ARTICLES

The Effect of Functional Electrical Stimulation on Balance Function and Balance Confidence in Community-Dwelling Individuals with Stroke

Jennifer A. Robertson, Janice J. Eng, Chihya Hung

ABSTRACT

Purpose: The purpose of this study was to evaluate the change in balance function and balance confidence in adults with chronic stroke who are starting a gait re-education program with functional electrical stimulation (FES).

Methods: The study used a before-after study design. Fifteen community-dwelling adults with chronic stroke completed four weekly sessions (2 hours each) of balance and ambulation training with FES applied to the ankle dorsiflexors during the swing phase. Following this familiarization period, participants were assessed for balance and mobility with and without the use of FES. Balance confidence was assessed before and after the familiarization period using the Activities-specific Balance Confidence (ABC) scale.

Results: There was a small but statistically significant improvement in toe clearance and balance function with the FES device, but no detectable change in gait speed. More than half of participants reported reduced balance confidence with the FES device; one-third showed a large (>11 ABC points) reduction in balance confidence.

Conclusion: Physical improvements can occur during FES treatment of individuals post-stroke; however, this may be associated with a clinically important impairment in balance confidence as patients with stroke familiarize themselves with FES treatment.

Key Words: balance, CVA, functional electrical stimulation, peroneal nerve, rehabilitation

Robertson JA, Eng JJ, Hung C. The effect of functional electrical stimulation on balance function and balance confidence in communitydwelling individuals with stroke. Physiother Can. 2010;62:114–119.

RÉSUMÉ

Objectif : L'objectif de cette étude était d'évaluer le changement dans la fonction d'équilibre et dans le degré de confiance en soi chez les adultes en AVC chronique amorcant un programme de rééducation à la marche par stimulation électrique fonctionnelle (SEF).

Méthodes : L'étude en question était une étude de type avant-après. Quinze personnes vivant en coopérative d'habitation et souffrant d'AVC chronique ont participé à quatre séances hebdomadaires de deux heures chacune en rééducation ambulatoire avec SEF appliquée aux muscles dorsifléchisseurs de la cheville au cours de la phase oscillante. À la suite de cette période de familiarisation, l'équilibre et la mobilité des patients ont été évalués, avec ou sans SEF. La confiance dans la capacité à garder son équilibre a été évaluée avant et après la période de familiarisation à l'aide de l'échelle ABC de confiance dans les capacités à garder son équilibre.

Résultats : On a observé de légères améliorations significatives sur le plan statistique pour ce qui est du dégagement des orteils et de la fonction d'équilibre avec SEF, mais aucun changement dans la rapidité de la démarche n'a été constaté. Plus de la moitié des participants ont affirmé avoir moins confiance dans leur capacité à garder leur équilibre avec l'appareil de SEF; le tiers des participants (> 11 points sur l'échelle ABC) ont démontré une diminution appréciable dans leur confiance à garder leur équilibre.

Conclusions : Des améliorations physiques peuvent survenir lors de traitements de patients par SEF après un AVC; toutefois, le tout peut être associé à une déficience clinique importante dans la confiance à garder son équilibre lorsque les patients avec AVC se familiarisent avec le traitement par SEF.

Mots clés : AVC, équilibre, péronier proximal, réadaptation, stimulation électrique fonctionnelle

DOI:10.3138/physio.62.2.114

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The authors wish to thank the G.F. Strong Rehab Centre Acquired Brain Injury Program for their support.

This study was supported by an operating grant from the William Fraser Clinical Rehabilitation Research Award and salary support to Janice J. Eng from the Michael Smith Foundation for Health Research and Canadian Institutes of Health Research (CIHR MSH-63617). This study evolved because of the enthusiasm and dedication of Jennifer Robertson, and we are saddened to report that she passed away prior to the publication of this article.

INTRODUCTION

Stroke is a leading cause of severe long-term disability; the majority of people with stroke have some balance and mobility impairment.¹ Foot drop is a common occurrence following stroke, resulting from partial or complete motor loss of the dorsiflexors. To prevent the foot from dragging along the ground, individuals may adapt their gait by circumducting the leg or raising the thigh excessively. Alternatively, an ankle-foot orthosis may be worn to keep the ankle in a neutral position (neither dorsi- nor plantarflexed) during swing.

Another alternative intervention is functional electrical stimulation (FES) timed to stimulate the ankle dorsiflexors during swing. Although Sheffler et al.² found similar results with respect to gait from FES and an ankle-foot orthosis (AFO), participants preferred the use of FES. Meta-analyses have shown that FES results in increases in gait velocity in individuals with paretic ankle dorsiflexors,³⁻⁵ but no studies have analyzed its effect on balance function or balance confidence. Balance function is important to assess because it is one of the main factors causing people with stroke to fall more frequently than the general population,⁶ which, in turn, contributes to the sevenfold increase in fracture risk reported poststroke compared to those without stroke.⁷ In fact, several studies examining falls in older adults and people with stroke reported the cause of the fall to be (1) a foot dragging during walking and turning, (2) a foot becoming stuck, or (3) tripping.^{8–10} As FES can improve dorsiflexion 11 (and hence foot clearance), this technology has the potential to reduce fall risk.

In addition to balance function, balance confidence is an important measure to assess. Balance impairments may reduce individuals' confidence in their mobility and restrict their participation in activities. Low balance confidence or fear of falling can thus contribute to the cycle of sedentary lifestyle and increased disability. FES may reduce the chances of catching the foot on the ground, reduce walking impairment, improve mobility, and, in turn, enhance balance confidence.

Since previous evidence has shown that a peroneal nerve stimulator can reduce foot drop, we hypothesized that balance function and balance confidence may be altered when commencing a gait re-education program with FES. These devices are becoming more accessible to the public, thanks to reductions in cost and improved technology; however, the effects of FES on balance are not known.

METHODS

The study used a before–after study design.

Participants

Participants living in the community were recruited through advertisements to support groups, stroke rehabilitation facilities, and physical therapists working in the private sector with individuals with neurological diagnoses. Individuals included in the study were community-dwelling adults with stroke who had residual unilateral weakness, were more than 6 months poststroke, were medically stable, had inadequate dorsiflexion during the swing phase of gait, were able to walk independently for a minimum of 10 m with or without a walking aid (excluding parallel bars), had normal ankle ligament integrity, showed greater than 5° passive ankle dorsiflexion range beyond neutral, were able to tolerate 2 hours of activity with rest intervals, were not participating in any in-patient therapy programs, and were able to follow two-step commands.

Exclusion criteria were medical instability (e.g., congestive heart failure), peripheral nerve damage affecting the common peroneal nerve of the affected leg, walking with a gait speed of 1.2 m/sec or more, significant musculoskeletal problems (e.g., active inflammatory arthritis) resulting from conditions other than stroke, cognitive impairment (as indicated by a score below 24 on the Folstein Mini-mental State Test $12,13$), or more than one stroke. Each participant's physician confirmed the presence of stroke and the inclusion/exclusion criteria. The protocol was approved by the ethics review boards of the University of British Columbia and Vancouver Costal Health. Participants gave their informed consent prior to participating in the study.

Descriptive Variables

The following descriptive data were collected: age, gender, height, weight, side of lesion, time since stroke, and type of stroke (ischemic/haemorrhage). In addition, the Chedoke-McMaster Stroke Assessment (CMSA) provided an indication of leg and foot impairment. The CMSA measures the stages of motor recovery on a scale from 1 to 7 (1 = flaccid paralysis, $7 =$ normal movement).¹⁴ Ankle dorsiflexor muscle strength was measured using manual muscle testing¹⁵ (0 = no activity, $5 =$ normal). Level of disability was determined by the American Heart Association Stroke Functional Classification (AHASFC). The AHASFC is based on the level of independence of an individual; level I represents complete independence in basic and instrumental daily activities of living, and level V represents complete dependence.¹⁶

FES Protocol

The WalkAide2 (Innovative Neurotronics, Austin, TX) is an FES device designed to minimize foot drop by stimulating the dorsiflexor muscles via the peroneal nerve. The device is attached by a Velcro cuff just below the knee. The stimulation can be triggered by either a change in pressure through the heel or vertical orientation of the leg. In either case, the device was programmed to deliver a 100 sec pulsewidth asymmetric biphasic wave form at 25 Hz for the duration of the stimulation period, starting just after the heel-off milestone and maintained throughout the swing phase. The majority of participants used the tilt sensor to trigger the stimulation; only four required the heel sensor. The heel sensor had to be used mostly because of severe hyperextension of the knee on the more affected side during the stance phase of gait, which erroneously triggered the tilt sensor to stimulate the peroneal nerve in this phase.

Participants underwent a short practice period using the FES system that consisted of one or two sessions to set up and optimize the stimulation to each individual's gait and to determine which sensor (foot switch or tilt sensor) worked most reliably for that participant. The other purpose of these sessions was to acclimate participants to how the device would behave during various balance/ambulation tasks. After one or two set-up sessions, subjects participated in four weekly 2-hour sessions during which they performed a variety of activities while wearing the FES, so as to allow them to become familiar with the effects of the FES during these activities. Activities included walking over increasing distances, turning, ascending/descending stairs and ramps, negotiating obstacles, and walking onto and over different surfaces.

Outcome Measures

The primary outcome measures were the Activitiesspecific Balance Confidence Scale (ABC) and Berg Balance Scale (BBS). The ABC is a scale with 16 activities that quantifies an individual's perceived capabilities (self-efficacy) in balance function and provides an inverse measure of perceived fear of falling.¹⁷ A score of 0 represents no confidence, while a score of 100 represents complete confidence in performing the activities. The ABC has been found to have excellent reliability (testretest reliability: ICC = 0.85 ; 95% CI: 0.68-0.93) between two sessions 1 month apart in individuals with chronic stroke.¹⁸ The ABC is similar to the Falls Efficacy Scale,¹⁹ which assesses fear of falling, except that it was designed to be more appropriate for varying levels of function and to accommodate individuals with moderate to high function.

The Berg Balance Scale (BBS) is a 14-item scale that challenges balance while sitting, standing, or stepping and has been shown to have acceptable internal consistency, test–retest reliability, and responsiveness as well as excellent correlation with the Barthel Index, the Postural Assessment Scale for Stroke Patients, the Functional Reach Test, the balance subscale of the Fugl-Meyer Assessment, the Functional Independence Measure, and gait speed.20–22

Each item is scored from 0 (inability to complete) to 4 (independent), for a maximum score of 56. A systematic review of the BBS demonstrated excellent interrater, intrarater, and test–retest reliability (all >0.94).²² The standard error of measurement (SEM) of the BBS, representing the smallest change threshold, is 2.4 points.²³ The SEM was calculated from 52 subjects with chronic stroke who were tested on 2 days separated by 1 week using the formula $SD\sqrt{r-1}$, where SD is the standard deviation of the set of scores and r is the reliability coefficient of that measurement set.

The timed up-and-go (TUG) test is a test of mobility that measures the time it takes for the subject to stand up from an armchair, walk 3 m, turn and walk back to the chair, and sit down again. Interrater reliability has been found to be high for this test.²⁴ TUG values differ between fallers and non-fallers for individuals with stroke.²⁵

Participants were asked to walk at their ''most comfortable speed'' (i.e., self-selected speed) and at a ''fast speed'' (fast but safe speed) along a 10 m walkway. An optoelectronic sensor (Northern Digital, Waterloo, ON) was used to track infrared emitting diodes (IREDs) attached to participants' lateral malleoli and fifth metatarsal-phalangeal (MT) joints. In this camera set-up, the margin of error for locating the coordinates of an IRED in space was 0.9 mm in the anterior/posterior direction and 0.45 mm in the up/down direction. For each individual, at least three ''good'' trials were collected in which all IREDS could be viewed (range: 3–5 trials). Data were collected at 60 Hz. Gait speed was calculated using cumulative consecutive stride lengths (forward distance covered by the lateral malleolus marker from initial contact to the next initial contact of the same leg) in the middle 4 m section (i.e., representative window of constant gait speed) of the 8 m walkway and the corresponding elapsed time. Over the three trials, between 16 and 20 steps were analyzed and averaged. In addition, for each of these steps, the MT marker was used to calculate toe height (i.e., foot clearance), which was averaged over steps. The minimum vertical displacement of the MT marker during stance was set as ''zero.'' For each gait cycle, toe height was defined as the difference in vertical height between "zero" and the maximum vertical displacement of the MT marker during swing.

Outcome Measurement Protocol

Balance confidence for the no-FES condition was assessed prior to any introduction of the FES system, using the ABC Scale. Following the last FES practice session, participants again rated their balance confidence, but this time were asked to score their balance confidence perceptions according to their experiences with the FES system. Participants then returned within 1 week after the last FES practice session for one session to assess their balance and mobility performance. During this session, the order was randomized to start with

Table 1 Participant Characteristics $(n = 15)$

Variable	$Mean + SD (min-max)$		
Age (years)	$54.4 + 10.4$ (25-67)		
Height (cm)	$171.1 + 8.3(155 - 181)$		
Mass (kg)	$81.5 + 18.6 (48.8 - 118.1)$		
Post-stroke (years)	$4.7 + 5.4$ (0.5-15.7)		
R/L lesion side (n)	7/8		
Male/female (n)	12/3		
Ischemic/hemorrhage stroke (n)	8/7		
AHASFC (median)	$\overline{2}$		
CMSA-Foot score (median)	$3(2-4)$		
CMSA-Leg score (median)	$4(3-6)$		
Dorsiflexor (MMT) grade $(0/2/3-7/3)$ (number of subjects)	$4/2/4/5$ (0-3)		

either the FES or the no-FES condition for the BBS, gait speed, and TUG. The assessor was blinded as to which condition (FES or no-FES) was being performed. The participant wore the system hidden from view under a pant leg for both conditions; for the FES condition, the stimulation was turned on by an assistant.

Statistical Analysis

Descriptive statistics (mean, SD) were calculated for all measures. Since the absolute values of skewness of the data (ABC, BBS, TUG, gait speed) were less than 1.5, parametric analyses were performed. Using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL), paired *t*-tests were performed to compare the FES to the no-FES condition for the two primary outcome measures—balance function (BBS) and balance confidence (ABC). An alpha of 0.05 was used. In addition, the minimal detectable change (MDC) at the 90% confidence interval $(MDC_{90})^{26}$ was calculated for the ABC and BBS (based on the literature), and the number of participants who exceeded the MDC_{90} between the FES and no-FES conditions was reported. The MDC_{90} determines the magnitude of change that must be observed before the change can be considered to exceed measurement error and variability at the 90% confidence level. It is important that the MDC be derived from participants similar to those in the current study. We calculated the MDC₉₀ from Botner et al.¹⁸ and Eng et al.,²⁷ because participants in these studies were similar to those in our study: participants were from our health authority; measurements had been carried out in our laboratory; and we had access to the full data to calculate the MDC_{90} . For both measures, the MDC_{90} was calculated from two measures 1 month apart.^{18,27} The MDC₉₀ for the ABC was 11.5, and the MDC_{90} for the BBS was 3.5.

Lastly, the secondary measures (TUG, gait speed, and toe height) were also compared using paired t-tests.

RESULTS

Eighteen individuals consented to participate in the study, 15 of whom completed the assessment sessions (see Table 1). One participant did not begin the practice phase because he was admitted to hospital, where he subsequently died. Two more participants completed the practice phase but did not undertake the outcome measure evaluation. One of these participants had intolerance and hypersensitivity to the stimulation; this individual had also moved a considerable distance away from the hospital and was not willing to come in again to complete the tests. The other participant suffered a severe fall in the community and consequently required a lengthy hospital admission. Only four of the 15 participants had an AFO; therefore, the FES was not compared to an AFO condition but, rather, was compared to a no-FES condition without any device or orthosis. Participants who had an AFO were comfortable walking without one, as they often walked without the AFO at home and for short distances in the community. As noted earlier, most participants used the tilt sensor to trigger the FES; only four used the heel sensor because of ill-timed triggering from the tilt sensor, resulting from extreme early-stance knee hyperextension. Thirteen participants attended all four familiarization sessions; two participants attended three.

BBS performance was better with the FES than without it (see Table 2). However, on examination of the individual subject data, we found that 9 of 15 subjects showed an improvement of 1 or 2 BBS points, and only 2 subjects showed an increase greater than the MDC_{90} value of 3.5 BBS points. There did not seem to be common BBS tasks to which the improvement could be attributed.

Use of the FES had no effect on ABC scores across the entire group (see Table 2). However, a large variability in individual ABC scores was seen: six subjects showed increased ABC scores, while the other nine showed decreased scores. Six of these showed a decrease in excess of the MDC_{90} milestone of 11.5 ABC points.

Toe height during self-paced and fast gait assessments was significantly higher for the FES condition than for the no-FES condition (see Table 2). However, this apparent improvement did not translate into discernible changes in gait speed or TUG performance between the FES and no-FES conditions (see Table 2).

DISCUSSION

FES produced an increase in toe height during the swing phase of gait, which could translate into a decreased fall risk for participants, as they may be less

Table 2 Comparison of Variables between the no-FES and FES Conditions

Variable	No-FES Mean (SD)	FES Mean (SD)	Mean (SD) <i>Differences</i>		p	
BBS*	46.7(6.3)	47.9(5.4)	1.13(1.92)	-2.28	0.039	
ABC	69.0 (16.1)	62.9(23.7)	$-6.1(16.4)$	1.44	0.17	
Self-paced gait speed (m/s)	0.65(0.21)	0.63(0.22)	$-0.01(0.91)$	0.60	0.56	
Fast-paced gait speed (m/s)	0.81(0.30)	0.81(0.31)	$-0.004(0.04)$	0.41	0.69	
TUG(s)	18.9(7.8)	18.2(6.7)	$-0.67(2.0)$	1.29	0.22	
Toe height (mm) (self-paced)*	65.0 (24.4)	78.4 (26.1)	13.3 (17.3)	-2.99	0.010	
Toe height (mm) (fast-paced)*	69.9 (27.0)	81.0 (27.2)	11.1(12.9)	-3.35	0.005	

 $BS = Berq$ Balance Scale; ABC $=$ Activities-specific Balance Confidence Scale; TUG $=$ timed up-and-go

* Significance difference between conditions at $p < 0.05$

likely to trip as a result of their foot's catching the ground. The increase in toe clearance corresponds to the activation of the dorsiflexors by the peroneal stimulation. The lack of change in gait speed and TUG score may be due to the short practice time frame (8 hours over 4 weeks); perhaps more sessions or a longer time period is required for individuals to change their natural walking speed. In addition, our small sample size may have reduced our ability to detect small changes.

Although balance was improved, the change was very small, less than the MDC_{90} , and likely not clinically relevant. The BBS includes a number of activities (e.g., turning, stepping) during which the FES may be triggered and consequently improve performance, but the observed 1- or 2-point improvement was not specific to any particular item on the scale across participants.

Although toe height during swing was improved, which might lead to a safer gait pattern, balance confidence deteriorated in the majority of participants, with reductions larger than the MDC_{90} (>11 points) in more than one-third of participants ($n = 6$). In general, ABC scores were low (in the 60s); it has been suggested that a score of less than 80 indicates deficits in balance confidence.¹⁷ The results imply that the 8 hours of practice may not have been sufficient for participants to have confidence in their mobility abilities with the FES device. It does take time to get used to adapting one's gait to get the best response from the stimulation and to avoid occasional unwanted stimulation during the stance phase of gait. The experience of mistimed stimulations could be destabilizing, although we observed that participants would stop walking or slow down when this happened and that no participants lost their balance during their practice time. We suggest that balance confidence should be assessed to ensure that subjects are confident of their ability when using FES devices that enhance walking ability.

This study has several limitations. Although the study identified that some individuals may experience deterioration of their balance confidence upon introduction of an FES system, the small sample precluded us from determining factors that may predict which individuals may improve or deteriorate in balance confidence. Although our results show a significant difference in BBS scores the study was underpowered to detect changes in ABC score. This study can inform future studies with appropriate sample sizes for assessing the effect of FES on the ABC. Using the ABC means and standard deviations (Table 2) and a correlation between conditions of 0.72, we calculated an effect size of 0.37. Given a power of 0.80 and alpha of 0.05, this suggests that 59 subjects would be appropriate to detect changes in ABC score with the use of FES.

Although we found that more than half the participants still had a deterioration in balance confidence after 8 hours of practice over 4 weeks, we are not able to determine how many hours or weeks would be required to restore participants' confidence to their baseline levels. Individuals who fear falling have been shown to limit their activities significantly.²⁸ Therefore, it is important that practice and gait re-education be included with the fitting of the device, in order to improve comfort and confidence for eventual full-time use. Proper prescription of an FES device, fitted to the user's gait, with adequate practice opportunities provided by a trained professional, plus follow-up visits, may bring the user beyond fear of falling and its self-limiting behaviours.

KEY MESSAGES

What Is Already Known on This Subject

Previous evidence has shown that a peroneal nerve stimulator can reduce foot drop in people with stroke; however, no studies have previously examined the effects of FES on balance function or balance confidence. Balance function and balance confidence could potentially be altered when commencing a gait re-education program with FES.

What This Study Adds

Our study demonstrated that physical improvements in gait and balance function can occur during FES treatment applied to the ankle dorsiflexors during the swing phase of gait in individuals following a stroke. However, use of FES may be associated with a clinically important impairment in balance confidence as individuals familiarize themselves with FES treatment.

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