ACC Rapid Review IV

The effectiveness of FES bikes for people with Spinal Cord Injury

Bernadette Cassidy PhD

Joanne Nunnerley MHealSc (Rehab)

Claire Freeman MHealSc (Rehab)

Jason Nicholls PT Dip Phty PGD Rehab

K. Anne Sinnott PT MPhty

Burwood Academy of Independent Living, Christchurch

Rehabilitation Teaching and Research Unit, University of Otago Wellington

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Executive Summary

In this review the evidence supporting the effectiveness of Functional Electrical Stimulation (FES) bicycles for people with spinal cord injury (SCI) is reviewed with particular reference to health benefits in areas such as cardiovascular health, muscle strength, bone density, risk of pressure sores and deep vein thrombosis, and well-being. In addition the evidence regarding the effectiveness of FES bikes for functional outcomes in the SCI population is considered. Findings of the review suggested that FES cycles have potential therapeutic benefits for the cardiopulmonary, muscular, and skeletal systems, as well as psychological functions for people with SCI. Compared with conventional therapeutic interventions such as passive exercises, arm crank ergometry, upper limb strengthening programmes, FES bikes allow for either passive, active assisted or active exercise for the muscles of paralysed (complete or incomplete) limbs to help improve circulation following SCI[1].

While there is insufficient evidence to determine the effectiveness of FES cycling compared with conventional therapeutic interventions there is evidence that the use of FES bikes in conjunction with conventional therapeutic interventions (e.g. arm crank ergometry including Saratoga) can improve cardiovascular health in people with SCI.

Key findings:

- FES may reduce the risk of secondary medical complications such as cardiovascular problems, bone density and muscle health issues, and pressure sores in people with SCI.
- In motor **complete** SCI below the level of T12, FES cycling may not be a suitable treatment, as these individuals do not appear to respond to the stimulation.
- In motor **incomplete** injuries the FES cycle is a beneficial adjunct to rehabilitation.
- In tetraplegia above C4 there are limited options for any cardiovascular workout *other than FES cycling.*

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[1] The determinants for exercise to become passive, active assisted or active will depend on the severity of SCI. The greater the SCI incompletion the less passive the exercise will be, therefore the greater the physiological effects. Essentially, FES assisted cycling artificially creates ACTIVE EXERCISE.

- Compared with other technologies including conventional therapeutic interventions, FES bikes use exact electrical stimulation to actively exercise the muscles of paralysed limbs to improve circulation following SCI. There is a lack of evidence to suggest that FES cycling is more effective than conventional therapeutic interventions

- The benefits of FES cycling appear dose dependent and diminish once the exercise is discontinued.

- FES bikes in combination with traditional interventions (e.g. arm crank ergometry) have been shown to improve cardiovascular health outcomes in people with SCI over and above FES bikes alone.

- Of the FES bikes currently on the market, the RT300 cycle has the advantage of an online system where clinicians can monitor and adjust programmes and setting for clients remotely.

- Development of a low-cost FES cycle to use in the home may be a feasible way to promote the wide use of FES bikes in SCI where appropriate.

- Information about the cost-effectiveness of using FES bikes for New Zealand clients could not be sourced.

Recommendations

- ACC consider requests for FES bikes on a case-by-case basis taking into account both the level and severity of the SCI.
- ACC remain cognizant that for FES to be beneficial it needs to be used regularly with high intensity at least for the first year of use.
- ACC consider that the MOTOmed bikes were designed for passive cycling and although they have FES attachments they may not be as effective as RT300 bikes.
- ACC should continue to monitor research in this area, particularly the findings of collaborative Australasian research programme, the SCIPA trials, which will be highly relevant for ACC.

1. Background to Review

1.1 Purpose

The research literature reports that the benefits of using FES bikes are an increase in muscle strength, increased bone density, lowered risk of pressure sores (Petrofsky, 1992; Deitrick, 2007; van Lander, 2008; Peng et al., 2011), reduced risk of deep vein thrombosis (DVT) and an increased sense of well-being. The aim of this Rapid Review was to explore what evidence exists to support the effectiveness of using FES bikes for achieving these health benefits, in particular improvements in cardiovascular health. The cardiovascular disease concerns specifically for SCI are provided in Appendix 1.

NB: We refer to all standard care, conservative therapies and therapeutic interventions as *conventional therapeutic interventions*.

1.2 Definitions of SCI and FES

SCI is damage to the spinal cord resulting in a loss of motor power (movement) or feeling. A complete SCI means that there is no function below the level of the injury, that is no sensation and no voluntary movement. An incomplete injury means that there is some functioning below the level of the injury. The level of completeness denotes severity of impairment[2].

FES is a procedure whereby an electrical current is applied to peripheral nerves that control specific muscles or muscle groups. This action can be used to restore or improve function. Generally FES is used for exercise, but it can also be used to assist with breathing, grasping,

[2] The degree of impairment is defined using the American Spinal Injuries Association (ASIA) Scale, this is an internationally recognised scale to describe the completeness of a SCI (Maynard et al., 1997). The ASIA scale is a five-point scale ranging from ASIA A to E. ASIA A indicates complete loss of motor power and sensation below the level of injury. ASIA B, C and D (often referred to as incomplete injuries), reflect increasing levels of sensation and motor power through to ASIA E, which depicts normal motor power and sensation. The ASIA impairment scale has a limited utility as it describes impairment not function and is therefore limited when describing characteristics of SCI samples.

transferring, standing and walking. For example, Bremner et al. (1992) and Glaser (1994) reported an increase in range of motion after FES cycling was used for lower limb exercise, which can be useful when making transfers and carrying out daily activities.

Research has shown that FES cycling increases muscle volume (Skold et al., 2002), strength (Belanger et al., 2000), and endurance (Gerrits et al., 2000), and decreases metabolic risk factors (Sabatier et al., 2005; Griffin et al., 2009). Wolfe et al. (2010) stated "interventions that involve FES training a minimum of three days per week for two months can improve muscular endurance, oxidative metabolism, exercise tolerance, and cardiovascular fitness" (p.29). An important advantage of FES cycling is the improvement in cardiopulmonary fitness (Berkelmans, 2008; Mohr et al., 1997; Petrofsky & Stacy, 1992; Facebook Survey, 2012 [Appendix 2]). In those with complete injuries, FES can be used in the lower limbs to promote muscular endurance and also improve cardiovascular fitness. FES can also be used to augment function and strengthen partially innervated muscles (Pouran, Garstang & Kida, 2009).

ACC undertook an evidence-based review in 2005 of ERGYS FES devices (a specific brand of FES bike) employed to improve the health and well-being of people with SCI. The ACC review found that people with SCI have reduced cardiopulmonary fitness due to their difficulty in exercising, loss of muscle mass and sympathetic autonomic impairment (ACC, 2005). The ACC review focused on the effectiveness of FES bikes for people with SCI during their rehabilitation and concluded that there was moderate evidence that the use of FES cycles for people with SCI was beneficial (ACC, 2005). The ACC evidence based review looked at studies from 1996 to 2005, this rapid review looked is inclusive of studies from 1992 to 2011 in order to include any new evidence and highlight any new developments with FES cycles.

1.3 FES Bikes currently available

FES routinely uses an ergometric device (e.g. stationary cycles, rowing machine) to exercise upper or lower extremities. All commercially available FES cycle ergometers have safeguards in place to stop the motor if it encounters resistance such as spasm, to reduce the risk of damage to the limbs. NB: Saratoga ergometric hand cycles are commonly used but not in conjunction with FES.

TABLE 1 FES cycles currently available on the market.

Type of Bike	**Advantages**	**Cost**
REGYS & ERGYS 2	The first commercial bike, used in rehab/research centres internationally.	Approx US$18500
RT300 motorized FES ergometer	Provides lower & upper limb exercise as well as combination arm and leg cycle. Has online system where clinicians can monitor/adjust programmes for clients remotely	≥US$ 20000
MOTOmed	Lower body ergometer designed to provide a lower body (or upper body if optional upper body ergometer is used) cardiovascular workout. No integrated FES system but can be fitted with external FES device. Combined use of 2 different systems can make using machine difficult for clients. Little is known about use of MOTOmed bikes in NZ.	$5850.00AUD
MOTOmed Basic model	Viva 1 exercise machine includes bicycle pedals & remote control with training functions. Other models include MOTOmed letto1/letto2 which is a therapy system on wheels for patients confined to bed. The MOTOmed letto can easily be fixed and adjusted to the bed without having to transfer the patient. All models of the MOTOmed can be retrofitted with the Hasomed RehaStim FES Unit.	Approximate cost for the base model MOTOmed bike: $5850.00AUD Accessories and other equipment, including the FES unit, not included in cost.

1.4 Distinctions within SCI regarding injury levels

In clinical practice it is clear that there are important distinctions within SCI and these relate to the level of the damage and severity of injury to the spinal cord, that is complete or incomplete lesions. In SCI below the level of T12, regardless of the level of completeness, FES cycling may not be a suitable treatment as these individuals have a lower motor neuron injury which does not respond to the electrical stimulation. This is because FES stimulation relies on an intact sensory–motor loop pathway which is interrupted in the case of a lower motor neuron lesion.

In tetraplegia, regardless of the level of completeness, access to a Saratoga hand cycle, enables cardiovascular exercise options. Yet, for people with a complete tetraplegia above C4 who are unable to use a Saratoga hand cycle, other than FES cycling there are limited options to produce cardiovascular benefits (Peng, et al., 2011). For individuals with motor incomplete injuries above T12 the FES cycle is a beneficial adjunct to rehabilitation (Lam et al., 2007). However once in a community setting many such individuals will have access to other forms of exercise to achieve cardiovascular and bone benefits for example, static cycling, walking and swimming. There may be some individuals who find the specific strengthening to the gluteal muscles beneficial to improve comfort with sitting or to assist with gait rehabilitation (Wahman K, Personal Communication June 2012). A cost effective way of providing this equipment for such individuals could be through a community resource where a number of bikes are available for use by individuals with SCI in the community, monitored by a therapist (Wahman K, Personal Communication June 2012).

Appendix 3 (Batty, Personal Communication, March 2012) outlines expert opinion illustrating the potential role and place of FES cycle training for individuals with SCI depending upon the level and extent of their impairment.

2. Review Methods

2.1 Search Strategy

A search was carried out using the following databases: Web of Knowledge, CINAHL, EMBASE, Medline, PUBMED, ScienceDirect and Web of Science focusing on articles of relevance to FES cycling and SCI. In addition SCI networks known to the review authors were also monitored and a brief Facebook survey of FES users was undertaken (Appendix 2).

The search strategy covered the period 1992 to 2011 and the following keywords were employed:

- FES bikes
- FES cycle
- Functional electrical stimulation

These terms were combined with:

- SCI
- Spinal cord
- Spinal cord injury
- Spinal cord impairment

3. Findings of the Review

In total 35 research articles were found and of these, 19 were included in the review based on title and article content, for their relevance to the cardiovascular and health benefits of FES in SCI populations. The studies included in the review and summarized in Table 2 have a number of limitations including:

(i) Small sample sizes

(ii) Inclusion of mixed SCI participants (incomplete and complete injuries)

(iii) Significant variability in training regimes across studies.

These limitations reduce the external validity of the research findings. In mixed samples of SCI participants where the results were not analysed on the basis of injury type or severity (e.g. complete, incomplete, level of lesion), the relative effectiveness of FES across different levels of SCI severity is unable to be assessed. This also means pooling results (e.g. as part of a systematic review with meta-analysis) is difficult and most importantly high quality evidence available to guide clinical management decisions is lacking.

There are currently two Australasian trials underway investigating the use of FES cycling as part of the Spinal Cord Injury Physical Activity (SCIPA) study series (Galea et al., 2009). These two studies are the SCIPA Full On and SCIPA Switch On studies.

SCIPA Full-On is a randomised controlled trial (RCT) comparing a triad of innovative therapy techniques (body weight support treadmill training, FES cycling and trunk training) [the intervention group] with a control group using a traditional upper limb and cardiovascular circuit training programme. Full On is in its second year of recruitment and includes study sites in Australia and New Zealand.

SCIPA Switch-On is an RCT comparing the use of FES cycling and passive cycling in 50 individuals with a SCI above T12 across four sites: Christchurch, Melbourne, Perth, and Brisbane. This 12-week treatment programme will start within a week of injury. Ethical approval has been given for this study, which commenced in New Zealand in April 2012. The two groups that individuals will be randomized into are:

Group A: FES Cycling Group

Participants assigned to this group will undertake up to 60 minutes of leg cycling four days a week for 12 weeks. Surface electrodes will be applied to gluteal, quadriceps, and hamstrings muscles. Stimulation intensity will be gradually increased to a maximum of 140 mA, pulse width of 0.3 – 0.5ms and frequency of 35Hz. Participants will exercise at the maximal power output possible at their level of recovery. While patients are confined to bed, the MOTOmed Letto cycle with a Hasomed RehaStim FES Unit will be attached to the end of the bed and patients will cycle whilst supine. Once mobilised, patients will use an upright RT300 bike.

Group B: Passive Cycling Group

Participants allocated to this group will undertake up to 60 minutes of passive cycling four days a week at identical pedal cadence to Group A. Cycling while the participant is confined to bed will be with the MOTOmed Letto device and once mobilised into a wheelchair with the RT300 cycle but without FES-evoked contractions.

The primary outcome of this study relates to changes in muscle mass - the cross-sectional area of thigh and calf muscles.

The secondary outcomes are:

a) Serum sclerostin levels (an inhibitor of bone formation, and could be a link between mechanical unloading and disuse osteoporosis in humans).

b) Neurological function and body composition.

c) Depression and quality of life.

TABLE 2: Summary of Studies included in the Review

Author	Study	Method	FES cycle	Results/conclusion
Johnston, et al., 2009	Effects of cycling with and without electrical stimulation on cardiorespiratory and vascular health in children with SCI.	RCT. 3 groups. FES cycling, Passive cycling, or non cycling group who received electrical stimulation	RT300 for FES cycling RT 100 motorized cycle for passive cycling and Portable FES unit for electrical stimulation group	Overall looking at pre-post values there were no differences between groups however, for the cardiorespiratory and vascular measures studied, only children in the FES cycling group showed significant positive differences. Interestingly the electrical stimulation only group had the largest decrease in cholesterol levels. To note the assessor was not blinded to the group and the groups were not equal in age and injury level and the information was based on parental provided information.
Johnston, et al., 2011	Muscle changes following cycling and/or electrical stimulation in paediatric spinal cord injury.	RCT 3 groups	RT 100 motorised cycle	Children received either electrically stimulated exercise experienced changes in muscle size, stimulated strength or both. Electrical stimulation only had the greatest change in quadriceps volume. While the FES cycling group had increases in strength and volume.
Decker, et al., 2010	Alternating stimulation of synergistic muscles during FES cycling improves endurance in persons SCI.	Pre-post intervention study	Ergys2 automated recumbent bicycle	FES-cycling performance can be enhanced by a synergistic muscle alternation stimulation strategy. This article looked at alternative ways of using the stimulation in FES but has limited clinical applicability at this stage.
Hunt, et al., 2006	Comparison of stimulation patterns for FES-cycling using measures of oxygen cost and stimulation cost.	Single case study	Recumbent tricycle adapted for paraplegic FES-cycling	Oxygen cost and stimulation cost measures both allow discrimination between the efficacies of different muscle activation patterns during constant-power FES-cycling. However, stimulation cost is more easily determined in real time, and responds more rapidly and with greatly improved signal-to-noise properties than the ventilatory oxygen uptake measurements required for estimation of oxygen cost. No clinical applicability from this single case study.

Table 2: Continued

Frotzler, et al., 2009	Effect of detraining on bone & muscle tissue in subjects with chronic SCI after a period of FES cycling.	Pre-post intervention study	High-volume FES-cycling programme (up to 5 sessions per week, for one year) with one subject continuing a reduced Programme (2–3 training sessions per week,).	Bone and muscle benefits achieved by one year of high-volume FES-cycling are partly preserved after 12 months of finishing training, whereas reduced cycling 2-3 sessions a week maintains the bone and muscle mass gained. The authors suggest that high-volume FES-cycling has clinical relevance for at least one year after stopping training. However, this is based on the results of one individual. The subjects did use high intensity training 5 sessions a week for one year and were all ASIA A.
Liu, et al., 2007	Effects of functional electrical stimulation on peak torque and body composition in patients with incomplete spinal cord injury.	Pre-post intervention study	Hybrid cycling system with portable FES device	A significant increase in bilateral thigh girth and significant increase in muscular peak torque of knee flexion and extension were found after 8 weeks of training. Lean body mass increased mildly after complete treatment. However there was no change in BMI, fat percentage, and bone mass. This was only an eight-week study.
Perret, et al., 2010	Feasibility of functional electrical stimulated cycling in subjects with spinal cord injury An energetic assessment.	Pre-post intervention study	Individually adapted recumbent tricycle with Stanmore Stimulator	FES cycling appears to be a feasible and promising training alternative to upper body exercise for subjects with spinal cord injury. 4 - 8 hours of FES cycling were necessary to reach the recommended weekly exercise caloric expenditure essential to induce persistent health benefits.
Szecsi, & Schiller, 2009	FES propelled cycling of SCI subjects with highly spastic leg musculature.	Pre-post intervention study	A stationary tricycle its front wheel replaced by a torque transducer	Findings suggest that modulated middle frequency alternating current (MFAC) stimulated cycling of strongly spastic SCI subjects is more effective in terms of generated isometric torque and power than stimulation with LFRP. Thus, more health benefits, e.g., cardiovascular and muscular training and spasticity-decreasing effects, can be expected faster using MFAC instead low frequency rectangular pulse (LFRP) in stimulation-propelled cycling. Paper looks at methods of applying FES to legs with spasticity rather than functional outputs.

Table 2: Continued

Griffin, et al., 2008	Functional electrical stimulation cycling improves body composition, metabolic and neural factors.	Pre-post intervention study	Ergys2	30 minutes of FES cycling per day, 3 times a week, for 10 weeks significantly improved lean muscle mass, cycling power, work capacity, endurance, glucose tolerance, insulin levels, inflammatory measures, and motor and sensory neurological function. There were no significant differences in bone or adipose (fat) tissue.
Frotzler, et al., 2008	High-volume FES-cycling partially reverses bone loss in people with chronic spinal cord injury.	Pre-post intervention study	Individually adapted recumbent tricycle with portable FES	Study concluded that high-volume FES-induced cycle training has clinical relevance as it can partially reverse bone loss and thus may reduce fracture risk. NB trabecular and total bone mineral density (BMD) as well as total cross sectional area in the distal femoral epiphysis increased significantly but no changes were seen at the tibia. Participants worked up to 5 sessions a week of 60 mins. Participants had 76.6% compliance.
Haapala, et al., 2008	Leg joint power output during progressive resistance FES-LCE cycling in SCI subjects developing an index of fatigue	Pre-post intervention study	FES-LCE system – ERGYS 1	An index of fatigue was successfully developed, proportionalizing knee power capacity during cycling to a predetermined value of fatigue. The findings suggest that the present cycling protocol is not sufficient for a rider to gain the benefits of FES and thus raises speculation as to whether or not progressive resistance cycling is an appropriate protocol for SCI subjects.
Mutton, et al., 1997	Physiologic responses during functional electrical stimulation leg cycling and hybrid exercise in SCI subjects.	Subjects acted as own control.	REGYS1 ergometer and computer system with FES-LCE	Subjects demonstrated that hybrid exercise performed twice a week provided sufficient intensity to improve aerobic capacity and provide a medium whereby patients with SCI could burn more calories than via FES-Leg Cycle Exercise alone. This has important implications for improving the health and fitness levels of individuals with SCI and may ultimately reduce their risk of cardiovascular disease. Again this link is speculated rather than proven. The participants completed the three treatments sequentially, which may have meant training adaptations were made prior to the hybrid training. Eleven participants completed stage 1 and 2 with only 8 participants continuing to the third phase.

Table 2: Continued

Duffell, et al., 2010	Power output during functional electrically stimulated cycling in trained spinal cord injured people.	Pre-post intervention study	Individually adapted recumbent tricycle with portable FE	In SCI people, muscle thickness, strength, & peak power output (PO) reached 88, 34, and 13% of able-bodied (AB), respectively. Peak PO was lower than expected in trained SCI people. Muscle recruitment and efficiency during FES cycling require optimization to improve PO. A Maximal Stimulation Test (MST) is a more convenient and informative measure of PO during FES cycling. Information useful for research but has little clinical applicability.
Bhambhani, et al., 2000	Quadriceps muscle de-oxygenation during FES in adults with spinal cord injury.	Cross-sectional study compared healthy subjects with SCI subject's injury levels from C5 to T12).	ERGYS II FES cycle ergometer	FES exercise in SCI subjects elicits: (a) modest increases in the cardiorespiratory responses when compared to resting levels; (b) lower degree of muscle de-oxygenation during maximal exercise, and (c) faster changes in muscle de-oxygenation. This is based on 7 individuals with SCI and matched healthy subjects on one fitness test. Little clinical applicability.
Kakebeeke, et al., 2008	Training and detraining of a tetraplegic subject high-volume FES cycle training	Pre-test post-test case study	FES cycle ergometer (StimMaster)	It is possible to increase maximal power output, cardiopulmonary fitness, and bone parameters of the paralyzed limbs in tetraplegia by high-volume cycle training. However, if training is not maintained, these improvements are lost. In tetraplegic subjects, it may be difficult to maintain the high level of training required to achieve benefits. Only one subject very difficult to generalize these results.
Peng, et al., 2011	Review: Clinical benefits of FES cycling exercise for subjects with central neurological impairments	Review	FES cycle	The review supported findings for the clinical efficacy of FES Cycling Exercise reducing the risk of secondary medical complications in subjects with paralysis. Pilot study indicated that the decrease of leg spasticity in subjects with CP is one of the acute effects of FESCE. Viewed abstract not article.

4. Discussion

4.1 Discussion of the evidence

The findings of this report highlight the following conclusions;

- Intensive FES cycling training of 4-8 hours a week can provide the recommended weekly exercise caloric expenditure essential to induce persistent health benefits and muscle and bone effects.
- The effects of the FES cycling are more evident with increased intensity and duration of use.
- The beneficial effects from the uptake of exercise diminish once the FES cycling ceases.

Studies comparing FES cycling with passive cycling showed *only* cardiovascular benefits of FES cycling. These findings may be limited by the quality of the studies. Results are reported for mixed samples of SCI participants with no separate analyses of participants with different levels and severity of SCI may obscure important group effects for different SCI levels. More research is required to examine these issues. Therefore the outcomes of the SCIPA trials are highly relevant and of particular interest regarding the focus of this Rapid Review. The SCIPA Switch-On study is a large scale RCT and the results will provide high quality data to determine whether FES cycling or passive cycling is the preferred treatment in the acute stage of SCI. Results from the SCIPA Switch On study will be available by early 2014.

There appears to be a lack of evidence around the cost benefit of FES bikes in SCI.

There is a lack of evidence investigating the impact of FES on overall patient outcomes. However, in tetraplegia at C4 and above it is likely that they will have limited options for any cardiovascular workout other than FES cycling.

There is evidence of increased risk of cardiovascular problems, reduced bone density, poor muscle health and pressure sores as secondary complications in SCI (Wahman, et al., 2010a, Wahman, et al., 2010b, Wahman, et al., 2011). While the literature demonstrates benefits for cardiovascular and muscle outcomes with the use of FES cycling, the prevention of secondary complications such as cardiovascular problems, reduced bone density, poor muscle health, and pressure sores is not directly shown in this research. In a review for the Spinal Cord Injury Rehabilitation Evidence (SCIRE) publication, Warburton et al. (2010) stated that "physical inactivity appears to play a central role in the increased risk for CVD [cardiovascular disease] in persons with SCI" (p 30). Therefore, exercise training should lead to significant reductions in the risk for CVD and improved overall quality of life in the SCI population. However, the relationship between increasing physical activity and health status of SCI has not been evaluated adequately to date. This work is currently underway in Stockholm, Sweden (Wahman, Personal Communication June 2012). Large scale longitudinal studies examining the effects of different training modalities are needed to contribute to a better understanding of the physiologic adjustment processes during FES exercise (Theissen et al., 2002) and the long-term benefits of this approach. Given prevalence rates for SCI in countries such as New Zealand, sufficiently large samples are difficult to sustain without collaborative research efforts and multi-site trials across centres and countries.

Finally, from a pragmatic perspective the research reviewed has commented on the cardiovascular, physiological and psychological health benefits for people with SCI using FES bikes. The article by Peng et al. (2011) emphasized the benefits of having an FES bike in the home for disabled people. An alternative option would be to make FES bikes available in a rehabilitation or community centre. However, people with SCI may find it difficult to travel daily to a clinical/rehab centre in order to use an FES cycle, and this in turn could impede their participation in cycling exercise training. Currently in New Zealand the availability of this equipment in private or community gyms is limited. A review of the clinical benefits of FES cycling carried out by Peng recommended the development of a low-cost FES-cycling ergometer for use in the home as a feasible way to promote health benefits of FES cycling for people with SCI (Peng, et al., 2011).

4.2 Limitations of the review

- This review provides an overview to highlight the key issues and findings regarding the role of FES bikes for SCI populations. An in-depth examination of the evidence and a systematic review of available research was beyond the scope of this review.
- Second, information about the cost-effectiveness of using FES bikes for New Zealand clients could not be sourced, as this information is not readily accessible locally. One of the difficulties compiling such information is that these costs need to be assessed on a case-by-case basis considering individual injury and needs. Given concerns already identified regarding the variability evident based on level and severity of SCI, and the relatively low prevalence of SCI, pooled local information on cost-effectiveness may be of limited value.

5. Summary and Conclusions

This review has highlighted a number of issues pertaining to the use and application of FES cycles for people with SCI, namely:

- FES cycling is not a suitable intervention for individuals with a motor complete SCI below the level of T12, as these individuals do not generally respond to the stimulation.
- In motor incomplete injuries the FES cycle can be a beneficial adjunct to rehabilitation.
- In tetraplegia at C4 and above there are limited options for any cardiovascular workout *other than FES cycling.*
- Of the FES bikes currently on the market, the RT300 cycle has the advantage of an online system where clinicians can monitor and adjust programmes and setting for clients remotely.

Studies included in this review (see Table 2) in combination with those included in the earlier ACC review (2005) support the following conclusions:

- FES cycles have been shown to have potential therapeutic benefits for the cardiopulmonary, muscular, and skeletal systems, as well as psychological functions for people with SCI.
- Compared with conventional therapeutic interventions FES -assisted cycling creates the opportunity for the muscles of paralysed limbs to contract which improves circulation following SCI and increases cardiac output.
- Given what is known about the physiological benefits of increased exercise for people with SCI, it is evident the use of FES bikes in conjunction with conventional interventions will positively influence cardiovascular health in this at risk population. This is supported by the known physiological benefits of *any* increase in exercise (either passive, active assisted or active) in the presence of extreme inactivity due to widespread paralysis (Wahman 2009).
- FES may help to reduce the risk of secondary medical complications such as cardiovascular problems, reduced bone density, poor muscle health and pressure sores in clients with SCI who experience ongoing significant impairment of motor function. Maintenance of gains appears linked to continued use of FES based exercise.

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Appendix 1 Cardiovascular concerns in spinal cord injury

- Higher prevalence of cardiovascular disease
- Greater morbidity and mortality from cardiovascular causes
- Heightened cardiovascular risk factors:
  - Low high-density lipoprotein cholesterol
  - High total cholesterol and low-density lipoprotein
  - Elevated C-reactive protein
  - Higher prevalence of obesity and greater visceral adipose tissue
  - Increased rate of smoking
  - Physical inactivity
  - Higher prevalence of insulin resistance, diabetes, and metabolic syndrome
- Blood pressure abnormalities (orthostatic hypotension, autonomic dysreflexia)
- Deep vein thrombosis, thromboembolic events
- Rhythm disturbances
  - Bradyarrhythmias, particularly in the acute phase, (e.g., bradycardia, A-V block, cardiac arrest)
  - Reduced heart rate variability
- Blunted cardiovascular response to exercise

(Wahman, 2009)

Appendix 2: Facebook survey of FES bike users March 2012 of SCI clients for feedback on the use of FES bikes in New Zealand

1. How long did you use a FES bike?

I've been using the bike since around Jan/Feb 2008 when it arrived from the USA.

I hadn't used one before. It arrived at Burwood and I came down and learnt to use it with ……. at the ABC centre.

2. What was the brand you used?

RT300 from Restorative therapies

3. What benefits did you gain from using the FES bike?

Reduced spasm. Reduced pain. Increased bowel function. Increased muscle mass. Thus...increased quality of life

4. How often do you use the bike?

Three times per week.

5. Any difficulties/problems you encountered.

Occasional dysreflexia, which stops as soon as I stop biking. Nothing else really.

6. How did you purchase or obtain funding for the bike?

All funds were obtained through fundraising, which took around 12 months over the 2006/07 period. Approx $25k NZD was raised.

(Freeman, March 2012)

Other Comments

1. I used the FES bike on a regular basis for a couple of months when I was in the auck spinal unit just over a year ago, be happy to share my experience

2. I have been riding an ordinary recumbent trike pedaling with my feet. In fact I cycled across South Island and half of North Island last year. I must have overdone it as I got joint pains and had to pause at Putaruru.
3. I am incomplete paraplegic and still have a foot drop in my both feet so I had to design my own pedals to overcome my weakness. These pedals might be useful for other paras who can use their legs but lack on the lower feet muscles? I had a swollen lymph node in my neck after my bike journey. After starting oil pulling it went down in size so obviously I got the toxins removed.
4. Much of the benefit that comes from FES is due to the movement of the ankle. The ankle and the lungs are the pumps of the lymphatic system just like the heart is the pump of the blood system. By introducing a regular activity that not only provides lymphatic drainage but also electric stimulation the results can be amazing
5. I used the FES bike for approx 10 weeks, 3 half hour sessions a week.
6. I strengthened the muscles in my calves and thighs - helped with ankle flexion - improved stamina - increased confidence - FES was an all round positive experience for me.
7. We only had the one bike at ASU and it takes about 5-8 minutes to get set up and another 5 minutes to detangle - demand was high and you need staff time to get you on and off
8. I used the FES bike in the gym at the Auckland Spinal Unit
9. Don't know the brand - the bike was donated to the ASU by the Rugby Union in 2009.

Appendix 3: The potential role of FES cycle training for individuals with SCI (Batty, 2012)

Injury	**Voluntary exercise**	**FES cycling**	**Cardiovascular Fitness**
	Options	**Options**	**Options**
Higher Level Tetraplegia **(C1 – C4)**	Very Limited Arm cranking (Low intensity)	FES leg cycling	FES cycling
Lower Level Tetraplegia **(C5 – T1)**	Arm cranking (Low intensity)	FES leg cycling	Hybrid FES FES cycling Arm cranking
Paraplegia **(T2 – T6)**	Arm cranking	FES leg cycling	Hybrid FES FES leg cycling Arm cranking
Paraplegia **(T7 – T12)**	Arm cranking	Probably limited (Likely lower motor neuron injury)	Active cycling if able Hybrid FES Arm cranking or FES cycling
Paraplegia **(L1 – S5)**	Arm cranking or limited active cycling	FES leg cycling	Active cycling if able Hybrid FES Arm cranking or FES cycling
Incomplete Injuries **ASIA, C, D**	Arm cranking or limited active cycling	FES leg cycling	Active cycling if able Hybrid FES Arm cranking or FES cycling