

**Neurotechnology Fundamentals
and Emerging Devices for the
Treatment of Paralysis**

Neuroprosthesis for Foot Drop

Keith McBride, MPT, DPT
Director of Clinical Support and Education
PT 2008: ANNUAL CONFERENCE & EXPOSITION OF THE
AMERICAN PHYSICAL THERAPY ASSOCIATION
★ San Antonio, Texas ★ June 11-14, 2008 ★

Presenter Profile

Keith McBride, MPT, DPT is the Director of Clinical Support and Education for Bioness Inc., Valencia, CA.

Opinions express in conference sessions and handout materials are those of the speaker and do not reflect the opinion of APTA, its officers or staff, or the APTA Annual Conference.

Bioness®, the Bioness Logo®, and LiveOn™ are trademarks of Bioness Inc., Valencia, CA

Electrotherapy

- Neuromuscular Electrical Stimulation (NMES)
 - stimulates the muscle when the patient is in a resting state to treat muscle atrophy¹
- Functional Electrical Stimulation (FES) Neuroprosthesis
 - used to enhance functional activity in neurologically impaired patients. These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence¹
- Therapeutic Electrical Stimulation (TES)
 - FES has also been found to enhance motor recovery in neurologically impaired patients.

¹CMS (2006). Decision Memo for Neuromuscular Electrical Stimulation (NMES) for Spinal Cord Injury (CAG-00153R)

Definition

Neuroprosthetics (also called Neural Prosthetics) is a discipline related to [neuroscience](#) and [biomedical engineering](#) concerned with developing neural [protheses, artificial devices to replace or improve the function of an impaired nervous system](#). The neuroprosthetic seeing the most widespread use is the [cochlear implant](#), with approximately 100,000 in use worldwide [as of 2006](#).^[1]

From Wikipedia, the free encyclopedia

Foot Drop Stimulation: Neuroprosthetic Benefit

- Performance Benefits
- Energy Cost Savings
- “Learning” Effect
- Motor Recovery

Burridge, J.H., et al., *The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients*. Clin Rehabil, 1997. 11(3): p. 201-10.

**Foot Drop Stimulation (FDS)
The Technological Barrier**

Conventional Systems

- Stimulator
- Event Detection
- Control Unit
- Leads



“Challenges have resulted in poor patient compliance and limited clinical adoption of a proven rehabilitative intervention”⁴

Conventional Systems: A Barrier

In a survey* performed in 2002 among 98 users of non-invasive, drop foot stimulators, the following was found:

- 13% - Reported that they have no problems
- 72% - Problem with finding the correct electrode positions
- 58% - Difficulties with wires and foot-switches
- 25–30% of the users ultimately reject the device

* (Gerard M. Lyons, Thomas Sinkjær, Jane H. Burridge, and David J. Wilcox, IEEE, Vol.10, no.4, December 2002)

WalkAide: General Overview

- University of Alberta
- Design Goals
- Neuromotion (FDA 1998)
- Hanger: Innovative Neurotronics
- Southern Prosthetic Supply



Advancements in FDS: NESS L300

- Reproducibility
- Sensing Technology
- Clinical Utility
- Home use Utility
- Electrode Management
- Comfort
- Safety
- Compliance/Outcome Measurement
- Cosmesis

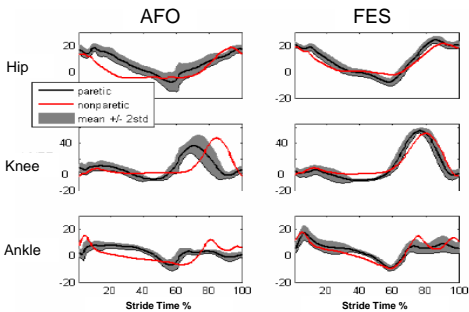


NESS® and NESS L300™ are trademarks of Bioness Neuromodulation Ltd, Ra'anana, Israel. Manufacturer: Bioness Inc, Valencia, CA, Rx only

The NESS L300™



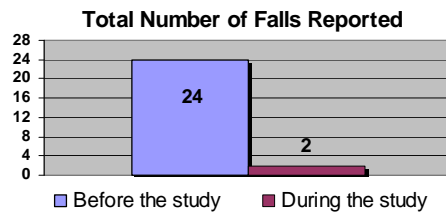
New Findings: Foot Drop Stimulation versus AFO



Peroneal stimulation in stroke patients with a drop foot may have more benefits than ankle dorsiflexion support to facilitate gait. *ISPR Conference, Montreal*
 Roos van Swinchem, Vivian Weendertsew, Alexander Geurts

Joint Abstracts: Accepted for APTA Combined Sections 2007 & The Vancouver Brain Injury Conference 2007
 H. Weingarden, Jeffrey M. Lissendorff

The L300 Versus the AFO



P < 0.01

Significance of Gait Speed

<u>Walking Speed</u>	<u>Ambulation Status</u>
< .4 meters/second:	Household
.4 -.8 meters/second:	Limited Community
> .8 meters/second:	Full Community

Associated Changes in Quality of Life

Schmid, A., et al., *Improvements in speed-based gait classifications are meaningful*. Stroke, 2007. 38(7): p. 2096-100.

The NESS L300 effect on Gait speed

Mean Changes

Baseline: .62 m/sec
 One month: .70 m/sec
 Two Month: .8 m/sec
 One Year: .91 m/sec

P < 0.01

From International Stroke Conference New Orleans 2008: Alon, G., *One year follow-up of patients who are using the Ness L-300 neuroprosthesis: Effects on gait performance*

Training for Clinic Implementation

Clinical Specialists

Clinical Training Program





Interactive Training CD



NMES/FES Coverage: As it stands today

- NCD 160.12
 - Allows coverage only for Spinal Cord Injury patients to walk (after completing 32 PT visits)
 - Based on the Parastep, manufactured by Sigmedics
 - DMERC(s) issued advisory March 2003
- NMES approved by most for orthopedic disuse atrophy*

Barrier: Reimbursement

- Private insurance coverage has covered ~ 20% of our home users
- We offer:
 - \$500/month trial program renewable for up to 4 months
 - A healthcare financing program with 0% interest
- Cost for a system is \$6,200 and the entire trial payments are applied to the purchase price

Thank you!

Demonstration with Lorrie Hemery