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ORIGINAL RESEARCH ARTICLE

Effects of a Foot Drop Neuroprosthesis on Functional Abilities, Social Participation, and Gait Velocity

ABSTRACT

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Objective: To determine the long-term effects of a neuroprosthesis used to correct a foot drop on functional ability in activities of daily living, social participation, and gait velocity.

Design: Prospective, single group, repeated measures 1-yr follow-up of 16 patients (aged 55 ± 14.6 yrs) with chronic hemiparesis who used a neuroprosthesis for 1 yr and were available for follow-up. Outcome measures included the Short Version of the Stroke Impact Scale, the Participation domain of the Stroke Impact Scale, and the gait velocity.

Results: Significant increases of 18.0% in physical functioning and of 25.2% in participation in community life were attained 2 mos after the application of the neuroprosthesis. The gains were maintained at the 1-yr follow-up. Gait velocity increased significantly by 29.2% by 2 mos, with significant further increases of 22.6% observed at the 1-yr follow-up.

Conclusions: Use of the studied neuroprosthesis to correct foot drop significantly enhanced functional abilities, social reintegration, and gait velocity. These results support the prolonged use of the neuroprosthesis in patients with chronic hemiparesis.

Key Words: Neuroprosthesis, Foot Drop, Participation, Function

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The ultimate goals of rehabilitation include regaining functional abilities and the participation and reintegration in all aspects of life that are meaningful to the individual.[1] Many stroke survivors achieve sufficient recovery to perform some degree of limited indoor mobility essential to the ability to carry out many daily functions.[2] However, incomplete recovery after a stroke and inability to resume community level ambulation is estimated to afflict at least 55% of stroke survivors[3] and continues to have a detrimental effect on many aspects of the survivors' quality of life.[4]

One of the more common impairments affecting the gait of approximately 20% of stroke survivors[5] and individuals with other upper motor neuron afflictions is the difficulty to dorsiflex the ankle effectively and clear the ground during the swing phase of walking. This impairment, termed a foot drop, is caused by a combination of weak dorsiflexors and increased spasticity and stiffness of the plantar-flexors[6] and is strongly associated with reduced gait speed,[7] increased energy expenditure,[8] and increased instability and tendency to trip and fall.[9]

An ankle foot orthosis (AFO) is the conventional and most commonly prescribed device used to compensate for foot drop. Functional electrical stimulation (FES) to the peroneal nerve, which elicits dorsiflexion and eversion of the ankle in the precise sequence and magnitude needed to aid foot clearance during the swing phase of walking, provides an alternative approach to AFO. The effectiveness of FES devices has generally been examined by determining their impact on gait velocity and on energetic expenditure while walking on an even surface.[10–14] However, gait velocity does not consistently reflect the recovery of functional ambulation, particularly at the community level.[15] To determine the effect of FES on functional mobility, recent studies have also incorporated measures, such as gait velocity on uneven surfaces, around obstacles, and up and down stairs[16–18]; gait endurance, as measured by the distance covered during a 6-min walk test[19,20]; and stride-time variability that is considered an important index of dynamic stability.[19] Although gait performance measures such as "comfortable" and "fast" gait speed, as well as functional tests such as the Timed Up and Go Test and stair negotiation, have been shown to correlate significantly with the perceived social participation of individuals 4–6 mos after stroke,[21] there is a need to examine directly the effect of FES devices on the physical functioning and participation in community life of patients with hemiparesis. Furthermore, most of the studies examining gait performance with FES have focused primarily on short- to medium-term effects (e.g., several weeks) and do not present sufficient information on relatively long-term effects of using such systems.

In a recent pioneering study attempting to address the effect of FES on social participation, Fernandes et al.[22] examined the effect of 20 FES sessions on the quality of life of 50 patients after a stroke. The effect, as determined by the short form 36-item questionnaire, pointed to significant improvement, particularly in physical functioning. However, as the short form 36-item questionnaire is a generic health-related quality-of-life instrument, it is not well suited to capture physical functioning or social well-being of patients with stroke.[23] The Stroke Impact Scale (SIS) is a recently developed self-report questionnaire designed to comprehensively assess stroke-related outcomes,[24] which has been found to be valid and reliable, accurately assessing recovery after stroke.[24–26] A shortened version of this instrument, the SIS-16 and the eight items comprising the SIS Participation domain, can be used as stand-alone scales to assess physical functioning and social integration.[23] These instruments capture a wide range of physical function limitations and social well-being aspects of patients with stroke,[23,26] which are sensitive to differences across all levels of stroke severity.[27]

The primary objective of the present study was to examine the effects of a neuroprosthesis designed to correct foot drop (NESS L300, Bioness Inc., Santa Clarita, CA) on functional abilities and participation in community life after 1 yr of device application. Although the short-term (i.e., 8 wks) positive effects of this device on gait velocity have been reported previously,[19] the present study presents the effects of the device on function and social participation as well as on gait velocity after 1 yr of use. Finally, the study also examines the correlation between changes in gait velocity and physical functioning and community participation.

METHODS

Participants

A sample of 24 subjects with chronic hemiparesis who were fitted with the NESS L300 neuroprosthesis to correct a foot drop participated in the study. Inclusion criteria were as follows: (1) diagnosis of an upper motor neuron lesion; (2) more than 6 mos since initial diagnosis when first fitted with the neuroprosthesis; (3) observed foot drop during the swing phase of gait; (4) calf muscle spasticity not higher than grade 4 according to the Modified Ashworth Scale; (5) passive ankle range of motion to neutral position; (6) sufficient motor ability and endurance to ambulate at least 10 m independently with or without an assistive device; (7) a score of at least 23/30 on the Mini-Mental

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State Examination; and (8) no skin lesion in the area of the electrodes. Excluded from the study were patients who were medically unstable or receiving medication that could affect their ability to self-report their function. Also excluded were patients who suffered from depression, as defined using the *DSM IV* criteria. As detailed below, a subset of these patients were studied at follow-up.

Study Design

The study was approved by the Institutional Review Board of the Lowenstein Rehabilitation Hospital, Israel. All subjects signed an informed consent form and provided demographic and medical information. After initial fitting with the neuroprosthesis, the subjects were advised to gradually increase their daily application of the device so that by the fourth week they used it for the entire day. Each subject was assessed three times: (1) just before receiving the FES neuroprosthesis, when gait performance was assessed with no assistive device (either the AFO or the FES neuroprosthesis) (T1); (2) 2 mos later (T2); and (3) after 1 yr (T3). Gait performance at T2 and T3 was assessed with the neuroprosthetic device operating.

The Neuroprosthesis

The NESS L300 is a single-channel wireless neuroprosthesis, which activates the ankle dorsiflexors during the swing phase of gait (Fig. 1). The unit provided to the subject includes the following three components that communicate via radio frequency signals. (1) A hybrid orthosis that includes the stimulation unit (weight 50 g) and two round (45-mm diameter) electrodes. To elicit dorsiflexion with some eversion, one electrode is located over the common peroneal nerve, posterior and distal to the fibular head, and a second electrode is located over the tibialis anterior muscle. Once the optimal location of the electrodes is identified by the clinician fitting the device, they are adhered to the inner surface of the orthosis. The orthosis with the two embedded electrodes can then be attached by the patient using only one hand at the optimal location identified by the clinician, thus ensuring consistent and proper electrode placement without the need for daily adjustments. (2) A gait sensor that includes a pressure sensor worn underneath the shoe insole at the heel and a small transmitter attached to the shoe rim. The gait sensor uses dynamic gait recognition algorithms to detect and analyze events during walking (e.g., heel strike and toe off). This information is transmitted to the system to control the timing of the stimulation. (3) A miniature control unit ($7.4 \times 4.6 \times 1.7$ cm, weighing 45 g) allowing simple operation and displaying real-time information regarding the system status. In addition, a handheld computer is used by the clinician during the fitting process to set the stimulation parameters (e.g., intensity, pulse duration, and pulse frequency) and the timing of the stimulation in accordance with the patient's gait characteristics (e.g., the percentage of the stance time during which stimulation continues after heel contact). The NESS L300 also includes a gait log that enables the clinician to note the number of steps and hours of use.

FIGURE 1 *The NESS L300 neuroprosthesis.*

Outcome Measures

The impact of the neuroprosthesis on physical and social functioning was evaluated with the SIS-16 and the Participation domain of the SIS questionnaires, as completed by the subjects at each evaluation session. Each item on both the SIS-16 and the Participation domain was scored by the subject on a 1–5 scale, with lower scores indicating worse function. For each subject, the mean score of the SIS-16 items was calculated and converted into a percentage (1–100) value: $100 \times$ (the mean value of the 16 items $-1)/(5-1)$.[28] A similar process was used for the Participation domain, using the mean value of the eight items comprising this domain.

Gait velocity was assessed with the 10-m walk test. For this test, the subjects were told to walk safely at a comfortable pace without running along a 14-m marked course. The test was performed once, using a digital stopwatch (with an accuracy of two decimal points) to record the subjects' ambulation time over the middle 10 m of the course. Velocity was determined as meters walked per second (m/sec).

Statistical Analysis

Demographic variables were summarized using descriptive statistics. *t* tests were used to compare demographic characteristics of participating subjects with those who were not available for testing at follow-up, as well as the performance of these subgroups at T1. Analysis of variance was used to deter-

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TABLE 1 Subjects' characteristics at baseline

Study Size	Study Group (n = 16)	Dropouts (n = 8)
Age (mean ± SD, range)	55.0 ± 14.6 (28.0–76.0)[a]	54.0 ± 13.9 (27.0–71.0)
Sex (male/female)	15/1	4/4
Body mass index (mean ± SD, range)	26.5 ± 3.4 (22.6–36.3)[a]	25.0 ± 4.7 (19.5–33.7)
Paretic side (right/left)	7/9	3/5
Primary diagnosis (stroke/traumatic brain injury)	13/3	8/0
Time since hemiparesis, yrs (mean ± SD, range)	5.3 ± 4.8 (0.5–16)[a]	6.6 ± 4.6 (2–15)
Orthotic device used before (none/AFO/dictus)	3/12/1	1/5/2
Walking aid used before (none/cane)	5/11	1/7

[a] No significant difference between groups.
AFO, ankle foot orthosis.
Dictus band, OrtoPed, Canada.

mine the effect of time separately for each variable. Tukey's honestly significant difference test was used for all pairwise comparisons of significant effects. The relationship between gait velocity and the functional questionnaires assessed before and after treatment were examined using regression models. This was necessitated by the need to control for the effect of repeated assessments at different times (pre- *vs.* post-therapy). Time (a fixed factor), gait velocity (a continuous factor), and their interaction along with subject as a random factor (to control for the repeated-time measures) were predictors, and the functional questionnaire score was the outcome measure. The interaction effect was included to determine whether the gait effect on the questionnaire is different pre- or posttherapy. Significance was determined at $P \leq 0.05$. Data analyses were performed with JMP and SAS (both SAS Institute, Cary, NC).

RESULTS

Twenty-four subjects were recruited for this study. [Gait performance before the application of the FES neuroprosthesis and at the 2-mo follow-up evaluation of the entire group was previously reported.[19]] Eight subjects were not available for the 1-yr follow-up evaluation and were not included in the present analysis: one of these subjects stopped using the neuroprosthesis after a tendon transfer; a second subject stopped its use because she felt she had improved sufficiently and no longer needed the device; the other six subjects reported on the phone that they continued using the device with satisfaction but were followed by another clinic and could not come to the clinic for assessment. The NESS L300 gait log indicated that all participating subjects used the device for at least 80% of the days. Table 1 presents the demographic characteristics of the 16 subjects who were available at follow-up and included in the present study, as well as the characteristics of those who dropped out. No significant difference was observed between groups in terms of age, body mass index, or time since hemiparesis. Comparison between performance of these groups at T1 revealed no significant difference between groups in terms of SIS-16 or the SIS Participation domain. Those who were not available for follow-up testing tended to have a slower 10-m gait velocity ($P = 0.06$).

Table 2 presents the mean and standard deviation values of the SIS-16 and the SIS Participation domain. Analyses of variance indicated that time had a significant effect on both the SIS-16 ($F_{2,30} = 7.45$, $P = 0.002$) and the SIS Participation domain test ($F_{2,30} = 10.64$, $P = 0.0003$). For both variables, Tukey's honestly significant difference test indicated a significant difference between T1 and T2, as well as between T1 and T3 ($P \leq 0.05$), but no significant difference between T2 and T3 was noted.

Table 2 also presents the mean, standard deviation, and range of the gait velocity before the use of the neuroprosthetic device and at the 2-mo and 1-yr follow-up assessments. Analysis of variance

TABLE 2 Results of all measured variables before the use of the neuroprosthetic device, at the 8-wk and at 1-yr follow-up assessments [(mean ± SD (range)]

	Pretreatment (T1)	8-wk Follow-Up (T2)	1-yr Follow-Up (T3)
Stroke impact scale-16	63.6 ± 12.3 (37.5–84.4)	72.8 ± 12.9 (53.1–100.0)	74.1 ± 12.1 (53.1–100.0)
Participation domain	50.2 ± 17.7 (15.6–78.1)	62.9 ± 14.9 (40.6–100.0)	68.6 ± 16.3 (43.8–100.0)
10-m velocity (m/sec)	0.67 ± 0.22 (0.34–1.07)	0.86 ± 0.26 (0.42–1.33)	1.06 ± 0.27 (0.68–0.52)

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indicated that time had a significant effect on the 10-m gait velocity ($F_{2,30} = 43.58$, $P \leq 0.0001$). Tukey's honestly significant difference test indicated a significant difference between the time before the use of the FES device and both the 2-mo and the 1-yr follow-up assessments, as well as a significant difference between the two follow-up assessments (T2 *vs.* T3) ($P \leq 0.05$). Regression analysis indicated no significant relationship among gait velocity, time, or their interaction and either of the self-report questionnaires.

DISCUSSION

The present study examined the effects of a recently developed wireless FES neuroprosthesis designed to ameliorate a foot drop during ambulation in a group of individuals with chronic hemiparesis. The results demonstrate that the use of the neuroprosthesis has significant favorable short-term and long-term effects on self-reported physical functioning in activities of daily living and social integration, as well as on gait velocity.

Recent research indicates that gait performance variables such as gait velocity, which is normally considered when evaluating peroneal FES, does not necessarily reflect the level of community ambulation actually attained by stroke survivors and that patients' self-reports are important for determining actual participation in community life.[15] To the best of our knowledge, the present study is the first to report the short-term and the long-term effects of a neuroprosthesis for the correction of a foot drop on functional performance and social participation. The results indicate significant increases of 18.0% in physical functioning and of 25.2% in participation in community life attained 2 mo after the application of the neuroprosthesis. Although the incremental additional improvement of 9% in social participation attained at the 1-yr follow-up assessment did not reach statistical significance, the progress in both measures was maintained at the 1-yr follow-up. The initial mean gait velocity of our subjects assessed before the application of the device was 0.67 m/sec, which is well within the gait velocity accepted as necessary for unlimited household ambulation.[29,30] Furthermore, as 75% of the subjects habitually used an AFO, it is very likely that their gait velocity with the AFO was even higher. Therefore, it is not surprising that the initial SIS-16 scores, which captured overall functional ability in the home environment, were relatively high. Nor is it surprising that the gains in physical functioning were not as substantial as those made in social participation. In fact, any detectable change in physical functioning in this highly functional group supports findings indicating that the SIS-16 is sensitive to change and does not suffer from a ceiling effect.[31]

The loss of independent ambulation, especially in the community environment, is often identified by patients as the most debilitating aspect of stroke that affects their quality of life.[32] Thus, the most significant finding of the present study relates to the subjects' perceived improvement in social participation. Furthermore, as gait velocity is not expected to change spontaneously in patients with chronic hemiparesis, the observed significant and persistent improvements in gait velocity, which extended beyond the 2-mo adaptation period and were observed in the 1-yr follow-up assessment, are encouraging. Furthermore, the fact that 22 of 24 (91.7%) of the original subjects who received the device continued to use it for as long as at least 1 yr suggests that the advantages offered by the L300 system were meaningful to the users. Previous studies using peroneal stimulators that require daily manual application of wired electrodes indicate a much lower rate of compliance,[33–35] with problems of electrode positioning and equipment operation cited most frequently as the cause for discarding the system. Thus, the features of the present wireless system, which combine operational simplicity with a hybrid orthotic element that ensures both precise and reproducible positioning of the stimulating electrodes, may be responsible for the high rate of compliance observed in this cohort group.

Various studies have sought to determine what changes in gait velocity are clinically meaningful. In older adults without specific impairments and in adults after a hip fracture, a change in gait velocity of 0.10 m/sec has been determined as a minimal clinically important difference.[36,37] In subjects with hemiparesis, the smallest change in gait velocity that indicates a clinical improvement has been determined to be 7.9%.[38] By both criteria, the changes observed in the present group of subjects were clinically meaningful. It has been claimed that when gait velocity is used to stratify subjects into functional ambulation categories, it may be used as a clinically meaningful outcome measure.[30] Thus, for example, using a three-category classification of gait ability (limited household ambulation—gait velocity <0.4 m/sec; limited community ambulation—gait velocity of 0.4–0.8 m/sec; and functional community ambulation—gait velocity greater than 0.8 m/sec), it was demonstrated that gait velocity gains that result in a transition to a higher ambulation category are associated with better function and quality of life as determined by SIS scores.[30] However, these changes were not consistent across ambulation categories, and one cannot assume that similar changes in gait velocity are clinically meaningful for all levels of severity.[30]

In the present study, mean gait speed achieved at the 2-mo assessment period (0.86 m/sec)

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reached a level considered to be sufficient for community ambulation,[29,30,39] whereas the mean gait velocity reached by the 1-yr follow-up (1.06 m/sec) approached the normal walking speed of unimpaired adults (1.15 m/sec).[40] Given the statistically and clinically significant changes in gait velocity observed in the present study, it was somewhat surprising that the change in this variable did not correlate with the observed changes in physical functioning and social participation. Although some studies have indeed demonstrated such correlations,[41,42] a review of the literature demonstrates inconsistent results in this respect.[15] Thus, whereas changes in gait velocity are related to ambulation abilities and to changes in mobility and participation scores, this relation probably is affected by additional factors. It is possible that once the subjects reached a gait velocity that allowed for a certain degree of community ambulation (i.e., at the second assessment), further increases in gait velocity were not the most important determinants of physical functioning or social participation.

The primary limitations of the present study are the small number of subjects and the lack of a control group. Although the participating subjects did not report changes in their medications for spasticity, or any other motor-related interventions (e.g., Botox injections), it is possible that some uncontrolled confounding factors may have affected the observed changes in their reported functional and social performance, as well as in their gait velocity. Furthermore, although the initial scores of the subjects who dropped out of the study did not differ from those who completed the study, the large proportion of dropouts (33%) may present a selection bias. Similarly, because only subjects without major depression were included, the results may not be generalized. Although the positive findings are consistent over an extended follow-up period, strongly suggesting that these results are robust, further investigations using an appropriate control group are warranted. Future research also should focus on the long-term effects of FES on a wider variety of gait performance measures.

CONCLUSIONS

The present study demonstrates that the use of the NESS L300 neuroprosthesis by patients with chronic hemiparersis results in significant improvements, both in their functional activities of daily living and in their social participation. The positive effects achieved after 2 mos of application were maintained with continued use of the L300 FES device 1 yr later. Gains in gait velocity continue to improve over the 1-yr span. These findings emphasize the benefits of using the neuroprosthesis in rehabilitation of stroke and traumatic brain injury survivors.

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