Report of practicability of a 6-month home-based functional electrical stimulation cycling program in an individual with tetraplegia

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Background: Sedentarism is common among people with spinal cord injury (SCI). However, new technologies such as functional electrical stimulation cycles with internet connectivity may provide incentive by removing some of the limitations and external barriers.

Objective: To determine the effectiveness of a long-term home-based functional electrical stimulation lower extremities cycling (FES-LEC) program on exercise adherence, body composition, energy expenditure, and quality of life (QOL) in an adult with chronic tetraplegia.

Participant: A 53-year-old man, 33 years post-motor complete C4 SCI participated in FES-LEC in his home, three sessions per week for 24 weeks.

Methods: Exercise adherence was calculated as the percentage of performed cycling sessions relative to the recommended number of cycling sessions. Body composition was measured by dual-energy X-ray absorptiometry. Energy expenditure was measured using a COSMED K4b2 and QOL via the World Health Organization Quality of Life (WHO-QOL) Brief Questionnaire. Testing was performed before and after the 24-week exercise program.

Results: The participant cycled 59 out of a recommended 72 sessions which is an exercise adherence rate of 82%. Body composition displayed increases in total body lean mass (LM) with an increase of 3.3% and an increase in leg LM of 7.1%. Energy expenditure increased by 1.26 kcal/minute or greater than 200%. The physical and psychological domain scores of QOL increased by 25 and 4.5%, respectively.

Conclusion: This case study provides encouragement concerning the practicality of a home-based FES-LEC program for those with SCI.

Keywords: Spinal cord injuries, Functional electrical stimulation, Tetraplegia, Exercise regimen

Introduction

Maintaining the health and wellness of individuals with chronic spinal cord injury (SCI) is particularly challenging due to the inherent effects of muscular paralysis. Negative changes in body composition that include decreased muscle mass, increased fat mass (FM), and decreased bone mineral density (BMD) give rise to secondary conditions such as obesity, metabolic syndrome, diabetes mellitus, and osteoporosis.¹⁻⁵ The combined results of these and other effects related to chronic SCI are increased morbidity, decreased independence, and

decreased quality of life (QOL).^{1,6,7} Intertwined with these negative effects is the problem of hypo-physical activity.¹

Relative physical inactivity or sedentarism is common among those with SCI. Because of the physical limitations resulting from paralysis and the environmental barriers that persist in many indoor and outdoor exercise facilities, innovation is required to accommodate the special considerations needed to provide regular physical activity within this population.^{8,9} Buchholz *et al.*¹⁰ reported that physical activity levels of those with SCI are only 40% of the general population which is also intrinsically sedentary.

However, the advent of new technology may provide incentive by removing barriers to exercise and minimizing the impact of physical limitations. One such

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innovation is the use of functional electrical stimulation lower extremities cycling (FES-LEC) in the home with an internet-connected system that stores the performance data for review and allows distant altering of the cycling program by healthcare professionals. This system not only allows physical activity utilizing paralyzed muscles but also increases the optimization and safety of a graduated physical activities program. However, in light of the low physical activity rate of those with SCI, it is questionable whether a program of long-term physical activity would be utilized by an individual with chronic SCI even if it were made readily available and monitored by experts. Previous work at our SCI exercise physiology laboratory involving a 64-year-old male with motor complete C5 tetraplegia showed a high rate of exercise adherence, positive changes in body composition, and QOL with home-based FES-LE cycling over a 9-week period.¹¹ The purpose of this case study was to determine the effectiveness of a long-term home-based FES-LEC exercise program on exercise adherence, body composition, energy expenditure, and QOL in an adult with chronic tetraplegia.

Case report

Participant

A 53-year-old man, 33 years post-traumatic motor complete C4 SCI participated in FES-LEC with an RT300 (Restorative Therapies Inc. Baltimore, MD, USA) in his home. The program consisted of three sessions per week for 24 weeks. Sessions were monitored by the research staff via internet connection. At initiation of the program the participant weighed 62.1 kg, height was 172.72 cm, and calculated body mass index was 20.85, which is categorized as normal in the general population. The participant reviewed and signed a written VA Human Subjects Research Consent form. This study was approved by the institutional review board of the McGuire VA Medical Center and all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed.

Prior to receiving the rental RT300 FES-LEC in his home the participant underwent a screening process that included clearance from his physician and a lab-based cycling session to check for possible adverse effects and to familiarize that participant with the FES-LEC activity.

Because the participant did not have sensation below the level of injury and tolerated electrical stimulation without difficulty, the electrical stimulation amplitude was initiated at the maximum intensity of 140 mA.

During the initial monitored laboratory session, there were no episodes of autonomic dysreflexia or adverse changes in heart rate and blood pressure thus the subject was cleared for home exercise. Pulse width was set at 250 μ s (50% of maximum) and frequency at 33.3 Hz (1/3 capacity). These parameters remained at these levels throughout the study. The target control speed was set at 50 rpm. This speed was recommended by John McDonald, MD, PhD, Director of the International Center for Spinal Cord Injury at Kennedy Krieger Institute (KKI), Baltimore, MD, USA, and the founder of Restorative Therapies Inc., the manufacturer of the FES cycle that we used in our study. During a presentation at an Activity-Based Restorative Training workshop held at KKI in 2011, Dr McDonald explained that a high number of repetitions are advisable in order to promote central nervous system training. The initial resistance was set at 0.5 N m, which is the lowest default setting for resistance. During the study, cycling time was increased as tolerated from 14 minutes to a maximum of 60 minutes and the resistance was increased as tolerated up to 1.7 N m. The resistance setting was kept on automatic so that the safety mechanism within the RT300 cycling system would automatically lower the resistance if the selected cycling speed could not be maintained by the participant. This allowed the research staff to be sure that each sustained increase in resistance was well tolerated by the participant.

Disposable adhesive gel electrodes were placed on the knee extensors, hamstrings, and gluteal muscles for the transmission of electricity to those muscle groups and performance of the cycling activity. Bilateral electrode placement included three muscle groups.

Electrode placements

(1) *Knee extensors*: one electrode was placed on the skin 2–3 cm above the superior aspect of the patella over the vastus medialis muscle, and the other lateral to and 30 cm above the patella over the vastus lateralis muscle; (2) *Hamstrings*: one electrode was placed 2–3 cm above the popliteal fossa and the other electrode 30 cm above the popliteal fossa; and (3) *Gluteus maximus*: two electrodes were placed parallel and on the bulk of the muscle belly of each buttock with 3–4 cm width separation between both electrodes.

Assessment

Practicability was largely determined by the percentage of exercise adherence. Exercise adherence was calculated as the percentage of performed cycling sessions relative to the recommended number of cycling sessions. For

example, if 10 sessions were recommended and 5 were completed, then the exercise adherence rate would be 50%.

To determine body composition effects that may result from the exercise program a Lunar Prodigy Advance Dual-Energy X-Ray Absorptiometry (DXA) scanner (General Electric, Madison, WI, USA) was used to measure body composition including percent body fat (%BF), FM, lean mass (LM) and BMD before and after the 6-month cycling program. DXA scans were performed with the participant in the supine position.

Energy expenditure while performing FES-LEC was determined prior to and after the 6-month FES-LEC program by use of a COSMED K4b2 (COSMED USA, Chicago, IL, USA) portable metabolic cart. After calibration, a mask was placed on the face of the participant in order to monitor kilocalories per minute (kcal/minute) production. Data were collected during a 5-minute non-cycling rest phase to allow the subject to get acclimated to breathing with the mask on. During the FES-LEC exercise oxygen consumption was monitored to determine total energy expended. Data continued to be collected during a 5-minute rest phase after the exercise. The pre-program FES-LEC testing was performed at the initial cycling parameters, (speed = 50 rpm, resistance = 0.5 Nm) for a duration of 14 minutes. The FES-LEC pre-test was stopped at 14 minutes because the participant was no longer able to actively cycle at the set parameters. The post-test FES-LEC was performed at the cycling parameters achieved at the end of the exercise program (speed = 50 rpm, resistance = 1.7 Nm) and a duration of 43 minutes. Although the participant was fully capable of cycling longer than 43 minutes during the post-test FES-LEC, the testing was concluded at 43 minutes due to participant complaints of intolerance to continued use of the mask collecting the data. A 2-minute warm-up and 1-minute cool down consisting of passive cycling were performed for all testing and exercise sessions. Electricity parameters remained as indicated in the methods section for the training sessions throughout the 6-month program.

In addition to calculating exercise adherence and the physical effects of FES-LEC, measurement of possible psychological changes was determined by pre- and post-program completion of the World Health Organization Quality of Life (WHO-QOL) Brief Questionnaire. This questionnaire has been validated and is reported to be the most acceptable and established instrument to assess QOL after SCI.¹² Testing was performed prior to the 6-month FES-LEC program and then after completion of the program.

Results

The participant cycled 59 out of a recommended 72 sessions at home during the 24-week period (Fig. 1), which is an exercise adherence rate of 82% and much higher than the reported 35% exercise rate of the general population.¹³ During the study, the duration of exercise increased as tolerated by the participant from 14 minutes to a maximum of 60 minutes, both including a 2-minute warm up and 1-minute cool down. The distance cycled increased from 2.0 miles to a 9.0-mile maximum.

Body composition displayed positive changes in LM with an increase of 1.3 kg from 39.12 to 40.42 kg or 3.3%. More specifically leg LM increased 0.78 kg from 10.93 to 11.71 kg or 7.1%. FM increased slightly from 20.85 to 21.23 or 0.38 kg (1%). Leg FM remained unchanged at 3.51 kg. Although FM increased the overall %BF decreased from 33.6% to 33.3%. BMD increased slightly from 1.024 to 1.027 g/cm² with no change in leg BMD.

Energy expenditure increased from 0.51 kcal/minute for the pre-test FES-LEC to 1.77 kcal/minute for the post-test FES-LEC, which is an increase of 1.26 kcal/minute or greater than 200%. Total kilocalories burned for the pre-test and post-test cycling were 7.14 and 76.11, respectively (Table 1).

QOL scores increased positively in the physical and psychological domains which reflect (comfort or pain level, energy level, and restfulness) and (positive feelings, self-esteem, body image and appearance, and

Figure 1 Number of recommended versus completed session across 6 months of home-based FES cycling in a person with C4 motor complete spinal cord injury.

Table 1 Changes in body composition and energy expenditure

	Weight (kg)	Height (cm)	Body mass index	%Body fat	Fat mass (kg)	Lean mass (kg)	kcal/session
Pre-exercise	62.1	172.72	20.8	33.6	20.85	39.13	7.14*
Post-exercise	63.8	172.72	21.4	33.3	21.23	40.24	74.33**

*Total kcal burned during 14 minutes pre-test FES cycling.

**Total kcal burned during 43 minutes post-test FES cycling.

concentration), respectively. The raw score for the physical domain increased by 3.43 from 13.71 to 17.14 (25%), while the psychological domain score increased by 0.66 from 14.67 to 15.33 (4.5%). Interestingly, the social domain which represents the participant's feelings about personal relationships and social support decreased by 2.0 from 16.0 to 14.0 (12.5%). The Environmental domain which represents the participant's feelings concerning freedom, physical safety and security, work satisfaction, and financial resources was unchanged.

Discussion

The exercise adherence rate of 82% was much higher than the reported exercise rate of 35% in the general population and demonstrates the practicability of using home-based FES-LEC as an exercise program. The importance of removing external barriers and physical limitations to exercise are key factors in promoting regular physical activity. By developing and demonstrating safety for an exercise program in the clinic/laboratory that can be performed and monitored in the participant's home, many of the physical barriers typically faced by individuals with SCI can be eliminated. Also, the RT300 cycle can be utilized while sitting in one's own wheelchair thus providing the convenience of not needing to physically transfer onto the cycle. Additionally, increases in exercise intensity such as resistance and speed can be monitored by healthcare staff via the internet to optimize exercise progression and to increase safety. The greater than 3-fold increase in time of cycling and distance traveled per session over the length of the program represents an increase in physical endurance.

Over the 6-month period of regular physical activity changes emerged in body composition. The positive alterations in body composition of the participant in this case study, especially the 3.3% increase in LM and the 7.1% increase in leg LM, are reflective of muscular hypertrophy that takes place with regular physical activity.¹⁴ Increased LM has been associated with increases in metabolic rate and energy expenditure and in turn reportedly affects the risk of obesity, metabolic syndrome, and diabetes mellitus.¹⁴⁻¹⁸ The 1% increase in FM although minimal is not surprising since we did

not apply guidelines for dietary intake. Although FM has been shown to be positively affected (decreased) by regular exercise and increased energy expenditure, not controlling for energy consumption results in less than adequate regulation of FM. BMD was essentially unchanged; however, no change in BMD, especially in the lower extremities, may actually be a positive result for a 53-year-old man with chronic SCI. The DXA does not differentiate between trabecular and cortical bone; thus, possible changes in trabecular bone, which is highly metabolic and more likely to undergo change, could not be determined in this study.¹⁹

With an increase in LM one would expect an increase in the ability to perform work. By the end of the 6-month program the participant was able to perform FES-LEC for up to 60 minutes with a resistance increased to 1.7 Nm from the initial 0.5 Nm. As more muscle was added and the participant was able to cycle at increased workloads the ability to burn calories increased. For the participant in this case report, LM and caloric expenditure during FES-LEC appear to have improved concurrently.

Although changes resulting from regular physical activity are usually thought of in terms of physical manifestations, the psychological effects of physical activity are being studied with increasing ebullience. The increases in the physical and psychological domains of the WHO-QOL questionnaire after 6 months of FES-LEC may reflect perceived changes in body composition and a feeling of having some measure of control over one's body. These results support the premise that individuals living with chronic disability often suffer from poor body image, low self-esteem, and a feeling of loss of control over their lives and may be ameliorated by routine exercise.⁷

The results of this 6-month case study substantiate the results of our previous work concerning the 9-week home-based FES-LEC program of a 64-year-old man with motor complete C5 tetraplegia.¹¹ In that case report the participant completed 25 of 27 exercise sessions over 9 weeks for a 93% compliance rate and increased cycling distance from 2.47 to 5.59 miles, for an increase of 126%. Total body LM increased by 8.3% from 48.94 to 53.02 kg and %BF decreased from

29.6 to 28.4(−1.2%). Total body weight, FM, and BMD remained unchanged. The psychological domain of the QOL questionnaire improved from 12.67 to 14. This domain is reflective of perception of body image, appearance, and self-esteem.

Limitations

From this single case study, no causal conclusion can be made concerning the results. Furthermore, the results of this study reflect the behavior of one individual and cannot be generalized to the overall SCI population or to the general older population. Further research is needed to provide evidence that may corroborate the results of this case study as well as to demonstrate positive impact on metabolic parameters associated with chronic SCI such as obesity, glucose intolerance, dyslipidemia, and hypertension.

Conclusions

This case study reported many positive effects of a 6-month home-based FES-LEC exercise program on an older adult with chronic tetraplegia. Even though persons with SCI are typically sedentary, the high exercise adherence rate in this case study provides encouragement concerning exercise options that may assist others in becoming physically active. The increase in total body LM and especially leg LM demonstrates that electrical stimulation cycling is capable of producing muscle hypertrophy in paralyzed leg muscles. The positive changes in QOL also indicate that regular home-based FES-LEC may have played a role in improving the QOL of this gentleman with SCI. BMD was essentially unchanged in this case study; however, the fact that BMD did not decrease during a 6-month period for an older adult with SCI may well be seen as a positive result in future years as bone loss and aging in SCI are investigated further. Deductions concerning conclusions of the effects of FES-LEC and generalization to the general SCI population are not possible with this single case report; however, the results of this study do provide evidence concerning the possible practicability of a home-based FES-LEC program and the possible positive effects that may result. Further study will provide evidence corroborating or contradicting the evidence supplied by this case report.

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