Response and Prediction of Improvement in Gait Speed From Functional Electrical Stimulation in Persons With Poststroke Drop Foot

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Objective: To describe changes in and predictors of comfortable gait speed (GS-C) after using a foot-drop stimulator (FDS; Bioness L300; Bioness Inc, Valencia, CA) for 42 weeks in persons who had sustained a stroke.
Design: Secondary analysis of prospective assessments.
Setting: Multicenter clinical trial.
Participants: A total of 99 subjects who had sustained a stroke ≥3 months earlier and who had GS-C ≤0.8 m/s and drop foot with a mean age of 60.7 years and a poststroke time of 4.8 years.
Methods: GS-C was assessed at baseline and at 30 weeks with and without use of an FDS (therapeutic effect) and at 6, 12, 30, 36, and 42 weeks with use of an FDS (total effect). After subjects participated in 8 physical therapy sessions, an FDS was used for ambulation over the course of 42 weeks.
Main Outcome Measurements: Changes in mean GS-C over time, FDS "responder" status defined as either ≥0.1 m/s gain in GS-C (the minimal clinically important difference [MCID]) or advancing by one Perry Ambulation Category (PAC), and the incidence and nature of adverse events (AEs).
Results: A total of 74 (75%) and 69 (70%) of 99 subjects completed assessments at 30 weeks and 42 weeks, respectively. Baseline GS-C was 0.42 m/s without use of an FDS and 0.49 m/s with use of an FDS. GS-C improved to 0.54 m/s at 30 weeks without use of an FDS (effect size = 0.75) and 0.54, 0.55, 0.58, 0.60, and 0.61 m/s at 6, 12, 30, 36, and 42 weeks with use of an FDS, respectively (effect size 0.84 at 42 weeks). Half of the subjects achieved a maximum GS-C by 12 weeks. Approximately 18% were PAC responders and 29% were MCID responders for 30-week therapeutic effect, and 55% were PAC responders and 67% were MCID responders for 42-week total effect. After logistic regression, the following factors emerged as the strongest predictors of FDS responders: younger age, faster baseline GS-C and Timed Up and Go, and balance. At 42 weeks, 60% reported a device-related AE; 92% were mild and 96% were anticipated.
Conclusions: When an FDS was used, GS-C improved progressively over 42 weeks, with ≥50% of patients achieving a clinically meaningful 42-week total effect and 50% achieving a maximum GS-C by 12 weeks. Younger patients with greater mobility levels may benefit most from use of an FDS. AEs were frequent, mild, and reversible.

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INTRODUCTION

Seven million Americans are living with the effects of a stroke, and nearly 800,000 new and recurrent cases of stroke are reported annually [1]. Impairments resulting from stroke include language and cognitive deficits, visual changes, and contralateral hemiplegia, among many others [2,3]. Sustained distal weakness in the hemiparetic leg is manifested by an inability to adequately dorsiflex the foot during the swing phase of gait and can impede mobility profoundly [4]. This condition, known as "drop foot," occurs in up to 20% of persons who have had a stroke [5]. Drop foot is seen with either weakness of the anterior

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Table 1. *Published studies of surface foot-drop stimulation and gait speed in persons with chronic stroke (n > 10)*

Study, Year (Reference)	Total N (Stroke, n)	F (%)	Mean Age, y	Mean Time Poststroke, y	Mean Baseline GS (no FDS), m/s	F/U Time, wk	F/U, %	IE*
Current analyses	99	48	60.7	4.8	0.42	30	75%	0.07 17%
						42	70%	0.07 17%
Everaert et al, 2013 (23)	38	33	57.1	0.53	0.52	6	88%	0.07 15%
Taylor et al, 2013 (22)	62	47	59.6	4.8	0.49	>14.3†	90%	0.08 16%
van Swigchem et al, 2010 (24)	26	19	52.8	3.2	1.02 (with AFO)	8	96%	NR
Stein et al, 2010 (25)	73 (26)	46	58.8	7.5	0.64	44	32%	0.05 6.5%
Sabut et al, 2010 (28)	16	20	49.5	1.5	0.37	12	100%	NR
Hausdorff and Ring, 2008 (14)	24 (21)	17	54.0	5.8	0.53	8	100%	0.09 17%
Laufer et al, 2009 (26)	16 (13)	7	55.0	5.3	0.62	52	67%	NR
Stein et al, 2006 (16)	26 (12)	NR	57	NR	0.69	12	100%	0.02§ 3%
Taylor et al, 1999 (27)	140 (111)	NR	55.4	5.4	0.57	18	93%	0.07 12%
Burridge et al, 1997 (15)	16	38	52.3	3.6	0.64	12	100%	0.04 6%
Granat et al, 1996 (29)	19	16	56	7	0.87	11	84%	NR

F = female; GS = gait speed; FDS = foot-drop stimulator; F/U = follow-up; IE = immediate effect; TrE = training effect; ToE = total effect; ThE = therapeutic effect; AE = adverse event; NR = not reported; TUG = Timed Up and Go; BBS = Berg Balance Scale; GS-C = comfortable gait speed; 10-MWT = 10-meter walk test; ODFS = Odstock Dropped Foot Stimulator; PAC = Perry Ambulation Category; MCID = minimal clinically important difference; AFO = ankle foot orthosis; TBI = traumatic brain injury; 6-MWT = 6-meter walk test; 6/10-MWT = 6- to 10-meter walk test; PCI = physiologic cost index.

*Numbers are gains in gait speed in m/s; % is percent gain in gait speed from baseline as defined in text.

† Average of all assessments taken after 100 days.

‡ Assuming no FDS at baseline (not stated in study).

§ Estimated or calculated value for this table.

muscles, spasticity of the posterior muscles of the leg, or both. Subsequent development of plantar-flexion contracture at the ankle further complicates limb clearance. Drop foot contributes to undesirable compensatory movement patterns, slowed gait speed, limited functional mobility, and an increased risk of falls [6-8].

A number of treatment strategies for drop foot may be used depending on the underlying cause. Contracture at the ankle joint in a person with good ambulation potential may be managed surgically [9]. Posterior compartment spasticity is treated with exercise and a combination of oral, injection, or intrathecal medications [10]. The most common treatment is an ankle-foot orthosis (AFO), which is a brace that holds the ankle in a neutral position and improves limb clearance during the swing phase of gait. AFOs have significant drawbacks, however, including limitation of ankle mobility, which contributes to contracture development [11], possible undermining of motor recovery [12], difficulty in standing from a seated position [6], and poor acceptance by the wearer as a result of discomfort and the perception of undesirable aesthetics [13].

Another strategy to combat drop foot is the use of functional electrical stimulation (FES). FES is used to stimulate branches of the common peroneal nerve just below the knee, thus activating dorsiflexion and eversion of the foot. A foot-drop stimulator (FDS) is a commercially available FES system designed specifically for use during ambulation. These devices synchronize surface stimulation of the nerve with the swing phase of the gait through the use of either pressure sensors or heel switches placed in the shoe [14,15] or a tilt sensor [16]. The potential effects of FDS devices have been described previously by Dunning et al [17]. Gait speed has been studied most often, but any relevant parameter could be used. An immediate device effect refers to changes that occur at once (ie, within minutes) when "FDS off" is compared to "FDS on." A training effect above and beyond the