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THE IMPACT OF ASSISTIVE DEVICES ON GAIT BIOMECHANICS AND MUSCLE ACTIVITY IN STROKE SURVIVORS: (a) The Impact of Regulated AFO Plantarflexion and Dorsiflexion Resistance on Biomechanics and Muscle Activity of Individuals Post-stroke. (b) How Treadmill Handrail-use Impacts the Paretic Side Margin of Stability in Individuals' Post-stroke

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THE IMPACT OF ASSISTIVE DEVICES ON GAIT BIOMECHANICS AND MUSCLE ACTIVITY IN STROKE SURVIVORS:

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The purpose of this thesis was to investigate how different assistive devices impact the gait characteristics of stroke survivors. In two different sections, we investigated how an ankle foot-orthosis (AFO) impacts the gait and muscle activity of stroke survivors, and how the use of treadmill handrails impacts the stability margins of stroke survivors while walking on the treadmill. First, we used an articulated AFO device fabricated with an individual specific design using a 3D scanner and a 3D printer in personalizing the AFO foot plate and calf section, which we assembled with a triple action joint for each participant. The joints enabled independent tuning and testing of the impact of plantarflexion and dorsiflexion resistances on the participants and we tested a low, medium, and high resistance for each condition. Our findings showed that the AFO device systematically changed the muscle activity and the kinetics and kinematic gait characteristics of the participants. We noted significant phase changes for the plantarflexion resistances on the peak tibialis anterior and rectus femoris muscle activity in swing, the peak ankle dorsiflexion moment, knee flexion angle at initial stance, and the ankle angle at initial stance. The dorsiflexion resistance significantly impacted the peak dorsiflexion angle and the peak positive ankle power of the participants.

In the second study, we used a visual biofeedback system to modulate the treadmill conditions of No hold, Light touch, and a self-selected handrail use in order to examine

how three treadmill handrail-use situations effect the stability margins of stroke survivors. When holding the handrails with a self-selected hold while walking on the treadmill, the participants' anteroposterior and mediolateral margins of stability for their paretic leg increased as compared to a light touch or no handrail use. The self-selected handrail-use also impacted the participants' non-paretic leg, increasing its anteroposterior margin of stability and decreasing its mediolateral margin of stability.

These findings from both studies demonstrate that assistive devices can help improve the biomechanics and walking characteristics of stroke survivors, though additional research will provide a clearer guide on how to prevent unintended adaptations and potential complications from prolonged use.

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CHAPTER 1

1. INTRODUCTION

The walking mechanism results from a series of underlying anatomical, neurological, and physiological processes that cumulates into the observed gait in individuals. These processes could be disrupted in the case of medical or neurological conditions, causing functional limitations [1]. For example, some individuals affected by stroke often experience a decreased ability to push off with their ankles due to plantar-flexor muscle weakness [2,33], and some show a typical dragging of the foot in a foot-drop presentation due to weakness of their dorsiflexors [4]. Most of these stroke survivors experience long-term disability so that about two-thirds of acute stroke patients are unable to ambulate independently [5] following the cerebrovascular accident. More than 60% of those who attain independent ambulation walk below the community walking optimum speed due to motor weakness, poor coordination, limited endurance, and gait instability[5,6]Stroke survivors may also present with an altered weight distribution pattern, greatly increased sway in their posture, and smaller excursions when moving their paretic side leg [7]. In such cases, clinicians and/or physical therapists tend to recommend assistive devices in the form of orthotics (like Ankle Foot Orthosis) or walking aids (like the cane in over-the-ground walking and/or handrails in treadmill walking) to enable standing and walking while also preventing long-term disability in persons with lower limb weakness resulting from neuromuscular and/or musculoskeletal impairments [891011].

The type of assistive device prescribed to stroke survivors is mostly based on the presentation or level of affectation of the patient/client coupled with the discretion of

the clinician or therapist. Decisions could also widely vary depending on the type of device, whether a walking aid or an orthotic device [1213]. For example, assistive aids like treadmill handrails are prescribed to decrease postural sway and/or aid stability in stroke survivors during treadmill walking [11].

Some previous studies showed that individuals derive sensory cues from stable surfaces unto their fingertips, and these cues enable the reduction of postural sway in static or dynamic cases [1415]. Bellicha *et al*. showed in their study that the light-grip of an instrumented cane handle reduced anteroposterior (AP) and mediolateral (ML) sway compared to no-grip of the handle [16], and Kang *et al*. also showed that treadmill walking while holding the handrails facilitated somatosensory changes that improved plantar foot pressure and foot contact area of his stroke participants, thereby improving their gait [17]. Also, Houdijk *et al.* showed that lower-limb amputees experienced a reduction in their energy cost of walking while offered external support through handrails [10], and the authors speculated that the result could be due to changes in balance control because of the assistive device. In a similar work, IJmker *et al*. showed that stroke survivors experienced normalization of their step parameters and a reduction in their energy cost of walking on the treadmill while holding the handrail but not with a light touch of the handrail [11,18]. They also suggested the result was due to the balance support available in the treadmill handrail condition. These studies show that the use of the handrail in treadmill walking impacts the gait and/or the stability of different clinical populations. ***Despite this, there exists a limitation in studies that show the mechanism with which treadmill handrails impact the mechanical gait stability of stroke survivors to aid their balance.***

Orthotic devices like Ankle Foot Orthosis (AFO) come in diverse types and designs. In 2016, more than $1.0 billion was expended on orthotics in the United States [according to the American Orthotic Prosthetic Association], and AFOs made up about 26% of prescribed orthoses, with 22% being for stroke survivors [19]. AFOs are prescribed to individuals' post-stroke to ensure stability, improve gait, prevent foot drop through the swing phase of motion, and improve their overall functional capacity [20]. Specifically, in the stance phase of movement, the AFO could offer plantar-flexor support to enable heel strike at early stance, while also ensuring the anterior progression of the shank over the stationary foot by offering a plantarflexion moment to prevent increased dorsiflexion in the case of weak plantarflexor muscles at the 2nd rocker of the gait cycle. It also enables push-off at the terminal stance and clearance of the foot through the swing phase of gait [21222324]. Overall, the AFO works to reinforce or replace the eccentric work of the plantarflexor and/or dorsiflexor muscles in stroke survivors [24]. These roles or supports offered by the AFO are design and prescription dependent [22,25], and the different characteristics of a prescribed AFO impact factors such as the individual's gait kinematics and kinetics, the activity level of lower leg muscles [26], and the individual's energy cost of walking [27]. These factors make it paramount for the therapist and/or orthotist professional to appropriately prescribe the AFO as needed by the patient but achieving this remains a clinical limitation due to the inability to clinically ascertain the patient's specific AFO characteristics like the alignment and stiffnesses [2829].

The issue of definitive individual-specific AFO prescription has been persistent in the clinical rehabilitation setting. The clinician has the challenge of utilizing objective and

subjective clinical indicators to decide on the best fit in tackling the problem of knee and ankle instability [3]. The inability to fully translate clinical characteristics into the laboratory has impeded most investigations into AFO optimum prescription despite numerous AFO studies evaluating how the different AFO types impact gait and function in clinical populations. In their study into how incremental changes in dorsiflexion and plantarflexion resistance affects lower limb joint kinematics and walking kinetics, Kobayashi *et al*. [30] noted a significant reduction in peak ankle positive power as the plantarflexion resistance was increased and the plantarflexion range of motion reduced. Also, they noted significant interactions between different plantarflexion and dorsiflexion resistance settings for joint angles and moments[30], and these results are similar to those in some studies that have tested the impact of varying AFO resistances in healthy individuals [31] and/or stroke patients [4,32]. While these results seem tenable, the majority of these studies were performed on a split-belt treadmill, and some also fall short of some set of outcome measures that could more clearly define efficacy in AFO prescription as recommended in the international classification of functioning, disability, and health for clinical studies [2833]. Such measures include those covering the functions of joints and bones, gait patterns, and muscle activities [34], and they are a necessity in properly establishing the efficacy of assistive devices. ***It is, therefore, necessary to tackle these issues through structured experiments that could birth results that will further inform the available mechanisms for prescribing AFOs in the clinical or rehabilitation setting.***

2. INNOVATION

Ankle foot orthoses can be articulated or non-articulated in design. The non-articulated AFOs are those without joints; their design specifics have to be decided during the fabrication and tuning process and this makes it difficult to alter the devices' resistance and stiffness properties after fabrication [35]. Kobayashi *et al*. (2017) described the tuning method for non-articulated AFOs as a trial-and-error method due to the difficulty in correcting stiffness and alignment errors after initial fabrication [4]; this statement underscores the limitation in the use of non-articulated AFOs. Some studies have evaluated the dorsal-leaf spring non-articulated AFO-types which may enable changing of the AFO struts when an optimum strut stiffness is determined for an individual patient [6]. Although good, this design is limited in the case of patients who could still experience improvements as they progress in recovery. Unlike these non-articulated AFOs, articulated types are made with joint components which can ensure independent tuning of the alignment, allowed range of motion, and resistance of the AFOs [34] following the characteristic presentations of individual patients. The opportunity to make these adjustments post-fabrication offers the merits of saving time and enabling the tuning of these key AFO mechanical characteristics independent of one another [2030]. This study uses a triple action joint articulated AFO-type that will enable adjustment of the alignment, range of motion, and spring stiffness (plantarflexion and dorsiflexion resistances) of the AFO independently.

Also, in a bid to guide AFO prescription, diverse studies have assessed the efficacy of different AFO designs and characteristics on the gait of stroke patients using different methodologies [32362137], but most of these studies have focused on mechanical evidence

exclusive of reporting activity level or vice versa. In a systematic review to examine the efficacy of AFO on the different patient groups, Harlaar *et al*. (2010) [33] proposed the motion for the use of a two-edged review in studies investigating AFO efficacies in clinical populations. They argued that reporting activity level and mechanical evidence in AFO studies covers aspects of assessment entailing the efficacy of the device on patient performance, as well as the efficacy of the AFO to function appropriately [33]. These two essential highlights were defined from the International Classification of Functioning, Disability, and Health (ICF) for studies in clinical groups [38], in a bid to define guidelines that could better guide clinical prescription of lower limb orthoses [28]. This study adopts a holistic design that entails assessment of participants' performance capacity and component body function; our work in this study is tailored to report activity level (muscle activation) and mechanical evidence (walking kinematics and kinetics) as suggested in the above studies [28 33]. We believe using this methodology will strengthen the efficacy of our study and the results will further inform the prescription guidelines for Ankle foot orthoses in the stroke population.

Finally, this study will also be the first to investigate how handrails impact the mechanical gait stability of stroke survivors while walking on the treadmill. Most existent studies have focused on how walking aids like canes have impacted the gait of stroke participants while walking overground [1416]. Treadmills are a necessary tool for the rehabilitation of stroke patients and are mostly used in high-intensity gait training and walking re-education [39], making it a necessity to better understand how the use of the handrails can impact their balance as a means to fall prevention in the stroke

population. This study will use three different handrail conditions of ‘No-handrail use’, ‘Light handrail use’, and ‘Self-selected handrail use’ to evaluate how the use of handrails will impact the stability of chronic stroke participants while walking on the treadmill, with their anteroposterior and mediolateral margins of stability used as the primary variable.

3. PURPOSE

This study will tackle two important issues pertaining to the prescription of assistive devices in the rehabilitation and management of stroke survivors. First, we will evaluate the impact of regulating the plantar flexion and dorsiflexion resistances of an articulated ankle foot orthosis on the gait and muscle activity level of stroke survivors. Secondly, this study will investigate how three different treadmill handrail-use conditions impact the mechanical gait stability of stroke survivors.

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CHAPTER 2

THE IMPACT OF VARYING THE PLANTARFLEXION RESISTANCE AND DORSIFLEXION RESISTANCE ON LOWER LIMB KINEMATICS AND KINETICS OF STROKE SURVIVORS DURING AMBULATION.

1. INTRODUCTION

Stroke is a major neurological condition that disrupts the normal walking mechanism observed as a result of the simultaneous underlying processes between the anatomical, neurological, and physiological systems. This neurological condition resulting from a cerebrovascular accident hampers the normal walking biomechanics in stroke survivors. These individuals present with weakness of the muscles of the affected lower extremity, especially the plantarflexor and dorsiflexor muscles, [1,2] which are essential in controlling the ankle biomechanics through the phases of the gait cycle. In context, the plantarflexor muscles function at the midstance and terminal stance phases of the gait cycle. During the midstance, the gastrocnemius and soleus muscles contract eccentrically to control the anterior translation of the shank over the foot, and at the terminal stance, they propel the body forward through a concentric contraction. Also, the dorsiflexor muscle plays an essential role in the first rocker phase of the gait cycle by eccentrically contracting at the heel strike to prevent slapping of the foot on the walking surface; it also prevents the dropping of the foot through the swing phase of the gait cycle [3]. This expected normal ankle function is disrupted after stroke occurrence.

The weakness or hemiparetic presentation in stroke survivors is such that results in long-term disabilities in about 29-44% of the stroke population [4,5], and clinicians and Physical Therapists tend to prescribe orthotic devices like the Ankle Foot Orthosis (AFO) for walking support. The AFO is an orthotic device worn on the lower leg to the foot of individuals experiencing weakness in their plantarflexor and dorsiflexor muscles. The device offers stability, improves gait, and improves the overall functional capacity of the users [6,7]. An AFO can augment the function of weak plantarflexor muscles during the gait cycle by offering a support plantarflexion moment at midstance when the shank rotates over the foot to enable stability in gait, a function called dorsiflexion support [8]. The AFO can also contribute to the propulsion power of the weak plantarflexor muscles during the toe rocker phase of the gait cycle just before the swing phase [9,10]. For weak Dorsiflexor muscles, an AFO offers dorsiflexion assistance for insufficient eccentric contraction of the Tibialis anterior muscle at the heel rocker phase of the gait cycle, and it could also prevent dropping of the foot through the swing phase of the gait cycle; stopping a foot drop deformity [9,11]. These AFO support functions are design and prescription-specific, and the different AFO characteristics impact the gait kinematics and kinetics, the activity level of the affected leg muscles, and the energy cost of walking of the individual [12–14].

Different studies have investigated an AFO characteristic called its stiffness or its resistance to plantarflexion and/or dorsiflexion, which is a major characteristic that impacts walking energy cost and the walking biomechanics of the affected limb of AFO users based on the prescription quality of the clinical personnel [6,10,15]. This

stiffness characteristic is quantified as the slope of the graph of the ankle torque vs ankle angle during mediolateral (sagittal plane) rotation of the ankle, and tuning the different properties of the AFO such as its trim lines, alignment, and the fabricating material impacts this stiffness characteristic [15].

The complexity of combining the different properties of the AFO material and parts distinctly of one another has created a limitation in the prescription of this stiffness quantity for different AFO types based on the presentation of the individual patient. There exists a persistent limitation in clinically prescribing individual stiffnesses and clinicians often use objective and subjective clinical measures of the individual patients in choosing the AFO stiffness for these patients; they often have to adjust the fabricated AFO device after molding it and this can be a tasking process [6]. Researchers have used lab-centered methods to prescribe and show how the stiffness properties of different AFO designs impact the gait biomechanics of stroke survivors. Arch *et al* (2016) used an objective method (with motion capture) in personalizing the bending stiffness of a passive dynamic AFO (PD-AFO) for two post-stroke participants with plantarflexor weakness. While this method of stiffness prescription is not clinically reproducible, the study results showed that the PD-AFO increased the subjects' net plantarflexion moment so that they concluded that the device was able to augment the function of the weak plantarflexor muscles of the participants [8]. Another study by Yamamoto *et al* (2022) compared a moderate to relatively stiff non-articulated AFO with an articulated AFO with oil damper (AFO-OD) which had only plantarflexion stiffness in 41 sub-acute stroke patients. Their findings showed that the AFO-OD with resistance during plantarflexion movement

and without dorsiflexion resistance had greater impacts in increasing the participant's ankle kinematics and kinetics when compared with the non-articulated AFO device [16]. The AFO-OD used in their study has the advantage of enabling the regulation of the plantarflexion stiffness of the device through different settings, which is a merit over the non-articulated type.

Similar to the Yamamoto study, Kobayashi *et al* (2018) utilized an articulated AFO with a triple action joint which has the advantage of enabling the individual tuning of the resistance settings (plantarflexion and dorsiflexion), the AFO alignment, and the allowable range of motion of the device. They utilized objective clinical indicators and subjective feedback from the participants in fitting the device for each individual and then regulated the device using observational gait analysis and subjective feedback to determine the baseline plantarflexion resistance, dorsiflexion resistance, and alignment settings of the AFO joints. These settings were randomly tuned as their participants walked over a treadmill, and the results showed how regulating the stiffness characteristics influenced the ankle and knee joint kinematics of the participants systematically. This study showed the modulating tendency of the articulated AFO with the triple action joint as a clinically viable device able to allow the use of clinical indicators in optimizing and tuning AFO resistance settings for individuals in the stroke population.

In this study, we looked to further explore the mechanism of the articulated AFO with a triple action joint on stroke survivors while they walk over the ground, as this will further inform the clinical prescription of AFOs in the same population.

1.1. AIM

This study aimed to determine the effect of varying the plantarflexion (PF) and dorsiflexion (DF) resistance of an articulated AFO device on the lower limb kinematics and kinetics during ambulation. We used the triple action Joint with an individualized AFO design where we fabricated specific AFO devices for each of the participants.

1.2. HYPOTHESES

We hypothesized that increasing the plantarflexion resistance will lead to an increase in the peak ankle dorsiflexion moment, the peak knee flexion angle at initial contact, and the ankle dorsiflexion angle at initial contact. We also hypothesized that increasing the dorsiflexion resistance will result in decreased peak dorsiflexion angle at stance, peak knee extension moment, and peak positive ankle power at stance, while there will be increased peak ankle plantarflexion moment. These hypotheses were based on results from the Kobayashi *et al*. (2018)[6] studies and off the respective proposed responses to tuning the plantarflexion and dorsiflexion resistances in a typical gait. For example, we would expect that increasing the resistance to dorsiflexion of an articulated AFO will result in decreased dorsiflexion angle at the midstance of the gait cycle for the user of the device, and increasing an AFO's resistance to plantarflexion will likely result in increased ankle angle towards dorsiflexion at the initial contact phase of the gait cycle for the AFO users.

2. METHODS

2.1. PARTICIPANT DEMOGRAPHICS

Five Subjects (S01 – S05) with Chronic stroke were recruited for this study (3M and 2F). The enrolled participants were from ages 19 – 80 (age; 64.6 ± 5.7), have had a stroke for more than 6 months (stroke onset; 6.0 ± 5.2), and could walk independently with or without a walking aid. The other inclusion criteria were a blood pressure of between 90/60 and 170/90 mmHg and a resting heart rate of between 40-100 beats per minute (bpm). Exclusion criteria were individuals who had pain in their legs or spine while walking, unexplained dizziness in the last six months, Botox treatment, and those who have had more than one stroke or a cerebellar stroke. The study was carried out in two visits of a minimum of one week apart at the Biomechanics Research Building of the University of Nebraska at Omaha. The study was explained to all participants orally and in written form before written consent was collected from the participants at the first visit. The study was approved by the University of Nebraska Medical Center Institutional Review Board.

2.2. ARTICULATED ANKLE FOOT ORTHOSIS DESIGN AND TUNING

The articulated AFO used in this study was personalized for each of the participants using 3D scanning, 3D printing, and a commercially available AFO joint (Triple Action.® 2.0 by Becker Orthopedic alliance CO.). The participant's first visit entailed clinical assessment along with the scanning of the paretic leg of each individual, from the shank to the foot (*the inferior border of the patellar cap to the toe and underfoot*) with a Creaform scanner (Ametek, Ultra Precision Technologies,

USA). The leg is positioned in a neutral position (90°) on a scanning platform where the scan is collected. A certified orthotist fits the mesh image (stereolithography file-STL) from the scan into a predetermined design for each participant's footplate and calf section. The design was such that the footplate extended anteriorly to terminate just behind the proximal phalanx while the calf section extends superiorly to the superior border of the medial gastrocnemius and extends distally to terminate with a joint and pivot attachment with which it is assembled with the foot section. The AFO foot plate was designed in a way that its anterior aspect encompassed the medial and lateral borders of the foot to ensure that the joint's support forces were central to the sagittal plane; this was done to minimize frontal and transverse plane movements. The final design for each participant was used in 3D printing the calf section and foot plate with a Polylactic Acid (PLA) printing material (Fig.1). The calf section was printed in a BCN3D Epsilon W50 printer (*BCN3D Technologies, Inc. Barcelona, Spain*) while we printed the foot section using a Prusa MINI+ (*Prusa Research a.s., Czech Republic*) printer. The printed AFO device was assembled with the triple action joint and pivots in the machine shop of the University of Nebraska at Omaha's Biomechanics Research Building. Two Velcro straps were added to each of the calf section and the foot section to hold the AFO device in place when worn by the participants.

The triple action joint used in the study enables the independent adjustment of ankle alignment, plantarflexion and dorsiflexion resistance, and ROM of the AFO. For this study, we tuned the plantar flexion and dorsiflexion resistance settings independently of one another by using an adjustable wrench to rotate two booster compartments

each housing the dorsiflexion (*anteriorly*) and plantarflexion (*posteriorly*) resistance spring. A clockwise rotation of either the plantarflexion or dorsiflexion booster compartment increases the joint resistance (*increasing preload*) of the tuned compartment by the number of turns in that direction, while a counterclockwise rotation of either of the compartments also decreases the resistance property (*decreasing preload*) of that compartment. We quantified the impact of regulating 3 plantarflexion and 3 dorsiflexion resistance settings as Low, Mid, and High resistances following the graded resistances from a study by Kobayashi *et al.* (2018) in which the same triple action joints were used (*Fig.2*) [6].

2.3. DATA COLLECTION

Clinical tests like the measurement of their passive plantarflexion (PF) and dorsiflexion (DF) range of motion (ROM), Manual Muscle Testing (MMT) of the paretic lower limb muscles using Oxford muscle grading scale, 10-meter walk test, Timed up and Go test, and 3D scanning of the shank to the foot of the participants was done at the first visit to prepare for the design and printing of each participant's ankle-foot orthosis (AFO). At the second visit, the participants were first fitted with their custom-printed specific ankle foot orthosis, and confirmation was made for fit and the comfort of the participants through each individual's feedback on their level of comfort and stability with the device. We utilized a double randomized set-up between the two-resistance settings group of plantarflexion and dorsiflexion, and within each of the groups for the 3 conditions of low, medium, and high resistance settings.

Forty-seven (47) retroreflective markers were placed on anatomical landmarks of the participants' shoulder, sternum, torso, and lower extremities using a modified Cleveland marker placement protocol [17]. For the foot markers, the markers were placed on the participant's shoes on anatomical landmarks. The lateral malleolus marker (ANL) for the affected leg was placed on the AFO triple-action joint. The offset distance from the anatomical lateral ankle malleolus to the ANL marker on the AFO joint was measured and referenced in the calculation of affected ankle and foot kinematic variables.

A 20-camera motion capture system at 100Hz (Motion Analysis Corporation, Rohnert Park, CA, USA) with inground force plates at 1000Hz (AMTI, Watertown, MA, USA) was used in collecting kinematic and kinetic data while the participants walked over the ground on the force plates for 3 different walking trials along the same direction for each of the AFO resistance setting totaling 18 walking trials. The participants were allowed a 2-minute walking adaptation period before each of the AFO resistance settings, and each participant walked at their comfortable walking speed for each resistance setting of plantarflexion low (PF1), plantarflexion medium (PF2), plantarflexion high (PF3), dorsiflexion low (DF1), dorsiflexion medium (DF2), and dorsiflexion high (DF3). They had a 5-minute rest period before each walking trial, and those who requested more rest time between trials were allowed. A safety harness was worn by each participant for their safety throughout the walking trials.

2.4. DATA ANALYSIS

The walking data was collected using the motion capture system and exported to Visual 3D software (C-Motion, Inc., Germantown, MD, USA) where the different kinematic and kinetic variables were calculated. The data was filtered using a 4^{th}-order low-pass Butterworth filter for the kinetic data (*cutoff frequency of* 60Hz) and kinematic data (*cutoff frequency of* 6Hz). The peak joint angles were derived using the segment coordinate system as the maximum angles in the orientation of the main segment to a reference segment (*usually the most proximal segment to the main segment*) in the Cardan sequence of the capture environment. For example, the peak ankle plantarflexion angle was calculated as the maximum negative angle between the foot segment and the shank segment as its reference segment in the laboratory's Cardan sequence. The mean of the peaks for all gait cycles through the time series for each walking trial was exported, and the mean of all trials for each resistance condition was found for statistical analysis.

The kinetic variables were calculated using inverse dynamics analysis in visual 3D while using a resolution coordinate system which is the coordinate system of the nearest proximal segment to the joint. The peak ankle dorsiflexion moment, for example, was calculated as the maximum positive moment between the foot segment and the reference shank segment of the paretic leg. The ankle power was also calculated as the product of its moment vector component and the associated relative angular velocity component of the shank. The mean of the peaks for all gait cycles through the time series for each walking trial was exported, and the mean of all trials for each resistance condition was found for statistical analysis.

2.5. STATISTICAL ANALYSIS

Simulation modeling analysis (SMA v11.10.16) for single-case time-series data was used in analyzing the data on a case-by-case basis for each participant. This statistical analytical method was used because of its strength in assessing improvements between phases (usually a baseline vs a treatment phase) for a single variable in small sample studies. SMA is a variant of bootstrapping methods able to evaluate short autocorrelated time-series data by assessing phase differences between a baseline (A) and treatment phase (B) in a non-normal crop of data for single-subject analyses [18,19]. By using the SMA, we were able to evaluate how the change in resistances from one lower level (baseline- A) to a higher level (treatment- B) impacted the different variables for each participant. Specifically, we tested for significant differences in tuning of the low plantarflexion resistance (PF1) to medium (PF2), tuning of the low plantarflexion resistance (PF1) to high (PF3), and tuning of the medium plantarflexion resistance (PF2) to high resistance (PF3), so that we had 3 testing conditions (**PF1 vs PF2**; **PF1 vs PF3**; **PF2 vs PF3**) for each of the selected variables. The lower resistance settings in each pair served as the baseline (Var2-PHASE = 0) entered into the Var 1 (dependent variable column) and the tested effect was the higher resistance setting in the pair (Var2-PHASE = 1). For example, in testing the PF2 vs PF3 pair, PF2 was the baseline and PF3 was the effect. This pattern explained above was also repeated for the dorsiflexion resistance settings (**DF1 vs DF2**; **DF1 vs DF3**; **DF2 vs DF3**), and this analysis was done for each participant independently of others.

SMA generates 5000 randomized iterations of the same data points from the inputted data and then returns a Pearson correlation (r) and p-value for significance using the overall autoregulation (AR) estimate between the tested phases at $\alpha = 0.05$. Using the SMA we analyzed comparisons for the 3 plantarflexion resistance phases (PF1, PF2, and PF3) on the peak dorsiflexion moment, knee flexion angle at initial contact and the ankle angle at initial contact. For the 3 dorsiflexion resistance phases (DF1, DF2, and DF3) we evaluated phase changes in the peak dorsiflexion angle at stance, peak knee extension moment, peak ankle positive power at stance, and the peak plantarflexion moment. The Knee flexion angle at initial contact was not assessed for participant S04 *due to pronounced knee hyperextension which kept the knee angle in flexion all through stance.*

3. RESULTS

As shown in figure 3-7, the time series data for the individual participants showed tuning the resistance characteristics of the articulated AFO systematically changed the gait characteristics of all participants, albeit not to a significant extent in all participants.

For participant S01, the SMA revealed that changing the plantarflexion resistance had significant phase changes on the *peak dorsiflexion moment* with noted mean increases between PF1 and PF2 ($r = -0.843$, $p = 0.0128$), PF1 and PF3 ($r = -0.949$, $p = 0.0128$), and PF2 and PF3 ($r = -0.510$, $p = 0.0268$); mean decreases in K*nee flexion angle at initial contact* between PF1 and PF2 ($r = -0.563$; $p = 0.0486$) and between PF1 and PF3 ($r = -0.810$, $p = 0.0102$); mean increases in *ankle dorsiflexion angle at*

initial contact between PF1 and PF2 (r = +0.839, p = 0.0496), PF1 and PF3 (r = +0.956, 0.001), and between PF2 and PF3 (r = +0.826, p = 0.0082). Tuning the dorsiflexion resistance for S01 also had significant phase changes for the *peak dorsiflexion angle at stance* with a mean decrease between DF2 and DF3 (r = -0.798; p = 0.038); and a mean decrease in the *peak ankle power at stance* between DF1 and DF3 (r = -0.711, p = 0.0250). As shown in tables 1-7, tuning the plantarflexion and dorsiflexion resistance did not result in significant phase changes for the other assessed variables for S01 (p > 0.05).

For Participant S02, tuning of the AFO plantarflexion resistance characteristics impacted the *knee flexion angle at initial contact* with a mean decrease between PF1 and PF3 (r = +0.686, p = 0.0470). The AFO dorsiflexion resistance impacted the *peak dorsiflexion angle at stance* with a mean decrease between DF1 and DF2 (r = -0.590, p = 0.0346); the *peak ankle power in stance* with a mean decrease between DF1 and DF3 (r = -0.795, p = 0.0500) and between DF2 and DF3 (r = -0.896, p = 0.0110). As shown in the results table (table 1 – 7), the AFO resistance settings did not result in significant differences for the other comparisons (p > 0.05).

Participant S03 experienced significant phase changes with a noted increase in the *ankle angle at initial contact* between PF1 and PF3 (r = +0.718, p = 0.0484). Tuning the dorsiflexion resistance of the articulated AFO device resulted in phase changes only for the participant's *peak dorsiflexion angle at stance* with mean decreases between DF1 and DF3 (r = -0.937, p = 0.0014) and between DF2 and DF3 (r = -0.924, p = 0.0048). The other assessed variables showed no significant differences

for the comparisons of the AFO dorsiflexion and plantarflexion resistances ($p > 0.05$).

Participant 4 also showed significant phase changes when the AFO plantarflexion resistance settings were tuned with a noted increase in the *peak ankle dorsiflexion moment* between PF1 and PF3 ($r = -0.903$, $p = 0.0142$); and a decrease in the *ankle angle at initial contact* between PF1 and PF3 ($r = +0.847$, $p = 0.0416$) but there were no significant phase changes on the knee flexion angle at initial contact ($p > 0.05$). Tuning the AFO dorsiflexion resistance characteristics only impacted phase changes on the *peak dorsiflexion angle at stance* with noted mean decreases between DF1 and DF2 ($r = -0.974$, $p = 0.0001$), and between DF1 and DF3 ($r = -0.914$, $p = 0.0020$). We noted no significant phase changes on the peak ankle power in stance, peak knee extension moment, and the peak plantarflexion moment when the dorsiflexion resistance was tuned ($p > 0.05$).

Participant 5 also had significant phase changes when the AFO plantarflexion resistance was tuned with a noted increase in the mean *peak ankle dorsiflexion moment* between PF1 and PF3 ($r = -0.558$, $p = 0.0362$); there were no phase changes for the knee flexion angle at initial contact and the ankle angle at initial contact ($p > 0.05$). Also, tuning the dorsiflexion angle impacted the *peak dorsiflexion angle* at stance with a noted decrease in the mean between DF1 and DF2 ($r = -0.885$, $p = 0.0058$), DF1 and DF3 ($r = -0.966$, $p = 0.0001$), and also between DF2 and DF3 ($r = -0.946$, $p = 0.0004$); the peak ankle power at stance with a mean decrease between DF1 and DF3 ($r = -0.680$, $p = 0.0220$). We noted no significant phase changes in the

peak knee extension moment and the peak ankle plantarflexion moment when the dorsiflexion resistance was tuned in this participant ($p > 0.05$).

4. DISCUSSION

This study aimed to evaluate how an articulated ankle foot orthosis (AFO) specifically designed and fabricated for each participant, with a triple action joint, impacts the kinematics and kinetics gait characteristics of stroke survivors. The triple action joint enabled us to individually tune the dorsiflexion and plantarflexion resistance characteristics of the AFO device so that we were able to see how changes to these characteristics changed the walking parameters of the participants. A single-case statistical analytic method was used in comparing phase changes for 3 plantarflexion resistances (low-PF1, medium-PF2, and high-PF3) and 3 dorsiflexion resistances (low-DF1, medium-DF2, and high-DF3) randomly assigned within trials. The SMA revealed phase changes between the compared resistance levels for the individual participants, bringing visibility to the distinct response of each participant to changing the AFO resistance characteristics.

Our findings showed significant phase changes were found when the plantarflexion resistance settings were varied so that participants S01, S04, and S05 experienced an increase in their dorsiflexion moment with increased plantarflexion resistance. The time series data showed that this dorsiflexion moment was increased at the loading phase of their gait, a finding similar to that of a pilot study by Kobayashi *et al*. (2017) where they tested the mechanical properties of a similar triple action joint and reported a more normalized dorsiflexion moment in the heel rocker phase of their

participant's gait cycle [20]. This result may imply that increasing the plantarflexion resistance may optimize the heel rocker phase of the gait cycle, but we cannot be exceedingly certain because the participants responded differently to changing the plantarflexion resistance of the AFO device.

The SMA also revealed significant phase changes with decreased mean peak dorsiflexion angles in the stance phase of the gait cycle for all the participants when the dorsiflexion resistance was increased. Prevention of excessive dorsiflexion in the stance phase of the gait cycle becomes a necessity when stroke survivors present with weak plantarflexor muscles. The plantarflexor muscles play an important 'support-dorsiflexion' role in guiding the anterior translation of the shank over the foot at mid-stance so that weakness of the plantarflexors results in excessive dorsiflexion to cause instability, and the AFO dorsiflexion resistance settings can help prevent this increased dorsiflexion [6,8]. Although our study did not assess for improved stability margins in any participant, all the participants experienced significant phase changes in their peak dorsiflexion angles to extents distinct in one participant compared with others.

Kobayashi *et al*. (2017) reported that the triple action joint device with the articulated AFO could change the ankle and knee joint kinematics and kinetics when the resistance and alignment characteristics of the joint are tuned [20]. Our findings in this study confirmed this because along with previously stated significant phase changes in the ankle biomechanics of our participants, 2 participants also showed significant changes in their knee biomechanics with participants S01 and S02 experiencing significant phase changes in their knee flexion angles at initial contact,

a result similar to that in a recent study where the researchers found significant main effect on the ankle and knee angles at initial contact when AFO plantarflexion resistances were tuned in a triple action joint [6]. None of the participants showed significant phase changes for their peak knee dorsiflexion moment when the dorsiflexion resistance settings were tuned, and this was also noted in the previously mentioned study [6].

Importantly, we also noted that 3 participants had significant phase changes in their peak ankle power at the stance phase of gait with noted decreases when the dorsiflexion resistance was increased, and a previous study has indicated that a decreased ankle power generation may imply limited propulsion at the 3rd rocker of the gait cycle [21]. Our study did not evaluate the propulsion characteristics of the participants, although 2 participants experienced no significant phase changes in their ankle positive power at stance when the AFO was tuned to the same resistance condition, yet we understand that AFOs could also impede optimal gait function when wrongly prescribed. Future studies should explore the impact of changing AFO resistance characteristics on the propulsive forces and affected lower limb muscle function of stroke survivors.

Also, stroke survivors tend to have distinct characteristics and clinical presentations following the occurrence of stroke, so the use of the SMA enables us to see these distinct individual responses to changes in the AFO resistance conditions, especially when compared to statistical methodologies that show group averages. Rightly so, though the time series graph showed systematic changes for the different kinematic and kinetic variables of the participants, these phase changes were distinct across the

board. Participant S01 seemed to experience the most impact when the plantarflexion and dorsiflexion resistances of the AFO were tuned, and we believe this should be expected because the manual muscle clinical testing (MMT) showed that he had the least grade in plantarflexor and dorsiflexor muscle power amongst the participants, and the functional clinical tests (Timed-up and go; 10 meter walk test) showed that he spent the most time in covering the same distance as the other study participant. Also, this participant had been using a clinically prescribed AFO for about 16 years so that we could expect that he was appreciably adapted to using the device, so that introducing a different AFO design with possibly better assistive and resistive property would result in significant changes in this participants' kinetics and kinematics characteristics. Participants S01 and S02 were also current AFO and one-point cane users at the time of this study, while participants S03 – S05 were able to walk without the use of an assistive device. This may imply that this device would be more beneficial in some individuals than others, say individuals with more functional deficiencies compared to less, and may offer the possibility of being tuned in a clinical setup as patients improve as they record functional improvement after stroke. This inference is yet to be tested and further establishes the need for a more in-depth study to better clarify the grey areas in the prescription of these articulated AFO type.

Assistive devices like the ankle foot-orthosis are necessary clinical and rehabilitation tools in ensuring independence in stroke survivors after the cerebrovascular accident [22,23], and diverse AFO designs and types are existent in the clinical space so that there remains a limitation in clinically prescribing and optimizing the characteristics

of these AFO devices like the bending stiffnesses and resistances. Most of the existent stiffness prescription mechanisms are only tenable in the laboratory space [8,24,25.] The articulated AFO type with triple action joint used in this study gives the merit of on-site regulation of the plantarflexion and dorsiflexion resistance characteristics of the device [20], and this study has shown that the device systematically and significantly enables phase changes with on ankle and knee kinetics and kinematics for stroke survivors, albeit distinctly.

We should also mention that while we tested either of the plantarflexion or the dorsiflexion resistance, the untested resistance was left on the low settings for both conditions. For example, while testing the 3 dorsiflexion resistance settings, the plantarflexion resistance condition was left on the low (PF1) settings for all the tested dorsiflexion resistance conditions. This method enabled us to test each resistance condition independent of the other, yet we understand the propensity of possible interactions between both Plantarflexion and dorsiflexion resistance settings and will therefor look to investigate the interactions between these conditions to see how it changes the users gait biomechanics. A study of this nature will be done under controlled conditions using objective and subjective clinical measures to optimize the resistance settings for each individual. Therefore, further investigations are necessary to have a clearer understanding of a standardized structure for the clinical prescription of articulated AFOs using objective and subjective clinical measures both in the acute and chronic stroke population. Having this understanding will further inform the clinical prescription of AFO devices for the stroke population.

4.1. LIMITATIONS

This study had a few limitations. First, we had a limited sample size due to the difficulty in recruiting chronic stroke survivors and our currently minimal participant registry. The small sample size inferred less analytical power and also meant that we had a less diversified crop of stroke survivors in this study, considering that the stroke population is a highly heterogeneous one. Despite this limitation, the study structure, using an individual-specific AFO design (through 3D scanning and printing) and the use of the Simulation Modelling Analysis (SMA) as our statistical method, helped give a more clear-cut picture of how this articulated AFO device with the triple action joint could be a tenable clinical tool in improving the gait characteristics of stroke survivors while walking over the ground. Also, we should mention that the SMA as a statistical analytical method can be ambiguous because of the number of simulations making it difficult to note all important changes within the compared phases, especially in the cases of noisy data. The foundational assumption of the SMA is that the generated simulation data are representations of the general data from which the analyzed time series data is drawn; this assumption remains untested as at the time of this study, so that we encourage some caution in the interpretation of our results.

Although this study investigated how the articulated AFO device impacted the joint kinematics and kinetics of the chronic stroke population, we neglected other measures that define functional levels and capacities in society; measures like the energy cost of walking, walking speed, and stability margins amongst others. Understanding how the tuning of resistance characteristics of the articulated AFO

device impacts these functional measures will give a clearer picture of how the device can be prescribed to optimize the functional capacity of users in the stroke population. Future studies can investigate this.

5. CONCLUSION & FUTURE DIRECTIONS

In this study, we investigated how random tuning of the plantarflexion and dorsiflexion resistance settings of an articulated AFO with triple action joint impacted the walking biomechanics of stroke survivors. Our findings showed that the device significantly ensued phase changes resulting in improvements of the ankle and knee joint kinematic and kinetic gait characteristics of our participants, while we also noted a decrease in the positive power at the stance phase of gait in three of our participants when the dorsiflexion resistance of the AFO was increased. These findings infer the promise in the use of an articulated AFO device with tunable joints, although further work is necessary to determine a structural ***clinical prescription mechanism*** for stroke survivors with this device to ascertain stiffness and resistance characteristics that will best optimize the functional capacity of the users while avoiding possible complications.

6. ACKNOWLEDGEMENTS

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7. FIGURES

Table 1. Demographics and basic clinical information of each participant.

ID	Age(yrs)	weigh t (Kg)	SEX	Paretic Limb	Assistive Device	Clinical AFO type	Yrs since stroke
S01	64	87.09	M	Left	cane	carbon fiber	15.75
S02	70	84.82	F	Right	cane	carbon fiber	2.33
S03	66	97.62	M	Left	Nil	Nil	3.42
S04	69	65.09	F	Left	Nil	Nil	5.72
S05	54	97.52	M	Left	Nil	Nil	1.00

Table 2. Manual muscle testing (MMT) grades of the affected lower limb and plantarflexion range of motion (ROM) of each participant

S.ID	Hip flexors	Hip extensors	Knee flexors	Knee flexors	Dorsi-flexors	Plantar-flexors	Plantarflexion ROM (deg)
S01	5	5	4	5	-3	2	20
S02	5	5	5	5	3+	4	31
S03	5	5	4	5	4	5	35
S04	4+	4+	3+	4	3+	4	34
S05	5	4+	5	5	4+	4+	32

Table 3. The effect of varying the plantarflexion resistances (PF1, PF2, PF3) on the peak dorsiflexion moment (Nm/kg) for all participants. (significant p-values are in bold).

Effect of plantarflexion Resistance(res) on Peak dorsiflexion moment (Nm/kg)					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	PF1	-0.04(0.027)	**PF1 V PF2**	-0.843	**0.0128**
	PF2	-0.14(0.036)	**PF1 V PF3**	-0.949	**0.0008**
	PF3	-0.18(0.015)	**PF2 V PF3**	-0.510	**0.0268**
S02	PF1	-0.02(0.009)	**PF1 V PF2**	-0.422	0.4262
	PF2	-0.04(0.02)	**PF1 V PF3**	+0.181	0.6066
	PF3	-0.02(0.009)	**PF2 V PF3**	+0.491	0.3552
S03	PF1	-0.11(0.13)	**PF1 V PF2**	+0.276	0.3392
	PF2	-0.06(0.01)	**PF1 V PF3**	+0.063	0.8516
	PF3	-0.10(0.07)	**PF2 V PF3**	-0.345	0.3642
S04	PF1	-0.099(0.03)	**PF1 V PF2**	-0.611	0.1622
	PF2	-0.32(0.20)	**PF1 V PF3**	-0.903	**0.0142**
	PF3	-0.20(0.02)	**PF2 V PF3**	+0.393	0.4262
S05	PF1	-0.15(0.01)	**PF1 V PF2**	-0.307	0.2706
	PF2	-0.18(0.07)	**PF1 V PF3**	-0.558	**0.0362**
	PF3	-0.38(0.24)	**PF2 V PF3**	-0.485	0.0706

Table 4. The effect of varying the plantarflexion resistances (PF1, PF2, PF3) on the knee flexion angle at initial contact (degrees) for all participants. (significant p-values are in bold).

Effect of plantarflexion Resistance(res) on Knee flexion angle (deg) at initial contact					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	PF1	5.60(1.08)	**PF1 V PF2**	-0.563	**0.0486**
	PF2	7.54(1.69)	**PF1 V PF3**	-0.810	**0.0102**
	PF3	8.34(0.92)	**PF2 V PF3**	-0.293	0.0746
S02	PF1	12.60(0.91)	**PF1 V PF2**	+0.542	0.1010
	PF2	11.33(1.06)	**PF1 V PF3**	+0.686	**0.0470**
	PF3	11.13(0.63)	**PF2 V PF3**	+0.113	0.6372
S03	PF1	11.77(1.62)	**PF1 V PF2**	+0.731	0.0842
	PF2	8.77(1.13)	**PF1 V PF3**	+0.567	0.1782
	PF3	9.98(0.87)	**PF2 V PF3**	-0.511	0.1588
S04	PF1	-11.05(4.86)	**PF1 V PF2**	+0.242	0.6554
	PF2	-12.94(2.24)	**PF1 V PF3**	-0.115	0.8192
	PF3	-10.19(2.03)	**PF2 V PF3**	-0.541	0.2720
S05	PF1	7.61(1.50)	**PF1 V PF2**	-0.046	0.9276
	PF2	7.73(1.08)	**PF1 V PF3**	-0.399	0.3148
	PF3	8.67(0.85)	**PF2 V PF3**	-0.435	0.3262

Table 5. The effect of varying the plantarflexion resistances (PF1, PF2, PF3) on the ankle angle at initial contact (degrees) for all participants. (significant p-values are in bold).

Effect of plantarflexion Resistance(res) on Ankle angle at initial contact (deg)					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	PF1	-10.27(1.33)	**PF1 V PF2**	+0.839	**0.0496**
	PF2	-6.27(1.26)	**PF1 V PF3**	+0.956	**0.0001**
	PF3	-3.25(0.72)	**PF2 V PF3**	+0.826	**0.0082**
S02	PF1	-0.08(2.01)	**PF1 V PF2**	+0.474	0.0652
	PF2	1.75 (1.32)	**PF1 V PF3**	+0.025	0.9226
	PF3	-0.04(2.59)	**PF2 V PF3**	-0.384	0.4312
S03	PF1	0.26 (2.15)	**PF1 V PF2**	-0.058	0.8634
	PF2	0.02 (1.93)	**PF1 V PF3**	+0.718	**0.0484**
	PF3	3.48(0.49)	**PF2 V PF3**	+0.775	0.0832
S04	PF1	-11.94(2.12)	**PF1 V PF2**	+0.541	0.0694
	PF2	-9.45(2.02)	**PF1 V PF3**	+0.847	**0.0416**
	PF3	-4.59(0.51)	**PF2 V PF3**	+0.693	0.1292
S05	PF1	-0.12(0.23)	**PF1 V PF2**	+0.169	0.6890
	PF2	-0.06(0.70)	**PF1 V PF3**	-0.259	0.5424
	PF3	-0.47(0.90)	**PF2 V PF3**	-0.313	0.4072

Table 6. The effect of dorsiflexion resistances (DF1, DF2, DF3) on the peak dorsiflexion angle (degrees) at the stance phase of the gait cycle in all participants. (p-values in bold were significant).

Effect of dorsiflexion Resistance (res) on Peak dorsiflexion angle (deg) at stance					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	DF1	10.34(0.85)	**DF1 v DF2**	-0.014	0.9782
	DF2	10.32(0.34)	**DF1 v DF3**	-0.743	0.1440
	DF3	8.15(1.11)	**DF2 v DF3**	-0.798	**0.0338**
S02	DF1	12.39(1.02)	**DF1 v DF2**	-0.590	**0.0346**
	DF2	10.77(1.19)	**DF1 v DF3**	-0.632	0.0760
	DF3	10.50(1.29)	**DF2 v DF3**	-0.110	0.6898
S03	DF1	26.21(1.39)	**DF1 v DF2**	-0.617	0.1080
	DF2	24.33(0.98)	**DF1 v DF3**	-0.937	**0.0014**
	DF3	20.84(0.28)	**DF2 v DF3**	-0.924	**0.0048**
S04	DF1	15.92(0.32)	**DF1 v DF2**	-0.974	**0.0001**
	DF2	8.61(1.15)	**DF1 v DF3**	-0.914	**0.0020**
	DF3	9.75(1.91)	**DF2 v DF3**	+0.341	0.1912
S05	DF1	17.49(0.73)	**DF1 v DF2**	-0.885	**0.0058**
	DF2	15.30(0.35)	**DF1 v DF3**	-0.966	**0.0001**
	DF3	13.01(0.43)	**DF2 v DF3**	-0.946	**0.0004**

Table 7. The effect of varying the dorsiflexion resistances (DF1, DF2, DF3) on the peak knee extension moment (Nm/kg) for all participants. We found no significant phase change between the conditions.

Effect of dorsiflexion Resistance(res) on peak knee extension moment (Nm/kg)					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	DF1	0.26(0.07)	**DF1 v DF2**	+0.460	0.0860
	DF2	0.37(0.13)	**DF1 v DF3**	+0.226	0.5222
	DF3	0.30(0.06)	**DF2 v DF3**	-0.358	0.0780
S02	DF1	0.21(0.02)	**DF1 v DF2**	+0.523	0.1100
	DF2	0.25(0.04)	**DF1 v DF3**	+0.560	0.1834
	DF3	0.26(0.05)	**DF2 v DF3**	+0.192	0.6036
S03	DF1	0.66(0.05)	**DF1 v DF2**	+0.068	0.8160
	DF2	0.67(0.10)	**DF1 v DF3**	+0.105	0.6172
	DF3	0.67(0.10)	**DF2 v DF3**	+0.029	0.8906
S04	DF1	0.08(0.02)	**DF1 v DF2**	+0.020	0.9456
	DF2	0.08(0.01)	**DF1 v DF3**	-0.160	0.6932
	DF3	0.075(0.01)	**DF2 v DF3**	-0.222	0.3914
S05	DF1	0.71(0.27)	**DF1 v DF2**	+0.146	0.4964
	DF2	0.77(0.16)	**DF1 v DF3**	+0.035	0.8884
	DF3	0.72(0.33)	**DF2 v DF3**	-0.085	0.7756

Table 8. The effect of varying the dorsiflexion resistances (DF1, DF2, DF3) on the peak positive ankle power (W/kg) for all participants. (significant p-values are in bold).

Effect of dorsiflexion Resistance (res) on peak positive ankle power (W/kg) at stance					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	DF1	0.51(0.06)	**DF1 v DF2**	-0.441	0.1066
	DF2	0.46(0.05)	**DF1 v DF3**	-0.711	**0.0250**
	DF3	0.37(0.09)	**DF2 v DF3**	-0.276	0.1492
S02	DF1	1.09(0.12)	**DF1 v DF2**	+0.466	0.1926
	DF2	1.20(0.08)	**DF1 v DF3**	-0.795	**0.0500**
	DF3	0.79(0.12)	**DF2 v DF3**	-0.896	**0.0110**
S03	DF1	1.36(0.23)	**DF1 v DF2**	-0.104	0.8206
	DF2	1.31(0.20)	**DF1 v DF3**	-0.658	0.1096
	DF3	1.06(0.07)	**DF2 v DF3**	-0.650	0.1802
S04	DF1	0.48(0.19)	**DF1 v DF2**	-0.493	0.1298
	DF2	0.30(0.13)	**DF1 v DF3**	-0.483	0.1326
	DF3	0.31(0.12)	**DF2 v DF3**	+0.037	0.8824
S05	DF1	2.05(0.22)	**DF1 v DF2**	-0.539	0.0706
	DF2	1.77(0.21)	**DF1 v DF3**	-0.680	**0.0220**
	DF3	1.63(0.23)	**DF2 v DF3**	-0.305	0.3776

Table 9. The effect of varying the dorsiflexion resistances (DF1, DF2, DF3) on the peak ankle plantarflexion moment (Nm/kg) for all participants. (significant p-values are in bold).

Effect of dorsiflexion Resistance(res) on Peak ankle plantarflexion moment (Nm/Kg)					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	DF1	0.72(0.07)	**DF1 v DF2**	-0.274	0.2394
	DF2	0.68(0.07)	**DF1 v DF3**	-0.189	0.3574
	DF3	0.69(0.09)	**DF2 v DF3**	+0.053	0.8284
S02	DF1	1.02(0.04)	**DF1 v DF2**	+0.482	0.1580
	DF2	1.07(0.04)	**DF1 v DF3**	+0.724	0.0512
	DF3	1.12(0.05)	**DF2 v DF3**	+0.542	0.0952
S03	DF1	1.05(0.09)	**DF1 v DF2**	-0.308	0.3270
	DF2	0.98(0.11)	**DF1 v DF3**	-0.686	0.0576
	DF3	0.88(0.09)	**DF2 v DF3**	-0.455	0.2098
S04	DF1	0.75(0.19)	**DF1 v DF2**	+0.245	0.3806
	DF2	0.81(0.13)	**DF1 v DF3**	-0.259	0.2910
	DF3	0.67(0.12)	**DF2 v DF3**	-0.390	0.1178
S05	DF1	1.51(0.48)	**DF1 v DF2**	-0.313	0.2798
	DF2	1.23(0.36)	**DF1 v DF3**	-0.431	0.1078
	DF3	1.18(0.18)	**DF2 v DF3**	-0.117	0.7100

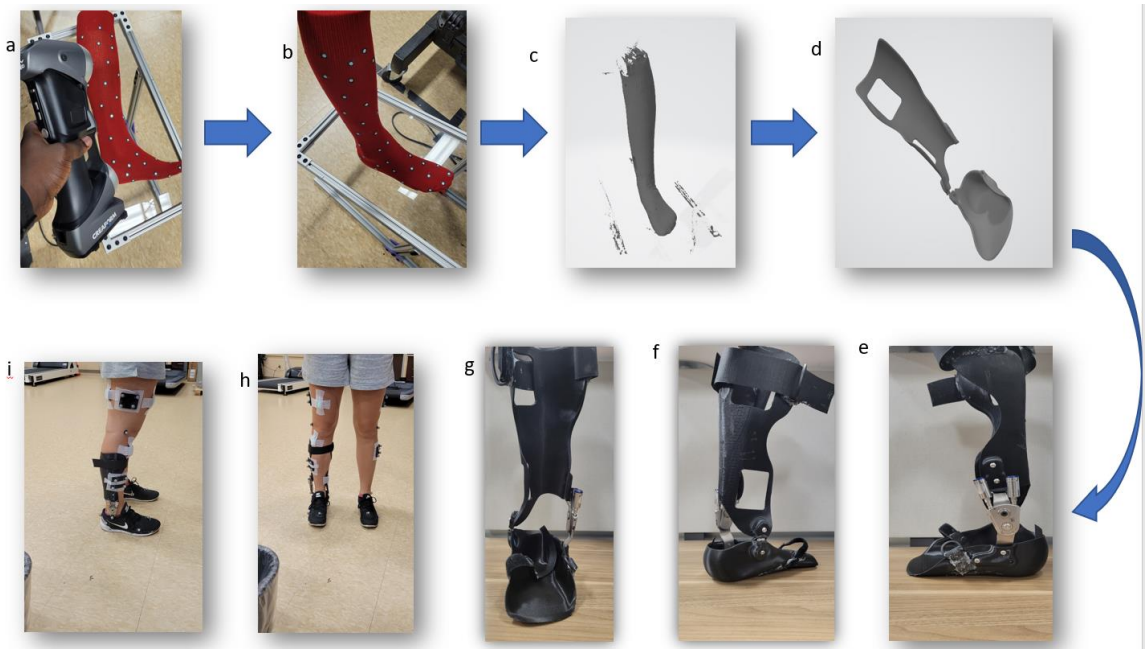

Figure 1: Phases in the fabrication process of the ankle foot-orthosis device for each participant. (a-b) Shows the scanning process; (c) Shows the image from the scan; (d) Shows the design fitted to each participant by the orthotist professional; (e-g) Shows the 3D printed device assembled with the triple action joint and Velcro straps; (h-i) shows a participant donning the device in a pilot study.

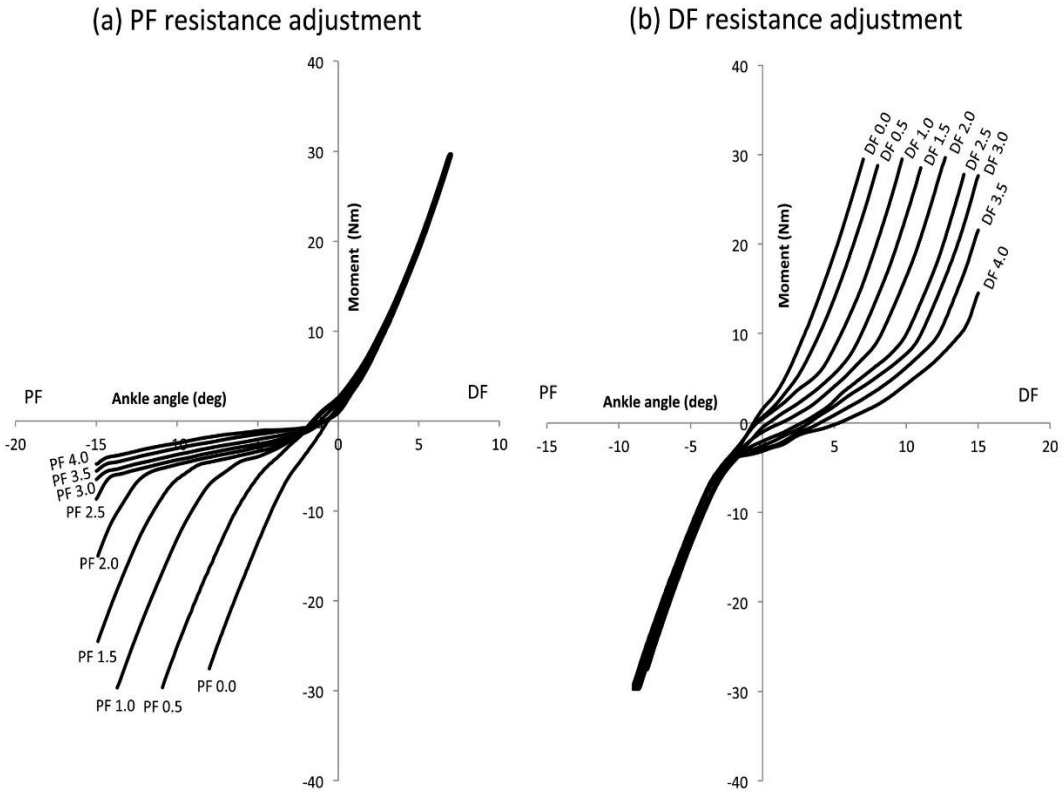

FIGURE 2. The angle – moment relationship for the Triple action joint (Triple Action.® 2.0 by Becker Orthopedic alliance CO.) device assembled with the articulated AFO [6].

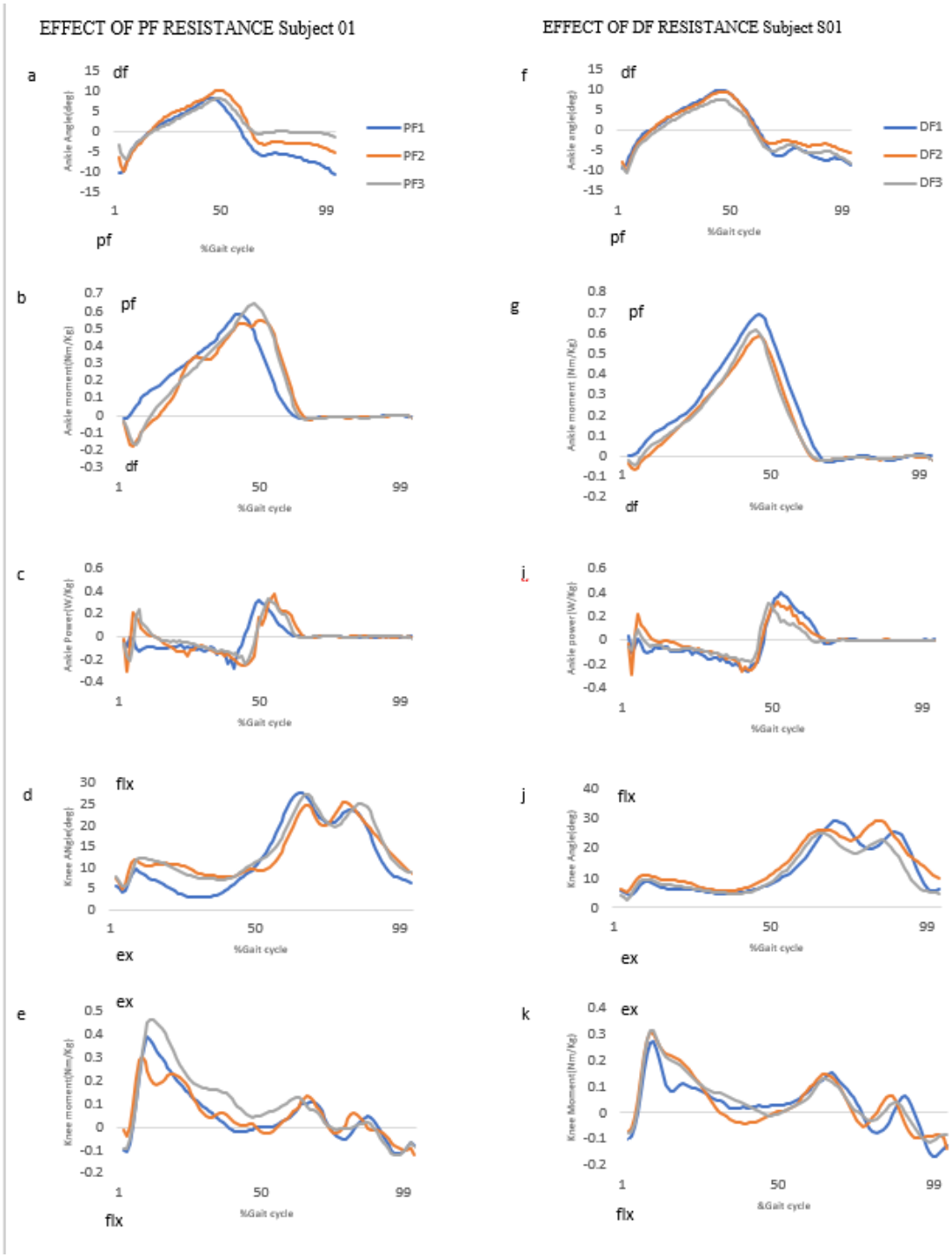

Figure 3: The effect of changing the plantarflexion resistance (a-e) and dorsiflexion resistance (f-k) of the AFO on the ankle and knee joints kinematics and kinetics of participant S01.

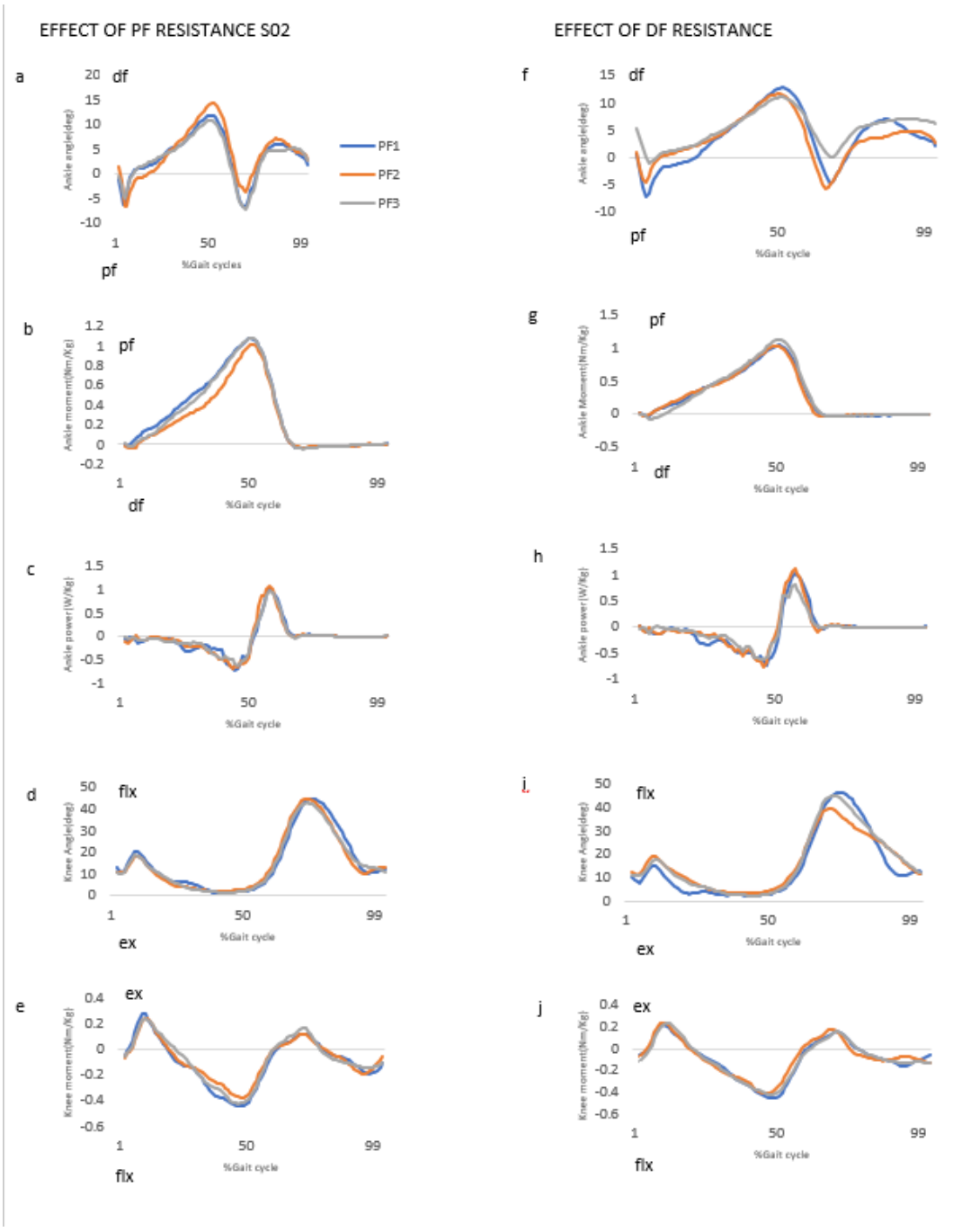

Figure 4: The effect of changing the plantarflexion resistance (a-e) and dorsiflexion resistance (f-j) of the AFO on the ankle and knee joints kinematics and kinetics of participant S02.

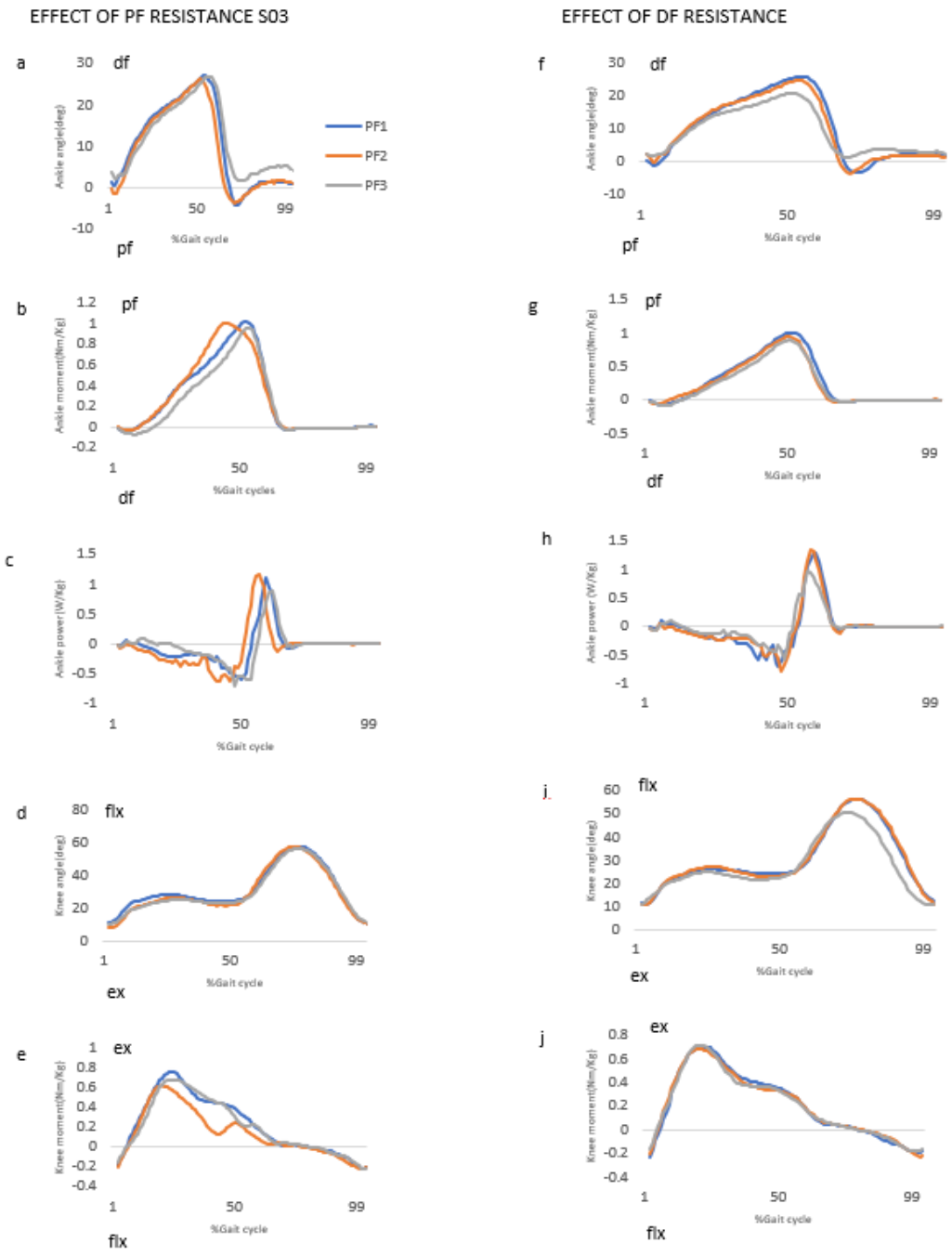

Figure 5: The effect of changing the plantarflexion resistance (a-e) and dorsiflexion resistance (f-j) of the AFO on the ankle and knee joints kinematics and kinetics of participant S03.

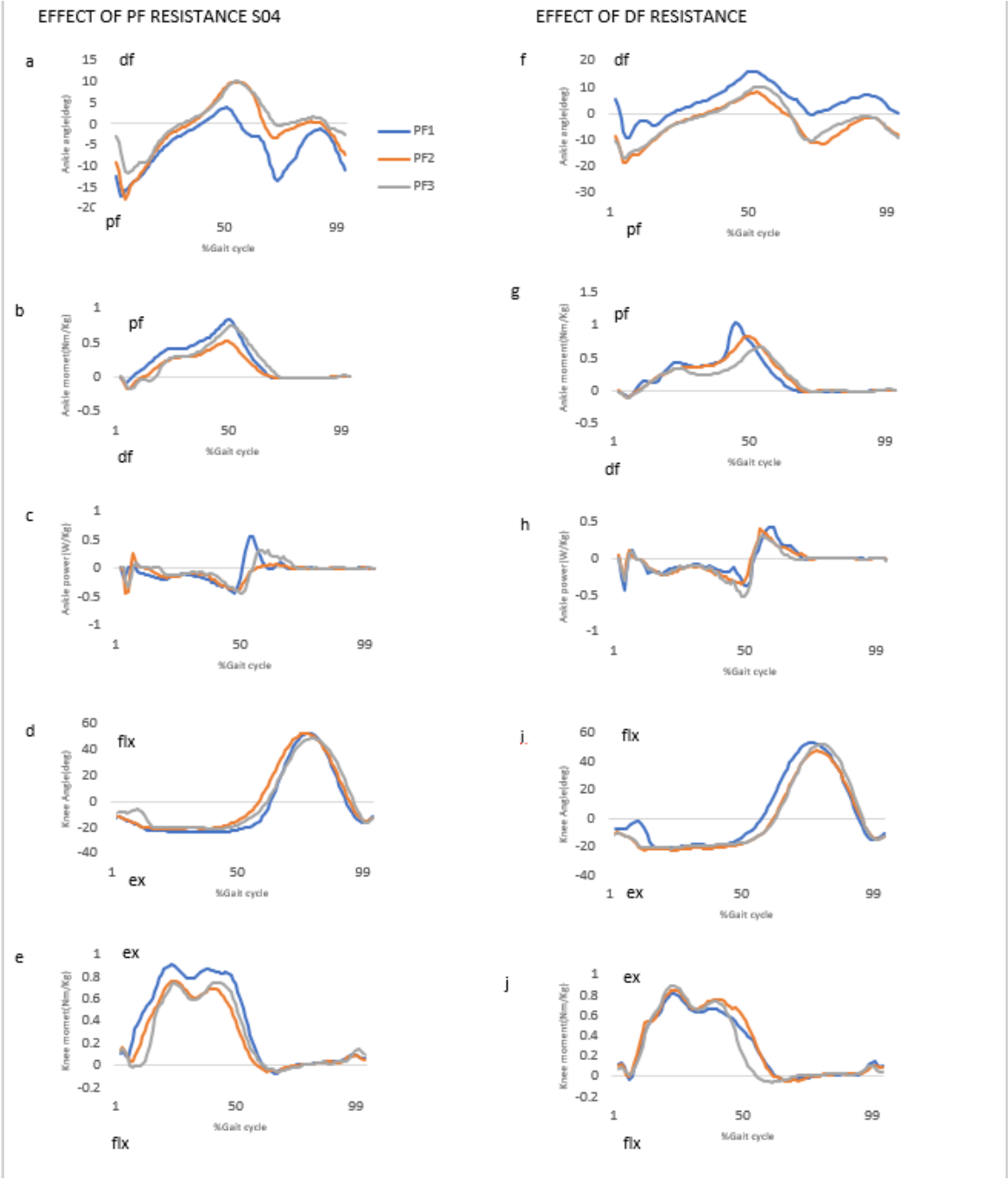

Figure 6: The effect of changing the plantarflexion resistance (a-e) and dorsiflexion resistance (f-j) of the AFO on the ankle and knee joints kinematics and kinetics of participant S04.

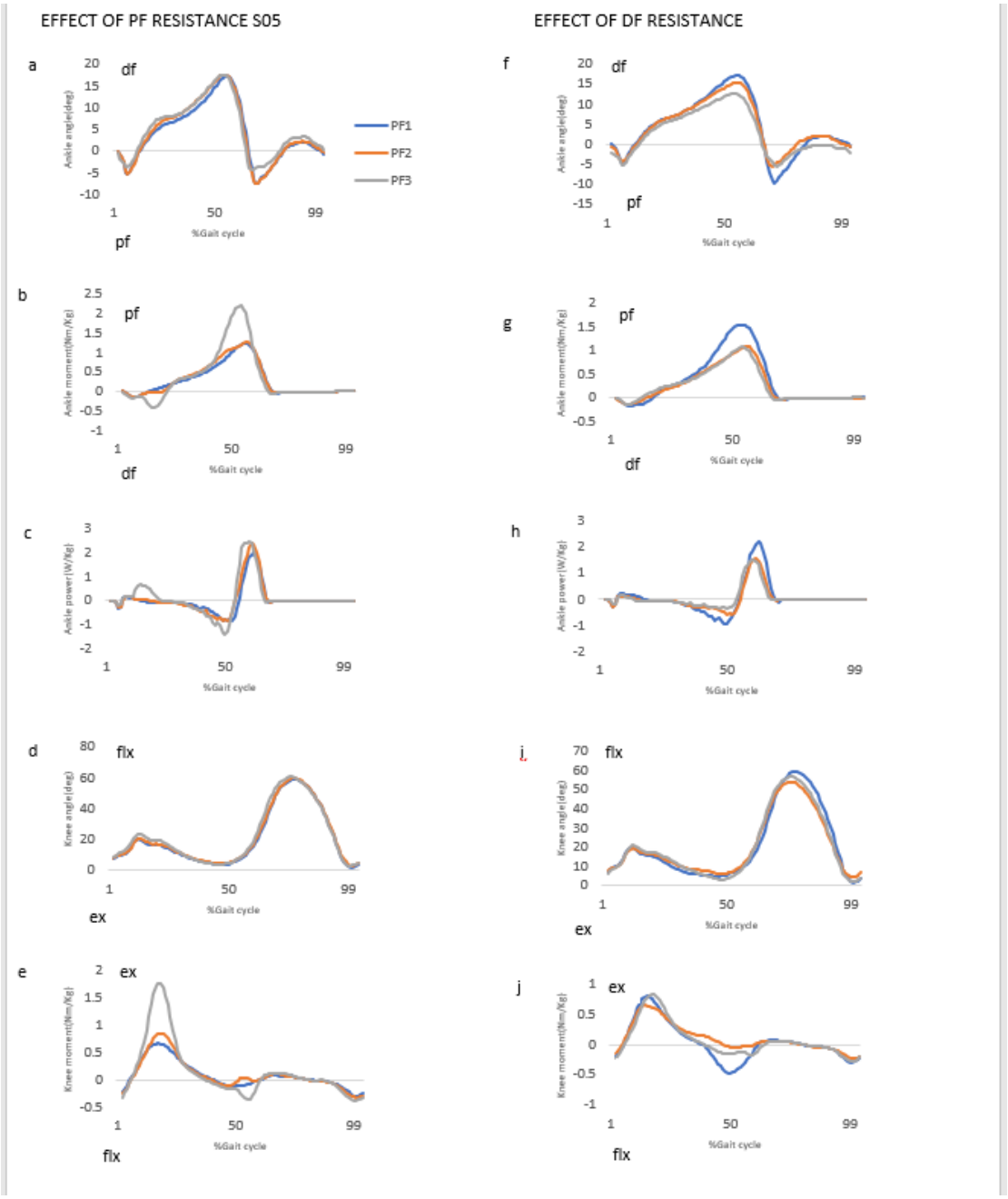

Figure 7: The effect of changing the plantarflexion resistance (a-e) and dorsiflexion resistance (f-j) of the AFO on the ankle and knee joints kinematics and kinetics of participant S05.

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CHAPTER 3

THE EFFECT OF REGULATING THE PLANTARFLEXION RESISTANCE AND DORSIFLEXION RESISTANCE OF AN ARTICULATED ANKLE FOOT-ORTHOSIS ON THE MUSCLE ACTIVITY OF AFFECTED THE LOWER LIMB OF STROKE SURVIVORS.

1. INTRODUCTION

Ankle Foot Orthoses (AFOs) are assistive devices that enable stroke survivors to walk or ambulate independently [1,2]. These devices are worn on the affected leg of the users to ensure an improved walking ability for persons with weak lower leg muscles, as observed after stroke occurrence [3,4]. A stroke typically causes a hemiparetic presentation in affected persons, causing the weakness of half of the body contralateral to the affected hemisphere of the brain. That is, the right half of the body is hemiparetic in the case of a left-sided cerebrovascular accident and vice versa. This observed presentation could lead to an impairment of the ankle function because of the weakness of its primary actuator muscles enabling dorsiflexion (*Tibialis anterior*) and plantarflexion (*Lateral and medial Gastrocnemius and Soleus muscles*) movements [5–7].

Following a stroke, weak plantarflexor and/or dorsiflexor muscles may lose their ability to perform the primary functions of the gait cycle. In a typical gait cycle, the Tibialis anterior (*TA*) muscle plays an important role in the early phase of stance during initial contact (IC) when it eccentrically contracts while the foot goes into plantarflexion to allow the body weight to be accepted (*loading*

response- LR), and it also prevents foot drop during the swing phase [1,8]. The plantarflexor muscles function as stabilizers by preventing excessive ankle dorsiflexion and knee flexion at mid-stance, and they also generate large torques at the terminal stance to propel the foot into the swing phase while also aiding forward acceleration [9–11]. Impairment of these muscle functions may result in limitations such as decreased gait speed, decreased stability, increased walking energy cost, and gait asymmetry, so-that AFOs are a go-to for rehabilitation purposes or to ensure a more efficient gait [9,11,12].

Previous studies have shown how AFOs with different designs and stiffness characteristics positively impact the gait of stroke survivors. Arch et al. (2016) demonstrated that when the bending stiffness of a Passive Dynamic AFO was systematically prescribed, it improved the net plantarflexion function of the participants in their study to investigate how the device impacted the gait of stroke survivors [11]. In a similar study, Kobayashi et al. (2017) discovered that an AFO regulated the ankle and knee joint motion of their participants based on the amount of moment supplied by the AFO while their stroke survivors walked on a split-belt treadmill [13]. Despite these positives, there is an existent discussion on how different AFO types impact the muscles of the affected lower leg of AFO users in the long term.

In a 2011 study, Lairamore *et al* compared tibialis anterior muscle electromyography in stroke survivors walking in two AFO types (dynamic ankle orthosis - DAO and posterior leaf spring-AFO), and they found that the participants had significantly reduced tibialis anterior muscle activity during the

swing phase of their gait cycle [6]. This study is similar to others that have predicted the possibility of muscle atrophy following the use of AFOs for long periods [1,7]. Murayama and Yamamoto (2020) also looked at how an AFO with plantarflexion resistance affected the muscle activity of stroke patients after 2 months of continuous use, and their findings showed that the AFO-induced plantarflexion movement, resulting in increased tibialis anterior muscle activity ratio at the loading response phase of the gait cycle [8]. The findings of this study contradicted those of previous studies, with the authors stating that AFOs with plantarflexion resistance may be able to alter the muscle activity of stroke survivors differently than other AFO designs [8]. This statement suggests that different AFO designs may have different effects on the gait biomechanics and muscle function of stroke survivors, as evidenced by previous comparative studies. [6,14].

Kobayashi et al. (2017) described an articulated AFO with joints that allowed for independent tuning of plantar flexion and dorsiflexion resistance, AFO alignment, and the device's allowable range of motion. [15]. The AFO was tested in a pilot study to evaluate its mechanical properties and effects on a stroke survivor, and they discovered that the device systematically changed the participant's gait biomechanical characteristics as its settings were tuned [15]. This study like others carried out with a similar articulated AFO with a triple action joint shows the potential of the device as a rehabilitation tool for long-term use [15–17]; this is based on the opportunity to tune the joint settings through different phases of the users' recovery. This current study will investigate how the plantarflexion and dorsiflexion resistance settings of a similar articulated AFO device with a triple

action joint impact the function of the lower extremity muscles of the affected leg of stroke survivors. We believe that the findings of this study can set a precedent for the effect of the long-term use of this AFO device and similar ones on the muscles of the affected lower extremity of stroke survivors.

1.1.AIMS

This study aimed to determine the effect of varying the plantarflexion and dorsiflexion resistance of an articulated ankle-foot orthosis on the activity level of the muscles of the affected leg of stroke survivors. All participants were tested with three dorsiflexion (DF1-low, DF2-medium, DF3-high) and three plantarflexion (PF1-low, PF2-medium, PF3-high) resistance settings.

1.2.HYPOTHESES

We hypothesized that increasing plantarflexion resistance would increase Tibialis anterior and rectus femoris muscle activity during the swing phase of the gait cycle. We also hypothesized that increasing dorsiflexion resistance would reduce soleus muscle activity at the terminal stance and tibialis anterior muscle activity during the swing phase of the gait cycle. These hypotheses were made of findings from a study by Lairamore *et al*. [6] and using the expected AFO dorsiflexion and plantarflexion resistance function with a proposition that increasing the AFO's resistance to dorsiflexion, a decreased dorsiflexion angle at midstance may also result in a decreased energy return at the terminal stance phase of the gait cycle thereby noting decreased peak soleus muscle activity at this phase of the gait cycle.

2. METHODS

2.1.PARTICIPANT DEMOGRAPHICS

For this study, four participants (S01 – S04) with chronic stroke were recruited (3M, 1F). The participants ranged in age from 19 to 80 (age(yrs); 63.5 ± 5.9), had a stroke for more than 6 months, and could walk independently with or without a walking aid. Three of the participants presented with a left-sided hemiparetic presentation. Other inclusion criteria included having a blood pressure between 90/60 and 170/90 mmHg and a resting heart rate between 40-100 beats per minute (bpm), while people with pain in their legs or spine while walking, unexplained dizziness in the previous six months, Botox treatment, and having had more than one stroke or a cerebellar stroke were excluded. The research was carried out over two visits to the University of Nebraska at Omaha's Biomechanics Research Building. Before collecting written consent from participants at the first visit, the study was explained to them both orally and in writing. At the first visit, clinical tests such as measuring their passive PF and DF range of motion (ROM), Manual Muscle Testing (MMT) of the paretic lower limb muscles using the Oxford muscle grading scale, 10-meter walk test, Timed up and Go test, and 3D scanning of the participants' shank to the foot were also performed to prepare for the design and printing of each participant's AFO. The University of Nebraska Medical Center’s Institutional Review Board approved the study.

2.2. ARTICULATED ANKLE FOOT ORTHOSIS DESIGN AND TUNING

The articulated ankle foot orthosis used in this study was personalized for each participant using 3D scanning, 3D printing, and a commercially available AFO

joint (Triple Action.® 2.0 by Becker Orthopedic alliance CO.). The first visit included clinical assessment as well as scanning of each participant's paretic leg from the shank to the foot (from the inferior border of the patellar cap to the toe and underfoot) with a Creaform scanner (Ametek, Ultra Precision Technologies, USA). The leg is scanned in a neutral position (90°) on the scanning platform (Fig), and the STL image from the scan is fitted by a certified orthotist into a predetermined design for each participant's footplate and calf section (*Fig.1*). The footplate design extends anteriorly to terminate just behind the proximal phalanx. The final design for each participant was used in 3D printing the calf section and foot plate with a Polylactic Acid (PLA) printing material. The calf section was printed in a BCN3D Epsilon W50 printer (*BCN3D Technologies, Inc. Barcelona, Spain*) while we printed the foot section using a Prusa MINI+ (*Prusa Research a.s., Czech Republic*) printer. When worn, the AFO is held around the leg by two Velcro straps, one on the calf section and the other on the foot section. To create the final device, we assembled both 3D printed sections using Becker's Triple action joint and a pivot. The AFO foot plate was designed in a way that its anterior aspect encompassed the medial and lateral borders of the foot to ensure that the joint’s support forces were central to the sagittal plane; this was done to minimize frontal and transverse plane movements.

The study's triple action joint allows for independent adjustment of ankle alignment, plantarflexion and dorsiflexion resistance, and AFO range of motion. For this study, we independently tuned the plantar flexion and dorsiflexion resistance settings by rotating (clockwise or counterclockwise) two booster

compartments, each housing the dorsiflexion (anteriorly) and plantarflexion (posteriorly) resistance spring. A clockwise rotation of the plantarflexion or dorsiflexion booster compartment increases the joint resistance (increases preload) of the tuned compartment by the number of turns in that direction, whereas a counterclockwise rotation of either compartment decreases the resistance property (decreases preload). We quantified the impact of regulating 3 plantarflexion and 3 dorsiflexion resistance settings as Low, Mid, and High resistances following the graded resistances from a study by Kobayashi et al. (2018) in which the same triple action joints were used [16](*Fig.2*).

2.3. DATA COLLECTION

At the second visit, the participants were first fitted with their custom-printed specific ankle foot orthosis, and confirmation was made for fit and the comfort of the participants through each individual's feedback on their level of comfort and stability with the device. We used a double randomized set-up between the plantarflexion and dorsiflexion resistance settings group, and within each of both groups for the 3 conditions of low, medium, and high resistance settings. Five electromyography (EMG) sensors (Trigno Avanti, Delsys, Natick MA, USSA) were used in assessing the muscle activity of the *rectus femoris, biceps femoris, medial gastrocnemius, tibialis anterior, and soleus* for the affected lower leg. The EMG sensors were placed using guidelines from Beattie's anatomical guide for the electromyographer [18]. The EMG sensors for the Medial gastrocnemius and Soleus muscles were placed at the first session during the 3D scanning of each

participant's leg to account for their location (EMG sensors gap) in the calf section of the printed AFO.

Forty-seven (47) retroreflective markers were also placed on anatomical landmarks of the participants' shoulder, sternum, torso, and lower extremities using a modified Cleveland marker placement protocol [19]. For the foot markers, the markers were placed on the participant's shoes at anatomical landmarks. The lateral malleolus marker (ANL) for the affected leg was placed on the AFO triple-action joint. The offset distance from the anatomical ANL to the ANL marker on the AFO joint was measured and referenced in the calculation of affected ankle and foot kinematic variables.

The EMG system had a sampling rate of 1000Hz and it was synchronized with a 20-camera motion capture system at 100Hz (Motion Analysis Corporation, Rohnert Park, CA, USA) with 8 big square-shaped and 4 small square-shaped) inground force plates (AMTI, Watertown, MA, USA) at 1000Hz were used in collecting muscle activity and walking data while the participants walked for 3 different walking trials along the same direction for each of the AFO resistance settings totaling 18 walking trials. The participants were allowed a 2-minute walking adaptation period to get accustomed to each new resistance setting before walking biomechanics data was collected for each of the AFO resistance settings. Each participant walked for 6 different walking trials at their comfortable walking speed for each resistance setting of plantarflexion low (PF1), plantarflexion medium (PF2), plantarflexion high (PF3), dorsiflexion low (DF1), dorsiflexion medium (DF2), and dorsiflexion high (DF3). They had a 5-minute rest period

between each walking trial, and those who requested more rest time were allowed. A safety harness was worn by each participant for their safety throughout the walking trials.

2.4 DATA ANALYSIS

The EMG data were collected with the motion capture system, and both EMG and biomechanical data were calculated in Visual 3D software (C-Motion, Inc., Germantown, MD, USA) where the muscle activity data and the different kinematic and kinetic variables were derived. The biomechanical data was filtered using a 4^{th} order low pass Butterworth filter for the kinetic data (*cutoff frequency of* 60Hz) and kinematic data (*cutoff frequency of* 6Hz). The time series joint angles were derived using the segment coordinate system as the angles in the orientation of the main segment to a reference segment (*usually the most proximal segment to the main segment*) in the Cardan sequence of the capture environment. For example, the ankle angle was calculated as the maximum negative angle between the foot segment and the shank segment as its reference segment in the laboratory's Cardan sequence. The normalized (100% gait cycle) time series data were exported for all gait cycles within each walking trial, and the mean was found for each resistance condition for the different participants. The kinetic variables were calculated using inverse dynamics analysis in visual 3D while using a resolution coordinate system which is the coordinate system of the nearest proximal segment to the joint. The ankle moment, for example, was calculated as the positive moment between the foot segment and the reference shank segment of the paretic leg. The ankle power was also calculated as the product of its

moment vector component and the associated relative angular velocity component of the shank. The normalized (100% gait cycle) time series moment data were exported for all gait cycles within each walking trial, and the mean was found for each resistance condition for the different participants.

The EMG raw signal was stored as analog data exported into Visual 3D. A bandpass filter between 50 and 500Hz was applied to raw data to remove movement artifacts, and a linear envelope was computed from the average Root Mean Square (RMS) value obtained every 50ms in each phase/window interval. The peak value from all walking trials of the plantarflexion and dorsiflexion resistance conditions was derived from all the gait cycles of each muscle, and all frames through the gait cycle were set to the maximum value so that the linear envelope signal was divided by the derived peak to normalize using the maximum to 1.0. This normalization method was used because of the difficulty in isolating a maximum voluntary contraction for stroke participants under isometric conditions [8]. The EMG waveforms were normalized to a 100% gait cycle to account for the different phases of the gait cycle, and the mean of all processed trials for each resistance condition was derived and utilized for each of the participants.

2.5 STATISTICAL ANALYSIS

Simulation modeling analysis (SMA v11.10.16) for single-case time-series data was used in analyzing the data on a case-by-case basis for each participant. This statistical analytical method was used because of its strength in assessing improvements between phases (usually a baseline vs a treatment phase) for a single variable in small sample studies. SMA is a variant of bootstrapping

methods able to evaluate short autocorrelated time-series data by assessing phase differences between a baseline (A) and treatment phase (B) in a non-normal crop of data for single-subject analyses [20,21]. By using the SMA, we were able to evaluate how the change in resistances from one lower level (baseline- A) to a higher level (treatment- B) impacted the different variables for each participant. Specifically, we tested for significant differences in tuning of the low plantarflexion resistance (PF1) to medium (PF2), tuning of the low plantarflexion resistance (PF1) to high (PF3), and tuning of the medium plantarflexion resistance (PF2) to high resistance (PF3), so that we had 3 testing conditions (**PF1 vs PF2**; **PF1 vs PF3**; **PF2 vs PF3**) for each of the selected variables. The lower resistance settings in each pair served as the baseline (Var2-PHASE = 0) entered into the Var 1 (dependent variable column) and the tested effect was the higher resistance setting in the pair (Var2-PHASE = 1). For example, in testing the PF2 vs PF3 pair, PF2 was the baseline and PF3 was the effect. This pattern explained above was also repeated for the dorsiflexion resistance settings (**DF1 vs DF2**; **DF1 vs DF3**; **DF2 vs DF3**), and this analysis was done for each participant independently of others.

SMA generates 5000 randomized iterations of the same data points from the inputted data and then returns a Pearson correlation (r) and p-value for significance using the overall autoregulation (AR) estimate between the tested phases at $\alpha = 0.05$. Using the SMA we analyzed comparisons for the 3 plantarflexion resistance phases (PF1, PF2, and PF3) on the peak tibialis anterior muscle activity at the swing phase of the gait cycle, and the peak soleus muscle

activity at the stance phase of the gait cycle. For the 3 dorsiflexion resistance phases (DF1, DF2, and DF3) we evaluated phase changes in the peak tibialis anterior muscle activity at the swing phase of the gait cycle and the peak rectus femoris muscle activity at the swing phase of the gait cycle.

3. RESULTS

The SMA revealed no significant phase changes for the tibialis anterior muscles at the swing phase of gait and the soleus muscle at the stance phase of gait, for all the participants when the dorsiflexion resistance characteristics of the AFO device were tuned. The time series graph showed systematic changes in the activation patterns of the tibialis anterior and soleus muscles when the dorsiflexion resistance was varied for all participants, but none of the observed changes resulted in a significant phase difference ($p > 0.05$).

Tuning the plantarflexion resistance resulted in significant phase changes for the tibialis anterior mean muscle activity at swing for participant S01 between PF1 and PF2 ($r = -0.788$, $p = 0.0046$) and participant S03 between PF2 and PF3 ($r = -0.705$, $p = 0.0210$) both showing decreased mean muscle activation. Also, the rectus femoris muscle activity in the swing phase was significantly impacted in participant S03 only, with phase changes noted between PF1 and PF2 ($r = -0.638$, $p = 0.0130$) and between PF1 and PF3 ($r = -0.541$, $p = 0.0350$). Participants 02 and 04 showed no significant phase changes when the plantarflexion resistance settings and dorsiflexion resistance was tuned ($p > 0.05$). The time series data for

muscle activity also showed that the AFO systematically changed the muscle activity level of the participants at different resistance conditions.

4. DISCUSSION

This study aimed to investigate the impact of varying the plantarflexion and dorsiflexion resistance of an articulated ankle foot-orthosis (AFO) on the muscle activity level of stroke survivors while walking overground. We used the simulation modeling analysis (SMA) statistical method to analyze how tuning the dorsiflexion resistance settings through 3 different resistances of low (DF1), medium (DF2), and high (DF3) impacted the activities of the tibialis anterior muscle in swing and the soleus muscle in stance for the individual participants. Our study is the first to investigate the impact of increasing dorsiflexion resistance on the soleus and tibialis anterior muscle activity, and we noted that the time series graphs of the different participants showed varied activation patterns at the different dorsiflexion resistance settings. Despite the observed variations in activation patterns of the muscles, there were no significant phase changes in any of the participants for the different dorsiflexion resistance settings, although this may be because we had a limited sample size of 4 participants. A larger sample size will give the advantage of more variability in the characteristics of the population and this could impact findings in future studies.

We also investigated how the tuning of the plantarflexion resistance settings through a low (PF1), medium (PF2), and high (PF3) settings impacted the tibialis anterior and rectus femoris muscles at the swing phase of the gait cycle as both

muscles play an essential role in foot clearance through the swing phase. Stroke survivors with weakness of the tibialis anterior usually have a 'toe dragging' gait pattern or the 'drop foot' presentation so they compensate by increasing the flexion of their knees through the swing phase. AFOs are essential tools in managing this condition to aid toe clearance [22], although a study by Yamamoto *et al*. (2019) revealed that increasing the plantarflexion resistance of their ankle foot orthosis with plantarflexion resistance decreased the tibialis anterior (TA) muscle function of the stroke survivors while also reducing the muscle force exerted by the same TA muscle [22]. Similar to the results in this study, our findings showed that only participants S01 and S03 had significant phase differences with mean reductions in their tibialis anterior muscle activity through the swing phase of the gait cycle. Also, we noted a significant phase change with mean decreases in the rectus femoris muscle activity level for participant S03 when the plantarflexion resistance was increased with significant phase changes between PF1 v PF2 and PF1 v PF3, but our study was not structured to ascertain the long- or short-term implication of this noted changes in the rectus femoris and TA activation with increased AFO plantarflexion resistance. A study that investigated the long-term impact of an AFO with plantarflexion resistance on patients in the recovery phase of stroke also found that the participants significantly decreased TA muscle activity in the swing phase of gait compared to the other phases of gait when the participants used the plantarflexion resistance AFO for 2 months [8]. Studies like this infer the tendency for AFOs to result in muscle atrophy with long-term use if wrongly prescribed for users [6–8] so it becomes necessary to ascertain how the

resistance settings of an articulated AFO device can be optimized to functionally benefit AFO users in the short term and long term.

Utilizing the AFO dorsiflexion and plantarflexion resistance conditions in synchrony could also make some difference in expected results for our study participants. Here, we investigated each resistance condition independently of the other, so that while investigating the plantarflexion resistance we set the dorsiflexion resistance to the low settings (DF1) and vice versa. Tuning the resistances in a synchronized manner would create more interaction between the conditions and may change our study results. This is an aspect we will look to investigate in future studies. Overall, further investigations could also evaluate how this articulated AFO with triple action joint impacts the muscle activity of acute and/or chronic stroke patients with long-term use.

4.1. LIMITATIONS

This study is limited in that we focused only on evaluating the activity level of the muscles when the resistance characteristics of the ankle foot orthosis were tuned without attention to kinetic gait characteristics like the propulsive force and the force generated by the affected muscles in tandem with their activity levels; assessing this could give a clearer picture of the functional level of the muscles at the different resistance settings and could also serve as a guide in prescribing the AFO resistance for optimal performance and the prevention of possible muscular atrophy with long-term use. Another limitation of the study was the small sample size which may have not covered the broad characteristics of the stroke

population knowing that this population is highly heterogenous in distribution. Although, the individual-specific AFO design gives the advantage of a more structured study, having more participants would have offered the merit of greater statistical power and a more universal result for this population. We should also point out that the SMA, as a statistical analytical tool, can be misleading because of the sheer volume of simulations involved, which makes it challenging to identify all significant differences across phases, particularly when dealing with noisy data. The underlying premise of the SMA is that the generated simulation data are representations of the general data from which the analyzed time series data is derived; however, as of the time of this study, this premise has not been validated, hence we advise using caution when interpreting our findings.

5. CONCLUSION AND FUTURE DIRECTION

The study results showed that plantarflexion resistance significantly resulted in phase changes with mean differences for the tibialis anterior and rectus femoris at the swing phase of the gait cycle while the dorsiflexion resistance did not significantly impact the assessed muscles. A decrease in the activation of the TA and rectus femoris may infer decreased functioning of those muscles at the tuned plantarflexion resistance, this makes it necessary for further studies to investigate variables that establish the muscles' functional capacity or exerted force along with activity levels to further inform the optimal prescription of AFO resistances and stiffness characteristics.

6. ACKNOWLEDGEMENTS

Funding for this study was provided by GRACA – 31254.

7. FIGURES

Table 1. Demographics and basic clinical information of each participant.

ID	Age(yrs)	weight (Kg)	SEX	Paretic Limb	Assistive Device	Clinical AFO type	Yrs since stroke
S01	64	87.09	M	Left	cane	Carbon fiber	16
S02	70	84.82	F	Right	cane	Carbon Fiber AFO	3
S03	66	97.62	M	Left	Nil	Nil	4
S04	54	97.52	M	Left	Nil	Nil	1

Table 2. Manual muscle testing (MMT) grades of the affected lower limb and plantarflexion range of motion (ROM) of each participant

S.ID	Hip flexors	Hip extensors	Knee flexors	Knee flexors	Dorsi-flexors	Plantar-flexors	Plantarflexion ROM (deg)
S01	5	5	4	5	-3	2	20
S02	5	5	5	5	3+	4	31
S03	5	5	4	5	4	5	35
S04	5	4+	5	5	4+	4+	32

Table 3. The table shows the effects of changing the dorsiflexion resistance on the activity of the tibialis anterior muscle of the participants in the swing phase of the gait cycle. There were no significant phase changes noted.

Effect of dorsiflexion Resistance on Tibialis Anterior muscle in swing (m.volts)					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	DF1	0.41(0.24)	**DF1 v DF2**	+0.656	0.1658
	DF2	0.76(0.14)	**DF1 v DF3**	+0.711	0.1138
	DF3	0.80(0.11)	**DF2 v DF3**	+0.161	0.6500
S02	DF1	0.82(0.17)	**DF1 v DF2**	-0.033	0.9406
	DF2	0.81(0.13)	**DF1 v DF3**	+0.343	0.4124
	DF3	0.92(0.08)	**DF2 v DF3**	+0.455	0.1956
S03	DF1	0.57(0.16)	**DF1 v DF2**	-0.373	0.4186
	DF2	0.47(0.06)	**DF1 v DF3**	-0.351	0.4226
	DF3	0.46(0.13)	**DF2 v DF3**	-0.059	0.8768
S04	DF1	0.17(0.04)	**DF1 v DF2**	+0.083	0.8466
	DF2	0.18(0.06)	**DF1 v DF3**	+0.568	0.3042
	DF3	0.25(0.08)	**DF2 v DF3**	+0.491	0.3924

Table 4. The table shows the effects of changing the dorsiflexion resistance on the activity of the Soleus muscle of the participants in the stance phase of the gait cycle. There were no significant phase changes noted.

Effect of dorsiflexion Resistance on Soleus muscle activity (m.volts) at stance					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	DF1	0.82(0.15)	**DF1 v DF2**	+0.215	0.6130
	DF2	0.88(0.13)	**DF1 v DF3**	+0.244	0.4180
	DF3	0.89(0.11)	**DF2 v DF3**	+0.020	0.9618
S02	DF1	0.79(0.06)	**DF1 v DF2**	-0.026	0.9274
	DF2	0.78(0.12)	**DF1 v DF3**	+0.566	0.1786
	DF3	0.89(0.07)	**DF2 v DF3**	+0.446	0.2604
S03	DF1	0.89(0.12)	**DF1 v DF2**	-0.291	0.2346
	DF2	0.81(0.15)	**DF1 v DF3**	+0.134	0.7418
	DF3	0.92(0.10)	**DF2 v DF3**	+0.403	0.2038
S04	DF1	0.77(0.24)	**DF1 v DF2**	+0.208	0.2712
	DF2	0.86(0.13)	**DF1 v DF3**	+0.066	0.6382
	DF3	0.80(0.20)	**DF2 v DF3**	-0.157	0.4316

Table 5. The table shows the effects of changing the plantarflexion resistance on the activity of the tibialis anterior muscle of the participants in the stance phase of the gait cycle. Significant p-values are in bold.

Effect of PLANTARFLEXION Resistance on Tibialis Anterior muscle activity (m.volts) in swing					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	PF1	0.79(0.10)	**PF1 V PF2**	-0.788	**0.0046**
	PF2	0.57(0.07)	**PF1 V PF3**	-0.333	0.3872
	PF3	0.69(0.17)	**PF2 V PF3**	+0.422	0.2372
S02	PF1	0.88(0.11)	**PF1 V PF2**	-0.413	0.3182
	PF2	0.75(0.17)	**PF1 V PF3**	+0.123	0.6272
	PF3	0.90(0.09)	**PF2 V PF3**	+0.490	0.2046
S03	PF1	0.64(0.18)	**PF1 V PF2**	+0.066	0.7698
	PF2	0.66(0.05)	**PF1 V PF3**	-0.508	0.0788
	PF3	0.46(0.13)	**PF2 V PF3**	-0.705	**0.0210**
S04	PF1	0.26(0.14)	**PF1 V PF2**	-0.252	0.5088
	PF2	0.21(0.03)	**PF1 V PF3**	-0.326	0.3732
	PF3	0.12(0.02)	**PF2 V PF3**	-0.311	0.3826

Table 6. The table shows the effects of changing the plantarflexion resistance on the activity of the rectus femoris muscle of the participants in the stance phase of the gait cycle. Significant p-values are in bold.

Effect of plantarflexion Resistance on Rectus Femoris muscle activity (m.volts) in swing					
Subject ID	Res	Mean (sd)	Comparisons	r	p-value
S01	PF1	0.80(0.12)	**PF1 V PF2**	-0.252	0.4466
	PF2	0.73(0.15)	**PF1 V PF3**	-0.322	0.4434
	PF3	0.68(0.22)	**PF2 V PF3**	-0.126	0.7114
S02	PF1	0.35(0.097)	**PF1 V PF2**	+0.475	0.1480
	PF2	0.44(0.07)	**PF1 V PF3**	+0.055	0.8478
	PF3	0.36(0.07)	**PF2 V PF3**	-0.505	0.1476
S03	PF1	0.31(0.08)	**PF1 V PF2**	-0.638	**0.0130**
	PF2	0.19(0.06)	**PF1 V PF3**	-0.541	**0.0350**
	PF3	0.21(0.07)	**PF2 V PF3**	+0.152	0.5574
S04	PF1	0.64(0.10)	**PF1 V PF2**	-0.081	0.8884
	PF2	0.62(0.10)	**PF1 V PF3**	+0.186	0.6138
	PF3	0.70(0.20)	**PF2 V PF3**	+0.232	0.5460

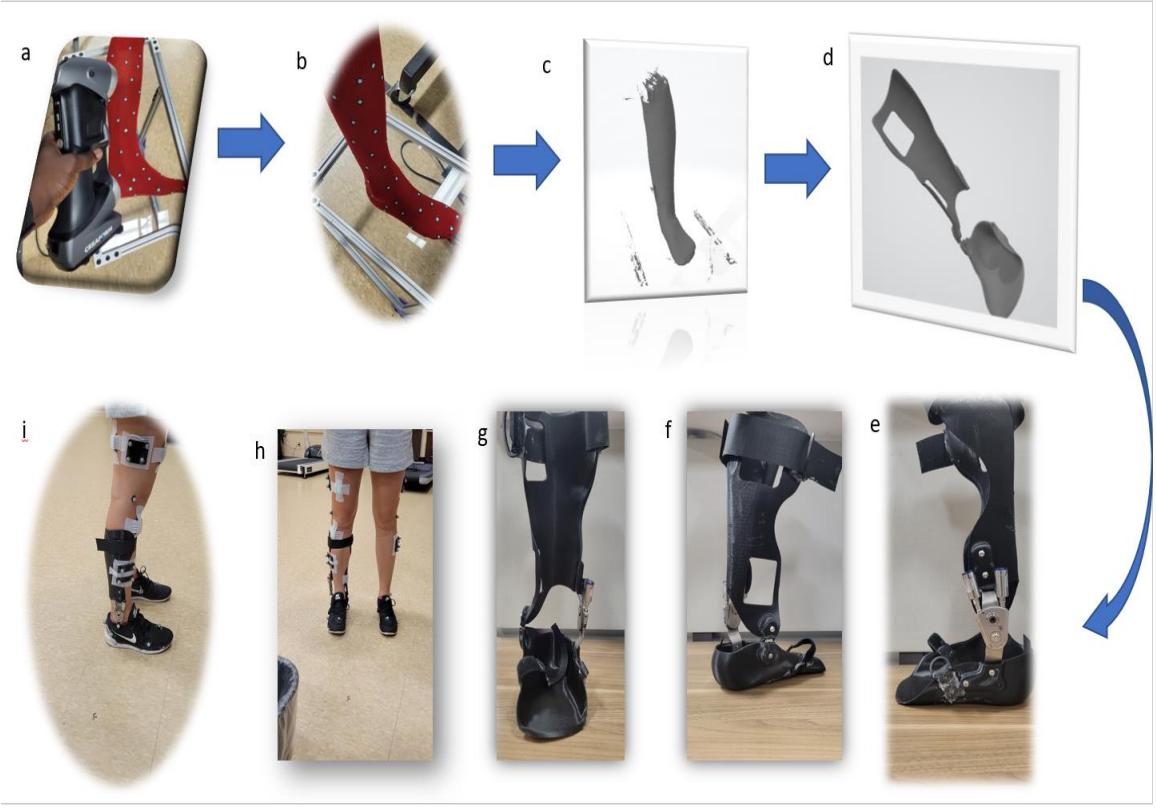

Figure 1: Phases in the fabrication process of the ankle foot-orthosis device for each participant. (a-b) Shows the scanning process; (c) Shows the image from the scan; (d) Shows the design fitted to each participant by the orthotist professional; (e-g) Shows the 3D printed device assembled with the triple action joint and Velcro straps with visible a visible space for the soleus muscle EMG sensor; (h-i) shows a participant donning the device in a pilot study.

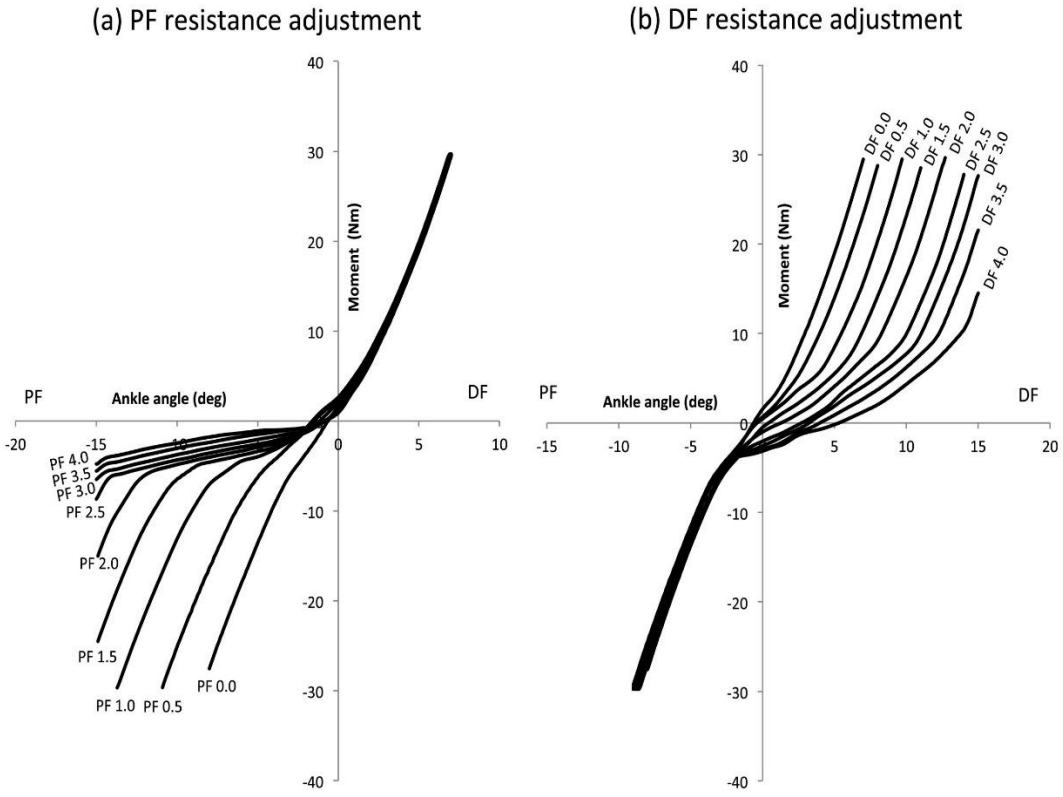

FIGURE 2. The angle – moment relationship for the Triple action joint (Triple Action.® 2.0 by Becker Orthopedic alliance CO.) device assembled with the articulated AFO [6].

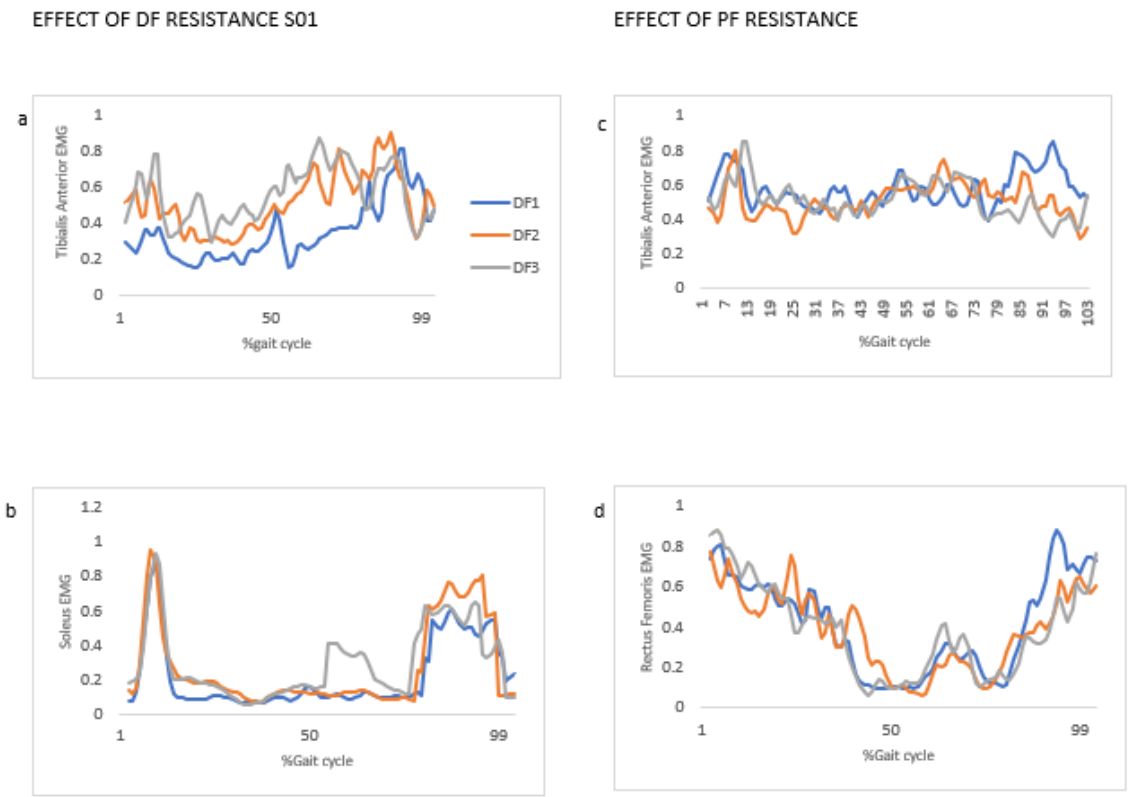

Figure 3. The effect of changing the dorsiflexion resistance of the articulated AFO device on the tibialis anterior and soleus muscles (a – b), and the plantarflexion resistance of the AFO on the tibialis anterior and rectus femoris muscles (c – d) of participant S01.

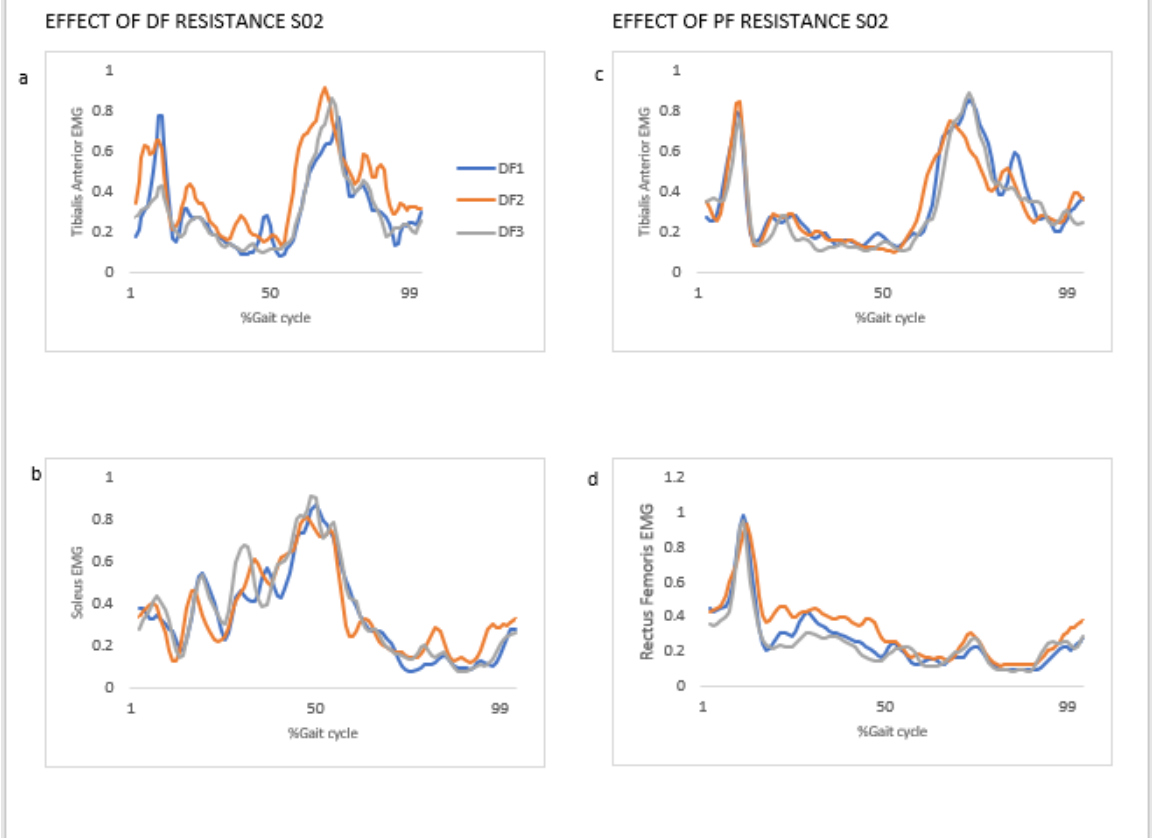

Figure 4. The effect of changing the dorsiflexion resistance of the articulated AFO device on the tibialis anterior and soleus muscles (a – b), and the plantarflexion resistance of the AFO on the tibialis anterior and rectus femoris muscles (c – d) of participant S02.

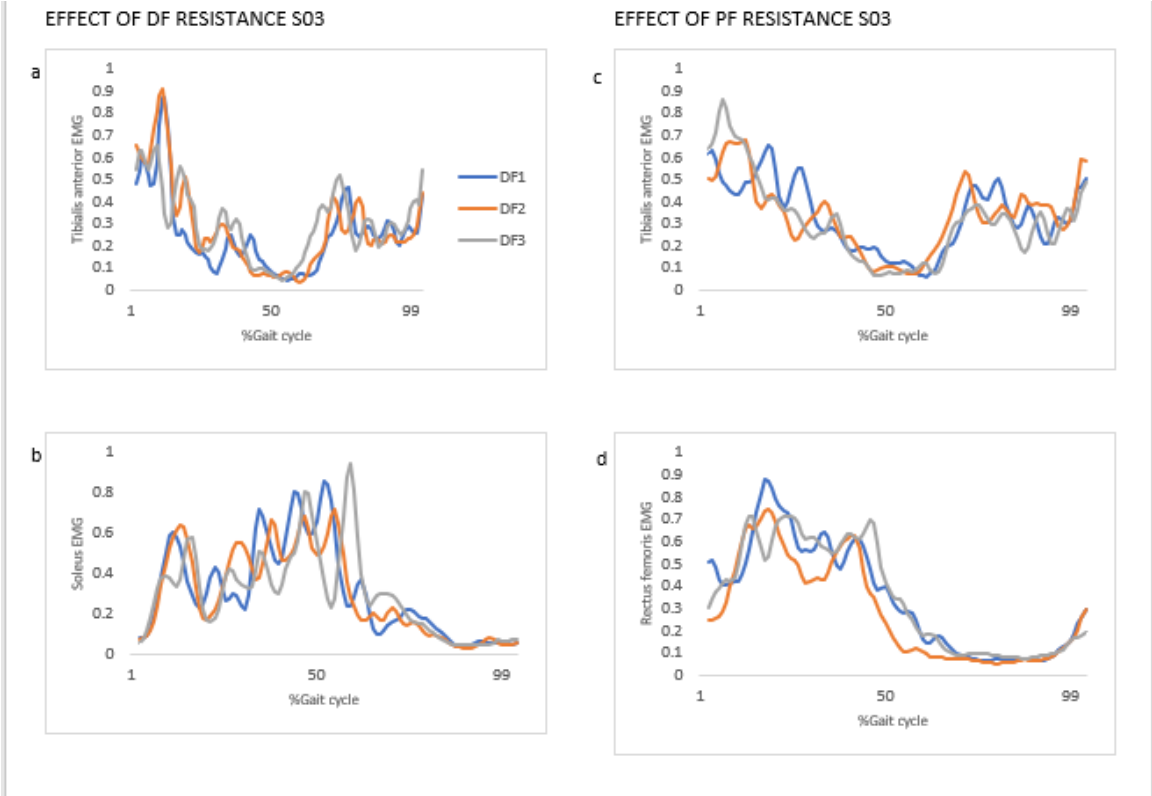

Figure 5. The effect of changing the dorsiflexion resistance of the articulated AFO device on the tibialis anterior and soleus muscles (a – b), and the plantarflexion resistance of the AFO on the tibialis anterior and rectus femoris muscles (c – d) of participant S03.

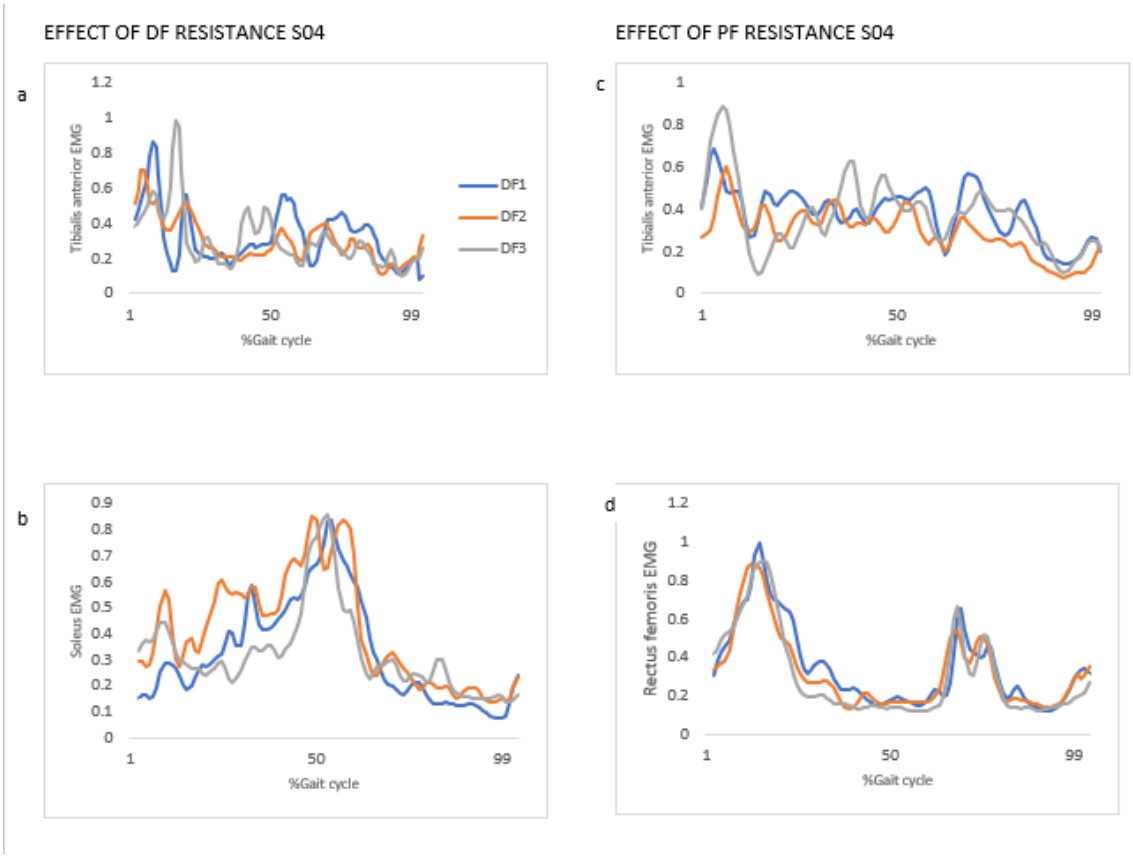

Figure 6. The effect of changing the dorsiflexion resistance of the articulated AFO device on the tibialis anterior and soleus muscles (a – b), and the plantarflexion resistance of the AFO on the tibialis anterior and rectus femoris muscles (c – d) of participant S04.

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CHAPTER 4

TREADMILL HANDRAIL-USE INCREASES PARETIC SIDE MARGIN OF STABILITY IN INDIVIDUALS' POST-STROKE

1. INTRODUCTION

Stroke leads to long-term disability [1], and about two-thirds of acute stroke patients lose the ability to independently ambulate [2] after the cerebrovascular accident. More than 60% of those who attain independent ambulation walk below community walking optimum speeds due to motor weakness, poor coordination, limited endurance, and gait instability [2,3]. Research evidence has shown that the inability to control mechanical gait stability in post-stroke persons limits their ability to attain gait economy due to the increased metabolic cost of controlling balance [4,5]. Hof *et al*. (2008), with an inverted pendulum model, suggested a balance attaining theory in which a perturbing moment - resulting from the short center of pressure (CoP) to extrapolated center of mass (xCoM) distance - must be controlled by timely displacing the CoP, to attain balance [6]. This theory implies that mediolateral (ML) and/or anteroposterior (AP) stability can be attained through the anterior and lateral placement of the foot in motion to control an individual's magnitude of margin of stability (MoS)[6,7], but this balance strategy may be difficult to attain in stroke survivors due to improper gait adaptations resulting from the paresis of their affected leg.

Stroke survivors often present with altered weight distribution patterns and a greatly increased sway in their posture, as well as smaller excursions when

moving their paretic side leg resulting in poor gait biomechanics and exposing some to the risks of falls[7]. Physical therapists look to address these gait asymmetries correlated with balance impairments through therapeutic interventions including the introduction of assistive devices like the walking cane in over-the-ground walking and handrails in treadmill rehabilitation [3,5]. These devices are recommended in some cases for immediate fall prevention in individuals unable to walk without support, while in other cases are recommended for rehabilitation processes to improve gait biomechanics. A previous study by Jeka *et al.* proved the effectiveness of this intervention by showing that light contact sensory cues at the fingertips are sufficient to reduce postural sway in static or dynamic situations in individuals [8,9]. Further research has also corroborated this by using light touch on cane handles. Bellicha *et al*. deduced that the light-grip of an instrumented cane handle reduced AP and ML sway compared to the no-grip of the handle [10], and Kang *et al*. also showed that treadmill walking while holding the handrails facilitated somatosensory changes that improved the plantar foot pressure and foot contact area of his stroke participants, thereby improving their gait [11].

Other studies investigating how assistive device use impacted the gait of stroke survivors found benefits such as compensation for impaired motor control in the affected limb, as well as the improvement of functional mobility and prevention of falls [12,13]. In their study to investigate how treadmill handrail and cane support (in over the ground walking) impact the energy cost of walking in different amputee groups, Houdijk *et al.* showed that lower-limb amputees experienced a

reduction in their energy cost while offered external support through handrails [14], and speculated that the result could be due to changes in balance control. In a similar work, IJmker *et al*. showed that stroke survivors experienced normalization of their step parameters and a reduction in their energy cost of walking on the treadmill while holding the handrail but not with a light touch of the handrail [4,5]. The investigators also suggested that this result was due to the balance support available in the treadmill handrail condition.

Despite this evidence, limited information exists to show how different extents of handrail use influences the biomechanical parameters that define balance to ensure mechanical gait stability in stroke survivors while walking on the treadmill for rehabilitation purposes. Improved understanding of these influences could guide how handrails are used in treadmill walking for stroke patients to attain gait stability during rehabilitation. In this study, we investigated how three handrail-use conditions influence the margins of stability magnitude of stroke survivors during treadmill walking. We looked into **adopted adaptation** control mechanisms while individuals with chronic stroke used a one-sided treadmill handrail while assessing the anteroposterior and mediolateral margin of stability (AP-MoS and ML-MoS), the step width (SW), and lateral foot placement (LFPL) of the paretic and unaffected legs of the participants. We hypothesized that the participants' paretic and non-paretic leg MoS would increase while the SW would decrease when the participants hold the handrails with a Self-selected support compared with a Light Touch or No-Hold of the handrails, as the Ijmker *et al*.

studies showed evidence of reduced energy cost of treadmill walking and reduced SW at a similar condition for stroke survivors [4,5].

2. METHODS

2.1.PARTICIPANTS

Nineteen individuals' post-stroke (12F, 7M; Age = 59.21 ± 13.86) were included in this analysis (Table 1). The study took place at the University of Nebraska at Omaha. Participants included were between the ages of 19-80, had a stroke greater than 6 months (mean years since stroke = 2.16 ± 2.07 years), could walk independently or while using an ankle foot orthosis, a cane or walker for 3 minutes, had a resting heart rate between 40-100 beats per minute and had resting blood pressure between 90/60 and 170/90 mmHg. Individuals were excluded if they had pain in their legs or spine that limits their walking, more than one stroke, evidence of a cerebellar stroke on an MRI, any unexplained dizziness in the last 6 months, visual impairments that prevent viewing content on a screen 5 feet away, Botox treatment within the past 3 months or an inability to communicate with investigators. Written consent was collected from all participants and the study was approved by the Institutional Review Board at the University of Nebraska Medical Center.

2.2.EXPERIMENTAL PROCEDURE

Sixty-five retroreflective markers were attached to each participant's torso and upper and lower extremities. The treadmill gait analysis session took place on a

split-belt instrumented treadmill with 2 embedded six-degree-of-freedom force platforms (Bertec Corp, Columbus, OH) and custom-designed instrumented handrails (Bertec Corp, Columbus, OH). Force data were collected at 1000 Hz from each side using the embedded force platforms and handrails. The marker data were collected using a 16-camera motion analysis system at 100 Hz (Vicon Motion Systems, CO). All treadmill trials were performed at the participants' self-selected speed. To determine the participants' self-selected walking speed, the treadmill was initially set to 0.1 m/s and increased by 0.1 m/s until the participant verbally indicated they were walking at a comfortable speed and the participant proceeded to walk at their comfortable speed for thirty seconds before stopping the treadmill [15,16]. The self-selected speed was determined without using the handrails if they could. Each treadmill condition was three minutes long and the three conditions included: no handrails (NHR), light support handrail (5%HR), and self-selected handrail (SSHR) use. Individuals wore a safety harness for all trials with no body weight support. For the SSHR, participants could use the handrail however they want, and they were instructed to hold onto a side handrail with their non-paretic hand because not all stroke survivors fully recover use of the paretic hand [17]. For the 5%HR, real-time feedback of the handrail forces was displayed on a screen that was in front of the participants. Participants saw either a red "X" or a green "O" in front of them on the screen (*Figure 1*). The screen displayed the green "O" while all force (vertical, horizontal, lateral) applied to the treadmill handrail remained below 5% of the participant's body weight. If the force threshold was exceeded, a red "X" was displayed instantaneously. Prior to

the gait trials, the symbols were explained to the participants, and they were instructed to reduce the amount of force they applied on the handrails if the red "X" appeared. For the NHR, participants were instructed not to use the handrails during the three-minute trial. 3 out of 19 total participants were not able to complete this trial. The participants were not allowed any familiarization period for any of the treadmill handrail conditions, and the order of the three conditions were randomized. Participants were allowed 3-5 minutes or longer of rest between walking trials if needed.

2.3.DATA ANALYSIS

Kinematic and kinetic data from the treadmill conditions were collected in Nexus (VICON, Oxford, UK). Calculations were performed in Visual 3D software (C-Motion, Inc., Germantown, MD, USA) as well as MATLAB (Mathworks, Natick, MA, USA). A 4^{th} order low pass Butterworth filter was used in filtering both the Kinetic (60Hz) and Kinematic (6Hz) data. The MoS, LFPL, and the SW were calculated as shown below.

***Margin of Stability (MoS)*:** The MoS is a variable for defining mechanical gait stability in dynamic situations [18], and more studies are beginning to adopt it to quantify mechanical gait stability in post-stroke populations [19]. While earlier studies had established that the regulation of the position of the center of mass (CoM) relative to an individual's base of support (BoS - the area bounded by the feet) is the primary condition for stability, the limitation of this condition for dynamic situations warranted further work [6,20]. In 2005, Hof et al. introduced an extrapolated center of mass concept (XcoM) on the premise that the CoM path is

extrapolated in the direction of its velocity(vCoM)[20]. Using the XcoM in an inverse pendulum model (*Figure 2*) where the pendulum length 'l' suspends the CoM and 'g' is the gravitational force, they calculated the MoS (*equation 1*) as the perpendicular distance between the position of the XcoM and the BoS, also taken as the tenable range confining the center of pressure (CoP) [6,20].

Where XcoM = $CoM + \frac{vCoM}{\sqrt{\frac{g}{l}}}$ ***equation1***

MoS = BoS - $(XcoM)$ ***equation2***

vCoM is the velocity of the CoM which we calculated using Visual 3D. Also 'l' for both legs was derived as the magnitude of leg length pendulum at the sagittal plane calculated from the leg vectors (distance from the CoM to Ankle Joint center) in vertical and anteroposterior direction. The MoS was calculated using Visual 3D, and we derived the AP-MoS and ML-MoS for both the paretic and non-paretic feet of the participants. The MoS was calculated at initial contact for each limb with the BoS defined using the toe marker of both legs in the frontal plane for the AP-MoS, and the calcaneal marker for both legs in the sagittal plane for the ML-MoS. The anteroposterior BoS for the leg was calculated as the distance from the anteroposterior location of the toe markers to the anteroposterior location of the CoM while we calculated the mediolateral BoS as the distance from the mediolateral position of the lateral calcaneal marker to the mediolateral position of the CoM.

***Step width*:** The SW was defined as the mediolateral distance between the lateral malleoli markers of the leading and the trailing legs at initial contact of each of the limbs [3]. This analysis was done using Visual 3D (C-Motion, Germantown, MD, USA).

***Lateral foot placement*:** The LFPL was calculated as the mediolateral distance between the CoM and lateral malleolus of the leading limb at initial contact [3]. This analysis was done using Visual 3D (C-Motion, Germantown, MD, USA).

All the variables were averaged across the 3 minutes trials.

2.4.STATISTICAL ANALYSIS

We performed a multilevel-model analysis (hierarchical linear models) in R/R-studio (R Core Team, 2021; RStudio Inc., Boston, MA, USA) using the '1merTest' package (Kuznetsova, Brockhoff & Christensen, 2017) to evaluate the effects of the handrail conditions on each variable for the affected and unaffected side. This multilevel-model analysis is based on the assumptions of linearity, and it was used because it has less strict assumptions than a standard regression model and it enables incorporation of variables from every level [21]. With this model, we can evaluate unique intercepts for each participant individually. The model can evaluate variances at its different levels so that it identifies changes within a participant, and variables that change across all individuals. The multilevel-model was done to analyze the paretic and non-paretic side AP-MoS, ML-MoS, SW, and LFPL. The first step in the model tested the effect of the handrail conditions on the different variables individually, and when this was found significant, a post-

hoc comparison was also done for the different handrail conditions, to compare the between effects of the 3 different handrail conditions for each variable.

3. RESULTS

Relationship of handrail use conditions on AP-MoS

Paretic AP-MoS: Handrail-use-effect significantly improved the model fit for paretic AP-MoS (X^2 (2, N=19) = 8.22; p = 0.0164). Tukey's method for pairwise post-hoc comparison showed a significant increase from the NHR to the SSHR conditions (t = -2.96, p = 0.0151), while there was no significant difference between both the NHR and 5%HR (t = -1.925, p = 0.1474), and the 5%HR and SSHR (t = -1.106, p = 0.5172) (*Figure 3*).

Non-Paretic AP-MoS: Handrail-use-effect significantly improved the model fit for non-paretic side AP-MoS (X^2 (2, N = 19) = 8.99; p = 0.0112). Tukey's method for pairwise post-hoc comparison showed a significant difference with an increase from the NHR to SSHR conditions (t = -3.127, p = 0.0100), while there was no significant difference between both the NHR and 5%HR (t = -1.863, p = 0.1655), and the 5%HR and SSHR (t = -1.349, p = 0.3787) (*Figure 3*).

Relationship of handrail use conditions on ML-MoS

Paretic ML-MoS: Handrail-use-effect significantly improved the model fit for the paretic side ML-MoS (X^2 (2, N=19) = 11.95; p = 0.0025). Pairwise post-hoc comparison showed significant differences with an increase from the NHR to the

SSHR conditions (t = -2.998, p = 0.0138), and from the 5%HR to the SSHR (t = -3.244, p = 0.0074), while there was no significant difference between the NHR and 5%HR (t = 0.040, p = 0.9991) (*Figure 3*).

Non-Paretic ML-MoS: Handrail-use-effect significantly improved the model fit for the non-paretic side ML-MoS (X^2 (2, N=19) = 12.64; p = 0.0018). Pairwise post-hoc comparison showed a significant decrease between the NHR and SSHR (t = 3.712, p = 0.0012) conditions, and between the 5%HR and SSHR (t = 2.480, p = 0.0471), while there was no significant difference between the NHR and 5%HR (t = 1.388, p = 0.3584) (*Figure 3*).

Relationship of handrail use conditions on SW

Paretic SW: The handrail-use-effect significantly improved the model fit for the participants' paretic side SW (X^2 (2, N=19) = 27.26; p < 0.001). Specifically, there were significant differences with decreases noted in the SW from the NHR to the 5%HR conditions (t = 4.817, p = 0.0001), and from the NHR to the SSHR (t = 6.003, p < 0.0001), while there was no significant difference between the 5%HR and SSHR (t = 1.399, p = 0.3531) (*Figure 4*).

***Non-Paretic SW*:** The handrail-use-effect significantly improved the model fit for the participants' non-paretic SW (X^2 (2, N=19) = 26.75; p < 0.001). Specifically, there were significant differences with decrease in SW from the NHR to the 5%HR conditions (t = 4.836, p = 0.0001), and from the NHR to the SSHR (t = 6.127, p < 0.0001), while there was no significant difference between the 5%HR and SSHR (t = 1.246, p = 0.4351) (*Figure 4*).

Relationship of handrail use conditions on LFPL

Paretic LFPL: The effect of handrail use did not improve the model fit for the placement of the paretic LFPL of the participants (X^2 (2, N=19) = 2.34; p = 0.3101) (*Figure 4*).

***Non-Paretic LFPL*:** The effect of handrail use improved the model fit for the placement of the non-paretic LFPL of the participants (X^2 (2, N=19) = 36.78; p < 0.0001). There was a significant difference with decreases from the NHR to the 5%HR conditions (t = 3.861; p = 0.0014), NHR to the SSHR (t = 7.824, p < 0.0001), and from the 5%HR and SSHR (t = 4.231, p = 0.0005) (*Figure 4*).

4. DISCUSSION

In this study, we investigated how three different treadmill handrail-use conditions impacted the margin of stability in stance of stroke survivors. Stroke survivors experience an unstable gait due to their altered bodyweight distribution resulting from the imbalance of their paretic or weak leg [7]. Our results showed that the participants' mean paretic side ML-MoS and paretic and non-paretic side AP-MoS increased when they had increased support from the treadmill handrails at the SSHR condition and this was consistent with our hypothesis. Only the non-paretic side ML-MoS decreased in opposition to our hypothesis, and we believe that this was due to the stepping strategy adopted by the participants. Our findings suggest that there can be improved stability margins for stroke survivors when they have increased support from the treadmill handrails compared to a light

touch. These results were like those of a study by IJmker *et al*. in which they investigated how handrail hold and light touch impacted stroke patients' step parameters, neuromuscular activity, and energetics. Their findings demonstrated the participants walked with smaller SW, improved step symmetry, and expended less energy in walking on the treadmill during the handrail hold condition compared to a light touch of the handrail. The authors suggested their findings could be due to improved stability during the handrail hold condition [5]. Lack of balance control or stability in an individual could be a cause for an increased energy cost of walking which may be alleviated by offering assistive devices or walking aids to affected individuals; this has been noted in some studies for different clinical populations [5,14].

A commonly adopted motor control mechanism for attaining stability and increasing AP and ML MoS is by taking wider and / or longer steps, which invariably results in increased SW and step length [22]. Here we observed that the handrail condition significantly decreased the SW for the paretic and nonparetic side, specifically between the NHR and 5%HR conditions, and between the NHR and SSHR conditions. The observed progressive reduction in SW with increased handrail support may have resulted from the added BoS from the treadmill handrails. The concept of the MoS considers the position and excursion of the CoM in relation to the BoS of an individual as defined by the feet [20], and previous studies have shown that light touch and force contact from an object impacts the control of both factors, by essentially enabling a better control of the CoM to ensure postural stability and improve step parameters [11,23–25] Following these

studies, we also speculated that the use of the treadmill handrails could have ensured the participants better controlled the excursion of their CoM and attain a better step symmetry resulting in the observed decrease in SW. While using the handrails, the participants were able to place the non-paretic foot closer to the CoM and decrease the SW. This probable adaptation mechanism was reinforced in the observed significant decrease in the LFPL of the non-paretic foot at the 5%HR and SSHR conditions distinct from the NHR conditions.

This LFPL of the non-paretic leg decreased significantly with the use of the treadmill handrails from the NHR condition through the 5%HR to the SSHR condition. This result was expected, considering the observed decrease in mean SW for both the paretic and non-paretic feet of the participants as mentioned above. Also, all the participants in this study were instructed to hold the handrails with their non-paretic hands as not all stroke survivors fully recover the use of their paretic hands after stroke occurrence [17,26]. We believe that the observed significant decreases in the non-paretic foot LFPL at the 5%HR and SSHR conditions could have occurred because of the position of the handrail support, also noting that the treadmill handrails had no main effect on the paretic leg LFPL. We speculated that the participants had the opportunity to lean towards the support of the handrail on the non-paretic side enabling them to bring their non-paretic foot closer to the CoM as noted in the decreased LFPL. This adaptation could have resulted in the observed decreased mean non-paretic leg ML-MoS, a possible diminished stability of the non-paretic leg in stance, resulting from increased weight support due to a likely sway towards the handrails while the

participants leaned to the handrails on the non-paretic side at the 5%HR and SSHR conditions. Although, the accompanying decrease in the non-paretic LFPL sways us to the possibility that the decreased ML-MoS resulted from this foot placement rather than a postural sway.

Previous studies have shown that the light touch of the fingertip on a stable object surface sends sensory information to the brain, and this information could aid in mediating postural sway in individuals standing on one leg, both legs, and persons with balance issues [9,10,23]. Our study investigated how different treadmill handrail conditions impacts the margin of stability in stance for stroke survivors. The high level of importance of treadmills in the rehabilitation of stroke patients for high intensity training and walking re-education makes this study clinically relevant [27]. Studies have reported improved symmetry, longer paretic leg single stance period, improved walking distance and speed, and a more normalized paretic leg muscle activation pattern following treadmill rehabilitation [27–29]. This study is the first to report how different handrail use condition impacts the stability of stroke survivors in treadmill walking using the margin of stability measures. We showed that the use of treadmill handrails with a self-selected force could better improve the anteroposterior and mediolateral margin of stability of the paretic limb of stroke patients when compared to light-touch handrail use. Also, we presumed that the participants tend to lean towards the handrail when on the non-paretic side and this decreased their non-paretic leg mediolateral MoS following the decreased lateral placement of the non-paretic foot. Though, the participants also recorded increased non-paretic leg anteroposterior stability.

Despite the positives in this study, it is limited first in that we are not certain if the observed adaptations in the participants during treadmill walking would be retained following rehabilitation, or if these results are transferrable to overground walking with the use of a cane or other walking aids. Also, we did not evaluate the paretic limb load at the different treadmill handrail conditions, and this information could be a helpful addition for rehabilitation purposes since a major goal in post-stroke rehabilitation is to encourage increased weight bearing or use of the paretic limb as this can contribute to regaining walking ability [25]. Although, we may want to predict that increased margin of stability with a self-selected hold or force contact on the handrail may encourage increased weight bearing, a study that reported how handrail use in treadmill walking impacted lower extremity muscle activation reported increased activation of the muscles at light touch handrail use compared to force-contact use [5]. Also, in overground walking, a Buurke *et al*. study reported reduced burst duration and amplitude of lower extremity muscles while the stroke survivors walked with assistive devices, and they also mentioned the evaluated muscles developed a normalized activation pattern with these devices [30]. While both studies may infer that the paretic limb load decreases with assistive device use, our study is not structured to address this information. Future studies can investigate the retention tendencies of acquired adaptations that ensure paretic limb stability with handrail use during treadmill rehabilitation and evaluate the impact of assistive device use on paretic leg loading and muscle activity level in relation to the observed level of stability in stroke survivors. These information could further inform handrail-use in treadmill

rehabilitation. Also, the results from this study may not be translatable to overground walking with the use of the cane since the treadmill environment differs from walking overground [31]; this is also a limitation that should be tackled in future studies.

In making treadmill rehabilitation decisions, factors such as the phase of stroke (*acute or chronic*), initial level of stability and tendency of the patient to fall and observed changes in progression-to-recovery will have to be considered by the physical therapist in making decisions on the use of support devices (*handrails and/or harness*) during interventions [28]. While we understand that support devices are necessary for individuals unable to walk independently and those at immediate risks of falls, it is necessary to evaluate how this devices impact stability and gait in individuals in the chronic phase of stroke as some may benefit more from walking without assistive device use. Our findings inform the use of treadmill handrails in the rehabilitation of stroke survivors, as one of the major goals of rehabilitation is to improve the stability of the paretic leg of these individuals in order to encourage increased weight transfer to this leg while walking. Increased walking stability could invariably aid in recovery of leg strength, while also reducing fall risk in the stroke population. Stroke survivors may gain greater benefits from the self-selected use of treadmill handrails during rehabilitation compared to a light-touch, but there is also a need to exercise caution in making such therapeutic choices due to likely adaptation mechanisms that could result in a possible decreased non-paretic leg mediolateral margin of stability despite the observed improved mediolateral and anteroposterior margins

of stability for the paretic leg. Factors such as the patient's level of independence, and their ability to walk with or without the use of the treadmill handrails could be helpful information in guiding the clinician or Physical therapist's decision, knowing that the end goal of rehabilitation is to wean off assistive devices to ensure peak independence.

5. CONCLUSION

This study demonstrated that self-selected handrail use can increase the anteroposterior and mediolateral margin of stability of the paretic or affected leg of stroke survivors compared to a light touch or no handrail use when walking on a treadmill. The handrail conditions also impacted the non-paretic leg by increasing the anteroposterior and decreasing the mediolateral margin of stabilities. These findings inform the use of handrails in treadmill walking for stroke survivors, indicating that unstable stroke survivors and those prone to falls may benefit more when walking on the treadmill with a self-selected handrail force compared with a light handrail force, though caution should be applied in making decisions on handrail use due to probable adaptations that could lead to a possible non-paretic leg margin of stability; a likely opposition to rehabilitation goals in stroke survivors capable of independent ambulation.

Further research will give a more vivid structure on how handrail use could impact paretic leg use in treadmill rehabilitation.

6. ACKNOWLEDGEMENTS

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7. FIGURES

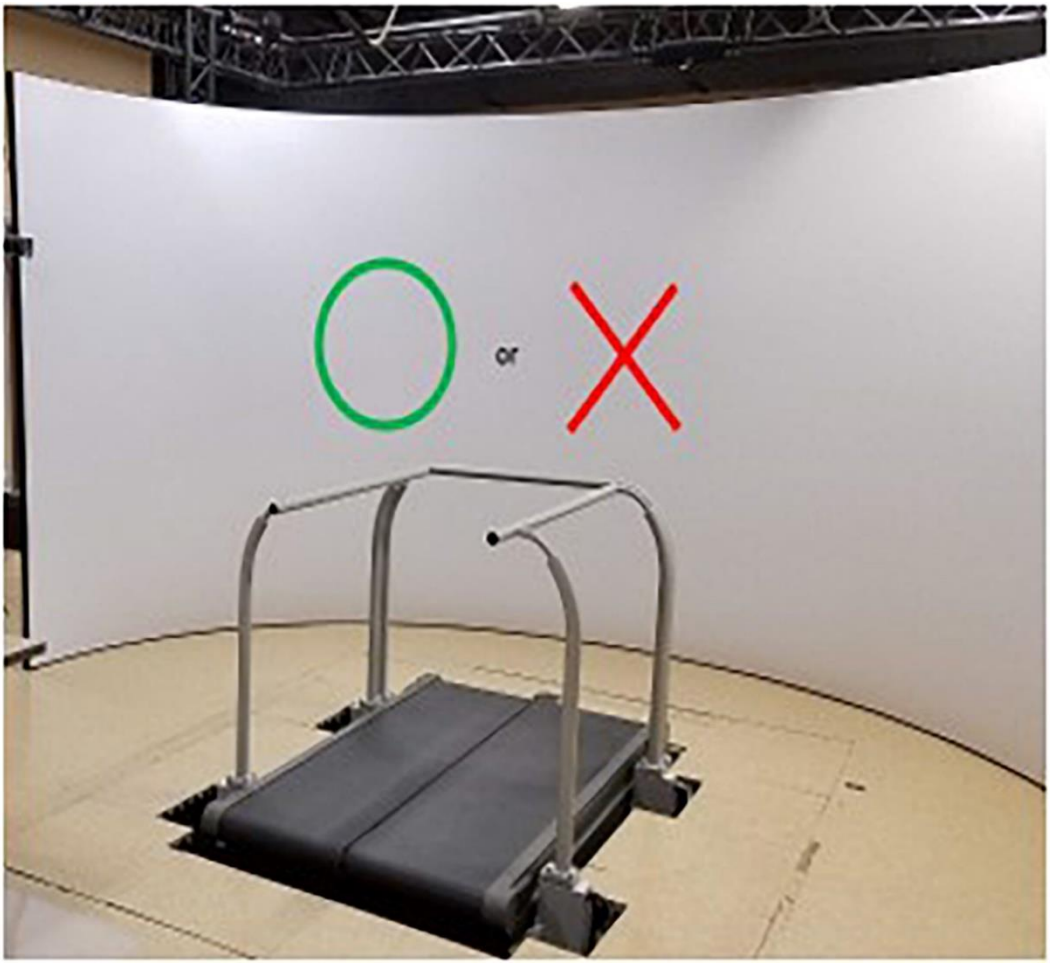

Figure 1. Experimental setup of the real-time biofeedback for the Light Handrail support treadmill condition. The projection screen showed the participants the green circle when they had less than 5% of their bodyweight on the handrail, and it turns to the red X when they had more than 5% of their bodyweight on the handrail support.

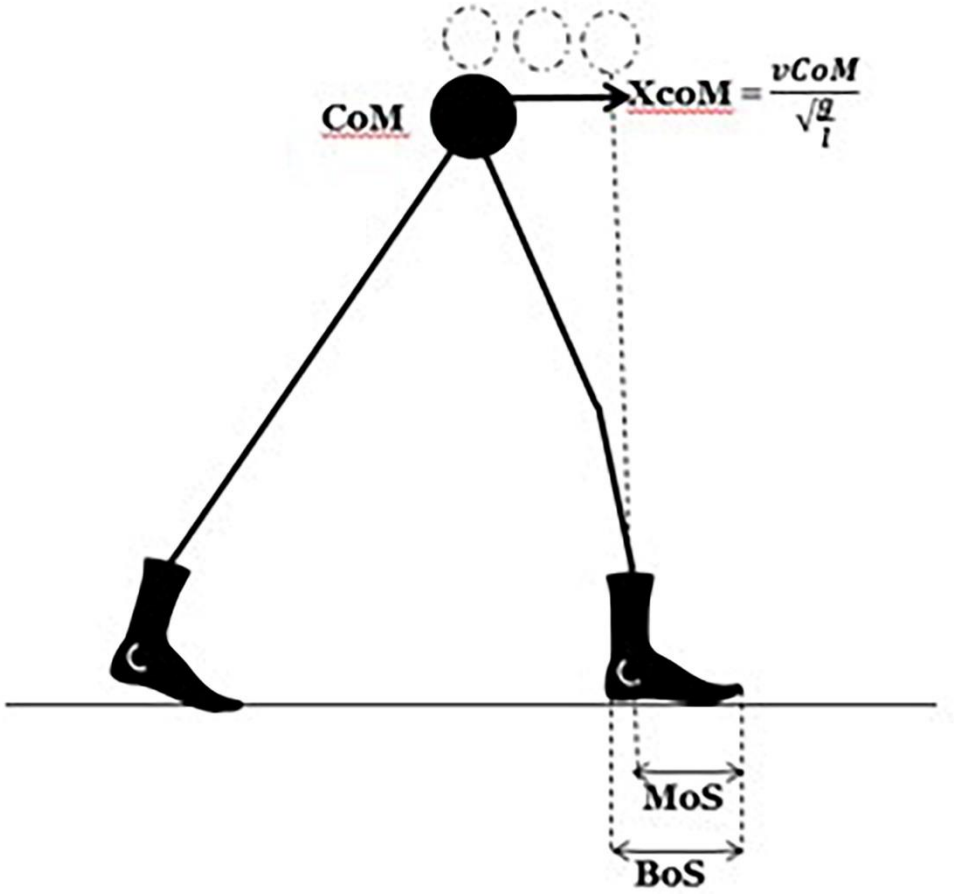

Figure 2. The inverse pendulum model shows the motion of the black mass (CoM) suspended on the leg length (pendulum height 'l') as the leading foot moves in mid-stance. The dotted circles show the swing of the CoM to account for the extrapolated CoM (XcoM), which represents the position of the CoM about its velocity (VcoM). 'g' represents the gravitational acceleration, and the anterior limit of the BoS in relation to the foot is shown.

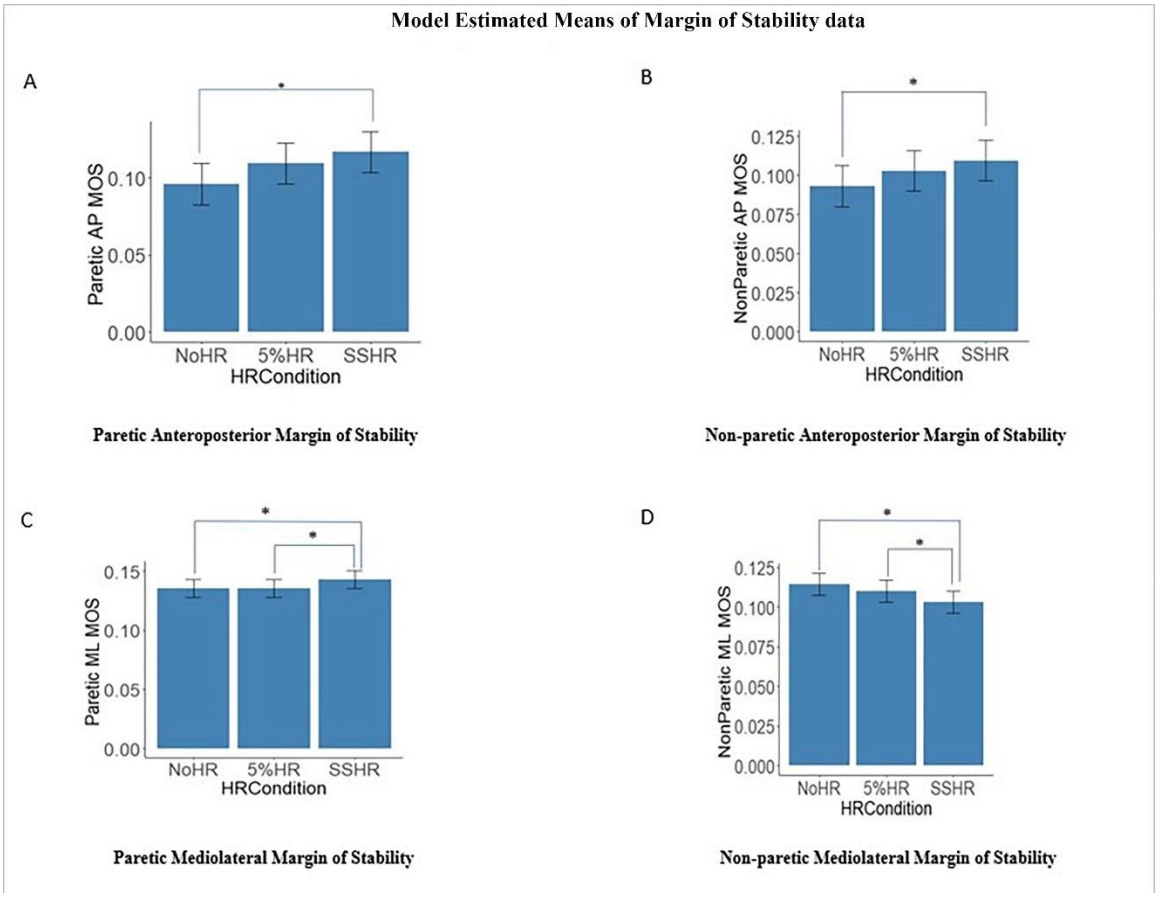

Figure 3. Graph of the model estimated means of margin of stability values with the standard deviation bars for the participants' paretic and non-paretic limbs both in the anteroposterior and mediolateral walking planes. * entries indicate where significant relationship exists between the 3 different trials of No handrail (NoHR), Light handrail (5%HR), and Self-selected handrail support (SSHR).

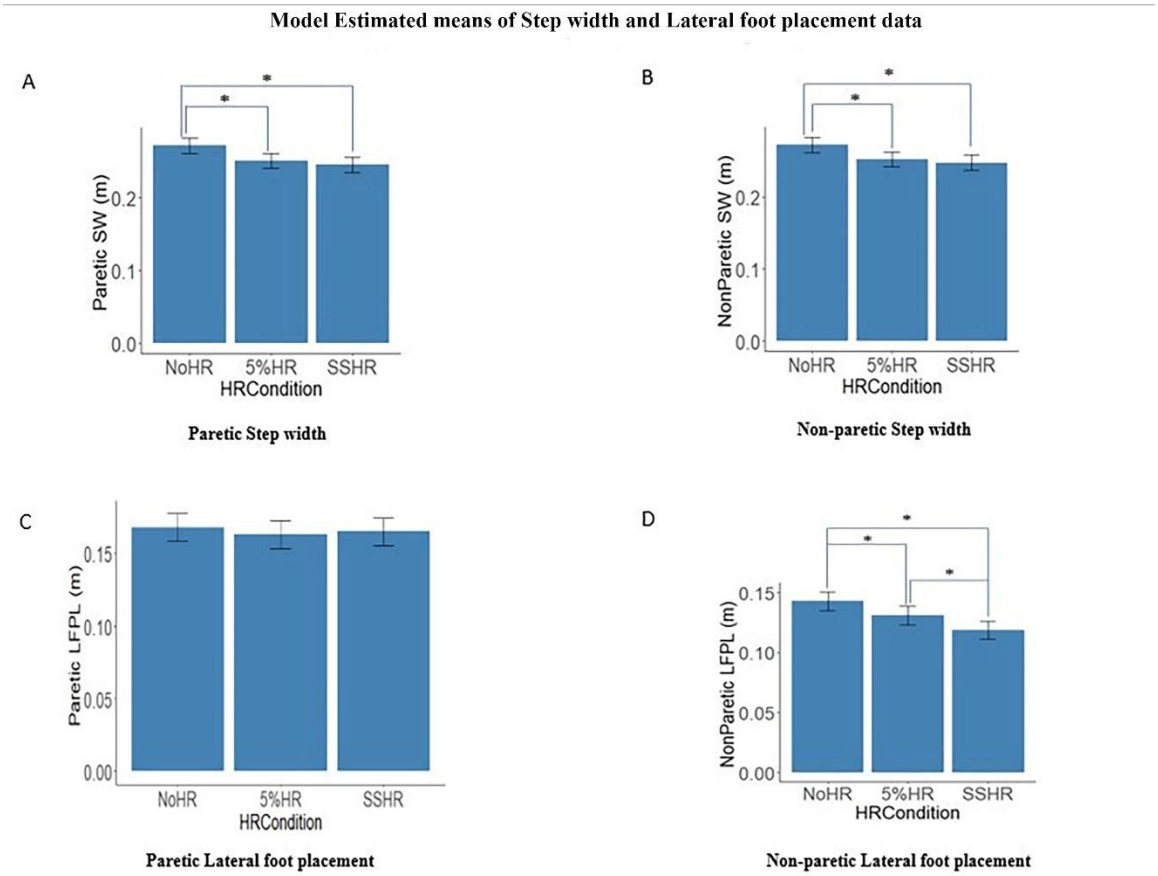

Figure 4. Graph of the model estimated mean Step width (SW) and Lateral foot placement (LFPL) values with the standard deviation bars for the participants' paretic and non-paretic limbs. * entries indicate where significant relationship exists between the 3 different trials of No handrail (NoHR), Light handrail (5%HR), and Self-selected handrail support (SSHR).

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CHAPTER 5

1. THESIS DEFENSE CONCLUSION

The purpose of this thesis was to investigate how assistive devices impact the walking biomechanics of stroke survivors in ensuring independent walking. This thesis was sectioned in two parts.

First, we investigated the impact of regulating the plantarflexion and dorsiflexion resistance of an articulated ankle foot-orthosis (AF) on the biomechanics and muscle activity of the study participants. This aspect of the study was structured in a way that we utilized an individual specific ankle foot orthosis design for each of the participants using 3D scanning and 3D printing, and the AFO device was assembled with a triple action joint which enabled independent tuning of the dorsiflexion and plantarflexion resistance of the AFO. Three plantarflexion resistance settings (low-PF1, medium-PF2, and high-PF3) and 3 dorsiflexion resistance settings (low-DF1, medium-DF2, and high-DF3) were evaluated and the participants were asked to walk over the ground on force plates, while their kinematics and kinetics data, and the muscle activity data were collected using electromyograph sensors synchronized with the motion capture system. Simulation modelling analysis was used in evaluating the changes for 3 plantarflexion resistances (PF1 v PF2; PF1 v PF3; PF2 v PF3) and 3 dorsiflexion resistances (DF1 v DF2; DF1 v DF3; DF2 v DF3) in 5 participants (S01-S05), and this statistical method was used because it enables detection of significant changes in phase between a baseline measure and a treatment measure for individual participants. We were able to detect how the plantarflexion resistance settings impacted the peak dorsiflexion moment, knee flexion angle at

initial contact and the ankle angle at initial contact, and how the dorsiflexion resistance settings of the AFO impacted the peak dorsiflexion angle at stance, peak knee extension moment, peak ankle positive power at stance, and the peak plantarflexion moment. Our findings showed that the articulated AFO device systematically changed the ankle and knee joints kinematics and kinetics of the participants. Specifically, we noted significant phase changes in the peak dorsiflexion angle for all the participants and the peak positive ankle power in participants S01, S02, and S05 when the dorsiflexion resistance was tuned, while the plantarflexion resistance resulted in significant phase changes in the peak ankle dorsiflexion moment (S01, S04, and S05), the knee flexion angle at initial contact (S01 and S02), and the ankle angle at initial contact (S01, S03, and S04). Also, only the plantarflexion resistance resulted in significant phase changes with a mean decrease in the activity level of the rectus femoris (S03) muscle and the tibialis anterior muscle (S01 and S03) at the swing phase of the gait cycle. These findings showed the AFOs ability to distinctly impact the gait characteristics of stroke patients as previous studies had shown when they had stroke survivors walk with similar devices on a split belt treadmill [1,2]. We concluded that the device may be a viable option enabling ease in clinically regulating or tuning AFO resistance settings, although further investigations are necessary to ensure a more systematic prescription mechanism that will prevent possible complications like muscle atrophy with long-term use.

Secondly, we utilized a visual biofeedback system to modulate 3 treadmill handrails-use conditions (No handrail use- NHR; Light touch- 5%HR, and self-selected hold-

SSHR) in stroke survivors as they walked on a split belt treadmill (with force instrumented handrails) at their comfortable walking speed. Our goal was to investigate how the 3 handrail-use conditions impacted the margins of stability, lateral foot placement, and the step-width of these participants. We found that the participants increased their anteroposterior and mediolateral margin of stability of the paretic or affected leg when they held the handrails with a self-selected hold compared to a light touch or no handrail use when walking on the treadmill, and the same SSHR condition impacted the non-paretic leg by increasing the anteroposterior and decreasing the mediolateral margin of stabilities of the participants. Also, the step-widths of the paretic and non-paretic leg decreased significantly, while only the lateral foot placement of the non-paretic leg significantly decreased with increased hold of the handrail (SSHR) compared with no hold and light touch. We concluded that caution should be applied in making decisions on handrail use due to probable adaptations that could lead to a possible non-paretic leg margin of stability; a likely opposition to rehabilitation goals in stroke survivors capable of independent ambulation.

The results from both studies show that assistive devices are able to aid improvements in the biomechanics and walking characteristics of stroke survivors though further research could give a more vivid stricture on to prevent unwanted adaptations and possible complications due to long term use.

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