EFFECT OF QUANTITATIVELY MATCHED PASSIVE-DYNAMIC ANKLE-FOOT ORTHOSES ON POST-STROKE GAIT

by

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ABSTRACT

The plantar flexors play a critical role in moving the body forward during gait by eccentrically contracting to control shank rotation. Insufficient control of shank rotation due to plantar flexor weakness, a common post-stroke impairment, may result in gait dysfunctions. Plantar flexor function during gait, or lack thereof, can be quantified by the peak plantar flexor moment. Passive-dynamic ankle-foot orthoses (PD-AFOs) can be prescribed to improve post-stroke gait. PD-AFO bending stiffness is a key orthosis characteristic that can replicate many functions of the plantar flexors. However, outcomes with ankle-foot orthoses (AFOs) are variable, likely because of the orthosis characteristics not being properly matched to each individual’s needs. We have developed a novel design and prescription process that quantitatively matches PD-AFOs based on each individual’s level of plantar flexor weakness. However, preliminary data collected by our lab showed that individuals post-stroke were unable to fully use the quantitatively matched PD-AFOs. We hypothesized that providing the individuals with real-time biofeedback on how to properly use the PD-AFO would help acclimate them to PD-AFO use and help them reap full benefits from the orthosis. Thus, the purpose of this study was to first evaluate if the quantitatively matched PD-AFOs improved gait biomechanics (peak plantar flexion moment) better than the originally prescribed AFO. Then, we developed and evaluated if a real-time biofeedback tool helped individuals post-stroke more effectively use the PD-AFO while walking. Eleven individuals with chronic stroke (> six months post-stroke) underwent an instrumented gait analysis to gather baseline data. Using our design and prescription process, a carbon fiber PD-AFO was then quantitatively matched for each subject. Once the PD-AFOs were manufactured, seven of the subjects visited the lab
for one evaluation visit and underwent an instrumented gait analysis using his/her Original AFO and the quantitatively matched PD-AFO. The other four subjects visited the lab for two evaluation visits and underwent an instrumented gait analysis with his/her Original AFO and the quantitatively matched PD-AFO and used the biofeedback tool. A one-way repeated measures ANOVA was performed on the subject’s mean peak plantar flexion moment between his/her Original AFO and the quantitatively matched PD-AFO. If a significant difference was observed, simulation modeling analysis (SMA) was then performed to determine which subjects achieved a significant difference between the two conditions. The subject’s mean peak dorsiflexion angle was compared to the range assigned to each individual post-stroke to determine if the subject was able to reach that targeted dorsiflexion range. A one-way repeated measure ANOVA was performed on the subject’s mean peak plantar flexion moment between pre-biofeedback and post-biofeedback for both evaluation visits. SMA was also performed to determine if a significant increase in mean peak plantar flexion moment was achieved pre- and post-biofeedback for each subject individually for both evaluation visits. The subject’s change in mean step length (pre-vs. post-biofeedback) while walking with the quantitatively matched bending stiffness PD-AFO was compared to the pre-feedback step length variability for both visits. Results showed that 9 out of the 11 subjects had a significant increase in mean peak plantar flexion moment from the Original AFO to the quantitatively matched PD-AFO. Furthermore, two of the four subjects, on the second evaluation visit, were able to reach their targeted dorsiflexion range post-biofeedback. However, the individual post-stroke’s mean peak plantar flexion moment and mean step length did not improve from pre- to post-biofeedback for either evaluation visit. This study’s findings begin to
lay the foundation of a novel quantitative prescription process to improve the gait of individuals post-stroke.
A goal of gait is to move the body forward [1], [2]. In particular, the ankle is largely responsible for moving the body forward between the flat-foot and maximum dorsiflexion angle stance phase of gait, referred to as the mid- to late-stance phase of gait [2]. During the mid- to late-stance phase of gait, the ankle moves from 5° plantar flexion to 10° dorsiflexion via the shank’s forward rotation [2], and the plantar flexors play a critical role in controlling this action of the shank [2]–[6]. Specifically, the plantar flexors eccentrically contract to provide the resistance needed to control the shank’s forward rotation [2]–[5]. In fact, this action of the plantar flexors reduces the rate of shank’s rotation to half its former speed [2]. As the center of pressure moves anteriorly during the shank’s forward rotation, the plantar flexor moment increases. Furthermore, controlling shank’s forward rotation allows energy to be stored that is returned during push-off [4], which aids in the transfer of kinetic energy to the leg [3] and trunk [7]. This transfer of energy helps in forward progression [2]–[6], initiating swing [3], [7], [8], and generating power [3], [4]. Therefore, having control of shank’s forward rotation is essential for maximum step length [9], greater gait velocity [2], and metabolically efficient gait [10]–[12].

Insufficient control of the shank’s forward rotation due to plantar flexor weakness [4], [13]–[15] is an impairment seen in individuals post-stroke [2], [4], [13]. Each year, 795,000 people suffer a stroke, which is the leading cause of long-term disability in the United States [16]. As a result of their plantar flexor weakness,
individuals post-stroke typically dorsiflex their ankle excessively [9] or hyperextend their knee [2] throughout the stance phase of gait. Both of these compensations compromise stability and forward progression [2] resulting in gait dysfunctions, such as asymmetric step lengths [1], [17]–[19] and decreased gait velocity [2], [4], [15], [20]. These two gait dysfunctions can both result in an increase in metabolic cost of transport [10]–[12]. This increase in metabolic cost of transport, which studies show is one and a half to two times greater than in healthy individuals [21], can lead to physical inactivity among individuals post-stroke [22]. Furthermore, physical inactivity has been associated with lack of participation in the community and activities [23], [24], increase chronic diseases [25], and earlier mortality [26].

Researchers encourage individuals post-stroke to be physically active [27], but studies have shown that these individuals are more sedentary and less active than age-matched healthy individuals [28]. In fact, healthy individuals walk, on average, over six thousand steps per day [29], [30], which is three times more than the average individual post-stroke [28]. Additionally, researchers have found that ninety percent of individuals post-stroke have some functional disability, with mobility being the most prevalent impairment [31], [32]. Thus, a focus of most rehabilitation programs for individual post-stroke is regaining the ability to walk to become more physically active [31], [33]. Individuals post-stroke spend about $28 billion a year on rehabilitation, which includes costs such as medical care and therapy [34]. By 2050, the total number of stroke victims is supposed to more than double [35], which will further increase the annual cost of rehabilitation. However, even after rehabilitation, gait abnormalities, such as decreased walking speed, still persist in these individuals [31].
Ankle-foot orthoses (AFOs), are rehabilitative devices that can be prescribed, by highly trained and skilled orthotists, to individuals post-stroke with mobility limitations to assist with weakened musculature [15]. The current standard for AFO prescription is to manually fabricate AFOs through a craft-based, time-consuming, and trial-and-error process [6], [36]–[38]. Due to this fabrication process, by the year 2025, the supply of certified orthotists would need to increase by about 90% to meet the demand for certified orthotists [39]. Additionally, costs associated with orthotic devices are high. In 2016, Medicare expenditures for orthotics reached ~$1 billion [40]. Moreover, while AFOs offer excellent benefits to some, others reap limited benefits with AFO use [41], [42]. These variable outcomes may be a result of the orthosis characteristics not being properly matched to each individual’s needs [43]. This improper patient-orthosis matching may be due to the lack of objective prescription guidelines [44] and general consensus on how to prescribe AFOs [43].

Passive-dynamic AFOs (PD-AFOs) are a type of AFO that use material and design characteristics to dictate their mechanical properties. A key characteristic of a PD-AFO is its spring-like bending stiffness, which can potentially replicate the function of the plantar flexors [36], [37], [43], [45]–[49] by providing the resistance needed to control the shank’s forward rotation [15]. Researchers believe that quantitatively matching PD-AFO bending stiffness to each individual’s needs will result in more effective orthoses that allow each individual to achieve greater improvements in gait [36], [37], [43], [44], potentially leading to an increase in physical activity and decrease healthcare costs. Matching the PD-AFO to their level of need is key because too little bending stiffness will not provide enough resistance, resulting in persistent excessive dorsiflexion, or too much bending stiffness will
provide too much resistance, causing the shank to not advance at all and inhibit any
degree of dorsiflexion. However, a method to effectively match PD-AFO bending
stiffness to each individual’s needs has not been developed.

Researchers have begun to look at the effects of PD-AFO bending stiffness on
gait through simulations [50] and experiments [6], [44], [51]. These studies have
indicated that PD-AFO bending stiffness can be adjusted to improve the energy
storage during mid-stance and return during late-stance, which results in more
efficient gait and decreased metabolic cost of transport [50], [52]–[54]. However,
these studies used subjectively-prescribed AFOs or the same stiffness values across
subjects. Furthermore, studies by Esposito and by Haight concluded that change in
PD-AFO bending stiffness values had little effect on the kinematics and kinetics of
individuals post limb salvage while walking and running, over flat and inclined
surfaces [6], [55]–[57]. The individuals in these studies were prescribed three PD-
AFOs with different stiffnesses, one stiffness equivalent to the clinically-prescribed
orthosis, one stiffness that was 20% more compliant, and one stiffness that was 20%
more stiff. To accommodate the different PD-AFO bending stiffness values, the
individuals post limb salvage appeared to adapt their muscle activity to reach typical
gait. In fact, the individuals reached typical peak plantar flexion moment for each of
the orthoses, indicating that the individuals likely just substituted muscle activity and
thus did not need enhancement from the PD-AFO stiffness. Moreover, since the
subjects were individual post limb salvage, they may have lacked the ankle range of
motion (ROM) needed to fully utilize the PD-AFO bending stiffness. While subjects’
active or passive dorsiflexion ROM was not provided in these studies, results showed
that the individuals’ post-limb salvage had minimal dorsiflexion during mid to late-
stance of gait while using the PD-AFO, in comparison to the healthy controls. With these shortcomings, a conclusion cannot be drawn that changing the bending stiffness of prescribed PD-AFOs does not affect the gait of individuals.

Arch and colleagues recently showed that PD-AFO bending stiffness can substitute for healthy plantar flexor function [15]. Thus, part one of this study worked towards developing a quantitative prescription model that matches PD-AFO bending stiffness to each individual post-stroke’s plantar flexor function deficit. Plantar flexor function can be quantified by the peak plantar flexion moment during gait [3], [51]. We hypothesized that PD-AFO bending stiffness can be quantitatively matched to add to an individual post-stroke’s peak plantar flexion moment, enabling the net (individual + PD-AFO) moment to reach a typical level. Therefore, a quantitatively matched PD-AFO bending stiffness can potentially restore the control of shank’s forward rotation and thus improve gait symmetry [17]–[19], [58], increase gait velocity [4], [20], and decrease metabolic cost of transport [10]–[12] of individuals post-stroke.

However, preliminary data collected by our lab showed that individuals post-stroke were unable to fully use the quantitatively matched PD-AFOs because they either did not bend into the PD-AFO enough or bent into the PD-AFO too much. Both patterns result in improper use of the PD-AFO’s spring-like characteristics. To reap the full benefits of the quantitatively matched PD-AFO bending stiffness, the individual must be able to load the PD-AFO into dorsiflexion and then release the ankle/PD-AFO to return to a more neutral position. Therefore, these individuals post-stroke likely need to become acclimated to walking with the quantitatively matched PD-AFOs to reap the full benefits from the PD-AFO. Research has shown that real-
time biofeedback can effectively retrain gait [59]–[61] that is not accomplished during the six to twelve months of rehabilitation that normally occurs after their stroke [31], [62]. Current studies on retraining individuals post-stroke have used auditory biofeedback, such as cueing cadence [59], visual feedback, such as placing one’s swinging foot on lighted targets appearing on a walkway [63], or both auditory and visual feedback, such as an individual visualizing line graphs while hearing a beeping noise when the specified target peak propulsive force range has been reached [64], with the main goal of improving gait parameters. Additionally, visual biofeedback has been used on body alignment [60] and body movement [65] to improve postural control. Other researchers have developed biofeedback devices to improve gait. One device was embedded with force sensors to give real-time auditory biofeedback to correct gait asymmetry [66] while another device included an electromyography (EMG) triggered biofeedback close-loop control system to improve the effects of drop foot [67]. Since real-time biofeedback has been shown to improve gait parameters, this technique can be used to potentially acclimate the individual post-stroke to walking with the quantitatively matched PD-AFO.

Thus, the purpose of this study was to first evaluate if the quantitatively matched PD-AFOs improved gait biomechanics (peak plantar flexion moment) better than the originally prescribed AFO. Then, we developed and evaluated if a real-time biofeedback tool helped individuals post-stroke more effectively use the PD-AFO while walking. To our knowledge, there is no previously-established method to acclimate individuals post-stroke in properly walking with a PD-AFO. Furthermore, understanding if quantitatively matched PD-AFO bending stiffness improves gait and how acclimating individuals post-stroke to walking with the quantitatively matched
PD-AFOs affects their gait will be vital steps forward in developing a method to more effectively prescribe PD-AFOs. To reach this purpose, the following three aims were conducted:

**Specific Aims and Hypotheses**

**Aim 1:** Determine if the quantitatively matched PD-AFOs improved gait biomechanics (peak plantar flexion moment) better than the originally prescribed AFO for individual’s post-stroke.

The individual post-stroke’s mean peak plantar flexion moment while walking with the quantitatively matched PD-AFO bending stiffness was compared to the mean peak plantar flexion moment while the individual walked with their originally prescribed AFO. If the quantitatively matched PD-AFO bending stiffness significantly increased the mean peak plantar flexion moment, then the PD-AFO was deemed effective in improving gait biomechanics (peak plantar flexion moment).

**Hypothesis 1.1:** The mean peak plantar flexion moment will be significantly greater while wearing the quantitatively matched PD-AFO bending stiffness than while wearing the originally prescribed AFO.

**Aim 2:** Develop a real-time biofeedback tool to help individuals post-stroke become acclimated to using the quantitatively matched PD-AFO.

The individual post-stroke wore a PD-AFO with a quantitatively matched bending stiffness based on the individual’s level of plantar flexor weakness. The goal of the real-time biofeedback tool was to be able to read in raw motion capture data, and then provide visual biofeedback to the individual to help them acclimate to using the PD-AFO.
Aim 3: Determine if the real-time biofeedback tool acclimated the individual post-stroke to using the quantitatively matched PD-AFO while walking.

The individual post-stroke’s objective was to reach a targeted dorsiflexion range. If the individual post-stroke was able to reach that targeted dorsiflexion range, the biofeedback tool was deemed effective.

The individual post-stroke’s mean peak plantar flexion moment pre-biofeedback will be compared to the mean peak plantar flexion moment post-biofeedback. The individual post-stroke’s change in mean step length (pre vs. post) while walking with the quantitatively matched PD-AFO will be compared to the pre-biofeedback step length variability. If the mean peak plantar flexion moment is greater post-biofeedback compared to pre-biofeedback and the mean step length exceeds the pre-biofeedback step length variability, then the real-time biofeedback tool was deemed effective in using ankle angle as the key parameter in improving PD-AFO use.

Hypothesis 3.1: The individual post-stroke will reach the targeted dorsiflexion range for at least one trial for both visits.

Hypothesis 3.2: The individual post-stroke’s mean peak plantar flexion moment and mean step length will both improve from pre- to post-biofeedback for both visits.
Chapter 2
METHODS

Subjects

Eleven individuals with chronic stroke were recruited from a registry of individuals post-stroke who were interested in participating in research at the University of Delaware. **Criteria for Inclusion:** 1) Age 21-85. 2) Chronic stroke (>6 months post stroke). 3) Prescribed an AFO by a clinician but able to walk for at least 2 minutes without assistance from another person (assistive device allowed). 4) Adequate paretic dorsiflexion ROM (≥ 12° measured via instrumented ROM test - see ‘Baseline Visit’). 5) Plantar flexor strength deficits (paretic peak plantar flexion moment in gait at least 0.15 Nm/kg lower than scaled, speed-matched value from our normative database). **Criteria for Exclusion:** 1) Evidence of cerebellar stroke on clinical MRI. 2) Other neurologic conditions in addition to stroke. 3) Sensorimotor neglect. 4) Inability to walk outside the home prior to the stroke. 5) Total joint replacement or orthopedic problems in the lower limbs or spine that limit walking. 6) Coronary artery bypass graft or myocardial infarction within past 3 months. 7) Unexplained dizziness in last 6 months. 8) Inability to communicate with investigators.

Testing Procedures Overview

Medical clearance was sought from potentially-eligible, interested subjects’ physicians via an Institutional Review Board-approved medical clearance protocol at the University of Delaware. After obtaining clearance, subjects underwent two or three visits (Baseline and one or two Evaluation visits) in the Orthotics and Prosthetics for
Enhanced Mobility Research Laboratory. All study procedures were explained to the subjects, and they were asked to sign the informed consent.

**Baseline Visit**

During the first visit, anthropometric measurements and other baseline measurements were recorded.

**Part 1: Self-Selected Walking Velocity**

A 10-meter walk test was performed in the Orthotics and Prosthetics for Enhanced Mobility Research Laboratory to measure the subject’s self-selected walking speed. The subject walked in a straight line for 10 meters but was only timed between two and eight meters to account for acceleration and deceleration. This test was completed two times. The averaged time of the two trials was divided by 6 meters to get the subject’s self-selected walking speed [68].

**Part 2: Maximal Dorsiflexion ROM**

Retro-reflective markers were attached to the subject’s specific anatomical landmarks using a six-degree-of-freedom marker set [69], [70]. Active and passive ankle ROM, on the subject’s paretic side, were recorded. The subject first sat with his/her knee at 90° and actively dorsiflexed their ankle. Then, the subject passively dorsiflexed their ankle, with the assistance of a physical therapist. The subject repeated the two ROM tasks with the knee at 180°. While these tasks were performed, kinematics of the foot and shank were tracked using a motion capture system (Motion Analysis Corporation, Santa Rosa, CA) [69] to measure the subject’s ankle ROM.
Part 3: Peak Plantar Flexion Moment Measurement

The subject walked under two conditions: (1) without his/her AFO and (2) with his/her originally prescribed AFO, at his/her self-selected walking speed on a split-belt, instrumented treadmill (Bertec Corp., Columbus, OH) that was calibrated to optimize center of pressure measurements [71]. If he/she was not able to walk without an orthosis, the subject only walked with his/her originally prescribed AFO. Three trials of 10 gait cycles were recorded. All subjects wore a safety harness and were allowed a light touch of the handrails if needed. Kinematic data was collected using a 7-camera motion capture system to track the 3D positions of the retro-reflective markers (240 Hz) using Cortex Software (v5.0, Motion Analysis Corp., Santa Rosa, CA). Kinetic data was recorded from the treadmill force plates (1200 Hz) synchronously. The kinematic and kinetic data were filtered at 6 Hz and 25 Hz, respectively, using a zero-lag low-pass Butterworth filter [72]. These data were used to calculate each subject’s mean peak plantar flexion moment, which provided a measure of each subject’s level of plantar flexor weakness and drove the quantitative matching of the PD-AFO bending stiffness to each individual’s needs.

Part 4: Limb Size and Shape Characterization

While seated, 44 points on the subject’s shank and foot were digitally captured using a 3D Fusion FaroArm (FARO Technologies Inc., Lake Mary, FL). The 3D points were used to determine the size and shape of the shank and foot, which were needed to quantitatively fit of each subject’s PD-AFOs [73].

**PD-AFO Quantitative Matching & Manufacturing**

The subject’s net peak plantar flexion moment during stance was averaged from the baseline data and normalized by body mass [72] in Visual 3D (C-Motion
Inc., Germantown, MD). Active and passive ROM, knee flexed at 90° and knee fully extended at 180°, of their paretic leg was averaged from the baseline data in Visual 3D. If the subject did not have at least 12° dorsiflexion ROM (passive, knee flexed at 90° condition), he/she did not continue in the study. The subject’s averaged scaled mean peak plantar flexion moment was compared to a scaled, speed-matched mean peak plantar flexion moment from our lab’s normative database to determine the subject’s plantar flexor function deficit. The specified typical bending stiffness of the PD-AFOs was calculated by subtracting the subject’s mean peak plantar flexion moment from the typical, speed matched, mean peak plantar flexion moment (typical - subject) divided by the typical average change in ankle angle during the period of dorsiflexion in stance (12°). The PD-AFO was made from carbon fiber composite material (Fig. 1). After the PD-AFOs were manufactured, the bending stiffness values were verified using our custom stiffness testing device [37]. Once the PD-AFOs stiffness values were verified, an arch support was glued on the footplate (UCO International, Wheeling, IL) and foam padding was glued around the cuff. Adjustments to improve comfort were made as needed.
Evaluation Visits:

Seven subjects visited the lab for one evaluation visit and underwent an instrumented gait analysis on his/her Original AFO and the quantitatively matched PD-AFO. Four subjects visited the lab for two evaluation visits and underwent an instrumented gait analysis on his/her Original AFO and the quantitatively matched PD-AFO, while also testing the biofeedback tool. The biofeedback tool showed how the subject’s shank and foot moved in real-time with the goal of helping the subjects properly load the PD-AFO by bending into (dorsiflexing) the brace. During these visits, the tasks to be performed that day were explained to the subject. Anthropometric measurements and other baseline measurements were recorded.
Part 1: Self-Selected Walking Velocity

A 10-meter walk test was conducted using the same procedure from the Baseline Visit.

Part 2: Re-Evaluation of Original AFO

Eleven subjects were re-collected walking with his/her originally prescribed AFO at his/her self-selected walking speed, on a split-belt, instrumented treadmill for three trials of 10 gait cycles. Data was recollected to account for the individuals post-stroke day-to-day variability in gait. All subjects wore a safety harness and were allowed a light touch of the handrails if needed. Kinematic and kinetic data were recorded and filtered using the same procedures from the Baseline visit.

Part 3: Evaluation of Quantitatively Matched PD-AFO

The quantitatively matched PD-AFOs were checked for fit by adjusting the padding and straps as necessary. Each subject was given time to walk in the PD-AFO around the lab (overground) to initially get used to walking while wearing the PD-AFO. Then, the eleven subjects walked with his/her quantitatively matched PD-AFO at his/her self-selected walking speed, on a split-belt, instrumented treadmill for three sets of 10 gait cycles (these trials were considered pre-biofeedback; Fig. 2). All subjects wore a safety harness and were allowed a light touch of the handrails if needed. Kinematic and kinetic data were recorded and filtered using the same procedures from the Baseline visit.
Part 4: Real-Time Biofeedback

In addition to Parts 1-3, four subjects also completed a real-time biofeedback condition. Once the subject was well rested after Part 3, a custom-written real-time biofeedback tool was explained. The purpose of the biofeedback tool was to help the subjects visualize how their shank was moving relative to their foot with the goal of bending into to (dorsiflexing) the PD-AFO to harness the bending stiffness. The biofeedback tool was written in LabView software (National Instruments, Austin, Texas) and consisted of two visual features. The first feature displayed three green markers connected by either black or gray lines, which created a foot and shank segment. The superior-most green marker resembled the position of the lateral femoral epicondyle, which was read in from the real-time motion capture data recorded by the Cortex Software. The second and third green markers represented the subject’s foot.

Figure 2  Individual post-stroke walking with the quantitatively matched PD-AFO.
flat on the ground, which was locked in place in the biofeedback tool to reduce the amount of information the subject needed to decipher. If the foot and shank (lines connecting the three markers) were black, then the subject was in the stance phase of gait (Fig. 3a), and if the foot and shank were gray, then the subject was in the swing phase of gait (Fig. 3b).

![Figure 3](image)

**Figure 3**  
a) Individual post-stroke in stance phase of gait, indicated by the black line. b) Individual post-stroke in swing phase of gait, indicated by the gray line.

The second feature displayed a red/green region that represented the virtual position the lateral femoral epicondyle needed to be at to reach the targeted dorsiflexion range. Typical dorsiflexion ROM during late-stance was defined as 10° [2]. The targeted dorsiflexion range was determined to be between 8 and 14° based on
this typical dorsiflexion ROM. The subject’s objective was to reach the targeted dorsiflexion range, seen as a highlighted region in the tool (Fig. 4), during mid- to late-stance of gait. The region turned from red to green when the subject achieved the targeted range. However, two of the subjects were already within the targeted 8-14° dorsiflexion range when they stood in a neutral position for the static trial. Therefore, these two subject’s targeted dorsiflexion ranges were increased to give the subject an additional few degrees before reaching the targeted range.

Figure 4  

a) Individual post-stroke outside of dorsiflexion range, indicated by the red range. b) Individual post-stroke within dorsiflexion range, indicated by the green range.

The subject was told to concentrate on the biofeedback tool, displayed on a projector in front of the instrumented treadmill, and when the lines connecting the
three markers were black, to bend into the PD-AFO until the dorsiflexion range turned green. Once the dorsiflexion range turned green, the subject was told to release to allow the ankle/PD-AFO to return to a more neutral position. Prior to collecting data, the subject was given the opportunity to squat in place to get a better understanding of how the biofeedback tool worked. The subjects were instructed to do a series of squats to understand how the biofeedback tool worked as they were flexing/extending their ankle. Each subject was given time to walk in the PD-AFO around the lab (overground) to initially get used to walking while wearing the PD-AFO. Once the subject acclimated themselves to the biofeedback tool, he/she walked with the PD-AFO at their self-selected walking speed for eight minutes (10 gait cycles collected every 30 seconds). Verbal cues and encouragement were given to the subject as they were following the biofeedback tool. After the eight minutes, the biofeedback tool was turned off and the subject continued to walk for another four minutes while data continued to be collected (post-biofeedback). All subjects wore a safety harness and were allowed a light touch of the handrails if needed. Kinematic and kinetic data were recorded and filtered using the same procedures from the Baseline visit.

The four subjects who participated in the real-time biofeedback condition (Part 4) returned for a second Evaluation visit 2-12 days following the first Evaluation visit. For the second Evaluation visit, subjects completed Parts 3 and 4 of the Evaluation visit’s protocol, as described above.

**Data & Statistical Analysis**

Joint angles and moments were computed for use in the data analysis. Ankle angles, ankle moments, and knee angles were calculated using the thigh, shank, kinetic foot, and kinematic-only foot coordinate systems. A static trial was captured where the
thigh coordinate system consisted of a longitudinal axis connecting the hip and knee joint centers and a flexion/extension axis parallel to the frontal plane in anatomical position (Fig. 5). The shank coordinate system consisted of a longitudinal axis connecting the knee and ankle joint centers and a flexion/extension axis parallel to the frontal plane in anatomical position (Fig. 5). The kinetic foot coordinate system was the traditional anatomical-based foot coordinate system (Fig. 5). The ankle joint center and one virtual landmark, created by projecting the ankle joint center to the ground, were used to create the kinematic-only foot coordinate system. The kinematic-only foot’s coordinate system consisted of a longitudinal axis connecting the ankle joint center and the virtual landmark and a flexion/extension axis parallel to the frontal plane in anatomical position (Fig. 5).

Figure 5  Sagittal plane diagram of the thigh, shank, kinetic, and kinematic-only foot coordinate systems. The flexion/extension axes are perpendicular to the sagittal plane (into the page) and therefore are not seen in the diagram.
Ankle angles were calculated as the angle of the kinematic-only foot relative to the shank. Knee angles were calculated as the angle of the shank relative to the thigh. When the subject was standing in a neutral position during the static trial, these angles were set to 0°. Thus, via the right-hand rule, knee extension was positive and knee flexion was negative. Additionally, ankle dorsiflexion from the static position was positive and ankle plantar flexion was negative. Ankle moments were calculated as the moment at the proximal end of the kinetic foot segment and resolved in the shank’s coordinate system. Using the right-hand rule, an ankle dorsiflexion moment was positive, and an ankle plantar flexion moment was negative.

**Aim 1:** Determine if the quantitatively matched PD-AFOs improved gait biomechanics (peak plantar flexion moment) better than the originally prescribed AFO for individual’s post-stroke.

A one-way repeated measure analysis of variance (ANOVA) was performed on the subject’s mean peak plantar flexion moment between the two conditions from the first Evaluation visit. The statistical analyzes were performed in SPSS (SPSS v24, IBM, Armonk, NY) and the significance level was set an $\alpha = 0.05$, with a power of 0.8. If a significant difference was observed, simulation modeling analysis (SMA v11.10.16) was then performed to determine which subjects achieved a significant difference between the two conditions with an $\alpha = 0.05$ [74].
**Aim 2:** Develop a real-time biofeedback tool to help individuals post-stroke become acclimated to using the quantitatively matched PD-AFO.

No statistical analysis was performed because a program was developed. There were some analyses completed to test and troubleshoot the program to develop a clear visual real-time biofeedback tool.

**Aim 3:** Determine if the real-time biofeedback tool acclimated the individual post-stroke to using the quantitatively matched PD-AFO while walking.

The mean peak dorsiflexion angle was compared to the range assigned to each individual post-stroke to determine if the subject was able to reach that targeted dorsiflexion range.

To determine if the real-time biofeedback tool was effective in helping the individual post-stroke acclimate to the PD-AFO, mean peak plantar flexion moment and mean step length were analyzed for each subject. A one-way repeated measure ANOVA was performed on the subject’s mean peak plantar flexion moment between pre-biofeedback and post-biofeedback for both visits. The statistical analysis was performed in SPSS and the significance level was set an $\alpha = 0.05$, with a power of 0.8. SMA was also performed to determine if a significant increase in mean peak plantar flexion moment was achieved pre- and post-biofeedback for each subject individually for both evaluation visits ($\alpha = 0.05$). The subject’s change in mean step length (pre-vs. post-biofeedback) while walking with the quantitatively matched bending stiffness
PD-AFO was compared to the pre-feedback step length variability for both evaluation visits.
Chapter 3

RESULTS

Subject Demographics

Eleven individuals post-stroke were recruited and consented to participate in this study, seen in Table 1 (male: 7, female: 4, average age: 55.6 ± 8.8 years, average mass: 78.6 ± 13.1 kilograms, average height: 1.75 ± 0.1 meters). The average self-selected walking speed was 0.45 ± 0.1 statures/second (0.79 ± 0.2 meters/second).

Four of the eleven individuals post-stroke (Subjects 4, 6, 7, and 8) also participated in the biofeedback portion of this study (male: 3, female: 1, average age: 59.5 ± 3.7 years, average mass: 89.5 ± 12.4 kilograms, average height: 1.74 ± 0.1 meters). The average self-selected walking speed was 0.43 ± 0.1 statures/second (0.76 ± 0.2 meters/second).

Table 1 The subject demographics: gender, age, mass in kilograms, height in meters, self-selected walking speed in statures/second, and self-selected walking speed in meters/second.

<table>
<thead>
<tr>
<th>Subject</th>
<th>Gender</th>
<th>Age</th>
<th>Mass (kg)</th>
<th>Height (m)</th>
<th>Speed (st/s)</th>
<th>Speed (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>M</td>
<td>61</td>
<td>79.1</td>
<td>1.92</td>
<td>0.56</td>
<td>1.08</td>
</tr>
<tr>
<td>S2</td>
<td>M</td>
<td>62</td>
<td>71.8</td>
<td>1.77</td>
<td>0.28</td>
<td>0.50</td>
</tr>
<tr>
<td>S3</td>
<td>F</td>
<td>37</td>
<td>73.7</td>
<td>1.66</td>
<td>0.48</td>
<td>0.80</td>
</tr>
<tr>
<td>S4</td>
<td>M</td>
<td>61</td>
<td>97.4</td>
<td>1.79</td>
<td>0.54</td>
<td>0.96</td>
</tr>
<tr>
<td>S5</td>
<td>F</td>
<td>62</td>
<td>56.8</td>
<td>1.69</td>
<td>0.43</td>
<td>0.73</td>
</tr>
<tr>
<td>S6</td>
<td>F</td>
<td>62</td>
<td>76.7</td>
<td>1.67</td>
<td>0.30</td>
<td>0.50</td>
</tr>
<tr>
<td>S7</td>
<td>M</td>
<td>61</td>
<td>102.5</td>
<td>1.74</td>
<td>0.38</td>
<td>0.67</td>
</tr>
<tr>
<td>S8</td>
<td>M</td>
<td>54</td>
<td>81.3</td>
<td>1.77</td>
<td>0.51</td>
<td>0.91</td>
</tr>
<tr>
<td>S9</td>
<td>M</td>
<td>43</td>
<td>65.0</td>
<td>1.82</td>
<td>0.60</td>
<td>1.10</td>
</tr>
<tr>
<td>S10</td>
<td>M</td>
<td>60</td>
<td>75.0</td>
<td>1.75</td>
<td>0.46</td>
<td>0.80</td>
</tr>
<tr>
<td>S11</td>
<td>F</td>
<td>49</td>
<td>85.2</td>
<td>1.70</td>
<td>0.35</td>
<td>0.60</td>
</tr>
</tbody>
</table>
Aim 1:

A PD-AFO was successfully quantitatively matched and manufactured for each subject (Table 2). Results for Aim 1 were analyzed to determine if the quantitatively matched PD-AFOs improved gait biomechanics (peak plantar flexion moment) better than the originally prescribed AFO for individual’s post-stroke. All but one subject had an increase in mean peak plantar flexion moment while wearing the quantitatively matched PD-AFO (Table 3). However, subjects 4, 7, 9, 10, and 11 had considerable within-subject variability in the mean peak plantar flexion moments while wearing the quantitatively matched PD-AFO (Table 3). Notably, this variability was higher in the quantitatively matched PD-AFO than the originally prescribed AFO.

Table 2 The subjects quantitatively matched PD-AFO bending stiffness values.

<table>
<thead>
<tr>
<th>Bending Stiffness (Nm/°)</th>
<th>Quantitatively Matched PD-AFO</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>3.5</td>
</tr>
<tr>
<td>S2</td>
<td>4.1</td>
</tr>
<tr>
<td>S3</td>
<td>2.0</td>
</tr>
<tr>
<td>S4</td>
<td>3.3</td>
</tr>
<tr>
<td>S5</td>
<td>2.8</td>
</tr>
<tr>
<td>S6</td>
<td>3.4</td>
</tr>
<tr>
<td>S7</td>
<td>2.4</td>
</tr>
<tr>
<td>S8</td>
<td>2.6</td>
</tr>
<tr>
<td>S9</td>
<td>1.8</td>
</tr>
<tr>
<td>S10</td>
<td>2.5</td>
</tr>
<tr>
<td>S11</td>
<td>2.5</td>
</tr>
</tbody>
</table>

The one-way repeated measure ANOVA revealed a significant difference between mean peak plantar flexion moment while wearing the quantitatively matched
PD-AFO and while wearing the Original AFO \((F_{1,10} = 14.541, p = 0.003)\). Since a significant difference was seen, SMA was conducted. SMA revealed that 9 out of the 11 individuals post-stroke had a significant increase in mean peak plantar flexion moment from the Original AFO to PD-AFO (Table 3). Additionally, SMA revealed that 9 of these subjects had Pearson R correlation coefficient less than -0.681 (\(R < -0.681\)). The Pearson R correlation is negative because the peak plantar flexion moments inputted into SMA were negative values.

Lastly, the achieved effect size was estimated using Cohen’s d, where values of 0.2 were considered a small effect, values of 0.5 a medium effect, and values of 0.8 a large effect [75]. Results revealed that there was a medium-to-large effect size (Cohen’s d = -0.613) between the quantitatively matched PD-AFO and originally prescribed AFO. These data support hypothesis 1.1 as the mean peak plantar flexion moment was significantly greater while wearing the quantitatively matched PD-AFO bending stiffness than while wearing originally prescribed AFO.
Table 3  The subjects’ mean peak plantar flexion moments during the stance phase of gait while wearing the PD-AFO and Original AFO (*significant increase based on SMA).

<table>
<thead>
<tr>
<th></th>
<th>Original AFO</th>
<th>Quantitatively Matched PD-AFO</th>
<th>Pearson R</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>-0.659 ± 0.073</td>
<td>-0.754 ± 0.059*</td>
<td>-0.812</td>
</tr>
<tr>
<td>S2</td>
<td>-0.715 ± 0.051</td>
<td>-0.875 ± 0.049*</td>
<td>-0.918</td>
</tr>
<tr>
<td>S3</td>
<td>-0.812 ± 0.060</td>
<td>-0.993 ± 0.062*</td>
<td>-0.964</td>
</tr>
<tr>
<td>S4</td>
<td>-1.174 ± 0.065</td>
<td>-1.389 ± 0.098*</td>
<td>-0.788</td>
</tr>
<tr>
<td>S5</td>
<td>-0.730 ± 0.088</td>
<td>-0.756 ± 0.052</td>
<td>-0.062</td>
</tr>
<tr>
<td>S6</td>
<td>-0.806 ± 0.045</td>
<td>-0.934 ± 0.058*</td>
<td>-0.870</td>
</tr>
<tr>
<td>S7</td>
<td>-1.248 ± 0.091</td>
<td>-1.682 ± 0.176*</td>
<td>-0.901</td>
</tr>
<tr>
<td>S8</td>
<td>-0.999 ± 0.061</td>
<td>-0.930 ± 0.043</td>
<td>0.444</td>
</tr>
<tr>
<td>S9</td>
<td>-1.116 ± 0.073</td>
<td>-1.436 ± 0.222*</td>
<td>-0.928</td>
</tr>
<tr>
<td>S10</td>
<td>-0.918 ± 0.083</td>
<td>-1.031 ± 0.100*</td>
<td>-0.681</td>
</tr>
<tr>
<td>S11</td>
<td>-1.018 ± 0.056</td>
<td>-1.131 ± 0.095*</td>
<td>-0.738</td>
</tr>
</tbody>
</table>

To further analyze the changes in gait biomechanics, the subject’s knee and ankle angles were analyzed during the stance phase of gait. Results showed that seven subjects (Subjects 2, 3, 4, 6, 8, 9, and 11) had persistent knee flexion throughout the stance phase of gait while wearing the quantitatively matched PD-AFO (Fig. 6). Four of these seven subjects (Subjects 2, 3, 8, and 9) also had excessive knee flexion throughout the stance phase of gait while wearing the quantitatively matched PD-AFO (Fig. 6). Excessive knee flexion was defined as having a maximum knee flexion angle, in mid- to late-stance phase of gait, of at least 10° greater than the maximum knee flexion angle seen in healthy individuals (20°) [2]. One interesting case was Subject 3 who went from knee hyperextension while wearing the originally prescribed AFO to persistent and excessive knee flexion while wearing the quantitatively matched PD-AFO (Fig. 7). Additionally, six subjects (Subjects 2, 3, 7, 8, 9, and 11) had persistent
ankle dorsiflexion throughout the stance phase of gait while wearing the quantitatively matched PD-AFO (Fig. 8). Furthermore, eight of the eleven of the subjects had a reduction in their mean peak dorsiflexion angle, toward a typical peak dorsiflexion angle, while wearing the quantitatively matched PD-AFO in comparison to the originally prescribed AFO (Table 4).

Figure 6  Representative knee angle during the stance phase of gait demonstrating persistent and excessive knee flexion while wearing the PD-AFO. Flexion is negative, extension is positive.
Figure 7  Subject 3’s knee angle during the stance phase of gait while wearing the PD-AFO and Original AFO. Flexion is negative, extension is positive.

Figure 8  Representative ankle angle during the stance phase of gait demonstrating persistent ankle dorsiflexion while wearing the PD-AFO. Flexion is negative, extension is positive.
Table 4  The subjects’ mean peak dorsiflexion angle during the stance phase of gait while wearing the PD-AFO and Original AFO (bolded angles show a decrease in mean peak dorsiflexion angle)

<table>
<thead>
<tr>
<th></th>
<th>Original AFO</th>
<th>Quantitatively Matched PD-AFO</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>17.07 ± 0.79</td>
<td>9.82 ± 0.68</td>
</tr>
<tr>
<td>S2</td>
<td>14.83 ± 0.48</td>
<td>18.72 ± 0.51</td>
</tr>
<tr>
<td>S3</td>
<td>14.64 ± 1.45</td>
<td>15.18 ± 0.72</td>
</tr>
<tr>
<td>S4</td>
<td>25.86 ± 1.32</td>
<td>22.95 ± 1.58</td>
</tr>
<tr>
<td>S5</td>
<td>19.61 ± 1.65</td>
<td>11.94 ± 0.83</td>
</tr>
<tr>
<td>S6</td>
<td>20.91 ± 0.75</td>
<td>18.24 ± 1.17</td>
</tr>
<tr>
<td>S7</td>
<td>19.12 ± 1.96</td>
<td>17.96 ± 1.48</td>
</tr>
<tr>
<td>S8</td>
<td>28.74 ± 1.24</td>
<td>24.38 ± 0.71</td>
</tr>
<tr>
<td>S9</td>
<td>14.19 ± 1.00</td>
<td>17.55 ± 0.63</td>
</tr>
<tr>
<td>S10</td>
<td>11.91 ± 1.24</td>
<td>9.28 ± 0.49</td>
</tr>
<tr>
<td>S11</td>
<td>22.48 ± 0.67</td>
<td>14.75 ± 0.92</td>
</tr>
</tbody>
</table>

Aim 2:

The biofeedback tool read in marker position data of the paretic limb real-time from the Cortex motion analysis software and displayed a visual 2D figure to help the subjects visualize how their shank was moving relative to their foot with the goal of bending into (dorsiflexing) the PD-AFO to harness the bending stiffness. In the biofeedback tool, two vectors were created: (1) a vertical vector, from the lateral malleolus marker to the lateral femoral epicondyle marker, (2) a vector parallel to the ground, from the heel marker to the marker labeled FT1 on the foot cluster. The inverse cosine of the dot product between these two vectors unitized resulted in the shank angle relative to the ground. The targeted dorsiflexion range values were computed using trigonometry since the 2D plot’s x and y coordinates were known. The force data was also read into the biofeedback tool. If the force data was greater
than 20 N, the subject was in the stance phase of gait, and if the force data was less than 20 N, the subject was in the swing phase of gait.

Below are images of the motion capture and biofeedback tool’s display of the subject while he/she was in different parts of the stance phase of gait: heel strike (Fig. 9), mid-stance (Fig. 10), and late-stance (Fig. 11).

Figure 9  
a) The subject’s heel strike displayed in the Cortex Software (Green leg).  
b) The subject’s heel strike displayed in the biofeedback tool.
Figure 10  
a) The subject’s mid-stance displayed in the Cortex Software (Green leg).  
b) The subject’s mid-stance displayed in the biofeedback tool.

Figure 11  
a) The subject’s late-stance displayed in the Cortex Software (Green leg).  
b) The subject’s late-stance displayed in the biofeedback tool.
**Aim 3:**

Results for aim 3 were analyzed to determine if the real-time biofeedback tool helped acclimate the individual post-stroke to using the quantitatively matched PD-AFO while walking.

The four subjects targeted dorsiflexion ranges for the evaluation visits were: 10-18° for Subject 4, 8-14° for Subject 6 and Subject 7, and 12-18° for Subject 8. All subjects started with a mean dorsiflexion angle higher than their targeted range. During the first evaluation visit, no subject was able to reduce their mean peak dorsiflexion angle enough to reach their targeted range while using the biofeedback tool. Subject 7 was able to reduce their mean peak dorsiflexion angle during the biofeedback trials but still overshot the targeted range, while the other subjects still maintained similar mean peak dorsiflexion angles throughout the evaluation visit. Table 5 displays the mean peak dorsiflexion angles pre-biofeedback, for each 30 second trial during biofeedback, and post-biofeedback. Subject 4, 6, and 8 were not able to complete all eight minutes of biofeedback. Subject 4 only had one gait cycle to report during trial 2 and no data to report during trial 4 and 5 because of treadmill crossover (displayed as a dash in Table 5). Additionally, no subjects were able to reach their targeted range post-biofeedback and instead maintained similar pre- and post-biofeedback mean peak dorsiflexion angles (Fig. 12).
Table 5  The four subjects (Subjects 4, 6, 7, and 8) mean peak dorsiflexion angles pre-biofeedback, all trials (one trial = mean peak dorsiflexion angle of 10 gait cycles collected every 30 seconds) of biofeedback, and post-biofeedback on evaluation visit one.

<table>
<thead>
<tr>
<th>Target Range</th>
<th>S4</th>
<th>S6</th>
<th>S7</th>
<th>S8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre</td>
<td>22.95 ± 1.58</td>
<td>18.24 ± 1.17</td>
<td>17.96 ± 1.48</td>
<td>24.38 ± 0.71</td>
</tr>
<tr>
<td>Trial 1</td>
<td>20.94 ± 0.56</td>
<td>22.49 ± 1.05</td>
<td>14.99 ± 0.93</td>
<td>24.47 ± 0.44</td>
</tr>
<tr>
<td>Trial 2</td>
<td>24.26</td>
<td>22.89 ± 1.55</td>
<td>15.27 ± 0.69</td>
<td>24.25 ± 0.66</td>
</tr>
<tr>
<td>Trial 3</td>
<td>22.10 ± 0.39</td>
<td>24.84 ± 1.67</td>
<td>16.18 ± 0.54</td>
<td>23.90 ± 0.62</td>
</tr>
<tr>
<td>Trial 4</td>
<td>-</td>
<td>21.34 ± 5.55</td>
<td>15.59 ± 0.72</td>
<td>23.49 ± 0.90</td>
</tr>
<tr>
<td>Trial 5</td>
<td>-</td>
<td>23.62 ± 3.03</td>
<td>14.80 ± 0.67</td>
<td>23.50 ± 0.50</td>
</tr>
<tr>
<td>Trial 6</td>
<td>21.81 ± 1.32</td>
<td>23.12 ± 2.10</td>
<td>14.59 ± 0.84</td>
<td>23.91 ± 0.98</td>
</tr>
<tr>
<td>Trial 7</td>
<td>21.84 ± 1.21</td>
<td>18.97 ± 2.21</td>
<td>15.88 ± 0.73</td>
<td>23.33 ± 0.92</td>
</tr>
<tr>
<td>Trial 8</td>
<td>21.67 ± 1.43</td>
<td>18.97 ± 2.76</td>
<td>17.05 ± 0.71</td>
<td>24.96 ± 0.52</td>
</tr>
<tr>
<td>Trial 9</td>
<td>22.33 ± 1.25</td>
<td>18.41 ± 1.86</td>
<td>17.03 ± 0.79</td>
<td>25.01 ± 0.66</td>
</tr>
<tr>
<td>Trial 10</td>
<td>22.01 ± 0.82</td>
<td>20.02 ± 0.69</td>
<td>16.09 ± 0.77</td>
<td>24.39 ± 0.67</td>
</tr>
<tr>
<td>Trial 11</td>
<td>23.03 ± 0.65</td>
<td>-</td>
<td>15.51 ± 0.58</td>
<td>24.37 ± 0.40</td>
</tr>
<tr>
<td>Trial 12</td>
<td>21.55 ± 1.58</td>
<td>-</td>
<td>16.08 ± 0.54</td>
<td>-</td>
</tr>
<tr>
<td>Trial 13</td>
<td>21.92 ± 0.88</td>
<td>-</td>
<td>15.88 ± 0.69</td>
<td>-</td>
</tr>
<tr>
<td>Trial 14</td>
<td>21.20 ± 1.35</td>
<td>-</td>
<td>15.39 ± 0.50</td>
<td>-</td>
</tr>
<tr>
<td>Trial 15</td>
<td>21.89 ± 0.80</td>
<td>-</td>
<td>15.99 ± 0.58</td>
<td>-</td>
</tr>
<tr>
<td>Trial 16</td>
<td>-</td>
<td>-</td>
<td>16.03 ± 0.58</td>
<td>-</td>
</tr>
<tr>
<td>Post</td>
<td>22.62 ± 1.11</td>
<td>19.96 ± 0.95</td>
<td>17.77 ± 0.72</td>
<td>24.59 ± 0.74</td>
</tr>
</tbody>
</table>
The four subjects targeted dorsiflexion ranges were the same on the second evaluation visit as they were on the first evaluation visit: 10-18° for Subject 4, 8-14° for Subject 6 and Subject 7, and 12-18° for Subject 8. In contrast to the first visit, all subjects were able to reduce their mean peak dorsiflexion angle into the targeted range for at least one of the biofeedback trials. Subject 6 and 8 were able to keep the mean peak dorsiflexion angle within the targeted range throughout all the biofeedback trials. Table 6 displays the mean peak dorsiflexion angles pre-biofeedback, for each 30 second trial during biofeedback, and post-biofeedback. In fact, Subject 6 and 8 were
able to reach their targeted peak dorsiflexion range post-biofeedback, while Subject 7 was close to reaching his/her targeted range (Fig. 13).

Table 6 The four subjects (Subjects 4, 6, 7, and 8) mean peak dorsiflexion angles pre-biofeedback, all trials (one trial = mean peak dorsiflexion angle of 10 gait cycles collected every 30 seconds) of biofeedback, and post-biofeedback on evaluation visit two (bolded angles are within targeted range).

<table>
<thead>
<tr>
<th>Evaluation Visit 2 – Mean Peak Dorsiflexion Angle (°)</th>
<th>S4</th>
<th>S6</th>
<th>S7</th>
<th>S8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Range</strong></td>
<td><strong>10 - 18°</strong></td>
<td><strong>8 - 14°</strong></td>
<td><strong>8 - 14°</strong></td>
<td><strong>12 - 18°</strong></td>
</tr>
<tr>
<td>Pre</td>
<td>20.70 ± 1.49</td>
<td>15.98 ± 2.12</td>
<td>16.82 ± 1.22</td>
<td>21.03 ± 1.00</td>
</tr>
<tr>
<td>Trial 1</td>
<td>18.65 ± 0.76</td>
<td>13.01 ± 0.75</td>
<td>12.68 ± 0.62</td>
<td>17.37 ± 0.65</td>
</tr>
<tr>
<td>Trial 2</td>
<td>17.80 ± 1.34</td>
<td>12.68 ± 1.96</td>
<td>13.82 ± 0.90</td>
<td>16.61 ± 0.58</td>
</tr>
<tr>
<td>Trial 3</td>
<td>17.84 ± 1.68</td>
<td>12.70 ± 1.87</td>
<td>16.46 ± 0.68</td>
<td>16.39 ± 0.93</td>
</tr>
<tr>
<td>Trial 4</td>
<td>18.28 ± 1.85</td>
<td>13.85 ± 1.15</td>
<td>16.31 ± 0.65</td>
<td>16.22 ± 0.51</td>
</tr>
<tr>
<td>Trial 5</td>
<td>18.29 ± 1.14</td>
<td>13.04 ± 1.57</td>
<td>16.27 ± 1.13</td>
<td>16.90 ± 1.49</td>
</tr>
<tr>
<td>Trial 6</td>
<td>18.51 ± 1.99</td>
<td>12.38 ± 2.48</td>
<td>16.65 ± 0.78</td>
<td>16.76 ± 0.42</td>
</tr>
<tr>
<td>Trial 7</td>
<td><strong>17.91 ± 1.52</strong></td>
<td>13.64 ± 1.13</td>
<td>15.87 ± 0.58</td>
<td><strong>16.41 ± 0.75</strong></td>
</tr>
<tr>
<td>Trial 8</td>
<td>18.15 ± 1.82</td>
<td>12.35 ± 2.23</td>
<td>16.06 ± 0.50</td>
<td>16.55 ± 0.97</td>
</tr>
<tr>
<td>Trial 9</td>
<td><strong>17.77 ± 1.24</strong></td>
<td><strong>12.05 ± 1.83</strong></td>
<td>16.53 ± 0.63</td>
<td><strong>17.44 ± 0.56</strong></td>
</tr>
<tr>
<td>Trial 10</td>
<td>18.09 ± 2.12</td>
<td><strong>11.83 ± 1.39</strong></td>
<td>17.04 ± 0.62</td>
<td><strong>17.24 ± 0.49</strong></td>
</tr>
<tr>
<td>Trial 11</td>
<td><strong>17.93 ± 1.64</strong></td>
<td>11.35 ± 1.69</td>
<td>-</td>
<td>16.75 ± 0.72</td>
</tr>
<tr>
<td>Trial 12</td>
<td>19.19 ± 1.00</td>
<td><strong>12.18 ± 0.86</strong></td>
<td>-</td>
<td>17.15 ± 1.21</td>
</tr>
<tr>
<td>Trial 13</td>
<td>18.74 ± 1.28</td>
<td><strong>12.59 ± 3.71</strong></td>
<td>-</td>
<td>16.83 ± 0.79</td>
</tr>
<tr>
<td>Trial 14</td>
<td>18.32 ± 0.77</td>
<td><strong>12.10 ± 2.73</strong></td>
<td>-</td>
<td>16.82 ± 0.83</td>
</tr>
<tr>
<td>Trial 15</td>
<td>18.90 ± 0.91</td>
<td><strong>12.25 ± 2.14</strong></td>
<td>-</td>
<td><strong>16.57 ± 0.56</strong></td>
</tr>
<tr>
<td>Trial 16</td>
<td>19.03 ± 0.94</td>
<td>-</td>
<td>-</td>
<td>16.82 ± 0.85</td>
</tr>
<tr>
<td>Post</td>
<td>20.41 ± 0.87</td>
<td><strong>12.63 ± 2.84</strong></td>
<td>15.75 ± 1.09</td>
<td><strong>16.92 ± 0.81</strong></td>
</tr>
</tbody>
</table>
In summary, these data partially support hypothesis 3.1, that the targeted dorsiflexion range would be reached by the individuals post-stroke. On the first evaluation visit, the subjects were not able to reach the targeted dorsiflexion range, while on the second visit, all four subjects were able to reach their target for at least one of the feedback trials. Two of the subjects were able to stay within the targeted range post-biofeedback.

The four subjects’ mean peak plantar flexion moments varied pre- to post-biofeedback during both evaluation visits. Subject 4’s mean peak plantar flexion moment increased pre- to post-biofeedback while having similar values during both
evaluation visits. Subject 6’s mean peak plantar flexion moments decreased pre- to post-biofeedback while having similar values during both evaluation visits. Subject 7’s mean peak plantar flexion moment increased pre- to post-biofeedback during the first evaluation visit. During the second evaluation visit, Subject 7’s moments were much smaller and decreased pre- to post-biofeedback. Subject 8’s peak plantar flexion moment did not change pre- to post-biofeedback during both evaluation visits, but the moments were much larger during the second evaluation visit.

In evaluating hypothesis 3.2, the one-way repeated measure ANOVA did not reveal a significant difference between mean peak plantar flexion moment pre-biofeedback and post-biofeedback on the first or second evaluation visit (Day one: ($F_{[1,3]} = 0.647, p = 0.480$), Day two: ($F_{[1,3]} = 1.169, p = 0.359$). Additionally, SMA revealed that no subjects had a significant increase in mean peak plantar flexion moment from pre-biofeedback to post-biofeedback on the first or second evaluation visit (Table 7 and Table 8). In contrast, on the second evaluation visit, Subject 7 had a significant decrease in mean peak plantar flexion moment.

Table 7  The four subjects (Subjects 4, 6, 7, and 8) mean peak plantar flexion moments while wearing the PD-AFO and Original AFO on evaluation visit one.

<table>
<thead>
<tr>
<th>Evaluation Visit 1 – Mean Peak Plantar Flexion Moment (Nm/kg)</th>
<th>Pre-Biofeedback</th>
<th>Post-Biofeedback</th>
<th>Pearson R</th>
</tr>
</thead>
<tbody>
<tr>
<td>S4</td>
<td>-1.389 ± 0.098</td>
<td>-1.406 ± 0.112</td>
<td>-0.007</td>
</tr>
<tr>
<td>S6</td>
<td>-0.934 ± 0.058</td>
<td>-0.889 ± 0.049</td>
<td>0.564</td>
</tr>
<tr>
<td>S7</td>
<td>-1.682 ± 0.176</td>
<td>-1.889 ± 0.113</td>
<td>-0.743</td>
</tr>
<tr>
<td>S8</td>
<td>-0.930 ± 0.043</td>
<td>-0.930 ± 0.043</td>
<td>-0.096</td>
</tr>
</tbody>
</table>
Table 8  The four subjects (Subjects 4, 6, 7, and 8) mean peak plantar flexion moments while wearing the PD-AFO and Original AFO on evaluation visit two (‘*’significant decrease).

<table>
<thead>
<tr>
<th>Evaluation Visit 2 – Mean Peak Plantar Flexion Moment (Nm/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Biofeedback</td>
</tr>
<tr>
<td>S4</td>
</tr>
<tr>
<td>S6</td>
</tr>
<tr>
<td>S7</td>
</tr>
<tr>
<td>S8</td>
</tr>
</tbody>
</table>

The subject’s change in mean step length (pre- vs. post-biofeedback) while walking with the quantitatively matched bending stiffness PD-AFO was not greater than the pre-biofeedback step length variability for the first evaluation visit for neither their paretic or non-paretic limb (Table 9). During the second evaluation visit, Subject 7 had a change in mean step length greater than the baseline variability on their paretic and non-paretic limb (Table 10). However, Subject 7’s paretic limb had a positive change in mean step length (post-biofeedback > pre-biofeedback), while Subject 7’s non-paretic limb had a negative change in mean step length (post-biofeedback < pre-biofeedback).

Table 9  The four subjects (Subjects 4, 6, 7, and 8) change in mean step length (pre- vs. post-biofeedback) and baseline variability on evaluation visit one.

<table>
<thead>
<tr>
<th>Paretic Limb – Evaluation Visit 1</th>
<th>Non-Paretic Limb – Evaluation Visit 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>S4</td>
<td>S6</td>
</tr>
<tr>
<td>Δ Mean Step Length</td>
<td>-0.012</td>
</tr>
<tr>
<td>(meters)</td>
<td></td>
</tr>
<tr>
<td>Baseline Variability</td>
<td>0.037</td>
</tr>
</tbody>
</table>
Table 10  The four subjects (Subjects 4, 6, 7, and 8) change in mean step length (pre- vs. post-biofeedback) and baseline variability on evaluation visit two (*mean step length > baseline variability & mean step length increased); +mean step length > baseline variability & mean step length decreased).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>S4</td>
<td>S6</td>
</tr>
<tr>
<td>Δ Mean Step Length (meters)</td>
<td>0.009</td>
<td>0.017</td>
</tr>
<tr>
<td>Baseline Variability</td>
<td>0.034</td>
<td>0.025</td>
</tr>
</tbody>
</table>

In summary, these data did not support hypothesis 3.2 as neither the mean peak plantar flexion moments and mean step lengths were significantly improved from pre-to post-biofeedback for both evaluation visits.
Chapter 4
DISCUSSION

The purpose of this study was to first evaluate if the quantitatively matched PD-AFOs improved gait biomechanics (peak plantar flexion moment) of individuals post-stroke better than the originally prescribed AFO. Then, we developed and evaluated if a real-time biofeedback tool helped individuals post-stroke more effectively use the quantitatively matched PD-AFO while walking. Results showed that 9 out of the 11 subjects had a significant increase in mean peak plantar flexion moment from the Original AFO to the quantitatively matched PD-AFO. Additionally, a biofeedback tool was successfully developed, which read in marker data from a motion analysis software program and provided visual real-time biofeedback to the individual to help them acclimate to using the PD-AFO. Furthermore, two of the four subjects on the second evaluation visit were able to reach their targeted dorsiflexion range post-biofeedback. However, the individual post-strokes’ mean peak plantar flexion moment and mean step length did not significantly improve from pre- to post-biofeedback for either evaluation visit.

Aim 1:

This study showed that quantitatively matching PD-AFO bending stiffness to the individual post-stroke’s plantar flexor function deficit can significantly improve gait biomechanics (peak plantar flexion moment) compared to the originally prescribed AFO, which supported hypothesis 1.1. In fact, over 80% of the subjects had a significant increase in their mean peak plantar flexion moment while wearing the quantitatively matched PD-AFO. SMA revealed that these nine subjects had strong to very strong negative correlations between the originally prescribed AFO and
quantitatively matched PD-AFO, based off their Pearson R correlation coefficient, using the guide that Evans suggests for the absolute value of R [76]. Five of these nine subjects had a change in mean peak plantar flexion moment greater than the established MDC for this parameter (0.15 Nm/kg) [77]. Thus, these results agree with previous research that matching PD-AFO bending stiffness to each individual’s needs can improve gait function [36], [37], [43], [44].

Previous studies have found similar results on the benefits that wearing a PD-AFO can have on an individual’s gait. Bregman and colleagues reported a significantly greater peak ankle moment while wearing a PD-AFO compared to not wearing an AFO for individuals post-stroke and individuals with multiple sclerosis [52]. However, it should be noted that the PD-AFO bending stiffness was clinically prescribed [36]. Another study compared three stiffnesses (rigid, stiff, and flexible) of ventral dynamic AFOs for children with cerebral palsy [54]. In comparison to no shoes, all three-ventral dynamic AFOs decreased the net energy cost of walking. Additionally, Kerkum and colleagues found that children with cerebral palsy had a median reduction of 9% in net energy cost and reduced knee flexion while wearing the optimal PD-AFO in comparison to a shoes-only condition [53]. One of three standardized PD-AFO bending stiffness values was determined optimal by using a decision scheme based on peak knee extension angle during single support and walking energy cost. Thus, our study differs from these studies in that we quantitatively matched PD-AFO bending stiffness instead of using standardized or subjectively-prescribed PD-AFOs. Quantitatively matched PD-AFOs could provide greater improvement in gait since they are objectively prescribed based off an individual’s plantar flexor function deficit.
Results showed that eight of the eleven individuals post-stroke had a reduction in their mean peak dorsiflexion angle while wearing the quantitatively matched PD-AFO in comparison to the originally prescribed AFO. In concurrence with this finding, Kobayashi and colleagues found a 44% decrease in peak dorsiflexion angle from the control to the most stiff AFO condition [78]. Our study also showed that four subjects (Subjects 2, 3, 8, and 9) had persistent and excessive knee flexion and persistent ankle dorsiflexion, three subjects (Subjects 4, 6, and 11) had just persistent knee flexion, and one subject (Subject 7) had just persistent ankle dorsiflexion throughout the stance phase of gait while wearing the quantitatively matched PD-AFO. Thus, the subjects did not properly use the PD-AFO since they never unloaded the PD-AFO in late-stance of gait, which is important for reaping the full benefits of the PD-AFO and improving gait mechanics and forward progression. One potential reason for this improper use could be that the subjects were primarily cued to bend into the PD-AFO during the stance phase of gait, so bending into the orthosis, as opposed to releasing later in stance, may have been the subject’s focus. Another potential reason could be that the quantitatively matched PD-AFOs were not providing enough dorsiflexion resistance because the bending stiffnesses could have been too compliant. Previous studies have examined whether a range of stiffness values can alter an individual’s gait. One study found that in comparison to no shoes, all three-ventral dynamic AFOs decreased the net energy cost of walking, but no differences were found among the three different stiffness levels in children with cerebral palsy [54]. Additionally, studies have used the clinically prescribed IDEO and showed no differences in gait kinematics and kinetics across the 40% range in strut stiffness tested for walking and running over both flat and inclined surfaces [6], [55], [56].
Thus, these studies have shown that a range of bending stiffness values do not show significant differences in gait data. However, these ranges of stiffness values may not have been large enough, there may have been too much variability in the clinically-prescribed stiffness levels across individuals that prevented differences from being detected when analyses were performed, and/or the clinically-prescribed stiffness level may not have been optimally matched to the individual. Our study used objective parameters to determine the PD-AFO bending stiffness as opposed to using standardized or subjectively-prescribed bending stiffness values. Thus, a stiffer quantitatively matched PD-AFO bending stiffness value could potentially show differences in gait data.

Moreover, this study, to our knowledge, was the first to quantitatively match PD-AFO bending stiffness to an individual post-stroke level of plantar flexor weakness. The magnitude of the quantitatively matched PD-AFO bending stiffness values averaged $2.81 \pm 0.69 \text{ Nm/}^\circ$ in this study. Kerkum and colleagues used objective parameters, including peak knee extension angle during single support and walking energy cost, to optimize which of three PD-AFO bending stiffness values were prescribed to the children with cerebral palsy. The three PD-AFO bending stiffness values were either $0.7 \pm 0.2 \text{ Nm/}^\circ$, $1.6 \pm 0.4 \text{ Nm/}^\circ$, or $3.8 \pm 0.7 \text{ Nm/}^\circ$ [53]. However, one study used clinically prescribed PD-AFO bending stiffness values which averaged $6.36 \pm 7.55 \text{ Nm/}^\circ$ [52] and the studies involving the IDEO used an average bending stiffness of: $789 \pm 189 \text{ N/mm}$ [6], $832 \pm 182 \text{ N/mm}$ [56], and $785 \pm 196 \text{ N/mm}$ [55]. The subjects that used the IDEO were limb salvage and needed stiff PD-AFOs to reduce the amount of pain they experienced while walking. Thus, the quantitatively
matched PD-AFO bending stiffness values used in our study were on average much smaller than all but one of the presented studies.

This study showed that quantitatively matched PD-AFOs have the potential to improve gait biomechanics (peak plantar flexion moment) of individuals post-stroke with plantar flexor weakness. Thus, clinical practice should be informed that AFO efficacy may be improved by quantitatively matching PD-AFOs. Additionally, improved gait biomechanics (peak plantar flexion moment) while using the quantitatively matched PD-AFOs may potentially lead to more symmetric step lengths and increased gait velocity, which both can result in a decrease in metabolic cost of transport. Decreasing metabolic cost of transport can potentially lead to an increase in physical activity and participation in the community while decreasing healthcare costs.

Aim 2 & 3:

The results from part two of this study showed that none of the individuals were able to reach the targeted dorsiflexion range on the first evaluation visit, but on the second evaluation visit, all four individuals were able to reach their targeted dorsiflexion range for at least one trial. Two of the individuals were able to stay within the targeted range post-biofeedback. Thus, the biofeedback tool was effective on the second evaluation visit, partially supporting hypothesis 3.1. However, the individual’s mean peak plantar flexion moment and mean step length did not improve from pre- to post- biofeedback for either evaluation visit. These results do not support hypothesis 3.2.

The individuals post-stroke mean peak dorsiflexion angle only changed slightly during their first evaluation visit. On the second evaluation visit, all the individuals were able to reduce their peak dorsiflexion angle during at least one of the
biofeedback trials and two of the individuals were in their targeted dorsiflexion range post-biofeedback. However, results showed variable peak plantar flexion moments pre- and post-biofeedback during both evaluation visits. Peak plantar flexion moment was calculated by multiplying the ground reaction force with the individual’s moment arm. The moment arm was defined as the distance from the ankle joint center to the location of the center of pressure where the ground reaction force occurred. Therefore, the plantar flexion moment should decrease if the dorsiflexion angle is decreasing because the center of pressure would be moving posteriorly. Additionally, the mean step length should have decreased, since decreased ankle moments have been shown to decrease step lengths [79]. However, the mean peak plantar flexion moment and mean step length were not consistent with changes in mean peak dorsiflexion angle, meaning as the mean peak dorsiflexion angle decreased, these two parameters did not decrease for all four individuals as well. Thus, suggesting that the individuals post-stroke could be compensating elsewhere during gait or using a different strategy to walk.

Furthermore, the individuals post-stroke did have variable mean peak dorsiflexion angles throughout both evaluation visits. One reason for this variability may be due to the individuals only having eight minutes, per visit, to familiarize themselves and practice using the biofeedback tool. Previous research has demonstrated that multiple training sessions can lead to improvements in gait parameters. One study had individuals post-stroke come in three days per week for four weeks, with each session consisting of six five-minute trials of split-belt treadmill training [80]. This study saw an improvement in step length symmetry and an increase in self-selected walking speed and fastest walking speed. In our study, Subject 6 was
able to reduce their peak dorsiflexion angle variability on the second visit, while Subject 7 did not show any improvement further suggesting more visits could help reduce the variability for all subjects. Furthermore, the individuals in this study were able to retain the targeted dorsiflexion range from the biofeedback tool since two individuals were able to stay within that range post-biofeedback during the second evaluation visit. This agrees with previous literature in that individuals post-stroke can retain biofeedback [81], [82]. Aiello and colleagues collected five trials of EMG biofeedback on individuals post-stroke to improve ankle mechanics. Results showed a significant improvement in gait speed, ankle power at push-off, and time of single support on the affected side post-biofeedback [82]. In addition, one study showed that individuals post-stroke were able to similarly retain a novel locomotor task compared to individuals that are neurologically intact if given enough time to learn the desired task [83].

Thus, this study showed that individuals post-stroke were able to follow the real-time visual biofeedback tool, but that ankle angle is likely not the ideal parameter for acclimating the individuals post-stroke to using the quantitatively matched PD-AFO. Potentially looking into other kinetic, kinematic, or spatio-temporal parameters may hold the key to improving the acclimation of the individuals post-stroke to the quantitatively matched PD-AFO.

**Limitations/Future Studies**

While this study demonstrated that quantitatively matched PD-AFOs can improve gait biomechanics (peak plantar flexion moment) and individuals post-stroke were able to use, but not gain benefit from, the real-time biofeedback tool, some limitations should be noted. At the baseline visit, the individuals post-stroke either
walked without an AFO or if he/she was not able to walk without an orthosis, walked with his/her originally prescribed AFO to determine each subject’s mean peak plantar flexion moment, which drove the quantitative matching of the PD-AFO bending stiffness. Therefore, the quantitative matching of the PD-AFO bending stiffness could have been influenced by the AFO’s properties for the subjects that walked with their originally prescribed AFO. Additionally, part one of this study focused on the immediate effects of the quantitatively matched PD-AFOs on the individuals post-stroke mean peak plantar flexion moment. Thus, these individuals were not able to walk with the quantitatively matched PD-AFO outside the lab or receive multiple acclimation visits prior to testing. Moreover, this study did not evaluate whether the quantitatively matched PD-AFO bending stiffness did indeed add to the individual’s peak plantar flexion moment or replaced some of the individual’s existing plantar flexion moment. Knowing if the quantitatively matched PD-AFO bending stiffness enhanced plantar flexion function or substituted for some available plantar flexion function through future analysis will help refine the personalization process of these PD-AFOs. Furthermore, two individuals were unable to improve their peak plantar flexion moment in comparison to their originally prescribed AFO. Future studies should investigate the subject characteristics to attempt to explain why these two individuals did not reap benefits from the quantitatively matched PD-AFO. These findings could also lead to improvements in the biofeedback tool.

In part two of this study, four individuals took part in two evaluations visits using a biofeedback tool to acclimate themselves to the quantitatively matched PD-AFO. Results showed improvement in the targeted peak dorsiflexion range on the second evaluation visit, while no improvement was seen on the first evaluation visit.
Previous research has shown that individuals post-stroke need more time to adapt to locomotion tasks [81], [82]. Thus, future studies should increase the number of real-time biofeedback evaluation visits to determine if increased exposure to the feedback tool will enable individuals to reach the targeted dorsiflexion range and potentially reduce variability in the data. Also, it should be noted that the evaluation visits using the biofeedback tool were underpowered since only four subjects participated. Even though results showed that the biofeedback tool did not improve peak plantar flexion moment or mean step length, future studies should provide a larger sample size to develop a clearer picture of the effect the biofeedback tool has on the individuals post-stroke gait. Additionally, the study should focus on a different targeted parameter, excluding the peak dorsiflexion angle during the stance phase of gait, for the biofeedback tool.

Moreover, this study only focused on the quantitatively matched PD-AFOs influence on peak plantar flexion moment, peak dorsiflexion angle, and mean step length. Thus, other joints and gait parameters were not examined which can aid in understanding the compensatory strategies. Future studies should investigate the influence the quantitatively matched PD-AFOs have on ankle, knee, and hip joint kinematics and kinetics of both limbs, spatio-temporal parameters of both limbs, and energy cost while walking. Lastly, since this study demonstrated that quantitatively matched PD-AFO bending stiffness can enhance control of shank rotation during gait, future work should investigate if these benefits can translate into improved outcomes longer-term.
In conclusion, this study demonstrated that quantitatively matching PD-AFO bending stiffness to each individual post-stroke has the potential to improve gait biomechanics (peak plantar flexion moment). Additionally, individuals post-stroke were able to follow the real-time visual biofeedback tool, but ankle angle is likely not the ideal parameter for acclimating the individuals post-stroke to using the quantitatively matched PD-AFO. Further research needs to examine the compensatory strategies exhibited by these individuals post-stroke to better understand the human-orthotic interaction and implications on gait biomechanics. Improved gait biomechanics can lead to an increase in physical activity and decrease healthcare costs. Therefore, researchers and clinicians need to work together to ensure this quantitative prescription model can be ultimately translated into clinical practice. With the quantitatively match PD-AFOs improving gait biomechanics and visual real-time biofeedback deemed feasible in targeting gait parameters, this work begins to lay the foundation of a novel quantitative prescription process to improve the gait of individuals post-stroke.
REFERENCES


[23] S. Lord, “How feasible is the attainment of community ambulation after stroke?


Appendix A

IRB APPROVAL DOCUMENTATION

DATE: November 3, 2017
TO: Elise Arch, PhD
FROM: University of Delaware IRB
SUBMISSION TYPE: Continuing Review/Progress Report
ACTION: APPROVED
APPROVAL DATE: November 3, 2017
EXPIRATION DATE: November 12, 2018
REVIEW TYPE: Expedited Review
REVIEW CATEGORY: Expedited review category # (9)

Thank you for your submission of Continuing Review/Progress Report materials for this research study. The University of Delaware IRB 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 Famese-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: Evaluation of a Prescription Model to Customize Passive-Dynamic Ankle-Foot Orthoses for Persons Post-Stroke

Principal Investigator:
Name: Elsa S Arch, Ph.D.
Department/Center: Kinesiology & Applied Physiology
Contact Phone Number: 302-831-7268
Email Address: schranka@udel.edu

Advisor (if student PI):
Name:
Contact Phone Number:
Email Address:

Other Investigators:
Darcy Reisman, PT, Ph.D.
Sarah Colon
Martha Callahan
Liza Walker
Jennifer Marmo
Corey Koller
Tamara Wright, DPT, PT
Cory Cacciola

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 occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

1. Is this project externally funded? Yes

   If so, please list the funding source: ACCEL CTR Pilot Grant

2. Research Site(s)

   - University of Delaware

   Is UD the study lead? Yes
3. Project Staff
Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

<table>
<thead>
<tr>
<th>NAME</th>
<th>ROLE</th>
<th>HS TRAINING COMPLETE?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elisa Arch, Ph.D.</td>
<td>Principal Investigator</td>
<td>Yes</td>
</tr>
<tr>
<td>Darcy Reisman, PT, Ph.D.</td>
<td>Investigator</td>
<td>Yes</td>
</tr>
<tr>
<td>Sarah Colon</td>
<td>Student/Investigator</td>
<td>Yes</td>
</tr>
<tr>
<td>Martha Callahan</td>
<td>RESCORE: Coordination of Travel, Scheduling</td>
<td>Yes</td>
</tr>
<tr>
<td>Liza Walker</td>
<td>RESCORE: Coordination of Travel, Scheduling</td>
<td>Yes</td>
</tr>
<tr>
<td>Jennifer Marmon</td>
<td>RESCORE: Coordination of Travel, Scheduling</td>
<td>Yes</td>
</tr>
<tr>
<td>Corey Koller</td>
<td>Student/Research Assistant</td>
<td>Yes</td>
</tr>
<tr>
<td>Tamara Wright</td>
<td>Research Physical Therapist</td>
<td>Yes</td>
</tr>
<tr>
<td>Cory Cacciola</td>
<td>Student/Research Assistant</td>
<td>Yes</td>
</tr>
</tbody>
</table>

4. Special Populations
Does this project involve any of the following:

Research on Children? No

Research with Prisoners? No

If yes, complete the Prisoners in Research Form and upload to IRENet as supporting documentation.

Research with Pregnant Women? No

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe No

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

When people walk, their ankle joints help to hold them upright and move them forward. Ankle braces are often given to people who have had a stroke to help their ankle joints work properly. We have developed a method to design and make a special type of ankle brace that allows us to control every characteristic of the ankle brace, allowing us to customize the ankle brace to fit and function just the way we want it to. We think that ankle braces customized to meet the needs of each individual person will help them walk better. We have also developed a prescription model that tells us how to customize these ankle braces to address different levels of two common impairments experienced by people post stroke—decreased ability to move the ankle joint and weakened calf muscles [1-7]. The purpose of this study is to test the prescription model to see if wearing the ankle brace customized based on the prescription model improves people’s ability to walk. To accomplish this goal, we will first measure each person’s ability to move his/her ankle joint and the strength of his/her calf muscles. We will put this information in to our prescription model to determine how to customize the ankle brace for each person. We will then use the method we developed to make the customized ankle brace. Finally, we will measure how each
person walks in the ankle brace customized just for them. This study will allow us to validate and/or refine our prescription model and also teach us how persons post-stroke adapt to walking in ankle braces with different characteristics.

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

Overview
This study will be a multi-visit study. Prior to the first visit, a pre-participation phone screening will be conducted to assist in determining subject eligibility. At the first visit, the subject’s comfortable over-ground walking speed will be determined, an instrumented joint range of motion and gait analysis will be performed to determine the subject’s baseline joint range of motion and walking ability, and a brace fitting procedure will be performed. Prior to the second visit, an ankle brace will be fit and function customized and fabricated based on data from the first visit input into our prescription model. At the second visit, the subject will undergo another instrumented gait analysis while wearing the customized ankle brace and the subject’s comfortable over-ground walking speed while wearing the ankle brace will also be determined.

6.1. Pre-Participation Phone Screening & Medical Clearance
A pre-participation screening form (attached) will be conducted over the phone, which will serve to provide subject’s medical history regarding lower extremity injuries and conditions that might influence the subject’s walking ability. This screening will be one method used to determine subject’s eligibility to participate in the study. Medical clearance will also be obtained from the subject’s physician prior to participation in the study via the IRB-approved medical clearance protocol here at the University of Delaware. Under this protocol, potential participants who have had a stroke will be asked to provide consent to allow the investigators to contact the referring or primary physician to obtain clearance for participation (Medical Clearance Form contained in attached Combined Medical Clearance Protocol Form 5.12). Once this study is approved by the IRB, it will be added to the list of approved stroke-related studies in the Medical Clearance protocol.

6.2. Initial walking tests and ankle brace fitting visit
6.2.1. Initial walking test
First, subjects will undergo a guarded visual gait analysis during which they will be asked to walk normally over-ground while guarded from falls by an investigator. The purpose of this initial walking test is to determine each participant’s comfortable over-ground walking speed.

6.2.2. Instrumented Joint Range of Motion and Gait Analysis
Subjects may be excluded from the study after the instrumented joint range of motion and gait analysis if they do not meet the study inclusion criteria (see inclusion/exclusion criteria below for details). The following general data collection and analysis procedures constitute the technical aspects utilized in all instrumented movement analyses. Subject gait characteristics will be measured at the University of Delaware STAR Health Sciences Complex, using a 6-camera motion capture system with ground force measurement capabilities. Subjects will be asked to perform ankle movements while seated and walk on an instrumented treadmill.

Subjects will be asked to wear shorts and a t-shirt during testing. First, baseline oxygen consumption (VO₂) data to measure metabolic expenditure will be collected as the subject sits quietly in a chair for five minutes. During this test, the subjects will wear a mask that covers their nose and mouth or breathe through a mouthpiece while wearing a nose clip.

Once the baseline VO₂ data are collected, clusters of 3 to 4 reflective spherical targets, 14 mm 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 landmarks used to designate segment ends and joint centers. Surface electromyographic (EMG) electrodes may be placed bilaterally near the motor points of primary lower extremity muscle groups.

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).

After the targets are affixed and anthropometric measures are made, a static subject calibration trial will be collected. The subject will stand upright on the treadmill facing in the direction of walking 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, seated ankle range of motion trials will be performed. First an investigator will passively move the ankle and then the subject will be asked to actively move the ankle while motion capture data is collected.

For the walking trials, the participants will be asked to walk on the instrumented treadmill while wearing a safety harness. Stride dimensions (cadence, velocity, stride and step lengths), joint kinematics and kinetics will be collected using a motion capture system that records the 3D locations of the reflective targets on the body. Force platforms mounted side-by-side beneath the belt will continuously capture the ground reaction force on each limb. The treadmill belt speed will be set to each subject's comfortable walking speed. During the walking trials, oxygen consumption data will also be collected, so the subjects will wear the face mask or breathe through a mouthpiece while wearing a nose clip. Subjects will be given ample time to get acclimated to walking on the treadmill.

Heart rate will be monitored throughout the motion analysis testing with a heart rate sensor that is placed on the chest under clothing (Polar USA, Lake Success, NY). Continuous heart rate is sent telemetrically to a small wristwatch sized receiver that displays heart rate data. Blood pressure will be monitored at each rest break. It a subject's blood pressure exceeds 190/100 mmHg the session will be stopped and their blood pressure will be continually monitored until it returns to baseline. The subject's primary or referring physician will be notified. Subjects will wear a safety harness and an emergency shut-off switch can be used at any time and the experimenter will be positioned within arm's reach of the subject when walking on the treadmill. Subjects will be allowed rest breaks as often as requested or deemed appropriate by the investigator.

Subjects will rate their perceived exertion on the Borg Scale of Perceived Exertion every 2 minutes. If a subject reaches level 13 on the Borg scale (i.e. between 'Fairly Light' and 'Somewhat hard') they will be given a rest break [3].

For persons who have insulin-dependent diabetes, blood sugar levels will be monitored before and after the treadmill session, and if any clinical signs/symptoms of abnormal blood sugar arise during the session. If their blood sugar levels are less than 125 mg/dl, prior to the treadmill walking, they will be asked to test their blood sugar levels during the session. If any blood sugar reading is less than 60 mg/dl, the subject will be provided with juice and crackers, or if the blood sugar reading is greater than 300 mg/dl, the subject will be instructed to provide themselves with insulin per their normal routine. In both cases the subject will not participate in any further treadmill walking that day and the physician will be contacted to discuss appropriate follow-up.

6.2.3. Brace fitting procedure
This procedure is focused on a patented method we have developed for rapidly and non-invasively customizing the ankle brace size and shape directly from the subject's lower extremity anatomy [5]. This non-invasive, yet automated method of producing subject-specific shape information will be utilized to custom fit the ankle brace. The technique uses a commercially available three-
dimensional point digitization system (Faro, Inc., Lake Mary, FL). The Faro arm is a mechanical device used to measure the locations of select landmarks on the person's shank and foot. These skeletally relevant landmark locations are used to drive the fit customization of a fully-parameterized virtual prototype model of the ankle brace. In order to collect the landmark data, the subject is asked to wear shorts and stand motionless on a slightly raised surface with their lower back resting against an adjustable support surface. Select landmarks from the knee downward are identified visually and via palpation and subsequently digitized using the scan arm. Total digitizing time is expected to last 3-5 minutes.

6.2.4. Strength Testing of Calf Muscles
Subjects may be asked to participate in a procedure to test the strength of their calf muscles. For this procedure, subjects will perform a toe pointing test while seated in a leg press machine. Subjects will be seated in the leg press machine, with their back against the leg press chair, their parietal leg fully extended and their parietal foot on the footplate of the leg press machine. The leg press machine's weight stack will be set to 50% of the subject's body weight. If the subject is unable to perform the test at this weight, the weight will be decreased in 5 lb increments until the subject can comfortably perform the test. For this 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 – the box will be secured underneath the footplate of the leg press machine and the string will be taped to the subject’s heel. The encoder measures linear displacement and velocity of the string at the nearest 0.07 mm per second as the subject performs the test. Once in place, subjects will be asked to perform as many toe points (equivalent to a heel rise) if they were standing) as they can until they feel fatigued. A metronome will be used to maintain the frequency of the toe pointing. The number of toe pointing repetitions as well as the distance of each toe point and the total work (weight moved x total distance) in joules will be recorded by the MuscleLab®. This test is part of the standard procedures to evaluate the strength and endurance of the leg. There is no risk of weakening the leg after applying this evaluation.

6.3. Brace customization via prescription model and manufacturing
The digitized landmark data from the Faro arm collected during the brace fitting procedure will be used to customize the fit of the ankle brace by scaling a fully-parameterized computer aided design model of the ankle brace. The gait data obtained from the first visit will be used to estimate subject-specific ankle dorsiflexion range of motion and natural ankle joint stiffness, a measure of calf muscle strength. These data will be input into our prescription model to determine the subject-specific ankle brace characteristic settings to customize the function of the ankle brace. The fit and function customized brace will be manufactured from medical-grade polycarbonate using rapid prototyping technology (Fused Deposition Modeling). Following fabrication, brace fit and functional characteristics will be experimentally verified prior to its use in the walking tests. Final preparation prior to ankle brace use by the subject includes: lining the inner surface of the cuff with contact padding, adhering a flexible foot pad to the foot plate, adhering a non-slip material to the bottom of the foot plate, and adding Velcro retaining straps to the cuff and foot plate components. One or more ankle braces with different functional characteristics will be customized and fabricated for each subject.

6.4. Brace receipt and gait analysis visit
6.4.1. Brace fit evaluation
During the second visit, one of the investigators (with input from the subject) will evaluate the manufactured brace(s) for fit and comfort. When adequate comfort or fit cannot be achieved through using customary adjustments, the subject will be invited to repeat the brace shape determination process during which an improved brace will be constructed and fit evaluation
process repeated.

6.4.2. Instrumented gait analysis
Using the initial visit instrumented gait analysis methods, participants will walk on the treadmill with the ankle brace for up to five minutes to acclimate to walking with the ankle brace. Data will be collected during this acclimation period. Next, the subjects will walk on the treadmill wearing the ankle brace. Subjects may walk for up to 10 minutes at their comfortable speed wearing the ankle brace. Heart rate will be monitored continuously during the entire treadmill walking period.
To help subjects fully use the ankle brace, one or more of the following techniques may be used:

1. Fast Walking. Subjects may be asked to walk at their fastest possible safe speed for at most 2 minutes. Fastest possible safe speed will be determined by gradually increasing the treadmill speed until the subject acknowledges he/she cannot walk any faster, or an investigator determines it is not safe for the subject to walk any faster. This fast walking procedure has been used with individuals post-stroke by several other investigators before, including Dr. Darcy Reisman (Investigator on this protocol).

2. Real-time bio-feedback. Subjects may be shown (via an image projected on the wall in front of the subject) a real-time streaming graph of their joint angle or joint moment. Subjects will also be shown the typical joint angle or moment, projected on the wall next to the real-time streaming graph. Subjects will be instructed to try to match their joint angle/moment to the typical graph, and an investigator will provide verbal cues to help the subject learn how to use the ankle brace to achieve the typical graph. Color-coded feedback (e.g., the graph will turn green when the subject reaches the typical pattern within a given threshold) may be provided on the real-time streaming graph as well.

Finally, the subjects will walk with their ankle brace over ground to determine their comfortable over-ground walking speed while wearing the ankle brace. This process will be repeated for each ankle brace, up to three ankle braces per visit, if more than one ankle brace is fabricated. Subjects will be given as much rest as they need during and/or in between conditions.

6.4.3. Post-test evaluation
Upon completion of the instrumented gait analysis for each ankle brace, the subject will remove the brace with assistance from an investigator. The investigator will inspect the subject’s lower extremity skin for redness or evidence of cuff pressure patterns. Additionally, the subject will be asked to complete a satisfaction questionnaire (see attached) to rate his/her comfort and satisfaction with each of the ankle braces.

Based on the gait analysis result, subjects may be invited to repeat the gait test on a future date (up to 10 times) in order to walk at a different targeted walking speed or walk at the same relative speeds using an ankle brace having different characteristics (e.g., stiffness, or shape).

7. STUDY POPULATION AND RECRUITMENT
Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

30 persons who have sustained a stroke, age 21-85 years old will be recruited from local physical therapy practices, physicians and support groups. This study will include persons post stroke who have limited ankle dorsiflexion range of motion (less than 10 degrees) and/or decreased peak ankle plantar flexor moment on the paretic side compared to the non-paretic side as assessed during the instrumented joint range of motion and gait analysis at the first visit. Eligibility for participation will be determined based on responses to a pre-participation phone screening as well as joint range of motion and walking ability data collected at the first visit.
Attach all recruitment flyers, letters, or other recruitment materials to be used. If verbal recruitment will be used, please attach a script.

There are several current stroke studies underway at the University of Delaware. These studies all use a general recruitment flyer already approved by the IRB, and therefore we will also use this flyer for our study (see attached). We may also use verbal recruitment for this study if individuals have participated in other stroke studies at the University of Delaware, have indicated they are willing to be contacted for future studies, and we believe they are well suited for our study. The verbal script will be: "Based on information or data we have collected about you in previous studies you have participated in, you can participate in another study here at University of Delaware focused on designing ankle braces customized for you. Would you be willing to learn more about participating in this study?"

Describe what exclusionary criteria, if any will be applied.

Those that will not be included in this study are subjects with cerebellar signs (ataxic ("drunken") gait or decreased coordination during rapid alternating hand or foot movements), neurologic conditions other than stroke, more than one stroke, sensorimotor neglect, intermittent claudication, inability to walk outside the home prior to the stroke, total joint replacement and orthopedic problems in the lower limbs or spine that limit walking, coronary artery bypass graft or myocardial infarction within past 3 months, and unexplained dizziness in last 5 months. Subjects will be excluded if they cannot understand spoken instruction, communicate with the investigators and/or walk for 2 minutes at a self-selected speed without assistance from another person (assistive device allowed). Subjects must also have a resting heart rate between 40-100 beats per minute and a resting blood pressure between 90/60 to 170/90. The cerebellar signs and sensorimotor neglect criteria will be evaluated through subject observation at the first session. Persons post-stroke will also be excluded if they do NOT have limited ankle dorsiflexion range of motion (less than 15 degrees) and/or decreased or decreased peak ankle plantar flexor moment on the parietal side compared to the non-parietal side as assessed during the instrumented joint range of motion and gait analysis at the first visit. For medical conditions, the exclusion criteria will be evaluated through completion of a Pre-participation Medical Screening Evaluation (attached) that will be administered over the phone by an investigator prior to scheduling the subject to come to the lab. Subject answers to the screening questionnaire will be reviewed with them to ensure accuracy prior to the start of data collection. Potential participants who have had a stroke will be asked to provide consent to allow the investigators to contact the referring or primary physician to obtain clearance for participation (Medical Clearance Form contained in attached Combined Medical Clearance Protocol Form_5_12).

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:
- A subject’s limb size exceeds the capacity to build a brace in the Fused Deposition Modeling machine
- Failure to follow instructions
- The investigator decides that continuation could be harmful to the subject
- The subject 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)

8. RISKS AND BENEFITS
List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here
should be included on the consent form).

Much like any repeated gait test, there is a slight chance of experiencing a fall and mild skin irritation from the attachment of adhesive circles to the skin during the instrumented gait analysis portion of the study. There is also a slight risk of skin irritation due to ankle brace use. There is also a slight risk of skin irritation due to the oxygen consumption mask or nose clip. Finally, there is a slight, minimal risk of local muscle soreness and fatigue from the strength testing of the calf muscles.

In your opinion, are risks listed above minimal or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

(*Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

The risks involved in participating in the proposed series of non-invasive instrumented gait studies with and without ankle brace use are minimal. The risks associated with this study are no greater than those incurred during customary use of a typical ankle brace, which many if not all of the subjects in our study wear on a daily basis.

What steps will be taken to minimize risks?

To minimize the risk of injury due to falls, subjects will wear a safety harness during treadmill walking and safety will be monitored by an investigator. If the oxygen consumption mask or nose clip causes discomfort, they will be adjusted as much as possible to relieve the subject's discomfort. Subjects will not be allowed to keep the ankle braces or use them outside the purview of study personnel.

Describe any potential direct benefits to participants.

Subjects will receive no direct medical benefits from participation in this study. Subjects will not be allowed to keep the ankle brace or use the ankle brace outside the framework described in this research proposal.

Describe any potential future benefits to this class of participants, others, or society.

The technology developed from this study could lead the design of a commercially available customized brace that could more efficiently enhance gait function. However, if that happens participants in this study will not be entitled to any additional compensation.

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.

9. COMPENSATION
Will participants be compensated for participation?
If so, please include details.

Subjects will receive compensation for their time and participation in this study. The compensation rate will be $25 for each visit to the laboratory.
Additionally, transportation costs for travel to/from our laboratory will be provided for study participants. If study participants request transportation to be provided, round trip shuttle service will be provided for them from their requested pick up/drop off location to/from our laboratory. The cost of this shuttle service will be covered.

10. DATA
Will subjects be anonymous to the researcher? No

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how) Yes

All subjects will be assigned a unique numerical subject code. This subject code will be used on all data collection forms and data records. A single document containing the subject’s name, contact information and date of birth along with his/her subject code will serve as the key to linking subject identifiable data to his/her subject code. This will be the only document containing both subject identifiable data and the subject code.

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see http://www.udel.edu/research/preparing/datastorage.html)

The consent forms will be stored as hard copies. The data collection forms and data will be stored as hard copies and/or electronic files. All of these documents will only contain the subject code. The document serving as the key to link subject identifiable data to the subject code will be stored separately as an electronic file. Paper data records will be stored in a locked file cabinet. Electronic data records will be stored on a password-protected computer.

How long will data be stored?

This protocol does not constitute a clinical trial. The coded experimental data will be stored for a minimum of 3 years after completion of the project.

Will data be destroyed?

Yes, when the time comes, the paper records will be shredded and the electronic data will be erased from the electronic database and the storage device reformatted.

Will the data be shared with anyone outside of the research team? No

How will data be analyzed and reported?

Typical biomechanical analysis techniques, including but not limited to gait event identification, inverse dynamics and/or power flow analysis, will be used to analyze the data. Many of these techniques will be performed using algorithms contained within Visual3d (C-Motion Inc., Germantown, MD). These analysis techniques will result in measures such as joint motions, net muscular moments, joint powers as well as other kinematics and kinetic measures. Additionally, ankle brace contributions to gait function will be determined by isolating the ankle brace moment via the following method. The net internal moment at the ankle determined via inverse dynamics will be divided into two sources: the active moment due to tissue (muscles, ligaments, tendons and joint capsule) and the ankle brace moment due to brace stiffness [10]. The brace moment about the
Ankle joint is easily obtained from its spring property and extent of deflection. Data may also be input into OpenSim, an open-source musculoskeletal modeling and simulation program, to identify muscle function and explore the muscles' roles in gait with and without the ankle brace. The oxygen consumption data will be analyzed to calculate the oxygen cost per unit distance walked (mL O₂/kg/m), which can be termed the metabolic cost of walking, for each ankle brace compared to the subject's baseline (no ankle brace) condition. Finally, parameters captured by the MusclesLab software during the strength testing of the calf muscles will be compared to parameters obtained from the baseline instrumented gait analysis. This analysis will help determine if the strength testing procedure can be used instead of the baseline gait analysis to drive prescription for the customized ankle braces. All of these procedures will provide the necessary measures to evaluate the prescription model used to customize the ankle braces for each subject. These measures will also be used to document movement control adaptations when subject walk with the brace compared to walking without the ankle brace.

The results will be reported in a series of journal articles and presentations. These results may include data, in graphical or tabular form, reporting distance and time parameters that describe how the subjects walk, motion of the joints, and ankle brace and/or forces of the joints and ankle brace. Figures or photos may also be included to help describe this research project.

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

Yes, participants may be photographed or videotaped during this study 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 code that will be used to label and track all data. A single document containing the subject's name, contact information, and date of birth along with his/her subject code will serve as the key to linking subject identifiable data to his/her subject code. This will be the only document containing both subject identifiable data and the subject code and will be kept in a separate, secure location as an electronic file. If photo or video of participants are used, all identifying features will be blocked or removed before being published or presented.

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

12. CONFLICT OF INTEREST
(For information on disclosure reporting see: http://www.udel.edu/research/preparing/conflict.html)

Do you have a current conflict of interest disclosure form on file through UD Web forms?

Yes, Dr. Arch has a conflict of interest form on file.

Does this project involve a potential conflict of interest*?

*As defined in the University of Delaware's Policies and Procedures, a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment,
actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

If yes, please describe the nature of the interest.

Drs. Elisa Arch and Steven Stanhope are the co-inventors of the patented technology used to customize and manufacture the passive-dynamic ankle-foot orthoses used in this study (U.S. Patent No. 8,530,570).

13. CONSENT and ASSENT

_X_ Consent forms will be used and are attached for review (see Consent Template under Forms and Templates in IRBNet)

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

____ Waiver of Documentation of Consent (attach a consent script/information sheet with the signature block removed).

____ Waiver of Consent (Justify request for waiver)

14. 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.

15. Supporting Documentation

Please list all additional documents uploaded to IRBNet in support of this application.

- Consent - PD-AFO with Stroke Patients_final
- Photo-Video Consent - PD-AFO with Stroke Patients_final
- Subject Contact Info form - PD-AFO with Stroke Patients_final
- Recruitment Ad - Final Ad for Stroke
- Pre-participation Medical Screening Evaluation
- Combined Medical Clearance Protocol Form_5_12
- AFO Satisfaction Questionnaire

References

5. Peterson CL, Hall ÄL, Kautz SA, Neptune RR. Pre-swing deficits in forward propulsion, swing initiation and power generation by individual muscles during hemiparetic walking. J Biomech 43:2340-2355, in press.
Title of Project: Evaluation of a Prescription Model to Customize Passive-Dynamic Ankle-Foot Orthoses for Persons Post-Stroke

Principal Investigator(s): Elisa S. Arch, Ph.D.
Other Investigators: Darcy Reisman, PT, Ph.D.
  Sarah Colon
  Martha Callahan
  Liza Walker
  Jennifer Marmon
  Corey Koller
  Tammari Wright, DPT, PT
  Cory Cacciola

You are being asked to participate in a research study. This form tells you about the study including its purpose, what you will do if you decide to participate, and any risks and benefits of being in the study. Please read the information below and ask the research team questions about anything you do not understand before you decide whether to participate. Your participation is voluntary and you can refuse to participate or withdraw at anytime without penalty or loss of benefits to which you are otherwise entitled. If you decide to participate, you will be asked to sign this form and a copy will be given to you to keep for your reference.

WHAT IS THE PURPOSE OF THIS STUDY?

We have developed a prescription model, which provides guidelines that tells us how to customize our ankle braces to different levels of two common impairments suffered by people post stroke – decreased ability to move the ankle joint and weakened calf muscles. Therefore, the prescription model allows us to customize the ankle brace to meet an individual’s specific needs. The purpose of this study is to test the prescription model to see if wearing the ankle brace customized for you improves your ability to walk. You are being asked to participate in this study because you meet the strength and joint movement criteria needed to customize an ankle brace for you based on our prescription model, and we want to learn how you walk in the customized ankle braces. You may be excluded from this study if your muscle strength and/or joint mobility do not meet the criteria needed for our ankle brace prescription model, if you have additional neurological conditions other than stroke, or if you have additional health or medical concerns that may make it harmful for you to participate in our study. We expect 30 individuals to participate in this study.
WHAT WILL YOU BE ASKED TO DO?

Before participating in this study, all of the tasks you will be asked to carry out will be explained by Dr. Arch or another member of the research team. You can decline to perform a specific task or decline to continue participating in the study at any time. If you wish to continue, you will be asked to visit the University of Delaware on a minimum of two separate occasions and potentially more occasions.

During the first visit, you will be asked to do an initial walking test, where you will be asked to walk over the ground at your comfortable walking speed while guarded by a researcher. Next, you will be asked to move your legs and walk while several scientific cameras record your movement. You will be requested to wear a t-shirt and shorts during these movements. 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. 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. Finally, you may be asked to wear a mask that covers your nose and mouth or breathe through a mouthpiece while wearing a nose clip. This equipment will enable us to record your oxygen consumption while you are performing the movement tasks. For the oxygen consumption analysis, you will first be asked to sit quietly in a chair for five minutes before performing any movement tasks. You should not feel any discomfort with this test.

Once the above items are in place, you will be asked to move your ankle while seated both on your own and with the assistance of an investigator. You will then be asked to walk several times on a treadmill while scientific cameras record the positions of the reflective balls. You will be wearing a harness for your safety during all walking tests on the treadmill. The cameras do not take pictures of your face or body parts. After we have tested your walking, you will be asked to stand for three to five minutes while we use a pointer device to take special measurements of your leg.

Finally, you may be asked to participate in a procedure to measure the strength of your calf muscle using a leg press machine. For this procedure, you will be seated in the leg press machine, with your back against the leg press chair, your paretic leg fully extended and your paretic foot on the footplate of the leg press machine. A small box with a string coming out of it will be attached to the footplate of the leg press machine, and the string will be taped to your heel. You will be asked to point your toes (similar to doing a heel rise if you were standing) and then relax as many times as you can until you feel fatigued. All of these procedures will require a maximum of 2 hours to complete.

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Participant Initials _______
You will be asked to return for a second visit to learn how to walk while wearing one or more custom ankle brace(s) we will make from your leg measurements. The custom ankle brace(s) are a unique type of brace designed to improve walking ability. During this visit you will be asked to walk on the treadmill while wearing the brace(s). You may be shown a graph of your joint movement patterns (projected onto the wall in front of you) as you are walking while wearing the ankle braces. Along with the graph of your joint movements, you may be shown a graph of a typical joint pattern and asked to try to match your joint movements to the typical pattern. You will be wearing a harness for your safety during all walking tests on the treadmill. You may be asked to walk while wearing up to three different ankle braces during a single visit, and/or you may be asked to return several times (up to a maximum of ten times) to walk on the treadmill again wearing ankle braces with different prescription characteristics. The additional visits would allow us to see how you walk wearing ankle braces with different characteristics. However, you may decline our request and ask to stop participating at any time. You may rest at any time. We will look at your leg to make sure the brace fits you, you may be asked to fill out a questionnaire about the brace, and will ask you questions about the brace. Each visit will require a maximum of 2 hours to complete. For your protection you will not be allowed to take the brace or use it outside the supervision of the research team.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The risks involved in participating are no more than those incurred during normal walking and customary training and supervised use of an ankle brace. There is a slight chance of suffering a fall, but you will be wearing a harness for safety during all walking tests on the treadmill. There is a slight risk of skin irritation due to ankle brace use, from the attachment of adhesive circles to the skin during the gait analysis portion of the study and/or from the face mask used to collect the oxygen consumption data. If you feel skin irritation, tell one of the investigators and adjustments will be made so that you will remain as comfortable as possible. The soft, rubber-like material may feel tight, but if it is uncomfortable or interferes with your movements, tell one of the investigators and it will be readjusted. You will be safely monitored when you try the brace on and begin adjusting to the feel and fit of the brace while you walk. Finally, there is a slight, minimal risk of local muscle soreness and fatigue from strength testing of the calf muscles.

WHAT ARE THE POTENTIAL BENEFITS?

It is unlikely that you will receive any direct medical benefits from participation in this study. You will not be allowed to keep the ankle brace or use the ankle brace outside the framework described in this research study. While you will not benefit directly from taking part in this research, knowledge gained from this study may contribute to our understanding of how
individuals walk in our customized ankle braces and therefore help us learn how to customize ankle braces that are designed to meet any individual’s specific needs. This understanding may help us design ankle braces that are optimally customized for each individual in the future.

HOW WILL CONFIDENTIALITY BE MAINTAINED?

We will make every effort to keep all research records that identify you confidential to the extent permitted by law. All subjects will be assigned a unique numerical subject code. This subject code will be used on all data collection forms and data records. A single document containing the subject’s name, contact information and date of birth along with his/her subject code will serve as the key to linking subject identifiable data to his/her subject code. This will be the only document containing both subject identifiable data and the subject code. Once the study is concluded, this key document can be destroyed. Video or photographs may be taken during the walking test portions of the study visits if you sign the photo/video consent form, however all identifying features in these videos and photographs will be blocked or removed. All data and records related to this study will be stored for a minimum of three years after completion of the study. Paper data records will be stored in a locked file cabinet. Electronic data records will be encrypted. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. Researchers and professional audiences may see the de-identified data and/or see the de-identified videos and photographs. Your research records may be viewed by the University of Delaware Institutional Review Board, but the confidentiality of your records will be protected to the extent permitted by law.

WILL THERE BE ANY COSTS RELATED TO THE RESEARCH?

There are no fees for participation in this study.

WILL THERE BE ANY COMPENSATION FOR PARTICIPATION?

You will be compensated $30 for each visit you make to the laboratory. Additionally, if you request transportation to be provided to facilitate your participation in this study, round trip shuttle service will be provided for you from your requested pick up/drop off location to/from our laboratory. The cost of this shuttle service will be covered.

Finally, while the technology and devices used in this study are still investigational, the technology developed from this study could lead the design of a commercially available customized brace that could more help people walk better. However, if that happen, you, as a participant in this study, will not be entitled to any additional compensation.
WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THIS STUDY?

It is very unlikely that you will be injured as a result of this study. However, if you are injured during research procedures, you will be offered first aid at no cost. If you require additional medical treatment, you will be responsible for the cost. If you need additional medical expenses 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.

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 refusal will not influence current or future relationships with the University of Delaware.

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)
DISCLOSURE:

Dr. Elisa Arch, the Principal Investigator for this study is a co-inventor of an issued U.S. patent for the customization and manufacturing process for these ankle braces (passive-dynamic ankle-foot orthoses). Thus Dr. Arch and the University of Delaware have a financial interest in any commercial development of the device.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator Elisa S. Arch, Ph.D.; 101 Discovery Blvd, Newark, DE 19713; Telephone: (302) 831-7268. 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 302-831-2137.

________________________________________________________

Your signature below indicates that you are agreeing to take part in this research study. You have been informed about the study’s purpose, procedures, possible risks and benefits. You have been given the opportunity to ask questions about the research and those questions have been answered. You will be given a copy of this consent form to keep.

By signing this consent form, you indicate that you voluntarily agree to participate in this study.

_________________________   _________________________
Signature of Participant     Date

_________________________
Printed Name of Participant

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