

The Effect of a New Lower-Limb Neuroprosthesis on Physical and Social Function



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INTRODUCTION

For traumatic brain injury and stroke survivors, independent ambulation is fundamental to their level of independence and social participation. Foot drop is one of the common pathological gait patterns caused by hemiplegia. Hemiparesis not only causes serious motor limitations but also interferes with a patient's social activities, relationships and emotional well-being. Consequently, most categories included in the comprehensive international classification of functioning (ICF) refer to social participation.

Effective management of foot drop and ambulation is critical for enhancing physical functioning. By improving the level of physical function, patients may increase their level of social participation and improve their quality of life.

AIM

1. To assess the effect of the NESS L300™, an FES neuroprosthesis designed to ameliorate foot drop, on the physical and social function of patients with foot drop.

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).

PROTOCOL

Subjects were assessed before and after they used the neuroprosthesis for 8 weeks.

ASSESSMENTS

- Physical function was quantified in two ways:
 - a) level of physical activity was measured using Step Activity Monitors (SAM, Cyman Inc.)
 - b) Stroke Impact Scale 16 (SIS-16).
- Social function was evaluated using the social section of the SIS-16.

- Study design included baseline measurements followed by eight weeks of walking with the NESS L300 neuroprosthesis. During week eight, the same outcome measures were collected, reflecting a post test data collection.

The NESS L300 Neuroprosthesis

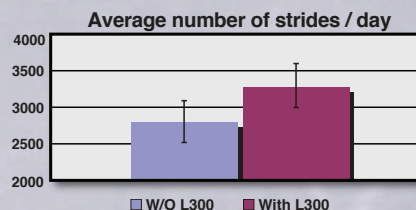
The neuroprosthesis delivers electrical pulses to the common peroneal nerve in order to activate the peroneal and tibialis anterior muscles, resulting in ankle dorsiflexion throughout the swing phase of gait, and thereby preventing foot drop. The device includes features intended to overcome major user related barriers: a hybrid orthosis enables accurate electrode placement and attachment, use of radio frequency (RF) communication eliminates external wires and connectors, and gait sensor algorithms designed to optimize the synchronization of foot movements.



RESULTS

Physical Functioning

A significant improvement in the SIS-16 score (p=0.003) was found after eight weeks of walking with the NESS L300. The mean difference between the SIS-16 score with the neuroprosthesis and without it was 6.0±8.6 points.



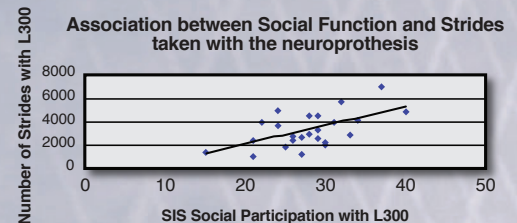
Comparing the daily number of strides per day with the NESS L300 and without it,

revealed an increase of 18% (p<0.001) while the subjects used the neuroprosthesis. The increased number of strides represents an improvement in the physical activity.

Social Functioning

Significant improvement in the SIS social participation score (p=0.008) was found after eight weeks of walking with the NESS L300. The mean difference between the SIS-participation score with the neuroprosthesis and without it was 3.1±4.6 points.

Spearman's correlation between the total number of strides while using the neuroprosthesis and the SIS-participation at the end of the study was significant (r=0.51, p=0.012), demonstrating the positive association between these two parameters.



CONCLUSIONS

Chronic stroke and traumatic brain injury survivors who walked with the NESS L300 neuroprosthesis increased their community participation and physical functioning. The significant association between physical activity and social participation for this group of patients supports the idea that an enhanced social life can be expected when mobility improves.

The present findings underscore the potential of using an advanced FES technology in the rehabilitation of stroke and TBI survivors. This technology may be used effectively by physical therapists to augment the ambulation skills of these patients and consequently improve their social participation and quality of life.