Research paper

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Functional electrical stimulation after spinal cord injury

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Research question: What is the efficacy of intensive lower limb Functional Electrostimulation Therapy (FES) for individuals with Spinal cord Injury OR C2 level Tetraplegia?

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1. Contents

2. Summary

This research paper focussed specifically on functional electrical stimulation (FES), a therapeutic treatment used in rehabilitation for people with spinal cord injury (SCI). This paper focuses on FED used as an exercise or therapeutic modality to improve lower limb health and function. Most research focusses on FES cycle training. This paper will not discuss FES used for improving upper limb function or FES used as a neuroprosthesis to aid standing and walking.

There is consistent evidence that FES training can improve muscle health, power output and aerobic fitness and spasticity in people with SCI. Despite the consistency, there are some quality issues in the literature which downgrade the reliability of this evidence. There is inconsistent evidence for other outcomes such as bone health, cardiovascular and metabolic factors, fat mass, muscle strength, subjective well-being and functional and neurological outcomes.

Effects are present for people with incomplete and complete SCI, though effects appear greater for people with complete SCI. There is limited evidence for older people (over 65 years) and for people with high cervical lesions and so evidence may not generalise for this group.

Some studies recommend dosage though specific recommendations are less reliable. Typical frequency of FES training for clinical studies is 2 – 3 times per week.

The only clinical guideline available for this research concerned only FES for upper limb exercise. A clinical practice guideline focussing on FES cycle training is currently in development though the publication date is unknown.

3. Functional Electrical Stimulation

FES is a type of neuromuscular electrical stimulation (NMES). FES is distinguished from other types of NMES (for example, transcutaneous electrical nerve stimulation (TENS)) as electrical stimulation is applied while the muscles are engaged. A typical FES session can involve electrical stimulation to paralysed muscles during an activity like cycling or rowing. FES can be used to improve blood circulation, range of motion, muscle strength, muscle spasticity, fitness and may improve capacity to engage in functional activities. FES can be used to stimulate muscles or nerves and may be applied on the surface of the skin (transcutaneously) or under the skin (percutaneously). FES has been investigated for people who have experienced SCI, stroke, traumatic brain injury or who have other neuromuscular conditions such as multiple sclerosis (Karamian et al, 2022; van der Scheer et al, 2021; Luo et al, 2020; Marquez-Chin & Popovic, 2020).

The treatment can vary by activity (eg. reaching, grasping, standing, walking etc.), frequency and duration of sessions, length of treatment as well as the specific characteristic of the electrical pulse including width, frequency and amplitude. Pulse width can be between 300 and 1000 microseconds (μs). Frequency is usually between 20 and 50 Hertz (Hz). Amplitude can vary between 0 and 100 milliampere (Ma) (Karamian et al, 2022; Luo et al, 2021; Dolbow et al, 2021).

3.1 FES Cycle

Most exercise programs for people with SCI depend on remaining voluntary function of upper limbs. However this cannot prevent the progression of muscular atrophy or circulatory disorders in the paralysed lower limbs (Kasukawa et al, 2022). Other types of exercise programs are also required for people with SCI without voluntary upper limb function (Martin Ginis et al, 2018). FES cycling has been used since the 1980s to assist people with SCI to exercise their paralysed lower limbs (Kasukawa et al, 2022; Luo et al, 2020). FES cycle training utilises a device which delivers electrical impulses to a user's paralysed muscles, enabling them to pedal a motorised cycle machine. Many FES cycle devices are portable and can be used in the home (RT300, 2019).

4. Guidelines

Martin Ginis et al (2017) stated in their general exercise guidelines for people with SCI, that recommendation around FES training were not possible due to the limited number of high quality studies. The authors also note that the panel responsible for developing the guidelines determined that recommendations could not be offered for exercise guidelines for people with acute SCI. This was the same year that Fehlings et al (2017) published their clinical practice guideline for the management of patients with acute SCI. Fehlings et al offer a weak recommendation based on low quality evidence for FES to improve hand and upper limb

function for people with acute and subacute cervical SCI. They do not make any recommendations regarding use of FES training for lower limb health or function.

The state of the evidence changed in subsequent years and van der Scheer et al (2021) stated their intention to use their systematic review to develop evidence-based clinical practice guidelines for FES cycling training. These guidelines are not yet published.

5. Efficacy of FES after spinal cord injury

Several narrative reviews describe evidence the FES training can improve outcomes for people with SCI including functional independence, spasticity, muscle health and body composition (Atkins et al, 2022; Dolbow et al, 2021; Luo et al, 2020). A more systematic review of the evidence shows greater inconsistency in the literature for some outcomes.

The most comprehensive review of the evidence to date (van der Scheer et al, 2021) found with moderate certainty that FES led to improved muscle health for adults with SCI and high certainty that FES led to improved muscle health for young to middle-aged adults. While there were consistently positive findings among the studies reviewed, the authors found some imprecision around effect sizes and limited generalisability for adults over 65 years. Further, subjects with high cervical or lumbar lesions were under-represented in the literature so conclusions may not generalise for this group. van der Scheer et al also found low certainty evidence that FES training improves aerobic fitness and power output of lower limbs. Both outcomes showed very serious risk of bias despite a high level of consistency across studies. Inconsistent evidence of very low certainty was found for bone health, cardiovascular and metabolic factors, fat mass, muscle strength, subjective well-being and functional and neurological outcomes.

Of note, while van der Scheer et al reviewed 92 studies including 999 participants, only two studies were RCTs with low risk of bias. Neither of these two studies produced significant results. The authors were not able to complete a meta-analysis due to limitations in the literature and so they were not able to draw conclusions about optimum dose or pulse characteristic required to achieve the observed effects.

Bekhet et al (2022) investigated the effect of NMES and FES on body composition parametres such as muscle mass, cross-sectional area, fat mass, fat-free mass, intramuscular fat, and lean mass. They found FES training could assist in muscle growth as measured by cross-sectional area, lean mass and fat-free mass. The greatest effects could be seen in stimulated muscles with little or no change to non-stimulated muscles. Inconclusive evidence was obtained for reductions in intramuscular fat and fat mass. In contrast, both Dolbow et al (2021) and Atkins et al (2022) suggested FES training could reduce fat mass or intramuscular fat, though their review articles are not systematic and did not include a meta-analysis.

Bekhet et al (2022) were not able to draw conclusion about duration of FES training though they suggest twice weekly sessions are more appropriate than training 3 - 5 times per week. This frequency:

ensured reasonable recovery time from muscle fatigue after an acute bout of NMES/ FES exercise, considering that skeletal muscle in persons with SCI is highly fatigable and more susceptible to exercise-induced or delayed onset muscle injury (Bekhet et al, 2022, p.1175).

van der Scheer (2021) found minimal evidence to support a reduction of spasticity after FES training. However, they did not consider spasticity separately but grouped it with other secondary outcomes. Reviews that target spasticity find more consistent evidence that FES training can improve spasticity (Bekhet et al, 2019; Fang et al, 2022; Alashram et al, 2022). In their meta-analysis, Bekhet et al (2019) found FES training delivered with a pulse frequency of 20-30Hz can reduce spasticity by 45-60%, though they note lack of evidence that the effect is maintained for more than 24 hours after treatment. Fang et al (2021) show improvements in spasticity, walking ability and lower limb strength. The authors also support Bekhet et al's conclusion regarding pulse frequency and further show that reduced spasticity can be obtained after 20 sessions. However, they also note that evidence does not show that more sessions produces a greater effect, suggesting a possible plateau. The sub-group analysis showed the effects are present for both complete and incomplete SCIs and that reduction in spasticity was greater in people with complete SCIs. Sessions were between 20 and 60 minutes and occurred between 2 and 4 times per week. Time since injury was either varied (4 weeks to 17 years) or not reported. Furthermore, they found that the effects are not simply due to the electrical stimulation but the cycling itself also contributed. While Alashram et al (2022) supported the efficacy of FES training on reduction of spasticity, they could not draw conclusion around frequency or duration of sessions, treatment duration or pulse characteristics. Despite significant overlap in the studies included in these three reviews, the researchers assess the quality of the included studies differently. Bekhet et al (2019) rate the overall quality as moderate to high, whereas Alashram et al (2022) rate the overall quality as low. While quality may be an issue, the consistency of the effect on spasticity found in the literature should upgrade the strength of the evidence. More specific conclusions around dosage should still be read with caution.

6. Risks

According to the review by van der Scheer et al (2021) adverse events were not widely reported. Some adverse events were reported in only 21 of the 92 studies. A total of 18 participants experienced adverse events including hypotension, increased spasticity, light-headedness, skin redness, bowl accident, autonomic dysreflexia, leg swelling, and haematoma.

Marquez-Chin and Popovic (2020, pp.9-10) list the following clinical considerations which may prompt reconsideration of FES training intervention:

- Poor skin condition: Pressure injuries (a.k.a. pressure sores) or irritation prevents the use of self-adhesive electrodes.

- Poorly controlled epilepsy: when epilepsy is managed with medication with no seizure experienced for a reasonable period, FES can be used.
- A history of significant autonomic dysreflexia: autonomic dysreflexia can be present in individuals with SCI above the sixth thoracic level (T6).
- Pregnancy: the effect of FES on the unborn child is not known in pregnancy.
- Cardiac pacemakers: electrical stimulation may interact with the electrical signals from pacemakers interfering with their functioning.
- Cancerous tumour: patients with a cancerous tumour in the area of the electrical stimulation should be excluded as potential tumour growth is a concern with the increased local blood flow resulting from the stimulation.
- Exposed metal: patients with exposed orthopaedic metal work should not receive electrical stimulation in the involved area.
- Unhealed fracture: muscle contractions produced by FES around an unhealed fracture may result in a displaced fracture.
- Suspected, diagnosed, or uncontrolled cardiovascular conditions: the cardiovascular demand resulting from the muscle contractions produced by the FES may require special attention prior and during delivery of stimulation.
- Botulinum toxin: patients on botulinum toxin therapy for their upper limb, a procedure for reducing spasms after SCI, or that have received it in the last 6 months prior to the use of FES, may not respond to stimulation

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