Evaluation of a Drop Foot Stimulator FES Intensity Envelope Matched to Tibialis Anterior Muscle Activity during Walking

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Abstract – *A "natural" stimulation strategy is proposed based on muscle activation patterns observed in healthy gait. This stimulation approach was tested on a 52-year old hemiplegic drop foot subject who is ten years post-stroke using a computer-based FES control system. Dorsiflexion angle range was recorded for the subject while walking without orthosis, walking with the "natural" stimulation approach and walking with the conventional trapezoidal stimulation approach. The "natural" approach was found to result in a 76 % increase in dorsiflexion range for the subject, while using only on average 53 % of the stimulation used by the conventional approach. The improved performance of the "natural" stimulation approach is attributed in this case to the subject's calf spasticity, which was rated on the modified Ashworth scale as 3-4, indicating moderate to severe spasticity. The "natural" stimulation envelope is thought to result in a less severe spastic reaction of the calf muscles during dorsiflexion than the conventional trapezoidal approach, enabling a greater dorsiflexion range as a result.*

1. Introduction

The use of FES for the correction of hemiplegic drop foot is well established [2, 3, 4]. The method by which FES is applied in most Drop Foot Stimulators (DFS) can be described as using a Trapezoidal FES envelope. With this method, FES is linearly ramped up to its maximum value at toe-off, FES intensity is then kept constant until heel-strike, when it is ramped down to zero. This approach, which is very similar to that first proposed by Liberson et al in 1961, [2], results in a Tibialis Anterior (TA) muscle activation pattern during swing and loading response that is quite different to that occurring naturally in healthy gait. Tibialis Anterior muscle activation during these phases of gait has been identifed by several researchers as having two phases of activity, [5, 6, 7]. The first phase of TA activity occurs at toe-off, when concentric contraction of TA results in foot-lift to provide foot clearance during swing. This concentric phase is followed by a more intense activity phase at loading response, when the TA is eccentrically contracting to provide braking action on the plantarflexion moment at the foot at heel strike. Perry's data, [5], suggests that the muscle activation at loading response is approximately twice that occuring at toe-off. Assuming a linear relationship between FES intensity and muscle activity, it would appear that the Trapezoidal FES envelope approach to HDF correction does not match that observed in natural gait. This would suggest that the Trapezoidal FES envelope approach results in the application of FES that is not properly matched to the biomechanical demands occurring during gait.

A computer-based control system has been developed by the authors that enables different FES envelope configurations to be applied during gait correction. Using this system, a FES envelope which closely matches the TA muscle activation pattern during healthy walking has been developed. This paper describes the architecture of the control system employed and the results of the clinical evaluation of the system which were completed.

2. Method

Clinical Evalution System

To enable flexible prototyping of the gait correction controllers, the system was developed using Simulink® and was executed in real-time using a PC-based dSPACE® DS1102 real-time control card. Sensor and FES control signals were transmitted to/from the PC and the subject using a galvanically isolated 8.5 meters wire link.

Stimulation of the subject's common peroneal nerve, to elicit dorsiflexion, was carried out using an adapted, commercial, portable, battery-powered programmable stimulator, which applied FES to the subject under the control of the dSPACE® real-time system using a galvanically isolated control line between the PC and stimulator. A block diagram of the complete system is shown in Figure 1.

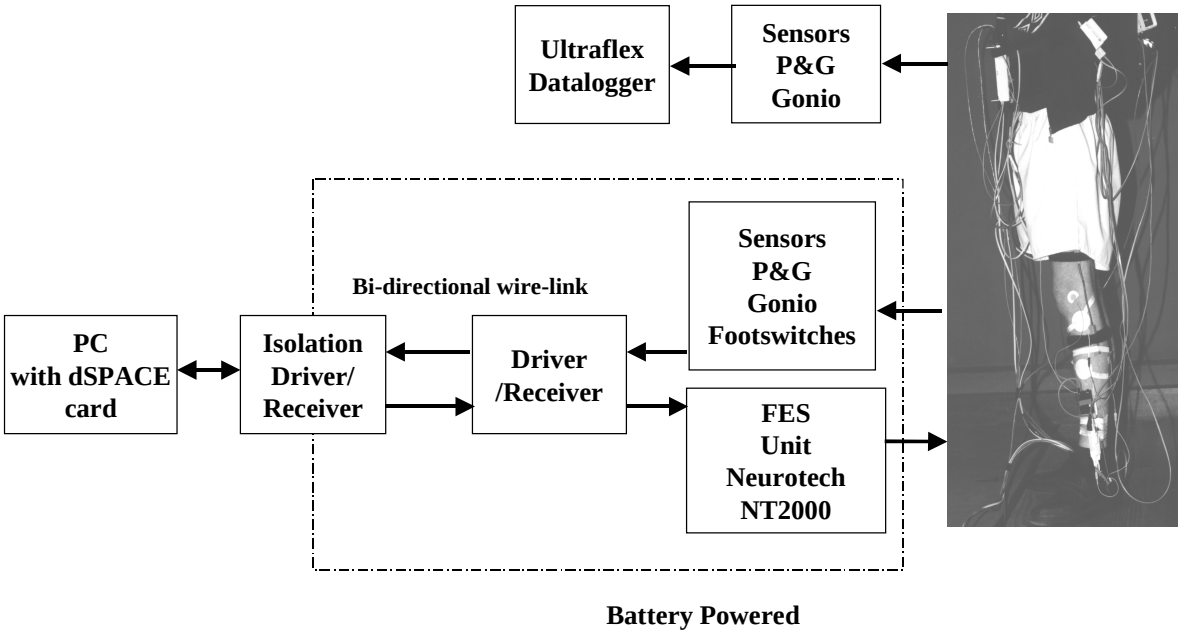

Figure 1 – Clinical Evaluation System

Stimulator Unit

The stimulator unit used was an adapted NeuroTech® NT2000 commercial stimulator. The NT2000 has a programmer unit that enables the following stimulation parameters to be manually set:

- Stimulus Pulse Width
- Stimulus Pulse Frequency
- ON Time
- OFF Time
- Ramp-up time
- Ramp-down time

The stimulus amplitude is adjusted using a control button on the stimulator unit itself. The stimulus pulse width is fixed once it is manually set using the programmer unit and cannot be changed dynamically. However, the NT2000 controls the stimulus intensity using a DAC whose reference voltage determines the maximum value of the stimulus amplitude. In normal circumstances, this is fixed at 5 V, in which case, the amplitude control button on the stimulator can adjust the stimulus amplitude from 0 to maximum. A value of 2.5 V on this reference pin enables the amplitude control pin to adjust the amplitude from 0 to only half of the maximum possible.

Thus a modulating 0-5 V signal connected to the voltage reference pin of the DAC, with the amplitude control button set at maximum, enables dynamic adjustment of the stimulus envelope. The controller output from the PC provides this modulating 0-5 V signal to the stimulator unit using the galvanically isolated link.

Stimulus Parameters:

A pulse frequency of 30 Hz and a pulse width of 350 μs were selected. These stimulation parameters were observed to provide good dorsiflexion, (in excess of 20 degrees ankle angular displacement during a test with the subject seated) and are in the range that provides better comfort to the subject [1].

Controller Architecture

The controller was implemented for real-time purposes using a Simulink® description, which was compiled for real-time execution on the DS1102. The envelope generator was implemented in the Simulink® controller using a 1-D look-up table, the FES envelope output of the controller for the "natural" FES envelope and the trapezoidal FES are shown in Figures 2 and 3, respectively.

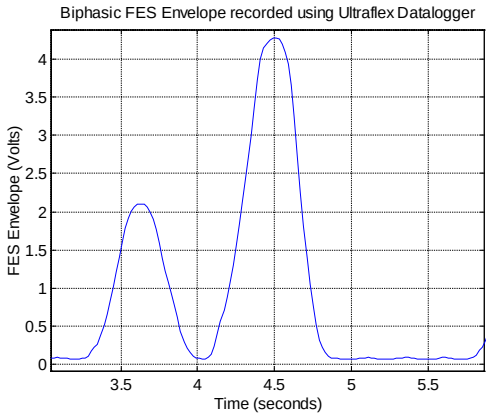

Figure 2 – Data-logged controller output versus Time for the "Natural" FES envelope controller

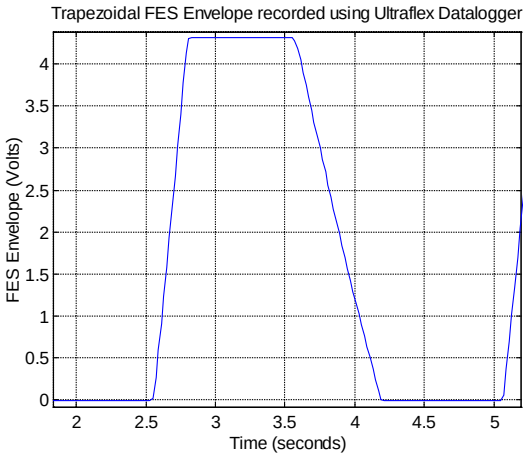

Figure 3 – Data-logged controller output versus Time for the Trapezoidal FES envelope controller

Subject Details

The system was evaluated on a male 52-year hemiplegic drop foot sufferer who is 10 years post-stroke and walks with pronounced circumduction and hip-hitching. The subject's walking speed is significantly affected by hemiplegia, with a recorded walking speed for the subject, over a seven meter walkway, of 0.54 m/s. When walking without an orthosis, the subject achieved an active dorsiflexion range of 2.15 degrees, which is consistent with hemiplegic drop foot. A healthy subject measured using the same measurement set-up achieved an active dorsiflexion range of approximately 32 degrees.

The subject was also tested for calf muscle spasticity using the modified Ashworth spastic scale of muscle spasticity by a Chartered Physiotherapist who is trained in this technique and was rated as being 3-4 on the modified Ashworth, which corresponds to moderate to severe calf spasticity.

Trial

The subject walked over a seven meter walkway while FES was applied using both the "natural" FES controller and the trapezoidal FES controller. The subject's affected ankle angle was measured using a Penny & Giles strain gauge goniometer, which was datalogged using an Infotronic Ultraflex datalogger. The subject's active dorsiflexion range on the affected ankle was measured during swing over several cycles and an average value and standard deviation were noted.

3. Results

"Natural" FES Envelope Stimulator

The average active dorsiflexion range obtained with "natural" stimulation applied to the subject is 7.68 degrees (standard deviation 0.44 degrees).

Trapezoidal FES Envelope Stimulator

To compare the performance of the "Natural" FES envelope controller with a conventional stimulator, a Trapezoidal FES envelope controller was developed and tested and the corresponding Trapezoidal FES envelope obtained using this controller is shown in Figure 3. The average active dorsiflexion range obtained with trapezoidal stimulation was 4.35 degrees (standard deviation 1.18 degrees). Table 1 summarises the dorsiflexion data for the subject walking without FES, walking with the "natural" FES envelope stimulation and walking with trapezoidal FES envelope stimulation.

	Average Dorsiflexion Range (degrees) (Standard Deviation)
Walking without FES	2.32 (0.35)
Walking with Trapezoidal FES envelope	4.35 (1.18)
Walking with "Natural" FES envelope	7.68 (0.44)

Table 1 – Dorsiflexion range dorsiflexion for walking without FES, walking with "Natural" FES envelope and walking with Trapezoidal FES envelope

To evaluate the effectiveness of the two FES envelope approaches in reproducing healthy TA muscle activity, the TA EMG was recorded on a healthy subject, while seated, while having FES applied using the two controllers, using a blanking EMG amplifier to record the EMG. The RMS of EMG signal recorded for Trapezoidal FES envelope stimulation is shown in Figure 4 and the RMS of the EMG signal recorded for "Natural" FES envelope stimulation is shown in Figure 5. Clearly, the "Natural" approach results in a TA muscle activation pattern, which is much closer to that occurring in healthy gait.

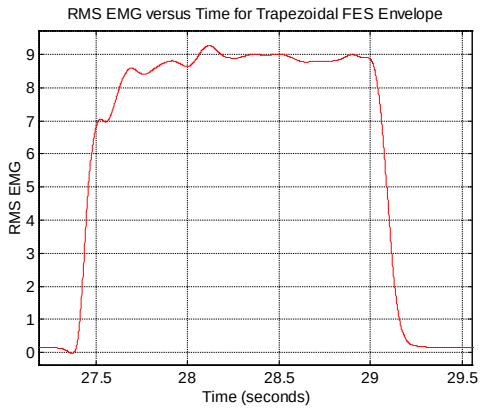

Figure 4 - RMS of TA EMG corresponding to Trapezoidal FES Envelope

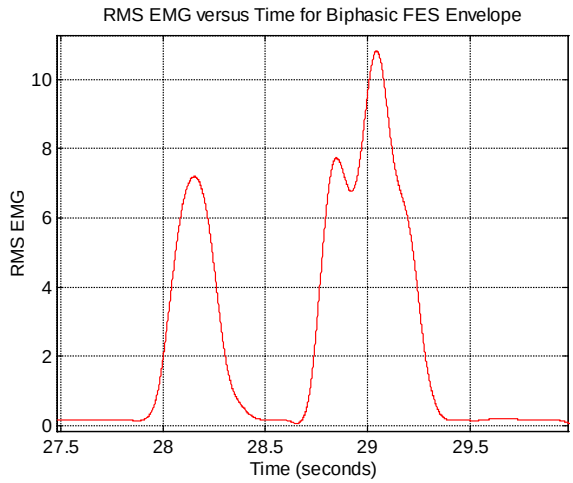

Figure 5 - RMS of TA EMG corresponding to the "Natural" FES Envelope

Conclusions

Thus we have a very significant finding that "natural"stimulation at intensity levels as low or lower than the trapezoidal stimulation resulted in a significantly higher dorsiflexion range than the trapezoidal stimulation. In fact the "natural" approach had a 76 % higher dorsiflexion range than the trapezoidal approach.

An additional and important benefit of the "natural" approach is that the charge delivered with "natural" stimulation is about half (53 %) that delivered by the trapezoidal stimulation. This is a very important result, as a better functional performance is thus obtained with less stimulation. Reduced stimulation has the additional advantages of reduced muscle fatigue and lower power consumption in the Drop Foot Stimulator.

It is suggested that the explanation for this result lies in the spasticity test carried out on the subject. The subject was found to have moderate to severe spasticity of the calf muscle.

The rate at which dorsiflexion occurs determines the rate of stretching of the calf muscle and hence it's spastic response. It is thus proposed that the relatively rapid application of stimulus in the trapezoidal case, triggers a greater spastic reaction by the gastrocnemius muscle than occurs with the "natural" case. This dorsiflexion induced spastic response resists the dorsiflexion movement being produced by the Tibialis Anterior, with a resultant lower dorsiflexion range.

This finding, if repeated in additional subjects, would strengthen the case for the proposed "natural" FES envelope stimulation, as being a more appropriate FES strategy for HDF correction in subjects suffering from spasticity of the calf muscles.

Ethical Considerations

The subject gave written informed consent before participating in this trial and full ethical approval for the study was obtained from the UL Research Ethics Committee.

Acknowledgements

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