

Initial results with fully implanted Neurostep™ FES system for foot drop

**Hoffer JA^{1,2}, Baru M^{2,3}, Bedard S^{2,3}, Calderon E², Desmoulin G^{1,2},
Dhawan P⁴, Jenne G², Kerr J^{1,2}, Whittaker M⁴, Zwimpfer TJ⁵**

¹ School of Kinesiology, Simon Fraser University, Burnaby, British Columbia, Canada V5A 1S6

² Neurostream Technologies, Port Coquitlam, British Columbia, Canada V3B 1A8

³ Victhom Human Bionics, Saint-Augustin-de-Desmaures, Quebec, Canada G3A 2J9

⁴ G.F. Strong Rehabilitation Centre, Vancouver Hospital, Vancouver, British Columbia, Canada V5Z 2G9

⁵ Dept. of Surgery, Faculty of Medicine, Univ. of British Columbia, Vancouver, BC, Canada V5Z 4E3

hoffer@sfu.ca

Abstract

In a pilot feasibility study, a prototype closed-loop FES walking assist system (Neurostep™) was fully implanted in the thigh of a 70 yr old male hemiplegic subject with hypotonia and foot drop who, 3 yr after the stroke, required ankle and knee braces and contact guard assistance and could only walk 5-10 m without fatiguing. Two multi-chambered Neurocuffs™ were implanted on the common peroneal (CP) and tibial (TIB) nerves and connected to a control unit that included custom low-power, low-noise ASIC amplifiers and a pacemaker battery. The Neurostep™ was programmed via telemetry to automatically turn On when the subject stood up, detect heel contact (HC) and toe lift (TL) events from the sensed nerve signals and stimulate selected nerve channels to control the foot trajectory during walking. An “Exercise Mode” provided trains of stimuli that strengthened the disused dorsiflexor muscles and supported walking. The subject was tested and trained with Neurostep™ in the laboratory and received gait re-education for 10 wk before he started to use the device at home. After 6 months, he was able to routinely walk 250 m without fatigue. Although the long-term benefit of using this prototype was limited by a connector malfunction, this pilot study shows the feasibility of treating foot drop with a totally implanted, neuroelectrically controlled FES system. The Neurostep™ technology is now being refined and expanded into an implantable assistive device platform for disabilities such as foot drop, incontinence, limb amputation, paraplegia and chronic pain.

1. INTRODUCTION

Waters et al. showed 30 yr ago the feasibility of correcting foot drop with a *partially implanted* peroneal nerve stimulator [1]. However, there is still no commercial, implantable FES system for foot drop. A reason may be that all device designs to date basically replicate Medtronic's

original, telemetry-based, *Neuromuscular Assist* prototype [1,2]: they include an external power source and RF transmitter, implanted receiver connected to electrodes placed on or near the peroneal nerve, and an external sensor (usually a heel switch) used to initiate stimulation during swing. Telemetry-based systems have several known limitations. Notably, Dr. Waters himself predicted that broad acceptance of a foot drop device would require a **fully implanted system**, as was shown earlier with heart pacemakers [2].

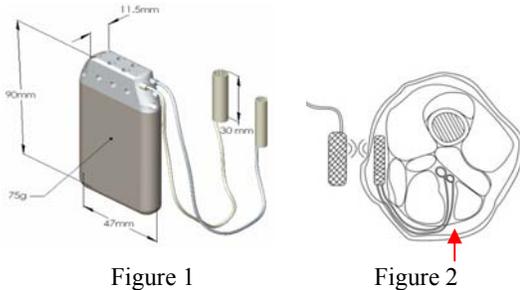
The concept of implanting nerve cuff electrodes to obtain electroneurographic (ENG) signals generated by natural sensory receptors in the body and use ENG as feedback to control FES, was originally proposed by Hoffer [3], tested in pilot human subjects in Aalborg and shown to provide gait-related signals robust enough to control FES for treating foot drop [4]. The long-standing challenge was to design a closed-loop FES system in a fully implantable package that has no external parts and is always ready to go.

With this in mind we developed Neurostep™, the first totally implanted, closed-loop FES device for foot drop. Key innovations that enabled this prototype Neurostep™ system implementation include multi-chamber record/stimulate Neurocuffs™ [5], custom low-power, low-noise, low-leakage, fully integrated ASIC bandpass amplifiers and rectifiers [6], and a computationally simple, low-power gait event detection algorithm [patents pending].

We summarize here our findings from an eight-month pilot feasibility study. The Neurostep™ subject was a 70 y.o. male 3 yr post-stroke with severe foot drop and flexor hypotonia that were managed with a knee brace in addition to an ankle-foot orthosis (AFO). He could only walk 5-10 m without fatiguing and required contact guard assistance. This study, approved by the Health Canada Medical Device Board and five institutional human research ethics committees, was carried out in Vancouver in 2003-2004.

2. METHODS

Figure 1 shows the Neurostep™ prototype and its dimensions. Circuitry, battery and telemetry antenna are sealed in a pacemaker-like welded titanium case. Two 30 mm Neurocuffs™ attach to the device header via 25 cm long flexible leads and 3-pole modified IS-1 connectors.



In a first surgery, through a 6 cm posterior thigh incision (Fig. 2; arrow) the surgeon isolated the common peroneal (CP) and tibial (TIB) nerves, measured nerve perimeters with a flexible ruler, implanted suitably sized, multi-chambered TIB and CP Neurocuffs™, and sealed each cuff with a suture through interdigitated closing elements [7]. The cuff lead connectors were inserted in a dummy device placed in a subcutaneous pocket in the medial thigh and the incision was closed. The dummy device had a percutaneous cable to allow external recordings of signals during the first 10 d. After the signals were evaluated, the incision was re-opened and the dummy device and its percutaneous wires were removed and replaced with an implanted Neurostep™ unit. The Neurostep™ was turned On or Off with a magnet or telemetry programming interface and programmed to automatically wake up when the subject stood up, detect heel contact (HC) and toe lift (TL) events from the nerve signals sensed while walking and stimulate selected CP channels to control foot trajectory during swing.

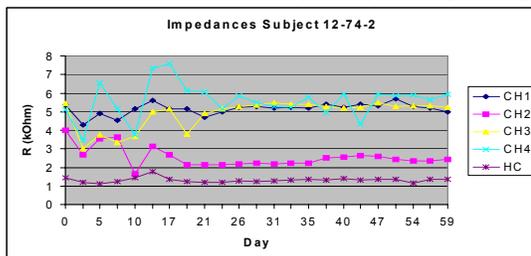


Figure 3. Resistive part of electrode impedances plotted vs. days after Neurocuff™ implant.

3. RESULTS

Impedances between the recording/stimulating electrode in each CP Neurocuff™ channel with respect to its indifferent electrode, and between the recording and the indifferent electrodes in

the TIB Neurocuff™ (“HC”) were measured by an internal Neurostep™ circuit and telemetered out of the body. Impedances initially fluctuated and stabilized about 3 weeks after Neurocuff™ implant (Fig. 3). The lower impedance in Ch. 2 is attributed to shorts in the header connectors.

Stimulation of each CP channel with brief trains of 100 μ s x 150-250 μ A pulses elicited tingling sensations that the subject consistently referred to specific locations of the left leg. Perceptual thresholds (Fig. 4) slowly doubled in Ch. 3 and 4 over the first nine weeks. The rise in Ch. 2 threshold was attributed to a shorted connector.

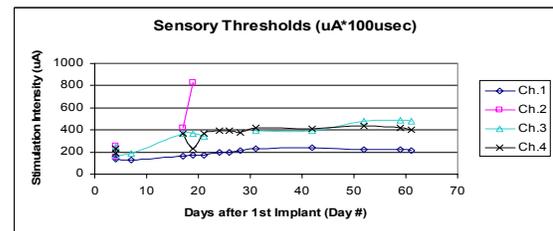


Figure 4. Sensory stimulation thresholds vs. time.

As expected, motor thresholds were higher than sensory thresholds. Motor thresholds also rose gradually for Ch. 3 & 4 and suddenly for Ch. 2 (Fig. 5). Stimulation of Ch. 3 and 4 produced strong dorsiflexion, indicating greater proximity to deep peroneal nerve axons. Stimulation of Ch. 1 sometimes elicited a limb flexion reflex.

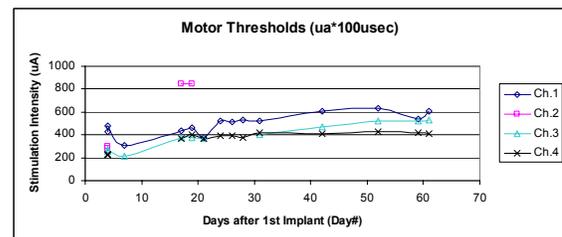


Figure 5. Motor stimulation thresholds vs. time.

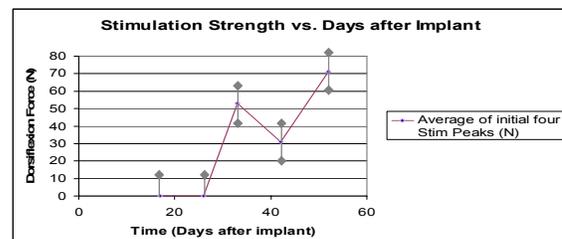


Figure 6. Improvement in dorsiflexion force elicited by similar Ch. 3 and Ch. 4 stimulation, vs. time.

During the second month of Neurostep™ mediated stimulation the ankle dorsiflexor force elicited by CP stimulation of standard intensity greatly increased (Fig. 6), indicating a reversal of the disuse atrophy in the paralyzed muscles. The fatigue resistance in the ankle dorsiflexors also improved (Fig. 7).

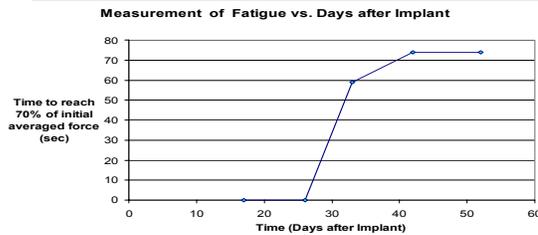


Figure 7. Improvement in resistance to fatigue during Ch. 3 and Ch. 4 stimulation vs. time.

The Neurostep™ circuitry amplified, rectified, smoothed, and could transmit to the external telemetry interface the digitally sampled ENG signal from any selected nerve channel. Fig. 8 shows ENG signals acquired during walking on day 19 together with foot pressure information recorded by shoe insole sensors (F-Scan). The TIB ENG profile closely resembled foot contact force during stance phase. The Neurostep™ event detection algorithm identified HC and TL events from the ENG signals (shown for one step by dotted lines in the example of Fig. 8).

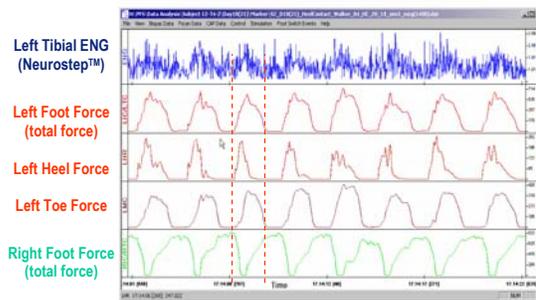


Figure 8. Example of tibial nerve signals recorded during walking (top trace) and F-Scan recordings of Heel, Toe and total force for same steps (day 19).

In early walking trials (day 19-24 post-implant) the ENG signal quality SQ, defined as (average signal modulation amplitude)/(average noise ripple), ranged from 1.3 to 1.7, and TL and HC event detection success rates ranged from 72 to 90%. With progressive connector failures, SQs declined further and success rates worsened. In previous animal data with $SQ \geq 2$, success rates for detecting comparable events were 99-100%.

4. DISCUSSION AND CONCLUSIONS

In this Neurostep™ prototype pilot feasibility study, the following positive findings emerged:

1. nerve signals can be used to control a fully implanted closed-loop FES system for walking.
2. multi-channel CP nerve stimulation produced correct ankle dorsiflexion and could recruit hip and knee flexion reflexes that assist walking.
3. use of Exercise Mode substantially increased paralyzed muscle force and fatigue resistance.
4. automatic On/Standby feature worked well.

Unfortunately, the successes achieved in this pilot study were marred by internal shorts in the connectors that caused progressive degradation of cuff impedances, amplitudes of recorded signals and threshold stimulation currents. Even though the functional benefit available from the Neurostep™ prototype was reduced by leaks, the subject no longer needed a knee brace after using the implanted system for 10 wk, and his gait had markedly improved. He continued to use the device in Exercise Mode at home, which proved very useful. Six months after implant, the subject reported that he often walked the length of his driveway and back (250 m) without fatigue and his balance control had greatly improved. The CP stimulation was never painful, nor unpleasant. The subject was appreciative of how much using the device had improved his mobility, balance and lifestyle until its battery ran out after eight months.

This pilot study shows that subjects with foot drop can benefit from a fully implanted system with neuroelectric control. The Neurostep™ technology is now being refined and expanded into an implantable assistive device platform for disabilities such as foot drop, incontinence, limb amputation, paraplegia and chronic pain.

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