Date: September 5, 2014

Title: The use of electrical stimulation (e-stim) during cycling for individuals with spinal cord injury (SCI) age 5 to 21 years [1]

Clinical Question

P	*(Population/Problem)*	Among children aged 5 to 21 years who sustain an incomplete* traumatic spinal cord injury
I	*(Intervention)*	does use of electrical stimulation during cycling
C	*(Comparison)*	compared to no electrical stimulation
O	*(Outcome)*	improve physical outcomes?

*Definitions for terms marked with * may be found in the Supporting Information section.*

Target Population for the Recommendation

Children, adolescents, and young adults with spinal cord injury age 5 to 21 years

Inclusions

- Diagnosis of spinal cord injury, traumatic onset
- Categorized according to the American Spinal Injury Association (ASIA) impairment scale as ASIA C and D* and
- A minimum of 12 months post SCI

Exclusions

- Individuals categorized as ASIA A, B, or E*
- Individuals with a history of seizure disorder, cardiovascular disease, or hip dislocation
- Individuals with severe spasticity or pathological fractures of the lower extremities
- Individuals who are ventilator dependent
- Individuals with uncontrolled autonomic dysreflexia or heterotropic ossification
- Individuals with lower motor neuron syndrome of the lower extremities

Recommendations

1. It is recommended that functional electrical stimulation (FES) cycling intervention be considered for children age 5 to 13 years, who are at least 12 months post SCI at the cervical or thoracic level and have innervated lower extremity muscles to improve rehab outcomes *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*.

   Note: In Johnston (2009), children in the FES cycling group showed a clinically significant improvement in VO2max, while children in the passive cycling group showed decreased VO2 and the e-stim alone group showed no change. Passive cycling and e-stim alone led to no or minimal changes in the cardiorespiratory or cardiovascular measures studied. Lack of effect on other variables suggests an increase intensity may be needed, but further study is required *(Johnston 2009b [2b])*.

[1] Please cite as: Strenk, M., Cincinnati Children's Hospital Medical Center: Best Evidence Statement The use of electrical stimulation (e-stim) during cycling for individuals with spinal cord injury (SCI) age 5 to 21 years, http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/best.htm, BESt 192, pages 1-9, September 5, 2014.

Location of e-stim	Pulse Duration	Frequency of Electrical Current	Amplitude	Treatment Frequency	Treatment Plan	Duration of Treatment
Bilateral quadriceps, hamstrings, and gluteal muscles *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*	150 µs to 300 µs *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*	33 Hz cyclical current *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*	Increased automatically in order to maintain a cadence of 50 rpm, with a maximum of 140 mA *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*	1 hour per day, 3 days per week *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*	10 minutes of passive warm-up, 40 minutes of FES cycling, 10 minutes of passive cool-down *(Johnston 2009b [2b])*	6 months of training *(Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*

Note 1: The literature recommends a lower frequency of 33 Hz *(Lauer 2011 [2b], Johnston 2009b [2b])* in the pediatric population compared to higher frequencies used in adult populations.

Note 2: A smaller pulse duration may be more comfortable for children *(Local Consensus [5])*.

Note 3: The child should be positioned to avoid hip internal rotation and adduction in order to minimize the risk of hip subluxation *(Johnston 2009a [2b])*.

2. It is recommended that FES cycling interventions be used for young adults age 18 to 21 with SCI who are at least 12 months post SCI and have innervated lower extremity muscles *(Sadowsky 2013 [4b], Griffin 2009 [4b], Local Consensus [5])*

Location of e-stim	Pulse Duration	Electrical Frequency	Amplitude	Treatment Frequency	Treatment Plan	Duration of Treatment
Bilateral quadriceps, hamstrings, and gluteal muscles *(Sadowsky 2013 [4b], Griffin 2009 [4b])*	500 µs *Griffin 2009 [4b])*	50 Hz burst modulated sinusoidal with 4 kHz middle frequency alternating current *(Griffin 2009 [4b])* 100 Hz constant current *(Sadowsky 2013 [4b])*	Not to exceed 140 mA, with a target cadence of 49-50 rpm *(Sadowsky 2013 [4b], Griffin 2009 [4b])*	2-3 times per week *(Sadowsky 2013 [4b], Griffin 2009 [4b], Local Consensus [5])*	1 minute of passive warm-up, 30-60 minutes of FES cycling with rest breaks if unable to pedal the full duration consecutively *(Sadowsky 2013 [4b], Griffin 2009 [4b])*	10 to 20-26 weeks of training *(Griffin 2009 [4b])*

Note 1: The literature recommends a higher frequency of 50Hz *(Johnston 2009a [2b], Griffin 2009 [4b])* to 100Hz *(Sadowsky 2013 [4b])* in adult populations compared to lower frequencies used in the pediatric population.

Note 2: When choosing stimulation settings for FES cycling, consideration should be given for the individual's physiological condition, as well as the intended exercise outcome *(Sadowsky 2013 [4b])*

Discussion/Synthesis of Evidence related to the recommendations

The evidence on electrical stimulation for rehabilitation in children with spinal cord injury is lacking, and much of the available evidence is low level. In general, sample sizes in the reviewed studies tended to be small and the population studied was not homogeneous in terms of level of SCI, making it difficult to generalize findings. Also, studies did not have control groups that received no intervention, as that would be unethical with a SCI population *(Johnston 2009b [2b])*.

Improvements were found with FES cycling, indicating physical benefits in both the pediatric and adult population *(Lauer 2011 [2b], Johnston 2009a [2b], Johnston 2009b [2b], Sadowsky 2013 [4b], Griffin 2009 [4b])*. Functional outcomes, however, were not assessed in any of the pediatric literature on FES cycling, so it cannot be determined whether FES in addition to cycling leads to improved functional outcomes in this population *(Peng 2011 [5b])*.

A 6 month home cycling program performed for 1 hour per day 3 times per week may have benefits for bone mineral density (BMD), muscle volume, stimulated quadriceps strength, resting heart rate *(Lauer 2011 [2b], Johnston 2009b [2b], Johnston 2008 [4b])* and VO2 *(Johnston 2009b [2b])*. BMD improvements were found at the hip, distal femur and proximal tibia, but did not reach statistical significance *(Lauer 2011 [2b])*.

FES cycling may lead to spasticity reduction *(Johnston 2009b [2b], Sadowsky 2013 [4b], Johnston 2008 [4b])*, cardiovascular *(Fornusek 2004 [2b], Johnston 2008 [4b])*, and muscular *(Sadowsky 2013 [4b], Hakansson 2010 [4b], Griffin 2009 [4b], Wilder 2002 [5b])* benefits, decreased inflammatory markers *[Griffin 2009 4b]*; decreased blood glucose and insulin levels *(Griffin 2009 [4b])* and a significant increase in ASIA motor and sensory scores *(Sadowsky 2013 [4b], Griffin 2009 [4b], Szecsi 2009 [4b])* in adults, age 18 and older, with SCI. In adults, FES cycling may also lead to increases in forced vital capacity (FVC), forced expiratory volume at 1 s (FEV1), forced inspiratory capacity (FIC), cardiac output (CO) and stroke volume (SV), as well as a reduction in pressure sores, improved cardiopulmonary capacity and reduced risk of cardiovascular disease *(Griffin 2009 [4b], Szecsi 2009 [4b], Johnston 2008 [4b])*.

Thirty minutes of FES cycling three times per week for 10 weeks significantly improved lean muscle mass, cycling power, work capacity, endurance, glucose tolerance, insulin levels, inflammatory markers, and motor and sensory neurological function; however no improvements were observed in plasma cholesterol level or triglycerides. FES cycling three times weekly for 8 weeks resulted in decreased body fat by 2%, but training was insufficient to impact bone mineral density *(Griffin 2009 [4b])*. FES pedaling at a higher cadence results in power training, while low cadence may be optimal for strength training. In addition, muscle fatigue is lower at a slower pedal cadence, allowing individuals to participate in sessions of greater duration *(Fornusek 2004 [2b])*.

In determining the strength of the recommendation, the development group made a considered judgment in a consensus process which was reflective of critically appraised evidence, clinical experience, and these dimensions:			
Given the dimensions below and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statement above reflect the strength of the recommendation as judged by the development group. (Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)			
1. Grade of the Body of Evidence	☐ High	☐ Moderate	☒ Low
Rationale:			
2. Safety/Harm (Side Effects and Risks)	☒ Minimal	☐ Moderate	☐ Serious
Rationale: Hip subluxation is a common complication with pediatric onset SCI, especially when the injury occurs before age 10 years. FES cycling was shown to be safe for children with SCI and did not cause hip subluxation *(Lauer 2011 [2b], Johnston 2009a [2b])*.			
3. Health benefit to patient	☐ Significant	☒ Moderate	☐ Minimal
Rationale: E-stim may result in spasticity reduction, cardiovascular, and muscular benefits *(Sadowsky 2013 [4b], Hakansson 2010 [4b], Szecsi 2009 [4b], Wilder 2002 [5b])*. Training intensity of current FES cycling systems may not be high enough to produce continual training gains over long periods of time *(Fornusek 2004 [2b])*.			
4. Burden to adhere to recommendation	☐ Low	☐ Unable to determine	☒ High
Rationale: Adherence to the FES cycling group is affected by added time for set-up, occasional computer malfunction, and the need for supervision to advance resistance *(Johnston 2009b [2b])*. One problem limiting FES exercise is rapid muscle fatigue, which limits the exercise load *(Fornusek 2004 [2b])*. Effective utilization of e-stim requires a significant time commitment on the part of the individual with SCI *(Local Consensus [5])*. Results suggest cycling can be performed at home with caregiver supervision *(Johnston 2008 [4b])*.			
5. Cost-effectiveness to healthcare system	☐ Cost-effective	☒ Inconclusive	☐ Not cost-effective
Rationale: Improved physical findings and reduced long-term complications associated with SCI may contribute to decreased cost of medical care, as measured by decreased hospital admissions and use of health resources over time *(Sadowsky 2013 [4b], Local Consensus [5])*. However, continuous use of FES is needed to maintain health benefits across the lifespan *(Griffin 2009 [4b])* and expense and time training required may outweigh any benefits gained by the individual *(Fornusek 2004 [2b])*.			
6. Directness of the evidence for this target population	☐ Directly relates	☒ Some concern of directness	☐ Indirectly relates
Rationale: For adults, studies have shown that cycling and FES produce positive effects, including increased muscle mass, lean body mass, muscle force, muscle endurance and energy expenditure, which translates to improved heart rate, stroke volume, and cardiac output during exercise and at rest *(Johnston 2009b [2b], Sadowsky 2013 [4b], Hakansson 2010 [4b], Griffin 2009 [4b], Szecsi 2009 [4b], Johnston 2008 [4b], Wilder 2002 [5b])*. However, there is little information on the potential benefits of e-stim on children with spinal cord injury *(Johnston 2009a [2b], Johnston 2009b [2b], Johnston 2008 [4b])*			
7. Impact on morbidity/mortality or quality of life	☐ High	☒ Medium	☐ Low
Rationale: Because of improvements in health care, individuals with SCI face some health problems experienced by the general population, in addition to neuromuscular effects of SCI which can lead to decreased quality of life and significant lifetime medical costs *(Johnston 2008 [4b])*. The benefits of exercise that can be achieved using cycling and FES may contribute to improved general health and quality of life *(Sadowsky 2013 [4b])*.			

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Implementation

Applicability & Feasibility Issues
It is important to identify effective intervention for patients with chronic spinal cord injury in order to maximize rehabilitation *(Local Consensus [5])*. While the impact of electrical stimulation on functional outcomes has not been definitively demonstrated in pediatrics, its use should be considered because of potential benefits for BMD, muscle volume, stimulated quadriceps strength, resting heart rate and VO2 *(Johnston 2009a [2b], Johnston 2009b [2b])*.

In order for FES cycling to be feasible for patients, appropriate cycling and e-stim equipment must be readily available for individual patient use. Cycling is an ideal mode of exercise in which to deliver e-stim, because it recruits a large lower limb muscle mass and is a familiar form of exercise to a majority of patients *(Johnston 2009b [2b], Fornusek 2004 [2b])*.

Electrical stimulation should be provided by occupational therapists and physical therapists knowledgeable on the use of electrical stimulation. Therapists should be able to individualize the treatment based on the patient injury and presenting problems. Consideration should be given for length of treatment sessions and therapists' schedules should be managed accordingly, because this intervention can require a high time resource. In addition, considerable physical effort may be required from the therapist(s) to set up the patient in the equipment *(Local Consensus [5])*.

Relevant CCHMC Tools
OTPTTR Workflow: Neuro-muscular Electrical Stimulation (NMES) Units

Outcome Measures and Process Measures
The percent of individuals aged 5-21 years with chronic traumatic spinal cord injury who receive FES cycling intervention and demonstrate a reduction in dependency in functional skills.

The percent of individuals aged 5-21 years with chronic traumatic spinal cord injury who receive FES cycling intervention and demonstrate improved cardiovascular/cardiorespiratory measures.

The percent of individuals aged 5-21 years with chronic traumatic spinal cord injury who receive FES cycle intervention and demonstrate reduced spasticity.

The percent of individuals aged 5-21 years with chronic traumatic spinal cord injury who receive FES cycle intervention and demonstrate improved lower extremity strength in a minimum of 1 muscle group.

The percent of individuals aged 5-21 years with chronic traumatic spinal cord injury who receive FES cycle intervention and whose individualized treatment plan minimally addresses any of the following components:

- Strength
- Endurance/cardiorespiratory function
- Functional skills
- Patient/caregiver education.

The percent of individuals aged 5-21 years with chronic traumatic spinal cord injury who receive FES cycle intervention and whose individualized family goals are captured reliably via the electronic medical record.

SUPPORTING INFORMATION

Background/Purpose of BESt Development

Pediatric spinal cord injury has an incidence of approximately 1.99 per 100,000 children in the United States. A conservative estimate of 5% of SCIs that occur in North America occur in individuals younger than 15 years old, and approximately 20% occur in those younger than 20 years of age *(Costacurta 2010 [4b], Nau 2010 [4b], NSCISC 2013 [5b], Hayes 2005 [5b])*. SCI results in temporary or permanent sensory and/or motor deficits and changes in functional abilities, mobility and activities of daily living. Motor vehicle accidents are reported to be the most common cause of spinal injuries in children. Other causes of pediatric SCI include birth injuries, falls, sports, diving, pedestrian injuries, and gunshot wounds *(Costacurta 2010 [4b], Nau 2010 [4b], Brown 2001 [4b], NSCISC 2013 [5b])*. Survival rates in children with SCI have increased due to advances in care, and children have been reported to show gains in ambulation, functional mobility and activities of daily living following SCI *(Choksi 2010 [4b])*.

Physical deconditioning resulting from sedentary lives of individuals with SCI are known *(Griffin 2009 [4b], Peng 2011 [5b], Wilder 2002 [5b])*. Loss of productive years is a major concern if overall health is not maintained. Individuals with SCI have been shown to have higher rates of type II diabetes than age matched controls and the risk increases with higher neurological deficits. With a SCI, individuals experience increased body fat mass and decreased lean body mass *(Griffin 2009 [4b])*. After SCI, muscle atrophy occurs quickly with decreased lean body mass and less muscle to participate in exercise that would maximally stress the CV system to obtain sufficient benefits. Individuals with SCI have increased risk of cardiovascular disease, metabolic syndrome, and diabetes *(Johnston 2009a [2b], Sadowsky 2013 [4b])*. As children with SCI age, they face typical health problems *(Lauer 2011 [2b], Peng 2011 [5b])*.

In FES, electrical current is used to artificially stimulate intact motor neurons of the peripheral nervous system *(Peng 2011 [5b], Faghri 2005 [5b])*. Muscle contraction is achieved by electrically stimulated motor neurons and motor units, which contract synchronously. Motor units closer to the stimulation source are activated at an increased rate compared to motor units further away, so higher stimulation may be required to maintain a strong muscle contraction. In addition, large diameter motor neurons have a lower threshold of excitation and therefore are activated at a higher rate. In normal muscle fiber, smaller diameter fibers are recruited first. This reversal of normal muscle fiber recruitment and the synchronous activation of motor unit results in less efficient and less selective contraction compared with normal physiology, so fatigue occurs more quickly. Selection of appropriate electrical stimulation parameters, electrodes, and type of control system all impact the smoothness of muscle contraction *(Peng 2011 [5b], Faghri 2005 [5b])*.

This BESt was developed to help guide practice for children and young adults with chronic spinal cord injury, in order to provide the most optimal level of care available.

Definitions

<u>Spinal cord injury:</u> any injury to the spinal cord that is caused by trauma. Symptoms of spinal cord injury, including pain, paralysis, and incontinence, can vary widely based on the level of injury. Spinal cord injuries are classified as "incomplete" or “complete.” Incomplete spinal cord injuries can vary from having no effect on the patient to causing severe functional limitations. A complete spinal cord injury results in a total loss of function.

ASIA Impairment Scale:

<u>ASIA A</u>: Complete SCI, with no sensory or motor function preserved in sacral segments S4-S5

<u>ASIA B</u>: Incomplete SCI, with sensory (but not motor) function preserved below the neurological level and includes sacral segments S4-S5

<u>ASIA C</u>: Incomplete SCI, with motor function preserved below the neurological level and more than half of key muscles below the neurological level have a muscle grade of less than 3

<u>ASIA D</u>: Incomplete SCI, with motor function preserved below the neurological level and at least half of the key muscles below the neurological level have a muscle grade greater than or equal to 3

<u>ASIA E</u>: Normal, with sensory and motor function intact

Chronic spinal cord injury: an injury that occurred greater than twelve months ago.
Functional electrical stimulation: an intervention using electrical currents to stimulate nerves innervating voluntary skeletal muscles affected by incomplete paralysis resulting from spinal cord injury.

Search Strategy
Databases: OVID MEDLINE, OVID CINAHL, WorldCat@OSU
Search Terms: spinal cord injury, SCI, pediatric spinal cord injury, electrical stimulation, functional electrical stimulation, FES, cycling, gait, ambulation, child, adolescent, pediatric
Limits, Filters, Search Date Parameters: English language
Date most recent search was completed: 4/1/2014

Group/Team Members

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Conflicts of Interest were declared for each team member and:

☒ No financial or intellectual conflicts of interest were found.
☐ The following conflicts of interest were disclosed:

Note: Full tables of the LEGEND evidence evaluation system are available in separate documents:

- *Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality (abbreviated table below)*
- *Grading a Body of Evidence to Answer a Clinical Question*
- *Judging the Strength of a Recommendation (dimensions table below and Rationale)*

Table of Evidence Levels *(see note above)***:**

Quality level	*Definition*
1a† or 1b†	*Systematic review, meta-analysis, or meta-synthesis of multiple studies*
2a or 2b	*Best study design for domain*
3a or 3b	*Fair study design for domain*
4a or 4b	*Weak study design for domain*
5a or 5b	*General review, expert opinion, case report, consensus report, or guideline*
5	*Local Consensus*

†a = good quality study; b = lesser quality study

Table of Language and Definitions for Recommendation Strength *(see note above)*:

Language for Strength	*Definition*
It is strongly recommended that… *It is strongly recommended that… not…*	*When the dimensions for judging the strength of the evidence are applied,* *there is high support that benefits clearly outweigh risks and burdens.* *(or visa-versa for negative recommendations)*
It is recommended that… *It is recommended that… not…*	*When the dimensions for judging the strength of the evidence are applied,* *there is moderate support that benefits are closely balanced with risks and burdens.*
There is insufficient evidence and a lack of consensus to make a recommendation…	

Copies of this Best Evidence Statement (BESt) and related tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.
Website address: http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/bests/
Examples of approved uses of the BESt include the following:
- Copies may be provided to anyone involved in the organization's process for developing and implementing evidence based care;
- Hyperlinks to the CCHMC website may be placed on the organization's website;
- The BESt may be adopted or adapted for use within the organization, provided that CCHMC receives appropriate attribution on all written or electronic documents; and
- Copies may be provided to patients and the clinicians who manage their care.

Notification of CCHMC at **EBDMinfo@cchmc.org** for any BESt adopted, adapted, implemented, or hyperlinked by the organization is appreciated.

Please cite as: Strenk, M., Cincinnati Children's Hospital Medical Center: Best Evidence Statement The use of electrical stimulation (e-stim) during cycling for individuals with spinal cord injury (SCI) age 5 to 21 years, http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/best.htm, BESt 192, pages 1-9, September 5, 2014.

This Best Evidence Statement has been reviewed against quality criteria by two independent reviewers from the CCHMC Evidence Collaboration. Conflict of interest declaration forms are filed with the CCHMC EBDM group.
The BESt will be removed from the Cincinnati Children's website, if content has not been revised within five years from the most recent publication date. A revision of the BESt may be initiated at any point that evidence indicates a critical change is needed.

Review History

Date	*Event*	*Outcome*
September 5, 2014	***Original Publication***	*New BESt developed and published*

For more information about CCHMC Best Evidence Statements and the development process, contact the Evidence Collaboration at EBDMinfo@cchmc.org.

Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.