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The Comparison of Utilizing Functional Electrical Stimulation Device Versus Ankle Foot Orthosis Brace and the Effect on Participants' Activities of Daily Living After a Cerebrovascular Accident

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Abstract

A cerebrovascular accident occurs in less than 24 hours resulting in chronic physical and cognitive deficits. However, little is known about how a cerebrovascular accident impacts the individual's activities of daily living (ADL). This study sought to compare and analyze the impact of two therapeutic devices on patients' responses to ADL questionnaire items from baseline to 6 months. It was hypothesized that the Functional Electrical Stimulation (FES) would be more effective and have a greater positive impact on patients' response of ADL items than the AFO brace. In this study, subjects' responses were recorded on the Stroke Impact Scale questionnaire (SIS) that contained eight sections. Subjects' responses were later assessed by calculating the average from each section, which was then summed up by adding all the averaged scores for a total score. Overall, the results were centered around time and treatment in a 2 by 2 mixed ANOVA. The independent variables were time and treatment with the dependent variables being the eight sections from the SIS with the focus on the ADL section. A primary limitation is the SIS is a unilateral questionnaire only administered to the subjects who have experienced a stroke thus providing a subjective view of the responses. The FES device was found to be neither inferior nor superior to the AFO brace and the results did not support the hypothesis.

Keywords: Psychology, Cerebrovascular Accident, Therapeutic devices, FES, Functional Electrical Stimulation, AFO, Ankle Foot Orthosis, The Stroke Impact Scale, SIS, Activities of Daily Living, ADL

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by

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A cerebrovascular accident (CVA) can be defined as "a transient episode of neurological dysfunctions caused by focal brain, spinal cord, or retinal ischemia, without acute infarction" (Coupland, et al., 2017). In other words, a CVA occurs in a short amount of time - less than 24 hours- yet can result in chronic physical, cognitive, and psychosocial deficits. It is suggested that 15 million people worldwide suffer from a CVA every year, of which 5 million become disabled (Sabut et al., 2011). Since numerous individuals have been, and continue to be, affected by CVAs, it's important to determine what effect a CVA has on performance of everyday tasks, as defined by activities of daily living (ADLs), in order to develop new therapeutic interventions.

Background of Cerebrovascular Accident

There are two types of CVA; ischemic and hemorrhagic. An ischemic CVA, accounting for 83% of diagnosed CVAs, is due to a blockage preventing blood flow and oxygen intake in the brain (Taylor, 2008). A hemorrhagic CVA, accounting for 17% of CVAs, is the rupture of an aneurysm. An aneurysm is a weakening in the wall of the blood vessel that expands outwards. Eventually, the wall becomes too thin and ruptures, releasing large amounts of blood into the brain (Taylor, 2008). In both cases, neurons begin to die, which can result in motor and cognitive deficits. These deficits can affect an individuals' quality of life; shown by the lack of ability to participate in everyday tasks and engage in social interactions (Lai, Studenski, Duncan, & Perera, 2002). There have been many advancements in recovery, like clinical therapeutic programs, in order to help individuals cope with the physical and cognitive deficits that may result from a CVA. However, there is currently no clinical procedure to prevent a CVA, only

precautionary measures to minimize the occurrence of a CVA (Mayo, Wood-Dauphinee, Cote, Durcan, &Carlton, 2002). Some preventive measures include: early usage of aspirin, monitoring blood pressure and glycemic control, following a heart healthy diet, and a consistent exercise regimen (Gurol and Kim, 2018).

Physical Deficits resulting from a CVA

The physical deficits of a CVA can include hemiplegia, foot drop, and spasticity. Hemiplegia is when one side of the body is paralyzed contralateral to the lesion (Taylor, 2008). In other words, if the right side of the brain has a CVA, the left side of the body is affected and vice versa. When the individual is hemiplegic, the individual could experience the inability to dorsiflex or plantarflex the foot due to weakness and spasticity, also known as foot drop (Ward, 2011). An individual with foot drop may experience tripping or falling while walking due to the lack of muscular activation in the foot. This risk decreases the individual's ability to function independently and perform activities many associate with daily life. Notably, foot drop interferes with the individual's ability to independently function in their home and/or community (Perry, Garrett, Gronley, & Mulroy, 1995). Foot drop causes early onset of fatigue, muscle weakness, and reduced balance that are attributed to the hemiplegia (Bulley et al., 2015), which can prevent the individual from being mobile in their community and home, further hindering their quality of life.

Another common symptom in individuals who had a CVA is spasticity (Watkins, et al., 2002). Spasticity is caused by deficits in voluntary control of muscles resulting in continuous contraction of affected muscles (Watkins et al., 2002). This could be a result of disturbance in locomotor skills that aid in neural feedback mechanisms between the peripheral nervous system (PNS) and the central nervous system (CNS) (Belda-Lois et al., 2011). A CVA may affect the

connection between the PNS and CNS, inhibiting the neural feedback an individual may have while controlling the movement of their arm, hand, foot and/or ankle, and muscle contraction in the arm and leg. This lack of neural feedback may result in spasticity of the muscle, forcing the muscle to continuously contract. This can cause pain and discomfort throughout the muscle, making it difficult to walk (Ward, 2012). Ward (2012) reviewed the pathophysiology and onset of post-CVA spasticity and found that while there is no universal definition of spasticity, the pathophysiology occurs when the CNS becomes hyperactive and the motor neuron response to sensory input is disintegrated (Ward, 2011). As such, spasticity occurs in the muscle of the side most affected from CVA due to the miscommunication of feedback. This involuntary activation affects the individual's quality of life by limiting their ability to partake in ADLs (Ward, 2012).

Rehabilitative Therapies

Common rehabilitative therapies to aid in physical deficits include exercises for handling curbs, stairs, and ramps as well as getting in and out of a car (Perry et al., 1995). Likewise, locomotor skills are retrained as they are often affected when an individual survives a CVA (Flansbjer, Holmback, Downham, Pattern, & Lexell, 2005).

AFO

To help with foot drop and spasticity, physical rehabilitation devices such as ankle foot orthosis (AFO), wheelchairs, and canes are used as the first solution. An individual experiencing foot drop and spasticity may be more prone to trip and fall requiring an AFO, which is an assistive device recommended to individuals who have experienced a CVA and present the physical deficit of foot drop (Nolan &Yarossi, 2011). AFO is a brace that wraps around the calf and ankle and extends underneath the foot strapping in the lower part of the leg securing it into a 90 degree angle (See Appendix F). The AFO helps the individual clear the ground during swing

phase to prevent the foot and ankle from rolling when the patient is walking. AFOs have been known to improve mobility as well as improving the quality of life indirectly in individuals with CVA (Carse, Bowers, Meadows, & Rowe, 2011).

There are two types of AFOs; metal and thermoplastic. Metal AFOs are most common for individuals with CVA with severe spasticity (Cakar et al., 2010). Thermoplastic AFOs are preferred by individuals with CVA due to their appearance and weight; a thermoplastic AFO is lighter than a metal AFO. Cakar et al. (2010) determined the differences in outcomes between the different kinds of AFO by measuring the balance and walking ability in individuals with CVA. Sixty-one participants were asked to perform various physical tasks in the Berg Balance Assessment (Berg, Wood-Dauphnee, Williams, and Maki, 1989), a physical test that measures balance, pattern of walking, and fall risk while walking with a thermoplastic AFO. In addition, participants were asked to continue to wear the AFO at home while doing their walking activities. Cakar et al. (2010) found that wearing a thermoplastic AFO improved balance and reduced fall risk (Cakar et al., 2010). Limitations of using an AFO include lack of ankle mobility, muscle weakness due to using the brace often, appearance of brace, and lack of shoes able to fit around the brace (Bulley et al., 2015).

FES

Even though the most common rehabilitative tool for managing foot drop is an AFO, there are new devices that have yielded promising results to manage foot drop and increase quality of life such as Functional Electrical Stimulation devices (Bulley et al., 2015). A Functional electrical stimulation (FES) device is an alternative approach to treat foot drop by electrically stimulating the damaged nerve in the leg (Walkaide, 2019). FES first emerged as an alternative treatment option for individuals with a CVA in 1978 (Sabut et al. 2011; Yan, Hui-

Chan, & Li, 2005). The FES device stimulates the dorsiflexor muscle of the foot when the foot is in the swing phase (Walkaide, 2019) (See Appendix E). The electrical stimulation of the dorsiflexor muscle may prevent the individual from tripping and falling. Prior research has found that FES usage increases natural gait pattern, improves stability, and provides confidence in walking in individuals with CVA (Walkaide, 2019). Sabut et al. (2011) investigated the effects of changes in walking ability with FES device therapy with standard of care versus with only standard of care. Sabut et al. (2011) found that participants who participated in FES therapy combined with standard of care therapy showed improvements in motor functions in participants with foot drop than with standard of care therapy alone. In a 12-week time period, participants in the FES with standard of care group achieved dorsiflexor strength of 75% versus those in the standard of care group who only achieved 27% of strength. Moreover, participants in the combination therapy group exhibited a reduction in plantar flexion spasticity thus allowing the gastrocnemius and soleus muscle to relax after staying in a contracting position preventing the individual from lifting his/her foot in neutral position. FES has also been attributed with beneficial walking effects with improvements in walking ability and voluntary muscle control (Everaert, Thompson, Su Ling Chong, & Stein, 2010). FES is used to stimulate the peripheral nerve by increasing the motor-potential and providing a carry-over effect where once the FES device is turned off, the affected leg continues to walk as if it is stimulated. This effect continues the momentum for some time shortly after the use of FES (Everaert et al., 2010). The long-term effect of FES used on a regular basis for longer than 3 months has shown improvements in corticospinal connectivity in the motor cortex (Everaert et al., 2010). FES as an alternative therapy has not only led to improved walking ability and stability but also to an increase in confidence in individuals with a CVA (Sabut et al., 2011).

The Present Study

This present study investigated the effect of utilizing two footdrop therapies (FES device and AFO brace) on individuals who have experienced a CVA and the impact a CVA has on the participant's activities of daily living (ADL). A CVA can be thought of as a quick but life altering event that may have lasting effects physically, cognitively, and/or psychosocially.

The Stroke Impact Scale

In order to assess the effect of foot drop and spasticity on ADLs, a specific questionnaire can be utilized; the Stroke Impact Scale (SIS). The questionnaire is CVA specific, patient centered, and has a range of domains such as cognition, mobility, and association in society (Lin et al., 2010). Because of this range in domains, changes of symptoms can be determined over time (Lin et al., 2010). Previous research has found that the SIS 3.0 had good test-retest reliability, internal consistency, and construct validity (Carod-Artal, Coral, Trizotto, & Moreira, 2008). The SIS also had less of a ceiling and floor effect and was more valid, reliable, and sensitive to change compared to other quality of life questionnaires (Lai et al., 2002; Duncan et al., 1999). The SIS 3.0 was also sensitive to detect changes in responses in ADLs between 3 and 6 months in individuals who had a moderate CVA (Duncan et al., 1999). For this reason, the present study utilized the SIS. The present study examined the effect of utilizing a FES device versus AFO, and the psychosocial impact on individuals who had a CVA at baseline and 6-months.

Hypothesis. This present study investigated two kinds of physical devices used in current practice for rehabilitation and the potential effect they may have on the activities of daily living based on the participants' responses on the SIS. The hypothesis for this study is the participants will score higher on the ADL questions when utilizing a FES device than participants using an

AFO device because the FES device's compact aesthetic and application of electrical stimulation helps the individual to perform daily tasks independently to a higher degree.

Material and Methods

Participants

This study was approved by the Montclair State University Institutional Review Board and the Kessler Foundation Institutional Review Board. Participants were recruited via cold calling from a database called Subject Information Management System (SIMS) at Kessler Foundation. SIMS is an encrypted database that converts participants' information into codes. Only Kessler Foundation employees have access to this database thus ensuring confidentiality of personal health information (PHI). After the participants were screened and consented, 68 participants participated in the study (53 males, 15 females; M_{age}=65.3 years old; SD_{age}=11.1 years; age range: 39-86) (Refer to Table 1 in Appendix A). 12 participants were excluded from the study due to medical reasons that prevented them from completing the study and as a result, 56 participants finished the study.

To qualify for the study, participants must have had a history of a CVA that occurred at least 90 days ago, have had weakness on one side of his/her body, have had foot drop, were not currently using the WalkAide system or any electrical stimulation device for assistance with walking. They must have not participated in inpatient or outpatient rehabilitation within the last 30 days, for CVA, heart disease, lung disease or other physical condition that affected his/her ability to walk. They must also have been eligible for Medicare or Medicare Choice/Advantage benefits at the time of consent, not have had a heart attack within the last 90 days, not had a stent placed in his/her coronary arteries or any other artery in the last 90 days, not had major orthopedic surgery (hip, knee or ankle joint replacement) within the last 90 days, not had a

coronary artery bypass surgery or a heart valve replacement within the last 6 months. They must have been able and willing to comply with study procedures, including follow-up requirements, and be willing and able to give informed consent, be able to walk at least 10 meters (about 10 yards) with or without an assist device, have a walking speed within acceptable range ($x < 0.8$ m/s), show ankle lift movement when tested by electrical stimulation, think clearly enough to accurately complete the evaluation tests and to correctly use the assist device he/she was assigned. Lastly, they must have undergone a neurological assessment by the study physician within 30 days before he/she starting the study.

The participant must NOT have had a history of a seizure disorder, currently have clinical electrical stimulation devices (for example: ICD, Pacemaker, Spinal Stimulation,TENS), botox injections in the past 6 months in the upper and lower extremity, and have had changes to an internal device for management of CVA muscle symptoms (for example: baclofen pump) in the last 3 months. They must not have ankle joint weakness, not related to his/her CVA, ankle, foot, or knee weakness that requires additional bracing or support for balance, difficulty walking safely with the study device, decreased sensation in his/her lower leg that would affect his/her ability to walk or participate in study procedures, have skin irritation or lesion on his/her lower leg that would limit study participation, or have any underlying medical conditions that would limit study participation. They must not have muscle problems that would limit study participation and require additional bracing, have pain due to CVA that would limit study participation, have difficulty with his/her breathing that would limit his/her study participation, moderate or severe heart disease. Lastly, they must not have depression that would limit or interfere with study procedures, have a life expectancy less than 12 months or have enrolled or participated in another research study that is likely to affect participation in this research study.

Design

The present study used a mixed design comparing time (Baseline vs. 6 months) and treatment (FES device vs. AFO), where time was within subject groups and treatment was between groups. The primary dependent variable was the participants' responses on ADL questions on the SIS questionnaire. The secondary dependent variables were the participants' response on SIS questionnaire questions of Strength, Hand Function, Mobility, Communication, Emotion, Memory and thinking, and Participation in social roles

Materials

This study used Walkaide, an FES device and an AFO brace. The Walkaide was developed by Neurotronics Inc. (WalkAide, Innovative Neurotronics, Austin, TX, United States). The WalkAide device uses surface electrodes in a single cuff located on the tibia about the peroneal nerve to stimulate during the swing phase of the gait cycle to produce the desired dorsiflexion during gait. The AFO brace was a custom brace that was molded to the participant's affected shin, ankle, and foot. The custom AFO was created by a fitting clinician. There were 25 participants in the FES group (17 male, 8 female) and 31 participants in the AFO group (21male and 5 female) (See Table 1).

*10 Meter Walk Test***:** Participants were asked to walk at their normal speed within a walk frame of 10 meters. The length of the test was 10 meters however, participants' time was recorded between 8 meters following the International Classification of Functionality, Disability, and Health (ICF) code for walking short distances. Participants were asked to perform two walks.

*Modified Emory Functional Ambulation Profile***:** Participants were asked to perform five tasks to assess overall ambulation. These tasks included a five-meter walk on a hard surface, a

five meter walk on a carpeted surface, rising from a chair, walking for three meters around an object and sitting back down in the chair, walking over obstacles, and walking up and down stairs.

*GaitRite Data Capture***:** Participants were asked to walk six times over an electronic mat that assessed their foot pattern and timing via sensors underneath the mat. The data from the sensors were recorded through the GaitRite software program on the computer that was connected to the mat through USB cables.

*Berg Balance Assessment***:** Participants were asked to perform 14 tasks that evaluated their balance. Each item had a scale of 1-4, 1 "being cannot perform independently therefore requiring complete use of physical help" and 4 "being can perform independently without the use of physical help." The highest total score a participant can receive is 56. The scoring range was as follows: balance impairment score of 0-20, moderate functioning balance 21-40, and high functioning balance 41-56.

*6 Minute Walk Test***:** Participants were asked to walk for six minutes. This test evaluated the participant's walking distance, which was reflected as an example of performing ADLs in participants with foot drop as well as a response to the device the participant was randomly assigned to use. The length of the test was about 100 feet long. Participants performed this test self-paced and were allowed to take breaks during the test if needed however, the stopwatch continued. The data was recorded at certain time intervals of every 30 seconds and recorded on the case report form (CRF) until the stopwatch reached six minutes. The results of analyses comparing the physical performance between the FES device and AFO brace can be found in Bethoux et al (2014) and (2015) for long term follow up.

SIS: The SIS is a self-report questionnaire that consisted of nine questions regarding mobility around the home and community, physical deficits that may have occurred due to the CVA, mood, ability to communicate with others, typical activities during the day, using the most affected hand, ability to participate in daily life, memory, and lastly, from 0-100 how much has the individual recovered since the CVA. Each main question had a series of sub-questions where a participant answered using a 5-point Likert scale; 5 being the highest (depending on the question) to 1 being the lowest (depending on the question). While it is not a part of the eight categories, there is a ninth question in the form of a rating scale regarding recovery based upon how much the participant feels they have recovered since the CVA on a scale from 0-100 (See Appendix B).

The psychometrics of the SIS questionnaire are similar in style and layout of each item and responsiveness. The SIS is a questionnaire with 59 items in 8 domains including strength, hand function, ADL/IADL, mobility, communication, emotion, memory/thinking, and participation in social roles, in addition to a question regarding recovery (Duncan et al., 1999; Lin et al., 2010). The SIS questionnaire has Likert scales where responses are based on a 5-point scale with 5 being strongly disagree, 4 disagree, 3 neither agree nor disagree, 2 agree, and 1 strongly agree (Lin et al., 2010).

Procedure

At screening, participants were evaluated based upon history and current medications, past medical events (i.e., hospitalizations, surgeries), CVA classification including type of stroke (ischemic or hemorrhagic), date of injury, time since stroke, and affected side as well as inclusion/exclusion criteria, demographics, and gait speed evaluation in which participants performed the 10-meter walk test and their times were recorded. In order to qualify for the study,

participants' times had to be less than 0.8 m/s. This process occurred 30 days prior to enrollment in the study. Following consenting, participants were randomly assigned to one of two groups, either the Walkaide group or AFO group. Participants were then asked to return another day for Walkaide and/or AFO fitting by a trained clinician. Participants in the Walkaide group were properly fitted with the Walkaide device on the area of the leg that would receive and react the most to the stimulation. Participants in the AFO group had one of their legs scanned or casted in order to make a custom orthotic. Participants were required to return for three visits to the Kessler Foundation after consenting to participate in the study (one fitting visit and two testing sessions; baseline and 6-month follow-up). After the fitting session, the participants participated in the baseline data collection where the participants were asked to participate in the following assessments; 10 meter walk test, Modified Emory Functional Ambulation Profile, GaitRite Data Capture, Berg Balance Assessment, six minute walk test, and self-report questionnaires Stroke Impact Scale (SIS). The baseline visit took about an hour to complete all required tasks. After the baseline visit, participants were asked to take the device home and use the device as much as possible throughout the day. There was no limit to how many times the participant could wear the FES device or AFO per day. After 6 months of device usage the participants returned for a follow-up data collection. The Follow-up visit included the same tasks as conducted at the baseline visit. The 6-month follow-up visit also took about an hour to complete all required tasks.

Analysis

A two (Treatment: Walkaide and AFO) x two (Time: Baseline versus Six months) mixed design ANOVA was used to analyze the average scores of each 8 dependent variables of items from the SIS; Strength, Hand Function, Memory and Thinking, Emotions, Communication,

Activities of Daily Living, Mobility, and Participation Role Thinking. ADLs items were a primary dependent variable analyzed in this study for the effect of treatment usage at pre and post time period for overall change in responses on the SIS. The dependent variables were tested by calculating the average score of each section.

Results

Descriptive Statistics

The two (Treatment: Walkaide and AFO) x two (Time: Baseline versus Six months) mixed design ANOVA descriptive statistics are presented in Tables 1 and 2. The results indicate the genders and ages of the participants in the study as well as the number of participants in each group in the study.

Response Averages from the SIS

There was no significant main effect of Time on responses of Strength items $F(1, 51) = 1.597$, $p = 0.212$. There was no significant main effect of Treatment on responses of Strength items $F(1, 51) = 0.707$, $p = 0.404$. There was no interaction between Treatment and Time on responses of Strength items $F(1, 51) = 0.103$, $p = 0.750$. Figure 1 shows group means of Strength responses utilizing Walkaide device was not statistically significantly different than utilizing an AFO (see Table 3).

There was no significant main effect of Time on responses of Hand function items $F(1, 51) = 2.776$, $p = 0.102$. There was no significant main effect of Treatment on responses of Hand Function items $F(1, 51) = 0.532$, $p = 0.469$. There was no interaction between Treatment and Time on responses of Hand Function items $F(1, 51) = 0.096$, $p = 0.758$.(see Figure 2).

There was no significant main effect of Time on responses of Activities of Daily Living/Independent Activities of Daily Living (ADL/IADL) items $F(1, 51) = 0.004$, $p = 0.952$.

There were no significant main effect of Treatment on responses of ADL/IADL items $F(1, 51) = 0.213$, $p = 0.647$. There was no interaction between Treatment and Time on responses of ADL/IADL items $F(1, 51) = 1.097$, $p = 0.300$. (see Figure 3).

There was no significant main effect of Time on responses of Mobility items $F(1, 51) = 0.938$, $p = 0.337$. There was a significant main effect of Treatment on responses of Mobility items $F(1, 51) = 6.445$, $p = 0.014$. There was no interaction between Time and Treatment on responses of Mobility items $F(1, 51) = 0.337$, $p = 0.564$.

There was no significant main effect of Time on responses of Communication items $F(1, 51) = 0.000$, $p = 0.993$. There was no main effect of Treatment on responses of Communication items $F(1, 51) = 0.439$, $p = 0.510$. There was no interaction between Time and Treatment on responses of Communication items $F(1, 51) = 1.447$, $p = 0.235$.

There was no significant main effect of Time on responses Emotion items $F(1, 51) = 0.492$, $p = 0.486$. There was no significant main effect of Treatment on responses Emotion items $F(1, 51) = 0.018$, $p = 0.895$. There was no interaction between Time and Treatment on responses Emotion items $F(1, 51) = 0.106$, $p = 0.746$.

There was no significant main effect of Time on responses of Memory and Thinking Participation items $F(1, 51) = 0.007$, $p = 0.935$. There was no significant main effect of Treatment on responses of Memory and Thinking Participation items $F(1, 51) = 0.000$, $p = 0.998$. There was no interaction between Time and Treatment on responses of Memory and Thinking Participation items $F(1, 51) = 0.075$, $p = 0.785$.

There was no significant main effect of Time on responses of Participation Role and Thinking items $F(1, 51) = 2.454$, $p = 0.123$. There were no significant main effects of Treatment on responses of Participation Role and Thinking items $F(1, 51) = 0.140$, $p = 0.710$. There was

no interaction between Time and Treatment on responses of Participation Role and Thinking items $F(1, 51) = 0.510$, $p = 0.479$.

Discussion

The purpose of this study was to determine whether utilizing the Walkaide device or AFO brace positively impacts psychosocial factors in individuals with CVA, more importantly ADLs. It was hypothesized that utilizing the Walkaide device would yield a positive increase in psychosocial outcomes, in particular, ADLs. The benefits of this device is to improve individual's walking, which can help improve stability, increase ambulation, and thus, improve participation in activities of daily living.

The hypothesis was not supported. Instead, CVA participants' responses on the SIS were neither impacted positively nor negatively by wearing a Walkaide device or AFO brace compared to either device or to baseline. Bethoux et al. (2014) found a similar result when comparing FES device with AFO. In six months, they found the use of FES device was noninferior to the use of AFO in gait speed, SIS composite score, and safety (Bethoux et al., 2014). However, in this present study, at baseline, each subject had a different total score when all eight sections from the SIS were summed up resulting in a difference of scores thus not establishing a true baseline across all subjects utilizing either a FES device or AFO brace (Please refer to Appendix D). Due to this difference already presented at baseline, this effect may have also been exhibited at 6-months (Please refer to Appendix D). Therefore, the 8 domains on the SIS questionnaire may not be significant suggesting that between baseline and six months, wearing an FES device or AFO does not impact the participant's psychosocial being. Furthermore, it does not affect the participant's ADLs.

FES device is a novel device that has yielded encouraging results in physical therapy for individuals with CVA but very little on how the quality of life of individuals who have survived a CVA has changed. Therefore, the premise of the present study was to investigate whether or not it did yield positive changes in responses on the SIS from baseline to 6-months. With that said, the results suggest that wearing an FES device is neither superior nor inferior to wearing an AFO.

Limitations

A main limitation found in this study was that the SIS was a self-report questionnaire. The responses are largely from the point of view of the participant thus, the responses are based upon perception and may not be objectively accurate. Therefore, the SIS is more subjective than objective.

Future Research

Due to the results being derived from responses from the participants' views, researchers should also administer the SIS to caretakers. By administering the SIS to both the CVA patient and the caretaker, the researchers would be able to compare the patient's view of how the CVA affected them and the caretaker's view of how the CVA has affected them. A study conducted by Pindus et al. (2018) found that majority of caregivers, whether a family member or nurse, felt ill prepared and pressured in knowing how to care for an individual who had a CVA (Pindus et al., 2018). This lack of knowledge is a barrier of the proper care needed for the individual to recover therefore, for future research, investigators should administer the SIS questionnaire to the caregivers as well since they play a direct role in the CVA individual's life and recovery.

Conclusion

Little is still known about the cause of a CVA and how to overcome deficits resulting from a CVA. While much of the CVA research continues to investigate advancements for physical and cognitive rehabilitation, psychosocial factors are neglected. Therefore, future research should take into account the effect a CVA has on the individual's ADLs because experiencing a CVA occurs in less than 24 hours yet the deficits resulting from one can last a lifetime.

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Appendix A

Table 1: Descriptives - Statistics of Gender in each Treatment group (Walkaide or AFO) at Baseline and Six month time points.

	Time			
	Baseline		6 Months	
	Male	Female	Male	Female
WA	17	8	17	8
AFO	23	5	23	5

Table 2: Descriptives - Average Age and Standard Deviation as a Function of Gender in each Treatment group (Walkaide or AFO) at Baseline and Six months. The cut off for each age group was 66 years old as shown in the table.

		Treatment					
		WA	$\underline{x}$	SD (±)	AFO	$\underline{x}$	SD (±)
BL Male	Under 66	12.00	51.16	1.00	12.00	57.50	0.99
	Over 66	5.00	75.20	0.99	11.00	75.55	0.99
BL Female	Under 66	3.00	51.33	1.01	4.00	54.75	0.99
	Over 66	5.00	72.20	0.99	1.00	72.00	1.00
6M Male	Under 66	12.00	51.16	1.00	12.00	57.50	0.99
	Over 66	5.00	75.20	0.99	11.00	75.55	0.99
6M Female	Under 66	3.00	51.33	1.01	4.00	54.75	0.99
	Over 66	5.00	72.20	0.99	1.00	72.00	1.00

Appendix B

Stroke Impact Scale. A CVA-specific self-report rating instrument that measures CVA-related behaviors (Duncan et al., 1999). These include:

1. mobility in and around the home or community,
2. physical problems as a result of the CVA,
3. questions about memory and thinking,
4. changes in mood and feelings,
5. ability to communicate with others,
6. activities done during a typical day,
7. ability to use the affected hand,
8. ability to participate in activities that are meaningful.

Scoring

Total help - Couldn't do it at all - Strongly agree 1

A lot of help - A lot of trouble - Moderately agree 2

Some help - Some trouble - Neither agree nor disagree 3

A little help - A little trouble - Moderately disagree 4

No help needed - No trouble at all - Strongly disagree 5

Appendix C

Table 3: Group means of responses on Strength as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Strength

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	2.79	0.109	2.94	0.172
AFO	2.66	0.139	2.75	0.166

Table 4: Group means of responses on Hand Function as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Hand Function

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	2.54	0.289	2.44	0.270
AFO	2.23	0.295	2.16	0.280

Table 5: Group means of responses on ADL/IADL as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

ADL/IADL

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	3.98	0.128	4.03	0.116
AFO	3.96	0.127	3.90	0.113

Table 6: Group means of responses on Mobility as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Mobility

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	3.96	0.109	4.06	0.108
AFO	4.33	0.102	4.35	0.091

Table 7: Group means of responses on Communication as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Communication

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	4.53	0.101	4.44	0.157
AFO	4.31	0.178	4.39	0.149

Table 8: Group means of responses on Emotion as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Emotion

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	3.51	0.109	3.43	0.114
AFO	3.47	0.065	3.44	0.0.80

Table 9: Group means of responses on Memory and Thinking as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Memory and Thinking

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	4.48	0.128	4.47	0.151
AFO	4.46	0.128	4.48	0.141

Table 10: Group means of responses on Participation Role and Thinking as a function of Treatment (Walkaide device or AFO) and Time (Baseline and 6 months).

Participation role and Thinking

	Time			
	Baseline		6 Months	
	$\underline{x}$	Error $\underline{x}$	$\underline{x}$	Error $\underline{x}$
WA	3.91	0.151	4.00	0.135
AFO	3.77	0.168	4.01	0.130

Appendix D

Figure 1: Group means and Standard of error for Strength responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

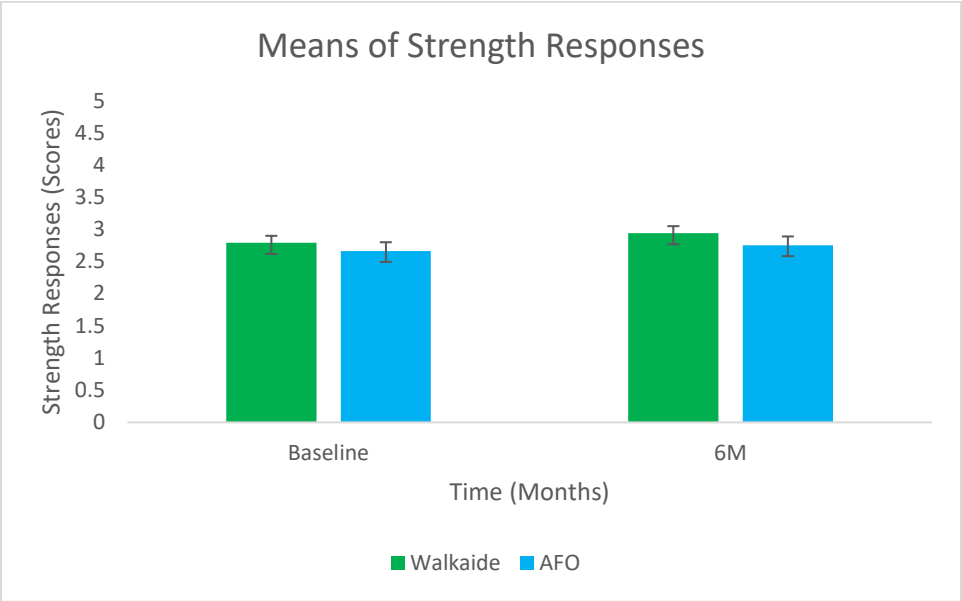


Figure 2: Group means and Standard of error of Hand Function responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

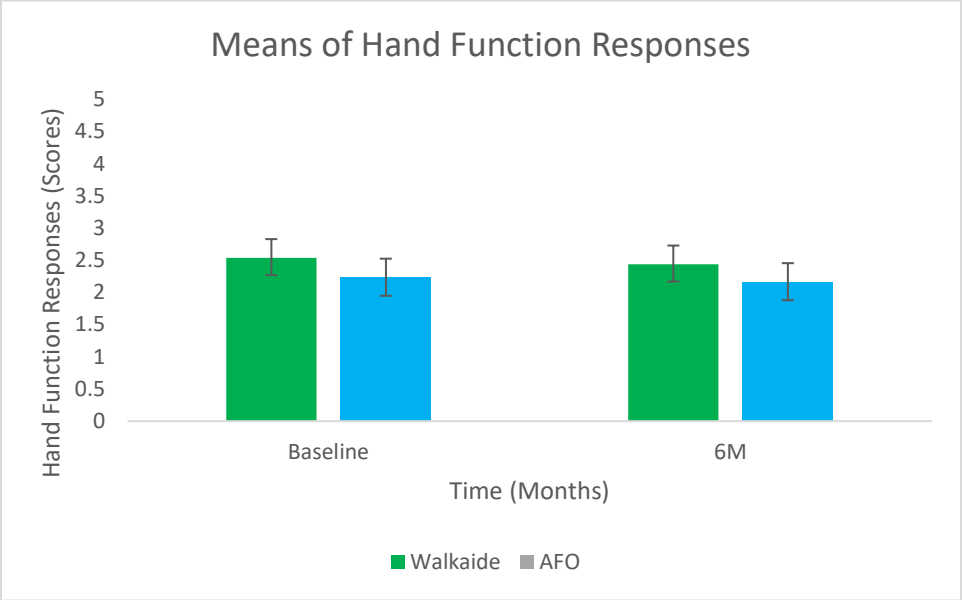


Figure 3: Group means and Standard of error from Activities of Daily Living/ Independent Activities of Daily Living (ADL/IADL) responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

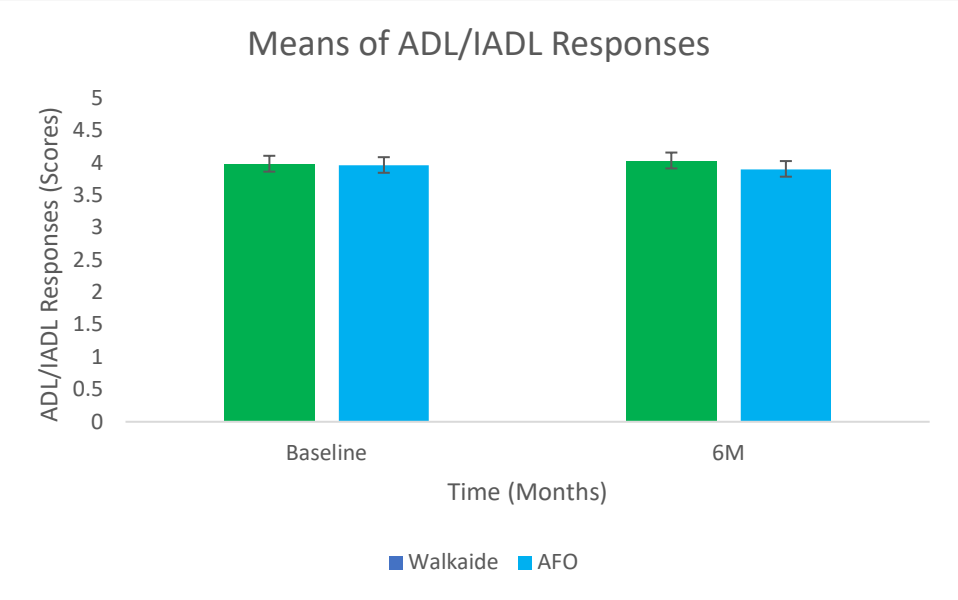


Figure 4: Group means and Standard of error from Mobility responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

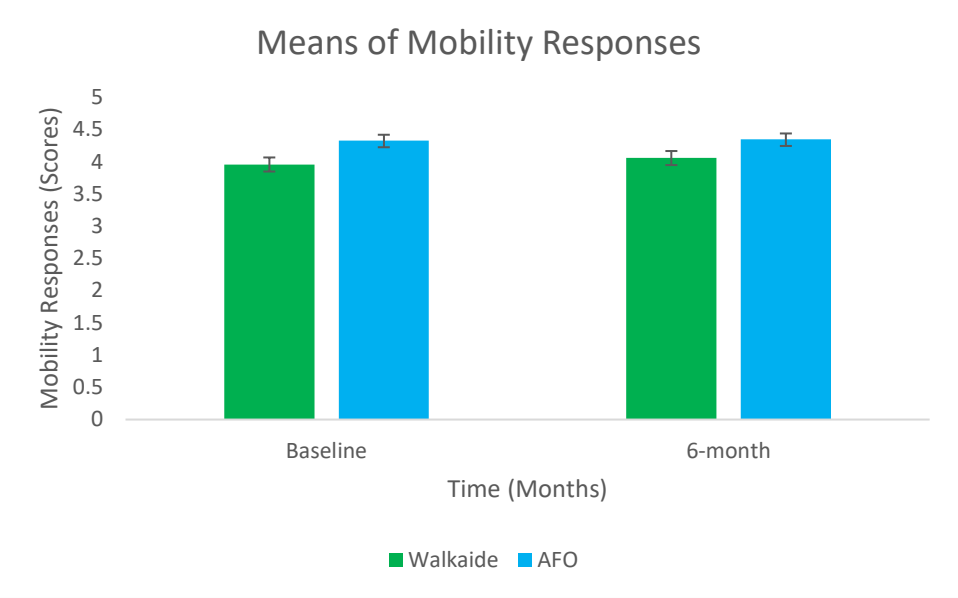


Figure 5: Group means and Standard of error from Communication responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

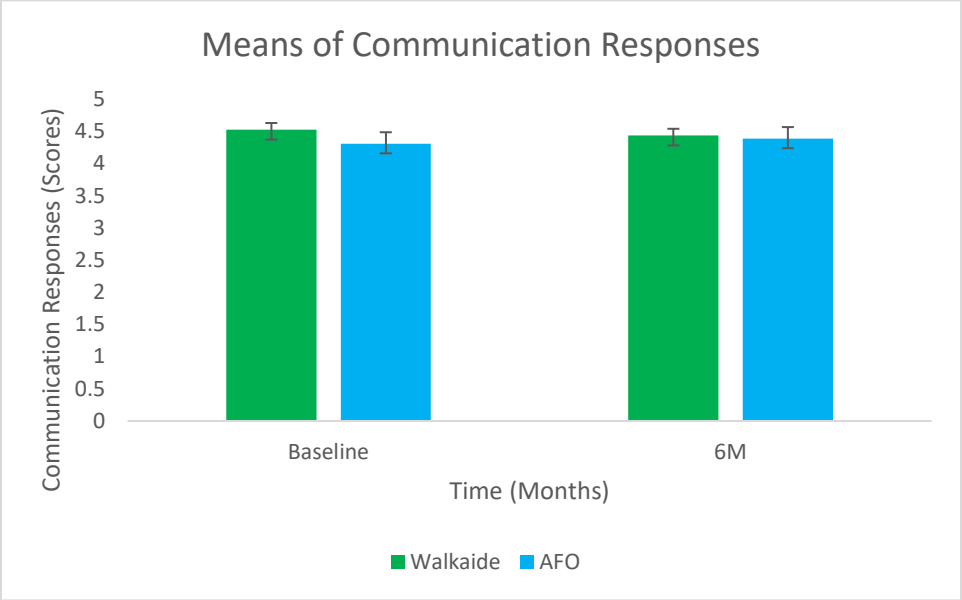


Figure 6: Group means and Standard of error from Emotion responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

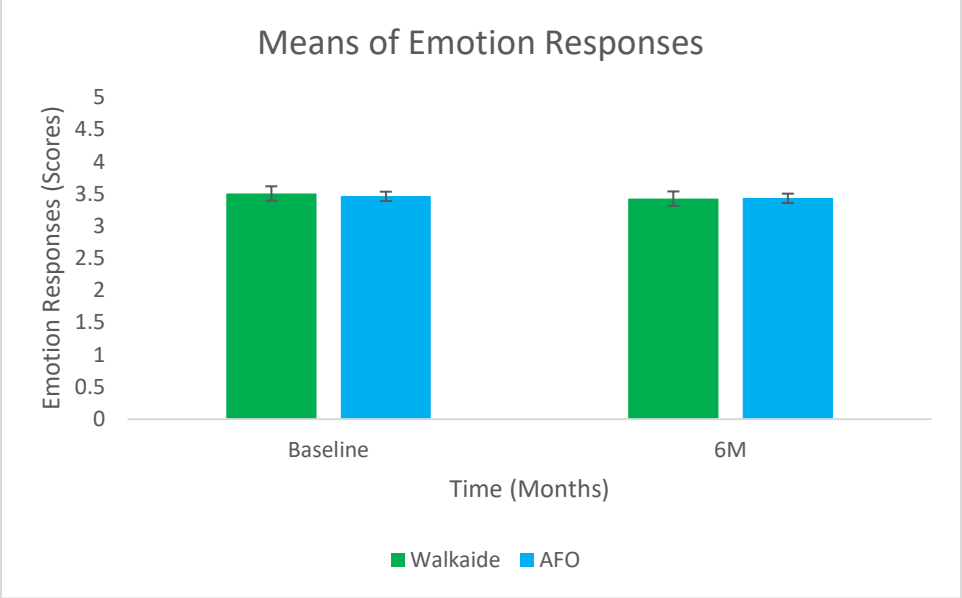


Figure 7: Group means and Standard of error from Memory and Thinking role responses as a function of Treatment (Walkaide or AFO) and Time (Baseline and 6 months).

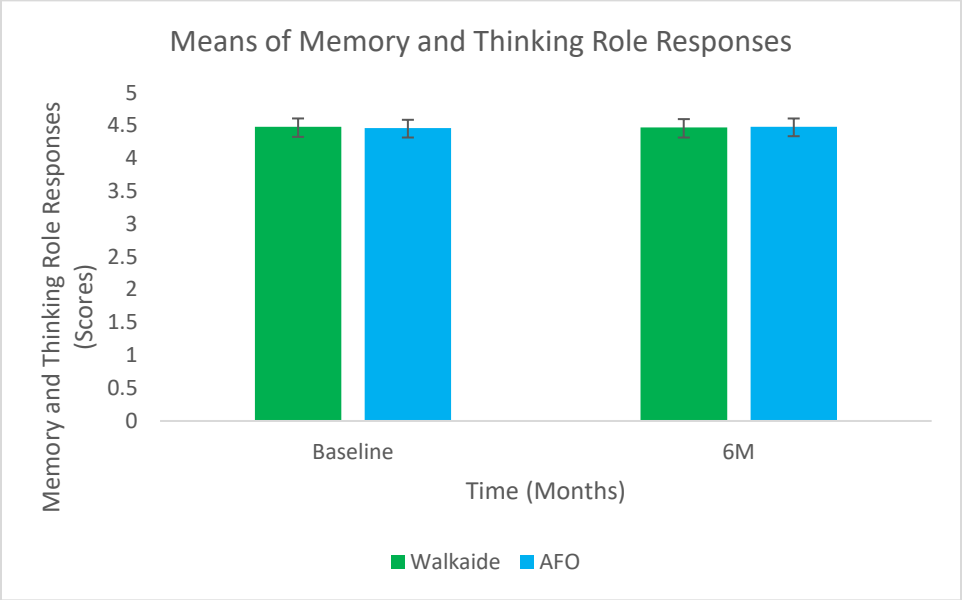
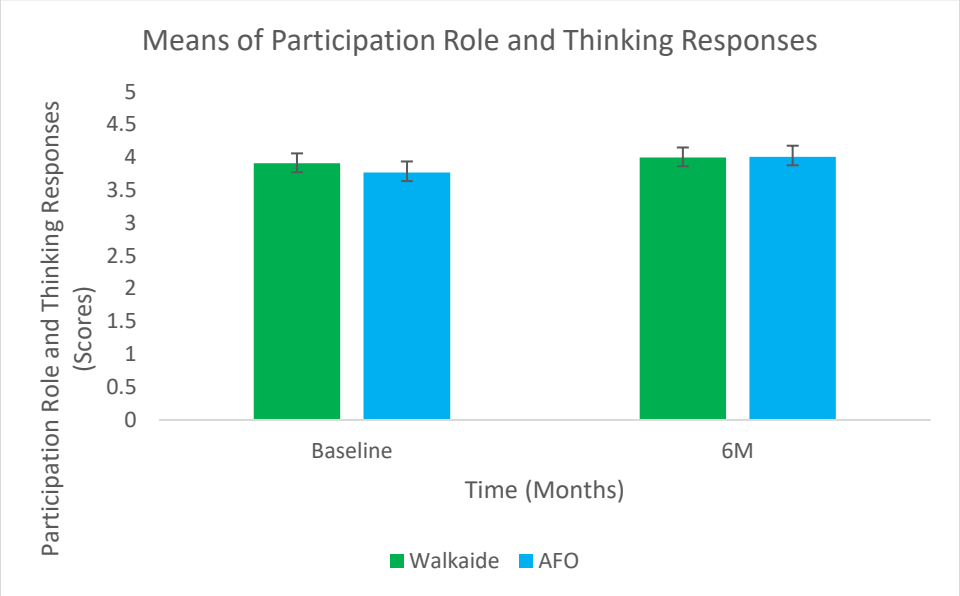


Figure 8: Group means and Standard of error from Participation Role and Thinking responses Treatment (Walkaide and AFO) and Time (Baseline and 6 months).



Appendix E

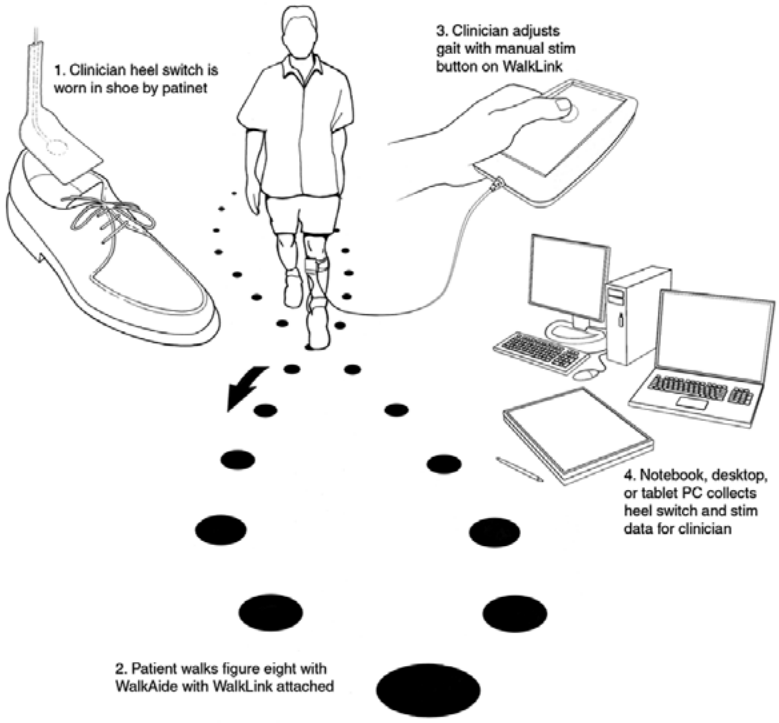


Figure 9: An image of the use of the Functional Electrical Stimulation (FES) device and how it was measured.

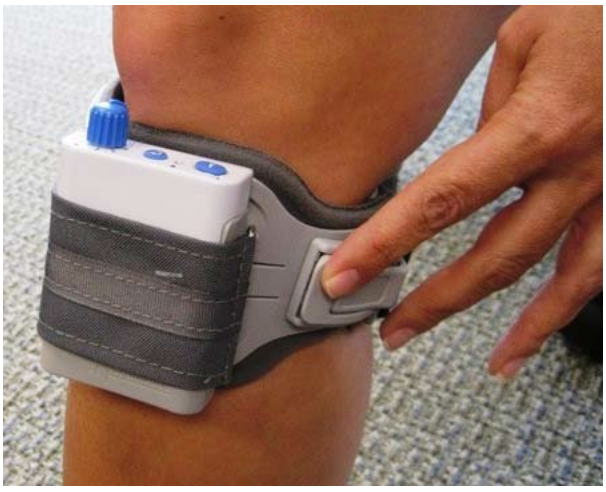


Figure 10: An image of the device itself and the placement of the device on the participants' upper leg, just below the knee.

Appendix F

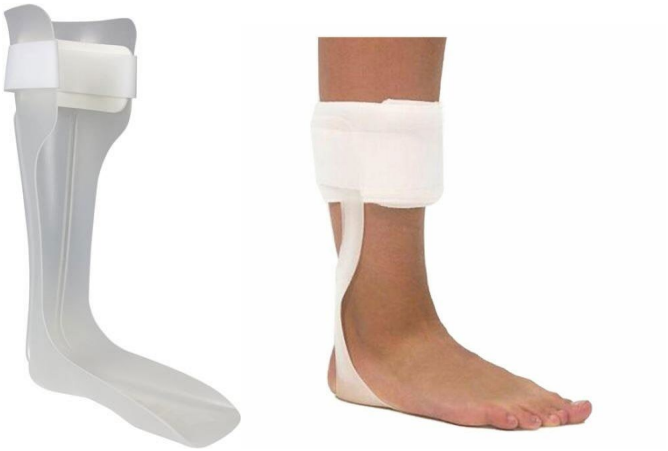


Figure 11: An image of the molding of the Ankle Foot Orthosis (AFO) brace that was custom made for the participant and fitted by a clinician.