A Multicenter Trial of a Footdrop Stimulator Controlled by a Tilt Sensor

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Objectives. To test the efficacy and acceptance of a footdrop stimulator controlled by a tilt sensor. Methods. A nonrandomized, test-retest study of 26 subjects with footdrop of more than 1 year’s duration, resulting from various central nervous system disorders, was performed in 4 centers for at least 3 months. Speed of walking in a straight line, speed around a figure of 8, and physiological cost index (PCI) were measured with and without the device. Hours/day and steps/day using the device were recorded. Results. All but 2 subjects used the tilt sensor at home, rather than a foot switch. Walking speed increased by 15% after 3 months (n = 26; P < 0.01), 32% after 6 months (n = 16; P < 0.01), and 47% after 12 months (n = 8; P < 0.05), while PCI decreased. The number of steps taken per day of use increased significantly over time, and increased speed was directly correlated with usage. Walking speed also increased with the stimulator off, but to a lesser extent, indicating a training effect. Subject feedback from a questionnaire indicated satisfaction with the stimulator. Conclusions. Both efficacy and acceptance of the stimulator were good in a population of subjects with chronic footdrop.

Key Words: Functional electrical stimulation—Footdrop—Multicenter trial—Stroke—Spinal cord injury.

Liberson and others1 reported the 1st functional application of neuromuscular electrical stimulation. They used a single-channel stimulator in 1961 to activate the common peroneal (CP) nerve in hemiparetic adults. The stimulation was timed with the swing phase of the gait cycle to stimulate the ankle dorsiflexors to correct footdrop. Inasmuch as it improved a functional behavior, walking, this field has become known as functional electrical stimulation (FES). Footdrop can occur as a result of a number of central (CNS) and peripheral (PNS) nervous system problems. Essentially, if the ankle dorsiflexor muscles are weak, the foot will drop and often drag on the ground during the swing phase of the gait cycle. PNS disorders, which damage the CP nerve or the muscles it innervates, can’t be treated, because the integrity of the nerve and muscles is needed for stimulation. Since Liberson’s original report, many investigators have studied the benefits of CP nerve stimulation in a variety of CNS disorders to correct footdrop, improve gait velocity and endurance, and prevent falls.2–7 Yet clinicians conventionally prescribe an ankle-foot orthosis (AFO) for footdrop, rather than FES. An AFO is typically a polyethylene brace that holds the ankle in a fixed position to prevent the foot from dragging on the ground. A variety of AFOs are available to meet individual patient needs, and hundreds of thousands of AFOs are fitted per year in the United States alone. Although AFOs provide mediolateral stability and maintain ankle dorsiflexion during gait, they have significant drawbacks. AFOs don’t allow air circulation and can be uncomfortable in hot weather. They can only be worn in shoes, and often the shoe with the AFO has to be larger in size than that for the other foot. AFO’s don’t change in size, if people gain or lose weight. Finally, hemiparetic gait abnormalities following CNS disorders often compromise hip and knee excursion and involve spasticity at one or more joints, not merely weakness of the ankle dorsiflexors.

In contrast, stimulating the CP nerve actively dorsiflexes the ankle and strengthens the muscles.8 At high levels, CP nerve stimulation can produce hip and knee flexion and has also been claimed to reduce or counter spasticity.9–12 Because of their different actions, the use of both an articulating AFO (which allows ankle dorsiflexion) and a footdrop stimulator has been suggested.13

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Nonetheless, the total number of FES devices fitted for footdrop in the 40 years since Liberson’s article is probably less than 10,000. Why has the acceptance of footdrop stimulators been so slow? Possible reasons might be cost, reliability, and ease of use. Also, electrical stimulation can be uncomfortable, and the intimate contact between electrodes and the skin for many hours a day can lead to skin problems. Finally, footdrop stimulators need a control method to decide when to turn the stimulator on and off. Liberson and others used a heel sensor to switch stimulation on and off, and heel sensors have been used subsequently in many studies with both surface and implanted stimulators. The heel sensor must be connected to the rest of the electronics either by a wire or a telemetry link. The heel sensor also has drawbacks, if people want to walk with bare feet or with other footwear that does not allow easy attachment of the sensor and associated electronics.

A few years ago, the idea of a tilt sensor, which measures the orientation of the leg with respect to the vertical, was introduced as a more convenient and reliable way to control a footdrop stimulator. We then designed a stimulator (WalkAide) to eliminate many deficiencies of previous footdrop stimulators (see Methods). The latest version has now received FDA approval for sale in the United States and is available from Innovative Neurotronics, a wholly owned subsidiary of the Hanger Orthopedic group. This report describes the 1st results from a multicenter study with a prototype device that is functionally equivalent to the device submitted for FDA approval. The participating centers were the University of Alberta and the Glenrose Rehabilitation Hospital, Edmonton, Canada; the G. F. Strong Rehabilitation Centre, Vancouver, BC; McGill University and the Jewish Rehabilitation Hospital, Laval, PQ; and the Yamagata Prefectural University of Health Sciences, Yamagata, Japan.

METHODS

Subjects

Twenty-six subjects were studied with footdrop arising from CNS disorders that spared the CP nerve and its muscular innervation. The design was a nonrandomized test-retest one without blinded outcomes. Table 1 gives the inclusion and exclusion criteria. We initially expected that a large majority of subjects meeting these criteria would be stroke patients, but a wide range of CNS conditions produce footdrop. Subjects were included with footdrop caused by the following conditions (numbers of subjects in parentheses): stroke (12), incomplete spinal cord injury (6), head injury (2), multiple sclerosis (2), hemiparesis following surgery (2), familial spastic paraparesis (1), and cerebral palsy (1). The man with familial spastic paraparesis used a WalkAide on each leg, because both legs were about equally affected with footdrop. The 2 surgical cases occurred after treating a meningioma and intractable epilepsy arising from Sturge-Weber syndrome.

The New Stimulator

Essentially, when the lower leg is tilted back at the end of stance (between heel-off and toe-off), the tilt sensor turns on a train of stimuli. When the leg tilts forward just after the foot strikes the ground, the stimuli turn off. The stimulator, together with the tilt sensor and control electronics, is contained in a package about the size of a pager. The package is worn on the leg just below the knee and is attached to a soft cuff that also contains the electrodes. The result is an integrated package that is called the WalkAide (WA) footdrop stimulator. The WA cuff contains an insert that can be molded to the shape of the leg, so the device goes on reproducibly from day to day.
Care has also been taken in the design so that it can be donned and doffed with one hand, inasmuch as people with hemiparesis often have limited hand function on the affected side. The current drain in the resting state is so low that a single AA battery typically lasted for 2 weeks of heavy use. Some subjects turned the unit off when seated to extend battery life even further.

Setting Up the Stimulator

Surface electrodes (Axelgaard Manufacturing, Fallbrook, CA) with added Velcro backing were placed over the CP nerve (cathode) near the head of the fibula and over the tibialis anterior muscle (anode). After the best place for stimulation was found, the cuff was placed over the electrodes and the Neoprene material adhered to the Velcro. Thus, the cuff and electrodes could be removed as a unit and placed reproducibly on subsequent days. Initially, subjects walked while a physical therapist pressed a hand switch after “heel off” in the step cycle to activate the stimulation and released the switch after the foot contacted the ground again. A foot sensor was placed in the shoe so that the pressure exerted by the heel on the ground was measured, as well as the tilt of the leg. An interactive, graphical Windows program (WalkAnalyst) allowed thresholds and various time parameters to be set manually or automatically. The time parameters included the minimum and maximum stimulation periods, as well as the time after a stimulation period before the next period could begin (wait time). Thresholds for turning the stimulation on using the foot sensor or the tilt sensor, as well as the time parameters, were adjusted so that the period of stimulation matched that produced by the physiotherapist. Subjects then walked again with the new parameters to be set manually or automatically. Setting up the parameters and training the subject to use the WA at home typically took 1 to 2 h.

Outcome Measures

The speed (2 methods) and effort in walking with and without the WA were measured before the subject took the device home and at approximately monthly intervals for at least 3 months after home use began. The comparison was done with the normal method of walking before entering the trial (i.e., some subjects used AFOs, canes, walkers, or no aids to assist their walking).

Magnetic Stimulation

For 6 subjects, who met the standard inclusion criteria (no metal in the head and neck, no history of epilepsy, etc.), transcranial magnetic stimulation was applied over the motor cortex. The best location was found with the subjects seated comfortably. A stimulus level was determined that produced a half-maximal response at the optimal location. Subjects were asked to maintain a steady effort to dorsiflex the ankle, and EMG feedback was used with a target level 15% to 20% of maximum voluntary contraction. A centimeter grid was placed over the scalp. Four stimuli were applied at each grid location before moving the cord to the next location. The responses at each location were averaged and plotted as shown for one subject in Figure 2.

Satisfaction

In addition, a “Satisfaction” questionnaire (Table 2) was given at the end. For an overall compilation of the results, a “yes” was given a score of 1 and a “no” a score of 0 (except for question 9, where the opposite was done). Because there were 5 choices in question 13, the most positive response was scored as 4 and the most negative response as 0. A similar method was used for scoring question 2.
RESULTS

Before considering the results from the population as a whole, the walking performance of one subject, a 43-year-old male who had a head injury 19 years earlier, will be highlighted. His walking speed was very slow (Figure 1) but increased from about 0.1 to 0.2 m/s over the period of 12 months, while the physiological cost declined from about 3 to 2 beats/m. Note that a similar change occurred when walking without the WA, even though he reported that his walking speed had not changed for many years before entering the trial. He decided that he had improved to the point that he didn’t need the WA after the period of 12 months. Recently, more than 2 years later, he approached us because he felt that he was not making any progress, despite walking several hours per day. The measurements (40 months) confirmed this, and he decided to resume use of the WA.

In this subject, we measured the motor-evoked potential (MEP) recorded by stimulating the motor cortex. Figure 2 shows maps of the responses before and after a period of 6 months. The best point for evoking an EMG potential in the tibialis anterior (TA) muscle is normally 1 cm lateral and 1 cm posterior to the vertex of the skull. In this subject, the responses are relatively

<table>
<thead>
<tr>
<th>Age: 43, Condition: Head Injury, Years: 19</th>
</tr>
</thead>
<tbody>
<tr>
<td>With WA2</td>
</tr>
<tr>
<td>_PCI (beats/m) Fig. 8 Vel. (m/s) Str. Vel. (m/sa)</td>
</tr>
<tr>
<td>Time (months)</td>
</tr>
</tbody>
</table>

Table 2. WalkAide Subject Satisfaction Form

<table>
<thead>
<tr>
<th>Subject Name</th>
<th>Medical Record No.</th>
<th>Case No.</th>
<th>Site</th>
<th>Date of Evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you understand the purpose of the WalkAide?</td>
<td>Yes 24 No 0</td>
<td>2. Is your walking ability improved by the WalkAide?</td>
<td>Much improved 15 Somewhat improved 7 Uncertain of its improvement 2 Not improved 0</td>
<td></td>
</tr>
<tr>
<td>3. Do you find the use of the WalkAide safe?</td>
<td>Yes 25 No 0</td>
<td>4. Did you feel greater confidence in walking on inclines and/or uneven ground while using the WalkAide?</td>
<td>Yes 17 No 6 Did not use the device on inclines and/or uneven ground 2</td>
<td></td>
</tr>
<tr>
<td>5. Did you feel comfortable in wearing the WalkAide in social situations?</td>
<td>Yes 21 No 4</td>
<td>6. Have you increased your physical activities because of using the WalkAide?</td>
<td>Yes 16 No 9</td>
<td></td>
</tr>
<tr>
<td>7. Is the WalkAide something you would use everyday all day?</td>
<td>Yes 24 No 1</td>
<td>8. Are you able to put the WalkAide on without anyone’s assistance?</td>
<td>Yes 21 No 4</td>
<td></td>
</tr>
<tr>
<td>9. Did you have any difficulty getting the appropriate stimulation response when you put the WalkAide on every day?</td>
<td>Yes 8 No 13 Sometimes 4</td>
<td>10. If your healthcare plan does not pay for the WalkAide, would you value it enough to pay for it? If so, what amount do you think is fair?</td>
<td>Yes 20 fair amount: $603 No 3</td>
<td></td>
</tr>
<tr>
<td>11. What do you like about the WalkAide?</td>
<td></td>
<td>12. What problems did you experience with the WalkAide? Please indicate whether any of these problems was serious enough that you would discontinue using the WalkAide.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. What is your overall reaction to the WalkAide compared to what you were using for walking before beginning the study?</td>
<td>Very positive 18 Somewhat positive 7 Neutral 0 Somewhat negative 0 Very negative 0</td>
<td>14. Any further comments you would like to provide regarding the WalkAide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Would you recommend a person with your condition to try the WalkAide?</td>
<td>Yes 25 No 0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
small in this region (a valley in the 3-dimensional plot), suggesting that the head injury damaged this area of the brain and thereby caused the footdrop. However, somewhat larger responses are seen surrounding this area. After 6 months using the WA, the MEPs were larger, suggesting that stimulation had strengthened the connections between the surrounding area and the TA muscle. This correlates well with the fact that his walking performance was improved even when the WA was off. Measurements of MEPs were repeated at 12 months, but no further change was seen.

The WA can be controlled either by a hand switch, a foot sensor, or a tilt sensor, and all 3 sensors are generally used in setting up the unit (see Methods). In the population studied, 24 subjects, including the subject discussed above, used the tilt sensor in the community, 2 used the foot sensor, and none used the hand switch. The reason some subjects used the foot sensor was that they walked with a “stiff leg.” There was so little change in tilt that this signal did not reliably trigger the stimulation to turn on and off.

Speed and Effort

Figure 3 shows results for the sample of 26 subjects studied for at least 3 months. Because walking speed tended to increase linearly, as shown in Figure 1, we computed the linear regression for each subject and determined the initial and final values from the linear regression. Thus, the changes depended on all measurements, rather than single values. On average, the straight walking speed increased from 0.69 m/s without WA initially to 0.77 m/s with WA after 3 months. The difference between walking speed with and without the WA initially was not significant. However, the difference in walking speed over 3 months using the WA was highly significant (paired Student’s *t* test, ** *P* < 0.01 or *** *P* < 0.001), as was the difference between the speed with and without the WA at the end of 3 months. The walking speeds around the figure of 8 were slower, as expected, but showed a similar increase over 3 months from 0.49 to 0.56 m/s. The statistical significance was also higher (compare the asterisks indicating the degree of statistical significance in Figure 3). A trend was seen in the PCI toward lower values (from 1.06 to 1.01), but only the difference between the initial and final values with the WA was statistically significant (*P* < 0.05).

The changes in speed in a straight line and around the figure of 8 were significant but fairly modest. The range of initial walking speeds was quite wide (e.g., for the figure of 8, mean ± SD = 0.49 ± 0.24 m/s), so we normalized the values to the initial walking speed. On average, the increase in walking speed from the initial value without the WA to the value at 3 months with the WA was 15%. Included within this average were several groups, which we can designate as stroke (12 subjects), spinal cord injury (6 subjects), and others (8 subjects). The changes for these groups were, respectively, 12% ± 4%, 13% ± 4%, and 24% ± 6% (mean ± SE). With the numbers studied, no significant differences were found (*P* > 0.05 using an unpaired Student’s *t* test). The average age was 50 ± 15 years (mean ± SD). The stroke group was older as expected (57 ± 16), compared to the spinal cord group (43 ± 9) and the others (45 ± 12). No significant correlations were observed between the benefits derived...
from WA and age or duration of the footdrop before treatment. The largest number of subjects was studied in Edmonton, and that was the center with the most experience in fitting the device. We also tested whether the results were different in this center than in the others, but no significant difference was observed between subjects in Edmonton or elsewhere. Therefore, we will treat the group as a whole in the following results.

Many subjects wished to continue using the WA after the trial. Where possible, this was allowed and 16 subjects were studied for at least 6 months. The mean increase in their normalized walking speed was 32% with the WA (Figure 4). Eight subjects were monitored for a year or more, and their increase with the WA was 47%. The PCI also continued to decrease with average changes of –20% for 12 months. Because we only studied a small group for 12 months, these people might have been ones that did much better over 3 months, but that proved not to be true. The continuing subjects increased their walking speed by 24% over 3 months, which was not significantly greater than the 15% increase in the general population.

There were significant changes in walking speed without the WA of 11% at 3 months. For those who used WA for 6 months, the increase was 24% and 31% at 12 months (see Figure 4). Clearly, there is a training effect that carries over, even when the WA is not being used. Recall that the conditions that led to the footdrop occurred at least 1 year and on average much longer before entering the trial (mean ± SD = 14 ± 16 years), so these continuing, substantial changes would not have been expected from natural recovery. We also found no significant correlations between the change in speed or change in PCI and the number of years since the onset of the condition.

Usage

The WA automatically records the number of hours that the unit is on each day and the number of stimulus trains it delivers. Because each stimulus train occurs with the swing phase of the step cycle, the number corresponds to the number of steps taken. Unfortunately, some data were lost due to malfunction of the system early in the study. The most complete data are from the subjects studied in Edmonton, and Figure 5 shows results from 13 subjects with recorded usage for more than 100 days. Again, linear regression lines were fitted to utilize all the data for each subject. On average, the subjects used the WA about 75% of the days in the period, and this usage did not change over the period of 100 days. On the days they wore the WA, the mean hours of use increased from less than 7 to more than 8 h/day (P < 0.05; Student’s t test to determine if the mean slope of the linear regressions was greater than 0). The hours that the WA was worn may have been even higher, in that some subjects turned the unit off to conserve battery life when seated (see Methods).
The mean number of step cycles taken per day increased from about 1500 to nearly 1900 \((P < 0.01)\). If we assume a step cycle covers about a meter, on average the subjects increased the distance walked to nearly 2 km/day by the end of the period. Figure 6A shows that the increase in walking speed was strongly correlated to the hours of use. However, the increase in walking speed was also correlated to a lesser degree with the initial walking speed. In other words, the people who initially could walk faster walked more and the increased use was associated with increases in both distance and speed.

### Acceptance

Twenty-five subjects filled out the subject satisfaction questionnaire, which contained yes/no, multiple choice, and questions with free answers (Table 2). In the free responses to question 11, many subjects mentioned increased mobility, decreased effort, safety, and ease of use. Others mentioned greater independence, freedom, and confidence, qualities that are hard to measure quantitatively. With respect to problems (question 12), positioning and electrode problems were most frequently mentioned. A few mentioned that the device inhibited them from wearing short skirts or shorts and mentioned deficiencies in the prototypes (e.g., no low-battery indicator, an intensity knob that could move when rubbing against a pant leg) that have been addressed in the commercial version. Most had positive or no further comments to question 14. A few mentioned wanting a smaller, sleeker, and more refined version. The average score on the questions that could be scored (see Methods) was 87% ± 12% (mean ± SD; numbers included in Table 2).

### DISCUSSION

Although based on a small number of subjects, these results are encouraging. The study was originally designed for 3 months, and walking speed increased and effort (PCI) decreased significantly over this period. No significant correlations were observed between the benefits derived from the WA and the age of the patients or the duration of the footdrop before trying the WA. Thus, even older individuals can benefit, despite having footdrop for a number of years. Many subjects insisted that they wanted to continue using the WA. Further increases in speed and decreases in effort continued in centers where subjects could be followed for 6 or 12 months. Although these subjects were in part a self-selected group, their improvement at 3 months was not statistically different from the rest of the subjects. The important point is that subjects who benefit over 3 months can increase these benefits over longer periods of time. The changes in speed are in the range found in other studies. We included subjects whose footdrop arose from a variety of conditions, and similar changes were observed irrespective of the cause. In addition, the automatic recording of usage information (number of
hours used and number of steps taken) revealed that subjects continued to use the device regularly and walked more. Furthermore, the increase in speed was correlated with the amount of use (Figure 6).

Increased activity in the stimulated nerve and in nerves under voluntary control will strengthen muscles. The example in Figure 2 indicates that connections from cortical structures may also be strengthened, but more data are needed from a variety of subjects. Strengthening of muscles and neural connections is probably responsible for the training effect, in which walking speed is increased, even with the WA off. These subjects had footdrop for at least 1 year and on average 14 years, so these changes would presumably not have occurred without the use of the WA. Nonetheless, the introduction of a new device may have motivated them to walk more and faster, and perhaps they were more motivated to walk fast when the WA was on. However, if they put more effort into walking fast with the WA, the PCI, which is a measure of effort, should have gone up, not down.

Eighty-seven percent of the responses to the “Satisfaction Questionnaire” that could be scored were positive (Table 2). Subjects commented that the quality of their walking and their endurance improved, which we did not measure explicitly. Some appreciated the fact that they didn’t have to put an AFO into their shoes, which may require buying two pairs of shoes of different size. Others had rejected an AFO, which they found uncomfortable, but now found that they didn’t wear out one shoe before the other by scuffing it on the ground. The use of a footdrop stimulator and an AFO are not exclusive. A hinged AFO that allows ankle dorsiflexion has been tried with a number of SCI subjects in single sessions, and the speed was highest with a combination of the stimulator and the brace. An AFO can provide mediolateral stability during stance, which is not controlled by the footdrop stimulator. A few subjects had skin irritation and rashes from having electrodes in intimate contact that deliver stimuli through the skin for 8 h or more a day. This can be a problem, particularly because electrodes are typically reused for about 2 weeks. Half had no difficulty getting an appropriate response to stimulation on a daily basis (question 9). Others had difficulty or wrote in “some times.” Although the insert in the cuff was molded to make the device easy to don reproducibly on a daily basis, work remains to improve ease of positioning for some patients.

This report is the 1st to study in detail the use of a footdrop stimulator controlled by a tilt sensor. The WA also has electrodes and the electronics attached to a cuff so that everything can be donned as a single package with no visible wires. The increases in walking speed were comparable to what has been reported in the literature, and many expressed pleasure in the questionnaire that the device was compact and could be worn barefoot or with sandals (no need for heel sensors in a shoe). Overall, this study indicates that clinical use of the improved FES device may benefit patients with footdrop, as Liberson and others’ first proposed more than 40 years ago.

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