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Relationship between peak and mean amplitudes of the stimulating output voltage for functional control of the knee by spinal cord patients and healthy volunteers

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Abstract ***Introduction:*** *Functional electrical stimulation (FES) may evoke movements in people with movement impairments due to neurological lesion. The mean value of electrical current or voltage during FES depends on the stimulatory profile parameters. To investigate the relationship between peak and mean amplitudes of the stimulator output voltage while causing a knee extension angle change from 90° to 40° to choose the best and safest profile to be applied in people who have suffered a spinal cord injury.* ***Methods:*** *Healthy (N = 10) volunteers and those with spinal cord injuries (N = 10) participated in this study. Each FES profile (P1, P2, P3 and P4) had 1-kHz pulses (100 µs or 200 µs on and 900 µs or 800 µs off) with burst frequencies of 50 Hz (3 ms on and 17 ms off) or 70 Hz (3 ms on and 11 ms off) and peak amplitudes set between 53-125V for healthy volunteers and 68-198 V for volunteers with spinal cord injury.* ***Results*****:** *The highest mean amplitude were obtained using a FES profile with active/total pulse period of 200 us/1000 us and burst frequency of 3ms/14ms. The best results of mean amplitude were observed using a FES profile duty cycle of 10% for pulses (100 µs/1000 µs) and 15% for bursts (3 ms/20 ms).* ***Conclusion:*** *The FES profile (100 µs – 50 Hz) seems to be the most suitable for both groups, inasmuch as it presents smaller mean amplitudes and peak amplitudes similar to other FES profiles.*

Keywords *Functional electrical stimulation (FES), Spinal cord injury, Stimulatory parameters, Stimulatory profiles.*

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Introduction

Functional electrical stimulation (FES) is the application of electrical pulses to neural pathways (Kesar *et al.*, 2010). This technique can be used to create functional movements artificially for people who have suffered spinal cord injuries (Kern *et al.*, 2010a). However, FES efficiency may be impaired due to physiological alterations, such as muscular fatigue (Enoka and Duchateau, 2008; Yu and Chang, 2010) and/or motoneuron adaptation (Nordstrom *et al.*, 2007).

In clinical application, the physical therapist should have theoretical knowledge regarding the best electrical stimulation pattern, which is directly related to the success of FES application (Krueger-Beck *et al.*, 2010a). Sometimes a poor choice of electrical stimulation protocol can cause tissue and neuromuscular damage or delay the patient's rehabilitation.

Several FES profiles have been used (Krueger-Beck *et al.*, 2010b). The most commonly used FES active pulse periods vary from 100 μs up to 500 μs, whereas burst frequencies are adjusted from 20 to 100 Hz (Bailey *et al.*, 2010; Baptista *et al.*, 2009; Fisekovic and Popovic, 2001; Fujita *et al.*, 1995; Gollee *et al.*, 2004; Jezernik *et al.*, 2004; Langzam *et al.*, 2007; Marsolais and Kobetic, 1988; Marsolais and Kobetic, 1987; Matsunaga *et al.*, 1999; McAndrew *et al.*, 2006; Thrasher *et al.*, 2005, 2006). Burst frequencies lower than 20 Hz may produce fasciculation during muscular contractions (Petrofsky, 2004), although frequencies over 70 Hz may cause discomfort during stimulation (Mesin and Merletti, 2008; Packman-Braun, 1988; Rabischong, 1996; Rooney *et al.*, 1992).

The FES magnitude required to evoke artificial functional movements are higher in individuals who have suffered spinal cord injuries than in healthy people (Gollee *et al.*, 2004). Due to the reduction in voluntary muscle contraction, paraplegics have decreased muscle mass, mainly in their fast fibres, and this alteration in the proportions of slow and fast fibres leads to a decrease in force production (Andersen *et al.*, 1999).

Tissue impedance varies depending on the coupling of the electrodes. Dry, intact skin has an impedance of approximately 93.0 kΩ/cm² at 60 Hz (Bronzino, 1992). When surface electrodes (silicon-carbon) are coupled to the skin with electrolyte gel, the impedance reduces to 10.8 kΩ/cm² (Bronzino, 1992). FES is delivered through bursts of voltage pulses (Ward and Shkuratova, 2002), and the mean amplitude is related to the energy inside these pulses. Tissue impedance is influenced by many variables, such as the frequency of the electric current, electrochemical processes, temperature, pH, hydration and the viscosity of the biological tissue under analysis (Neves *et al.*, 2009). An inadequate stimulatory profile can result in a high charge density and may create injuries in peripheral nerves (Jezernik and Morari, 2005), as well as in the central nervous system (McCreery *et al.*, 1990). Despite the enormous versatility of electrical parameters in the available stimulators, only the optimal settings will be safe and both physiologically and biomechanically effective.

Using FES to control paralysed limbs, it is essential to design safe stimulatory electrical profiles that will evoke the best muscle response. To this end, we are looking for a safe protocol that will achieve the most efficient contraction while delivering less energy to the patient. Thus, the goal of this study was to investigate the relationship between peak and mean amplitudes of the stimulator output voltage, while causing a knee extension angle change from 90° to 40° and to choose the safest and most effective profile among the profiles evaluated in this experimental study.

Methods

Volunteers

All volunteers who participated in this study read and signed an informed consent form before the beginning of any procedure. The experimental protocol was approved by the Human Research Ethics Committee. Ten healthy volunteers (HV) without neurological or orthopaedic disorders (28.30 ± 6.58 yrs) were selected from academic students of Pontifícia Universidade Católica do Paraná (PUCPR), and sixteen spinal cord injured volunteers (SCIV) (32.06 ± 9.68 yrs) were chosen from Hospital Rehabilitation Centre Ana Carolina Moura Xavier (Curitiba, Paraná, Brazil) to participate in this study. An assessment was conducted in SC to verify the inclusion/exclusion criteria. During the physical examination, power (Higuet scale from 0 to 5), reflexivity (Wexler scale from 0 to 5), spasticity (Ashworth modified scale from 0 to 4) and the American Spinal Injury Association (ASIA) impairment scale (from A to E) were evaluated. During the tests, the volunteers did not use any drugs that could change their motor condition. Among the volunteers with spinal cord injury, only ten met the criteria for inclusion in this study. Ten SCIVs is reasonable, considering (a) the specificity of the population studied and (b) that the number of subjects reported in the present study includes at least as many SCIVs as did similar experiments found in the literature (Davoodi and Andrews, 2004; Tepavac and Schwirtlich, 1997; Uhlir *et al.*, 2000; Williamson and Andrews, 2000).

Electrical stimulation parameters

A custom electrical stimulator (Ariana - 16 channels) (Zagheni, 1998) was calibrated with a two-channel oscilloscope Tektronix® TDS 1002B and a 1-kΩ resistor to simulate skin impedance (Bronzino, 1992). The stimulatory waveform was a monophasic square wave with four FES profiles shown in Table 1 configured with different duty cycles, frequencies, pulse periods and burst periods.

After trichotomy and skin cleaning procedures, two self-adhesive electrodes (4.5 × 9.0 cm) were positioned on the knee region (anode) and on the femoral triangle (cathode) to stimulate the quadriceps muscle (Figure 1).

Angular data acquisition

A custom monoaxial electrogoniometer built with a 10-kΩ linear potentiometer was placed laterally to the knee to acquire the knee joint angle (Figure 1). All signals and volunteer data were saved into European Data Format (EDF) files. The acquisition system contained a DT300 series Data Translation™ board working at a 1 kHz sampling rate.

Electrical stimulation protocol and data acquisition

All FES profiles (Table 1) were applied to each volunteer randomly, one profile per day, over four testing days with a minimal interval of two rest days (Kesar *et al*., 2008; Marion *et al*., 2010; Smith *et al*., 1997; Stock *et al*., 2010) between the tests to avoid physiological interference between consecutive protocols. The volunteer was positioned on an adapted chair with the hip and knee angles set to 70° (Matsunaga *et al.*, 1999) and 90°, respectively, as illustrated in Figure 1. The electrogoniometer signal was zeroed at the maximum knee extension (i.e., angle defined as 0°). After the zeroing step, the leg was placed at the 90° initial rest position (as shown in Figure 1). Then, the magnitude of the electrical stimuli was adjusted according to the knee movement range from 90° to 40°. When the knee joint reached an angle of 40°, the corresponding stimulator output amplitude was determined, and electrical stimulation was ceased.

Table 1. FES profiles chosen for the experimental protocol.

Profile	Pulse			Burst		
	On (µs)	Off (µs)	Frequency (kHz)	On (ms)	Off (ms)	Frequency (Hz)
P1	100	900	1	3	17	50
P2	100	900	1	3	11	70
P3	200	800	1	3	17	50
P4	200	800	1	3	11	70

On: active pulse duration; Off: inactive pulse duration; pulse on time: 100 µs, 200 µs (Jezernik *et al.*, 2004); pulse frequency: 1 kHz (Ward and Robertson, 1998); burst frequency: 50 Hz and 70 Hz (Chou *et al*., 2005).

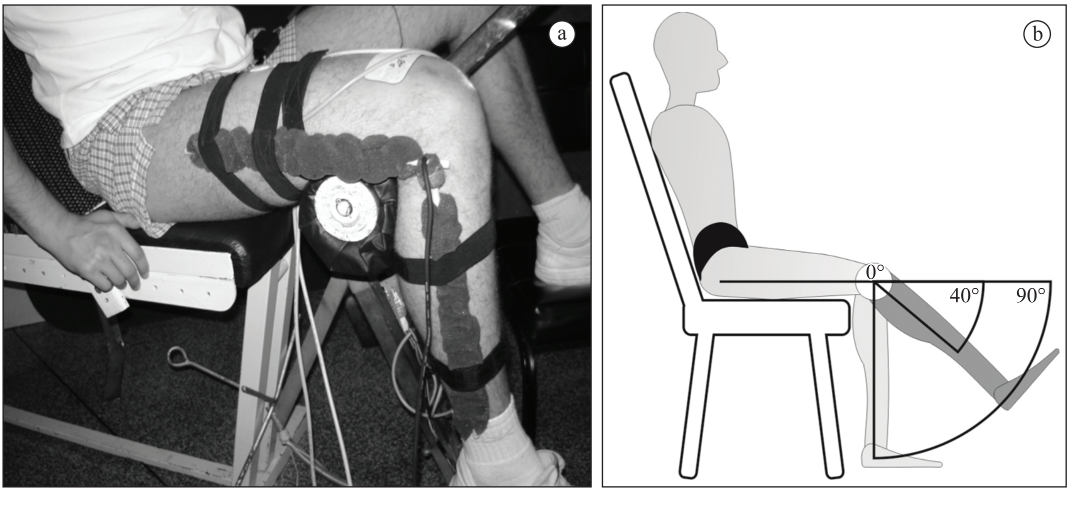

Figure 1. a) Volunteer positioned in the adapted chair. An electrogoniometer was fixed laterally to the knee joint, and FES electrodes were fixed on the skin over the supra-patellar and femoral triangle regions. b) Knee joint angle positions.

Analysis

The mean amplitude was calculated by means of Equation 1:

$$V_{Mean} = V_{Peak}\left(\frac{T_{on}}{T_T}\times\frac{T_{Bon}}{T_{BT}}\right) \quad (1)$$

where

- V_{Mean} is the mean amplitude expressed in volts (V);
- V_{Peak} is the peak amplitude;
- T_{on} is the active pulse period;
- T_T is the total pulse period;
- T_{Bon} is the active burst period;
- T_{BT} is the total burst period.

The application of the Kolmogorov-Smirnov test showed that the data followed a Gaussian distribution. The software PASW Statistics 18 was used to perform the statistical analysis: (I) One-sample Student's t-tests were applied to compare peak and mean amplitudes for HV and SCIV participants, split by FES profiles; (II) Independent t-tests were applied to compare HV and SCIV groups in terms of peak and mean amplitude split by FES profiles; (III) A one-way analysis of variance (ANOVA) with LSD post-hoc test was applied to data split into HV and SCIV groups to find the profile which resulted in the lowest peak and mean output amplitudes.

Ethical considerations

This study was performed according to the Declaration of Helsinki and was approved by Pontifícia Universidade Católica do Paraná's (PUCPR) Human Research Ethics Committee under register n. 2416/08.

Results

Six SCIVs were excluded from the initial group of volunteers because they either did not tolerate the sensation evoked by the electrical current or because of denervation of motor units. Table 2 presents demographic information for the participants and indicates the motor response parameters reflecting their neuromuscular conditions. Sudden onset of spasticity was not observed during the protocol due to FES-induced inhibition.

One-sample Student's t-tests indicated that peak and mean amplitudes are different ($p < 0.01$) for both HV and SCIV groups. Independent t-tests showed that peak and mean amplitudes necessary to stimulate HVs were smaller than those for SCIVs across all FES profiles. Table 3 shows the peak and mean voltage amplitudes applied during FES for healthy and spinal cord injured volunteers in different electrical stimulation profiles. Figures 2 and 3 show post-hoc comparisons of peak and mean voltages, respectively, for different FES profiles in HVs and SCIVs.

Discussion

The one-sample Student's t-tests demonstrated that peak and mean amplitudes were different ($P < 0.01$) for both HVs and SCIVs. According to the independent t-test, the peak and mean amplitudes required for raising the leg to 40° of knee flexion were higher

Table 2. Clinical data of volunteers with spinal cord injuries.

Vol	Age	Spinal cord injury				Sensibility	Motor system			Deliverance	
		Aetiology	Level	Months	ASIA	L1-L2	Power	Reflex	Spasticity	A	NA
A	25	Violence	T8	24	A	-	0	0	0		X
B	46	Automobile	T8	31	A	-	0	2	0	X	
C	30	Violence	T6	84	A	-	0	2	+1	X	
D	28	Automobile	T12	48	B	+	0	1	0	X	
E	29	Automobile	T12	108	C	+	1	3	2		X
F*	26	Violence	T10-11	168	A	-	0	2	+1		X
G	34	Automobile	T4-5	84	A	-	0	2	1		X
H	24	Violence	T12	24	A	-	0	0	0		X
I	25	Automobile	T12	18	A	-	0	0	0		X
J	37	Diving	C5-6	162	B	-	0	3	1	X	
K	19	Violence	T10	12	B	+	0	3	1	X	
L	48	Fall	T11	60	D	+	3	3	2		X
M	52	Other	L4	60	D	+	4	2	0		X
N	26	Automobile	C6-7	28	B	+	0	3	2	X	
O	28	Automobile	T3	60	A	-	0	0	1	X	
P	36	Other	L1	132	D	+	4	2	0		X

Vol: volunteer; ASIA: American Spinal Injury Association impairment scale (A-E) (Maynard *et al.*, 1997); nociceptive sensibility "-" absent, "+" present; Power: Higuet scale (0-5) (Cipriano, 2003); Reflex: Wexler scale (0-5) (Cipriano, 2003); Spasticity: Ashworth modified scale (0-4) (Bohannon and Smith, 1987); A/NA: accepted/not accepted in this research; *: withdrew from the study.

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Table 3. Peak and mean voltages for healthy volunteers and volunteers with spinal cord injuries.

		P1 (V)	P2 (V)	P3 (V)	P4 (V)
HV	V_{peak}	82.20±16.73	76.60±22.16	91.90±33.23	67.60±13.97
	V_{mean}	1.23±0.25	1.64±0.47	2.75±0.99	2.90±0.59
SCIV	V_{peak}	161.40±36.39	154.60±41.96	150.80±49.51	121.80±53.55
	V_{mean}	2.42±0.54	3.31±0.89	4.52±1.48	5.22±2.29

V_{peak}: Peak amplitude; V_{mean}: Mean amplitude.

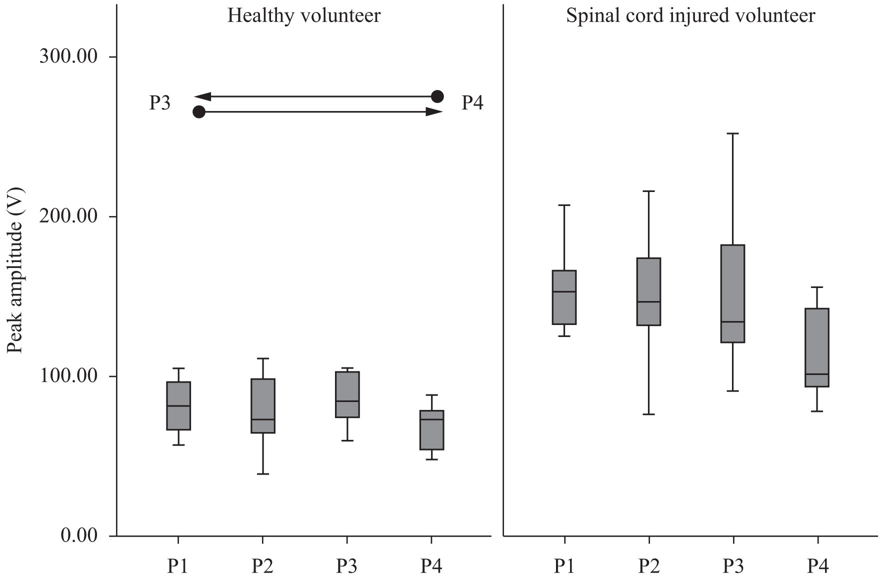

Figure 2. Peak amplitudes required to achieve 40° of knee flexion in four FES profiles and any statistically significant differences. Open circles: 35, 69 and 72 are outliers; Closed circles: control; Arrows: statistically significant differences ($p \leq 0.05$).

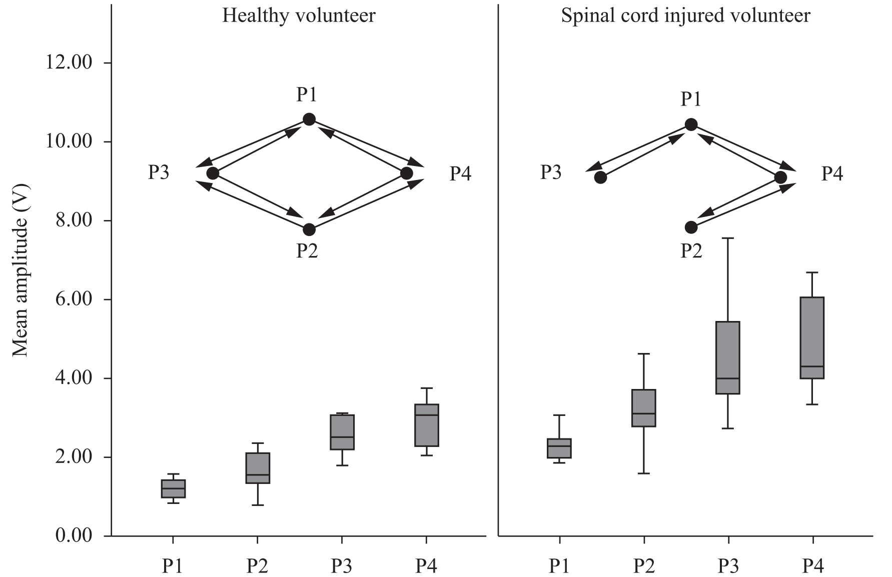

Figure 3. Mean amplitudes required to achieve 40° of knee flexion in four FES profiles and the statistical significance of the differences. Open circles: 35, 69 and 72 outliers; Closed circles: control; Arrows: statistically significant differences ($p \leq 0.05$).

in SCIVs than in HVs (Figures 2 and 3), which is consistent with the findings of Gollee *et al*. (2004). This result is most likely related to muscle atrophy in SCIVs (Andersen *et al*., 1999; Kern *et al*., 2010a) and the consequent difference in Ca^{++} activation of cross bridges in sarcomere cells (Gobbo *et al*., 2006). FES may have triggered a muscle cell recovery process (Thrasher *et al*., 2006) and may also lead to hypertrophy (Kern *et al*., 2010b); thus, the stimulation amplitude required to achieve a knee flexion angle of 40° may decrease during the recovery process of neuromuscular tissue.

Regarding peak amplitude, Figure 2 shows that P4 required the weakest amplitudes to achieve 40° of knee flexion for both HVs and SCIVs. The low peak amplitude in P4 is due to the greater pulse duty cycle (on time and its period ratio: 200 μs/1000 μs) and also to the 22% burst duty cycle (3 ms/14 ms, i.e., the active and total burst period ratio), which allow more energy to be released to the tissue compared to the other FES profiles investigated (Table 1). This finding may explain the fact that for HVs, there was only a statistically significant difference ($p < 0.05$) between P3 and P4 FES profiles. Laufer and Elboim (2008) found that a 20% burst duty cycle (4 ms/20 ms) was better than 50% burst duty cycle (10 ms/20 ms) in minimising muscle fatigue while evoking strong muscle contractions. The results of Laufer and Elboim (2008) were different from those obtained in the present study, in which the profiles with lower burst duty cycles (P1 and P3, 15%) required different mean amplitudes to achieve 40° of knee flexion. P1 required a weaker mean amplitude, even with the same burst duty cycle as that of P3. In fact, the FES profiles with low pulse duty cycles, as well as low burst duty cycles, were better than the FES profiles with only low burst duty cycles.

According to the results shown in Figure 3, P1 is the profile that required the weakest mean values of electrical stimulation to achieve 40° of knee flexion for both HVs and SCIVs; there was also no significant difference at the $p<0.05$ level between the active pulse ratios for P1 and P2 (100 μs/1000 μs). Considering the different trends between peak and mean amplitudes, P4 is the profile that required the highest mean amplitude and the lowest peak amplitude to achieve 40° of knee flexion for both HVs and SCIVs. McLoda and Carmak (2000) studied different burst duty cycles (10, 30, 50, 70 and 90%) and found that 10% was the optimum for eliciting the strongest muscle contraction. In the present study, the mean amplitude necessary to elicit 40° of knee flexion was minimised by the FES profile with a lower pulse duty cycle and lower burst duty cycle.

According to Shannon (1992), safety limits for electrical stimulation rely on several parameters, including waveform shape, electrode sizes and charge densities. These limits must be found for patient safety during FES. The P4 profile applied higher mean currents (Vanderthommen and Duchateau, 2007) to volunteers and, theoretically, may have produced greater increases in skin temperature; greater increases in skin temperature may cause lesions, such as burns (Popovic *et al*., 2001), especially in individuals with spinal cord injuries, who usually are less sensitive to nociceptive stimuli (Maynard *et al*., 1997). Because the P1 and P2 FES profiles did not show significant differences, choosing one of them would result in smaller applied mean currents, but P2, with a burst frequency of 70 Hz, may cause sensorial discomfort in patients with augmented nociceptive sensitivity (Packman-Braun, 1988; Rabischong, 1996; Rooney *et al*., 1992).

Due to the current research design, our study was limited by the inability to control certain variables, such as the skin-electrode interface, involuntary contraction (healthy subjects) due to FES and possible diffusion to other muscles (spill-over effect). However, the results showed that the stimulating profiles studied effectively generated functional muscular contractions (in our protocol, knee flexion) and can be generalised unless more detailed studies obtain different results.

In FES applications, peak and mean amplitudes delivered by electrical stimulation exhibited different values and responses. The peak and mean amplitudes required for raising the leg and changing the knee flexion angle from 90° to 40° were higher for SCIVs than for HVs. For both SCIVs and HVs, the FES profile with duty cycles of 200 μs/1000 μs and 3 ms/14 ms, for pulse and burst, respectively, required smaller peak amplitudes to achieve 40° of knee flexion. The smallest mean amplitudes were obtained for profile P1 with duty cycles of 100 μs/1000 μs and 3 ms/20 ms for pulse and burst, respectively. Therefore, P1 seems to be the most suitable FES profile for HVs and SCIVs because it presented the smallest mean amplitudes and, consequently, presents smaller hypothetical increases in skin temperature. Moreover, it can be postulated that the P1 burst frequency (50 Hz) might have caused less nociceptive sensation (low frequencies) compared to other FES profiles used in this study. Healthcare professionals involved with spinal cord injury rehabilitation may use this information to plan treatments using stimulation parameters that promote functional movements effectively and safely with regard to the energy transferred by the stimulating current.

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