The Effect of the NESS L300™ Neuroprosthesis on Gait Stability and Symmetry

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INTRODUCTION

Since Liberson and colleagues reported the first functional application of a drop foot stimulator in the 1960s, a number of studies have demonstrated the benefits of externally induced dorsiflexion for correction of drop foot using functional electrical stimulation (FES). Previous studies that applied FES did not, however, examine its effect on dynamic postural control, a characteristic of the hemiparetic gait that's essential for enhancing gait and reducing the risk for falls. Additionally, previous FES devices have had numerous ergonomic and technical problems. The neuroprosthesis used in this study (NESS L300) was designed to overcome these limitations.

AIMS

1. To investigate the effect of the NESS L300, on the stability and symmetry of the walking pattern in patients with foot-drop.
2. To test the ability of patients with chronic hemiparesis to use this new neuroprosthesis and to assess its safety and functionality.

SUBJECTS

24 patients (mean age: 54.0±13.5 yrs) with chronic hemiparesis (5.8±5.2 yrs) whose walking was impaired by foot-drop. Patients were post stroke (n=21) or traumatic brain injury (n=3).

STUDY DESIGN

Prospective, self controlled study; 8 weeks protocol.

ASSESSMENTS

1. Gait Tests

- Gait was first assessed with and without the neuroprosthesis at the first visit and again, with the neuroprosthesis 4 and 8 weeks later.
- At each assessment, patients walked for 6 minutes while wearing force-sensitive insoles that measured the timing of each gait cycle.
- The primary outcomes were a gait symmetry index and stride time variability (both markers of gait stability and fall risk).
- Average gait velocity was determined.
- Gait speed was also tested during obstacle course walking (Emory Functional Ambulation Profile; Wolf et al Phys. Ther 1999).

2. Falls History

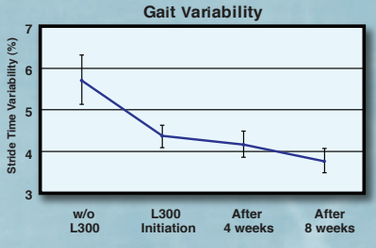
The history and frequency of falls, during the two months prior to the study period and during the study period, were obtained.

3. Subjective Questionnaire

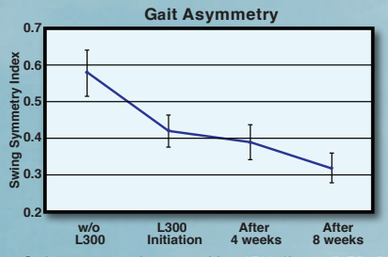
Was completed by the subjects at the end of the study period.

The Neuroprosthesis

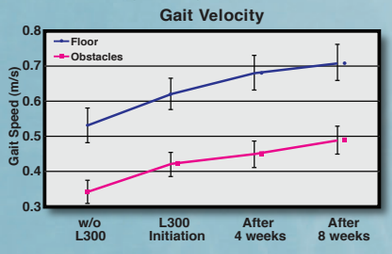
The NESS L300 delivers synchronized electrical pulses to the common peroneal nerve in order to activate the peroneal and tibialis anterior muscles, resulting in ankle dorsiflexion throughout the swing phase of gait, and thereby reducing foot drop. The device includes features intended to overcome major user related barriers such as a hybrid orthosis to ensure accurate electrode placement and attachment, radio frequency (RF) communication to eliminate external wires and connectors, and gait sensor algorithms designed to optimize the foot movement while walking.



Gait variability decreased by 33% (from 5.7±2.9% to 3.8±1.4%; p=0.002).

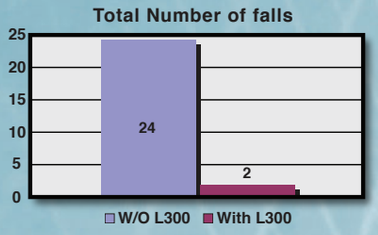


Gait symmetry improved by 45% (from 0.58±0.30 to 0.32±0.20; p<0.001).



Walking speed on level ground improved by 34% (from 0.53 ±0.24 to 0.71±0.25 m/sec; p<0.001).

Walking over the obstacle course improved by 44% (from 0.34±0.16 m/s to 0.49±0.20 m\sec; p<0.001).



The number of falls decreased by 92% (p=0.001).

RESULTS

All patients found the system safe for use, and reported an increase in physical activity with greater confidence in walking on slopes and uneven surfaces. The majority of the subjects (20 out of 24) did not need help in operating the NESS L300 and did not find it difficult to place the orthosis in the correct position.

CONCLUSIONS

This study demonstrates that the NESS L300 neuroprosthesis enhances gait and improves dynamic stability in chronic hemiparetic patients. These findings suggest that stroke and traumatic brain injury survivors may gain meaningful benefits by using the neuroprosthesis upon initial use, and that continued use further enhances their gait abilities. This new FES neuroprosthesis may be a viable alternative to augment the rehabilitation of patients with foot drop.

Hausdorff J, Ring H, The effect of the NESS L300 neuroprosthesis on gait stability and symmetry, (abstract) *J Neurol Phys Ther.* 2006 Dec 30 (4):209-22 (included in CSM 2007 Platform Presentations).

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