Original Article

COMPARING FOUR ELECTRICAL STIMULATORS WITH DIFFERENT PULSES PROPERTIES AND THEIR EFFECT ON THE DISCOMFORT AND ELICITED DORSIFLEXION

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ABSTRACT

Objective: To test the perceived comfort and efficiency of four functional electrical stimulators (FES). **Design:** The stimulators were applied over the dorsiflexors (DF) of 28 healthy volunteers. Electronic goniometers monitored changes in electrically-induced DF. Stimulus intensity was increased until full DF occurred or until the subject requested the stimulation stop before full DF. All data were stored on an oscilloscope. Subjects marked on visual analog scales their perceived amount of tingling, pins-needles-burning sensation, and muscle cramping. Data analyses were applied to the amount of dorsiflexion (deg), phase charge (µC), tingling perception, pins-needle-burning perception and muscle cramps perception. Significant differences were accepted at $p<0.05$. **Results:** Group means DF were 19.9±13.5 deg (Focus), 19.5±15.3 deg (300PV), 20.0±13.1 deg (L300), and 24.5±14.6 deg (GMES II) and statistically similar (F=1.627, P=0.189). The phase charge needed to elicit dorsiflexion yielded significant differences among the stimulators (F=54.61, $P=2.09E^{-19}$). Post-hoc comparison indicated that GMES II phase charge was significantly lower than the other stimulators. Similarly, the GMES II was perceived as having respectively 39.1%, 34.2%, and 28.1% less pins-needle-burning discomfort than Focus (p=0.0003), 300PV (p=0.0001), and L300 (p=0.006). **Conclusion:** Shortening the phase duration resulted in a more comfortable and more efficient stimulation that may lead to designing a lower profile, lighter weight, and more cosmetic FES.

KEY WORDS: Electrical stimulation; Comfort; Dorsiflexion; Phase charge.

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INTRODUCTION

Non-invasive functional electrical stimulation (FES) has been used in clinical practice for many years.[1] Essentially, FES uses a battery powered stimulator to generate pulses of sufficient electric charge to depolarize peripheral nerves.[2,3] The excited motor nerves propagate their action potentials to the muscles causing the muscles to contract.

Researchers frequently focus their efforts to improve the perceived comfort of stimulation and simplify the operation of FES systems for patients with deficits in the musculo-skeletal, and/or neurological systems. In addition, miniaturization of wearable FES systems increases compliance, ease and comfort of use and appears important for patients who wear the FES throughout the day by enhancing their functional ability.[4]

Perceived discomfort of non-invasive stimulation depends on the excitatory properties of peripheral nerves, on the non-linear relationships between the electrical stimuli parameters and the excitatory responses, and on the body part being stimulated.[5-9] For example Kantor et al. demonstrated that the threshold of motor excitation was 41.4% higher eliciting contraction of the dorsiflexors compared to the wrist extensors.[2] Excitation of peripheral nerves depends primarily on the stimulator's output charge, contained in each phase, termed phase charge. Phase charge is measured as the current-time integral of the stimulus, and it must be of sufficient magnitude to depolarize both sensory and motor nerves.[2,3] Current-time integral is a mathematical expression that combines current amplitude, phase duration, and the shape of the pulse. Commercially available FES systems in the USA and UK are designed to pre select the phase duration (commonly also labeled as pulse width or pulse duration[5-7]) and increase the peak current (amplitude) until the desired muscle contraction is evident.[1,7,10-14] The rationale for pre selecting phase duration and increasing the current amplitude has not been disclosed by the manufacturers. Moreover, the amount of phase charge needed to achieve the desired contraction is typically not measured and thus not reported. [13-20] Yet, electrophysiological knowledge clearly recognizes the dependence of sensory, motor, and pain conducting nerve fibers on phase charge.[2,3,5,8,21] In the current study we were able to quantify the phase charge associated with eliciting ankle dorsiflexion.

Excitation of sensory and motor nerves is related non-linearly to stimulus parameters.[6,22,23] Alon and colleagues reported that the shorter the phase duration, the less the charge needed to excite peripheral nerves. Moreover, they demonstrated that the shorter the phase duration, the easier it was to selectively excite non-noxious sensory and motor nerves, without exciting the noxious, pain conveying nerve fibers.[5] The clinical meaning of these non-linear relationships is the ability to elicit more comfortable muscle contraction when the phase duration is shorter. How short should the phase duration be is currently unknown.

Confirmation of similar findings can be found in other basic science research.[24,25] Taken together, published data support the hypothesis that designing an electronic circuit's output with very short phase duration (starting at 1-2 µsec) and relatively longer intra-pulse intervals (IPI), should enable activation of skeletal muscles accompanied by more comfortable perception of the stimulation, while requiring less phase charge to induce the desired muscle contraction.[5]

Another advantage of minimizing the phase charge is a reduction and simplification of the electronic circuit and battery size, leading to the development of miniaturized, low profile, comfortable, and easy to use wearable FES system. Accordingly, the purpose of this study was to test the hypothesis that a stimulator with predetermined maximum peak current amplitude where phase charge is increased exclusively by increasing phase duration will be perceived as more comfortable than stimulators with predetermined phase duration, where phase charge is increased by increasing the peak current amplitude. A second purpose was to quantify each stimulator's relationship between phase charge and degrees of elicited dorsiflexion range of motion.

METHODS

Twenty-eight healthy volunteers, 14 females and 14 males, participated in two sessions of testing. The group's mean ± standard deviation age was 46.1 ± 13.2 years, height was 169.6 ± 8.9 cm and weight was 77.3 ± 16.1 Kg. Males and females were grouped equally by age criteria, 20-49 and 50-75.

Session one was used to familiarize the subjects with the testing procedure including familiarization with the perception of tingling, pins-needle-burning, and muscle cramping, three typical perceptions of non-invasive electrical stimulation.[9,26] All subjects signed an informed consent approved by the MultiCare Health System Institutional Review Board. The testing procedure and data collection in session one and two were similar and included testing four stimulators: Focus™ (Empi,); 300PV™ (Empi,); L300™ (Bioness, Inc); and a new prototype, GMES II™ (MultiCare Health System, Thacoma and Puyallup, WA). All were electronically designed as constant current stimulators. Three commercially available stimulators: Focus, 300PV, and L300 provided geometrically symmetric biphasic waveform but the pulses properties were not identical. The Focus had predetermined phase duration of 280 µsec and no intra-pulse interval (IPI). The 300PV had phase durations selectable between 50 and 400 µsec and 660 µsec IPI. The L300 had 3 selectable phase durations of 100, 200, or 300 µsec and 50 µsec IPI. Pulse rate also varied having 25, 35, or 50 pps (Focus), 2-99 pps (300PV), and 20-45 pps (L300). To approximate the stimulators output as closely as possible, the phase duration was set at 100 µsec (300PV and L300) but increased to 200 or 300 µsec in few cases if the subjects "maxed out" the stimulus intensity. The Focus unit's phase duration was set at 280 µsec. Pulse rate was set at 50 pps (Focus and 300PV) and at 45 pps (L300). The new prototype (GMES II) is a constant current FES, having geometrically symmetric biphasic waveform and 160 µsec IPI. The pulse rate was set at 50 pps, and peak current was preset at 80 milliamps. The phase duration was set at 1 µsec and increased until full dorsiflexion was achieved.

Testing procedures

Stimulation was applied over the dorsiflexor muscle groups bilaterally. The dorsiflexors were selected because foot drop is the most common application of FES in clinical practice. A pair of square shape self-adhesive, 25.8 cm^2 area electrodes (Axelgaard Ltd, ValueTrode™) was placed over the dorsiflexors after the skin was cleaned and hydrated with tap water (figure 1). The dorsiflexors were stimulated to ascertain that maximal ankle dorsiflexion was achieved with minimal inversion or eversion. In cases of visually noted excessive eversion or inversion, the electrodes were repositioned to optimize pure dorsiflexion. Two flexible electronic goniometers (Noraxon™, USA, Scottsdale, Arizona) were attached on the medial side of the ankle and connected to a 4-channel digital storage oscilloscope (Tektronix™, model TDS 2014B) which monitored the changes in dorsiflexion motion of the ankle (figure 1).

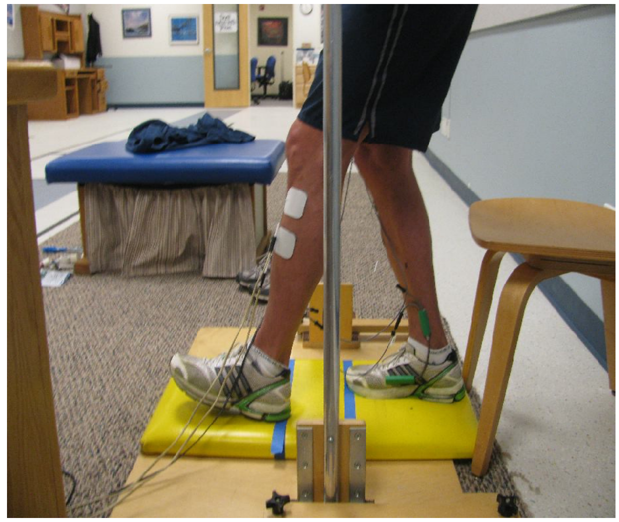

Figure 1. Subject set up for data collection.

Foot note: The electro-goniometer applied to the left ankle is secured on the medial side and thus not seen in the figure.

Next, the subject assumed a standing position with either right or left heel placed in front on a marked line and the other foot on a marked line 15 cm behind the first (figure 1). All four stimulators were operated by the researcher positioned behind a desk with a visual barrier, to conceal the stimulators from the subject. Each stimulator was connected to the electrodes via a connection box enabling a read out of peak current (mA) and phase duration (microseconds) directly from the digital oscilloscope. The connection box included measuring the voltage across a 10 ohm resistor in series with the electrodes-body interface and using Ohm's law to measure peak current. Stimulation order was fixed, stimulating the right dorsiflexors with one stimulator then the left dorsiflexors with a second stimulator, followed by a third stimulator applied to the right and the forth stimulator applied to the left. The order of the applying the four stimulators was rotated so that after 28 subjects each stimulator was applied seven times first, second, third, and forth on both left and right dorsiflexors. This sequential rotation was done to equalize the effect of accommodation to the perception of stimulation.[26]

Once the subject assumed initial standing position, the researcher instructed the subject to verbally state if the stimulation became too intense or uncomfortable, they could say stop and the stimulation would cease.

If she/he did not ask to stop, the researcher continued to increase the intensity until full dorsiflexion occurred. At that moment the subject achieved full dorsiflexion based on the researchers' visual determination (or if the subject said stop), the researcher stored the data on the oscilloscope, stopped the stimulation and asked the subject to mark on three separate visual analog scales the perceived amount of tingling, pins-needles-burning sensation, and muscle cramping. Following a five minute break, the next stimulator was tested. The second session was administered 1-2 days later.

Data management

After calibration and conversion, the goniometer data provided ankle dorsiflexion in degrees. Peak current (mA) and phase duration (µsec) were read directly from the storage oscilloscope and tabulated in an Excel file where phase charge (µC) was calculated as the peak current * time integral. Perceived tingling, pins-needles-burning, and muscle cramping were marked on a 100 mm line, zero being no perception and 100 the most excruciating-unbearable perception for each descriptor. The researcher used a 100 mm rigid tape measure to convert the subject's mark on the line to a number and tabulated it in the Excel file. Primary outcomes data included amount of dorsiflexion (deg), phase charge (µC), and perception of tingling, pins-needle-burning and muscle cramping. Data from the right and left lower extremities were combined.

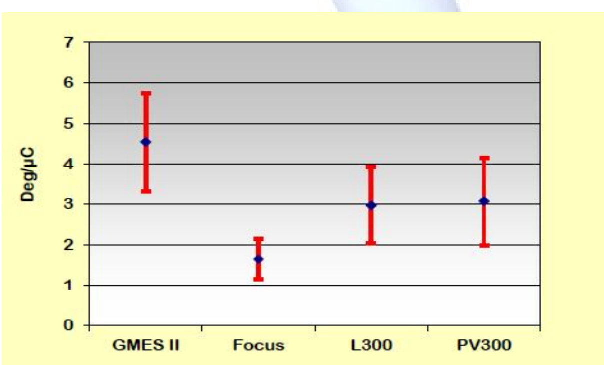

Figure 2. The amount of dorsiflexion generated by 1 µC of phase charge

Footnote: Bars represent 95% confidence interval

Statistical analysis

Repeated measure analyses of variance (ANOVA) compared the 4 stimulators with respect to each outcome variable. Bonferroni's correction was used for post-hoc multiple comparison of means. A $p<0.05$ was accepted as significant difference between stimulators.

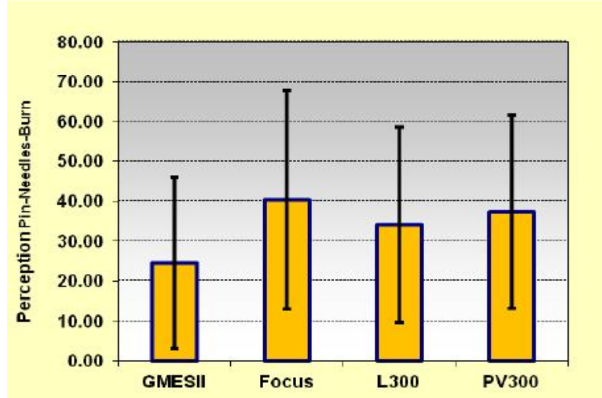

Figure 3. Group means and response variability perceiving pins-needles-burning sensation

Footnote: Bars represent 95% confidence interval

RESULTS

All four stimulators elicited measurable degrees of dorsiflexion that vary considerably between subjects. The group means combining the right and left ankles were 19.98 ± 13.5 deg (Focus), 19.53 ± 15.3 deg (300PV), 20.02 ± 13.1 deg (L300), and 24.54 ± 14.6 deg (GMES II). These values were statistically similar ($F=1.627$, $P=0.189$). Analysis of the amount of phase charge needed to elicit dorsiflexion yielded significant differences among the stimulators ($F=54.61$, $P=2.09E^{-19}$). Post-hoc comparison of group means indicated that GMES II phase charge was significantly lower than all 3 other stimulators, Focus generated the highest phase charge, while 300PV and L300 generated similar phase charges. Post-hoc data are summarized in table 1. To estimate efficiency in obtaining dorsiflexion the number of degrees per unit of phase charge was calculated. As seen in figure 2, GMES II was the most efficient, generating 4.53 deg/µC, followed by 300PV (3.07), L300 (2.97), and Focus (1.64). Noteworthy are the data of actual phase duration. The means and standard deviations were 78 ± 32 µsec (GMES II), 280 ± 0 µsec (Focus), 107 ± 0.03 µsec (300PV) and 118 ± 0.05 µsec (L300).

The comfort of stimulation as perceived by the subjects was analyzed with respect to how strongly they rated the sensations of tingling, pins-needle-burning, and muscle cramping. Sensation in which the four stimulators were perceived significantly different included pins-needles-burning, and muscle cramps data. The most comfortable stimulator was GMES II having respectively 39.1%, 34.2%, and 28.1% less pins-needle-burning discomfort than Focus (p=0.0003), 300PV (p=0.0001), and L300 (p=0.006). Both 300PV and L300 produced less pins-needles-burning sensation than Focus, but the data did not reach statistical significance (figure 3). As a group, there were also less perception of muscle cramps during the GMES II compared to Focus (p=0.0009) and L300 (p=0.01) while comparison with 300PV did not reach statistical significance (p=0.063).

Stimulator	Mean (SD)	GMES II (P value)	Focus (P value)	L300 (P value)
GMES II	6.21±2.6 µCoul			
Empi (Focus)	13.09±4.0 µCoul	$8.5E^{-12}$		
Bioness (L300)	7.86±4.5 µCoul	0.018	$4.56E^{-8}$	
Empi (300PV)	7.55±3.6 µCoul	0.008	$1.36E^{-10}$	0.506

Table 1. Summary of Post-hoc statistical analyses

DISCUSSION

The primary hypothesis in this study was that a stimulator with predetermined maximum peak current amplitude where phase charge is increased exclusively by increasing phase duration should be perceived as more comfortable than stimulators with predetermined phase duration. The data obtained clearly support this hypothesis. Specifically, the unpleasant perception of pin-needle-burning and muscle cramps were attenuated considerably using the GMES II. Among the more plausible electrophysiological explanation is the longstanding knowledge that having very short phase duration enables better excitatory discrimination between noxious and non-noxious afferent nerve fibers.[5,22,24] Moreover, extrapolation from the known inverse relationship between pulse frequency (cycles per second), pulse duration and electrode-tissue impedance imply that shorter phase duration is associated with less impedance.[27] Conceivably, the GMES II excited both sensory and motor nerves with less phase charge because the impedance (opposition to current flow in biological systems) was lower. Having required less phase charge[28,29] to achieve the same excitatory response may have been the primary explanation for achieving more comfortable muscle contraction of the dorsiflexors.

An alternate or concurrent explanation to more comfortable perception of FES may relate to charge density. Charge density refers to the amount of phase charge per unit area. Typical measurement for an implanted electrode is $\mu C/mm^2$ and for a non-implanted (surface) electrode is $\mu C/cm^2$. Charge density has long been recognized as a stimulation variable associated with safety, noting that access charge density damages the brain, spinal cord and peripheral nerves. [30,31] Implanted electrode size is very small (mm) compared to surface electrode (cm), thus safety issues regarding non-invasive stimulation focus on skin irritation[20] not on damage to peripheral nerves. While safety of prolonged daily application non-invasive FES is robustly documented,[13,19,32,33] lowering the phase charge density may have been the reason for the subjects' preference of the GMES II. Compared to Focus, 300PV, or L300, the GMES II phase charge density was 52.9%, 20%, and 17.2% less respectively. Pearson correlation between phase charge density and the perceived pins-needle-burning yielded r=0.87.

In addition to testing the perceived comfort of FES, this investigation compared the efficiency of the four stimulators. Estimation of efficiency can be derived from calculation of the amount of phase charge input needed to generate one newton of force[34] or one degree of joint motion, in this study, ankle dorsiflexion. Using the formula where relative efficiency (R_{eff})=1-[(stim 1/ stim 2)] The Focus, L300 and 300PV units proved to be 63.8%, 34.4%, and 32.2% less efficient than the GMES II, respectively. These findings support the premise that having a stimulator with predetermined maximum peak current amplitude where phase charge is increased exclusively by increasing phase duration is likely to provide a more efficient FES system. Efficient FES circuit design, particularly the ability to achieve electrically-induced ankle DF with less electrical charge, allows a miniature compact electronic circuit, and small battery. For example knowing the phase duration of symmetric biphasic pulse and using the formula mA/hour=phase duration x 2 x pps x ratio of duration/inter-pulse interval x hour yield 3.65, 6.75, 6.87, and 47.0 mA/hour of battery use for

GMESII, L300, 300PV and Focus respectively. As seen, this can save about 46% of battery drain using the GNESII compared to 300PV and L300 and may allow further reduction of battery size. Eliminating the need to control peak current amplitude, elimination of a transformer typically used in some FES systems, and reducing the size of the capacitors, combined with smaller battery may lead to a lower profile, lighter weight, and more cosmetic FES. [13,19,35,36]

There are limitations and possible confounding factors inherent in the experimental design of the study. From pure engineering perspective, if all four stimulators' pulse properties would allow the same control of phase duration, pulse rate (frequency), and intra-pulse intervals (IPI) the results might have been different than those reported herein. However, manufacturers of commercially available battery powered stimulator do not disclose the rationale or experimental data that led to their selection of pulse properties. Indeed the objective of this study was to compare clinically relevant FES systems that are available in many clinics in the USA and UK. Accordingly, the results should be interpreted with a degree of caution. For example, the 300PV provided variable phase duration between 50 and 400 µsec at 50 µsec increments. If all increments were tested, the phase charge required to elicit dorsiflexion would be conceivably lower. However, it would add significant amount of time to the procedure in order to avoid muscle fatigue and affect the conditioning known as "getting use to the perception of stimulation" to this stimulator.[26] Furthermore, it will require clinicians to add more steps in setting up a patient for FES compared to having a system with predetermined peak current were desired muscle contraction is achieved exclusively by increasing phase duration. Alternative approach may be to design a stimulator with one predetermined, few microseconds phase duration, and increase phase charge exclusively by increasing peak current. Such design is not available in commercial FES system to the best of our knowledge.

Mixing maximum DF (limit of DF joint range of motion) and maximum DF (limited by subject's tolerance of the stimulation) potentially present a confounding factor. However it is well accepted in clinical practice that individual subject's tolerance must guide the upper limit of FES stimulation intensity. Furthermore, achieving partial DF in patients with foot drop (such as after stroke, multiple sclerosis, or cerebral palsy) enable significant improvement in gait.[13,19,36,37] Considering these clinical realities we believe that analysis of those with full or partial DF is justified.

Another methodological confounding factor may have been the decision to visually determine when the electrically-induced full dorsiflexion was achieved. A better, more objective approach would have been to use a costly 3-D motion analysis to capture both dorsiflexion (DF) as well as inversion/eversion. Having only one plane electrogoniometer necessitated visual determination of how much inversion/eversion accompanied DF, movements that are rarely possible to avoid when using FES. To overcome the possibility of a single investigator bias, future studied should consider 3-D motion analysis.

The last possible confounding factor was the inclusion of data from subjects that required increasing the phase duration to 300 µsec and 200 µsec (2 same subjects) applying the L300 and 300PV respectively and one additional subject requiring 200 µsec applying the L300. The corresponding phase durations using the GMES II were 190 µsec, 104 µsec and 50 µsec. Separate analysis of these few subjects would not change the statistical findings in our view, nor would it provide additional findings of clinical or electrophysiological value.

CONCLUSION

There are worldwide ongoing efforts to miniaturize non-invasive wearable FES systems, simplify their operation, and improve the perceived comfort and ease of use by patients who wear the FES throughout the day. Based on the findings we concluded that having an electronic design with predetermined maximum peak current amplitude where phase charge is increased exclusively by increasing phase duration, proved advantageous over traditional circuit designs. The main advantages include having more comfortable perception of the stimulation, saving on battery drain, and consequently the opportunity to design a very low profile, wearable FES system.

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