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Functional electrical stimulation using microstimulators to correct foot drop: a case study[1]

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Abstract: This paper presents a case study that tested the feasibility and efficacy of using injectable microstimulators (BIONs®) in a functional electrical stimulation (FES) device to correct foot drop. Compared with surface stimulation of the common peroneal nerve, stimulation with BIONs provides more selective activation of specific muscles. For example, stimulation of the tibialis anterior (TA) and extensor digitorum longus (EDL) muscles with BIONs produces ankle flexion without excessive inversion or eversion of the foot (i.e., balanced flexion). Efficacy was assessed using a 3-dimensional motion analysis of the ankle and foot trajectories during walking with and without stimulation. Without stimulation, the toe on the affected leg drags across the ground. BION stimulation of the TA muscle and deep peroneal nerve (which innervates TA and EDL) elevates the foot such 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) measured effort during walking. The PCI equals the change in heart rate (from rest to activity) divided by the walking speed; units are beats per metre. The PCI is high without stimulation (2.29 ± 0.37, mean ± SD) and greatly reduced with surface (1.29 ± 0.10) and BIONic stimulation (1.46 ± 0.24). Also, walking speed 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. These results suggest that FES delivered by a BION is an alternative to surface stimulation and provides selective control of muscle activation.

Key words: FES, BION, foot drop, stroke, spinal cord injury.

Résumé : Cet article présente une étude de cas ayant évalué la possibilité d'utiliser des microstimulateurs injectables (BIONs^{MD}) dans un appareil de stimulation électrique fonctionnelle (SEF) ainsi que son utilité pour la correction de la chute du pied. Par comparaison à la stimulation de surface du nerf péronier commun, la stimulation par BION fournit une activation plus sélective de certains muscles. Par exemple, la stimulation des muscles tibialis anterior (TA) et extensor digitorum longus (EDL) produit une flexion de la cheville sans inversion ni éversion excessive du pied (c.-à-d. flexion équilibrée). L'efficacité a été évaluée à l'aide d'une analyse du mouvement en 3-D des trajectoires de la cheville et du pied pendant la marche avec et sans stimulation. Sans stimulation, l'orteil de la jambe touchée traîne sur le sol. La stimulation BION du muscle TA et du nerf péronier profond (innerve TA et EDL) soulève le pied de telle sorte

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que l'orteil se retrouve à 3 cm au-dessus du sol, c'est-à-dire l'équivalent de ce qui se passe dans la jambe moins touchée. L'indice du coût physiologique (ICP) a mesuré l'effort pendant la marche. L'ICP égale la modification de la fréquence cardiaque (du repos à l'activité) divisée par la vitesse de la marche; il s'exprime en battements/m. L'ICP est élevé sans stimulation (2,29 ± 0,37; moyenne ± écart-type) et grandement réduit lorsqu'il y a stimulation de surface (1,29 ± 0,10) ou BIONique (1,46 ± 0,24). La vitesse de la marche s'accroît aussi, passant de 9,4 ± 0,4 m/min sans stimulation à 19,6 ± 2,0 m/min avec stimulation de surface et à 17,8 ± 0,7 m/min avec stimulation BIONique. Ces résultats semblent indiquer que la stimulation électrique fonctionnelle par BION est une solution de rechange à la stimulation de surface et qu'elle fournit un contrôle sélectif de l'activation des muscles.

Mot clés: SEF, BION, chute du pied, accident vasculaire cérébral, traumatisme médullaire.

[Traduit par la Rédaction]

Introduction

Foot drop, in which the ankle is not properly flexed and may drag on the ground during the swing phase of the gait cycle, commonly occurs after stroke, spinal cord injury, or other disorders of the central nervous system. Various devices are used to treat this condition including ankle–foot orthoses (AFOs) (Geboers et al. 2002; Lehmann et al. 1983; Rubin and Cohen 1988) and functional electrical stimulation (FES) systems (Burridge et al. 1997; Liberson 1962; Stillings 1975; Takebe et al. 1975; Waters et al. 1975; Wieler et al. 1999). Although AFOs can prevent the foot from dragging on the ground, they can be uncomfortable to wear and do not prevent disuse atrophy of the ankle flexor muscles (Hesse et al. 1999).

Implanted and surface FES devices actively correct foot drop by electrically stimulating the ankle flexor muscles during the swing phase of gait. These devices may be less bulky than AFOs and the continued activation of the ankle flexor muscles prevents atrophy (Belanger et al. 2000). Furthermore, chronic FES use has been shown to improve mobility (Bonaroti et al. 1999; Burridge et al. 1997), reduce spasticity (Mirbagheri et al. 2002; Stefanovska et al. 1989), improve cardiovascular fitness (Faghri et al. 1992; Phillips et al. 1998; Wheeler et al. 2002), and enable persons to participate in exercises (Gritsenko and Prochazka 2004) that promote functional recovery. The increased function and health benefits of FES make it a preferable treatment for foot drop.

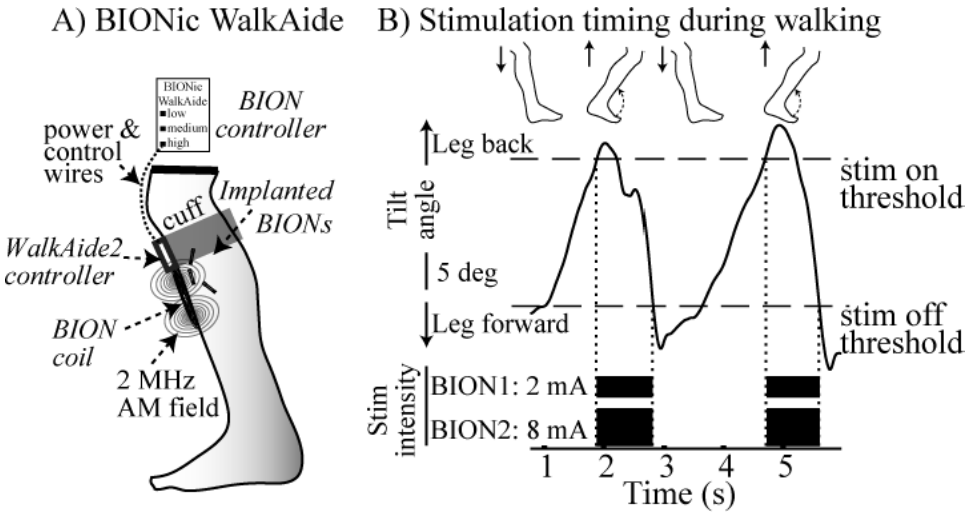
One of the earliest FES systems for correcting foot drop was developed by Liberson and colleagues (Liberson et al. 1961). Their approach was to place a foot switch in the shoe under the heel of a stroke patient who could not flex the ankle. During walking, removal of pressure from the switch at the end of the stance phase triggered stimulation of the common peroneal (CP) nerve to flex the ankle and prevent the foot from dropping or dragging on the ground during the swing phase. More recently, Dr. Richard Stein and colleagues developed a new foot drop stimulator (WalkAide2, Biomotion, Ltd.) taking a novel approach (Stein 1997, 1998) that reduces many of the clinical usage issues associated with traditional foot drop stimulators. For example, early foot drop stimulators were bulky and unattractive and used heel switches requiring wires to be routed from the controller to the foot. Also, those that used surface electrodes were often difficult to position on a daily basis. In the WalkAide2 stimulator, all the components (electrodes, electronics, sensor, battery) are built into a single garment that fits on the leg in a reproducible way and uses a tilt sensor instead of a foot switch to control the timing of stimulation during walking. To flex the ankle during swing, stimulation is applied through surface electrodes placed over the CP nerve.

Although the WalkAide2 is effective in correcting foot drop, surface stimulation has some remaining limitations. For example, some patients experience uncomfortable sensations from the stimulation and (or) skin irritation under the electrodes. Positioning the electrodes properly over the nerve on a daily basis is problematic. The WalkAide2 incorporates a number of features to ensure that the device goes on the leg reproducibly from day to day, but even a few millimetres of movement can adversely affect operation. It is difficult to produce a pure ankle flexion when stimulating the whole nerve because the CP nerve innervates muscles such as the tibialis anterior (TA), which dorsiflexes and inverts the ankle, and the peroneus longus (PL), which mostly everts the ankle.

Implanting stimulating electrodes near the motor points of individual muscles can achieve greater muscle selectivity (Haugland et al. 2000; O'Halloran et al. 2003). However, these approaches involve open surgery and are not acceptable to many people who are reluctant to undergo surgery for a problem that is bothersome but not life-threatening. A potential alternative to a completely implantable FES system is the BION microstimulator developed by Loeb and colleagues (Cameron et al. 1997; Loeb et al. 1991). BIONs (BIOnic Neurons) are small enough to be injected into muscle with a 12-gauge catheter needle. BIONs have already been used in clinical trials at Queen's University for pain due to shoulder subluxation after a stroke and at the Pini Orthopedic Institute of Milan for strengthening the quadriceps muscles in arthritis patients (Dupont et al. 2004). In these applications, muscles were stimulated as a therapy to strengthen them while the subject sat in a chair and the coil was connected to a controller powered from an AC receptacle. These applications are commonly referred to as therapeutic electrical stimulation, as opposed to FES, where goal-directed movements such as walking or grasping are made voluntarily with the help of stimulation.

We have combined the WalkAide2 and BION technologies to create a new foot drop stimulator (labelled the BIONic WalkAide) using BIONs instead of surface stimulation to activate the ankle flexor muscles. This represents the first human application of BIONs in a portable FES system. The goal of this case study is to demonstrate the feasibility and effectiveness of BION stimulation in correcting foot

Fig. 1. (A) Schematic of the prototype BIONic WalkAide system. The 4 primary components of the system are the WalkAide2 controller, BION controller, BION coil, and implanted BIONs (sites from top to bottom: DPN, TA, and PL). See text for details. (B) Timing diagram for stimulation during walking. The cartoon legs and arrows denote the heelstrike (down arrows) and toe liftoff (up arrows) times. The WalkAide2 controller determines the stimulation on and off times based on the thresholds (dashed lines) set for the tilt angle. The black boxes represent the timing and amplitude of BION stimulation sequences (25-Hz train) triggered by the WalkAide2 controller.



drop. The Methods section describes the portable BIONic WalkAide system and the procedures for BION implantation and testing during walking. The Results show that BIONs are more selective in activating the ankle dorsiflexor muscles than surface stimulation of the CP nerve, thus providing a more balanced flexion of the ankle during walking. We conclude that BIONs are feasible for this FES application, providing the selectivity of an implanted system with a minimally invasive injection procedure.

Methods

This paper is a case study on a 42-year-old male volunteer who received BION implants to correct his foot drop. The results are compared with those from a WalkAide2 surface stimulator that he had used since 2001.

BIONic WalkAide

There are 4 primary components to the prototype BIONic WalkAide system as diagrammed in Fig. 1. The WalkAide2 controller runs on a 16F876 PIC and contains a tilt sensor (Analog Devices, ADXL202) that monitors the shank angle (relative to vertical). The controller initiates a stimulation sequence when it detects the onset of the swing phase (maximum positive tilt), and stimulation is turned off when the leg swings forward (negative tilt angle) (Dai et al. 1996). The duration of the train was set to a maximum of 1.2 s to limit the amount of stimulation. Operating parameters for the WalkAide2 are configured through a serial interface with a laptop computer running customized fitting software (WalkAnalyst). The software is used to configure the parameters of the rule-base in the WalkAide2 controller including the upper and lower thresholds for the tilt sensor, which determine the on and off times for stimulation during walking.

The output from the WalkAide2 controller is a pair of triggers (TTL lines) that initiate and terminate stimulation by the BION controller. The BION controller runs on a 68HC11 microprocessor and stores 3 different user-selectable stimulation sequences corresponding to low-, medium-, and high-intensity stimulation patterns. Each stimulation sequence is a train of stimulation pulses whose amplitude, pulse width, and rate are set to provide sufficient ankle flexion. The BION coil inductively transfers power and control signals to the implanted BIONs by means of a 2-MHz amplitude-modulated carrier (Cameron et al. 1997). A rechargeable 7.2-V lithium (camcorder) battery supplies power to the system. BION operation and stimulation patterning are configured using another personal computer-based software application (ClinFit™) that allows the user to test and document stimulation thresholds and configure stimulation patterns for the group of implanted BIONs (Loeb et al. 2001).

Motor point mapping and insertion site selection

One goal of this case study was to identify locations for implanting BIONs to stimulate the muscles needed to produce ankle dorsiflexion. The TA is the primary ankle flexor muscle and the main target for stimulation. Although surface stimulation produces excessive foot eversion by overstimulating the PL muscle, some PL action is required to balance the inversion action of the TA muscle. Therefore, PL was another muscle target for BION stimulation. Another target for stimulation was the deep peroneal nerve (DPN) because it innervates the TA and extensor digitorum longus (EDL) muscles. This section describes the procedure used to locate sites for electrically stimulating the TA, EDL, and PL muscles prior to BION insertion.

Electrical stimulation and electromyography (EMG) were used to identify the motor point for maximal recruitment of the TA muscle (see Fig. 2). Surface EMG electrodes were placed over the TA and PL muscles to record the M-waves produced by electrical stimulation. The TA EMG record in

Fig. 2. (A) TA motor point mapping. (B) EMG recordings from the TA and PL. Supramaximal surface stimulation of the common peroneal nerve was done to identify the maximal M-wave in the TA. Surface stimulation was also applied directly over the TA to identify the location for maximal TA recruitment (S_{max}). Finally, the location and depth of the best site of intramuscular (IM_{max}) stimulation were found using a 27-gauge needle electrode.

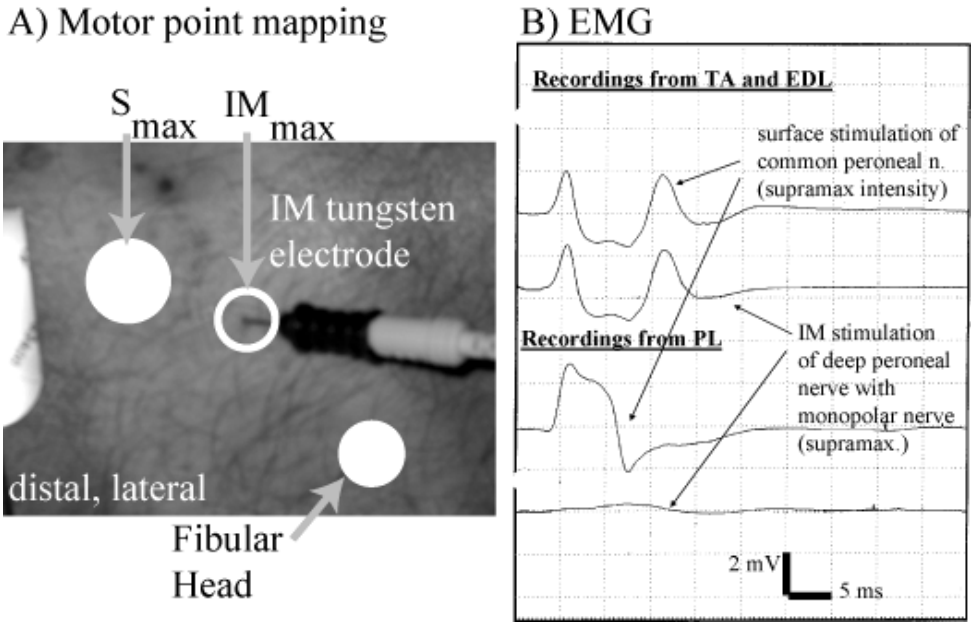


Fig. 2*b* shows 2 phases of activity, an early phase corresponding to TA activity and a second phase that is probably due to cross-talk from activation of the EDL muscle.

The maximal M-wave for the TA muscle was found by increasing the stimulus to the CP nerve using a surface electrode until the response did not increase further. Next, an initial mapping procedure was done with surface stimulation (single cathodal pulses, 200 μs) to find the motor point for the TA. The site of stimulation that yielded the maximal TA M-wave was marked on the skin (S_{max} in Fig. 2*a*). A second search was performed using intramuscular (IM) stimulation with a 27-gauge monopolar steel needle electrode (also 200-μs cathodal pulses). The position of the needle tip was continually monitored by regular single-pulse stimuli. The M-waves detected by the pair of surface electrodes were displayed on a storage oscilloscope. Changes in size and configuration of the M-waves provided clues on which nerve was being stimulated and its proximity to the needle tip. This helped to guide the operator when advancing the needle.

When the needle was in the proper position lying parallel to the DPN, the TA and EDL muscles could be activated at low stimulus threshold (see Fig. 2*b*). In contrast, the PL muscle, innervated by the superficial peroneal nerve, was quiescent. The result was a balanced dorsiflexion with little or no eversion or inversion. Using this method, the electrode was inserted approximately 15 mm proximal and lateral to the S_{max} point. A shallow insertion angle was used to simulate the BION insertion angle, which is nearly parallel with the skin surface. After identifying the location and depth that yielded the maximal M-wave with IM stimulation, the location (IM_{max}) was marked on the skin and the depth was recorded. The motor point mapping procedure generally took 15–30 min for each muscle.

BION insertion and tuning

Prior to insertion of BIONs, the skin at the insertion site was anesthetized with lidocaine. The BIONs were sterilized by autoclave and the insertion tools were sterilized by ethylene oxide gas prior to use. Immediately prior to insertion, each BION was tested to verify its functionality in a drywell tester that detects capacitively the output voltage swings on the electrode while the implant is still in its sterile capsule.

The BIONs were inserted using a 12-gauge Angiocath™ catheter needle that was modified to allow electrical stimulation through the tip of the needle. The insertion tool was inserted through the skin at the IM_{max} site and advanced in small steps. A single stimulation pulse (200 μs) was applied at each step and the size of the TA M-wave was noted in comparison with the maximal M-wave. When the best location was found, the trochar was removed and a BION was inserted through the lumen of the insertion tool. A plunger was then used to hold the BION in place as the sheath was withdrawn. Generally, the BION insertion procedure took fewer than 15 min, since the motor point mapping procedure provided good localization of the stimulation target.

Following insertion, each BION was tested for functionality and the motor threshold was measured. The BION coil was placed over the implant site for testing. Low-intensity (1–5 mA) stimulation pulses (200 μs) were applied in increasing steps until a noticeable muscle twitch was produced. Once this threshold was found, the stimulation was discontinued for 1 week to allow the surrounding tissue to heal. Threshold tests were performed at each visit to record a history of thresholds for each BION.

Finally, the insertion sites were cleaned with rubbing alcohol and an adhesive bandage was placed over each incision. During the 1-week recovery period, the patient was instructed to wear his AFO when walking to minimize me-

chanical strain at the insertion site. At the 1-week followup visit, the insertion site was inspected to ensure that there was no infection and the skin was healing properly. In this patient, the implant sites completely healed (i.e., no scabs) after 1 week.

One week after BION insertion, the patient returned to the laboratory to have the BIONic WalkAide fitted and programmed. BION stimulation patterns were configured and tested using the ClinFit software program (for details, see Loeb et al. 2001). During this testing, the patient was seated in a chair with his heel resting on a block (30 cm off the ground) and his ankle in a plantarflexed position.

The motor threshold for each BION was measured and recorded. Next, we tested the muscle responses to single BION stimulation at a range of intensities (typically 2 to 5 times threshold) at a 25-Hz pulse rate for 1 s. Rates between 16 and 50 Hz were available, but 25 Hz is chosen most commonly because it provides a smooth, nearly tetanic level of contraction without substantial fatigue. An exercise mode is provided in the stimulator for people whose muscles have become very fatigable from disuse, but the fatigue resistance increases with use and extra exercise is not needed by most WalkAide2 users. The lowest intensity that yielded a maximal contraction was recorded for each BION. Next, a variety of BION combinations were tested until we found a combination that produced reliable ankle dorsiflexion during sitting and standing.

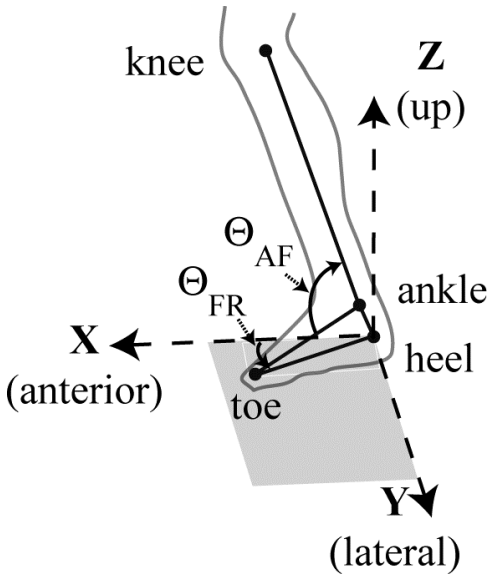
Gait analysis

Improvements in gait kinematics were measured using a 3-dimensional motion analysis of the leg and foot (Peak Motus system, 60 frames/s). Reflective markers were placed on the heel, toe, ankle, and knee of each leg (see Fig. 3). Kinematics were recorded during treadmill walking under 3 conditions: (*i*) no FES, (*ii*) surface (WalkAide2) FES, and (*iii*) BION FES. The treadmill speed was set to 1.1 km/h for the FES trials, but the subject could not walk faster than 0.8 km/h without FES. The subject walked for 60 s in each condition with 2 min of rest between each condition.

The gait was assessed in terms of the magnitude and balance of the ankle flexion. The magnitude of ankle flexion (Θ_{AF}) was measured as the angle between the foot (ankle – toe axis) and shank (ankle –knee axis) segments as shown in Fig. 3. The neutral (0°) position for Θ_{AF} corresponds to the foot perpendicular to the shank. In foot drop, the Θ_{AF} angle is too small because of weakness in the ankle flexor muscles. Balanced or pure flexion means that the foot does not rotate inwards (ankle inversion) or outwards (ankle eversion) when the ankle is flexed. This was assessed by measuring the rotation angle of the foot (external foot rotation, Θ_{FR}) in the horizontal plane (*X*–*Y*) relative to the *X*-axis (forward). A small positive Θ_{FR} angle represents a small amount of outward foot rotation.

Step cycle averages were made using 10 sequential steps in each condition. The times for heel strike of the left leg (affected leg) were used as the boundaries of the step cycle. Minima in the vertical position of the left heel marker were used to identify the ground contact times (heel strikes). Averages were taken by normalizing the time series for each step cycle to 100 points and then averaging across the normalized time series.

Fig. 3. Marker placement for gait analysis. The black dots represent markers placed over bony landmarks on the shank and foot. Ankle flexion (Θ_{AF}) was calculated as the angle between the ankle – toe axis and the ankle – knee axis with flexion as positive (perpendicular = 0°). The external foot rotation (Θ_{FR}) angle was calculated as the angle between the heel–toe axis and the *X* (forward) in the transverse plane.



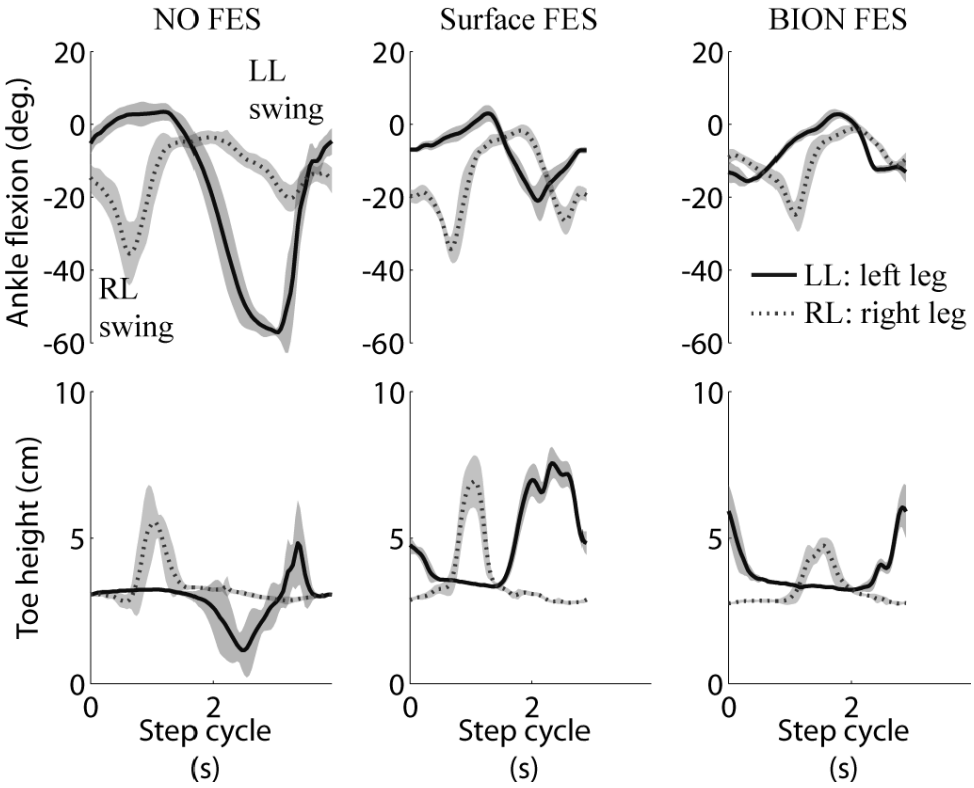
Physiological cost index (PCI) and walking speed

PCI and walking speed measurements were made while the subject walked around a 10-m figure-of-eight walkway for 4 min. The walkway had marks every metre so that the distance covered in the trial period could easily be measured. Resting heart rate was measured every 30 s for 2 min while sitting prior to the 4-min test and again for 2 min after it returned to a steady value (usually 2–4 min after the walking period). The active heart rate during the last 2 min of walking was also measured. The PCI (beats per metre) is measured by dividing change in heart rate (active minus rest, beats per minute) by the walking speed (metres per minute). It correlates with effort and oxygen consumption (Stein et al. 2001), and low values indicate a more efficient gait (MacGregor 1981). Paired *t* tests were used to compare walking speed and PCI measurements without and with FES.

Results

The subject in this study is a 42-year-old male who suffered an incomplete spinal cord injury at the C6/C7 level during a motor vehicle accident in 1998. He walks with forearm crutches but continues to have foot drop in his left leg and chronic back pain that makes it difficult to stand for long periods of time. He has been using a WalkAide2 surface stimulator to correct his foot drop since 2001. Because of his back pain, his preferred method of ambulation for long distances is with a wheelchair, but he prefers to walk (with a foot drop stimulator) when he is in his home. When his back pain is mild, he walks an average of 929 steps per

Fig. 4. Average ankle flexion angle and toe height during 10 sequential step cycles (left leg heelstrike to heelstrike). Data were collected during treadmill walking without and with FES (surface and BION). The lines represent the average of 10 sequential steps and the shaded regions correspond to ±1 SD. The solid line represents the left leg (affected by foot drop) and the dotted line is for the right, less affected leg.



day with the WalkAide2 (based on usage data collected by the WalkAide2 stimulator).

In 2003, this patient volunteered to receive BION implants as an alternative to the surface stimulation, which effectively corrects his foot drop but produces excessive foot eversion and requires daily adjustment of the electrode position. The goal of the present study was to test the effectiveness of BION stimulation in comparison with surface stimulation for correcting his foot drop.

BION insertion and tuning

The patient received a total of 4 BIONs in 3 separate sessions. One BION did not produce detectable stimulation pulses after insertion, despite having functioned properly in the preimplant drywell test. The most likely cause of this problem was an intermittent electromechanical connection between the electronic subassembly and the hermetic feedthrough to the electrode. Fabrication procedures have since been modified to minimize this possibility. A second BION was used to stimulate the TA muscle and a third to stimulate the DPN, which activates TA, EDL, and other muscles. Although the primary action of the TA muscle is ankle flexion, its insertion on the medial side of the foot results in a small amount of inversion. An additional BION was implanted in the PL muscle, which everts the foot and can compensate for the inversion action of the TA.

Stimulation patterns for dorsiflexing the ankle during walking were programmed using the ClinFit™ software program (Loeb et al. 2001). Each stimulation program was a 25-Hz train of stimulation pulses and the intensity for each BION was typically 2 to 5 times the muscle twitch threshold. Three different programs could be selected for low-, medium-, and high-intensity stimulation. This would allow the user to increase the stimulation intensity if the muscle becomes fatigued but thus far has not been necessary. We did not specifically tune each BION program to compensate for fatigue, but the high-intensity stimulation program was set at the highest intensity that did not cause pain. Among the TA, DPN, and PL BIONs, different combinations of BION stimulation were tested, and we found that stimulation with the TA and DPN BIONs together provided sufficient and balanced dorsiflexion of the ankle. The PL BION was not needed because the DPN BION provided partial recruitment of the PL and everted the foot.

Gait analysis

A 3-dimensional motion analysis was performed to compare walking kinematics with and without FES. Figure 4 shows the ankle flexion angle and toe height during the average step cycle (average of 10 steps) without (left panels) and with FES (middle panels: surface FES with WalkAide2, right panels: BION FES). Without FES, the subject is unable to flex his ankle actively as illustrated in the ankle flexion plot without stimulation. The left toe gets caught on the treadmill belt and holds the ankle in full extension until the foot eventually comes free and is thrown forward. The ankle

Fig. 5. Phase plot of foot external rotation versus ankle flexion angles. The "+" denotes toe liftoff, which proceeds clockwise as the ankle is flexed.

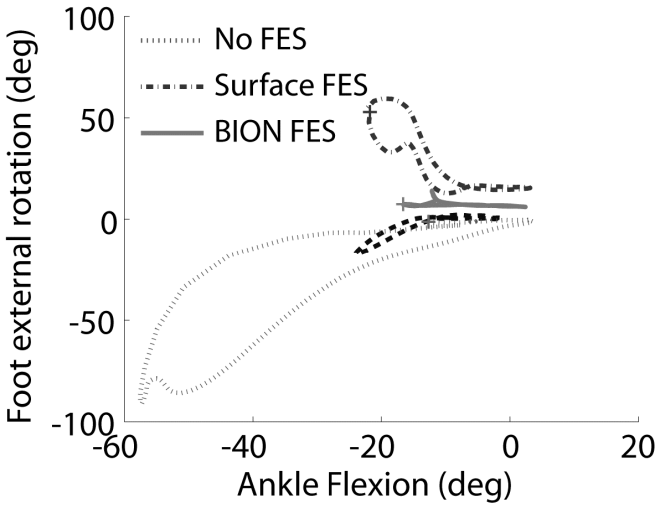


Table 1. Speed and physiological cost index (PCI) for various methods of stimulation during locomotion.

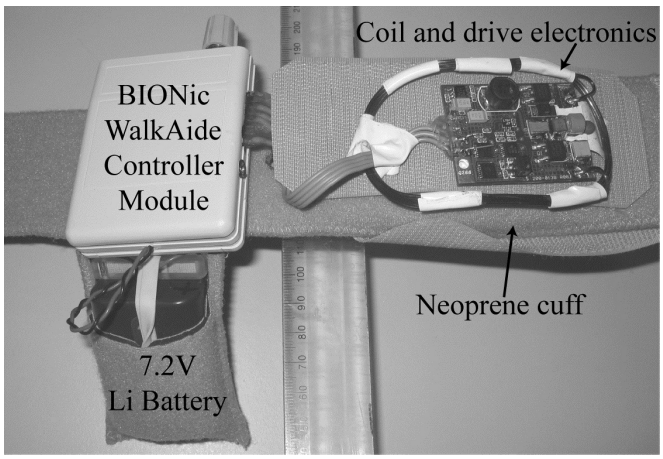
	No. stim. (n = 2)	Surface stim. (n = 4)	Implanted stim. (n = 3)
Speed (m/min)	9.4±0.4	19.6±2.0	17.8±0.7
ΔHR (beats/min)	21.6±4.4	25.2±2.0	26.0±5.3
PCI (beats/m)	2.29±0.4	1.29±0.10	1.46±0.24

passively flexes towards the end of the swing phase as the foot is thrown forward. The toe ground clearance (height) is much greater with both methods of FES. Surface stimulation (middle panels) provides slightly more ankle flexion than BION FES (right panels), but both are sufficient to prevent the approximately 40° of foot drop observed without FES. Also, note that the step cycle duration is approximately 50% longer without FES because the subject has to drag his foot rather than lifting and swinging it through.

Although surface and BION FES are both effective in preventing foot drop, the surface stimulation produces a large amount of external rotation. A physiotherapist initially positions the surface electrodes by electrically stimulating various sites around the head of the fibula towards the popliteal fossa. The optimal location is the stimulation site that provides the most effective and balanced flexion of the foot. The cuff helps to relocate the electrodes in the same place every day, but the patient usually needs to adjust it somewhat to get the best response. Nevertheless, in this patient surface stimulation of the CP nerve cannot selectively activate the TA, and the PL muscle becomes overstimulated. This was an important motivating factor for injecting BIONs to selectively stimulate the TA.

Figure 5 illustrates the hyperrotation produced by surface stimulation in a phase plot of the foot external rotation angle versus the ankle flexion angle. With surface stimulation, the foot is externally rotated nearly 50° prior to toe liftoff (denoted by the "+"). The BION stimulation produces minimal

Fig. 6. BIONic WalkAide foot drop stimulator. The controller, battery pack, drive electronics, and coil are packaged in a neoprene cuff that is worn around the leg just below the knee. The BION coil and drive electronics fit inside the sleeve of the neoprene cuff during use.



external rotation and the foot maintains a straight heading throughout the step cycle. Without FES, the foot undergoes 90° of internal rotation and 40° of extension because the toe gets caught on the treadmill belt and is dragged backward.

PCI and walking speed

Table 1 shows the preliminary measurements of walking parameters with the various methods of stimulation. The walking speed was slow without stimulation because of the need to drag the foot forward with each step. It increased by about a factor of 2 with either surface stimulation (paired t test, $p < 0.005$, WalkAide2) or implanted stimulation (BIONic WalkAide). The change in heart rate reached a steady value during the last 2 min of a 4-min walking period and was increased by about the same amount on all trials, indicating that the patient was exerting a similar level of effort under all conditions. The PCI was reduced (paired t test, $p < 0.05$) by about 40% with either surface stimulation or implanted stimulation, largely as a result of improved gait velocity.

Discussion

The goal of this single case study was to test the feasibility and efficacy of using BION microstimulators to correct foot drop, and this paper reports the first human application of BIONs in a portable FES device. This was achieved by combining the WalkAide2 system developed in Dr. Richard Stein's laboratory (Stein 1997, 1998) with the BION microstimulators developed by Loeb and colleagues (Cameron et al. 1997; Loeb et al. 1991). We have now integrated the 2 control functions (gait monitoring and command generation) into a single microcontroller that can be worn on the shin alone like the original WalkAide2 (see Fig. 6).

Compared with surface stimulation of the CP nerve, we found that BIONic stimulation of the TA produced a more balanced ankle flexion movement without everting the foot (see Fig. 5). Improvements in gait kinematics were measured with a 3-dimensional motion analysis of the ankle and foot

during treadmill walking. Without stimulation, the toe on the affected leg drags across the ground (see Fig. 4). The WalkAide2 and the BIONic WalkAide both elevated the foot so that the toe cleared the ground by 3 cm, which was equivalent to the toe clearance in the unaffected leg.

Preliminary measurements of speed and PCI (Table 1) indicate that both methods of stimulation greatly increase the speed and reduce the physiological cost. We have measurements with this subject with and without surface stimulation taken periodically over the last 3 years (2001–2004) and the differences in speed and PCI are significant (paired t tests, $p < 0.001$ and $p < 0.05$). Because we have only a few measurements with the BIONic WalkAide, statistical testing is not warranted, but it appears that the BIONic WalkAide will be significantly better than no stimulation and similar in its effect to surface stimulation. Over the period of this trial, we only have measurements of walking without stimulation on 2 days. This is because the amount of effort greatly tires the subject and also causes back pain, so he is reluctant to walk without stimulation. He reports that his endurance is much improved with either method of stimulation and it aggravates his back pain less. Thus, FES with BIONs appears to be a practical alternative to surface stimulation and provides more selective control of muscle activation.

We have also measured the subject's speed and PCI with an AFO and the values are intermediate between no stimulation and stimulation (R.B. Stein et al., unpublished observations). Although braces such as AFOs can be used to treat foot drop, they do not achieve the functional or health benefits that FES provides. Regular stimulation for 1–2 h a day of muscles that are paralyzed as a result of spinal cord injury (SCI) can increase fatigue resistance, strengthen muscles, and reverse to some extent the severe osteoporosis that follows SCI (Belanger et al. 2000; Rodgers et al. 1991; Stein et al. 1992). Similarly, use of even simple stimulators can improve the walking speed by more than 50% in persons with incomplete SCI that have localized deficits such as foot drop (Wieler et al. 1999).

Anecdotal reports by subjects suggest that use of the foot drop stimulator may improve voluntary control. This is consistent with recent ideas about use-dependent plasticity in the brain (Butefisch et al. 2000; Cohen et al. 1991; Liepert et al. 1995; Ziemann et al. 2001). Regular use of FES has also been shown to reduce spasticity in incomplete SCI patients using FES to assist walking (Mirbagheri et al. 2002) and in stroke or brain injury patients receiving therapeutic electrical stimulation (Tekeoglu et al. 1998; Weingarden et al. 1998). However, other groups have found electrical stimulation to be ineffective in reducing spasticity in complete SCI patients performing FES-enabled leg cycling (Skold et al. 2002).

We believe that FES is a preferred treatment for people with paralysis and that devices such as the BIONic WalkAide will eventually do more than simply correct foot drop. The studies referenced above show that long-term FES use can improve mobility, reduce spasticity, improve cardiovascular fitness, and enable persons to participate in activities that promote functional recovery. The increased function and health benefits of FES make it a preferable treatment for foot drop and potentially many other movement disorders. Hopefully, the development and availability of new technologies such as the BION microstimulator and WalkAide2 will increase the number of patients receiving FES and the range of indications for which it is prescribed.

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