Effect of modifying stimulation profile on loading response during FES-corrected drop foot.

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Introduction:

Drop foot stimulators today operate open loop with a trapezoidal stimulation profile. The traditionally applied profile originated as much from technological constraints as suitability for the physical pathology. It is proposed that by increasing the stimulation intensity during the loading response phase of gait, the ankle angle trajectory would become closer to that of normal gait and a more efficient heel rocker would be introduced.

The first system for correction of the drop foot with peroneal nerve stimulation was developed by Liberson et al [1] and different versions of this peroneal nerve stimulator (PNS) have since been developed and widely applied. The improvement of walking performance with PNS varies very much between patients, but there seems to be a general agreement that the application of the PNS, in general, has both a positive therapeutic and a positive orthotic effect. Since Liberson’s pioneering work, a number of laboratory devices have been developed and a number of commercial devices have been manufactured. (For a review see Lyons et al, 2003 [2]).

Liberson synchronised the application of FES with the swing phase of gait; the stimulation was on during swing and off during stance; a rectangular stimulation profile was effectively applied. This stimulation profile corrected for drop foot, which obstructs the advancing limb during the swing phase of gait. [1]

Several researchers have evaluated the effect of making changes to the stimulation intensity profile. Vodovnik added a slow ramp up time to prevent spastic reaction in the triceps surae. The commercially available ODFS, and KDC stimulators allow stimulation to be maintained for an adjustable time after heel strike, known as extension time, before stimulus is ramped down, to improve the loading response phase of gait and to prevent the occurrence of foot-slap. These stimulation profiles are trapezoidal in shape, ramping up to prevent spastic reaction in the triceps surae and down to provide smooth cessation of stimulation [2].

In 1977, Stanic customised a stimulation profile for two hemiplegic drop foot subjects [3]. He compared the gait of two subjects using a PNS when walking with the traditional trapezoidal stimulation profile and when walking with a stimulation profile based on qualitative information provided by EMG activity of a normal person. The stimulation sequence was adapted to each patient individually, in accordance with the specific anomaly of his gait. He reported a resulting ankle angle trajectory closer to the normal trajectory and an improved loading response phase, where audible foot slap was prevented and maximal plantarflexion decreased. However, no systematic analysis of the effect of different profiles was performed.

This study focuses on modifying the stimulation profile during weight acceptance as this is the most demanding phase of the gait cycle. Three functional patterns are needed: shock absorption, initial limb stability and the preservation of progression [4].

In normal gait after initial contact, brisk response of the pre-tibial muscles (tibialis anterior and long toe extensors) decelerates the rate of ankle plantar flexion. Two purposes are served by this dynamic response. The heel support period is extended, and the tibia is drawn forward as the foot drops. Both actions contribute to limb progression. The combined effects of the passive foot drop and active tibial advancement roll the body weight forward on the heel, hence the term heel rocker. While the arcs of ankle motion are not large, they are critical for progression and shock absorption during stance [4].
Method/Design

One hemiplegic subject suffering from drop foot participated in this study. He was selected from a group of three patients suffering from hemiplegic drop foot who had been using the prototype implantable drop foot stimulator developed at Aalborg University [5]. He had been using the stimulator for more than 2 years and suffered from foot-slap when he walked using the PNS.

The implantable drop foot stimulator was adapted to allow modulation of the stimulation intensity throughout gait. Stimulation is triggered by a heel switch at detection of heel rise. The stimulation intensity is modulated over the entire stride.

A Labview® graphical user interface (GUI) allows customisation of the stimulation intensity profile applied during gait. The GUI operates on a desk-top PC and the profile is downloaded via a serial link.

Three sets of stimulation profiles were used: one set examined the effect of increasing the delay after heel strike when stimulation is applied (extension time), while maintaining the stimulation intensity constant (figure 1a); the second set examined the effect of increasing the stimulation intensity during loading response while maintaining the extension time constant (figure 1b); the third set examined the effect of increasing stimulation intensity in advance of heel strike while maintaining the increment in intensity and the extension time constant (figure 1c).

The subject was fitted with the external unit of the modified stimulator. The stimulation threshold (the minimum pulse width which caused a twitch response in the muscle) was set to the threshold value used by the subject during everyday use. The subject was asked to walk and the maximum stimulation level was increased until the subject was satisfied that the del_20 profile created sufficient dorsiflexion for gait.
A heel switch and toe switch monitored the gait events of the affected leg. Goniometers measured the ankle, knee and hip angles. EMG was recorded from the TA and Soleus muscles. A stimulation profile was downloaded to the external unit. The subject was asked to walk along an 8m walkway turn around and return. This was repeated so that the walkway was traversed 5 times. A new stimulation profile was downloaded and the trial was repeated for each stimulation profile. The maximum and threshold stimulation intensities were maintained constant, as was the stimulation frequency.

Goniometer data was filtered at 12 Hz. EMG linear envelopes were generated by full wave rectification and filtering of the signals at 12 Hz. The data samples were analysed by visual inspection; the strides where the subject was turning around, accelerating or decelerating were removed. A number of consecutive strides were selected from the centre of each traversal of the walkway so that a total of 22 strides were selected. The ensemble averages of joint angles were calculated and were used to analyse the basic stride pattern.

The heel rocker duration was calculated as the difference between heel strike time and toe-on time. Heel rocker duration was calculated for each stride, and a mean value was generated over all selected strides. This was used as the outcome to assess the intervention.

Results/Discussion

Figure 2 shows the results of measuring the heel rocker characteristics for each stride and calculating the mean and standard deviation of these parameters. Statistical analyses were conducted using a one-way ANOVA and post-hoc Tukey tests. It can be seen that when the stimulation is maintained for a short duration after heel-strike, the heel rocker duration is increased (figure 2). However statistical analysis revealed no significant difference (p=0.26) between the three sets of results.

Examining figure 2, the heel rocker duration increases for the stimulation profiles amp_60 and amp_80 it decreases to a similar duration as amp_60 for profile, amp_100. Statistical analysis revealed a significant difference between the 4 groups (p=0.005) but only a significant difference between results for del_20 and amp_80 (p=0.002). The results obtained for stimulation profile amp_100 do not follow the normal trend of the data and can be considered an “outlier”.

Figure 2 shows the effect of increasing stimulation earlier in the gait cycle thus preparing the foot for the forces occurring during heel strike. If stimulation intensity is increased immediately at heel strike, pred_0, the heel rocker is of a similar duration (~2.1 %GC) to when the same level of stimulation is maintained after heel strike (del_0, del_10, del_20). If stimulation is increased before heel strike (treating amp_100 as an outlier and substituting amp_80) an increase in heel rocker duration is observed (2.6). If stimulation is increased 5%GC before heel strike, the heel rocker duration is further increased to 3.0%GC. Increasing the stimulation 10%GC before heel strike increases heel rocker duration to 3.5%GC. (Normal heel rocker duration 5-8%GC [4]). Statistical analysis showed a significant difference between all 4 groups (p=0.000). Statistical analysis showed statistical differences
between pred_0 and both pred_5 and pred_10; amp_80 and pred_10; almost between amp_80 and pred_5 (p=0.056); and almost between pred_5 and pred_10 (p=0.065).

It can be seen that as stimulation intensity is increased during loading response, more time is spent with the body weight supported by the heel alone. This indicates a greater confidence in putting weight on the affected leg in the early part of stance and a greater influence of the heel rocker.

The heel rocker plantarflexion arc becomes larger and more like that of normal gait. With little stimulation, the volunteer places his foot on the ground in an almost flat manner. There is very little plantarflexion needed to reach foot flat. As more stimulation is applied, during loading response, the volunteer makes a larger angle between the ground and the tibia at heel strike and more time is spent using the heel rocker.

In order to investigate the effects of the delay between increase in joint torque and increase in stimulation intensity it was proposed to take some isometric torque measurements. It was proposed to apply a sample of the stimulation profiles to the patient and measure what was the effect of recruitment delay and the non-linear intensity-torque curve. It was seen that the torque increases as the stimulation intensity increases thus verifying that the pulse-width modulation over the specified range causes the output torque to be modulated in a similar fashion. The results also showed a delay of 150ms between increase of the stimulation intensity and increase in joint torque. If heel rocker function is to be improved the stimulation intensity must be increased prior to heel strike to prepare the pre-tibial muscles for the greater demands imposed on them after heel strike. Increasing the stimulation intensity up to 150ms before heel strike (for this patient 10%GC) is beneficial. This is consistent with the isometric torque results as they indicate a delay of 150ms between increase of stimulation and increase in torque.

By increasing stimulation intensity during loading response, the heel rocker is prolonged. As this is an essential element for progression and provision of shock absorption during loading response, we believe it is a positive effect.

References


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