Functional Electrical Stimulation in Clinical Applications: Fitness and Cardiovascular Health

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***Abstract*—FES leg cycling exercise is a physical activity that has potential to provide aerobic fitness and cardiovascular health benefits for individuals with SCI. However, there are few high-quality studies or systematic reviews for sufficient Level I or Level II evidence supporting the putative benefits of FES-evoked exercise after SCI, to make sound determination of its clinical efficacy to reduce obesity diabetes and cardiovascular disease. This paper samples some of the recent evidence supporting FES lower-limb exercise, by itself, and makes recommendations about how "critical dose-potency" might be achieved to provide clinical and health benefits from FES-exercise.**

I. Introduction

Increasing physical activity and exercise has proven beneficial not only for the able-bodied population, but also for people affected by spinal cord injury (SCI). SCI can lead to moderate-severe muscle paralysis/paresis, loss of lower limb functionality and usually results in lower levels of aerobic fitness than is observed in the able-bodied (AB) population. Consequently, individuals with SCI have significant reduction in their aerobic fitness, muscle strength and cardiovascular health due loss of motor control over the large muscles in trunk and legs, disruption to neural signals through the spinal cord and due to a restricted movement capacity and increased sedentary behaviour as a wheelchair user.

A lack of physical activity (PA) has been linked to a number of chronic conditions, and this relationship is even more pronounced in people with SCI due to their elevated levels of sedentary behaviours. The prevalence of cardiovascular diseases (CVD), diabetes mellitus and visceral obesity are all much higher in this population than the able-bodied [1-3]. As people with SCI are at such a high risk of co-morbidities due to their decreased levels of physical activity, it becomes vital for them engage in regular physical activity of an intensity and duration to elicit improvements in their aerobic fitness, muscular strength and cardiovascular health.

Since the 1960's, functional electrical stimulation (FES) – induced muscle contractions have been widely used as a rehabilitation therapy or an exercise regimen for people with SCI. Paralysed lower-limb muscles can be artificially evoked to produce otherwise unattainable dynamic movements, such as cycling, rowing, knee extension, or standing and stepping.

Despite some pervious literature reviews [4-6], there has not been sufficient Level I or Level II evidence [7] supporting the putative benefits of FES-evoked exercise after SCI, to make sound determinations of its clinical efficacy to reduce obesity, Type-II Diabetes Mellitus (T2DM) and cardiovascular disease. There are numerous dimensions and outcomes within which FES-leg exercise *may* have beneficial role for positive health. Conceptually, reducing societal cardiovascular risk factors and lowering the burden of non-communicable disease can come about in (at least) two dimensions – reducing cardiometabolic risk and increasing aerobic fitness. Reducing cardiometabolic risk through physical activity and exercise refers to altering morphological characteristics of muscle ion a beneficial way and depressing precursors of vascular atherosclerosis. Morphological characteristics includes changes to muscle fibre type, histochemistry and energy utilisation. Precursors of vascular atherosclerosis includes lowered cholesterol, triglycerides, and other blood-borne agents that are associated with poor diet, a sedentary lifestyle and obesity. Increasing aerobic fitness refers to elevating peak oxygen uptake (e.g. VO_2peak) or altering sub-peak cardiorespiratory outcomes at rest and during exercise in a positive way.

The present work samples some of the recent publications since 2008 for the reader to make their determination about the clinical efficacy of FES-evoked exercise for aerobic fitness and cardiovascular health outcomes.

II. Methods

Literature Survey

This paper, and the oral presentation on which is was based, sampled some of the recent peer-reviewed published literature in the field of FES-evoked exercise for individuals with SCI. In general, more recent (i.e. post-2008) research has been favoured for interpretation, although some earlier work has also been presented herein. Inclusion criteria were; (i) spinal cord injury population, (ii) FES-induced muscle contractions for the primary purpose of physical activity or exercise promotion, and, (iii) FES-exercise of the legs without other voluntary muscle contractions, unless otherwise stated. Exclusion criteria were; (i) FES-induced muscle contractions for other outcomes than "exercise" or "physical activity"

978-1-4799-6483-3/14/$31.00 ©2014 IEEE

promotion (including gait restoration, pain reduction, etc) and (ii) most single-channel, single-muscle group studies, since it was considered that these would not recruit sufficient musculature for the purposes of reducing cardiometabolic risk or increasing aerobic fitness.

III. RESULTS

Aerobic Fitness

Several longitudinal studies have sought to investigate increases of aerobic ("cardiorespiratory") fitness after training. Berry and colleagues [8] trained 11 men and women with SCI for 1-year using an "at-home" program (Fig 1). Their clients trained between 3-5 times per week for up to 60-min of FES-cycling at 50 rev•min^{-1}.

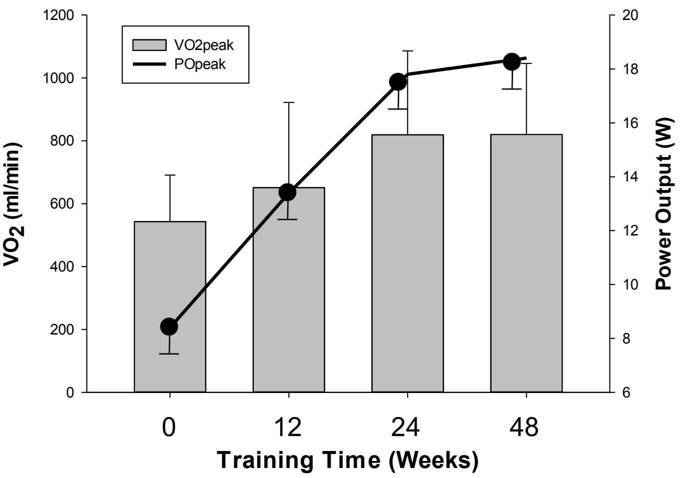

Fig 1. Changes of Peak Power Output (W) and Peak Oxygen Uptake (ml•min^{-1}) after 1-year of FES cycle training [8]

All increases of peak power output and VO_2peak were significantly different after the first 12 weeks, but no further improvements were observed after 24 weeks of home training.

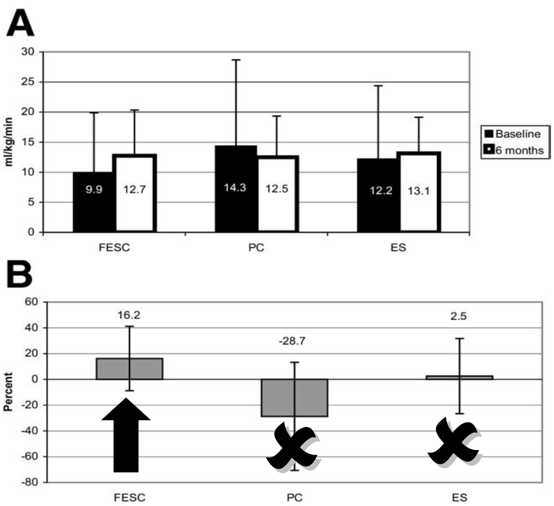

Fig 2. Changes of aerobic fitness (VO_2peak) after 6-months of home-based FES cycle training in a paediatric population [9]

Peak During the program, VO_2peak increased by 56% ($p<0.05$) and Peak Power increased by 132% ($p<0.05$). Unfortunately, there was no control group nor a control time period, which limited the generalizability of the study.

In one of the few RCTs conducted in FES research, Johnston et al [9] randomized three groups of children (aged 5-13 y) with spinal disorders amongst an FES cycling group, a FES-isometric muscle contraction group and a passive cycling group for 6-moinths of home-based training, 3-times per week for 60-min per session (Fig 2). Only the FES-cycling group significantly improved their VO_2peak by ~16% ($p<0.05$)

Cardiometabolic Health

In 2002, Crameri and colleagues [10] showed that FES cycle training could elicit muscle morphological adaptations, indicated by an improvement in total work output, an increase in vastus lateralis muscle fibre cross-sectional, a reduction in the percentage of type IIX fibres, an increase of capillary density and increases in activity levels key enzymes responsible for aerobic metabolism. More recently, Peng et al [11] has summarised some of the important muscular adaptations leading to putative improvements in cardiovascular health.

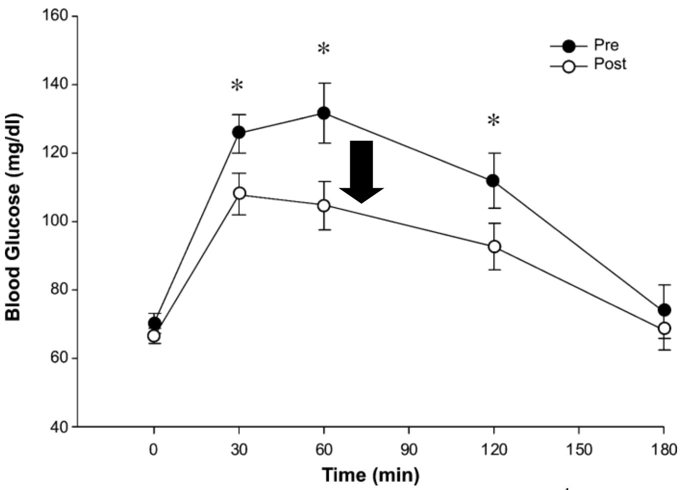

Fig 3. Changes of Blood Glucose after OGTT (mg•dl^{-1}) after 10-weeks of FES cycle training [12]

Griffin and co-workers [12], elegantly demonstrated that ten weeks of FES cycle training, 2-3 times per week led to significant reductions in blood glucose levels after an oral glucose tolerance test (Fig 3), and also lower concentrations of inflammatory bio-markers in conjunction with an increase of lean muscle mass and augmented sensorimotor ability following 10 weeks of FES cycling in persons with paralysis after SCI. The authors' implication was that such biochemical adaptations would lead to lower onset of T2DM in the SCI population, but it should be noted that claim was inferential. Although other authors have cited limited evidence that FES cycling or other FES-leg exercises may improve cardiometabolic risk factors, the scientific evidence is neither complete nor authoritative on this outcome.

IV. Discussion

The present work has sampled some key scientific evidence suggesting FES-evoked leg exercise, by itself, offers some benefits for aerobic fitness and cardiometabolic health. To date, the limited scientific evidence comprising Level I and Level II [7] high quality studies are sparse. Laboratory-based or community-embedded studies utilising control groups (or a control time-period) with sufficient subjects are not in good evidence, nor abundance.

Pertaining to this problem of quality of evidence in evidence-based clinical reasoning is a recent large-sample survey by Kressler et al [13]. The authors accessed de-identified data on 19,872 FES exercise sessions by 308 home-based users through an online database established by a commercial FES cycle manufacturer (Table 1)

Table 1. Take up of FES home cycling

Frequency	Percentage Participants	Frequency /week	Duration /week (min)
HIGH (≥5 days)	2%	6.3 ± 1.0	672 ± 621
MEDIUM (2-5 days)	27%	3.1 ± 0.7	118 ± 50
LOW (<2 days)	71%	0.9 ± 0.4	34 ± 21

Ref: Kressler et al, 2014

The authors' key findings was of a very low 'volume' of FES-cycling, with 71% of sessions not meeting current guidelines [14] for sufficient physical activity for cardiometabolic health. Exercise 'volume' is defined as a function of weekly frequency multiplied by duration per session, and in their e-survey the authors noted that the low-volume and medium-volume home users fell well short of the recommended 150 min•wk^{-1}. None of the participants met the energy expenditure requirement of >4000 kJ•wk^{-1}, with a maximal weekly expenditure of ~180 kJ. It would be deemed unlikely by most health epidemiologists that such low levels of physical activity would, by itself, modify cardiovascular risk, through the predominant risk factors of obesity, T2DM and hyperlipidaemia/hypercholesterolemia.

If total volume of FES-evoked physical activity was observed as low in the home-based trials, then exercise intensity is similarly problematical. Current guidelines for exercise [14] describe heart rate and other bio-markers for 'moderate' or vigorous' exertion needed to improve peak aerobic fitness in people with SCI. Yet, many of the studies cited herein did not even quantify exercise intensity. Anecdotal observations of patients and clients undertaking FES-leg exercise would not lead the observer to conclude such exercise provided very much exertion is terms of respiratory rate and/or heart rate.

A key "take home message" of this work is that clinicians must deploy FES-evoked leg exercise at a sufficient frequency (2 or more times per week) and duration (>45-min per session) to achieve sufficient 'volume' exceeding 150 min•wk^{-1}. Such volume of exercise must also be provided at least to evoke 'moderate' exercise intensity (e.g. >40% heart rate reserve, >64% of peak heart rate, or >46% of VO_2peak) based on peak heart rate observed during of maximal arm effort.

Acknowledgment

The author acknowledges the intellectual contribution of his co-authors. Portions of this work have drawn upon the scholarly writings of the co-authors, from within their unpublished PhD dissertations, and through discussions that have shaped current thinking. This work has been partly funded by a University of Malaya HIR grant UM.C/625/1/HIR/MOHE/ENG/39, tenable to ABAW Khairi and colleagues (2012-2015).

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