Stimulation of peripheral nerves with a microstimulator: experimental results and clinical application to correct foot drop

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Abstract

A foot drop stimulator using implanted microstimulators (BIONs) was developed by modifying a WalkAide2 stimulator. BIONs were implanted in a person with incomplete spinal cord injury and severe foot drop in one leg. Compared to surface stimulation, BIONic stimulation of the deep peroneal nerve produces a more balanced ankle flexion without everting the foot. For effective stimulation, the BION must be within 10-15 mm of the nerve. The BIONic WalkAide elevates the foot so that the toe clears the ground by 3 cm, which is equivalent to the toe clearance in the less affected leg. The physiological cost index (PCI), a measure of effort during walking, is high without stimulation (2.29 ± 0.37; mean ± S.D.) and greatly reduced with surface (1.29 ± 0.10) and BIONic stimulation (1.46 ± 0.24). Walking speed is increased from 9.4 ± 0.4 m/min. without stimulation to 19.6 ± 2.0 m/min. with surface and 17.8 ± 0.7 m/min. with BIONic stimulation. We conclude that FES with BIONs is a practical alternative to surface stimulation and can provide a more balanced dorsiflexion.

1 Introduction

Until recently, FES has been limited to three approaches: surface stimulation, percutaneous wires and fully implanted systems. Loeb et al. [1][2] developed a novel, injectable microstimulator (BION™) that does not require surgical implantation and receives power and data through a wireless link. BIONs have already been used in clinical trials for therapeutic electrical stimulation (TES) [3]. TES applications do not require the BION systems to be portable; stimulation is applied when the subject is seated and the system is powered from the AC line.

BIONs were originally designed for intramuscular stimulation of motor axons near the nerve entry zone. At this site, increasing stimulus intensity will increase the response gradually as more distant nerve branches are activated. This approach has a disadvantage in muscles with multiple neuromuscular compartments. Also, a functional movement may require activation of several muscles and so may require implantation and control of several BIONs. An alternative approach is to place a single BION near a peripheral nerve that innervates all relevant muscles. The disadvantage is that the recruitment of nerve fibers is much steeper [4-6] and graded control becomes more problematic. Obtaining a useful mixture of recruitment of muscles with different functions may not be possible.

We report here experiments in animals (two anesthetized cats) and a human subject. The animal experiments were designed to answer three questions: 1) How far can BIONs be from a peripheral nerve (sciatic) and still produce effective stimulation? 2) How steep are the recruitment curves with such nerve stimulation? 3) Is the orientation of the BION with respect to the nerve critical?

A human subject with an incomplete spinal cord injury (C6/C7) was implanted with BIONs near a peripheral nerve (deep peroneal) and in the tibialis anterior (TA) and peroneus longus (PL) muscles. He had received treadmill training with partial body weight support [7], but had a severe residual foot drop in his left leg. He had used a surface stimulator (WalkAide2) to correct this problem since 2001 and volunteered to be implanted with BIONs. A prototype of a wearable BION controller for foot drop was developed for this subject. Stimulation is turned on and off by a WalkAide2 device based on the tilt angle of the shin during walking [8]. When the leg tilts backward behind the body at the end of stance, the stimulator is turned on to flex the ankle. When the leg is tilted in front of the body toward the end of swing, the stimulator is turned off. This is the first application of BIONs for FES, although implanted stimulators with and without wires have been surgically implanted previously for foot drop [9-11].

2 Animal Studies
Two adult cats were anesthetized with Somnotol and the sciatic nerve was exposed by an incision along the lateral surface of the thigh. Glass capsules the size of BIONs with wire electrodes at each end were sutured in nearby muscles at various distances from the nerve. In one experiment the capsule was oriented perpendicularly with the cathode closest to the nerve. In the other the capsule was oriented parallel to the nerve (cathode distal). A Grass stimulator (SD9) applied monophasic pulses with 200\(\mu\)s duration. The current was monitored and displayed on a digital oscilloscope. EMG electrodes were implanted percutaneously into the lateral gastrocnemius (LG) muscle about 1 cm apart. The signals were amplified and also displayed on the oscilloscope. Peak-to-peak EMG and average current values were measured.

![Figure 1: A) Recruitment curves for activation of the LG muscle. Distances (mm) from the sciatic nerve are given in the legend. B) Effect of distance on the current for a half-maximal response.](image)

Figure 1A shows recruitment curves obtained with stimuli at various distances from the sciatic nerve. The curves shifted to the right as the distance increased, but showed similar, steep profiles. Given that the diameter of the cat sciatic nerve is about 3 mm, the distances to individual nerve fibers may vary by up to this amount. Note also that Figure 1A has a logarithmic scale, so the percentage increase in current (mean±SE), in going from 25 to 75% of the maximal response, is similar (25±5%; n=8), even though the absolute amounts will be much larger for the greater distances.

Figure 1B shows the half-maximal current as a function of distance in two experiments. In the experiment shown in Fig. 1A the capsule was perpendicular to the nerve and in the other experiment it was parallel to the nerve. Although there may be a small effect of orientation, the principal effect is distance. Clearly, BIONs must be within 10-15 mm to be able to activate a peripheral nerve or branches in a muscle within the output limit of the BIONs (30 mA).

### 3 Clinical Application

BIONs were inserted using procedures described in [2]. One BION stimulated the TA muscle and a second activated the PL muscle. Others stimulated the deep peroneal nerve (DPN) that activates TA, extensor digitorum longus (EDL) and other muscles. Although the primary action of the TA muscle is ankle dorsiflexion, it produces some inversion. The PL muscle everts the ankle and can compensate for the inversion of the TA. Thus far, we have not needed to stimulate the PL, because the BIONs near the DPN stimulate a group of muscles that provides a relatively balanced ankle flexion.

Without FES the subject is unable to flex his left ankle; the left toe catches the walking surface and holds the ankle in an extended position until the foot eventually pulls free and is thrown forward. Both methods of FES produce sufficient toe clearance (3cm) to permit an unobstructed swing phase.

![Figure 2: Foot external rotation during treadmill walking with FES using surface (A) and BIONic stimulation (B) during the swing phase of the left leg (LL).](image)

Although surface and BION FES are both effective in preventing foot drop, surface stimulation of the CP nerve also activates the PL muscle, which everts the ankle and externally rotates the foot 50 deg. as shown in Fig. 2A. With BIONic stimulation (Figure 2B) of the DPN, the flexed foot maintains a straight heading.

The physiological cost index (PCI) was used to measure effort during walking. The PCI is high without stimulation (2.29 ± 0.37; mean ± S.D.) and greatly reduced with surface (1.29 ± 0.10) and BION stimulation (1.46 ± 0.24). Walking speed is increased from 9.4 ± 0.4 m/min. without stimulation to 19.6 ± 2.0 m/min with surface and 17.8 ± 0.7 m/min. with BION stimulation.
4 Discussion

The goals of this study were: 1) to test the efficacy and sensitivity to orientation of BIONS placed near a peripheral nerve, rather than intramuscularly and 2) to apply BIONS to correct foot drop. As expected from previous work [4, 12], one advantage of stimulating near a peripheral nerve, instead of intramuscularly, is that several muscles can be recruited with a single BION. Also, the threshold current can be very small if the BION is placed sufficiently close to the nerve. The orientation has little effect on threshold but may affect stability. If the BIONs shift position with muscle contraction, the steep recruitment curves for nerve stimulation (see Figure 1), compared to the recruitment curves intramuscularly [4, 5], could make it difficult to maintain the appropriate strength and balance of recruitment of muscles with different actions.

In the one clinical case to date, the BION was placed near the DPN, distal to the branch that innervates PL. The resultant stimulation of TA, extensor digitorum longus (EDL) and other muscles is fairly well balanced, as judged by the gait analysis (Figure 2). However, the DPN BION only stimulates a fraction of the dorsiflexors, so the subject considers the movement to be marginal. A further implantation is planned to improve the functional outcome. Although these results are preliminary and based on a single subject, we believe that BIONS have an important role to play in FES for foot drop and other motor disorders.

References


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