Surface Electrical Stimulation for Foot Drop: Control Aspects and Walking Performance

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Abstract—Use of electrical stimulation to correct foot drop in hemiplegia was proposed over 40 years ago. Recently, improved control strategies have been developed and implemented in commercially available devices. In this article we review the control methods that have been used and present some results from a multi-center clinical trial. A foot-drop stimulator improves the gait pattern and results in an immediate increase in walking speed. In this sense it acts like an ankle-foot orthosis and this immediate increase will be referred to as an orthotic effect. Prolonged use of a foot drop stimulator over a period of months results in further, large increases in walking speed both with the stimulator on and off. Evidence indicates that a part of this increase results from daily use that strengthens residual cortico-spinal connections. Therefore the improvement over time will be referred to as a therapeutic effect. We found that people with non-progressive and progressive conditions of the central nervous system have an orthotic benefit, as well as a therapeutic up to 3 months of use. In generally non-progressive conditions such as stroke, further therapeutic increases are seen up to at least 11 months of use. In disorders such as multiple sclerosis, the progression of the disease eventually overcomes the early therapeutic effects. In conclusion, many individuals can benefit from commercially available foot-drop stimulators with improved control strategies and cosmetic design.

Index Terms—electrical stimulation, multiple sclerosis, stroke, walking.

I. INTRODUCTION

FUNCTIONAL Electrical Stimulation (FES) is a method for using electrical stimulation to replace function that has been lost as a result of damage to the central nervous system (CNS). The first application of FES was by Liberson et al. [1] for the condition of foot drop in hemiplegia. The ankle flexor muscles such as tibialis anterior (TA) have a strong projection from motor cortex and this is frequently damaged after a stroke or other CNS disorders. As a result the foot drops and may drag on the ground when the individual tries to take a step. Disruption of the normal gait pattern may reduce walking speed, decrease walking endurance and cause trips and falls. Electrical stimulation can use either surface electrodes or implanted electrodes [2-5], but this short article will only consider systems using surface electrodes.

II. CONTROL BY FOOT SWITCHES

To prevent foot drop, Liberson applied electrical stimuli to the common peroneal (CP) nerve that innervates the TA and other muscles that flex the ankle. He also used a heel switch to control the timing of the stimulation. When the heel came off the ground at the end of the stance phase, the switch opened. The switch opening initiated a train of stimuli to the CP nerve. When the heel contacted the ground again at the beginning of the stance phase for the next step, the train of stimuli was terminated. Fig. 1A illustrates this control strategy for switching between the two stimulation states based on whether the heel is on the ground or not. A similar strategy has been used in several foot-drop stimulators that were based on Liberson’s original idea. They have been fitted to several thousand individuals with foot drop (e.g., Mikrofes [6], Odstock [7]).

The Mikrofes stimulator included delays, if needed, between the heel coming on or off the ground and the initiation or termination of stimulation. This is helpful to prevent the foot flexing too soon before the initiation of the swing phase or turning off too quickly at heel strike. A rapid cessation of stimulation can lead to the foot slapping on the ground. The Odstock stimulator also allows the stimulus to increase or decrease gradually in a ramp-like fashion. A ramp increase may help prevent the occurrence of spasms, as the calf muscles are stretched by contraction of the ankle flexors. One problem with heel sensors is that their sensitivity changes over time. With the Odstock stimulator the sensitivity can be calibrated to compensate for at least some of the drift in sensitivity (Ian Swain, personal communication).

III. CONTROL BY TILT SENSORS

More recently, an accelerometer has been used as an alternative control method [8]. An accelerometer will record high frequency activity, for example when the foot hits the ground and produces a rapid deceleration of the limb. However, it will also respond to the tilt with respect to gravity (i.e., the gravitational acceleration). The tilt of the limb will change at much lower frequencies, so it can be largely extracted using a low pass filter. The WalkAide foot-drop stimulator that we developed [9] uses a fixed RC low-pass filter at 5 Hz, together with a variable, digital low-pass filter that can be adjusted by software. Low-pass filtering smoothes the signal, but introduces time delays. The software allows an appropriate balance to be selected for a given individual.
Fig. 2 compares the signals from the WalkAide sensors with force and kinematic data obtained with a Vicon gait analysis system. Fig. 2A shows the actual tilt of the shank, measured with the motion analysis system, for a control subject walking at a self-selected speed (0.7 m/s). Also shown is the accelerometer signal from the WalkAide, using the default setting for the digital filter (4 point running mean of samples at 40 ms intervals). The filtered accelerometer signal shows some delays compared to the actual tilt and some nonlinearity, since the gravitational component will vary as the sine of the angle. The delays will be less important for the slower walking typical of the hemiplegic population. Tilt angle is measured with respect to the horizontal in Fig. 2, so vertical will be -90°.

These times are incorporated into the rules for switching states in Fig. 1B. For example, to turn the stimulus on, the tilt must exceed a threshold (Th1) and the time that the stimulus has been off (Toff) must exceed Twait. Similarly, to turn the stimulus off, the period that it has been on (Ton) must exceed Tmin and one of two events must have occurred: either the tilt goes below Th2 or the duration of stimulation exceeds Tmax. The threshold and time parameters are all set using a software program (Fig. 3). Control can be either from the tilt sensor (filtered accelerometer) or from the foot switch. However, the vast majority of individuals (>95%) obtained adequate triggering parameters are all set using a software program (Fig. 3). Control can be either from the tilt sensor (filtered accelerometer) or from the foot switch. However, the vast majority of individuals (>95%) obtained adequate triggering using the tilt sensor and they chose to use this method of control at home.

The WalkAnalyst software (Fig. 3) allows manual or automated methods for customizing the WalkAide parameters for each user. Each of the 5 parameters (on and off thresholds, minimum, maximum and wait times) shown in Fig. 1B can be adjusted with a mouse or typed into a parameter screen. The parameter screen contains a variety of other parameters that will not be considered here. The automated method uses two steps: 1) choose a starting set of parameters and 2) optimize the set of parameters. The starting thresholds are set to the mean ±1.5 standard deviations of the sensor values recorded during a walking trial. The times are initially set to default values (Tmin = 0.5 s, Tmax = 1 s and Twait = 0.4 s).

For optimization, the walking trials will normally also contain data from a hand switch operated by a clinician (top line in Fig. 3). The clinician pushes the switch each time he or she thinks the stimulus should begin and releases it when he or she thinks the stimulus should end. The manually selected on and oFF times serve as a reference to calculate an error score for the state, as derived from the tilt signal. The error is calculated as the percent of sampled time points, where the actual stimulus state differs from the desired state.
stimulus state, based on the data from the hand switch. The
starting error percent is calculated from the starting set of
parameters. For this purpose, the operation is simulated
using the rules shown in Fig. 1B and the starting set of
parameters. For each time point the desired state signaled by
the hand switch can be compared with the actual state.

To minimize the error a gradient search algorithm is used.
Each parameter is varied in turn by ±50%. The performance
of the new parameter set is simulated and the error %
between the hand switch and the simulation is calculated.
The parameter set that produces the lowest error rate is
selected and the process is repeated using that modified data
set. When no reduction can be obtained with 50% variation,
the variation is reduced to half (±25%).

The process is repeated until variations of less than 1%
produce no further reduction. Fig. 3 illustrates a typical end
result of the optimization. The desired stimulation periods
signaled by the hand switch agree with the optimized
stimulation periods based on the tilt data; compare the light
blocks in the first line (actual stimulus using the hand
switch) and the second line (optimized stimulation periods
based on the tilt data). Fig. 3 also shows the tilt signal that
was sampled every 40 ms (dots in the graph). If the value
exceeded the on threshold (green horizontal line), the
stimulation was applied for a period (green portion of the tilt
signal) until the tilt dropped below the off threshold (red
horizontal line) or one of the other conditions indicated in
Fig. 1 occurred.

In our experience the WalkAnalyst optimization routine
usually delivers a parameter set that produces a satisfactory
walking pattern for the user. If the optimized set of
parameters is not satisfactory for any reason, clinicians can
modify the parameters as desired, based on their judgment.
The new parameter set from either the optimization
algorithm, clinical judgment or a combination of the two
can then be tested using a new walking trial. If the walking
is satisfactory under a variety of conditions (straight
walking, curved walking, walking fast or slow, up and down
stairs and ramps, etc.), the individual can be trained to put
the device on reliably each day, to replace electrodes and
batteries, etc., so that the device can be used in the
community.

IV. CLINICAL TRIALS

Over the past six years we have run a clinical trial of the
WalkAide foot-drop stimulator with the features described
above involving 74 individuals in 5 centers (Edmonton,
Vancouver and Montreal in Canada, Hannover, Germany
and Yamagata, Japan.) A full report of the results will be
published elsewhere, but some major findings will be
summarized here. The subjects were divided into a generally
non-progressive group (stroke, spinal cord injury, traumatic
and post-operative brain injury, N=41) and a progressive
group (secondary progressive multiple sclerosis, N=32). All subjects participated in the study for at least 3 months, and 33 subjects continued for about a year. Subjects used the WalkAide on a daily basis at home and while walking in the community. Walking speed was measured at regular intervals in the lab with a 4 minute walking test.

Figure 5 shows the walking speed for subjects that used the device on the more affected leg for about 11 months. In each recording session walking was tested with and without the WalkAide foot-drop stimulator (WA). The mean walking speed at all times was typically 5-15% higher with the device than without the device for both the progressive and non-progressive groups. This increase in walking speed is similar to what might be expected for an ankle-foot orthosis, a plastic brace that mechanically prevents the foot from dropping. Therefore the immediate improvement is referred to as an orthotic effect.

In addition to the immediate, orthotic effect, further increases in walking speed are seen after prolonged use. We refer to these long-term changes as therapeutic effects, since they take place as a result of using the stimulator on a regular basis. After 11 months the therapeutic effect was much larger for the non progressive group (about 30%) than for the progressive group (about 5%). Since the subjects were at least 6 months and on average 11 years after the onset of their disability, they would not be expected to show a spontaneous recovery. The overall increase in walking speed (combined therapeutic and orthotic effect) eventually reaches more than 40% in non-progressive conditions. The individuals with progressive disorders initially showed both an orthotic and a therapeutic effect, but after about 3 months the changes began to reverse on average. Even after nearly a year the combined orthotic and therapeutic increase in walking speed was more than 10% in a group that would be expected to decrease in walking speed over this period.

Another useful feature is that the device records the number of hours/day the stimulator is on and the number of steps/day that the device is used. In a previous study [9] we found that individuals use the WalkAide foot-drop stimulator in the community on about 75% of the days. On these days usage increased from 7 to over 8 hours/day during the trial and walking increased from about 1500 to over 1900 steps/day on average.

Fig. 6 shows an interesting example of an individual who had a head injury nearly 20 years before starting to use a foot drop stimulator [9]. He walked very slowly and only showed a small orthotic effect. However, his walking speed almost doubled over a year of using FES, so there was a substantial therapeutic effect. The mechanisms underlying this improvement were studied using transcranial magnetic stimulation (TMS). Normally, the largest response of 1 mV or more is observed in the tibialis anterior (TA) EMG when the stimulus is applied about 1 cm lateral and 1 cm posterior to the vertex. This is the classical leg area of the motor cortex. In this individual we applied TMS at various positions in cm increments up to 3 cm left and right and 3 cm forward and backward from the vertex, while recording the motor evoked potential (MEP) from the electromyogram (EMG) of the left TA muscle. The left side of the body was more affected by the head injury. Small responses were seen when the stimuli were applied to the right side of the brain (Fig. 7A). However, there was a valley at the point 1 cm lateral and 1 cm posterior, where a peak was expected. This suggests that the head injury damaged the right leg area of the motor cortex, and that the damage was responsible for his slow walking speed. Slightly larger responses were observed from areas near the valley, so a rim of tissue appears to have been spared to some extent, which enabled him to walk slowly and produce some ankle flexion.

Fig. 7B shows the TMS responses for the same area after using FES for six months. The valley is still present, but now the surrounding rim of tissue gives MEPs that are 2-3 times as large as they were initially. This suggests that the residual cortico-spinal connections were greatly strengthened by using FES and the strengthening could be responsible for the increased walking speed. These results have now been confirmed with a larger sample [11] and further details will be published in the future.
Thus, over 95% of the individuals studied chose the heel sensor initially, but then transferred to using the tilt sensor. A couple of other individuals used a heel switch or a tilt sensor. A heel switch is the traditional method for control, but requires shoes or other footwear that allow the switch to be fixed with respect to the heel. This may limit the ability of individuals to use the stimulator when walking barefoot, with socks or even sandals. The sensor may also respond differently with hard or soft shoes, if placement varies in the shoe from day to day and will change in sensitivity over time. This has led to the inclusion of a calibration routine when required. Finally, use of a heel switch requires wires or wireless transmission to connect the heel sensor to the control electronics. Broken wires or lack of reliable transmission is therefore a potential source of failure. Of the 73 individuals in this study, 72 chose to use the built-in tilt sensor. A couple of other individuals used the heel sensor initially, but then transferred to using the tilt sensor. Thus, over 95% of the individuals studied chose the tilt sensor initially and over 98% used it after a short transition period. The ease of use with a wide variety of footwear or no footwear, as discussed above, probably contributed to the overwhelming choice of the tilt sensor in this population. We were also pleasantly surprised how stable the settings were from day to day. Some individuals have now been using the WalkAide for up to 7 years with little or no adjustment of the parameters. Finally, the combination of three timing parameters, as well as two thresholds based on the individual’s walking pattern, offers additional reliability (compare Fig. 1B to Fig. 1A).

Another point of interest is that all groups studied showed an orthotic effect of FES, in that the mean walking speed was typically 5-15% higher with the device than without it on any given day. A passive device such as an ankle-foot orthosis (AFO) will also have an orthotic effect, but there has not been a long-term study comparing an AFO to FES. One long-term study showed no benefit in walking speed from using an AFO in individuals with MS. Many of the individuals in our study had been fitted with an AFO at some point, but had rejected it. They had discarded the AFO or indicated that it no longer fit properly, so we could not compare the use of an AFO to FES systematically. A few individuals did not have sufficient medio-lateral stability in the ankle so a light-weight brace was used that provided stability, while allowing the FES to flex the ankle. Others required a knee brace to prevent hyperextension, in combination with FES for ankle control. One study suggested that there may be an additive effect of using both an AFO and FES, but this was only a one-day trial in a laboratory setting. A properly controlled study over a period of time is needed.

A third finding of our study was that all patient groups showed a therapeutic effect. The non-progressive group contained individuals with a variety of conditions (stroke, incomplete spinal cord injury, brain injury, cerebral palsy or hemiplegia following surgical intervention for other conditions). The different subgroups were pooled because there were no significant differences in walking speed at any of the time points. Over the first three months there was also no statistical difference between the non-progressive and the progressive groups, but they diverged clearly after that time. We do not claim that the use of a foot-drop stimulator will have any effect on the ongoing deterioration of a disease such as MS, but even after 12 months, individuals with MS were still performing better than they were initially. Thus, we hope that FES will allow these individuals to avoid the need for a wheelchair for a few years. Only two studies have reported on a substantial number of individuals with MS. Although there were a few individuals who showed a therapeutic effect in the Taylor et al. study, they found no therapeutic effect in the group as a whole. The second study only studied the orthotic effect by measuring one time point in individuals who had been using FES often for years. Two reasons may be suggested for the discrepancy between Taylor’s study and our study. First, Taylor et al. only studied two time points: one before and the second after 18 weeks of FES. By that time performance is already declining in our study. Secondly, the individuals in our study were diagnosed as having the secondary progressive form of MS. Taylor et al. do not comment on whether some of their subjects had the primary form with acute attacks and remissions, which would have confounded a study of long-term trends.

Finally, we have tried to determine the mechanism for the therapeutic effect of FES. Figs. 6 and 7 show that cortico-
spinal connections were strengthened by comparable amounts to the increase in walking speed in one individual. This single example has now been confirmed in a larger sample ([11]; Everaert et al., in preparation). There may be other factors such as an increase in fitness from walking more, since our results show that the increased speed and decreased effort of walking with a foot-drop stimulator leads to increased walking in the community. These usage data are particularly important in relation to evidence-based medicine. Governments and insurance companies are reluctant to pay for devices unless there is evidence that they are well used and benefit the individuals who use them to treat a given problem. In conclusion, even a single channel of stimulation with appropriate control strategies and cosmetic design can improve the function and quality of life for individuals with foot drop arising from a number of disorders of the central nervous system.

REFERENCE


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