

**Development of an FES Biofeedback Cycling System for Exercise
Training of Hemiplegic Stroke Patients**

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ABSTRACT

Objective: To develop a cycling system for stroke rehabilitation that combines the advantages of functional electrical stimulation (FES) and biofeedback (BFB), and to observe if the new system leads hemiplegic stroke subjects to achieve higher power outputs while performing leg cycle exercise.

Materials and Methods: Four hemiplegic stroke subjects cycled with the developed system under three conditions: (i) regular cycling, (ii) BFB cycling, and (iii) BFB-FES cycling. Power output and HR were collected for analysis.

Results: The system was successfully developed and tested. Two of the subjects achieved higher power outputs with their paretic leg and all of them with their healthy leg when BFB and BFB-FES were provided.

Conclusions: The results suggest the developed system could become useful in the rehabilitation of hemiplegic stroke patients. A broader study is needed to determine the real effectiveness of the new system, and which group of stroke patients would benefit more from it.

KEY WORDS

Stroke, FES, cycling, biofeedback

INTRODUCTION

Isokinetic leg cycling exercise (ILCE) can be used to improve the cardiorespiratory (CR) fitness of people who have had a stroke (1). Exercise can be described as isokinetic when maximal muscular force is applied throughout the whole range of motion and the speed of the movement remains constant (2). Isokinetic training has been used in the past by Glasser (3) and Kelly (1) as part of the rehabilitation therapy of hemiplegic stroke patients

with positive results. In order for leg cycle exercise (LCE), whether isokinetic or not, to have an aerobic effect, subjects are required to pedal at power output levels that produce heart rates of approximately 70% maximal heart rate (4). A coordinated effort of both inferior limbs is therefore needed to produce the power output at which CR training and strength training of both legs occur. Brown and Kautz (5) reported in a study with hemiplegic stroke subjects that the force output by the plegic leg, although impaired, was enhanced at higher pedalling workload. This finding suggests that cycling at higher power outputs results in better strength rehabilitation of the plegic leg and therefore emphasizes the importance of achieving a good combination of coordination and strength while performing LCE.

Due to stroke, the motor neurofunction of one side of the brain may be affected or lost (hemiplegia), making difficult the coordination required to generate the symmetrical cycling pattern needed for a proper LCE training. This lack of coordination may be overcome by using biofeedback (BFB) to instruct the stroke subject when to activate his/her muscles to generate a symmetrical cycling pattern. BFB technology was introduced in the late 1970's for therapy in stroke rehabilitation.(6) "This technique allows subjects to gain conscious control over a voluntary but late neurofunction by alerting them, with an auditory or visual clue, that their efforts have activated a targeted neuromuscular pathway"(6). Dursun et al. (7) used a visual and auditory BFB device in addition to physical therapy in training stroke patients with impaired sitting balance. They reported that the use of BFB can provide an earlier postural trunk control. Moreland et al. (8) conducted a meta-analysis in electromyographic (EMG) biofeedback to improve lower extremity function after stroke. They (8) found statistically significant effects of EMG BFB for improving ankle dorsiflexor muscle strength and suggested it may have a clinically important effect in gait quality. The overall evidence advice that biofeedback may facilitate the partial restoration of motor neurofunction and therefore coordination.

Besides coordination, stroke subjects have difficulty achieving the power output required for CR training while performing LCE. This problem is due to the muscular weakness that comes after the stroke (1). By applying functional electrical stimulation (FES), muscular strength can be increased. FES is a technique in which electrical current is applied to induce contractions of paralyzed or weak muscles. LCE by means of FES has been successfully used with spinal cord injury subjects for CR training (9). FES has also been used as part of the rehabilitation process of stroke patients with the purposes of improving permanently the range of volitional mobility of paralyzed limbs (10), arm function recovery (11), and ankle dorsiflexion recovery (12), among others (13,14), having favorable outcomes. Glanz et al. (15) conducted a meta-analysis to assess the efficacy of FES in the rehabilitation of hemiparesis in stroke finding a statistically significant effect in favor of FES therapy and supporting its efficacy in improving muscle strength recovery after stroke.

This study had two main objectives: (i) to develop an ILCE system for stroke rehabilitation and CR training that combined the advantages of FES and BFB and (ii) to observe if the combination of BFB and FES, implemented by the new system, led hemiplegic stroke subjects to achieve higher power outputs while performing ILCE. The developed system was based on a commercial motorized isokinetic ergometer (MOTOMed Viva2®, Reck Medizintechnik, Germany) and a LabVIEW6i® (National Instruments, Austin, USA) programmed virtual instrument to generate BFB signals, control a FES stimulator, and collect and analyze data.

METHODS

Subjects

Male hemiplegic stroke subjects ($n = 4$) left side affected volunteered to participate in this study. The age of the subjects was 62.25 ± 3.90 years (1σ), and the time since stroke was 4.25 ± 3.49 years (1σ). These subjects had previously performed maximal and submaximal exercise tests on the isokinetic cycle ergometer. The subjects had weak lower limb muscles on their affected side with no other impairments which might affect their cycling ability. Subjects were all able to follow verbal instructions. Each subject provided written informed consent of their intended participation.

BFB-FES Isokinetic Training System

The purpose of the BFB-FES Isokinetic Training System was to provide CR training, quadriceps muscle strength training and neuromotor function training. The cycling activity performed by the subjects was limited to push the ergometer pedals with the quadriceps muscles. The tasks performed by other muscle groups, such as hamstrings and gastrocnemius, were in the majority carried out by the motor of the isokinetic ergometer. The reasons in limiting the activity performed by the subject were to lessen the degree of coordination needed for cycling and to address the issue that leg weakness diminishes the ability to cycle properly. The developed BFB-FES Isokinetic Training System was based on a MOTOMed® Viva2 motorised isokinetic ergometer. The MOTOMed has a built in motor to drive the shaft at a constant preset angular velocity. It also has a system for measuring the position and the angular velocity of the crank, and the electrical current induced to the motor coils, which is an indirect measurement of the torque being applied to the pedals. The data collected by the MOTOMed's measuring system was transmitted, with a sampling frequency of 100 ± 10 Hz, to a personal computer (PC) using the ergometer's serial port

interface. LabVIEW6i® was used to program a virtual instrument to interact with the user, the FES stimulator, and the ergometer. In order to make the virtual instrument user friendly, a graphic user interface (fig0) was designed to present clearly all the information needed on the screen. The program received the raw data transmitted by the ergometer and transformed it into torque [Nm], position of the right pedal [deg.], and angular velocity [rad/s]. The instantaneous power output [W] was obtained multiplying torque by angular velocity. The position of the right pedal was used to discriminate the power produced by one leg from the power produced by the other. The mean power output produced by each leg was presented on the PC screen as an absolute value and, for the leg defined as plegic, also as a percentage of the power attained by the healthy leg. Power expressed as a percentage was a clear way of comparing the performance of plegic versus healthy leg in each revolution. The mean power output per revolution was calculated by combining and averaging the instantaneous power output produced by both legs during a whole revolution; this value was also presented on the PC screen. A graph of instantaneous power versus right pedal position was drawn on the PC screen every revolution.

Based on the position of the right pedal, BFB signals were generated by the LabVIEW6i program to indicate the subject when to push on the ergometer's pedal with the plegic leg. The BFB signals could be either visual, auditory, or both. Visual BFB was provided by a virtual lamp and a PUSH!! Message on the PC screen; while auditory BFB consisted of a tone generated through the PC speakers. As an additional feature, the program could calculate the user's prefetch time (elapsed time between the stimuli and the reaction) to anticipate the BFB soon enough for the user's reaction to come on time. This was done by issuing a visual and/or auditory signal to the user and registering the elapsed time between the stimuli and the user's reaction.

An external FES multi-channel laboratory-grade skin surface stimulator (designed at the Rehabilitation Research Center, University of Sydney, by Che Fornusek) was controlled

with the program using the PC's parallel printing port. One channel of the stimulator was used to apply FES to the quadriceps muscle of the plegic leg. Before applying FES, the intensity (pulse amplitude) minimum and maximum values had to be fixed in a range from 0 to 140mA according to the toleration of each subject. FES could be given through a defined range between -25° to 120° , assuming that the 0° position is when the right pedal is on top with its crank vertically aligned. The FES intensity could be controlled, within the limits fixed for the user, in manual or automatic mode. In manual mode the FES amplitude was controlled directly by the user. In automatic, the amplitude was controlled by the program to obtain from the user a desired power output. In order for FES to be applied, the instantaneous power output generated by the subject's plegic leg needed to exceed a threshold value fixed according to the subject's limitations. The purpose of this was to force the user to push volitionally with the plegic leg, so the FES acted as a power enhancer and not as a replacement of the subject's neuromotor control.

Experimental Design

Each subject participated in three cycling sessions. Subjects were requested to cycle on the BFB-FES Isokinetic training system for 30 minutes at 40rpm. Rather than cycling for 30 minutes continuously, they were requested to cycle for 10 minutes, followed by a 10 minute rest period three times. The subjects cycled at 65% of their functional capacity in order to achieve a target heart rate:

$$\text{Age predicted maximal HR} = 208 - 0.7(\text{age in years}) \quad (16)$$

$$(\text{Maximal HR} - \text{Resting HR})0.65 + \text{Resting HR} = \text{Target HR} \quad (4)$$

To monitor heart rate, a polar heart rate monitor was used. Subjects were asked to push on the pedals with more or less effort until the target heart rate was achieved.

During each session, three different cycling conditions were tested:

1. standard isokinetic cycling (NA);
2. receiving BFB (BFB); and
3. receiving BFB (as in 2) and FES (BFB-FES)

Prior to undertaking the FES condition two surface electrodes, one proximal and one distal, were placed on the plegic quadriceps muscle of the subject. The minimum and maximum levels of electrical current to be applied were set based on the subject's sensitive tolerance. The values were determined by increasing the intensity of the FES starting from 0mA until the subject could feel the stimuli, to set the minimum, and until the stimuli caused discomfort, to set the maximum. The procedure was carried on while the subject was cycling, thus allowing familiarization with FES cycling. The order in which the three conditions were tested was determined by the investigators according to table 1. This order was chosen to ensure the BFB-FES condition was tested in the three different periods of exercise along the experiment. During each 10 minute period of cycling, the subject's heart rate was registered at rest, every two minutes during exercise, and 2 minutes after the cycling exercise. The power output of each leg, total power output, and the plegic leg performance was averaged every five revolutions and sent by the control program to a spreadsheet file. During the BFB-FES cycling session, the electrical current being applied was averaged every five revolutions and also registered in the spreadsheet file as a percentage of 140mA. The data collected under the three conditions was compared using repeated measures ANOVA to determine whether BFB or BFB - FES enabled the subjects to cycle at greater intensities than in the control condition. After completion of the experiment, each subject was asked for his personal appreciation of cycling using BFB and BFB-FES.

RESULTS

BFB and BFB-FES cycling were accomplished with the new system. The computer was able to handle all the online processing required for the system to function. All the subjects were able to interact with the designed graphic user interface and followed the visual and auditory BFB signals provided by the virtual instrument. The programmed strategy for calculating the prefetch time of the subjects proved useless because the subjects' reaction time was more than the elapsed between the issued signal and the end of the paretic leg downstroke. To compensate this, all the BFB signals were advanced 20° (maximum value the software would allow to keep operating properly) from their original issuing position. Three of the subjects acknowledged the BFB was useful for keeping the pace and indicating when to push the paretic leg; subject 2 reported the BFB was given lately. The maximum FES intensity tolerated by the subjects was $66.85 \pm 11.69 \text{mA}$ (1σ), all of them reported FES acted as a reminder for the paretic leg to push. Besides, subject 4 expressed FES provided an extra power output and subject 2 explained that after cycling with FES certain awareness of the stimulation remained for a couple of minutes when resuming cycling after the 10 minutes rest.

The power output of each leg, total power output, paretic leg performance, and HR achieved by each subject while cycling under the three different conditions are presented in tables 1 to 5. Only the data recorded from the beginning of the 3rd minute to the end of the 7th minute during each 10 minute cycling session were analysed, the rest was discarded to avoid the subjects' self motivation at the beginning and the end of exercise. Figures 1 to 5 represent tables 1 to 5; the error bars in the graphs are 1σ . Paretic leg performance, table 4 and fig4, represents the power achieved by the paretic leg expressed as a percentage of the power output of the healthy leg.

DISCUSSION

Power output, paretic performance, and HR were affected differently by BFB and BFB-FES among the subjects. Subjects 3 and 4 achieved a higher power output with the paretic leg when cycling with BFB, and even higher when FES was applied; subjects 1 and 2 attained the highest power output with their paretic leg while cycling in the traditional way (fig1). In contrast, the healthy leg power output increased when BFB was given and reached its highest with the application of FES for all the subjects (fig2). The different reaction of the paretic and the healthy leg suggests BFB and BFB-FES augmented the subjects' concentration in the exercise increasing the power output of the healthy leg, yet the paretic leg of subject 1 and 2 was either not strong enough or lacked the coordination to reflect it. After completion of the experiment, subject 1 reported BFB-FES reminded him of pushing on the pedal but his leg was too weary to do it strongly. The analysis on the data collected from subject 1 showed the paretic leg power dropped from one exercising session to the next independently of the cycling condition, thus achieving its highest power output always under the condition evaluated first. Subject 2 reported that BFB was given lately, which reflects very long prefetch time and lack of coordination. It is possible then that BFB interfered with the subject's learned timing for the paretic leg and got him out of pace. While performing regular cycling, subject 2 would focus completely on his paretic leg and forget his healthy leg; resulting in increased paretic leg power output but decreased on the other (fig1 and 2).

Total power output and paretic performance (fig4 and 5) show the combined effect of the paretic and the healthy leg while cycling under the three evaluated conditions. Subjects' 3 and 4 total power output augmented when BFB was provided and further more while FES was applied, remarking that both legs benefited from BFB and BFB-FES. The paretic performance of subject 4 (fig4) was augmented by both BFB and BFB-FES meaning the paretic leg benefited more and thus, the difference in power output between the two legs

shortened. In contrast, the paretic performance of subject 3 (fig4) dropped when BFB and BFB-FES were present, therefore his healthy leg benefited more and the power output gap between the legs was widened. The total power output achieved by subject 1 was almost the same for the three conditions, reflecting that the loss of power in the paretic leg, while cycling with BFB and BFB-FES, was compensated by a gain of power in the healthy leg (see fig1 and 2). This is analogous to the observed decrement in his paretic performance (fig4) under BFB and BFB-FES conditions. The minor difference in total power output may also indicate the changes observed in each leg separately were more related to fatigue than to the different conditions. Subject's 4 total power output resembled his paretic leg power output (fig1), which indicates that the loss of power output of the paretic leg, when cycling with BFB and BFB-FES, was more important than the gain on the healthy leg. This is confirmed by a decrement in the subject's paretic performance (fig4) when BFB and BFB-FES were applied.

Finally, HR (fig5) resembles total power output for all subjects except 1. This would be expected under the premise that higher power output demands higher oxygen consumption and thus a higher HR. Subject's 1 HR was highest under BFB-FES, followed by BFB and NA. This could indicate the subject made a bigger effort while cycling during BFB and BFB-FES, maybe to compensate fatigue and then it was not translated to higher power output.

CONCLUSION

The results obtained during this preliminary study suggest BFB-FES cycling with the developed system has the potential to become a useful tool in the rehabilitation process of stroke patients that present leg weakness and poor motor coordination. A study comprising a medium to long term exercise program with a broad range of stroke subjects is

needed to determine the real effectiveness of the new system, and which group of stroke patients would benefit more from it.

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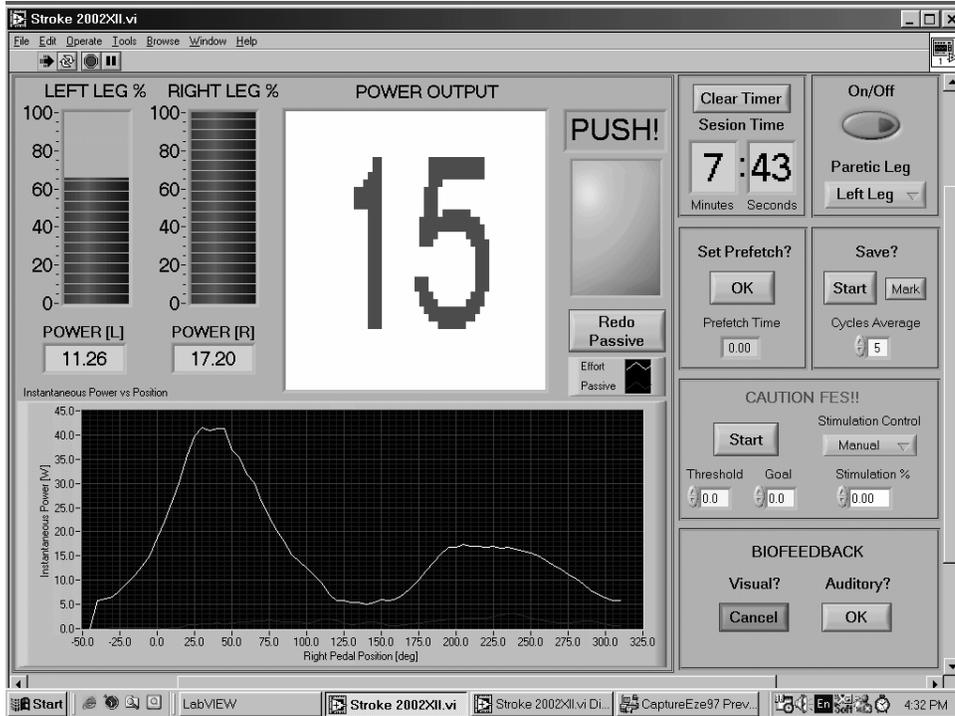


Figure 0. BFB-FES cycling system graphical user interface.

Table 1. Average power output achieved with the paretic leg after the three trials under the different cycling conditions.

Subject	Paretic Leg Power Output [W]					
	Na		BFB		BFB-FES	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
1	18.164	2.160	17.127	2.283	15.850	1.856
2	33.775	2.593	26.737	5.064	28.222	3.993
3	21.978	2.634	25.052	4.250	27.170	4.687
4	10.813	2.782	13.776	2.316	17.565	4.509

Table 2. Average power output achieved with the healthy leg after the three trials under the different cycling conditions.

Subject	Healthy Leg Power Output [W]					
	Na		BFB		BFB-FES	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
1	35.992	3.185	42.247	4.565	42.504	2.607
2	79.944	2.976	86.306	8.753	88.795	14.474
3	44.108	3.006	57.499	5.999	59.453	8.898
4	50.574	6.471	55.006	5.581	64.903	6.566

Table 3. Average power output achieved after the three trials under the different cycling conditions.

Subject	Total Power Output [W]					
	Na		BFB		BFB-FES	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
1	27.132	1.290	27.983	3.222	27.400	2.100
2	50.373	1.115	44.618	2.063	46.437	4.543
3	33.232	2.743	39.061	4.386	40.822	5.500
4	30.201	3.720	31.209	3.410	36.998	5.089

Table 4. Average paretic leg performance during the three trials under the different cycling conditions.

Subject	Paretic Leg Performance [%]					
	Na		BFB		BFB-FES	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
1	50.483	10.363	40.594	1.412	37.328	2.651
2	42.957	4.657	31.944	9.174	32.656	4.004
3	47.981	2.532	42.768	4.779	45.289	6.195
4	22.388	6.631	26.265	1.884	28.434	4.062

Table 5. Average heart rate during the three trials under the different cycling conditions.

Subject	Heart Rate [bpm]					
	Na		BFB		BFB-FES	
	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev
1	130.444	3.403	135.778	2.470	139.000	4.579
2	110.000	2.419	104.889	2.315	109.222	8.189
3	74.222	1.595	80.222	3.425	84.333	1.963
4	94.667	5.041	95.889	2.910	102.222	2.470

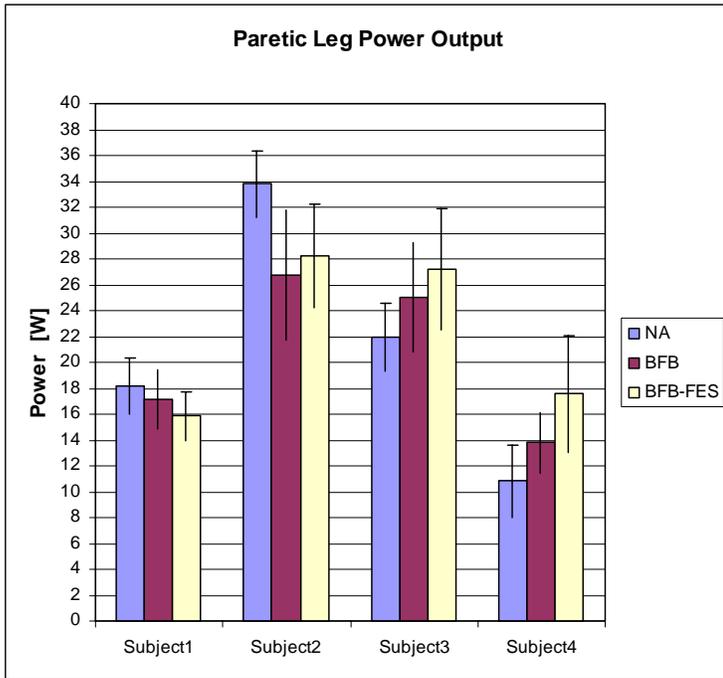


Figure 1. Paretic Leg Power Output

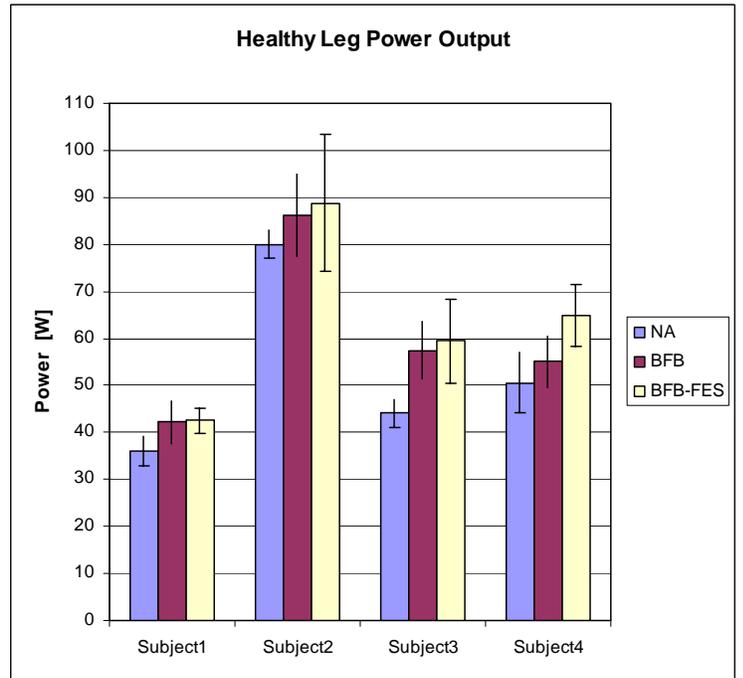


Figure 2. Healthy Leg Power Output

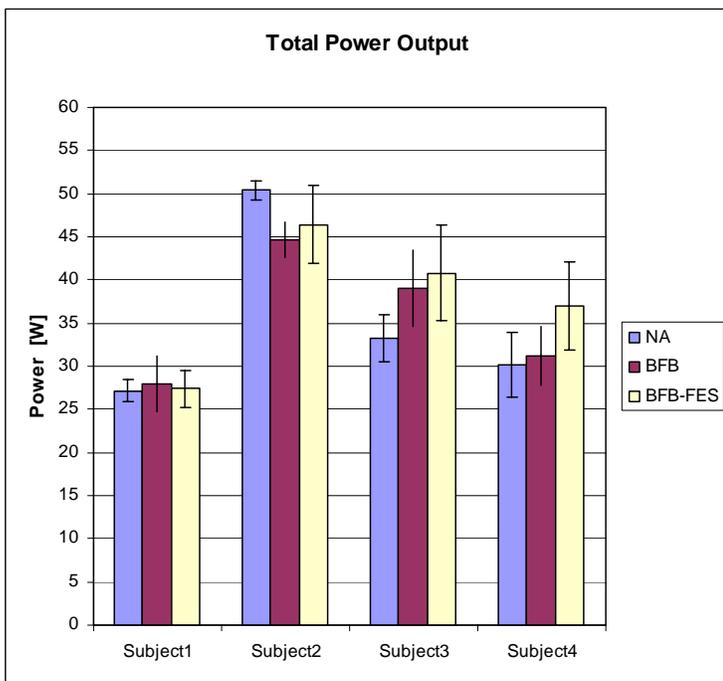


Figure 3. Total Power Output

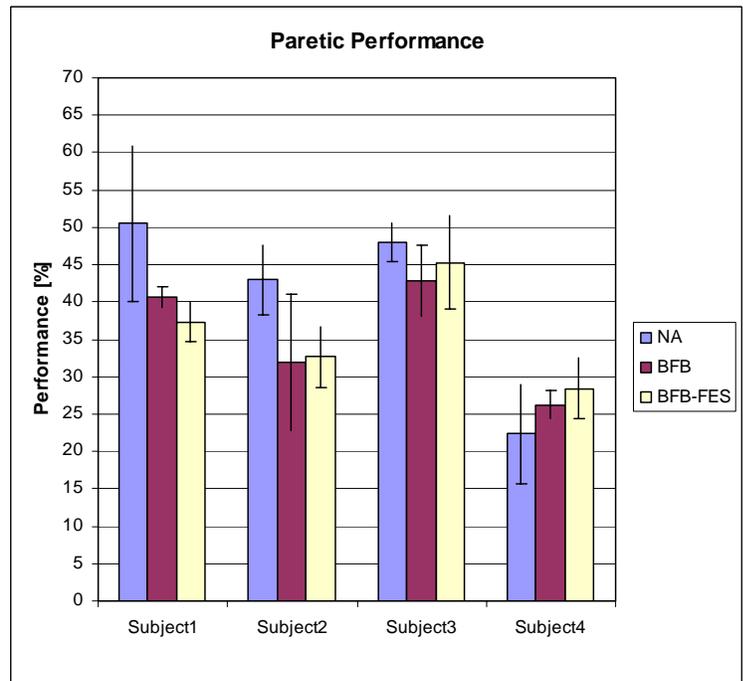


Figure 4. Paretic Leg Performance

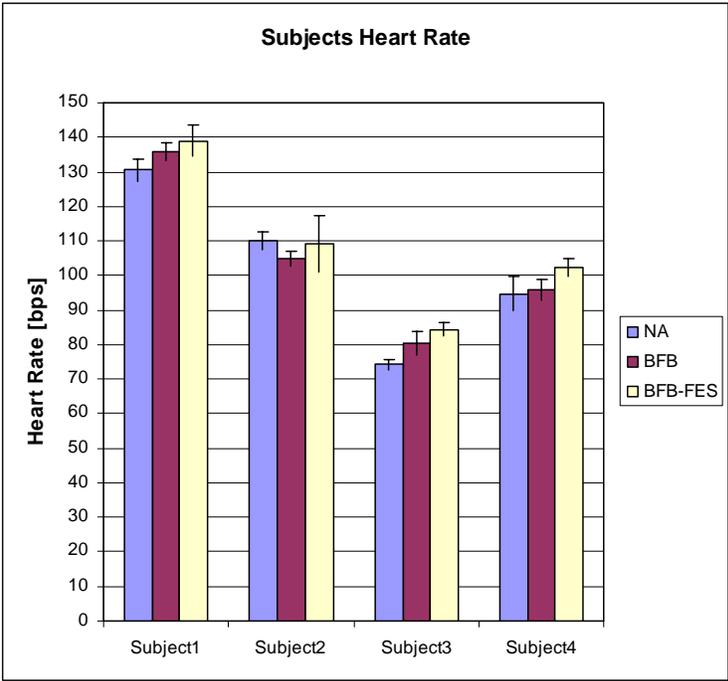


Figure 5. Heart Rate