m) multiplied by the heel rise displacement (d) divided by the time (s) it took the individual to perform the heel rise squared (Eq. 4).

$$W_{tot\_SLHR} = \Sigma \frac{Fd}{100} \quad \text{Eq. 3}$$

$$F = mg + m\frac{d}{(s)^2} \quad \text{Eq. 4}$$

The plantar flexion moment during the single-leg heel rise test was calculated by multiplying the force and the moment arm, which was determined from anthropometric measurements of the foot during the gait analysis (Eq. 2). The maximum plantar flexion moment during the single-leg heel rise test was determined to be at the maximum heel rise displacement (d_{max}; Eq. 5).

$$PF_{max} = F * PF_{moment\ arm}, at\ d_{max} \quad \text{Eq. 5}$$

Individuals Post-Stroke

After isometric muscle testing, individuals post-stroke performed single-leg heel rise test on their paretic leg using MuscleLab® software. The single-leg heel rise

test had to be modified since individuals post-stroke were unable to perform the test in a standing position. Thus, subjects performed this test either laying-down, seated, or both. For the laying-down single-leg heel rise test, subjects laid on a horizontal leg press machine (Monitored Rehab Functional Squat System, Fort Worth, Texas, USA), wore a knee brace locked at 0° to prevent knee hyperextension, and placed the foot of their paretic leg on a force plate attached to a custom-made platform that positioned their ankle at 10° dorsiflexion (Fig. 4). For this test, subjects tried to perform heel rises while displacing 25% of their body weight.

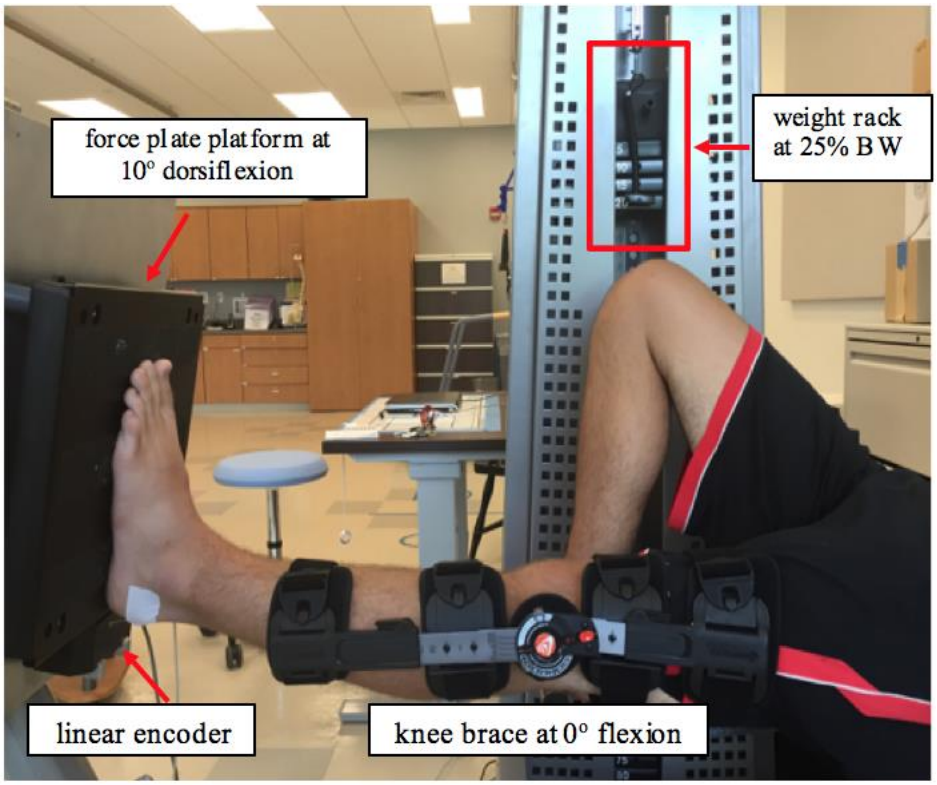

Figure 4 The testing position of individuals post-stroke during the laying-down single-leg heel rise test.

For the seated single-leg heel rise test, subjects sat in a chair with their knee at 90º and placed the foot of their paretic leg on a custom-built platform that positioned their ankle at 10º dorsiflexion (Fig. 5a). This test was performed with seven pounds, which was the weight of the device attached to the custom-made platform (Fig. 5b).

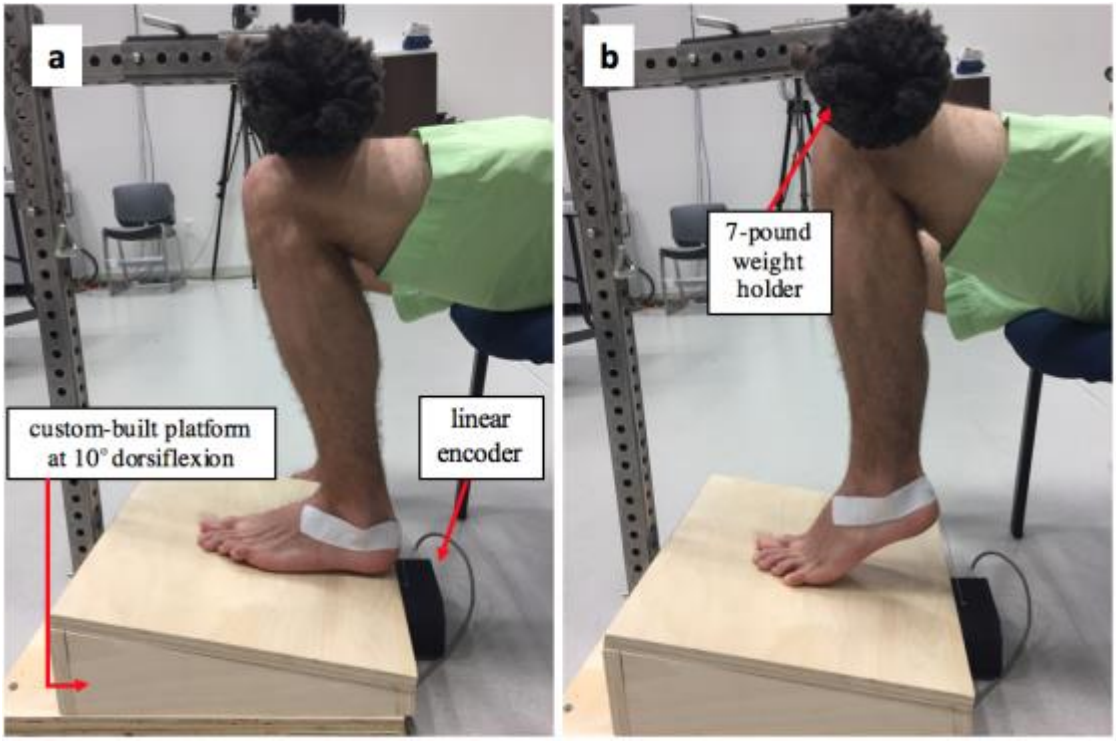

Figure 5 a) The seated single-leg heel rise test set-up using a custom-built platform that positioned the ankle at 10º dorsiflexion. b) Performing a heel rise during the seated single-leg heel rise test.

For both the laying-down and seated tests, a ring, which was attached to a linear encoder, was taped to the back of the subject's calcaneus. The linear encoder, with a 0.019mm resolution and a 200Hz sampling rate, measured heel rise height throughout the entirety of the test. To calibrate the linear encoder, subjects were asked

to perform their highest heel rise, pause, and then return to the resting position with their heel on the platform. Each subject was instructed to do as many heel rises as possible, as high as possible for the entirety of the test. A metronome was set to 60 beats/minute and subjects were instructed to perform heel rises every two seconds in sync with the metronome. Essentially, subjects performed 30 heel rises/minute. Subjects received verbal encouragement for the entirety of each test. The test(s) was terminated if the subject could not perform a single heel rise, when two heel rises were not in sync with the metronome, or if the subject acknowledged he/she could not complete any more heel rises.

Outcome variables including displacement height of each heel rise, force and total work were recorded in the MuscleLab® software. These data, in addition to anthropometric measurements of the foot, were used to calculate the plantar flexion moment of each heel rise (Eq. 2). The maximum plantar flexion moment during the single-leg heel rise test was calculated using the heel rise with the greatest displacement (Eq. 5).

Statistical Analysis

Aim 1: $M_{SLHR} \approx M_{GAIT}$

To determine if the absolute maximum plantar flexion moment calculated during the single-leg heel rise test was equivalent to the absolute maximum plantar flexion moment during gait for each population, the percent difference between these two values was calculated for each subject (Eq. 6). The absolute maximum plantar flexion moment during gait and that calculated from the single-leg heel rise test were determined to be equivalent if the percent difference between these two values was

less than 10%, which we considered an acceptable, conservative threshold to evaluate differences between these two variables. After average percent differences were calculated, the absolute values of these percent differences were averaged across subjects to determine the absolute average percent difference.

$$\%\ diff = \frac{(M_{SLHR} - M_{GAIT})}{0.5(M_{SLHR} + M_{GAIT})} * 100 \quad \text{Eq. 6}$$

Additionally, using SPSS version 24 (IBM, Armonk, NY, USA), a one-tailed Pearson correlation analysis was conducted to evaluate if maximum plantar flexion moment calculated from the single-leg heel rise test was correlated to absolute maximum plantar flexion moment during gait for each population.

Aim 2: W_{tot_SLHR} and HR_{avg_SLHR} correlates to M_{GAIT}

To evaluate if total work and average heel rise height during the single-leg heel rise test correlated to the absolute maximum plantar flexion moment during gait, a positive, one-tailed Pearson correlation analysis was conducted for each parameter and each population using SPSS version 24.

Aim 3: T_{max_ISO} correlates to M_{GAIT}

To evaluate if maximum isometric plantar flexor torque predicted absolute maximum plantar flexion moment during gait, a one-tailed Pearson correlation analysis was conducted between these two variables for each population using SPSS version 24.

Chapter 3

RESULTS

Subject Demographics

Fifteen young, healthy individuals were recruited and consented to participate in this study (female: 8, male: 9, average age: 24 ± 3 years, average mass: 74.8 ± 9.2 kilograms, average height: 1.8 ± 0.1 meters). The average self-selected walking speed was 0.79 ± 0.07 statures/second. Results from the Waterloo Footedness Questionnaire showed that 11out of the 15 young, healthy individuals were right-leg dominant. Fourteen older, healthy individuals were recruited and consented to participate in this study. However only ten subjects' data were analyzed (female: 2, male: 8, average age: 72 ± 4 years, average mass: 84.2 ± 13.0 kilograms, average height: 1.73 ± 0.06 meters) as four individuals were excluded as they could not comfortably walk at their over-ground self-selected walking speed on the split-belt treadmill. The average self-selected walking speed for the 10 older, healthy individuals was 0.82 ± 0.12 statures/second. Results from the Waterloo Footedness Questionnaire showed that eight out of the 10 older, healthy individuals were right-leg dominant. Eight individuals post-stroke were recruited and consented to participate in this study (female: 2, male: 6, average age: 59 ± 12 years, average mass: 93.5 ± 19.6 kilograms, average height: 1.75 ± 0.07 meters). The average self-selected walking speed for these eight individuals post-stroke was 0.31 ± 0.12 statures/second. The right side was the affected side for five out of the eight individuals post-stroke.

Aim 1: $M_{SLHR} \approx M_{GAIT}$

Results for aim 1 were analyzed to determine if the maximum plantar flexion moment calculated from the single-leg heel rise test was equivalent to the absolute

maximum plantar flexion moment during gait for young, healthy individuals, older, healthy individuals and individuals post-stroke.

Young, Healthy Individuals

Comparing plantar flexion moments calculated from the single-leg heel rise test and during gait, seven subjects had greater absolute maximum plantar flexion moments during gait than that calculated from the single-leg heel rise test (Fig. 6). Furthermore, ten subjects, indicated with an asterisk (*), had an absolute percent difference within a 10% threshold and three additional subjects, indicated with a plus sign ($^{+}$), had an absolute percent difference less than 15% (Table 1). Furthermore, the average absolute percent difference was 9.4 ± 5.6% (Table 1). These data support the hypothesis that maximum plantar flexion moment during the single-leg heel rise test was within 10% of the maximum plantar flexion moment during gait. The scatterplot of the data seemed to reach a threshold in the relationship between the two variables. At lower values, both the absolute maximum plantar flexion moment during gait and maximum plantar flexion moment calculated from the single-leg heel rise test appeared to increase. However, as higher values were reached, the maximum plantar flexion moment calculated from the single-leg heel rise test appeared to plateau even as the absolute maximum plantar flexion moment during gait continued to increase (Fig. 7). Statistical analysis showed there was not a significant correlation between the absolute maximum plantar flexion moments during gait and that calculated from the single-leg heel rise test ($r = 0.512$, $p = 0.051$; Fig. 7), however the correlation was very close to being significant.

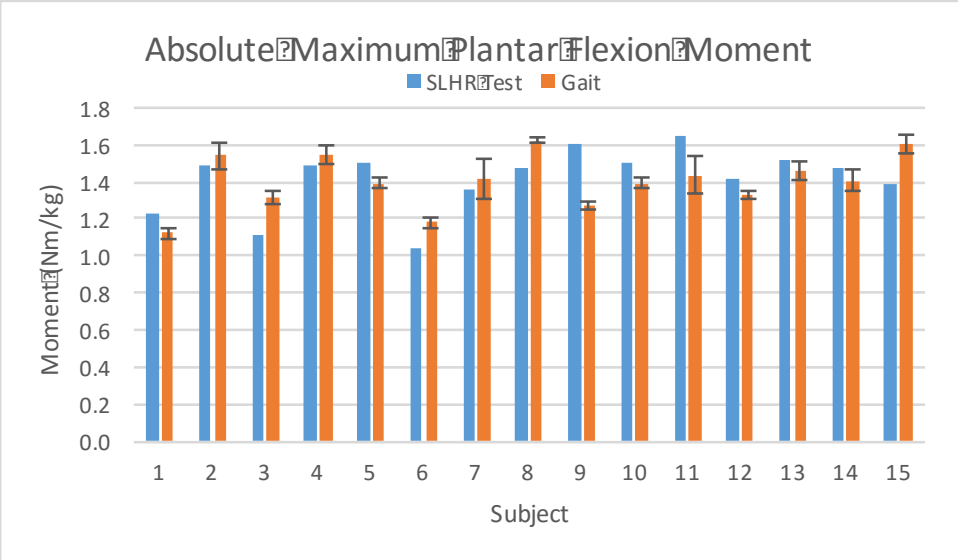

Figure 6 Absolute maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for young, healthy individuals.

Table 1 Percent difference of maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for young, healthy individuals.

Subject	Maximum PF Moment		Percent Difference
	SLHR	Gait	
	Nm/kg		%
1	1.234	1.121	9.6*
2	1.485	1.538	-3.5*
3	1.116	1.310	-16.0
4	1.480	1.545	-4.3*
5	1.499	1.390	7.6*
6	1.043	1.180	-12.3^{+}
7	1.355	1.415	-4.3*
8	1.478	1.621	-9.2*
9	1.599	1.265	23.3
10	1.507	1.393	7.9*
11	1.646	1.431	14.0^{+}
12	1.410	1.327	6.1*
13	1.517	1.459	3.9*
14	1.478	1.405	5.0*
15	1.393	1.606	-14.2^{+}
Abs. Avg. (S.D.)	**1.416 (0.168)**	**1.400 (0.145)**	**9.4 (5.6)**

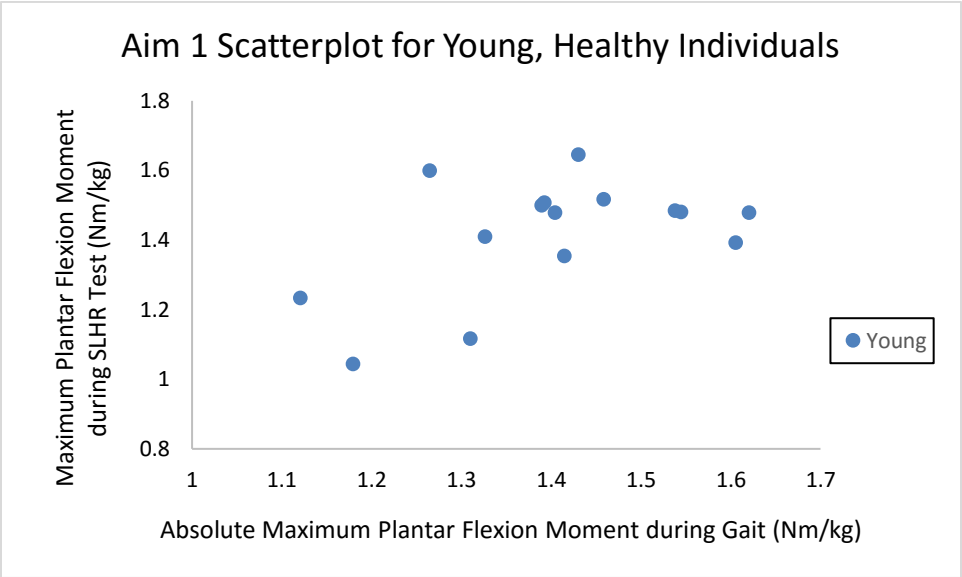

Figure 7 Scatterplot showing the relationship between the absolute maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for young, healthy individuals (r = 0.512, p = 0.051).

Older, Healthy Individuals

Comparing plantar flexion moments calculated from the single-leg heel rise test and during gait, four subjects had greater absolute maximum plantar flexion moments during gait than that calculated from the single-leg heel rise test (Fig. 8). Furthermore, half of the subjects, indicated with an asterisk (*), had an absolute percent difference less than 10% and three additional subjects, indicated with a plus sign ($^{+}$), had an absolute percent difference less than 15% (Table 2). Furthermore, the average absolute percent difference was 9.0 ± 6.9% (Table 2). These data support the hypothesis that maximum plantar flexion moment during the single-leg heel rise test was within 10% of the maximum plantar flexion moment during gait. The scatterplot of the data show the relationship between these two variables and indicated that as absolute maximum plantar flexion moment during gait increased, the maximum

plantar flexion moment calculated from the single-leg heel rise test also increased (Fig. 9). Statistical analysis showed there was a significant, moderate correlation between the absolute maximum plantar flexion moment during gait and that calculated from the single-leg heel rise test (r = 0.647, p = 0.043; Fig. 9). This finding further supports the notion that there is a relationship between these two variables.

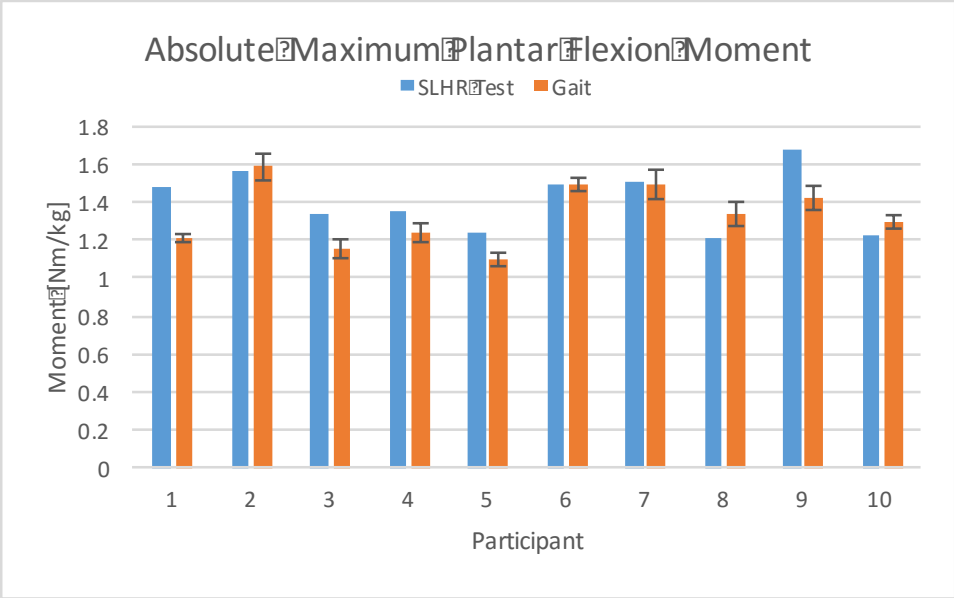

Figure 8 Absolute maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for older, healthy individuals.

Table 2 Percent difference of maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for older, healthy individuals.

Subject	Maximum PF Moment		Percent Difference
	SLHR	Gait	
	Nm/kg		%
1	1.473	1.213	19.4
2	1.568	1.587	-1.2*
3	1.333	1.151	14.7+
4	1.351	1.241	8.5*
5	1.240	1.093	12.6+
6	1.495	1.489	0.4*
7	1.508	1.496	0.8*
8	1.203	1.335	-10.4+
9	1.675	1.419	16.5
10	1.228	1.294	-5.2*
Abs. Avg. (S.D.)	**1.407 (0.160)**	**1.332 (0.163)**	**9.0 (6.9)**

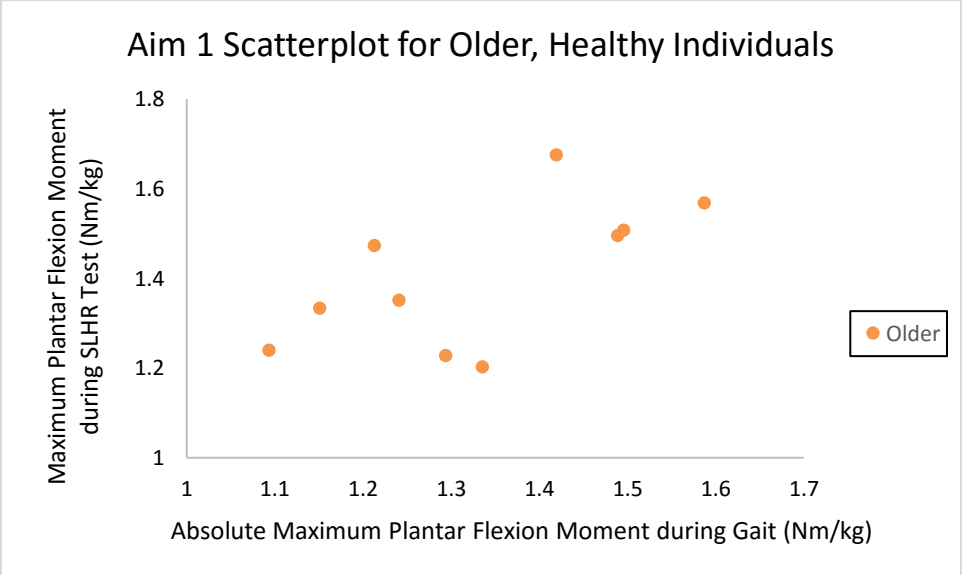

Figure 9 Scatterplot showing the relationship between the absolute maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for older, healthy individuals (r = 0.647, p = 0.043).

Individuals Post-Stroke

For the single-leg heel rise test, a heel rise is recorded if the displacement is greater than 2 centimeters. None of the individuals post-stroke were able to perform heel rises during the laying-down single-leg heel rise test that were large enough to be registered by the MuscleLab® software. Furthermore, only one individual post-stroke, out of two tested, could perform the seated single-leg heel rise test, thus a statistical analysis could not be conducted. However, this subject's absolute maximum plantar flexion moment during gait was 0.736 Nm/kg and the maximum plantar flexion moment calculated from the single-leg heel rise test was 0.059 Nm/kg, which is an absolute difference of 170%.

Summary of Aim 1 Data: Young and Older, Healthy Individuals

For further analysis, absolute maximum plantar flexion moments during gait and those calculated from the single-leg heel rise test for young and older, healthy individuals were combined. The plateau in the data was still evident when the data from young and older, healthy individuals were combined (Fig. 10). However, combining these two populations, which provided a wider range in plantar flexion moments, resulted in a significant, moderate correlation between the absolute maximum plantar flexion moment during gait and that calculated from the single-leg heel rise test ($r = 0.556$, $p = 0.004$; Fig. 10).

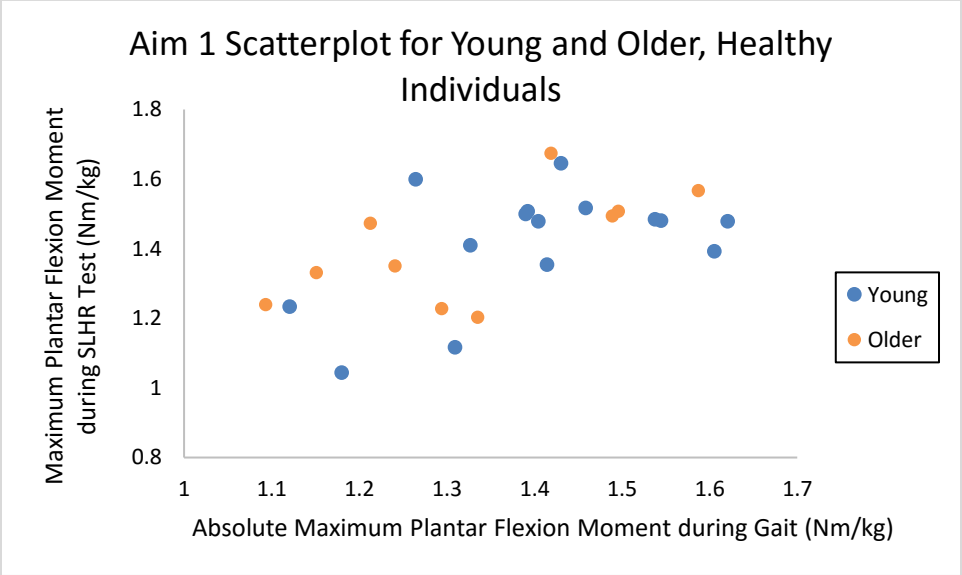

Figure 10 Scatterplot showing the relationship between the absolute maximum plantar flexion moment calculated from the single-leg heel rise test and during gait for young and older, healthy individuals (r = 0.556, p = 0.004).

Aim 2: W_{tot_SLHR} and HR_{avg_SLHR} correlates to M_{GAIT}

Results for aim 2 were analyzed to evaluate if total work and average heel rise height during the single-leg heel rise test correlated to the absolute maximum plantar flexion moment during gait for young, healthy individuals, older, healthy individuals and individuals post-stroke.

Young, Healthy Individuals

Evaluating gait data and data from the single-leg heel rise test, there was no clear trend in the data. Subject 8 had the greatest maximum plantar flexion moment during gait and had the greatest average heel rise height, but did not do the most amount of work (Table 3). Subject 1 had the lowest maximum plantar flexion moment during gait, but did not do the least amount of work or have the lowest average heel

rise height during the single-leg heel rise test (Table 3). Plotting the total work data against the absolute maximum plantar flexion moment data showed that total work done during the single-leg heel rise test did not noticeably increase as absolute maximum plantar flexion moment during gait increased (Fig. 11). Plotting the average heel rise height data against the absolute maximum plantar flexion moment data showed a positive and seemingly exponential relationship between the variables (Fig. 12). Statistical analysis showed there was not a significant correlation between the absolute maximum plantar flexion moment during gait and total work ($r = 0.150$, $p = 0.296$; Fig. 11) or average heel rise height ($r = 0.247$, $p = 0.187$; Fig. 12) during the single-leg heel rise test. Thus, these data do not support the hypothesis that there is a correlation between either of these two output variables from the single-leg heel rise test and to the maximum plantar flexion moment during gait.

Table 3 Maximum plantar flexion moment during gait, and total work and average heel rise height during the single-leg heel rise test for young, healthy individuals.

Subject	Max. PF Moment Gait	Total Work	Avg. Heel Rise Height
	Nm/kg	J	cm
1	1.121	1461	10.5 ± 2.2
2	1.538	1810	11.6 ± 0.6
3	1.310	1237	9.7 ± 0.8
4	1.545	1327	9.4 ± 1.1
5	1.390	4218	9.4 ± 1.8
6	1.180	1948	12.9 ± 1.8
7	1.415	1872	9.7 ± 0.8
8	1.621	2029	13.1 ± 0.6
9	1.265	1757	9.5 ± 0.7
10	1.393	1742	10.4 ± 0.7
11	1.431	1999	8.8 ± 1.5
12	1.327	1770	9.8 ± 0.8
13	1.459	2182	11.0 ± 0.8
14	1.405	2300	10.3 ± 2.9
15	1.606	2282	12.5 ± 0.1

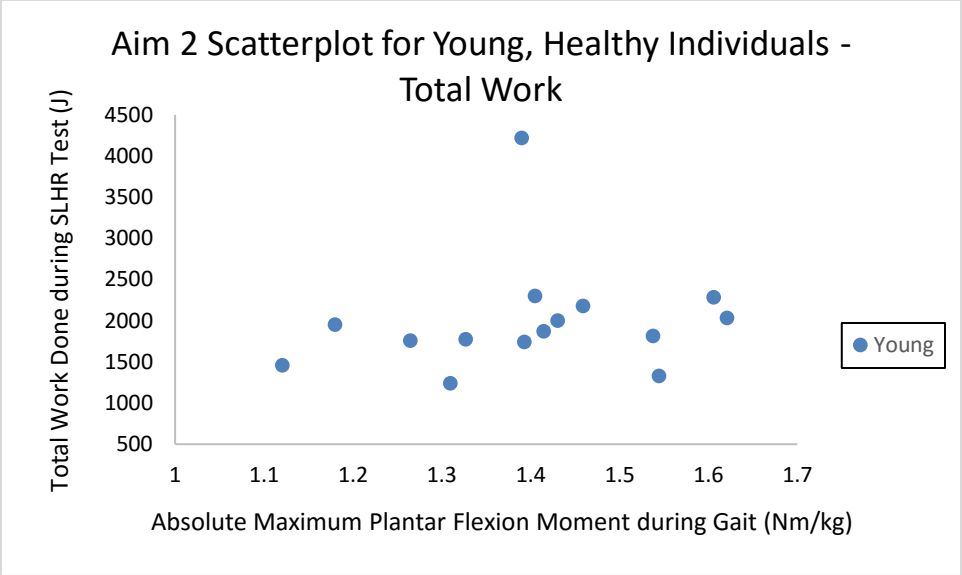

Figure 11 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and total work during the single-leg heel rise test for young, healthy individuals (r = 0.150, p = 0.296).

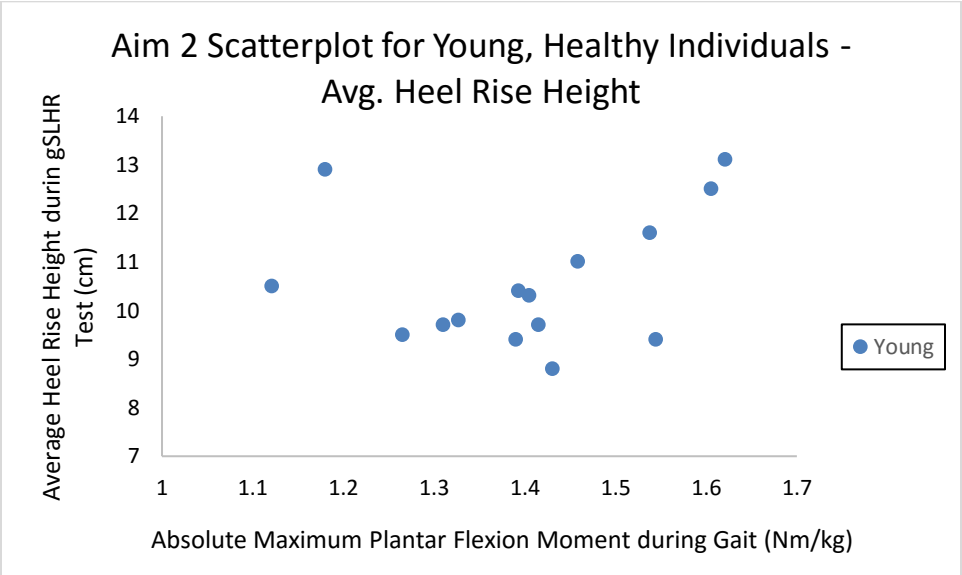

Figure 12 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and average heel rise height during the single-leg heel rise test for young, healthy individuals (r = 0.247, p = 0.187).

Older, Healthy Individuals

Evaluating gait data and data from the single-leg heel rise test, some trends were observed between absolute maximum plantar flexion moment during gait and total work. Subjects 2 and 7 had the highest absolute maximum plantar flexion moment during gait and did the most work during the single-leg heel rise test (Table 4). Overall, subjects that had a lower absolute maximum plantar flexion moment during gait generally did less work during the single-leg heel rise test (Fig. 13). Statistical analysis supported these observations, showing that there was a significant, moderate correlation between the absolute maximum plantar flexion moment during gait and total work during the single leg heel rise test ($r = 0.573$, $p = 0.042$; Fig. 13).

In contrast, no clear trends between absolute maximum plantar flexion moment during gait and average heel rise height. Subject 2 had the greatest absolute maximum plantar flexion moment during gait and average heel rise height, but subject 5 had the lowest absolute maximum plantar flexion moment during gait and the second highest average heel rise height (Table 4). Plotting the data did not show an evident relationship between these two variables (Fig. 14). Statistical analyses supported these observations as there was not a significant correlation between the absolute maximum plantar flexion moment during gait and average heel rise height during the single-leg heel rise test ($r = 0.405$, $p = 0.123$; Fig. 14). Overall, these results partially supported the hypothesis that total work and average heel rise height during the single-leg heel rise test are correlated to maximum plantar flexion moment during gait.

Table 4 Maximum plantar flexion moment during gait, and total work and average heel rise height during the single-leg heel rise test for older, healthy individuals.

Subject	Max. PF Moment Gait Nm/kg	Total Work J	Avg. Heel Rise Height cm
1	1.213	731	4.0 ± 0.6
2	1.587	2530	12.8 ± 1.7
3	1.151	519	5.1 ± 0.7
4	1.241	1875	9.1 ± 1.5
5	1.093	1554	9.4 ± 1.7
6	1.489	1082	7.1 ± 2.4
7	1.496	2069	7.8 ± 2.3
8	1.335	976	6.7 ± 1.9
9	1.419	1566	5.9 ± 1.7
10	1.294	1301	6.3 ± 1.4

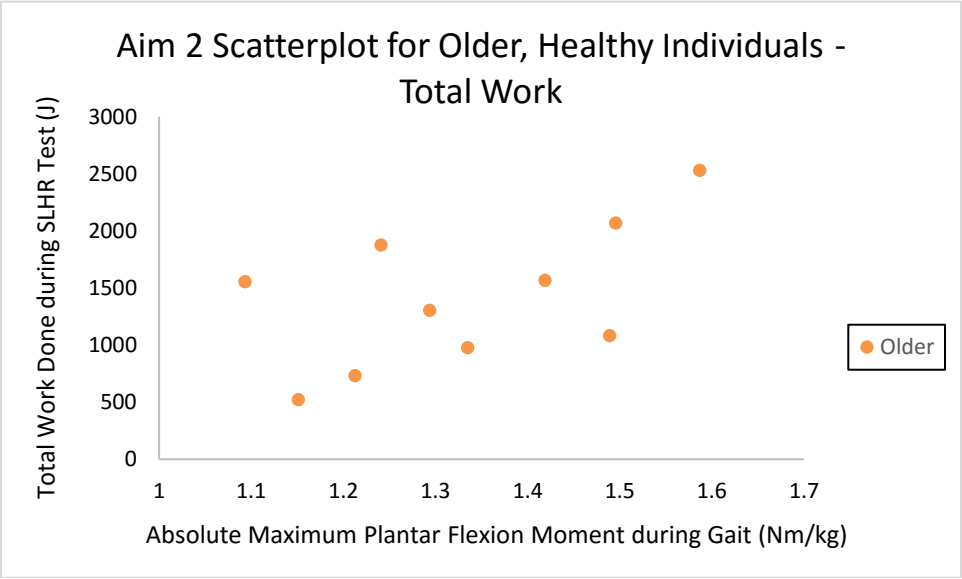

Figure 13 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and total work during the single-leg heel rise test for older, healthy individuals (r = 0.573, p = 0.042).

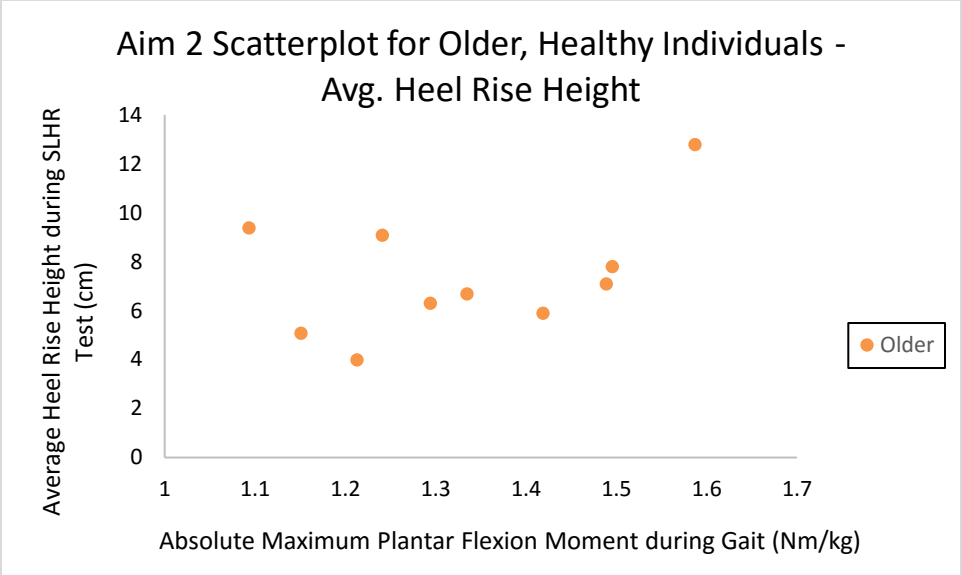

Figure 14 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and average heel rise height during the single-leg heel rise test for older, healthy individuals (r = 0.405, p = 0.123).

Individuals Post-Stroke

None of the individuals post-stroke were able to perform heel rises during the laying-down single-leg heel rise test. Furthermore, only one individual post-stroke could perform the seated single-leg heel rise test thus far, therefore statistical analysis could not be conducted. During gait, this subject's absolute maximum plantar flexion moment was 0.736 Nm/kg and during the seated single-leg heel rise test, the subject's total work was 9.72 J and average heel rise height was 1.63 cm.

Summary of Aim 2 Data: Young and Older, Healthy Individuals

The data for young and older, healthy individuals were combined for further analysis. Visual inspection of these combined data did not reveal any strong trends (Fig. 15). Furthermore, one young, healthy subject did not follow this trend and fell

outside of where the majority of the data lie (Fig. 15). A one-tailed Pearson correlation analysis was conducted between absolute maximum plantar flexion moment during gait and total work during the single-leg heel rise test. Statistical analysis showed that there was no significant correlation between absolute maximum plantar flexion moment during gait and total work during the single-leg heel rise test ($r = 0.363$, $p = 0.082$; Fig. 15).

Young and older, healthy individuals tended to have higher average heel rise heights during the single-leg heel rise test when they had higher absolute maximum plantar flexion moments during gait (Fig. 16). However, when the absolute maximum plantar flexion moments during gait were lower, the range of average heel rise height during the single-leg heel rise test was wider (Fig. 16). A one-tailed Pearson correlation analysis was also conducted between absolute maximum plantar flexion moment during gait and average heel rise height during the single-leg heel rise test. Statistical analysis showed that there was no significant correlation between absolute maximum plantar flexion moment during gait and average heel rise height during the single-leg heel rise test ($r = 0.376$, $p = 0.071$; Fig. 16).

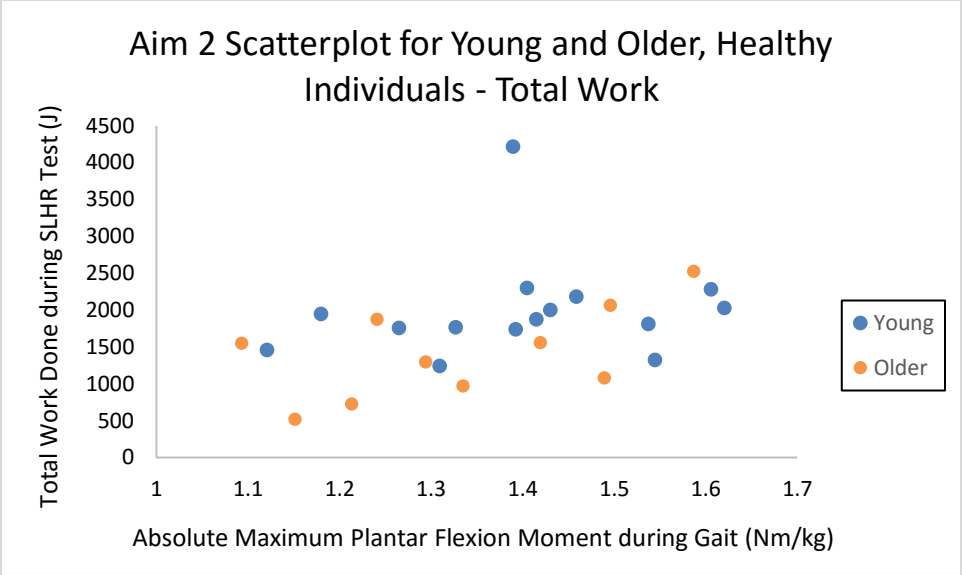

Figure 15 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and total work done during the single-leg heel rise test for young and older, healthy individuals (r = 0.363, p = 0.082).

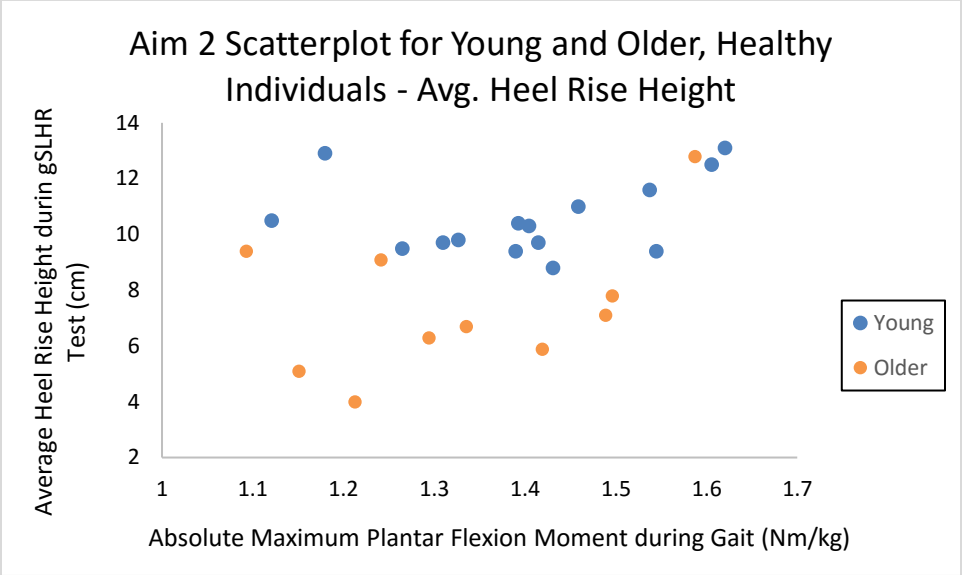

Figure 16 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and average heel rise height during the single-leg heel rise test for young and older, healthy individuals (r = 0.376, p = 0.071).

Aim 3: T_{max_ISO} correlates to M_{GAIT}

Results for aim 3 were analyzed to determine if the maximum plantar flexion torque during isometric muscle testing correlated to the absolute maximum plantar flexion moment during gait for young, healthy individuals, older, healthy individuals and individuals post-stroke.

Young, Healthy Individuals

Comparing the absolute maximum plantar flexion moments during gait and maximum isometric plantar flexion torques during isometric muscle testing, all subjects had greater moment values during gait (Fig. 17). The average absolute percent difference between the absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing was

77% ± 38% (Table 5). One subject had an absolute percent difference that was just over the 10% threshold (11%; Table 5), which is indicated with an asterisk (*). Additionally, one subject was just over the 15% threshold and had an 18% absolute percent difference (Table 5), which is indicated with a plus sign ($^{+}$). Moreover, there was a wide range of absolute percent differences between these two values (from 11% to 128% difference; Table 5).

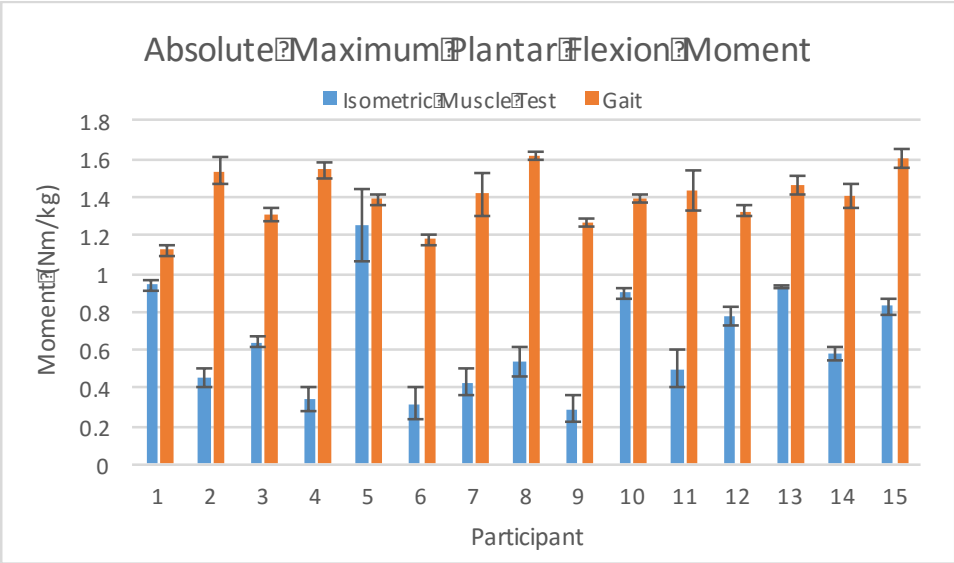

Figure 17 Absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque calculated from isometric muscle testing for young, healthy individuals.

Furthermore, statistical analysis showed that there was not a significant correlation between absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing (r = 0.046, p = 0.870; Fig. 18). Thus, these data support the hypothesis that maximum isometric

plantar flexion torque is not correlated to absolute maximum plantar flexion moment during gait.

Table 5 Percent difference between maximum isometric plantar flexion torque calculated from isometric muscle testing and absolute maximum plantar flexion moment during gait for young, healthy individuals.

Subject	Maximum PF Moment Gait	Isometric PF Torque	Percent Difference
	Nm/kg	Nm/kg	%
1	1.121	0.94	-18^{+}
2	1.538	0.46	-108
3	1.310	0.64	-69
4	1.545	0.34	-128
5	1.390	1.25	-11*
6	1.180	0.32	-115
7	1.415	0.43	-107
8	1.621	0.54	-100
9	1.265	0.29	-125
10	1.393	0.90	-43
11	1.431	0.50	-96
12	1.327	0.78	-52
13	1.459	0.93	-44
14	1.405	0.58	-83
15	1.606	0.83	-64
Abs. Avg. (S.D.)	**1.400 (0.145)**	**0.649 (0.279)**	**77 (38)**

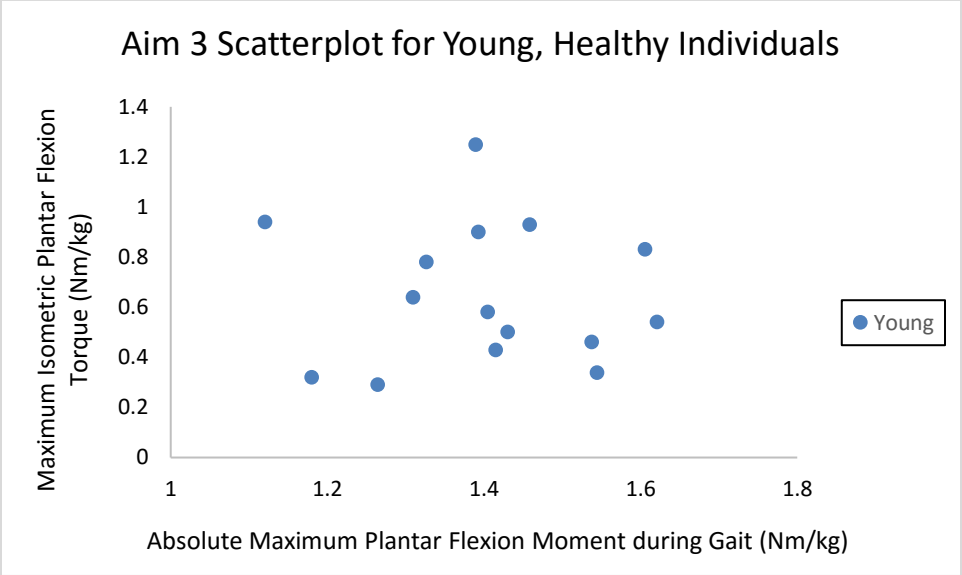

Figure 18 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing for young, healthy individuals (r = 0.046, p = 0.870).

Older, Healthy Individuals

Comparing plantar flexion moments and torques, all subjects had greater absolute maximum plantar flexion moments during gait than maximum isometric plantar flexion torques during isometric muscle testing (Fig. 19). There was a general trend in the data in that as absolute maximum plantar flexion moment during gait increased, so did maximum isometric plantar flexion torque during isometric muscle testing. Overall, the average absolute percent difference between the absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing was 68% ± 20% (Table 6). There was a wide range of absolute percent differences between these two values, the lowest absolute percent difference being 28% and the greatest being 89% (Table 6).

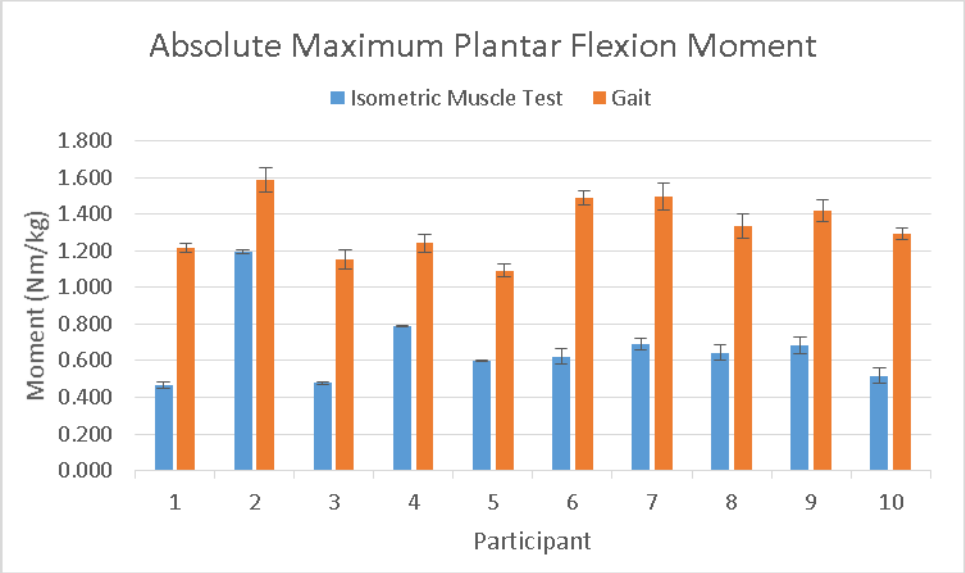

Figure 19 Absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque calculated from isometric muscle testing for older, healthy individuals.

None of the subjects had an absolute percent difference that was below the 10% or 15% threshold (Table 6). The lowest absolute percent difference was 28% difference, but this percentage value went as far as 89% (Table 6). Plotting the data showed that as absolute maximum plantar flexion moment increased, maximum isometric plantar flexion torque generally increased as well (Fig. 20). Moreover, statistical analysis showed that there was a significant, moderate correlation (r = 0.653, p = 0.041; Fig. 20) between plantar flexion moment and isometric plantar flexion torque values. Thus, these data did not support the hypothesis that maximum isometric plantar flexion torque during isometric muscle testing is not correlated to absolute maximum plantar flexion moment during gait.

Table 6 Percent difference between maximum isometric plantar flexion torque calculated from isometric muscle testing and absolute maximum plantar flexion moment during gait for older, healthy individuals.

Subject	Max. PF Moment Gait	Isometric PF Torque	Percent Difference
	Nm/kg	Nm/kg	%
1	1.213	0.466	-89
2	1.587	1.194	-28
3	1.151	0.478	-83
4	1.241	0.790	-44
5	1.093	0.601	-58
6	1.489	0.624	-82
7	1.496	0.690	-74
8	1.335	0.645	-70
9	1.419	0.683	-70
10	1.294	0.519	-85
Abs. Avg. (S.D.)	**1.332 (0.163)**	**0.669 (0.210)**	**68 (20)**

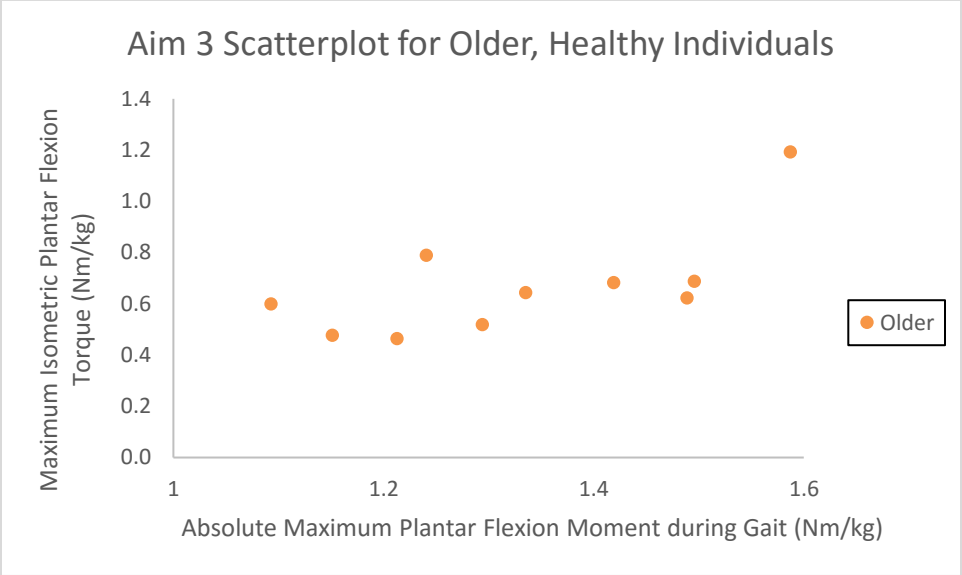

Figure 20 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing for older, healthy individuals (r = 0.653, p = 0.041).

Individuals Post-Stroke

Comparing the plantar flexion moments and torques, all subjects had a higher absolute maximum plantar flexion moment during gait than maximum isometric plantar flexion torque during isometric muscle testing (Fig. 21). There was no clear trend in the data. Subject 5 had the highest absolute maximum plantar flexion moment during gait, but had the fourth highest maximum isometric plantar flexion torque during isometric muscle testing (Fig. 21). Subject 2 had the lowest absolute maximum plantar flexion moment during gait, but had the third lowest maximum isometric plantar flexion torque during isometric muscle testing (Fig. 21).

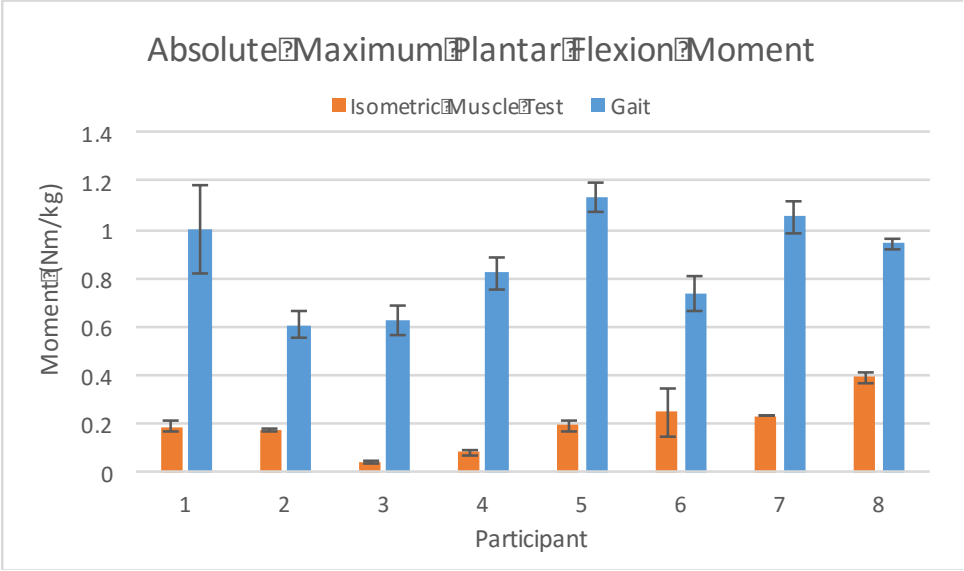

Figure 21 Absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing for individuals post-stroke.

The absolute average percent difference between absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing was 130% ± 32% (Table 7). There was a wide range of absolute percent differences between these two values, the lowest absolute percent difference being 83% and the greatest being 176% (Table 7). Furthermore, statistical analysis showed that there was not a significant correlation between absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing (r = 0.412, p = 0.310; Fig. 22). Thus, these data support the hypothesis that maximum isometric plantar flexion torque during isometric muscle testing is not correlated to absolute maximum plantar flexion moment during gait.

Table 7 Percent difference between maximum isometric plantar flexion torque calculated from isometric muscle testing and absolute maximum plantar flexion moment during gait for individuals post-stroke.

Subject	Max. PF Moment Gait	Isometric PF Torque	Percent Difference
	Nm/kg	Nm/kg	%
1	1.002	0.187	-137
2	0.608	0.172	-112
3	0.628	0.041	-176
4	0.822	0.082	-164
5	1.133	0.192	-142
6	0.736	0.248	-99
7	1.052	0.234	-127
8	0.941	0.391	-83
Abs. Avg. (S.D.)	**0.865 (0.197)**	**0.193 (0.107)**	**130 (32)**

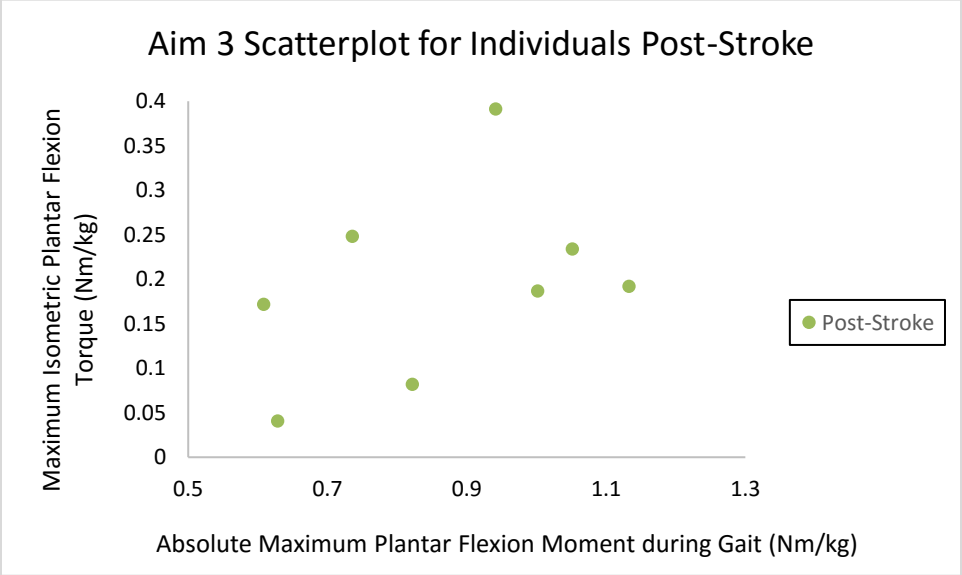

Figure 22 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing for individuals post-stroke (r = 0.412, p = 0.310).

Summary of Aim 3 Data: Young and Older, Healthy Individuals and Individuals Post-Stroke

Gait and isometric muscle testing data for all populations tested in this study were combined for further analysis. The scatterplot of the combined data shows that as absolute maximum plantar flexion moment increased, maximum isometric plantar flexion torque increased as well (Fig. 23). Furthermore, a one-tailed Pearson correlation analysis was conducted and a significant, moderate correlation between these two variables was found ($r = 0.630$, $p < 0.001$; Fig. 23).

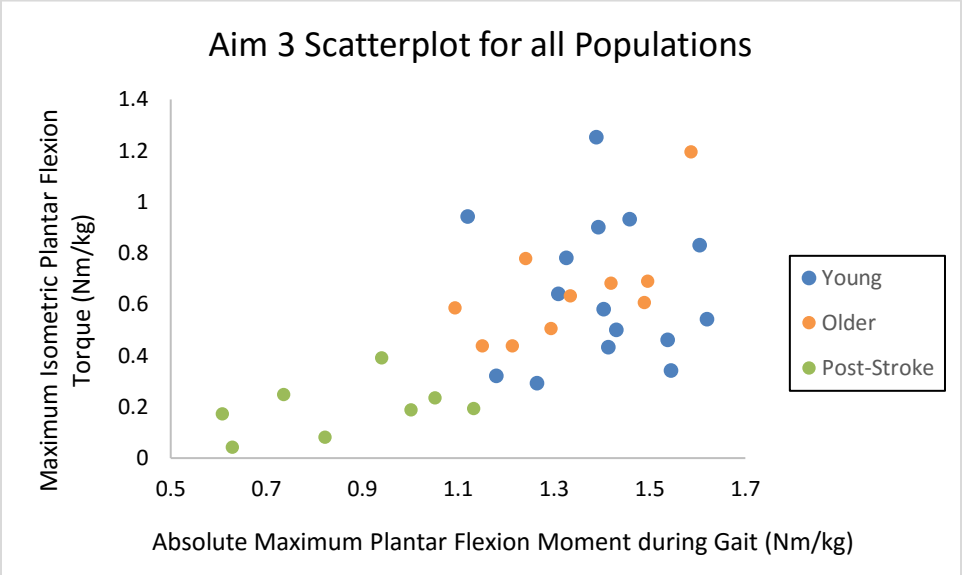

Figure 23 Scatterplot showing the relationship between the absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing for young and older, individuals and individuals post-stroke ($r = 0.630$, $p < 0.001$).

Chapter 4

DISCUSSION

This study aimed to evaluate the relationship, if any, between clinical measures of plantar flexor strength and plantar flexor function during gait in young, healthy individuals, older, healthy individuals, and individuals post-stroke. Results showed that maximum plantar flexion moment calculated during the single-leg heel rise test had a significant, moderate correlation to absolute maximum plantar flexion moment during gait for older, healthy individuals. Additionally, there was nearly a significant correlation between these two values for young, healthy individuals, which may become significant with a larger cohort. Moreover, there was a significant, moderate correlation between total work during the single-leg heel rise test and absolute maximum plantar flexion moment during gait in older, healthy individuals. Furthermore, there was a significant, moderate correlation between maximum isometric plantar flexion torque during isometric muscle testing and absolute maximum plantar flexion moment during gait in older, healthy individuals. Overall, the maximum plantar flexion moment calculated from the single-leg heel rise test was the clinical measure with the strongest relationship to the absolute maximum plantar flexion moment during gait.

Aim 1: $M_{SLHR} \approx M_{GAIT}$

This study provided initial evidence that there is a relationship between absolute maximum plantar flexion moment during gait and that calculated from a single-leg heel rise test. Namely, the average absolute percent difference between the moments calculated from the single-leg heel rise test and during gait was under a 10% threshold for young and older, healthy individuals, which supports the hypotheses of

this aim that the absolute maximum plantar flexion moment during gait and maximum plantar flexion moment calculated from the single-leg heel rise test would be equivalent if they fell within 10% of each other. To further evaluate how acceptable and conservative this 10% threshold of equivalence was, the minimal detectible change (MDC) of the absolute maximum plantar flexion moment during gait was evaluated. Wilken and colleagues determined that 0.15 was the MDC for the absolute maximum plantar flexion moment during gait [53]; in that, if the moments fell outside this MDC, then the moments are different. The post-hoc analysis showed that the 10% threshold of equivalence chosen for this study was more conservative than the MDC; thus, the 10% threshold used for this study is sufficient in detecting equivalence. Moreover, a significant, moderate correlation was found between the absolute maximum plantar flexion moment during gait and that calculated from the single-leg heel rise test for older, healthy individuals and a nearly significant correlation was found between these two variables for young, healthy individuals. All of these findings support the notion that the single-leg heel rise test may provide a clinically-feasible way to quantify plantar flexor function deficits during gait.

However, it should be noted that there was variability in the plantar flexion moment data. For instance, there were both positive and negative percent differences between the two moment values calculated from the two tests and the standard deviation of these moments was about 6% for both young and older, healthy populations. The differences in calculation of the moment arm during the single-leg heel rise test and gait may have contributed to the variability in the data. For the single-leg heel rise test, the moment arm was defined as a fixed distance between the individual's ankle joint center and the second metatarsal head, which was used since

this was the location about which foot anthropometrics were taken (i.e. $d_{MH2\text{-}TOE}$). For the gait analysis, the moment arm was defined as the distance from the ankle joint center and to the location of the center of pressure when the absolute maximum plantar flexion moment occurred during the stance phase. Thus, in the gait analysis data, the location of the distal end of the moment arm may differ for each subject. Furthermore, the moment arm during the gait analysis may differ a bit from the moment arm used for the single-leg heel rise test, which may be a reason as to why the absolute maximum plantar moment during gait was sometimes greater than the maximum plantar flexion moment calculated from the single-leg heel rise test, and vice versa.

If more young, healthy individuals are recruited for this study in the future, the correlation between absolute maximum plantar flexion moment during gait and maximum plantar flexion moment calculated from the single-leg heel rise test may become significant. Visual inspection of the scatterplot (Fig. 7) suggested that some of the data points are clustered together, which could result in lack of a significant correlation. Additionally, what seems to be a plateau in the data with higher absolute maximum plantar flexion moment values (Fig. 7) may have also contributed to the lack of a significant correlation and may indicate that there is a threshold of plantar flexor function above which the single-leg heel rise test is not effective for predicting an individual's absolute maximum plantar flexion moment during gait. When the young and older, healthy data were combined, there were similar ranges between the two populations, which provides further justification that a significant correlation between absolute maximum plantar flexion moment during gait and that calculated

from the single-leg heel rise test may be attained with more young, healthy individuals.

The maximum plantar flexion moments calculated from the single-leg heel rise test presented in this current study are comparable to data in the literature. A study conducted by Flanagan and colleagues evaluated the maximum plantar flexion moment during the single-leg heel rise test [54]. Subjects in Flanagan's study stood on a force plate that was imbedded into the ground and were asked to perform single-leg heel rises on their dominant leg at their self-selected speed. Results showed that the average maximum plantar flexion moment during the single-leg heel rise test in older, healthy individuals (roughly 75 years old) was 1.50 ± 0.23 Nm/kg [54], which is comparable to the average maximum plantar flexion moments of the older, healthy individuals in this current study (1.407 ± 0.160 Nm/kg). However, Flanagan and colleagues did not compare these results to the individual's absolute maximum plantar flexion moment during gait. Additionally, the subjects in Flanagan's study stood on a horizontal force plate whereas subjects in this current study stood on a platform that angled their ankle at 10^{o} dorsiflexion. This set-up variation of the single-leg heel rise test may explain the slight difference between the average maximum plantar flexion moments of Flanagan's study and this current study.

Absolute maximum plantar flexion moments during gait for all three populations in this study are comparable to what is presented in the literature. A study conducted by Huisinga and colleagues evaluated gait mechanics differences between healthy controls and patients with multiple sclerosis [55]. The average age of the healthy controls in Huisinga's study was 42 ± 12.5 years old and the average absolute maximum plantar flexion moment at their self-selected walking speed was 1.354 ±

0.219 Nm/kg [55]. If the data from this current study for young and older, healthy populations were to be combined, the average age (48 years old) and the average absolute maximum plantar flexion moment during gait (1.366 ± 0.048 Nm/kg) would be nearly identical to the data presented by Huisinga and colleagues. Kitatani and colleagues reported that individuals post-stroke had an average absolute maximum plantar flexion moment during gait of about 0.9 Nm/kg on their paretic side [56]. The average age of the subjects in Kitatani's study was 64.4 ± 8.5 years old and the average walking speed was 0.42 ± 0.14 statures/second [56]. The average absolute maximum plantar flexion moment during gait of the paretic leg, average age, and average walking speed for individuals post-stroke in this current study were: 0.865 ± 0.197 Nm/kg, 59 ± 12 years old, 0.31 ± 0.12 statures/second. Seventeen individuals post-stroke participated in Kitatani's study and only eight individuals post-stroke participated in this current study, which may explain the slight discrepancies between the data sets. However, results from this current study and Kitatani's study are still comparable.

The results for this aim fill a knowledge gap and support the notion that there is a relationship between absolute maximum plantar flexion moment during gait and maximum plantar flexion moment calculated from the single-leg heel rise test. Maximum plantar flexion moment calculated from the single-leg heel rise test has been evaluated in one previous study, however, the testing setup was different from the standard clinical test setup. Furthermore, a correlation analysis to absolute maximum plantar flexion moment during gait was not conducted. Thus, this current study evaluated the correlation between these two measures and found that the correlation was significant for older, healthy individuals and nearly significant for

young, healthy individuals. Furthermore, when the young and older, healthy individuals' data were combined, a significant correlation was found and may further justify that a significant correlation could be attained if more young, healthy individuals were recruited. Although the maximum plantar flexion moment calculated from the single-leg heel rise test likely cannot provide a direct measure of the absolute maximum plantar flexion moment during gait, clinicians may be able to easily and quickly evaluate a patient's plantar flexor function during gait based on his/her performance during the single-leg heel rise test.

Aim 2: W_{tot_SLHR} and HR_{avg_SLHR} correlates to M_{GAIT}

The results for this aim showed that neither total work nor average heel rise height were correlated to absolute maximum plantar flexion moment during gait for young, healthy individuals. Yet, total work was correlated to absolute maximum plantar flexion moment during gait for older, healthy individuals. Additionally, only one individual post-stroke, out of two tested, was able to perform the seated heel rise test, thus statistical analysis could not be conducted. The results for young, healthy individuals do not support the hypothesis that total work and average heel rise height during the single-leg heel rise test would be correlated to absolute maximum plantar flexion during gait. Furthermore, the results for older, healthy individuals partially support the hypothesis for this aim since only total work was correlated to absolute maximum plantar flexion moment during gait.

Total work can be considered a maximal measure of plantar flexor strength for the single-leg heel rise test as it is a summation of the time it takes an individual to displace his/her body weight across all heel rises. Absolute maximum plantar flexion moment during gait is also a maximal measure of plantar flexor function in that it is

the peak value on the plantar flexion moment curve during the stance phase of gait. Because these two values are both maximal measures of plantar flexor strength and function, respectively, the finding that there was a significant, moderate correlation between them for older, healthy individuals suggests that this population may use their maximum plantar flexor strength to walk at their self-selected speed. Since there was not a significant correlation between total work and absolute maximum plantar flexion moment during gait for young, healthy individuals, it is possible this population may have greater plantar flexor strength than what they require to walk at their self-selected speed. Additionally, plantar flexor strength in young, healthy individuals may vary more between subjects as compared to older, healthy individuals. Thus, the proportion of plantar flexor strength that young, healthy individuals require during gait may not be as consistent across subjects as compared to older, healthy individuals, which is shown in the results since young, healthy individuals had a greater standard deviation of the average total work than older, healthy individuals. Moreover, it should be noted that statistical analysis of the combined data for young and older, healthy individuals reduced the strength of the correlation between total work and absolute maximum plantar flexion moment. However, this may only be because the subject that did the most work during the single-leg heel rise test is skewing the data. In fact, a post-hoc analysis showed that if this subject's data were to be excluded, then the correlation between total work and absolute maximum plantar flexion moment would be significant ($r = 0.510$, $p = 0.011$) when data for young and older, healthy individuals is combined. While total work is not a direct measure of plantar flexor function during gait, this study suggested that it may be a surrogate measure of plantar flexor function

during gait and could potentially be used to evaluate plantar flexor function for patient populations with age-related plantar flexor weakness.

Average heel rise height during the single-leg heel rise test may be affected by subject-specific factors, such as the subject's plantar flexor endurance or motivation to complete the single-leg heel rise test, which may explain why no significant correlations were found in young or older, healthy individuals. Furthermore, when the data for both populations were combined, the spread of the data (Fig. 16) may have also contributed to the lack of a significant correlation and may suggest that average heel rise height could be a good indicator of an individual's plantar flexor function during gait if he/she is very strong, but not if he/she is weak. Moreover, unlike total work, average heel rise height during the single-leg heel rise test is a submaximal measure of plantar flexor strength as it is an average across all heel rises performed. This may also explain why there was not a significant correlation between average heel rise height and absolute maximum plantar flexion moment during gait for any populations tested in this study. Additionally, there are two factors that come into play when averaging heel rise height: (1) the number of heel rises performed and (2) heel rise height consistency. These two factors were not controlled and, thus, may also have contributed to there being no correlation between average heel rise and absolute maximum plantar flexion moment during gait for young and older, healthy individuals. For these populations, it may be beneficial to either control for number of heel rises performed or determine if another maximal measure from the single-leg heel rise test, such as maximum heel rise height, is correlated to absolute maximum plantar flexion moment during gait since two maximal measures may have a stronger relationship.

The magnitudes of the single-leg heel rise test parameters evaluated in this study are comparable to those presented in the literature for young, healthy individuals. A study conducted by Svantesson and colleagues analyzed the fatigue process of the plantar flexors via total work during the standing single-leg heel rise test in young, healthy individuals [57]. The average total work done by the subjects in Svantesson's study was 1449 ± 118 J and the average total work done by the subjects in this current study was 1996 ± 691 J [57]. There is about a 500 J discrepancy between the Svantesson study group and this current study, but it should be noted that all the subjects in Svantesson's study were female with an average age of 24 ± 3 years and average mass of 67 ± 8 kilograms. In this current study, there were 8 females and 9 males in the young, healthy individual group with an average age of 24 ± 3 years and average mass of 74.8 ± 9.2 kilograms. The gender and mass differences between each study's subjects may explain the 500 J discrepancy since outcome measures of the single-leg heel rise test are dependent on gender [28] and the individual's mass (i.e. mass is used in calculating total work). Additionally, the average number of heel rises completed by the subjects in Svantesson's study was 25 ± 1 and in this current study, even though not reported, the average number of heel rises was 26 ± 9. While the average number of heel rises were similar between the two studies, the standard deviation for the subjects in this current study was much higher. One subject in this current study completed 56 heel rises, which was substantially more than any other subject and thus a major contributor to the high standard deviation. If this subject was excluded, then the average number of heel rises completed for subjects would be 24 ± 3, which is more comparable to what is found in the literature.

Unlike the single-leg heel rise test data collected from young, healthy individuals, the single-leg heel rise test data collected from individuals post-stroke are not as comparable to those presented in the literature. A second study conducted by Svantesson and colleagues analyzed the fatigue process of the plantar flexors during the standing single-leg heel rise test in individuals post-stroke [58]. During the standing single-leg heel rise test, subjects stood on a platform that positioned their ankle at 10^{o} degrees dorsiflexion and were instructed to perform as many heel rises as possible and as high as possible to the beat of a metronome set at 30 beats/minute. The average total work done by the subjects in Svantesson's study was 1534 ± 234 J and the average number of heel rises performed was 23 ± 2 [58]. These data are very different than what was reported in this current study as the subjects could not perform standing heel rises or heel rises laying down with only 25% of their body weight as the force; thus, neither total work nor average heel rise height could be calculated. However, it should be noted that the subjects in Svantesson's study had a higher level of function than the subjects recruited for this current study. In both studies, all subjects had chronic stroke (i.e. subjects experienced their stroke at least six months prior to participating in the study) and all subjects could walk without assistance, but the subjects in Svantesson's study had an average self-selected walking speed of 1.22 ± 0.05 meters/second while the subjects in this current study had an average self-selected walking speed of about 0.54 ± 0.21 meters/second (0.31 ± 0.12 statures/second). Because the subjects in both studies have very different functional ability after stroke, it is difficult to compare the results from this study to what is presented in the literature. If individuals post-stroke with higher levels of function were recruited for this current study, it is possible that they would have been able to

complete the standing or laying-down heel rise test. However, the level of function recruited for this study (about 0.5 meters/second) is more representative of the majority of individuals post-stroke [14], [59]–[61]. Keeping the goal of clinical viability in mind, recruiting only individuals post-stroke with high functional levels would not further our efforts to identify a clinically-viable test that could be implemented across a range of patient populations.

Other gait and single-leg heel rise test parameters, such as gait speed and number of heel rises performed, from this current study are comparable to those presented in the literature. A study conducted by van Uden and colleagues evaluated gait and performance during the single-leg heel rise test via number of heel rises in controls and patients with chronic venous insufficiency [62]. The average number of heel rises in van Uden's study was 23.5 ± 6.5 [62], which is comparable to the results in this current study (26 ± 9 heel rises for young, healthy individuals and 23 ± 5 heel rises for older, healthy individuals). Van Uden and colleagues also evaluated gait parameters, such as gait speed, step length, stride length, etc., and results, for at least gait speed, were comparable to that in this current study. Average gait speed for the subjects (aged 21-71 years old) in van Uden's study was about 0.84 ± 0.09 statures/second and average gait speed for subjects in this current study was 0.79 ± 0.07 statures/second for young, healthy individuals and 0.82 ± 0.12 statures/second for older, healthy individuals. Even though van Uden and colleagues evaluated gait parameters as they relate to number of heel rises completed during the single-leg heel rise test, they did not evaluate absolute maximum plantar flexion moment and results from both of these studies cannot be compared any further.

Other studies have evaluated similar variables from the single-leg heel rise test, have tested the same populations as this current study, and have examined the relationship between gait and the heel rise test, but various factors limit direct comparison to this current study. Firstly, van Uden and colleagues found that patients with chronic venous insufficiency had significantly lower preferred gait speeds and performed significantly fewer heel rises as compared to healthy controls [62]. Results from a study conducted by Hashish and colleagues showed that community-dwelling older adults (average age 71.0 ± 4.3 years old) could complete an average of 21.3 ± 6.1 heel rises [63], which is comparable to the average number of heel rises for older, healthy individuals in this current study. Moreover, the results from this study cannot be compared any further as Hashish and colleagues did not evaluate absolute maximum plantar flexion moment during gait. However, Hashish and colleagues found that performance during the single-leg heel rise test was significantly associated with measures of static and dynamic balance in older, healthy individuals [63]. Fujisawa and colleagues compared plantar flexor muscle activity during the double-leg heel rise test and gait [64]. Although results from this study cannot be compared to results from this current study since this current study did not collect EMG data, Fujisawa and colleagues found that plantar flexor muscle activity significantly increased with heel rise height and gait speed [64]. All the results from these studies provide evidence that there is a relationship between outcome measures (i.e. total work, number of heel rises, muscle activity) from the heel rise test – double-leg and single-leg – and gait parameters (i.e. gait speed, step length, etc.) [62]–[64]. However, no other study to our knowledge has examined the relationship between the absolute

maximum plantar flexion moment during gait and outcome measures from the single-leg heel rise test.

Aim 3: T_{max_ISO} correlates to M_{GAIT}

The results from this aim showed that there was not a significant correlation between maximum isometric plantar flexion torque and absolute maximum plantar flexion moment for young, healthy individuals and individuals post-stroke. These findings support the hypotheses for both of these populations. The finding that there was a significant correlation between these two measures for older, healthy individuals did not support the hypothesis for this population. However, a post-hoc analysis revealed that if the older, healthy subject with the greatest absolute maximum plantar flexion moment, which appears to be an outlier, were to be removed, then the correlation between these two variables would not be significant ($r = 0.423$, $p = 0.257$). When the data for all three of these populations were combined, a significant correlation between maximum isometric plantar flexion torque and absolute maximum plantar flexion moment during gait was found.

Older, healthy individuals may use a consistent proportion of their maximum plantar flexor strength during gait, which could explain why there was a significant, moderate correlation between maximum isometric torque and absolute maximum plantar flexion moment for this population. Additionally, this correlation may as be explained by the theory that older, healthy individuals could be more capable of isolating their plantar flexors during isometric muscle testing. Since there was no correlation between these two values for young, healthy individuals and individuals post-stroke, it may suggest that these populations do not use a consistent proportion of their maximum plantar flexor strength during gait. It may also suggest that these

populations are not as capable of isolating their plantar flexors during isometric muscle testing. Moreover, these findings suggest that maximum isometric plantar flexion torque may be a surrogate measure of plantar flexor function during gait for patient populations with age-related plantar flexor weakness.

There was variability in that data between young and older, healthy individuals. Young, healthy individuals had a greater standard deviation of the absolute average percent difference between absolute maximum plantar flexion moment during gait and maximum isometric plantar flexion torque during isometric muscle testing than older healthy, individuals: 38% versus 21%, respectively. Additionally, the absolute average percent difference for young, healthy individuals was 6% greater than that of older, healthy individuals: 77% versus 71%, respectively. This variability in the data may be due to testing inconsistencies amongst subjects. Even though all subjects were instructed by the researcher to push on the forefoot pad as if they were pushing on a gas pedal as a way to isolate the plantar flexors, all subjects may not have only used their plantar flexors to produce a torque during the test. However, this may be a limitation of isometric muscle testing of the plantar flexors with the leg in a fully extended position.

For individuals post-stroke, there was a much greater absolute average percent difference between maximum isometric plantar flexion torque and absolute maximum plantar flexion moment, but a similar standard deviation to the other populations (130% ± 32% for individuals post-stroke, 77% ± 38% for young, healthy individuals, and 71% ± 21% for older, healthy individuals). The higher absolute average percent difference shows that individuals post-stroke had a substantially greater absolute maximum plantar flexion moment during gait than the isometric torque their plantar

flexors could produce during isometric muscle testing. Additionally, lack of volitional plantar flexor activation may also explain the high absolute average percent difference. Moreover, varying volitional plantar flexor activation amongst subjects may explain the variability of the absolute average percent difference. Thus, this variability may explain why a significant correlation between maximum isometric plantar flexion torque and absolute maximum plantar flexion moment was not found. During the isometric plantar flexor test, individuals post-stroke had to contract their plantar flexors volitionally in order to produce a plantar flexion torque. During gait, individuals post-stroke had to contract their plantar flexors volitionally as a way to remain upright and prevent themselves from falling. Since individuals post-stroke may be more able to volitionally contract their plantar flexors during gait, it would make sense that this population would have a greater absolute maximum plantar flexion moment during gait than maximum isometric plantar flexion torque during isometric muscle testing.

Isometric muscle testing of the plantar flexors may be able to predict plantar flexor function during gait. Combining the data from all three populations (n = 33) provided a wide range of plantar flexor strength and showed that there was a significant correlation between maximum isometric plantar flexion torque and absolute maximum plantar flexion moment. This supports the notion that if a large data set of isometric muscle testing is collected across a range of populations with varying levels of plantar flexor strength, then a regression equation could be developed to predict an individual's absolute maximum plantar flexion moment during gait. Thus, clinicians can use isometric plantar flexor testing to evaluate their patients' plantar flexor function during gait without the use of a gait analysis and may use this

evaluation to determine if their patients need to strengthen the plantar flexor muscles to be more functional.

The relationship between maximum isometric plantar flexion strength and the absolute maximum plantar flexion moment during gait has been evaluated in the literature. A study conducted by Dallmeijer evaluated the association between isometric plantar flexor strength and absolute maximum plantar flexion moment during gait in young adults with cerebral palsy [65]. Hand-held dynamometry was used to measure plantar flexor strength (i.e. force) and torque values were calculated by multiplying the average of two maximum plantar flexor force values from the dynamometer by the plantar flexor moment arm [65]. Additionally, subjects walked at their self-selected walking speed along a 12-meter walkway and joint kinetics were evaluated. Results from Dallmeijer's study found that maximum isometric plantar flexion torque was much lower than absolute maximum plantar flexion moment during gait, which is comparable to the results in this current study where all tested populations had a lower maximum isometric plantar flexion torque as compared to absolute maximum plantar flexion moment during gait. While individuals with cerebral palsy were not recruited for this current study, the results from Dallmeijer's study still add support to the purpose of this current study in that independent of age and impairment the relationship between isometric plantar flexion torque and absolute maximum plantar flexion moment during gait should be evaluated.

The literature has also noted how maximum isometric plantar flexion torque changes with age. A study conducted by Fugl-Meyer and colleagues evaluated isometric plantar flexion characteristics in 135 sedentary adults ranging between 20 and 65 years old [41]. Fugl-Meyer and colleagues found that men and women between

the ages of 20-29 years old had an average maximum isometric plantar flexion torque of 2.54 ± 0.48 Nm/kg and that men and women between the ages of 60-65 years old had an average maximum isometric plantar flexion torque of 1.64 ± 0.24 Nm/kg [41]. Subjects in this current study had much lower average maximum isometric plantar flexion torque values in both young and older, healthy individuals: 0.65 ± 0.28 Nm/kg and 0.66 ± 0.22 Nm/kg, respectively. In Fugl-Meyer's study, data were presented for both right and left legs and were separated by gender, which was not done in this current study. Additionally, isometric plantar flexor testing was conducted with subjects in maximum dorsiflexion, while in this current study subjects were position in only 10^{o} of dorsiflexion as this angle is the approximate ankle position when absolute maximum plantar flexion moment is reached. This may suggest that positioning subjects in maximum dorsiflexion would enable them to produce a greater isometric plantar flexion torque. However, since the subjects in Fugl-Meyer's study were sedentary, it is even more interesting that their torque values were so much higher than the physically active subjects in this current study.

Isometric plantar flexor strength when the foot is positioned at different plantar flexion angles has also been evaluated. A study conducted by Trappe and colleagues had subjects lay in a supine position with their knee flexed at 160^{o} and with their foot angled at 80^{o}, 90^{o}, and 100^{o} plantar flexion [66]. Thus, 80^{o} of plantar flexion was 10^{o} of dorsiflexion. Subjects were able to produce an average isometric plantar flexion torque of 1.92 ± 0.52 Nm/kg with their ankle positioned in 80^{o} of plantar flexion [66]. These torque values are not as high as those reported in Fugl-Meyer's study, however, Fugl-Meyer also tested maximum isometric plantar flexor strength in a flexed knee position, with the knee at 90^{o}, and results showed that maximum isometric plantar

flexion strength was about 15% lower with the knee flexed than with the knee extended [41]. Variation in set-up may explain the difference in torque values within the literature. Comparing the results from Trappe's study to the results in this current study, average isometric plantar flexion torque values were much lower in this current study. However, it is difficult to compare results since the subjects in Trappe's study completed isometric muscle testing with their knee flexed at 160^{o} and subjects in this current study completed testing with their knee fully extended. Overall, average maximum isometric plantar flexion torque values for young and older, healthy individuals in this current study were much lower than data that are presented in the literature.

Maximum isometric plantar flexion torque has also been evaluated in individuals post-stroke. A study conducted by Carlsson and colleagues evaluated isometric plantar flexion torque in individuals with motor neuron lesion due to stroke in sitting, standing, and prone positions [67]. Results from this study showed that average maximum isometric plantar flexion torque values were lower in the affected leg than the unaffected leg in all testing positions, but there were no statistically significant differences. Additionally, average maximum isometric plantar flexion torque values of the affected leg in sitting, standing, and prone were about 1.3 Nm/kg, 2.4 Nm/kg, and 1.0 Nm/kg, respectively. The average maximum isometric plantar flexion torque value of the affected leg for subjects in this current study was 0.19 ± 0.11 Nm/kg, which is much lower than the results presented in Carlsson's study. However, it should be noted that the subjects in both studies did not perform isometric muscle testing in the same position, so it is difficult to compare results. Additionally, because the subjects in Carlsson's study were able to perform a standing isometric

muscle test, these individuals post-stroke may have had higher levels of function after their stroke as compared to the subjects in this current study. Furthermore, this may also explain why the torque values in Carlsson's study were so high.

This study has set a foundation for identifying clinical measures that can likely be used as a surrogate measure for plantar flexor function during gait. The relationship between clinical and gait measures of plantar flexor strength and function was most evident in older, healthy individuals. However, data from young, healthy individuals and individuals post-stroke provided a breadth of levels of plantar flexor strength that will likely help guide future directions. For example, this study identified that there may be a plantar flexor strength threshold, above which there is not a strong relationship between the maximum plantar flexion moment calculated from the single-leg heel rise test and the absolute maximum plantar flexion moment during gait. Furthermore, this study also provides evidence that the clinical tests evaluated in this study may need to be modified to evaluate plantar flexor function during gait for populations with substantial plantar flexor weakness, like individuals post-stroke. Moreover, the relationships found between plantar flexor function and clinical measures of plantar flexor strength in this study have implications on clinical practice in that they could be used as measurements and intervention. For example, clinicians could use clinical measures of plantar flexor strength (i.e. total work and average heel rise height) as modifiable targets that indicate improvements in gait function. Thus, clinicians would be able to evaluate plantar flexor function without having to conduct a gait analysis.

Limitations

While this study evaluated the relationship between clinical and gait measures of plantar flexor strength and function during gait in three different populations, some limitations need to be noted. First, this study only had subjects walk at their self-selected walking speed. It is known that gait measures, such as absolute maximum plantar flexion moment, are dependent on gait velocity [68], [69]. Thus, some of the clinical measures tested in this study (i.e. total work for young, healthy individuals, average heel rise height for young and older, healthy individuals) may not have correlated to absolute maximum plantar flexion moment during gait because individuals did not walk at their maximum gait speed. For example, maximum plantar flexion moment and total work during the single-leg heel rise test may be correlated to the absolute maximum plantar flexion moment during gait for young, healthy individuals when they walk at their fastest possible walking speed. Another potential limitation is how maximum plantar flexion moment during the single-leg heel rise test was calculated. While this value is not currently a standard measure automatically calculated by the MuscleLab® software, determining this value only requires simple anthropometric measurements of the foot in addition to maximum force, which is already provided in the MuscleLab® software. Therefore, the ability to input the anthropometric measure can likely be added to the MuscleLab® software so maximum plantar flexion moment could be a measure readily output by the system. Moreover, it should be noted that this study only focused on three populations with varying levels of plantar flexor weakness: no plantar flexor weakness, age-related plantar flexor weakness, and neurological impairment-related plantar flexor weakness. Even though this study supports the notion that there is a relationship between plantar flexor strength and plantar flexor function during gait, these findings cannot

necessarily be extrapolated to other populations that have plantar flexor weakness. Thus, future studies should look at other populations with plantar flexor weakness to see if the results from this study hold. Lastly, it should be acknowledged that this study is underpowered because of the small sample sizes for each population tested in this study. However, significant results were revealed for two of the three populations despite the small sample size and findings would likely be strengthened with a larger cohort of subjects for all populations in this study.

Future Studies

The present study has provided many avenues for future studies. One future study would be to have subjects walk at varying walking speeds instead of just at their self-selected walking speed. Having subjects walk faster and slower than their self-selected walking speed could strengthen or identify other correlations between plantar flexor strength and plantar flexor function during gait, specifically for young, healthy individuals. Another future study would be to look at other output measures of the single-leg heel rise test, like maximum heel rise height, to see if these measures correlate to absolute maximum plantar flexion moment during gait in young, healthy individuals. Future studies can also investigate how the single-leg heel rise test can be modified as an intervention to strengthen the plantar flexors so that patients can use them more functionally. Moreover, testing young, healthy individuals in different positions during isometric muscle testing may minimize the use of muscles other than the plantar flexors, which may provide a better measure of plantar flexor strength and thus, possibly, determine the relationship between maximum isometric plantar flexion torque and absolute maximum plantar flexion moment for this population. For individuals post-stroke, future studies should determine if the single-leg heel rise test

can be a useful clinical test to measure plantar flexor strength and/or what modifications to the test should be done so that it can be a useful tool for a larger sector of the post-stroke population as none of the clinical measures for this population were correlated to absolute maximum plantar flexion moment during gait. It should also be noted that individuals post-stroke were able to walk, but were not able to perform laying-down or seated heel rises. Thus, other gait contributions and/or adaptations, such as passive tension, should be measured to see if there is any correlation between those measures and the absolute maximum plantar flexion moment during gait.

Chapter 5

CONCLUSION

Currently, plantar flexor function is quantified via a gait analysis by measuring an individual's maximum plantar flexion moment. However, gait analysis laboratories and equipment are not always accessible or clinically-feasible. Thus, clinical tests, such as isometric muscle testing and the single-leg heel rise test, are more commonly used to measure one's plantar flexor strength. Hence, the purpose of this study was to determine the relationship, if any, between plantar flexor function during gait and plantar flexor strength.

Three different populations were included in this study: young, healthy individuals; older, healthy individuals; and individuals post-stroke. It was anticipated that these populations would provide a spectrum of plantar flexor function – typical, age-related weakness, and neurological impairment-related weakness – across which the relationship between clinical measures of plantar flexor strength and plantar function during gait could be evaluated. Furthermore, identifying which, if any, of these clinical measures of plantar flexor strength provide a surrogate measure for plantar flexor function during gait may facilitate rehabilitation and/or orthotic management for individuals with plantar flexor weakness.

The first aim of this study was to determine if maximum plantar flexion moment calculated during the single-leg heel rise test is equivalent to the absolute maximum plantar flexion moment during gait in each patient population. For the majority of the young and older, healthy individuals, results showed that the maximum plantar flexion moment calculated from the single-leg heel rise test was within 15% of the absolute maximum plantar flexion moment during gait. Additionally, these two

measures had a nearly significant correlation for young, healthy individuals, which could become significant with more subjects, and a significant, moderate correlation for older, healthy individuals. For individuals post-stroke, only one individual could perform the seated single-leg heel rise test. The maximum plantar flexion moment values were not within 10% of each other, and a correlation analysis could not be conducted as there were not enough data.

The second aim of this study was to evaluate if total work and average heel rise height during the single-leg heel rise test was correlated to absolute maximum plantar flexion moment during gait. For young, healthy individuals, neither total work nor average heel rise height had a significant correlation to absolute maximum plantar flexion moment during gait. For older, healthy individuals, total work during the single-leg heel rise test had a significant, moderate correlation to absolute maximum plantar flexion moment during gait. For individuals post-stroke, correlation analysis could not be conducted as only one subject could perform the seated single-leg heel rise test. Thus, more individuals post-stroke should be included in this study to better evaluate if total work and average heel rise height during the single-leg heel rise test are correlated to the absolute maximum plantar flexion moment during gait. Furthermore, other measures from the single-leg heel rise test, such as maximum heel rise height, or modifying the single-leg heel rise test to control for the number of heel rises performed by subjects may enable a significant correlation between output measures from the single-leg heel rise test and absolute maximum plantar flexion moment during gait to be revealed.

The third aim of this study was to evaluate if maximum isometric plantar flexion torque during isometric muscle testing was correlated to absolute maximum

plantar flexion moment during gait. For two of the three populations (young, healthy individuals and individuals post-stroke), maximum isometric plantar flexion torque was not correlated to absolute maximum plantar flexion moment during gait. However, there was a significant, moderate correlation between these two measures for older, healthy individuals. When the data for all populations were combined, a significant correlation was found, which suggests that a regression equation can be developed to predict plantar flexor function during gait.

In conclusion, maximum plantar flexion moment calculated from the single-leg heel rise test was the clinical measure that had the strongest relationship to the absolute maximum plantar flexion moment during gait. Furthermore, the majority of the significant, moderate correlations between all measures from the single-leg heel rise test and the absolute maximum plantar flexion moment during gait were found in older, healthy individuals. This suggests that other output measures from the single-leg heel rise test and other testing positions of isometric plantar flexor testing should be used to identify the relationship, if any, between plantar flexor strength and plantar flexor function during gait for young, healthy individuals and individuals post-stroke. Moreover, the findings from this study may provide clinicians with surrogate measures to evaluate a patient's plantar flexor function during gait through the use of common clinical tests, like the single-leg heel rise test and isometric muscle testing of the plantar flexors.

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speed from 8 to 12 to 16 km·h^{-1}," *Clin. Biomech.*, vol. 29, no. 9, pp. 959–964, 2014.

Appendix

IRB APPROVAL DOCUMENTATION

RESEARCH OFFICE

210 Hullihen Hall
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Fax: 302/831-2828

DATE:	April 10, 2017
TO:	Steven Stanhope
FROM:	University of Delaware IRB
STUDY TITLE:	[324555-21] Human Movement Analysis Database
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	April 10, 2017
EXPIRATION DATE:	April 12, 2018
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *(4)*

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB (HUMANS) has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All SERIOUS and UNEXPECTED adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All sponsor reporting requirements should also be followed.

Please report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office.

Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Nicole Farnese-McFarlane at (302) 831-1119 or nicolefm@udel.edu. Please include your study title and reference number in all correspondence with this office.

HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: Human Movement Analysis Database (HuMAD Protocol)

Principal Investigator
Name: Steven J. Stanhope, Ph.D.
Department/Center: Kinesiology & Applied Physiology
Contact Phone Number: 302-831-3496
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Advisor (if student PI):
Name:
Contact Phone Number:
Email Address:

Other Investigators:

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects, including breaches of guaranteed confidentiality occur during this project, I will report such events to the Chair, Institutional Review Board immediately.

1. **Is this project externally funded?**

If so, please list the funding source:

2. **Project Staff**
Please list personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING COMPLETE?
Steven Stanhope, Ph.D.	Principal Investigator	Yes
Elisa Arch, Ph.D.	Investigator	Yes
John Horne, CPO	Certified Prosthetist/Orthotist	Yes
Anahid Ebrahimi, BS	Student/Research Asst	Yes
John Collins, MS	Student/Research Asst	Yes
Cassandra Gorman	Student/Research Asst	Yes
Sarah Colón	Student/Research Asst	Yes
Patrick Corrigan	Student/Research Asst	Yes
Karin Silbernagel, PT, ATC, Ph.D.	Investigator	Yes
Corey Koller	Student/Research Asst	Yes

Eryn Gerber	Student/Research Assistant	Yes
Rosa Kolbeinsdottir	Student/Research Assistant	Yes

3. **Special Populations**
Does this project involve any of the following?

Research on Children? No

Research with Prisoners? No

Research with any other vulnerable population (please describe)? No

4. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

Rehabilitation devices like artificial legs and leg braces help people with lost or injured legs to stand, walk, run and play. Many advances have been made in the designs of artificial legs and braces. To customize the prescription of these devices, clinicians must often choose from a large list of settings, alignments and device characteristics. The prescription process is currently a form or art because the field of human movement analysis lacks methods for understanding how device characteristics and settings contribute to human movement tasks such as walking. Often patients are prescribed multiple devices or use a range of device settings. Therefore, the primary purpose of the proposed project is to develop and use advanced methods of human movement analysis to relate normal, braced and artificial limb characteristics to the performance of movement tasks. After making sure it is safe for a person to participate, we will use a special motion capturing system in a laboratory setting to measure people as they perform movement tasks like walking, jogging, or running. The resulting database will contain examples of how medically healthy people use normal, braced and artificial limbs to perform these common movements. Our long term goal is to use the database to better understand how braces and artificial limbs help medically healthy people perform common movement tasks. We believe the techniques developed under and data contained within the human movement analysis database (HuMAD) will provide important information that one day will be used to better prescribe braces and artificial legs to assist patients with obtaining their highest ability to function.

5. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

All testing will take place on the University of Delaware campus in a motion capture facility where each subject will undergo an instrumented movement analysis while they walk, jog, or run. For each subject with prescribed rehabilitation devices, the movement task he or she will perform will be determined based on their prosthetic/orthotic prescription. For example, if select individuals are prescribed running-specific prosthetic or orthotic devices, he or she will be asked to jog or run at their customary pace. In addition, normal subjects without any rehabilitation devices will be recruited to create a speed-matched database of walking, jogging, and running to facilitate direct comparisons of lower extremity mechanics. Prior to testing, the movement task the subjects will be performing will be determined, and we will obtain an informed consent from each subject. Data analyses related to lower extremity joint motions, net joint moments, and powers will be used to characterize overall behavior of persons moving with and/or without rehabilitation devices.

Furthermore, if a clinician at Independence Prosthetics Orthotics sees a patient that the clinician

believes would be well suited to participate in this research study, the clinician will explain the goals of the study to the patient. If the patient expresses interest in learning more about the research study and/or participating in the study, the clinician will explain the details of the consent to contact authorization procedure and then ask the patient to sign a consent to contact form. This form is compliant with HIPPA requirements and authorizes Independence Prosthetics Orthotics to share the patient's contact information with the University of Delaware investigators associated with this research protocol. If the patient signs the form, Independence Prosthetics Orthotics will then provide that patient's contact information to the study investigators, who will in turn contact the patient to follow up on their interest to participate in the study and schedule them for a study visit, if they are interested.

Initial movement task test

Prior to performing any movement task, subjects will undergo a guarded trial of the task during which they will be asked to repeatedly perform the movement task under the watch of a research assistant. In addition, subjects will be asked to provide a medical history regarding lower extremity injuries and conditions that might influence their movement ability. At this time, the type, characteristics, settings and configuration of any brace or artificial limb to be worn during the test session will be recorded.

Functional and Strength Testing of the Ankle Joint

Subjects may be asked to perform two functional/strength tests to evaluate their ankle joint function and strength. These tests are part of the standard procedures to evaluate the strength and endurance of the leg. There is no risk of weakening the leg after applying these evaluations. These tests have previously been shown to be reliable and valid. Furthermore, these tests are regularly performed by the Achilles Tendon Research Group directed by Dr. Karin Silbernagel. If the subject wears a prosthesis, he/she will not be asked to perform either of these tests on the prosthetic side.

The first test subjects will perform is an isokinetic measurement of their ankle plantarflexion strength on a Kincom dynamometer. Subjects will be strapped into a chair and be positioned in a way that enables only the ankle muscles to be utilized during the test. One foot will be placed in the Kincom ankle attachment at a time. The subject's foot will be placed in a neutral ankle position (0 degrees of dorsiflexion). The subject will be asked to push the foot down (like pushing on a gas pedal) as hard as they can for 5 seconds. The ankle will not be allowed to move. Subjects will first perform a few submaximal trials to get familiarized with the test. Each subject will be asked to perform three maximal trials on each side. The maximal amount of torque produced will be collected from the Kincom.

Secondly, subjects will perform a heel rise test to measure the muscular endurance of their plantar flexors. For the heel rise test, a measurement system called The MuscleLab® (Ergotest Technology, Oslo, Norway) will be utilized. This system is a data collection unit, which includes a linear encoder, with accompanying software that has various measurement sensors. The linear encoder is a box with a spring-loaded string that is taped to the subject's heel. The encoder measures linear displacement and velocity of the string at the nearest 0.07mm per second as the subject performs the test. For this test, subjects will be asked to stand on one leg at a time on a box with an incline of 10°. Subjects will be allowed a light touch on the wall in front of them to help them maintain their balance. The string of the linear encoder will be taped to the subject's heel. Subjects will be asked to perform as many heel rises as they can until they fell fatigued. A metronome will be used to maintain the frequency of the heel rises. The numbers of heel rises as well as the height of each heel-rise and the total work (the body weight x total distance) in joules will be recorded by the MuscleLab®.

Instrumented Movement Analysis

Following the initial movement task test, and functional/strength testing of the ankle joint when necessary, an instrumented movement analysis will be performed on all subjects. The following

general data collection and analysis procedures constitute the technical aspects utilized in all instrumented movement analyses. Subject gait characteristics will be measured in at the STAR Health Sciences Complex at the University of Delaware, using a 6-camera motion capture system with ground force measurement capabilities. Subjects may be asked to walk, jog, or run overground and/or on an instrumented treadmill.

Subjects will be asked to wear shorts and a t-shirt during testing. Clusters of 3 to 4 reflective spherical targets, 14mm in diameter, will be affixed to the body and extremities with neoprene or self-adhesive wraps. Additional targets will be placed with adhesive circles on the skin over bony ladmarks used to designate segment ends and joint centers (Holden and Stanhope, 1998). Surface electromyographic (EMG) electrodes may be placed bilaterally near the motor points of primary lower extremity muscle groups. In addition, subjects may be asked to breathe through a valve to obtain estimates of oxygen consumption and metabolic energy expenditure during the movement tasks.

Anthropometric measurements will be made of each subject including height and body weight. An anthropometer will be used to measure select segment characteristics (e.g., forefoot width, ankle joint width, knee joint width, intertrochanteric distance, and pelvic width and depth). Analytic techniques will be developed in cases where artificial limbs or braces restrict access to or do not have like anatomic sites.

After the targets are affixed and anthropometric measures are made, a static subject calibration trial will be collected. The subject will stand upright in the middle of the motion capture image volume facing in the direction of walking in the laboratory with their feet pointed forward. The motion capture system will acquire the 3D locations of the reflective targets for a one second trial. Following this trial, gait trials will be collected.

For the overground walking trials, the subject will be asked to stand at the end of a 6 m walkway and walk across the laboratory floor. The motion capture system will acquire the 3D locations of the reflective targets on the body within the middle of 2 m of the walkway. The force platforms, mounted in series flush with the floor within the 2 meter volume, will be used to sample the ground reaction forces from the three subsequent stance phases, with the stance phase of interest occurring centrally in the sequence. Subject starting position will be adjusted so that each foot makes an isolated contact on each force platform during each walking trial. An optically-based gait velocity indicator will provide walking velocity feedback. Using the gait velocity data as verbal feedback, subjects will be asked to walk at a percent of natural walking velocity until a minimum of three and a maximum of 10 trials are acquired. Subjects will be allowed to rest between walking trials upon request.

For walking trials on a treadmill, the belt speed will be controlled as a percent of the natural walking velocity. Force platforms mounted side-by-side beneath the belt will continuously capture the ground reaction force on each limb, while the motion capture system acquires the 3D locations of the reflective targets on the body. Subjects will be given ample time to get acclimated to walking on the treadmill. An overhead harness system will be used to ensure safety for each subject.

When walking on the treadmill during the instrumented movement analysis portion of this protocol, a body weight support (BWS) system may be used during data collection. The support system has two modes of operations: 1) as a safety harness to prevent falls to the floor and 2) as a method for providing a precise level of body weight unloading, up to 100% body weight, for individuals up to 150kg. The body weight unloading is accomplished using a dynamically controlled motor and in-series load cells to actively supply a constant load over the gait cycle across all walking speeds and levels of support. The BWS system includes an overhead harness system that will be used as subjects walk over the split-belt treadmill. It is designed to catch subjects in the event of a fall and can be quickly removed. Before placement of tracking markers during the typical data collection procedures, subjects will be

fitted with the overhead harness. The harness will then be secured to the overhead BWS system. Each subject will be given time to acclimate to each BWS condition before data collection. The subjects will be monitored at all times. A range of BWS conditions may be tested where the BWS system is set to provide different levels of body weight support as the subject walks at a constant velocity.

For jogging or running trials (overground or on a treadmill), the protocol will follow closely with the previously described walking trials. For subjects with prescribed running-specific prosthetic or orthotic devices, they will jog or run at their customary speed. For individuals without prosthetic/orthotic devices, the speeds will be targeted to match those of the subjects jogging or running with rehabilitation devices.

For participants wearing rehabilitation devices, they may be asked to repeat the protocol (overground or treadmill) multiple times wearing different types of devices they have been prescribed (in the same visit or different visits). The selection and adjustment of devices will be under the direction of a certified prosthetist/orthotist. For example, an individual with below-knee amputation may be asked to undergo the protocol wearing different types of or settings on artificial legs. An individual wearing a brace may repeat the protocol with different braces. If multiple devices are tested within the same visit, subjects will be given ample time (a minimum of 5 minutes) to get acclimated with the new device. Testing with the new device will proceed whenever the subjects subjectively indicate that his/her movement pattern feels stable, comfortable, and reproducible. Immediately following the instrumented gait analysis while using a particular rehabilitation device, the subjects will be asked to complete a questionnaire, adapted from the Prosthetic Evaluation Questionnaire (Legro et al, 1998), to subjectively evaluate the quality of a particular rehabilitation device.

6. STUDY POPULATION AND RECRUITMENT

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information. Attach all recruitment fliers, letters, or other recruitment materials to be used.

To develop the HuMAD, approximately 300 medically healthy subjects (males and females) who are over 18 years of age will be recruited via the word of mouth or by their clinician. For this project, the term healthy is defined as a lack of active systemic disease that alters ability of subjects to participate in activities of their choice. In addition, healthy means no current pathology where there is any possibility of damage to muscle, ligament, or cartilage in the lower extremity.

In addition, the following people will be recruited:

-Individuals with lower extremity amputation and have prescribed artificial limbs.
-Individuals with impaired lower extremity function that have been prescribed a form of rehabilitation brace.

Describe what exclusionary criteria, if any will be applied.

Subjects with an unsafe, unsteady, or highly variable movement pattern upon visual observation will be excluded. Subjects who are unable to repeatedly execute the movement pattern in the desired manner will be excluded from participation

Describe what (if any) conditions will result in PI termination of subject participation.

A subject may be withdrawn from the study for any of the following reasons:

-failure to follow instructions
-the investigator decides that continuation could be harmful to the subject

-the study needs treatment not allowed in the study
-the study is canceled
-other administrative reason (e.g., necessary documentation is not in place at the time of the study)

7. **RISKS AND BENEFITS**

Describe the risks to participants (risks listed here should be included in the consent document). If risk is more than minimal, please justify.

The risks involved in participating in the proposed series of non-invasive movement tasks are minimal. Much like any repeated movement test, there is a slight chance of suffering a fall and mild skin irritation from the attachment of adhesive circles to the skin during the movement task portion of the study. Additionally, there is a slight, minimal risk of local muscle soreness and fatigue from the functional and strength testing of the ankle joint that some subjects will participate in.

What steps will be taken to minimize risks?

To minimize the risk of injury due to falls, subjects will be safely monitored by an investigator. In order to minimize risks associated with the functional and strength testing procedures, subjects will be given as many breaks as needed.

Describe any direct benefits to participants.

Subjects will receive no direct medical benefits from participation in this study. Compensation for time volunteered to this study will not be provided.

Describe any future benefits to this class of participants.

There are no future benefits to the participants.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

There is no Data Monitoring Committee for this project.

8. **COMPENSATION**

Will participants be compensated for participation? No.

If so, please include details.

9. **DATA**

Will subjects be anonymous to the researcher? No

If subjects are identifiable, will their identities be kept confidential? Yes

How and how long will data be stored?

The coded experimental data will be stored for a minimum of 10 years in a secure electronic database.

How will data be destroyed?

When the time comes, the data will be erased from the electronic database and the storage device formatted.

How will data be analyzed and reported?

The data obtained from the movement tasks (segment motions and ground reaction forces) will be input into Visual3D software (C-Motion Inc., Germantown, MD). Using Visual3D software, we will compute variables like joint motion (i.e., position, velocity, acceleration) and joint moments, and powers. In addition, we will use custom-analyses developed under this protocol and previously developed methods such as six degree-of-freedom ankle joint power (Buczek et al., 1994), distal foot power (Siegel et al., 1996), induced acceleration analysis (Kepple et al., 1997), power flow analysis (Siegel et al., 2004), natural ankle pseudo-stiffness (Razzook et al., 2011), roll-over dynamics (Takahashi et al., 2011), and unified deformable segment power (Takahashi et al., 2011). These and new analyses will be used to compare lower extremity mechanics of persons wearing rehabilitation devices relative to the natural limb function database. Additionally, results of the functional and strength testing of the ankle joint will be analyzed. Results may include maximum isometric force the subject can produce with his or her plantar flexor muscles as well as the number, height and work of the heel rises. These functional and strength measures will be related to the data obtained from the instrumented gait analysis to further understand how individuals move with and without braces and artificial limbs.

The results will be reported in a series of journal articles and presentations.

10. **CONFIDENTIALITY**
Will participants be audiotaped, photographed or videotaped during this study?

Subjects may be photographed or videotaped with his or her consent (Photo-Video Consent form attached)

How will subject identity be protected?

Each subject will be assigned a unique numerical subject identifier that will be used to label and track all data. Documents containing patient identifiers and the keys for breaking subject identification codes will be kept separately in a secured location with access limited to the PI.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).
No

11. **CONSENT and ASSENT**

__x__ Consent forms will be used and are attached for review.

____ Additionally, child assent forms will be used and are attached.

____ Consent forms will not be used (Justify request for waiver).

12. **Other IRB Approval**
Has this protocol been submitted to any other IRBs? No

If so, please list along with protocol title, number, and expiration date.

13. **Supporting Documentation**
Please list all additional documents uploaded to IRBNet in support of this application.

Adapted Prosthetic Evaluation Questionnaire – HuMAD Protocol.pdf
Consent – HuMAD Protocol.pdf
Prosthetic-Orthotic Info Sheet – HuMAD Protocol.pdf
Subject Contact Info form – HuMAD Protocol.pdf
Subject screening form – HuMAD Protocol.pdf
Anthro Measurements – HuMAD Protocol.pdf
Trial Info Sheet – HuMAD Protocol.pdf
Photo-Video consent – HuMAD Protocol.pdf
UD Consent for patient Contact Form – HuMAD Protocol.pdf

References

Buczek FL, Kepple TM, Siegel KL, and Stanhope SJ. 1994. Translational and rotational joint power terms in a six degree-of-freedom model of the normal ankle complex. Journal of Biomechanics, 27, 1447-1457.

Holden, JP, and Stanhope SJ., 1998. The effect of variation in knee center location estimates on net knee joint moments. Gait and Posture 7, 1-6.

Kepple TM, Siegel KL, and Stanhope SJ., 1997. Relative contributions of the lower extremity joint moments to forward progression and support during stance. Gait and Posture 6, 1-8.

Legro MW, Reiber GD, Smith DG, del Aquila M, Larsen J, Boone D., 1998. Prosthetic Evaluation Questionnaire for persons with lower limb amputations: assessing prosthesis-related quality of life. Archives of Physical Medicine and Rehabilitation 79, 931-938.

Razzook AR, Takahashi KZ, Guinn LD, Schrank ES, and Stanhope SJ. Predictive model for natural ankle stiffness during walking: implications for ankle foot orthosis prescription. Proceedings of the Gait and Clinical Movement Analysis Society Conference, Bethesda, Maryland, April 2011.

Siegel KL, Kepple TM, and Caldwell GE, 1996. Improved agreement of foot segmental power and rate of energy change during gait: inclusion of distal power terms and the use of three-dimensional models. Journal of Biomechanics 29, 823-827.

Siegel KL, Kepple TM, and Stanhope SJ., 2004. Joint moment control of mechanical energy flow during normal gait. Gait and Posture 19, 69-75.

Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, and Stanhope SJ. A model of normal gait roll-over dynamics: one step closer to customizing prosthetic ankle-foot components. Proceedings of the

Gait and Clinical Movement Analysis Society Conference, Bethesda, Maryland, April 2011.

Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Kepple TM, and Stanhope SJ. A unified deformable segment model of the combined ankle-foot system that does work. Proceedings of the annual meeting of the American Society of Biomechanics, Long Beach, CA, August 2011.

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: Human Movement Analysis Database

Principal Investigator(s): Stanhope, Steven J.

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to collect information on the different ways people use rehabilitation devices, such as artificial legs or ankle braces to move when they walk, jog, or run. Scientists and doctors often compare information obtained from diverse groups of people to patient information in order to better understand the effects of disease and treatment on patient problems. You will be one of approximately 300 participants in this study.

WHY ARE YOU BEING ASKED TO PARTICIPATE?

You are being asked to participate in this study because we expect that you use normal patterns to move and we wish to see how your pattern of moving changes when you wear different types of artificial legs or braces.

Subjects with an unsafe, unsteady, or highly variable movement pattern upon visual observation will be excluded. Subjects who are unable to repeatedly execute the movement pattern in the desired manner will be excluded from participation

WHAT WILL YOU BE ASKED TO DO?

Before participating in this study, all of the movement tasks you will be asked to carry out will be explained by Dr. Stanhope or another member of the research team. The type of movement task (walk, jog, or run) you will be asked to perform will be determined in advance by the research team based on your prosthetic/orthotic prescription. You may wish to not perform a specific task and not to take part in the study. If you wish to continue, your participation in this study will involve one or potentially more visits to the University of Delaware for a maximum of 2 hour per visit. A visual walking test will be performed by a member of the research team to determine how your joints move, how strong you are, and your comfortable walking speed. These procedures should not cause any discomfort.

Prior to your instrumented movement test, your ankle muscle strength may be measured while you are seated in a device, called a Kincom, which controls your ankle motion and measures how much force you can produce. The test will measure the strength of your ankle muscles during repetitive trials in which you will be provided with approximately 1-minute rest between each trial. Strength will be measured during a static test. Additionally, you may be asked to perform a heel rise test where you will stand on one leg with

Participant's Initials _____

your foot on an incline. You will be allowed a light touch on the wall in front of you to help you maintain your balance while performing the test. A thread will be attached to your heel. You will be asked to perform as many and as high heel-rises as you can until fatigued. You will hear a clicking sound that will guide you to the appropriate frequency of the heel-rises. If you wear a prosthesis, you will not be asked to perform either of these tests on your prosthetic side.

During your instrumented movement test, you will be requested to wear a t-shirt and shorts. You may be asked to walk, jog, or run overground and/or on a treadmill. When walking on the treadmill, a body weight support system may be used during data collection. The support system is designed to safely provide constant body weight support up to 100% body weight, for individuals up to 150kg. This system includes an overhead harness system that will be used as subjects walk over a split-belt treadmill. It is designed to catch subjects in the event of a fall and the harness can be quickly removed. Subjects will be fitted with an overhead harness.

Small plastic reflective balls will be attached to your body. To do this, your arms and legs will be wrapped with a soft, rubber-like material. A piece of firm material called a shell may then be attached to the rubber sleeves with Velcro or a self-adherent bandage. The small round balls may also be attached to your skin using an adhesive. After the reflective balls have been attached, the harness will then be secured to the body weight support system. Additionally, we may also want to test your muscles using electromyography (EMG). To do this, we will attach small metal electrodes to the surface of your skin using an adhesive. EMG is a measurement tool that is used to assess muscle function. Lastly, we may also ask you to breathe through an oxygen valve during the movement task to obtain a measurement of your metabolic energy expenditure. You should not feel any discomfort with these tests.

Once the above items are in place, you will be asked to perform a task several times while scientific cameras record the positions of the reflective balls. The cameras do not take pictures of your face or body parts. Each instrumented movement test will require a maximum of 2 hours to complete. You may rest at any time. Following the instrumented movement test, we will ask you to complete a questionnaire evaluating the performance of any artificial leg or brace you may wear.

If you are wearing an artificial leg or an ankle brace, you may be asked to repeat the protocol multiple times (in the same visit or different visits) with different types or settings of artificial legs or braces. However, you may decline our request and ask to stop participating at any time. If the protocol is repeated within the same visit, you will be given ample time to get acclimated to moving with the different artificial leg or brace (a minimum of 5 minutes), until you feel stable, comfortable, and until you feel that your movement pattern is reproducible.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research study are minimal; no more than those incurred during normal walking, jogging, or running and customary training and supervised use of a rehabilitation device. There is a slight chance of a mild skin irritation from the attachment of adhesive circles to the skin during the gait analysis portion of the study. The soft, rubber-like material may feel tight, but if it is uncomfortable or

Participant's Initials _____

interferes with your movements, tell one of the investigators and it will be readjusted. This material may cause a skin irritation, but the material is worn only for a short period of time and skin reactions are rare. There is also a slight chance of skin irritation due to wearing an artificial leg or brace or the harness of the body weight support system; however, adjustments will be made so that you will remain as comfortable as possible. Your safety will be continuously monitored while you are walking, jogging, or running with the artificial legs or braces.

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

WHAT ARE THE POTENTIAL BENEFITS?

You will not benefit directly from taking part in this research.

NEW INFORMATION THAT COULD AFFECT YOUR PARTICIPATION:

During the course of this study, we may learn new information that could be important to you. This may include information that could cause you to change your mind about participating in the study. We will notify you as soon as possible if any new information becomes available.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

Each subject will be assigned a unique numerical subject identifier that will be used to label and track all data. Documents containing patient identifiers and the keys for breaking subject identification codes will be kept separately in a secured location with access limited to the PI. When results of a University research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the University will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the University will give the insurance company information from your instrumented movement analysis record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The confidentiality of your records will be protected to the extent permitted by law. Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Records relating to this research will be kept for at least three years after the research study has been completed.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There are no costs for participating in this study.

Participant's Initials _____

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

You will not receive compensation for participating in this study.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware.

As a student, if you decide not to take part in this research, your choice will have no effect on your academic status or your grade in the class.

You may be withdrawn from the study for one of the following reasons:

-failure to follow instructions
-the investigator decides that continuation could be harmful to you
-you need treatment not allowed in the study
-the study is canceled
-other administrative reason (e.g., necessary documentation is not in place at the time of the study)

If, at any time, you decide to end your participation on this research study please inform our research team by telling the investigator(s).

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Principal Investigator, Steven J. Stanhope, Ph.D.; 540 South College Ave, Telephone: (302) 831-3496 or stanhope@udel.edu.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or (302) 831-2137.

Participant's Initials _____

Your signature on this form means that: 1) you are at least 18 years old; 2) you have read and understand the information given in this form; 3) you have asked any questions you have about the research and those questions have been answered to your satisfaction; 4) you accept the terms in the form and volunteer to participate in the study. You will be given a copy of this form to keep.

Printed Name of Participant	Signature of Participant	Date
Person Obtaining Consent (PRINTED NAME)	Person Obtaining Consent (SIGNATURE)	Date

OPTIONAL CONSENT FOR ADDITIONAL USES OF VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission for the researchers in this study to use videos and photographs of me collected as part of this research study to be used in publications, presentations, and/or for educational purposes. I understand that no identifying information beyond that contained in the video recording and/or photographs will be provided to educational/scientific audiences; however my facial features (and/or those of child) may be seen.

(Signature of Participant)	(Date)

(Printed Name of Participant)

Participant's Initials _____

OPTIONAL CONSENT TO REVEAL SUBJECT IDENTITY:

The data collected in this protocol may be useful to clinicians and healthcare providers to facilitate objective clinical decision-making on my behalf. Therefore, I hereby consent to allow my identity and associated data obtained in this protocol to be revealed to the following individual(s) or organization(s):

_____

(Name of individual/organization)

_____ _____

(Signature of Participant) (Date)

OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? Please write your initials next to your preferred choice.

_____ YES _____ NO

Participant's Initials _____

Waterloo Footedness Questionnaire – Revised

Questionnaire modified from:

Elias L, Bryden M, Bulman-Fleming M. "Footeness is a better predictor than is handedness of emotional lateralization." *Neuropsychologia* (1998): 37-43.

Instructions: Answer each of the following questions as best you can. If you *always* use one foot to perform the described activity, circle **Ra** or **La** (for **right always** or **left always**). If you **usually** use one foot circle **Ru** or **Lu**, as appropriate. If you use **both** feet **equally often**, circle **Eq**.

Please do not simply circle one answer for all questions, but imagine yourself performing each activity in turn, and then mark the appropriate answer. If necessary, stop and pantomime the activity.

1.	Which foot would you use to kick a stationary ball at a target straight in front of you?	La	Lu	Eq	Ru	Ra
2.	If you had to stand on one foot, which foot would it be?	La	Lu	Eq	Ru	Ra
3.	Which foot would you use to smooth sand at the beach?	La	Lu	Eq	Ru	Ra
4.	If you had to step up onto a chair, which foot would you place on the chair first?	La	Lu	Eq	Ru	Ra
5.	Which foot would you use to stomp on a fast-moving bug?	La	Lu	Eq	Ru	Ra
6.	If you were to balance on one foot on a railway track, which foot would you use?	La	Lu	Eq	Ru	Ra
7.	If you wanted to pick up a marble with your toes, which foot would you use?	La	Lu	Eq	Ru	Ra
8.	If you had to hop on one foot, which foot would you use?	La	Lu	Eq	Ru	Ra
9.	Which foot would you use to help push a shovel into the ground?	La	Lu	Eq	Ru	Ra
10.	During relaxed standing, people initially put most of their weight on one foot, leaving the other leg slightly bent. Which foot do you put most of your weight on first?	La	Lu	Eq	Ru	Ra
11.	Is there any reason (i.e. injury) why you have changed your foot preference for any of the above activities?	**YES**	**NO**	(circle one)		
12.	Have you ever been given special training or encouragement to use a particular foot for certain activities?	**YES**	**NO**	(circle one)		
13.	If you have answered **YES** for either question 11 or 12, please explain:					