

Study Title

Biofeedback to Increase Propulsion during Walking after Stroke

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## Protocol

1. **Project Title:** Biofeedback to Increase Propulsion during Walking after Stroke

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### 3. **Abstract:**

Background/Purpose: Approximately 15,000 Veterans are hospitalized for stroke each year. Impairments of motor control and the subsequent functional limitations in ambulation are the most common manifestations and regaining the ability to walk is the number one stated goal of Veteran stroke survivors. Forward propulsion of the body's center of mass is a cardinal feature of gait that depends on the generation of appropriate anterior-posterior ground reaction forces. Decreased propulsive force generation by the paretic limb of stroke survivors has been identified through both simulation and cross-sectional studies as a major contributor to walking dysfunction. Extrinsic verbal feedback from a therapist is the standard approach used during gait retraining to improve propulsion generation. However, this key component of gait is not directly observable by therapists and patients are often unable to sense propulsion generation due to impaired intrinsic feedback, specifically deficits in somatosensation and proprioception, hindering recovery of paretic propulsion and compromising walking function. The objective of this study is to provide preliminary evidence that biofeedback as an adjuvant to therapists' verbal feedback will improve propulsion and enhance walking function for Veterans post-stroke.

Subjects: Thirty individuals  $\geq$  6-months post-stroke will participate. Additional study criteria include: 1) Ambulation of household distances without physical assistance to advance or support the paretic leg; 2) Unilateral leg paresis confirmed by a score of  $< 32$  on the Fugl-Meyer Motor Assessment; 3) Step length asymmetry (paretic  $>$  non-paretic step length); 4) Ambulation without an assistive or orthotic device.

Methods: Participants will be randomized to either an experimental group that will train with propulsion biofeedback from commercially available pressure-sensitive insole sensors (Biofeedback group;  $n=15$ ) or a control group that will train with standard therapist-provided verbal feedback alone (Standard group;  $n=15$ ). The 12 session (3X/week for 4 weeks) gait training intervention will be delivered by a physical therapist-led team. For participants in the Biofeedback group, prior to the first intervention session, the baseline amount of pressure exerted by the paretic forefoot during late stance will be determined. The insole area underlying the forefoot will then be calibrated to produce a tone when pressure exceeds 5% of this baseline pressure. This threshold will be progressively increased at regular intervals throughout the intervention period to ensure participants are training at their challenge-point to improve propulsion of the paretic limb. An insole of similar thickness will be worn in the shoe of the non-paretic leg for symmetry and comfort but will not produce a tone during the intervention. Those in the Standard group will not wear insoles during intervention but will receive verbal feedback alone regarding propulsion of the paretic limb during gait training. Therapist-provided verbal feedback will be used to instruct participants on achieving and/or maintaining appropriate movement patterns that contribute to propulsion generation. For

both groups, the therapist will choose from a standardized bank of gait activities, suitable to each participant's ability level. The goal for total walking time for each session will be 50 minutes: 5, 10-minute bouts with a 2-minute rest between each bout.

Outcome Measures: Paretic limb propulsion is our primary outcome measure. Secondary measures include the Six Minute Walk Test, Functional Gait Assessment, Fall Self-Efficacy, temporal-distance gait measures and gait kinematics, and lower extremity strength measures, all of which will be measured pre- and post-intervention.

Data Analysis Plan: Descriptive statistics will be provided for all outcome measures. To identify the effect of the intervention, differences between the pre- and post-training assessment within each group (i.e. change scores) will be calculated. To test our hypotheses, we will apply independent sample t-tests to the change scores of the Biofeedback and Standard group. Hypothesis testing will be conducted at a two-sided  $p < 0.05$  level.

#### **4. Background:**

Improved walking ability is considered one of the most important outcomes of stroke rehabilitation<sup>1</sup> with walking speed a widely used measure of recovery<sup>2</sup> and surrogate for functional walking ability.<sup>3</sup> Forward propulsion of the body center of mass (COM) is a cardinal feature of normal, efficient adult gait that depends on the generation of appropriate anterior-posterior ground reaction forces (AP GRFs). Decreased propulsive force generation by the paretic limb of stroke survivors during walking has been identified through both simulation and cross-sectional studies as a major contributor to walking dysfunction.<sup>4-7</sup> Bowden et. al.,<sup>8</sup> demonstrated that propulsion symmetry during walking is able to differentiate individuals post-stroke as limited community versus community ambulators and that those who achieve clinically meaningful improvements in walking speed also improve propulsion symmetry. With this direct link between paretic propulsive ability and poststroke walking performance, it is important to develop rehabilitation interventions that target paretic propulsion.

The primary contributor to the propulsive impulse in healthy controls is activity of the ankle plantarflexors.<sup>9, 10</sup> Similarly, in individuals post-stroke, coordinated activity of the plantarflexor muscles in late stance and preswing positively correlated with paretic propulsive impulse.<sup>11</sup> From work in our own lab, Clark and colleagues, in their investigation of modular organization of muscle activity post-stroke revealed that deficits in independent modulation of the quadriceps and plantarflexors resulted in decreased propulsion of the paretic compared to the nonparetic leg.<sup>12</sup> Peterson and colleagues<sup>6</sup> further determined that hip extension angle was a significant predictor and positively correlated with propulsive impulse of the paretic leg. Given that activity of the ankle plantarflexors and hip extension angle are primary contributors to paretic propulsion,<sup>6</sup> Awad and colleagues implemented a gait rehabilitation intervention consisting of Functional Electrical Stimulation (FES) to the ankle plantarflexors (to increase muscle activation) while participants ambulated at their maximum speed (to facilitate greater hip extension) on a treadmill with overhead body-weight support.<sup>13</sup> Post-intervention, improvements in paretic propulsion were observed, demonstrating the responsiveness of this impairment to rehabilitation. However, the modalities used to achieve this improvement, FES and a treadmill with a body-weight support system, are resources not

available to many rehabilitation clinics. Additionally, this intervention strategy required 2-3 rehabilitation personnel to implement. More frequently in stroke rehabilitation when these resources are not available, therapists provide verbal feedback to encourage a patient (with right hemiparesis for example) to “take a large step” (with the left leg to increase hip extension of the paretic, right leg) or “push through to the floor” (with the right foot to increase plantarflexor activation). This type of feedback, with attention focused on the patient’s movement, defined as “internal-focus feedback” may not be sufficient as patients post-stroke often lack intrinsic feedback mechanisms (i.e. decreased proprioception, decreased somatosensation) to translate these verbal commands into desired movements. Furthermore, the therapist is unable to objectively determine the magnitude propulsion force generated by the patient. Therefore, this pilot study will test the use of biofeedback (external-focus feedback) as an adjuvant to therapist-provided (internal-focus) feedback to determine if this relatively simple and cost-effective intervention strategy will serve to increase paretic propulsion during gait.

Provision of feedback is a widely known requisite for motor learning to occur.<sup>14</sup> Physical rehabilitation following stroke primarily consists of re-learning motor skills that have been impaired or lost secondary to CNS damage. Intrinsic feedback mechanisms (i.e. proprioception, somatosensation), are crucial to motor skill learning in healthy adults, but are either impaired or absent post-stroke. Therefore, extrinsic feedback from a therapist or from technology becomes a crucial alternative feedback source in rehabilitation.

How best to augment the patient’s own impaired feedback mechanisms is a critical factor for rehabilitation scientists to determine in the development of efficacious rehabilitation practices. A recent systematic review<sup>15</sup> found that augmenting feedback through the use of biofeedback was superior to therapist feedback in terms of performance of lower limb activities in the short term, with the effect being maintained beyond the intervention, indicating that learning had occurred. These previous results in training muscle activity, joint position and limb position provides the impetus of this pilot study to examine the use of biofeedback in the acquisition of paretic limb propulsion during gait.

A systematic review on the use of biofeedback across a variety of lower limb activities following stroke determined that biofeedback with an external-focus was superior to therapist-generated feedback.<sup>15</sup> In this pilot study specialized shoe insoles that generate an audible tone when a prescribed threshold of loading on the forefoot during late stance is achieved (external-focus feedback) will be tested as an adjuvant to therapist-provided feedback. We hypothesize individuals who receive biofeedback intervention as an adjuvant to therapist-provided feedback will demonstrate improved paretic limb propulsion compared to those who receive therapist-provided feedback alone.

As achievement of walking independence, not necessarily the reduction in impairment, is often the standard for successful rehabilitation<sup>16</sup> and consequently the focus of rehabilitation services,<sup>17</sup> there exists a high prevalence of inefficient walking strategies among persons with chronic stroke.<sup>18</sup> Although a restitution-based versus compensation-based approach to rehabilitation implicitly seems most prudent, there is a current need to demonstrate the link between restoration of impairments and functional gains. Awad and

colleagues<sup>19</sup> recently demonstrated that improvement in propulsion of the paretic leg, following a 12-week locomotor training program, predicted improvement in distance walked, providing support for rehabilitation practice based in restitution of impairments. Aim 2 of this proposal will compare the effect of our two interventions on functional gait ability as determined by long-distance walking ability, dynamic balance and self-efficacy.

## **5. Specific Aims:**

Specific Aim #1: Compare the effect of two interventions for improving paretic limb propulsion in individuals with impaired, asymmetric gait post-stroke: standard therapist-provided verbal feedback (“verbal feedback group”) versus standard therapist-provided verbal feedback plus propulsion biofeedback (“biofeedback group”).

Hypothesis #1: Improvement in paretic propulsion during natural gait (i.e., tested without feedback) will be greater for the biofeedback group than for the verbal feedback group.

Specific Aim #2: Compare the effect of two interventions for improving functional mobility in individuals with impaired, asymmetric gait post-stroke: standard therapist-provided verbal feedback (“verbal feedback group”) versus standard therapist-provided verbal feedback plus propulsion biofeedback (“biofeedback group”).

Hypothesis #2: Improvement in functional mobility will be greater for the biofeedback group than for the verbal feedback group, as measured by the Six-Minute Walk Test, Functional Gait Assessment and Modified Falls Self Efficacy Scale.

## **6. Research Plan:**

This will be a prospective, single-blind, RCT enrolling individuals at 6-months post-stroke. Consent for participation and enrollment will occur in two parts: 1) Screening Consent and 2) Intervention Consent. Part 1, Screening Consent, consists of physical screening to determine study eligibility.

Participants who meet all inclusion/exclusion criteria will be enrolled and randomized to either the experimental (Biofeedback) or control (Verbal Feedback) group. Individual treatment allocations will be in sealed envelopes which will be opened only on enrollment of the next eligible participant.

Priority for participation in this study will be given to volunteers who are Veterans. To optimize our capability to recruit Veterans we will conduct our rehabilitation intervention at the Malcom Randall VA Medical Center in Gainesville FL.

Recruitment. Potential participants will be recruited from the Database (IRB# 457-1999) of the VA Brain Rehabilitation and Research Center (BRRC), a VA RR&D Center of Excellence. The database contains over 400 individuals with diagnosis of stroke who have been screened by a neurologist and interdisciplinary team to gather preliminary information about medical, motor and cognitive status. All individuals in the database have signed informed consent and agreed to be contacted for research participation.

*Inclusion criteria:* 1) Diagnosis of stroke, 2)  $\geq 6$  months < 10 years post-stroke onset, 3) Medically stable, 4) 18-85 years of age, 5) Impaired lower extremity sensation confirmed by a score of < 12 on the Fugl-Meyer Sensory Assessment or < 50% correct on monofilament testing on the plantar surface of the foot,<sup>20</sup> 6) Community-dwelling, 7) Step length asymmetry (paretic step length > non-paretic step length); this asymmetry has been determined to be correlated with minimal propulsive force of the paretic leg<sup>4</sup>, 8) Unilateral lower extremity paresis confirmed by a score of < 32 on the Fugl-Meyer Motor Assessment,<sup>20</sup> 9) Able to ambulate without an orthotic device, 10) Able to ambulate without an assistive device, 11) Ambulation of household distances without physical assistance to advance or support paretic lower extremity.

*Exclusion criteria:* 1) Presence of a neurological condition other than stroke, 2) Pain upon ambulation, 3) Receiving physical therapy services for mobility and/or gait, 4) Severe arthritis or orthopedic problems that limit passive ranges of motion (knee flexion contracture of  $-10^\circ$ , knee flexion ROM <  $90^\circ$ , hip flexion contracture >  $25^\circ$ , and ankle plantar flexion contracture >  $15^\circ$ ).

Inclusion and Exclusion criteria will initially be determined by medical record review. If following the medical record review a potential participant remains eligible, they will be scheduled for an in-person screen to determine if they meet the criteria listed below. Potential participants will sign the screening Informed Consent Form and then the following screening assessments will be administered:

1. Lower Extremity Fugl-Meyer Motor Assessment: The participant's ability to move their paretic lower limb will be assessed in the supine, sitting and standing position.
2. Lower Extremity Fugl-Meyer Sensory Assessment: The participant's ability to sense light touch and movement of their paretic lower limb will be assessed in the supine and sitting position.
3. Observational Gait Assessment: Participant will walk a distance of 14 meters, two times at their self-selected walking pace. The physical therapist assessor will observe participant's gait for asymmetry.
4. Range of Motion: Range of Motion of the hips, knees and ankles of both lower limbs will be assessed. This assessment will take place in the supine and sitting positions.
5. Monofilament Testing: A monofilament will be touched to the sole of the participant's paretic foot and they will be queried if they can feel the monofilament.

Participants who meet eligibility criteria following the screening assessment will be invited to sign Part 2 Consent, the Intervention Informed Consent Form. Intervention Informed Consent allows for baseline testing and study participation.

Procedure. Thirty individuals will be randomized to either the *Verbal Feedback Group* (n=15) or the *Biofeedback Group* (n=15) group. Participants in the *Biofeedback Group*

will wear a commercially available pressure-sensitive insole (Pedar, Novel Electronics, Inc.) in the shoe on the paretic lower extremity. Prior to the first intervention session, participants in the *Biofeedback Group* will walk wearing the pressure-sensitive in-soles to determine the baseline amount of pressure exerted by the paretic forefoot during late stance as the limb transitions to the pre-swing position. The insole area underlying the participant's forefoot will be calibrated to produce a tone when pressure exceeds 5% of baseline. This threshold will be progressively increased at regular intervals throughout the intervention period to ensure participants are gait training at their challenge-point. An insole of similar thickness will be worn in the shoe of the non-paretic leg for symmetry and comfort but will not produce a tone. Participants in the *Verbal Feedback Group* will not wear insoles during intervention.

Intervention. Intervention (12, 60-minute sessions, 3X/week for four weeks) will occur in an outpatient research setting. Participants will be supervised by a licensed physical therapist and wear a gait belt during all activities. The therapist will choose from a standardized bank of gait activities, suitable to each participant's ability level, such as: 1) walking along a straight indoor path, 2) negotiating obstacles, 3) walking up and down inclined surfaces, and 4) walking in a distracting environment. These varied environments will be utilized to assure participants continued engagement in the intervention. The goal for total walking time for each session will be 50 minutes: 5, 10-minute bouts with a 2-minute rest between bouts. This is the typical length and intensity of outpatient rehabilitation sessions for ambulatory patients discharged from inpatient rehabilitation.

*Biofeedback Group:* Biofeedback (external-focus feedback) will be provided as an adjuvant to therapist-provided feedback during the intervention. Therapist feedback is described in the "Verbal Feedback Group" section below. Participants will be instructed that a tone will sound when they "push off with their (paretic) leg to swing it forward" when the participant-specific pre-programmed threshold is exceeded.

*Verbal Feedback Group:* Therapist-provided internal-focus feedback ("directed towards components of body movement"<sup>21</sup>) will be used to instruct participants on achieving and/or maintaining appropriate movement patterns that contribute to propulsion generation. Feedback will be customized for each participant, but will generally focus on 1) shifting body weight onto the paretic side during stance 2) rolling over the front of the foot during late stance, 3) walking with symmetrical step length on both sides, 4) pushing off with the paretic leg when stepping forward. If participants are performing any/all of these movements well, feedback will be used to acknowledge and encourage continuation of the appropriate movements.

Outcome Measures. Assessments will take place pre- and post-intervention and conducted by a licensed physical therapist, blinded to group assignment.

The primary outcome for Specific Aim #1 will be Paretic Limb Propulsion (PLP).

Paretic Limb Propulsion (PLP). The propulsive impulse will be derived from the time integral of the positive A-P GRF for each leg.<sup>5</sup> Participants will walk along a 10 meter pathway equipped with embedded force platforms (Advanced Medical Technology, Inc.). The force plates are flush with the floor and are not an obstacle or tripping hazard.

GRFs will be measured throughout the stance phase for both legs. The A-P GRF component, normalized to body weight will be used to derive PLP.

Secondary outcome measures will be collected and assessed to more explicitly describe participants' gait. We will conduct exploratory analyses on these measures to guide formulation of future studies' aims and hypotheses in this line of research. Additional outcome measures will include:

1) Hip, knee and ankle angle data from the LE's will be acquired using a modified Helen Hayes marker set with rigid clusters on the pelvis and each thigh, shank and foot segments and recording the movement of these markers at 100 Hz using a 12 camera motion capture system (Vicon Motion Capture Systems, Oxford, UK). Data will be processed using Visual 3D (C-Motion, Inc., Germantown, MD). We are particularly interested in hip extension angle during late stance given its known contribution to forward propulsion.<sup>6</sup>

2) Spatial-temporal gait variables of stride time, stride length, step time, step length, step width and gait speed will be captured while walking across a GAITRite instrumented walkway (CIR Systems Inc, Havertown, PA),

3) Surface EMG will be recorded from the soleus (SO) and medial gastrocnemius (MG) of both legs because of their known contribution to forward propulsion.<sup>10</sup>

The primary outcome for Specific Aim #2 will be long-distance walking function as measured by the Six-Minute Walk Test (6MWT).<sup>22</sup>

Six Minute Walk Test: reflects a person's ability to maintain a moderate amount of exertion over a period of time. It has been identified as an excellent measure of poststroke walking capacity and community ambulation<sup>23, 24</sup> as well as indicative of community reintegration post-stroke.<sup>25</sup> Participants will walk for a total of six minutes at their comfortable walking speed and the total distance walked will be recorded. Participants will be guarded by research personnel and will be permitted to stand and rest or sit and rest during the six minute time-frame as needed.

Secondary Outcomes for Specific Aim #2 are:

Functional Gait Assessment (FGA),<sup>26</sup> a 10-item clinical gait and balance test during which participants perform the following activities: walk at normal speeds, at fast and slow speeds, with vertical and horizontal head turns, with eyes closed, over obstacles, in tandem, backward and while ascending and descending stairs. The FGA is a superior test of dynamic balance to other oft-used clinical performance tests such as the Performance-Oriented Mobility Assessment, the Berg Balance Scale, and the Dynamic Gait Index all of which have reported ceiling effects in community-living older adults.<sup>27</sup> Excellent test-retest<sup>28</sup> and intra- and inter-rater reliability<sup>29</sup> has been established patients post-stroke. Additionally, a FGA cut-off score of 22/30 to classify those who are at increased risk for falls has been established.<sup>26</sup> Although fall-incidence is beyond the scope of this current pilot study we hypothesize that increased contribution of the



paretic leg to forward propulsion would lead to improved dynamic balance and more stable gait, decreasing fall incidence.

Modified Falls Efficacy Scale (MFES)<sup>30</sup> is a 14-item questionnaire based on the Falls Efficacy Scale (FES),<sup>31</sup> modified for people with chronic stroke. It includes the 10 items from the FES plus 4 items considered complex for people with stroke and is designed to measure self-perceived fear of falling during task performance. Significant differences in MFES scores between patients in a Falls and Balance Clinic and healthy older adults ( $p < 0.05$ ) attests to the scales' validity.<sup>30</sup> Long-distance walking ability, dynamic balance during complex gait and falls self-efficacy will inform us regarding if restitution of paretic limb propulsion during gait translates into improvements in function and improved quality of life. These results will inform the next study in this line of research.

Lower Extremity Strength Testing: Muscle strength of both limbs will be assessed utilizing a hand-held dynamometer<sup>32</sup>. The dynamometer is placed between the hand of the assessor and the participant's limb, similar to a manual muscle test, with the advantage of the dynamometer providing a quantified measurement of force.

Participants will be instructed to contract their muscle and move their limb against the dynamometer. Muscle strength will be recorded.

Videorecording. For participants who signed the video recording consent, we will periodically videorecord training sessions. This will allow the intervention therapists to view the participant's training and strategize on how to progress the intervention.

Videorecordings will also provide the therapists feedback on how they can best assist the participant. Assessment sessions will also be periodically recorded. This will provide assessment therapists feedback on their implementation of the assessments.

Videorecordings may also be used in scientific presentations. Participants will be informed when videotaping is occurring.

## **7. Possible Discomforts and Risks:**

The risks undertaken in the walking therapy programs of the study are no greater than those in everyday physical therapy clinics where persons who have had a stroke are challenged daily to exercise, train, practice and improve beyond their current abilities. Safety in therapy is mandatory. Research personnel will walk beside participants during all aspects of the exercise intervention and all aspects of the assessment that assess gait. Participants may experience some fatigue while being tested or during the therapy sessions. Should they become tired, they will be allowed to rest. Participants may experience temporary muscle soreness as they increase the use of their trunk and limbs during the walking intervention. There is a risk of falling during walking activities, but guarding by research personnel will minimize the risk. Stroke patients, including those in this study, are at risk for another stroke, coronary heart disease related event and cardiac related death, regardless of intervention.

## **8. Possible Benefits:**

Subjects participating in this study may see improvements in their walking speed, balance, and/or the amount of walking that they are able to do. They may become more confident in their balance and walking ability.

## 9. Conflict of Interest:

There are no conflicts of interest apparent for any of the investigators.

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