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Effects of timing parameter changes on the gait of functional electrical stimulation users with drop foot

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Abstract

Introduction: Functional electrical stimulation uses clinician-set parameters to modify stimulation. This study aimed to investigate whether timing parameters in the ODFS Pace functional electrical stimulation device have an effect on the gait of the general population of functional electrical stimulation users who have a foot drop.

Methods: Twelve functional electrical stimulation users with foot drop resulting from upper motor neurone disorders were recruited from the functional electrical stimulation Service in Leeds, UK. A crossover trial design was used, comparing adjusted values of rising ramp, delay and extension. Instrumented gait analysis was carried out to measure ankle dorsiflexion during the swing phase of gait, foot clearance from the ground, and speed of ankle plantarflexion at initial contact. The effect of timing parameters on gait kinematics was studied.

Results: No statistically significant effects on the measured parts of gait were found for any of the timing parameters. Trends were identified in average mid-swing ground clearance and dorsiflexion associated with the delay and rising ramp timing parameters.

Conclusions: Further work in this area should use larger numbers of participants. Based on these results, the effects of ramping and delay would be of particular interest for further study.

Keywords

Functional electrical stimulation, gait analysis, drop foot, timing

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Introduction

Drop foot is the inability to raise the foot sufficiently during the swing phase of walking, caused by inadequate control of the dorsiflexor muscles.[1] It is a common functional impairment arising from upper motor neurone lesions, such as stroke, multiple sclerosis and spinal cord injury.[2] On average in human gait, the minimum clearance of the foot above the floor is only 8.7 mm.[3] Drop foot lowers the ground clearance of the foot in swing and so can cause trips and falls even on level ground. Secondary effects on walking include reduced speed, smaller step lengths and lack of confidence.[4–6]

Functional electrical stimulation (FES) is a functional orthotic intervention, which can be used as an alternative to ankle-foot orthoses to correct drop foot. First proposed by Liberson et al.,[7] FES uses an alternating electrical current to stimulate action potentials in neurons. By placing electrodes on the surface of the skin close to the relevant nerves, a changing electrical current between cathode and anode can depolarise nerve fibres, stimulating an action potential which propagates to the relevant muscles.[8]

This study used ODFS Pace devices (Odstock Medical Ltd, UK), although some other devices work on similar principles. Activation of the electrical stimulation is electronically controlled, with input from a force-sensitive switch (“footswitch”) beneath the foot,

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usually the heel. The form of stimulation most commonly used in clinical practice has not significantly changed since the inception of FES,[7] with a train of 3.5–360 µs current pulses at 20–60 Hz and 10–100 mA. The shape of the pulse width over time is known as the 'stimulation envelope'. In most current clinical practice, this is a trapezoidal shape. It begins after weight is lifted from the footswitch, rises to the set current level, then reduces to zero through an extension and falling ramp after weight is returned to the footswitch. In this work, the focus is on the stimulation envelope.

Without any timing parameters, stimulation would be active at a single level throughout the swing phase of gait, from heel-rise to footstrike.[9] Timing parameters, normally set by a clinician, alter this stimulation pattern. A graphical representation of the timing parameters in the swing phase of gait is included (Figure 1). The naming convention for timing parameters used in the ODFS Pace is as follows.

- Delay delays stimulation initiation by a set number of milliseconds. It can be used to prevent dorsiflexor activation from antagonising plantarflexors during push-off; excessive delay reduces the fraction of swing phase for which stimulation is active. Odstock Medical Ltd recommends a delay of zero in most circumstances.
- Rising ramp linearly increases the pulse width from zero to the set limit for that device user, within a set number of milliseconds. Ramping begins at the start of stimulation, after heel-rise and any delay. It is thought to increase comfort and prevent stretch reflex activation; excessive rising ramp length may reduce the stimulation amplitude in early swing.
- Extension extends stimulation beyond footstrike by a set number of milliseconds. It is thought to improve tibial progression and help control the foot to prevent fast forefoot strike during early stance phase; excessive extension may induce fatigue or reduce stability by keeping the foot dorsiflexed during stance.
- Falling ramp linearly decreases the amplitude of the electrical current within a set number of milliseconds. Ramping begins at the end of stimulation, after footstrike and any extension. It was expected to have a similar but lesser effect to extension, and because of this falling ramp was not studied in this trial.

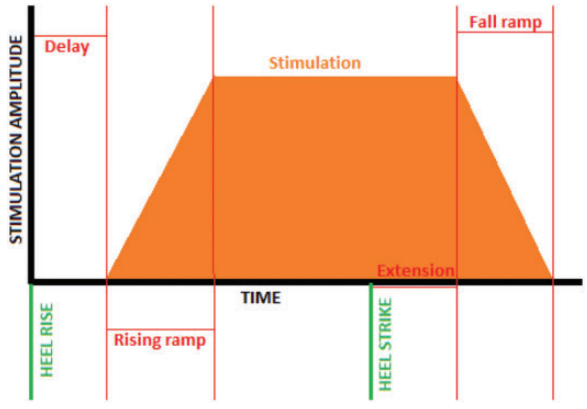

Figure 1. FES stimulation timing parameters.

There have been some previous attempts to change stimulation envelope parameters. Lyons et al. investigated changes in stimulation intensity[10–12] in order to better approximate a 'natural' stimulation of tibialis anterior. Other authors have studied other aspects of the stimulation envelope, including impulse type[13] and intensity.[11,12]

A review of the relevant literature has not found any previous work to investigate the effect on gait of timing parameters of the stimulation envelope. This is of clinical interest because optimisation of timing parameters is currently performed by using trial-and-error and individual experience. Research data on the effects of timing parameters' changes could improve the efficiency of current clinical practice.

This study aimed to investigate whether the delay, rising ramp and extension timing parameters have an effect on the gait of the general population of FES users who have a foot drop. The null hypothesis is that there is no detectable difference in the average gait of users.

Methods

Ethical approval for this study was granted by the West Midlands Research Ethics Committee (approval 16/WM/0132). The study was registered on the clinicaltrials.gov database.

Twelve participants were recruited from the users of the Leeds FES Service. Potential participants were initially identified by clinical staff at the Service, according to the inclusion and exclusion criteria listed here. Written consent was gained at the time of data collection.

Inclusion criteria

- Upper motor neurone lesion causing foot drop
- Currently using ODFS functional electrical stimulator
- Age 18 or older
- Attending Leeds FES follow-up clinics

Exclusion criteria

- FES user for less than three months
- Lower limb prosthesis
- Cannot independently walk for 5 m with walking aids
- Cannot walk 20 5-m walks within a 3-h period
- Uses FES less than once a week

Figure 2 shows the order of events for a participant in the study, together with the drop-out numbers at each stage.

Table 1 shows the characteristics of the participants in the study. The majority of participants had multiple sclerosis as the primary cause of their foot drop. The average age of participants was over 45.

Recruited participants were asked to visit the Leeds gait analysis laboratory at Chapel Allerton Hospital in Leeds, UK. The Leeds gait analysis laboratory uses 8 Vicon MX-T40 cameras,[14] with Vicon Nexus 1.8.5 software. Retroreflective markers (14 mm diameter) are placed using the Helen Hayes markerset.

The method for data collection was as follows: the volunteer was asked to set up their FES electrodes as they usually use them, and an identical device, set up to the same condition, was provided for the trial, so that no changes could be accidentally made to the participant's own device. The participant was asked to walk with FES at their usual walking speed, using any walking aid that they would usually use over the given distance. The walks were recorded. Stimulation parameters were then changed one at a time and the subject was recorded walking with these changed parameters. All other parameters, including non-timing parameters, were set to the user's usual settings, in order to best record their usual gait. The list of parameters tested, in the order that they were tested in, is given in Table 2.

The order in which settings are tested was non-sequential; this is to reduce the confounding factors of any short-term carry-over or training effect. Single-blinding was used, as double-blinding was not practicable due to limitations in staff time.

Data processing was completed initially in Vicon Polygon 4.2 software[14] by an experienced gait analyst. One stride was chosen as representative from each set of trials, and events in this stride were marked for both left and right: initial foot-strike, foot-off, and final foot-strike.

Data analysis was performed using Python 3.5.5.[15] Marker trajectories and joint angles for each marked stride were exported to comma-separated-value format, and data visualisation was performed using the matplotlib package for Python.

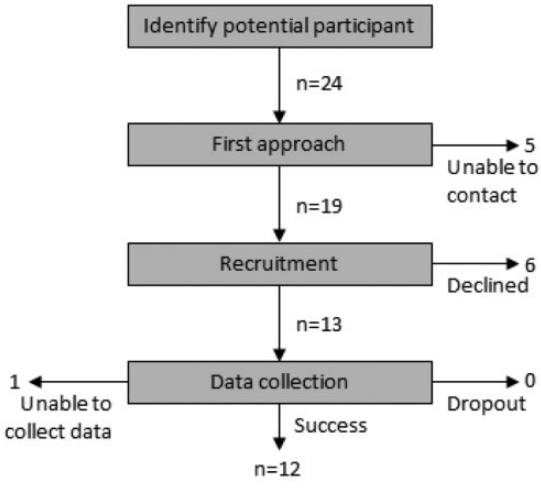

Figure 2. Flowchart showing the order of events for a participant in the study.

Table 1. Population characteristics.

Age	Sex	Condition
18–30: 0	Female: 10	Multiple sclerosis: 8
31–45: 1	Male: 2	Stroke: 1
46–60: 9		Cerebral palsy: 1
61+: 2		Other upper motor neurone condition: 2

Table 2. FES settings for each set of walks, where 'user' means the user's usual setting.

Set	Ramp up	Extension	Delay
1	0 ms	User	User
2	200 ms	User	User
3	100 ms	User	User
4	50 ms	User	User
5	300 ms	User	User
6	150 ms	User	User
7	User	0 ms	User
8	User	200 ms	User
9	User	100 ms	User
10	User	50 ms	User
11	User	300 ms	User
12	User	150 ms	User
13	User	User	0 ms
14	User	User	100 ms
15	User	User	50 ms
16	User	User	150 ms

Results were obtained for the ankle dorsiflexion, ground clearance, walking speed and speed of plantarflexion at initial contact. The results of interest were further analysed; these are ankle dorsiflexion and ground clearance for the delay and ramp conditions, and the plantarflexion speed at initial contact. Ground clearance of the toe at mid-swing was calculated as the minimum height of the toe in the central 60% of the swing phase. Plantarflexion speed was calculated as the fastest vertical speed of the toe in the first 20% of the stance phase.

Histograms showed approximately normal distribution of data. Tests for statistical significance were conducted on results for mid-swing ground clearance and foot plantarflexion using one-way analysis of variance (ANOVA). Effect size was calculated as $\frac{\text{mean}_2 - \text{mean}_1}{\text{SD}}$ for each timing parameter (mean_2) paired with the factory setting for that parameter (mean_1).

Results

Figures 3 and 4 show the mid-swing clearance of the foot from the ground for delay and rising ramp conditions. Figure 5 shows the speed of ankle plantarflexion after initial contact, for the extension conditions.

There was a marked divide in participants between those with a self-selected walking speed over 0.5 m/s (min 0.65, max 0.8 m/s average speed) and those with a walking speed below 0.5 m/s (min 0.2 max 0.4 m/s average speed). Sub-group analysis was performed on faster ($n = 6$) and slower ($n = 6$) participants. Figures 6 and 7 show the differing effects of delay on mid-swing

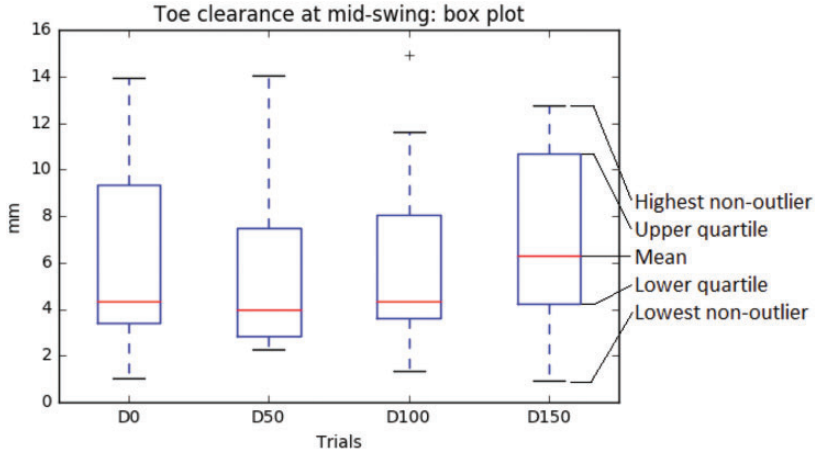

Figure 3. Box plot showing all participants' mid-swing clearance from ground at different delays.

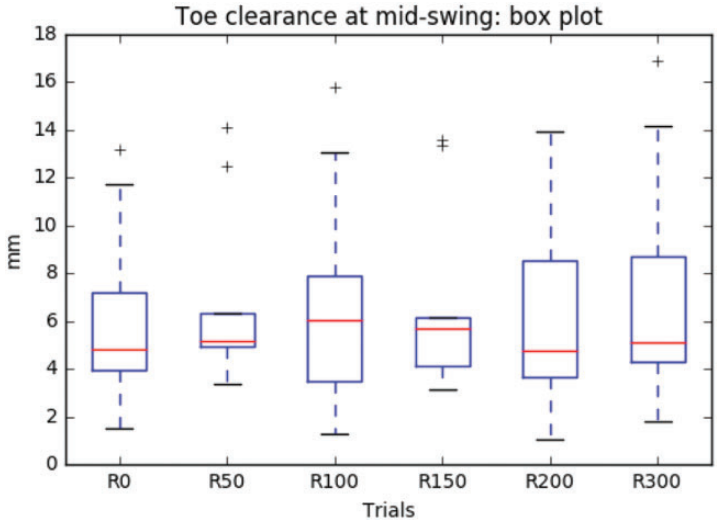

Figure 4. Box plot showing all participants' mid-swing clearance from ground at different rising ramps.

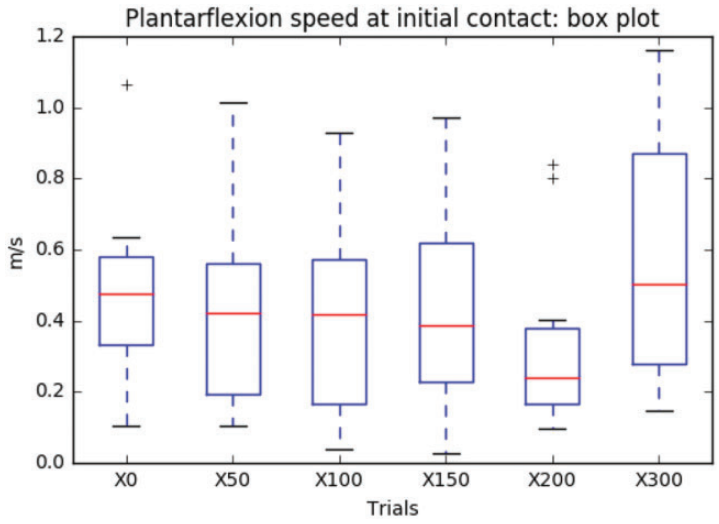

Figure 5. Box plot showing speed of all participants' ankle plantarflexion after initial contact, at different extensions.

Figure 6. Box plot showing slow participants' mid-swing clearance from ground at different delays.

foot clearance in slower and faster walkers, respectively. There was no difference between fast and slow walkers in average plantarflexion speed.

None of the effects of timing parameters on gait patterns were statistically significant ($p > 0.05$ in all cases). Table 3 gives numeric values for the basic statistics from each group, including effect sizes compared to the usual factory settings for ODFS Pace devices (which are rising ramp 200 ms, extension 200 ms, delay 0 ms).

Discussion

All participants were able to complete an effective gait with all timing parameters used. Calculations of effect sizes show small to negligible effects on walking speed, clearance and plantarflexion speed from most parameter changes. Two of the delay parameters gave had a moderately sized effect on plantarflexion speed, using Cohen's suggested medium effect size of 0.5–0.8.[16] No results were statistically significant and the limitations that may have caused this are discussed below.

A low number of participants who were successfully recruited, with data collected from only 12 participants. The low number is partly due to time constraints and partly due to limited uptake amongst potential participants. The study had broad inclusion criteria intended to identify adults with a foot drop who were regularly using an ODFS who were able to complete the study protocol. However that population with a foot drop is

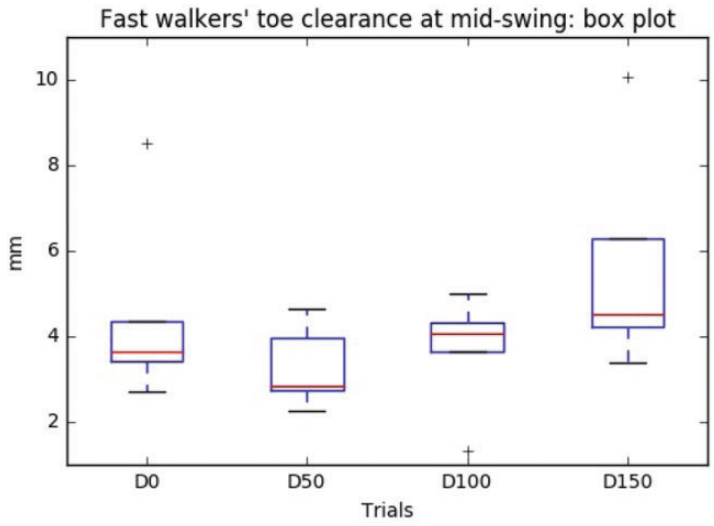

Figure 7. Box plot showing fast participants' mid-swing clearance from ground at different delays.

Table 3. Basic statistics for each timing parameter.

Timing parameter	Walking speed, mean ± SD	Speed effect size	Clearance, mean ± SD	Clearance effect size
0 ramp	0.50 ± 0.22	0.17	6.2 ± 3.7	0.02
50 ramp	0.59 ± 0.39	0.31	7.0 ± 3.5	0.23
100 ramp	0.51 ± 0.23	0.17	6.8 ± 4.5	0.15
150 ramp	0.52 ± 0.21	0.26	6.8 ± 3.7	0.17
200 ramp	0.47 ± 0.24	–	6.2 ± 3.8	–
300 ramp	0.51 ± 0.24	0.17	7.2 ± 4.8	0.21
0 delay	0.48 ± 0.24	–	6.4 ± 4.1	–
50 delay	0.48 ± 0.18	0.01	5.7 ± 3.9	0.17
100 delay	0.47 ± 0.21	0.06	6.3 ± 4.2	0.02
150 delay	0.43 ± 0.23	0.22	7.1 ± 3.9	0.20
			Ankle plantarflexion speed	Effect size
0 extension	0.61 ± 0.42	0.40	0.48 ± 0.25	0.56
50 extension	0.46 ± 0.18	0.04	0.43 ± 0.27	0.33
100 extension	0.49 ± 0.19	0.18	0.42 ± 0.28	0.29
150 extension	0.45 ± 0.18	0.01	0.44 ± 0.30	0.34
200 extension	0.45 ± 0.23	–	0.34 ± 0.25	–
300 extension	0.46 ± 0.20	0.07	0.60 ± 0.37	0.69

not heterogeneous. The study sample is likely to have contained participants with various degrees of lower-limb muscle spasticity. Ramping of stimulation is thought to help to reduce the stimulation of the reflex seen in spasticity, as it reduces the velocity of dorsiflexion.[9] If this were the case, for the rising ramp parameter one would expect participants with spasticity to have reduced dorsiflexion with smaller rising ramps, as spastic reflex of the plantarflexors would have reduced their ankle range of movement.

Fatigue could have an effect on results, as the order of walks was the same for each participant (i.e. not randomised). The first three participants to take part were timed walking 10 m with their usual FES settings, at the beginning and end of the data collection session. These participants slowed by 6%, $<1\%$, and $<1\%$, respectively. This gives some confidence that fatigue is not a large source of error in this study.

The limited resolution of timing parameters (50 ms steps) precluded normalisation of parameters to our

participants' walking speed or stride time. The effect of timing is dependent on the speed of walking because a given time period takes a different fraction of the gait cycle depending on the length of that cycle. For example, the longest rising ramp time in the study was 300 ms: this corresponds to about half of the swing phase in the slowest participants but nearly all of the swing phase in the fastest. Sub-group analysis of faster and slower walkers allowed us to see whether this difference in relative timings had any effect on the data recorded.

As described in the methods section, falling ramp was not studied. Future studies might find this parameter to be of interest.

Conclusions

This study has assessed the effect of FES timing parameters on the gait of FES users. The results were not statistically significant and so the null hypothesis has not been disproven; however, it is hoped that these results may be instructive for further research. Any further work in this area might be useful with larger numbers of participants. More restrictive inclusion criteria, perhaps including walking speed, may help in future studies.

Calculated effect sizes show that most timing parameter changes have small or negligible effects on the walking parameters measured here. The moderate effect sizes seen in ankle plantarflexion speed at initial contact, with changes in delay, suggest that this may be a potential avenue for future studies. Further analysis of these specific effects with a larger cohort of participants would be needed before recommendations could be given to clinicians.

Declaration of conflicting interests

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Guarantor

KT.

Contributorship

SM and KT conceived the study, gained ethical approval. SM researched literature, developed the protocol, analysed the data, and wrote the first draft of this manuscript. Both SMs and LM were involved in recruitment, data collection and analysis. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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References

1. Whittle M. *Whittle's gait analysis*. 5th ed. London: Churchill Livingstone, 2012.
2. Taylor P, Burridge J, Dunkerley A, et al. Clinical use of the odstock dropped foot stimulator: its effect on the speed and effort of walking. *Arch Phys Med Rehabil* 1999; 80: 1577–1583.
3. Winter D. *The biomechanics and motor control of human gait: normal, elderly and pathological*. 1st ed. Waterloo: University of Waterloo Press, 1991.
4. Lehmann JF, Condon SM, Price R, et al. Gait abnormalities in hemiplegia: their correction by ankle-foot orthoses. *Arch Phys Med Rehabil* 1987; 68: 763–771.
5. Holden MK, Gill KM and Magliozzi MR. Gait assessment for neurologically impaired patients. *Phys Ther* 1986; 66: 1530–1539.
6. Hausdorff JM and Ring H. Effects of a new radio frequency-controlled neuroprosthesis on gait symmetry and rhythmicity in patients with chronic hemiparesis. *Am J Phys Med Rehabil* 2008; 87: 4–13.
7. Liberson WT, Holmquest HJ, Scot D, et al. Functional electrotherapy: stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients. *Arch Phys Med Rehabil* 1961; 42: 101–105.
8. Taktak A, Ganney P, Long D, et al. *Clinical engineering: a handbook for biomedical engineers*. Cambridge, MA: Academic Press, 2014.
9. Odstock Medical Ltd. *Course booklet: odstock Medical functional electrical stimulation clinician's course*, 2015.
10. Lyons GM, Wilcox DJ, Lyons DJ et al. Evaluation of a drop foot stimulator FES intensity envelope matched to tibialis anterior muscle activity during walking. In: *Proceedings of fifth annual conference of the International Functional Electrical Stimulation Society*, Aalborg, Denmark, 18–20 June 2000.
11. O'Keeffe DT, Donnelly AE and Lyons GM. The development of a potential optimized stimulation intensity

envelope for drop foot applications. *IEEE Trans Neural Syst Rehabil Eng* 2003; 11: 249–256.
12. Byrne CA, O'keeffe DT, Donnelly AE, et al. Effect of walking speed changes on tibialis anterior EMG during healthy gait for FES envelope design in drop foot correction. *J Electromyogr Kinesiol* 2007; 17: 605.
13. Kesar TM, Perumal R, Reisman DS, et al. Functional electrical stimulation of ankle plantarflexor and dorsiflexor muscles: effects on poststroke gait. *Stroke* 2009; 40: 3821–3827.
14. Vicon Motion Systems, https://www.vicon.com/products/software/polygon (accessed 24 June 2019).
15. Python language reference, version 3.5.5, www.python.org (accessed 24 June 2019).
16. Cohen J. A power primer. *Psychol Bull* 1992; 112: 155.