Use of the Bioness L300® Functional Electrical Stimulator in Acute Stroke Rehabilitation

Christine Flanigan  
*Graduate Center, City University of New York*

Colleen M. Martinez  
*Graduate Center, City University of New York*

Beth N. Terranova  
*Graduate Center, City University of New York*

Nicholas Wildi  
*Graduate Center, City University of New York*

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USE OF THE BIONESS L300® FUNCTIONAL ELECTRICAL STIMULATOR IN ACUTE STROKE REHABILITATION

by

CHRISTINE FLANIGAN
COLLEEN M. MARTINEZ
BETH N. TERRANOVA
NICHOLAS WILDI

A capstone project submitted to the Graduate Center faculty in partial fulfillment of the requirements for the degree of Doctor of Physical Therapy, The City University of New York

2015
This manuscript has been read and accepted for the Graduate Center in satisfaction of the capstone requirement for the degree of Doctor of Physical Therapy.

Suzanne R. Babyar Rothbart, PT, PhD

__________________________
Date  Chair of Examining Committee

Jeffrey Rothman, PT, Ed.D.

__________________________
Date  Executive Officer
Purpose. Over 150,000 people in the U.S. every year experience foot drop following a stroke, slowing their ambulation and increasing their falls risk. We explore whether the use of functional electrical stimulation (FES) to the common fibular nerve during acute rehabilitation can maximize ambulation gains. Methods. Five in-patients admitted at Burke Rehabilitation Hospital experiencing foot drop participated. While receiving conventional physical therapy, four subjects wore the Bioness L300® device, and one subject used an elastic figure-8 wrapped elastic bandage. Gait parameters were evaluated at initial evaluation, an intermittent evaluation, and discharge. Results. During their stay, subjects significantly improved in gait velocity, percent of gait cycle in single-leg-stance for the involved lower extremity, percent of gait cycle in stance time for the involved lower extremity, and other gait-related variables. Conclusion. Future research is needed to confirm FES as a more helpful adjunct than an elastic wrap during acute rehabilitation.
ACKNOWLEDGMENTS

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Each year, stroke affects approximately 795,000 people in the United States, and approximately 15 million people worldwide (Bethoux et al., 2015). Approximately 75% of stroke victims survive, and the cost of medical care for these individuals is high at an estimated $3.6 billion dollars each year (Bethoux et al., 2015). Given the incredibly high costs, it is imperative that clinicians find the most efficient and effective rehabilitative methods to return these individuals to functional mobility as quickly as possible.

One of the primary problems facing therapists working with stroke patients is foot drop, a condition in which the individual has difficulty dorsiflexing the foot due to reduced or entirely absent stimulation of the deep fibular nerve. Foot drop affects an estimated 20% of stroke survivors, or approximately 159,000 people in the U.S. each year (Bethoux et al., 2015). The inability or weakened ability to dorsiflex the foot leads to an increased falls risk and poor gait quality because the individual will either drag the foot along the floor during swing phase, or circumduct or vault up on their other leg at the hip to clear the involved foot from the ground. These altered gait patterns lead to significantly slower gait speeds and increased risk of falls (Sackley et al., 2009; Weerdesteyn, de Niet, van Duijnhoven, Hanneke, & Geurts, 2008).

Given the high prevalence of foot drop in stroke populations, and its impact on gait patterns, special consideration should be given to developing the most effective techniques to address foot drop while rehabilitating stroke survivors. The treatment of foot drop varies depending on therapist preference and the patient’s degree of disability.

In the initial stages of stroke recovery, a therapist may use a temporary dorsiflexion assistive device, such as a figure-8 wrapped elastic bandage, to wrap the lower leg and foot and maintain it in a dorsiflexed position. This position will prevent foot drop and toe drag during walking, transfers, and stair climbing. Later in the recovery process, the patient may be fitted for
an ankle-foot orthosis (AFO), one of the most common long-term treatment methods for foot drop (van Swigchem, van Duijnhoven, den Boer, Geurts, & Weerdesteyn, 2012). The AFO is a plastic splint that covers the posterior aspect of the leg up to below the knee and keeps the ankle in neutral dorsiflexion throughout gait (van Swigchem et al., 2012). Although use of a figure-8 wrapped elastic bandage or AFO can help create a more functional gait, these treatment methods do not allow free ankle movement, can be bulky to wear, and do not allow for activation of both dorsiflexors and plantarflexors during ambulation to help normalize gait. (Ring, Treger, Gruendlinger & Hausdorff, 2009; Singh, Singh, Wangjam, Kiba & Nandabir, 2001; Taylor et al., 1999). Because of the bulky design of some AFO devices, and the restriction of movement they create, patient compliance in wearing the device is often a concern (Everaert et al. 2013; Taylor et al., 1999).

An alternative intervention to the use of wrap bandages or an AFO, is the use of a device that provides functional electrical stimulation (FES) during gait. FES uses a non-noxious electrical stimulus to activate the dorsiflexors and evertors of the ankle to produce smooth dorsiflexion during the early stance and swing phases of gait (van Swigchem et al., 2012). FES also allows plantarflexion during toe-off, resulting in a smooth toe-off without the restriction of movement by an AFO, which would keep the foot in a dorsiflexed position throughout gait. In plain terms, FES imitates the activation of muscle in a healthy individual.

FES, and electrical stimulation in general, has been shown to increase muscle strength and the maximum voluntary contraction, and reduce spasticity (Sabut, Sikdar, Kumar, & Mahadevappa, 2011; Yan, Hui-Chan, & Li, 2005). FES has also been shown to increase gait speed and the number of steps taken, without increasing the effort expended by the patient (Morone, Fusco, DiCapua, Coiro, & Pratesi, 2012; Stein et al., 2010; Everaert, Thompson,
Chong, & Stein, 2010). When used long term, FES has been shown to improve a patient’s functional ambulation and ability to avoid obstacles (van Swigchem et al., 2012). When paired with traditional physical therapy, FES significantly improves walking ability and motor control over conventional physical therapy alone (Sabut, Sikdar, Mondal, Kumar, & Mahadevappa, 2010). Patients also tend to feel that FES helps them with gait, and thus may help improve compliance (Taylor et al., 1999). Thus, FES may provide an addition to physical therapy treatment that is beneficial in producing a more functional gait profile (Everaert et al., 2013).

Many researchers hypothesized that FES may also improve corticospinal connections because it actively stimulates the nerve (Everaert et al., 2013; Sabut et al., 2011; Everaert et al., 2010; Stein et al., 2010; Sheffler, Hennessey, Naples, & Chae, 2007; Taylor et al., 1999). Studies have found that the gait parameters of individuals who have used the device continue to improve when the device is off (Everaert et al., 2010; Stein et al., 2010). Everaert and colleagues (2010) compared the effect of FES on gait speed of individuals with foot drop as a result of non-progressive neurological conditions (stroke) versus progressive neurological conditions (multiple sclerosis). The authors looked at gait speed both with the device on and the device off. The authors found a significant increase in gait speed in both groups with the device on and with the device off, suggesting an improvement in corticospinal connections from FES. These findings suggest that use of FES in rehabilitation may be preferable to the use of an AFO, which does not offer the same lingering improvements in gait parameters when walking without the device.

A problem with many of the studies touting the positive effects of FES, however, is that many of the studies did not have a control group and did not compare improvements made using an FES device to improvements made using more conventional, and cheaper, interventions such as a figure-8 wrapped elastic bandage. In the studies that included a non-FES wearing control
group, the definition of control parameters were often not clear, stating only that “conventional” therapy was provided without defining what “conventional” therapy entailed (Sabut et al., 2011). Of the studies that did use such a clearly-defined control, the findings regarding the benefits of FES over an AFO have been mixed; and most involve individuals who are chronic stroke survivors, rather than those that are in the acute stage of recovery. Some studies have found indications that FES may improve gait speed as compared to an AFO (Morone et al., 2012; van Swigchem et al., 2012), while other studies found no statistical difference between the use of an AFO and an FES device on gait speed after stroke recovery (Everaert et al., 2013; van Swigchem, Vloothuis, den Boer, Weerdesteyn, & Geurts, 2010; Ring et al., 2009; Sheffler, Hennessey, Naples, & Chae, 2006).

Morone et al., (2012) found that during the subacute phase of stroke recovery, patients that used the WalkAide™ FES device during therapy had a significantly increased gait speed as compared to the control. Similarly, van Swigchem et al., (2012), found that individuals with chronic stroke who used FES had a significantly improved ability to avoid obstacles as compared to individuals wearing an AFO, which is indicative of a more functional gait.

On the other hand, many studies have found no significant difference in the gait speed between stroke patients that use an FES device and those that use an AFO (Bethoux et al., 2015; Bethoux et al. 2014; Everaert et al., 2013; van Swigchem et al., 2010; Ring et al., 2009; Sheffler et al., 2006). One of these studies even found that an AFO has a better immediate orthotic effect than FES (Everaert et al., 2013). Everaert et al. (2013) designed a twelve-week study that compared the use of an AFO to FES (the WalkAide™ Device) for individuals with foot drop who were less than one year post-stroke. Participants were assigned to three groups: group one used the WalkAide™ FES device for six weeks followed by an AFO for the next six weeks;
group two used an AFO for six weeks, followed by the WalkAide™ device for the next six weeks; and group three used the AFO for all twelve weeks. The participants’ gait speed was measured while performing a four-minute figure-8 walk and while walking 10 meters. The energy cost of the participants was also measured. There was no statistical difference in participants’ gait speed when wearing either the AFO or the WalkAide™ device, but the AFO had a significantly improved orthotic effect. There was no significant difference in the energy cost expended.

Other studies have shown similar results (Everaert et al., 2013; van Swigchem et al., 2010; Ring et al., 2009; Sheffler et al., 2006), including two recent large-scale studies involving chronic stroke survivors (Bethoux et al., 2015; Bethoux et al., 2014). Bethoux et al., (2014), conducted a multicenter randomized trial involving 495 individuals with foot drop who were at least 6 months post-stroke. Bethoux et al., (2014), randomly assigned participants to wear either FES or an AFO for 6 months. The study found that both groups made significant gains in their gait parameters, but that there was no significant difference between those that wore the FES and those that wore an AFO (Bethoux et al., 2014). Bethoux et al., (2015) then followed 384 of these participants 12 months after the commencement of the study and again found no significant difference between those that used FES and those that used an AFO. Everaert et al. (2013) posited that one of the reasons there is little difference between the devices may be because the AFO reliably maintains the individual’s foot in a dorsiflexed position allowing for an immediate stabilizing effect comparable to that of an FES device.

Notwithstanding the contradicting evidence, FES poses several possible advantages over the use of an AFO. One such advantage is the possibility that it can help reestablish and/or strengthen the corticospinal connections as discussed above (Everaert et al., 2013). Another
possible advantage is that studies have shown that more patients report a favorable experience with the FES device, than with an AFO (Kluding et al., 2013; Everaert et al., 2013; van Swigchem et al., 2010). Patients preferred the FES device over the AFO based on the following factors: effort, stability, safety, quality of gait, distance walked, comfort, ankle mobility, and appearance (van Swigchem et al., 2010). Patients wearing either device reported feeling safe, but patients who wore an FES device reported feeling safer when walking without the FES device as compared to AFO users walking without the AFO (Everaert et al., 2013). Additionally, patients who have worn both an AFO and an FES device indicate a preference for wearing the FES device over the AFO (Everaert et al., 2013; van Swigchem et al., 2010; Bulley, Shiels, Wilkie, & Salisbury, 2011). This preference may help to increase patient compliance with wearing the device in the future, which can be a problem for AFO users (Everaert et al. 2013; Taylor et al., 1999).

Many studies investigating the efficacy of FES have focused on chronic stroke survivors in order to eliminate the possible confounding factor that gait improvements are due to spontaneous recovery (Everaert et al., 2010; Kottink et al., 2008). FES, however, may also offer additional benefits during the acute phase of recovery. It has been shown that repetition and progression of task specific exercises, such as gait training, even without FES, lead to greater functional outcomes during the acute phase of stroke rehabilitation, but that this effect is lost after 90 days (Rose et al., 2011). FES may be an important adjunct to therapy during this time.

The benefits of FES, such as increased gait speed, muscle strength and voluntary muscle contraction and reduced spasticity, may lead to improved overall recovery in the acute phase by allowing the therapist to accomplish more gait training and repetition during a therapy session. When used for training of the tibialis anterior muscle, FES treatment helped acute
stroke patients walk two to three days earlier than control subjects and increased the probability
they would be discharged home from the hospital (Yan et al., 2005). Other studies in acute
stroke populations have also found better outcomes in ambulation, functional activity, and
decreased length of stay with the use of FES therapy (Dunning, Black, Harrison, McBride, &
Israel, 2009). Studies of the use of FES during the acute stages of stroke recovery, however, are
few and have been limited in their scope.

Yan et al. (2005) examined the use of FES during acute stroke recovery and found less
spasticity together with significant improvement in a patient’s ability to walk (as measured by
the number of days until ambulation) when compared to patients who received placebo FES, but
did not compare FES to conventional therapy using a temporary dorsiflexion assist device.
Dunning et al. (2009) studied the effectiveness of FES on two patients in the acute stages of
stroke recovery. Dunning et al. (2009) found that the first patient, who had only mild weakness
on the involved side (4/5 dorsiflexion strength with heel support and 2/5 dorsiflexion strength
without heel support on manual muscle test) showed dramatic improvement until the device was
no longer needed, while the second patient, who had severe weakness on the involved side (0/5
dorsiflexion strength) had difficulty achieving a dorsiflexion contraction with the device, and had
inconsistent results. While the second subject was able to improve her dorsiflexion strength
during the study from 0/5 to 3-/5, she rapidly fatigued and continued to experience foot drop
during gait at the time of her discharge four weeks later. This study, however, was limited in the
number of participants and its application is therefore very limited. No study has, as of yet,
sought evidence comparing the use of FES to a temporary dorsiflexion assist device, such as a
figure-8 wrapped elastic bandage or AFO, in the acute phase of stroke recovery to determine if
more functional ambulation gains are made.
The purpose of this study was to determine if FES combined with conventional physical therapy used during the acute phase of stroke recovery improves gait parameters when compared to use of a temporary dorsiflexion assist device and conventional physical therapy. The temporary dorsiflexion assists were figure-8 wrapped elastic bandage wraps or AFO. The Bioness L300® was the FES device used in this study. Our research questionnaires asked whether patients and their treating physical therapists found any benefit of the FES when compared to the figure-8 wrapped elastic bandage wrap or AFO. In order to successfully use FES in acute care rehabilitation, the device must be easy to don and doff; the device settings must be easy to calibrate; and the initial set-up and subsequent device adjustments must not be time-consuming to the therapist. If these parameters are met, we hypothesize that the device may be easily incorporated into a patient's acute care rehabilitation and lead to greater therapist satisfaction.

In addition, for use of an FES device to be feasible during in-patient rehabilitation, it must generate sufficient patient satisfaction to ensure patient compliance with wearing the device. If the device is too uncomfortable or bulky, or makes the patient feel unstable, then it may hinder, rather than help, rehabilitation.

Our null hypothesis is that no difference in either the gait parameters or the patient and therapist preferences will exist. Our first alternate hypothesis is that a surface FES device, such as the Bioness L300®, will improve gait parameters as compared to a temporary assist device during acute rehabilitation. Our second alternative hypothesis is that the therapist will like using the device, and feel that they can accomplish more during a treatment session, leading to improved recovery. Our third alternative hypothesis is that this device will be preferred by the patient and their physical therapist over the traditional AFO. Evidence of the usefulness of this
device in an acute care setting may create a precedent for new treatment protocols for stroke rehabilitation involving FES therapy.
Method

Design

We used a prospective, within-subject design to determine if the FES intervention affected gait parameters during participants’ inpatient rehabilitation stay. Originally, a between-subject component was proposed to isolate the effect of group assignment, (FES+ conventional therapy, or temporary assist device + conventional therapy). However, the randomization (coin toss) technique failed to yield enough control subjects and enrollment was lower than anticipated. A prospective observational survey method was used to determine patient and therapist satisfaction with both treatment types. The study took place at Burke Rehabilitation Hospital (BRH) and was approved by the Institutional Review Board of BRH as well as the Human Research Participation Program of Hunter College.

Subjects

Participants were recruited from an in-patient acute neurological rehabilitation floor at BRH. To be eligible for the study, participants must have suffered a stroke less than four weeks prior to their admission to BRH and presented with foot drop upon their initial physical therapy evaluation. The pool of eligible subjects were divided randomly amongst the control and intervention groups, by method of a coin toss. Participation in this study, and assignment to either group, did not interfere with standard patient care as both groups received conventional physical therapy.

A total of six participants were enrolled in this study, and numbered 1-6. Of this number, one subject was consented but was found to have a neuropathy, which prohibited the use of the FES. Of the remaining five participants, one was assigned to the control group via coin toss and received treatment with only figure-8 wrapped elastic bandage. The remaining four participants
were all assigned to the FES group as a result of the coin toss. The disability of the four experimental participants ranged from minimal impairment to severe.

All individuals who had been admitted into the in-patient program at BRH after suffering a stroke within four weeks prior to admission and who exhibited foot drop during gait were considered for participation in this study. Inclusion criteria required all subjects to be able to achieve at least a neutral (or greater) degree of passive dorsiflexion, and be able to ambulate at least 10 meters either independently or with assistance prior to the intervention. These measures were assessed during the patient's initial evaluation, which was completed by the treating physical therapist. Participants were all English-speaking.

Exclusion criteria included individuals with demand-type cardiac pacemakers, defibrillators, or other similar electric cardiac stimulators; individuals with metastatic cancer; individuals presenting with acute fracture or dislocation of the lower leg; individuals with weight bearing or range of motion restrictions of the lower leg; individuals presenting with active cellulitis or infection of the lower leg to be stimulated; individuals presenting with a lower extremity wound prohibiting use of the Bioness L300® device; individuals who were medically unstable or are unable to participate in therapy; those with a calf circumference greater than 20 inches; and, individuals with inadequate language function to understand and respond appropriately to one-step commands. Exclusion criteria were based on precautions, contraindications, and regulations mandated by the Bioness® company. Based on previous protocols using the Bioness® device, inability to comprehend one-step commands was considered a reason for exclusion, specifically for safety purposes (Tong, Ng, Li & So, 2006).

Patients were first evaluated by a BRH physical therapist. After this initial evaluation, the lead investigator reviewed the patient’s information. If all the requirements of subject
inclusion and exclusion criteria were met, patients were invited to participate as research subjects, and patients providing informed consent were admitted into the study. Patients were then assigned to either the experiment or control group based on a coin toss. Research subjects were assigned a unique identifying code and for subjects assigned to the experimental group, a physician prescription for use of the Bioness® device was obtained. Figure 1 summarizes subject assignment.
Figure 1. Preparing Subjects and Group Assignment. This graphic demonstrates how subjects were recruited and assigned.
Intervention

Both research groups received treatment sessions of approximately the same duration and frequency. Participants assigned to the control group received standard therapy (6 days per week) as normally provided at BRH and used either a figure-8 wrapped elastic bandage or an AFO for passive dorsiflexion of the ankle-foot during gait training.

Subjects assigned to the experimental group received standard therapy (6 days per week) plus training with the Bioness L300® device for approximately three treatment days per week. Therapists using the Bioness L300® device followed manufacturer guidelines and were trained how to fit, program, and best utilize the device. On days where the experimental group was not receiving treatment with the Bioness L300® device, a figure-8 wrapped elastic bandage or AFO was utilized as an alternate dorsiflexion device.

Data Collection

Once patients were accepted in the study, information from their electronic medical record and their initial therapy session were retrospectively retrieved and inserted into a database that only used patients' unique identifying codes. The following information was obtained: age; gender; diagnosis and lesion type; date of incident; endurance ability of patient and gait velocity at initial evaluation, as measured with the 10-Meter Walk Test; spasticity at initial evaluation, as measured with the Modified Ashworth Scale, mobility as measured by Timed Up-and-Go, and balance as measured by Berg Balance Scale. Repeated outcome measurements for Zeno Electronic Walkway with PKMAS software variables, 10-Meter Walk Test, Timed Up-and-Go, Berg Balance Scale, and the Modified Ashworth Scale were obtained for each patient during weekly and discharge re-evaluations. Data were thus collected for individual patient subjects along the schedule presented in Table 1.
Table 1.

*Data Collection Schedule*

<table>
<thead>
<tr>
<th>Event/Day</th>
<th>Information and Measurements Obtained</th>
</tr>
</thead>
</table>
| Patient enrolled in study | Retrospective data from electronic medical record on initial evaluation:  
- Patient name (assigned to code)  
- Research group assignment  
- Age  
- Gender  
- Diagnosis and Lesion Type  
- Date of incident  
- 10-Meter Walk Test  
- Berg Balance Scale  
- Modified Ashworth Scale  
- Timed Up-and-Go |
| Weekly outcome measurements (captured every 7 days) | Repeated outcome measurements for:  
- Zeno Electronic Walkway variables  
- 10-Meter Walk Test  
- Berg Balance Scale  
- Modified Ashworth Scale  
- Timed Up-and-Go |
| 1 week pre-discharge | Survey instruments administered to patients or provided for completion to therapists:  
- Patient Survey Instrument  
- Therapist Survey Instrument |
| Discharge evaluation | Repeated outcome measurements for:  
- Zeno Electronic Walkway variables  
- 10-Meter Walk Test  
- Berg Balance Scale  
- Modified Ashworth Scale  
- Timed Up-and-Go |
Administering Patient and Therapist Surveys

Patient survey instruments were administered approximately one week before a patient’s anticipated discharge from BRH. For the purposes of this study, if a subject was unable to speak or write their responses, a proxy who had been present for approximately 50% or more of therapy sessions was permitted to complete the survey. Proxy respondents have been utilized in prior studies involving patient satisfaction with acute stroke care (Asplund et al., 2009; Reker et al., 2002). Patients unable to speak or write their responses that were without an eligible proxy were not asked to complete the survey instrument.

Primary attending physical therapists were also surveyed for their satisfaction with dorsiflexion assist devices (figure-8 wrapped elastic bandage, AFO, or Bioness L300®) as pertaining to specific patients. They were asked to complete a survey instrument for each patient for whom they acted as the primary therapist. Therapist survey instruments were required to be completed within one week of patient discharge from our experiment and only required a researcher to provide the survey instrument, but not actively administer it. All survey instruments utilized unique identifying codes and no patient names.

Materials

Bioness L300®. The Bioness L300® is a Functional Electrical Stimulation (FES) device. By means of a heel sensor in the user’s shoe, the FES providing cuff worn just below the user’s knee, administers an electrical impulse in sync with the user’s particular gait pattern. The electrical impulse stimulates the common fibular nerve, which, in turn, activates the tibialis anterior muscle and fibularis muscles and initiates ankle dorsiflexion and eversion. The dorsiflexion allows clearance of the participant’s foot from the ground during swing phase of

1 Manufactured by Bioness, Inc.
gait, thus avoiding toe drag or foot drop. The impulse was adjusted to each participant to be strong enough to produce a contraction of the tibialis anterior without creating a noxious or painful sensation.

The cuff worn by the user is made of a light-weight material meant to be breathable and comfortable. The Bioness L300® has been marketed as a device for chronic stroke patients, with a comfortable design to be worn for many hours a day as an assistive device. In our research, the device was worn for 15-30 minutes at a time, three times a week, during gait training of regularly scheduled therapy sessions. This device has been shown to be comfortable in a chronic stroke population for full-day wear (Everaert et al., 2013; van Swigchem et al., 2010; Bulley et al., 2011). Patient comfort with the device in acute rehabilitation was assessed with the patient satisfaction survey.

**Zeno Electronic Walkway with PKMAS Software.** Subjects’ improvements were measured weekly using the Zeno Electronic Walkway with PKMAS Software system. The system requires the subject to walk along a 10-meter mat and provides an animated mapping of the subject’s gait pattern. The recorded gait pattern is then analyzed using the PKMAS software, and all temporal and spatial parameters of gait are computed and recorded. The technology of the Zeno Electronic Walkway with PKMAS Software was developed from that of the GAITRite® walkway. Research has shown that the PKMAS software produces variables that can be used interchangeably with those derived from the GAITRite® (Egerton, Thingstad, & Helbostad, 2014). The GAITRite® is a reliable tool, and is particularly precise when measuring cadence (Vartiainen, Savolainen & Alaranta, 2009). Previous research has shown that the GAITRite® measurements are valid, and test-retest reliability is strong (Greene et al., 2012).

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2 Manufactured by ProtoKinetics, Havertown, PA.
In this study, data were used by the investigators to track improvements in gait kinematics. The Zeno Walkway provides quantitative expressions of velocity, cadence, and step length, which measures can be used as indicators of neurological recovery post stroke (Vartiainen et al., 2009).

To use the walkway, the patient ambulated with an appropriate assistive device and therapist guarding for the length of the mat. Two Zeno Electronic Walkway with PKMAS Software trials were completed at the conclusion of every therapy week, one with the device on and one with it off (using a figure-8 wrapped elastic bandage as needed). The data collected were only at “steady state” in the middle 50% of the mat to reduce error of acceleration and deceleration at the beginning and end of the mat.

Preparing and administering the Zeno Electronic Walkway with PKMAS Software testing is simple, and it has been shown to provide precise gait measurements in brain-injured populations (Vartiainen et al., 2009). Cheng, Yang, Cheng, Lin & Wang, (2010) successfully used the GAITRite® when assessing the effects of FES on chronic stroke patients who experienced foot drop and plantarflexor spasticity. That study investigated an intervention similar to our use of the Bioness L300® device, measured similar outcomes as our research, and studied a sub-acute stroke population that were at least three months post-stroke, which is closer in similarity to our sample than the studies on chronic stroke survivors that were greater than 1 year post-stroke. This previous research highlighted the GAITRite® as a feasible and convenient measure to use while doing research in a clinical setting.

**Outcome Measures**

All outcome measures used, with the exception of the satisfaction surveys, had been validated, and found reliable by previous research. Although different therapists administered
the measurement tests used in this research, all information was gathered in a standardized method, and all tests used have strong inter-rater reliability and test-retest reliability, making them ideal tools for research in a clinical setting.

**10-Meter Walk Test.** The 10-Meter Walk Test (10-MWT) has been approved for use in several studies as a meaningful outcome measure when looking at gait in stroke patients, both acute and chronic (Vartiainen et al., 2009; Laufer, Ring, Sprecher, & Hausdorff, 2009). Vartiainen et al. (2009) used a modified version of the 10-MWT, analogous to a primitive GAITRite® system, using pens attached to the subjects’ shoes to make comparisons to the modern day GAITRite® of the subjects’ velocity, cadence, and right and left step length. The two methods showed significant levels of agreement, when measuring gait in brain injured (stroke or traumatic brain injury) patients. A simpler form of the 10-MWT was used in this study, similar to that used in Laufer et al. (2009) as a second reliable method of calculating gait velocity. The simple version of the 10-MWT uses a stopwatch to measure the time it takes subjects to walk across a 10 meter long level, marked surface. The 10 meters are measured within 14 meters of level surface in order to avoid skewed results that include initial take-off and stopping time. Calculations taken from the 10-MWT provided a record of mid-route gait velocity, as initiation and termination speeds are not included.

For this study, the 10-MWT was used as part of the initial evaluation in order to determine if inclusion criteria were met. The 10-MWT is part of the standard evaluation completed by staff at BRH, and allowed the evaluating therapists to determine if the potential subject would be able to ambulate along the 10-meter mat of the Zeno Electronic Walkway used in this study. The 10-MWT was repeated during progress evaluations, as is standard at
BRH. The simplicity of this test helped to avoid the potential novelty effect the Zeno Walkway with PKMAS Software testing conditions may have on the participant.

**Berg Balance Scale (BBS).** The Berg Balance Scale (BBS) has repeatedly been used in patients post-stroke to quantify functional improvements. Tong et al. (2006) described the BBS as having "excellent interrater and intrarater reliability for elderly subjects, and for subjects with acute stroke" (p.1299).

The BBS is regularly used weekly at BRH to monitor improvements in their patients. The BBS requires two chairs, one with arm rests and one without, a step, a 15- meter walkway, and a timing device (stop watch or clock). It involves 14 different functional tasks, each scaled from 0-4 based on ability (Stevenson, 2001).

Van Swigchem et al. (2012) explored the possible influence of the Bioness L300® on balance of community dwelling, chronic stroke patients experiencing foot drop. The study specifically looked at functional balance, through obstacle avoidance ability, and found subjects wearing the Bioness L300® avoided obstacles better than when wearing the AFO. Our research attempted to find similar improvements in functional balance. As the BBS is a reliable tool when considering this measure in the population at hand it was a reasonable choice to record such improvements in our subjects (Tong et al., 2006).

**Timed Up-and-Go (TUG).** The Timed Up and Go (TUG) test is accepted as a reliable method of quantifying functional mobility. Cheng et al. (2010) used the TUG to assess functional mobility improvements in patients post-stroke experiencing spasticity, as one of four components of the Emory Functional Ambulation Profile (EFAP). The TUG test is administered as follows: Upon hearing the phrase "GO", the evaluator begins a stop watch, and the participant rises from a seated position, walks three meters, turns around and returns to the starting seated
position. Once seated, the evaluator stops the stop watch, and records the time in seconds (Ng & Hui-Chan, 2009; Cheng et al., 2010). The TUG test is used by the therapists at BRH as a functional outcome measure to determine improvements in walking velocity and to indicate falls risk. The TUG test has been accepted as a validated and useful measure for research similar to ours. Ng & Hui-Chan (2009) used the TUG as an outcome measure when investigating whether or not the use of TENS (transcutaneous electrical nerve stimulation) would yield meaningful improvements in gait velocity, walking endurance, and functional mobility in patients who were at least one-year after their first (and only) stroke. The 109 participants were split amongst four conditions: TENS only; TENS + exercise group; the placebo stimulation + exercise group; control group. The researchers found all interventions yielded reduced TUG scores, (faster time, indicating more functional abilities), but the TENS + exercise group achieved significantly better improvements in TUG scores from the second week of the intervention, to the conclusion at the fourth week.

**Modified Ashworth Scale.** Researchers investigating improvements in gait parameters of acute, sub-acute, and chronic stroke patients frequently regard the Modified Ashworth Scale (MAS) as an exclusion parameter, identifying patients who score greater than 2, as ineligible to participate in the study (Wening, Huskey, Hasso, Aruin, & Rao, 2009; Soloppova, Tihonva, Grishin & Ivaneko, 2011). However, Wang, Chan, and Tsai, (2000) used the MAS as an outcome measure when considering the effect of electrical sensory stimulation of the thoraco-lumbar region of the spine (between vertebrae T12 and L1) on knee extensor spasticity, of recovering stroke patients. The ten subjects were an average of 12.5 months post stroke, were suffering from hemiplegia, and ambulated with assisted devices. The study used the MAS and recorded EMG activity of the quadriceps and hamstrings to determine improvements in spasticity.
due to a 45-minute, sub-motor electrical stimulation treatment. Significant reductions in spasticity were found, and agreement between the improved EMG recordings and the improved MAS scores deemed the scale a sensitive tool when measuring spasticity in post stroke patients. In our study, the MAS was to be used as a covariant, along with the other outcome measures.

**Patient and therapist survey instruments.** Patient satisfaction was evaluated using a survey designed by the investigators (Appendix A). The mobility portion of the Stroke Specific Quality of Life Scale was used for several questions. All questions required close-ended responses from a multiple-choice list and two questions allowed for open-ended responses. Questions written by the research team addressed patient satisfaction with the device itself. Researchers were interested in learning if patients found the device comfortable, light-weight, easy to use, safe, and effective in improving their walking while wearing the device. The portion taken from the Stroke Specific Quality of Life Scale addressed the patients' perceived functional abilities while using the device. Therapist survey instruments included all open-ended questions generated by our research team and also addressed aspects of function and satisfaction (Appendix B).
Results

Sample

Investigators recruited six participants with control group (n=1) and experimental group (n=4) participants. One participant was removed from our study secondary to determination of neuropathy and insufficient ROM to for use of Bioness L300® device. Researchers were unable to recruit a larger sample due to: 1.) changes in patient population at BRH which led to fewer referrals for patients with stroke; 2.) location changes and scheduling conflicts which restricted access to use of Zeno Electronic Walkway with PKMAS Software; and, 3.) staffing changes at BRH which led to additional difficulties in research implementation as recently rotated therapists were new to the device and less likely to participate.

Table 2 presents demographic information for each participant. Experimental group (n=4) had a mean age of 51.3 yrs (SD = 4.3). Mean length of stay (LOS) was 23.3 days (SD = 7.9). Experimental group severity ranged from moderate to severe (moderate [n=2], moderate to severe [n=1], severe [n=1]). Only two subjects had increased tone on the MAS at initial evaluation, but it was not high enough to exclude them. Unfortunately, this measure was not collected regularly, so there may have been undetected changes in spasticity for any given subject during the study.
Table 2.

Subject Demographics

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Group Assignment</th>
<th>Gender</th>
<th>Age (yrs)</th>
<th>Time From CVA Onset to Enrollment (days)</th>
<th>Length of Stay (days)</th>
<th>Lesion Type</th>
<th>Involved Side</th>
<th>Severity¹</th>
<th>Discharge Disposition</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Control</td>
<td>F</td>
<td>51</td>
<td>11</td>
<td>21</td>
<td>Ischemic</td>
<td>L</td>
<td>Minimum</td>
<td>Home with outpatient care</td>
</tr>
<tr>
<td>3</td>
<td>Experiment</td>
<td>M</td>
<td>48</td>
<td>14</td>
<td>21</td>
<td>Ischemic</td>
<td>R</td>
<td>Moderate</td>
<td>Subacute</td>
</tr>
<tr>
<td>4</td>
<td>Experiment</td>
<td>M</td>
<td>55</td>
<td>4</td>
<td>14</td>
<td>Ischemic</td>
<td>L</td>
<td>Moderate</td>
<td>Home with outpatient care</td>
</tr>
<tr>
<td>5</td>
<td>Experiment</td>
<td>M</td>
<td>46</td>
<td>15</td>
<td>33</td>
<td>Hemorrhagic</td>
<td>R</td>
<td>Severe</td>
<td>Subacute</td>
</tr>
<tr>
<td>6</td>
<td>Experiment</td>
<td>M</td>
<td>56</td>
<td>24</td>
<td>25</td>
<td>Ischemic</td>
<td>L</td>
<td>Severe</td>
<td>Subacute</td>
</tr>
</tbody>
</table>

¹Impairment classification based on the lead investigator’s clinical experience and clinical decision making.
Subject #2 was the sole patient randomly assigned to control group and presented with acute non-hemorrhagic infarct of the posterior aspect of the right basal ganglia extending to the right periventricular space. This subject was discharged to home with outpatient care.

Subject #3 was assigned to the experimental group and presented with left basal ganglion infarct to the periventricular space. Regional and chronic microvascular changes to right frontal lobe and chronic infarct in right brainstem were also noted. This subject has a non-specified history of neuropathy of left upper extremity and left lower extremity. The patient’s right side was involved from the stroke. The subject was discharged to subacute care.

Subject #4 was assigned to experimental group and presented with lacunar infarct of right basal ganglia and posterior limb of internal capsule and discharged to home with outpatient care.

Subject #5 was assigned to experimental group and presented with a large left thalamic hemorrhage with 5mm mid-line shift requiring a left decompressive hemicraniotomy. Subject also received a placement of bone flap in abdomen. Subject was discharged to a subacute rehabilitation facility.

Subject #6 was assigned to experimental group and presented with right middle cerebral artery watershed infarct with right internal carotid artery occlusion. Subject was discharged to a subacute rehabilitation facility.

Outcomes

Due to administrative difficulties and time-constraints during clinical practice, not all outcome measures were collected. Table 3 provides baseline and outcome measurements excluding Zeno Electronic Walkway with PKMAS Software data. Outcome values for each patient are provided for initial evaluation, intermediate evaluation(s), and discharge evaluation. Intermediate evaluation values from the Zeno Electronic Walkway are reported as
the week one values for all subjects except #5, because data was lost due to a glitch in the software. For subject #5, the intermediate value with the “device on” was his week two evaluation. Not all patients had multiple weeks of data due to time-constraints, administrative issues, or short patient length of stay.
### Table 3.

**Patient Outcome Results**

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Modified Ashworth Scale</th>
<th>Initial Evaluation</th>
<th>Ambulation Distance (feet)</th>
<th>Ten-Meter Walk Test (seconds)</th>
<th>Berg Balance Scale</th>
<th>Timed Up-and-Go (seconds)</th>
<th>Intermediate Evaluation(s)*</th>
<th>Discharge Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>0</td>
<td></td>
<td>50, Rolling Walker, Contact Guard</td>
<td>260</td>
<td>23</td>
<td>61</td>
<td>68</td>
<td>Week 1: 30 Week 2: 36</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td></td>
<td>33, Narrow Base Quad Cane, Moderate Assist</td>
<td>142</td>
<td>10</td>
<td>140</td>
<td>-</td>
<td>Week 1: 14 Week 2: 27</td>
</tr>
<tr>
<td>4</td>
<td>1+(Hip extensors), 1+ (Hip adductors), 2 (Knee flexors)</td>
<td>45, Wide Based Quad Cane, Moderate Assist</td>
<td>-</td>
<td>-</td>
<td>22</td>
<td>-</td>
<td>40</td>
<td>17</td>
</tr>
<tr>
<td>5</td>
<td>1+(Hip extensors), 1 (Hip adductors), 1+ (Knee flexors), 1 (Ankle plantarflexors)</td>
<td>13, At Hemibar, Maximal Assist x 2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Week 1: 4 Week 2: 5 Week 3: 3</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>0</td>
<td></td>
<td>33, Wide Based Quad Cane, Moderate-Maximum Assist</td>
<td>160</td>
<td>6</td>
<td>-</td>
<td>19</td>
<td>78</td>
</tr>
</tbody>
</table>
Zeno Electronic Walkway with PKMAS Software Results and Analysis. All subjects’ spatio-temporal gait findings were collected by the Zeno Walkway with PKMAS Software. Experimental subjects’ spatio-temporal findings were statistically analyzed using Friedman and Wilcoxon analysis for within-subjects comparison. The level of significance required for quantitative verification of any significant findings was $p = .05$.

Subjects’ mean gait velocities throughout treatment are presented in Figure 2. All subjects demonstrated increased mean velocity from initial evaluation to discharge with the device on and with the device off.

Single leg stance mean percentages for the involved lower extremity are presented as a graph in Figure 3. This variable described the percentage of time during the gait cycle that the patient spent in single limb support on their involved lower extremity. For experimental subjects with the device on, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 6.0 which was significant, ($p = .05$). A Wilcoxon Signed-Ranks test indicated that Intermediate Evaluation approached statistical significance to be higher than Initial Evaluation, $Z = -1.826$, $p = 0.068$, and that Discharge Evaluation approached statistical significance to be higher than Initial Evaluation, $Z = -1.826$, $p = 0.068$.

For experimental subjects with the device off, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 6.5 which was significant, $p = .039$. A Wilcoxon Signed-Ranks test indicated that Discharge Evaluation approached statistical significance to be higher than Intermediate Evaluation, $Z = -1.826$, $p = 0.068$, and that Discharge Evaluation approached statistical significance to be higher than Initial Evaluation, $Z = -1.826$, $p = 0.068$. 

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Figure 2. Mean Velocity. This figure demonstrates the patient’s mean velocity during their gait evaluation on the Zeno Electronic Walkway. Each participant made an improvement in their gait velocity from baseline to discharge.
Figure 3. Single Leg Stance Mean Percentage, Involved Lower Extremity. This graph demonstrates each patient had an increase in the average percentage of time they spent in single limb support on their involved lower extremity during their rehabilitation stay in both the device on and off situations.
The percent of gait cycle in stance phase (stance mean percentage) for the uninvolved lower extremity is presented as a graph in Figure 4. For experimental subjects with the device on, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 6.0 which was significant, \((p=.05)\). A Wilcoxon Signed-Ranks test indicated that Intermediate Evaluation approached statistical significance to be lower than Initial Evaluation, \(Z=-1.826, p=0.068\), and that Discharge Evaluation approached statistical significance to be lower than Initial Evaluation, \(Z=-1.826, p=0.068\).

Mean step length for the uninvolved lower extremity is presented in Figure 5. For experimental subjects with the device off, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 8.0 which was significant, \((p=.018)\). A Wilcoxon Signed-Ranks test indicated that Intermediate Evaluation approached statistical significance to be higher than Initial Evaluation, \(Z=-1.826, p=0.068\), Discharge approached statistical significance to be higher than Intermediate Evaluation, \(Z=-1.826, p=0.068\), and that Discharge Evaluation approached statistical significance to be higher than Initial Evaluation, \(Z=-1.826, p=0.068\).

Mean stride length values for the involved lower extremity are presented as a graph in Figure 6. For experimental subjects with the device on, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 6.0 which was significant, \((p=.05)\). A Wilcoxon Signed-Ranks test indicated that Intermediate Evaluation approached statistical significance to be higher than Initial Evaluation, \(Z=-1.826, p=0.068\), \(p=0.068\), and that Discharge Evaluation approached statistical significance to be higher than Initial Evaluation, \(Z=-1.826, p=0.068\).
Figure 4. Stance Mean Percentage, Uninvolved Lower Extremity. This graph displays the percentage of time the patient spent in stance phase on their uninvolved lower extremity. Each patient demonstrated a decrease in this percentage.
Figure 5. Mean Step Length, Uninvolved Lower Extremity. This graph displays the average step length with the uninvolved lower extremity on each trial. The uninvolved lower extremity step length improved in the device on and off situations. Negative mean step lengths occurred when the patient did not step beyond their opposite leg.
Figure 6. Mean Stride Length, Involved Lower Extremity. This displays the average stride length with the involved lower extremity during the gait evaluation. Each patient improved this value from baseline to discharge.
Terminal double limb support mean percentage coefficient of variations for the uninvolved lower extremity are presented as a graph in Figure 7. This variable refers to the consistency throughout gait for the amount of time spent with the uninvolved lower extremity in push off and the involved lower extremity in heel strike. A lower value in this variable would indicate the patient is becoming more consistent in this phase of gait. For experimental subjects with the device on, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 6.0 which was significant, \((p=.05)\). A Wilcoxon Signed-Ranks test indicated that Intermediate Evaluation approached statistical significance to be lower than Initial Evaluation, \(Z = -1.826, p=0.068\), and that Discharge Evaluation approached statistical significance to be lower than Initial Evaluation, \(Z = -1.826, p=0.068\).

Terminal double limb support mean percentages for the involved lower extremity are presented as a graph in Figure 8. This variable indicates the amount of time the patient spends with their involved lower extremity in push-off and uninvolved lower extremity in heel strike. A lower value in this variable would indicate that the patient is taking less time to transition from terminal stance into swing phase on their involved lower extremity. The results were the same for the device on and off situations, a non-parametric Friedman test of differences among repeated measures was conducted and rendered a Chi-square value of 6.5 which was significant, \((p=.039)\). In both situations, a Wilcoxon Signed-Ranks test indicated that Intermediate Evaluation approached statistical significance to be lower than Initial Evaluation, \(Z = -1.826, p=0.068\), and that Discharge Evaluation approached statistical significance to be lower than Initial Evaluation, \(Z = -1.826, p=0.068\).
Figure 7. Terminal Double Support Mean Percentage Coefficient of Variation, Uninvolved Lower Extremity. This graph displays the coefficients of variation for the terminal double support time mean percentage. This variable improved in the device on condition, but not in the device off condition.
Figure 8. Terminal Double Support Mean Percentage, Involved Lower Extremity. This graph displays the average percentage of time the subject spent in push-off on their involved lower extremity. This value decreased from baseline to discharge in both the device on and off conditions.
Patient Survey Results. Patient and therapist surveys were completed for subjects #2, #4, and #5. Subjects #3 and #6 did not have patient or therapist survey results completed due to time-constraints and administrative difficulties. Control findings are represented solely by subject #2’s responses. Experimental findings are represented by responses from subjects #4 and #5.

Responses to patient survey questions #2-6 pertain to use of the Bioness L300® device or other dorsiflexion assist specifically in the context of gait. Control subject #2 reported the best possible review of the AFO of figure-8 wrapped elastic bandage along all questions and dimensions. The patient found the device comfortable, light-weight, easy to use, safe, and helpful within the context of gait and reported on the helpfulness of the device that it “helps me to walk better, foot not as heavy”.

Subject #4 in the experiment group also reported the best possible review of the Bioness L300® along all questions/dimensions and thus reported that they found the device comfortable, light-weight, easy to use, safe, and helpful within the context of gait. Subject #4 also reported, “There appeared to be no safety issues re: my device while using it. The machine was calibrated and customized for my use.” and, “[the] device helped prevent drag in my step. Preventing me from tripping”. Subject #5 in the experiment group reported the best possible review of the Bioness L300® along all questions/dimensions except for question #4 regarding ease of use, for which they were neutral.

Responses to patient survey questions 7-12 pertain to general mobility (questions were adapted from the Stroke Specific Quality of Life scale). Control subject #2 reported “no trouble at all” (the best possible review) for all questions and mobility tasks utilizing the AFO or figure-8 wrapped elastic bandage.
Experimental subject #4 reported “no trouble at all” for all questions and mobility tasks utilizing the Bioness L300® device. Experimental subject #5, however, reported varying levels of difficulty with mobility tasks while using the Bioness L300® device indicating “some trouble” with gait, “some trouble” with fatigue, “a little trouble” with standing, and “a little trouble” with sit-to-stand.

**Therapist Survey Results.** Therapist surveys for use of the AFO or figure-8 wrapped elastic bandage are limited to Subject #2. The therapist reported that positioning of the foot was the best aspect for use of the conventional dorsiflexion devices with Subject #2 but did not provide more detail. The therapist also reported that application of the wrap or brace prior to ambulation was the worst aspect of the AFO or figure-of-eight wrap with Subject #2. The therapist reported that the control devices were easy to don and doff for Subject #2 and that the devices improved Subject #2’s foot clearance through the swing phase of gait. Overall, the therapist reported satisfaction with Subject #2’s outcomes using the conventional dorsiflexion devices and noted that Subject #2 was able to ambulate safely with the AFO or figure-8 wrapped elastic bandage dorsiflexion assist.

Therapist surveys regarding use of the Bioness L300® experimental device with a specific patient are available for subjects #4 and #5. Subject #4’s therapist survey is incomplete. Subject #4’s therapist reported consistency of foot placement and clearance as the best aspect of the Bioness L300® device and set-up time as the worst aspect. Overall, the therapist reported satisfaction with Subject #4’s outcomes using the Bioness L300® device.

Subject #5’s therapist reported that assistance with dorsiflexion to improve lower extremity clearance was the Bioness L300® device’s best aspect for use with Subject #5 and that difficulty with sequencing and patient behavior was the worst aspect (no further clarification was
provided). The therapist noted that the Bioness L300® device was not easy to don and doff on Subject #5 and that Subject #5’s impulsivity made the device difficult to use. The therapist also reported that the Bioness L300® required increased time and effort for set-up. Overall, the therapist reported satisfaction with Subject #5’s outcomes using the Bioness L300® and reported that benefits of the Bioness L300® device include increased sensory feedback.
Discussion

The original purpose of this study was to determine whether FES, when used as an adjunct to conventional therapy in the acute stages of rehabilitation following a stroke, provides greater functional improvements in an individual’s gait, when compared to the use of a temporary dorsiflexion assist device such as a figure-8 wrapped elastic bandage or an AFO. Logistical problems, however, limited the scope of this study, converting this study from a prospective within- and between-subjects design to a preliminary case series that examined the feasibility and potential benefits of incorporating FES into acute stroke rehabilitation.

During the course of this study, many of the stroke patients admitted to BRH were medically complex and did not meet the inclusion criterion of this study, limiting the number of participants. Additionally, with a limited sample size, the coin-toss assigned virtually all participants to the experimental FES group, preventing a true comparison of FES to the use of temporary dorsiflexion assist device. Other logistical complications included staffing changes that resulted in inconsistent administration of the Berg Balance Scale (BBS), Timed Up and Go, and 10-Meter Walk Tests, and frequent changes to the location of the Zeno Electronic Walkway, made it difficult to coordinate patients’ treatment sessions and data collection. Furthermore, a glitch in recording on the Zeno Walkway for subject #5 led to a missing trial on week 1 with the “device on”, necessitating the change to an “intermediate” data reference.

Despite the logistical problems encountered during this study, we demonstrated that gait training with the Bioness L300® FES system can be integrated into an acute rehabilitation protocol without adverse effects to the patient. The therapists commented on its ease of use and the patients felt comfortable using it for gait training. Our results showed improvement in gait quality that would indicate the device may have some effect on recovery. The Friedman test,
comparing the measurements among the initial evaluation, intermediate assessment and discharge, found a significant improvement in most gait parameters in all subjects, in both the device on and device off conditions. Without a control group, it is uncertain whether the improvements derive from the use of the Bioness L300®, or are a result of normal recovery. Adding to this uncertainty is the fact that Subject #2 only used a temporary dorsiflexion assist device, and also demonstrated significant improvement in gait parameters during the course of this study. Furthermore, the Wilcoxon tests did not produce significant results on any of the gait parameters, indicating the time frame (between initial evaluation and intermediate evaluation or intermediate evaluation and discharge) of greatest potential for gains is still unclear.

**Stride Length and Step Length**

Subjects displayed a significantly improved stride length of the involved extremity with the device on at discharge. An improved stride length indicates better foot clearance as well as a better heel strike. The device off condition, however, did not yield the same results. This indicates that having the FES device on can improve stride length. We also documented a statistically significantly improved step length of the uninvolved side. This indicates individuals became more confident weight bearing on their involved side, with the device off, to make a greater advancement of the contralateral lower extremity. Unfortunately, we cannot contribute this result to the patient’s recovery or to use of the device itself.

Our results are similar to Sabut et al., (2010), who found statistically significant improvements in step length in the chronic stroke population with use of the FES device. In that study, chronic stroke patients who were three months post-stroke and community ambulators participated in a 12-week intensive training program. Pre and post-test measures were taken. The experimental group, using an FES device, displayed a significant improvement in
step length from pre to post-test. These improvements were significantly greater than the step length improvements in the control group, which received conventional rehabilitation.³

Our results also correlate with Cheng et al., (2010). Like Cheng et al., our finding of improved step length on the uninvolved side infers a more equal gait pattern between the two lower extremities, although our finding was with device off and Cheng et al.’s findings were with the device on. The Cheng et al., (2010) study examined the effects of electrical stimulation at the tibialis anterior during balance activities (on the balance master), rather than its use during ambulation, as our study did. The primary focus of the study was the impact on the electrical stimulation on the spasticity of the plantarflexors. Still, the study used improvement in gait as an outcome measure, and thus comparisons can be made. Cheng et al. (2010), found the ratio of asymmetrical spatial characteristics of gait significantly improved in the experimental group (using FES), but not the control group (not using FES), when subjects were compared to themselves at baseline to post-treatment, indicating that the experimental subjects gait became more equivalent from the involved to uninvolved lower extremity.

**Coefficient of Variation: Normalization of Gait Patterns**

Our research considered the overall temporal qualities of gait (initial double support as a percentage of gait cycle; terminal double support as a percentage of the gait cycle, time spent in single support, as a percentage of gait cycle etc.) individually, and found significant improvement in the terminal double stance of the uninvolved limb as the coefficient of variation decreased.⁴ This time of terminal double support (theoretically) refers to the time both lower extremities are in contact with ground, while the reference limb (the uninvolved limb) is

³ Sabut et al., (2010), did not define “conventional” therapy in their study, so it is unclear whether a temporary assist device was used.
approaching push off. This gives corresponding information of the involved limb, as it is simultaneously (theoretically) at initial contact or heel strike. An improvement in the coefficient of variation indicates that the time participants spent in terminal double limb support became more consistent in terms of temporal parameters, indicating their gait consistency improved. When evaluating the coefficients of variation for this variable, we found with the device on, subjects spent a more consistent amount of time in terminal double stance of the uninvolved lower extremity, which was not as consistent with the device off. This indicates the time the uninvolved limb spent in push off consistently decreased, and the involved limb required a consistent amount of time (and consistently less) to achieve a successful heel strike of the uninvolved limb. This finding is not reported individually, but as an overall temporal asymmetrical ratio between the affected and non-affected in the Cheng et al (2010) study. Our study describes an improvement in this variable, which would correlate to an improvement the ratio reference by Cheng et al (2010). In contrast to our study, however, Cheng et al. (2010) did not find statistically significant improvements or normalization in temporal asymmetrical ratio between the affected and non-affected sides in the experimental group. On the other hand, Dunning et al. (2009), conducted a case series (n=2) using the Bioness L300® device in acute rehabilitation and reported findings in line with ours in one subject, noting a general decrease in coefficients of variation for several variables during gait, insisting that this subject’s gait became more consistent through the course of their therapy.

**Single Limb Support Time and Terminal Double Support Time**

In our research, we saw an improvement in single limb support time and decrease in terminal double support time (as a percentage of the entire gait cycle) in the device on condition. The device off condition also displayed a significant improvement in these variables
as well. With such a small sample size, it is difficult to determine whether the improvements came from the use of the device, or the natural recovery that occurs following a stroke. The improvement in the coefficient of variation is a significant contribution to the use of the Bioness L300® device in acute rehabilitation because a more consistent gait pattern will make the physical therapist and patient more efficient in therapy. If the patient can train with a more efficient gait, we can assume the patient may be able to make more gains in those first three months of recovery.

We expected a similar change in the device on and off situations to support that training with the device can develop neuroplasticity, however some gait variables demonstrated improvements only in the device on situation, and without a control group we cannot determine which improvements were from the device and which were from general recovery.

**Impact of Stroke Severity on Outcomes**

Our results appear to indicate that the most severely impaired participants seemed to benefit the most from the FES device. This was seen specifically when single leg stance mean percent coefficient of variation of the uninvolved lower extremity was considered. The time spent in single leg stance of the uninvolved lower extremity, corresponds to the swing phase of the involved lower extremity. The subject with the most severe impairment, subject #5, showed the greatest decrease in gait variation while using the device compared to device off at discharge. This finding is comparable to the findings of Dunning et al. (2009). Dunning et al. (2009) examined two subjects. Baseline measurements show that Dunning et al.’s (2009) second subject was more impaired than subject number one, particularly in terms of endurance. Dunning et al. (2009) found the differences between the device off and device on condition to be less dramatic, after just seven days of using the device on subject number one, after which time
the researchers chose to discontinue use of the device. In the second subject, the differences still occurred at week four, and warranted the continued use of the device. Also interestingly, subject number five in our study, as well as both subjects in the Dunning et al. (2009), had sustained a hemorrhagic stroke. The rest of our subjects sustained ischemic stroke. These findings begin to highlight the need for larger experiments, with better control over severity and type of stroke, in order to pinpoint which particular population may benefit most from this adjunct to therapy.

**Berg Balance Scale (BBS) Outcomes**

While this study was not able to obtain reliable statistical data for the BBS for all participants, two subjects, Subject #2 and Subject #3, were assessed using the BBS allowing for an anecdotal examination of the findings. Subject #2 (control), who had minimal disability, was assessed with the BBS at initial evaluation, week one, week two, and discharge. Over the course of the study, subject #2 showed a steady improvement in balance, however it cannot be determined if this improvement is due to the use of AFO or spontaneous recovery of function. Subject #3 (experimental), ranked at a level of moderate disability showed a 7-point decrease in the BBS, from week two to discharge. It is unclear what caused this decrease.

**Patient Preference**

This study considered the subjects' preference of his or her device. We provided subjects with surveys, addressing concerns like comfort, lightweight feeling of the device, ease of use during gait, and safety. We used an adaptation of the mobility section of the Stroke Specific Quality of Life Scale, addressing trouble walking, balance while bending over, stair negotiation, increased need to stop and rest, difficulty standing, and difficulty transferring from sit to stand.

Because of logistical limitations in supervising survey administration, we did not obtain a
completed survey from all subjects. A total of three respondents (out of a total of five participating subjects) participated in the survey. Two of the three subjects that completed surveys used the Bioness L300®, and both agreed the device was easy to use during gait training. The third subject who completed the survey was the control, who used the elastic wrap bandage device. All three subjects agreed the device they used was comfortable, and lightweight and safe, and helped with walking, which reports were similar to Dunning et al.’s (2009) first subject, who had a similar opinion, and stated that he liked the stimulation because it helped him walk be keeping his foot up instead of dragging. Interestingly, however, subject #2, who was randomly assigned to the control group by coin toss, stated she would have deferred participation in the study if she was put in the experimental due to fear of using the FES device, indicating that not all patients may prefer FES or find it to be preferable to a figure-8 wrapped elastic bandage.

Future Research

Dunning et al. (2009) conducted exploratory research into this topic, which was used to model the methods for this case series. We were able to expand the sample size to five subjects, one who stood as a control subject, who did not use the Bioness L300® device; however, because of our small sample size, we were unable to provide statistical comparisons between the control and experimental conditions. Similar to Dunning et al. (2009), our five subjects trained between assessment times with their designated device, and subjects were assessed in outcome measures both with and without the chosen device. Unlike Dunning et al. (2009), however, we only required that the subjects use the device a minimum of three sessions per week, compared to the five days a week used by Dunning et al. (2009). Unfortunately, our study was unable to control for severity and demonstrate a significant difference between groups.

Future research could look to explore training with this device versus a control. This
would allow inference into whether the patient improved by recovery or via training. Our qualitative data led us to think that there may be a difference in usefulness of this device depending on the stroke severity. Future research may look into correlating severity with effects of the device.
Conclusion

Foot drop is a common impairment post stroke that leads to increased falls risk for patients. The Bioness L300® device’s effectiveness has been studied extensively in chronic stroke populations but its use in acute populations has been limited. We hypothesized that the Bioness L300® device may be useful in acute stroke rehabilitation as early ambulation gains are critical and the device may help normalize gait and increase corticospinal connections. While we were unable to make statistical comparisons of the Bioness L300® device against conventional dorsiflexion assist devices such as an AFO or figure-8 wrapped elastic bandage, our findings suggest that the Bioness L300® is feasible for study in acute in-patient rehabilitation. Future research should include a greater control sample to isolate the effect of Bioness L300® from spontaneous stroke recovery and compare its effectiveness against conventional devices.
Appendix

Appendix A

Research Patient ID#_____________________

Patient Survey Instrument

For all questions, please select only one answer. Please ask for clarification on any questions you are unsure about.

1.) Which device did you use in gait-training during treatment?
   a.) Ness300 only
   b.) Combination of Ness300 and another device
   c.) Foot-wrap only
   d.) Brace only
   e.) Combination of foot-wrap and brace

If answer to question 1 is a or b, questions 2-12 refer only to treatment utilizing the Ness300 device.

If answer to question 1 is c, d, questions 2-12 refer only to either the foot-wrap or brace device utilized in treatment.

If answer to question 1 is e, questions 2-12 refer only to the foot-wrap device utilized in treatment.

2.) The device used in gait training was comfortable.
   a.) Agree
   b.) Neutral
   c.) Disagree

3.) The device used in gait training was light-weight.
   a.) Agree
   b.) Neutral
   c.) Disagree

4.) The device used in gait training was easy-to-use.
   a.) Agree
   b.) Neutral
   c.) Disagree

5.) Did you feel safe using the device:
   a.) Yes
b.) No

Please explain:

The remaining questions 7 - 12 are adapted from the mobility section of the Stroke Specific Quality of Life Scale. Each item shall be scored with the following key:

1 – couldn’t do it at all;
2 – a lot of trouble
3 – some trouble
4 – a little trouble
5 – no trouble at all

If an activity in a particular question was not performed with the device, please skip that question or leave blank.

7.) While wearing the device, did you have trouble walking? ____

8.) While wearing the device, did you lose your balance when bending over to or reaching for something? ____

9.) While wearing the device, did you have trouble climbing stairs? ____
10.) While wearing the device, did you have to stop and rest more than you would like when walking or using a wheelchair? ____

11.) While wearing the device, did you have trouble with standing? ____

12.) While wearing the device, did you have trouble getting out of a chair? ____
Appendix B

Research Patient ID#_________________________

Therapist Survey Instrument

1.) For this patient, which device did you use in gait-training during treatment?
   a.) Ness300 only
   b.) Combination of Ness300 and another device
   c.) Foot-wrap only
   d.) Brace only
   e.) Combination of foot-wrap and brace

If answer to question 1 is a or b, questions 2-6 refer only to treatment utilizing the Ness300 device.

If answer to question 1 is c, d, questions 2-6 refer only to either the foot-wrap or brace device utilized in treatment.

If answer to question 1 is e, questions 2-6 refer only to the foot-wrap device utilized in treatment.

2.) For this patient, what was the best aspect of the device?
   Please explain:
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________

3.) For this patient, what was the worst aspect of the device?
   Please explain:
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________

4.) Were you satisfied with this patient’s outcome?
   Please explain:
   __________________________________________
   __________________________________________
   __________________________________________
5.) For this patient, was the device easy to don and doff?  
*Please explain:*

6.) What perceived benefits did the device confer for this patient?  *Please explain:*
Bibliography


