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The Use of Functional Electrical Stimulation with Patients with Incomplete Spinal Cord Injury: An Evidence-Based Approach

Introduction to FES

Functional Electrical Stimulation (FES) is a physical therapy treatment modality that incorporates the use of neuromuscular electrical stimulation with functional movement. It is commonly used for individuals who have neuromuscular impairments that are the result of a stroke, traumatic brain injury, degenerative neurological disease, or peripheral denervation. Individuals with these conditions have abnormalities in their neural impulses, thereby reducing the force of contraction, causing spasticity, or affecting muscle tone. However, FES can provide the energy needed to contract muscles that are needed for performance of daily activities.

Interestingly enough, people with the aforementioned conditions are not the only ones who can benefit from FES. Over the past 20-25 years, a progressively increasing number of studies have been published showing that this treatment strategy can be used with patients with incomplete spinal cord injury. The purpose of this review is to provide the reader with information regarding different types of units that can be used for implementing functional electrical stimulation, how to set up parameters to ensure the most effective treatment session with FES, different treatment techniques to use with FES in this of patient population, and what the latest research is finding.

The Mechanics Behind FES

Electrical stimulation can also be used to strengthen individual muscle groups throughout the lower extremity, upper extremity, and torso. For the purposes of this paper, we will focus mostly on lower extremity versus upper extremity strengthening.

FES can be performed by applying the leads from the electrical stimulation units to the target muscle groups, then performing activities that target concentric contraction of these muscle groups while simultaneously providing stimulation simultaneously from the unit. This is commonly performed with patients post-orthopedic surgery, but it can also be performed with the neurological population. This technique is not functional itself, but the strength built doing these activities with targeted muscle groups can help facilitate functional movements later on in the treatment progression.

FES can be used to assist with many functional movements. The most thoroughly researched of these functional movements is ambulation. FES can be used to facilitate ambulation by applying electrodes to muscles that are producing inadequate force at various points throughout the gait cycle. These muscles can then be sequentially stimulated to facilitate progression throughout the gait cycle in a normal pattern. This is commonly used for patients with foot drop, weak quadriceps, or weak hamstrings.

FES can also be used to facilitate transfers. In patients with weaknesses in lower extremity muscle groups the use of stimulation can facilitate transfers into and out of wheelchairs, chairs, and beds. In patients with upper extremity weaknesses, FES can facilitate transfers in or out of the supine position or with slide board transfers. There are different types of units that are available for physical therapists to use to implement FES. The most generic units used are standard bipolar handheld units. These units have two to four channels, with each channel having both an anode and a cathode. The anode and cathode of each channel are applied to individual muscles or muscle groups, and the therapist can either sequence the timing of their elicitation, or manually control each individual channel, depending on the unit being used. Unfortunately, this type of unit has many drawbacks. It has significant potential for error, as there is no feedback provided to the unit from the body, it relies solely on instructor skill and experience, and there is no way for patients to use it outside of the clinic to complete functional tasks without proper training.

There are also much larger FES units that are not handheld, but rather, sit on a table or counter. These units tend to have 4-8 channels, and function similarly to the handheld units. However, unless these units sit on a table with wheels, they are limited in their functionality. If they are not on a mobile table or counter, they cannot be used for over ground gait training. Furthermore, if they are on a counter or tabletop they will require another therapist to ensure safe mobility of the unit.

Technology has now advanced to a level where FES can be applied based on the patient's body positioning. Bioness and WalkAid are two different companies that have manufactured units that elicit stimulation to specific muscle groups based on body positioning. Two different types of lower extremity units are available. Some units provide stimulation based on the angle of the knee during the gait cycle. Other units provide stimulation based on heel strike or foot contact.^{1–4} Overall, these stimulation units tend to be more easily applicable than handheld or table-top units. The major drawback is that they are very expensive (\$3,000-

5,000), and most insurer's will not pay for them.³ However, both Bioness and WalkAide are working with Medicaid with the hope that they can become a part of regular coverage.³ Currently, health care providers must write a letter of medical necessity, supported by changes in outcome measures observed with the use of FES, to send to insurance companies.

Parameters to Use When Applying FES

When applying FES to patients in the population of individuals with incomplete spinal cord injury, the therapist should consider different factors related to stimulation parameters. When working with the non-affected population of patients, there are many different types of waveforms that can be used. Biphasic symmetrical, asymmetrical, and uniphasic wave forms tend to be the most effective for individuals with incomplete spinal cord injury.^{5,6} Selection of the specific type of waveform may be guided by the patient's dermatomal responses. When working in a region of the body with diminished sensation, the therapist should opt for symmetrical biphasic waveforms.⁷ Therefore, when applying stimulation to this region of diminished sensation, this waveform can decrease the likelihood of skin damage. However, when working in regions of the body with intact sensation, our selection should be dictated based on muscle size. Larger muscle groups tend to respond better to asymmetrical biphasic currents.⁸

When working with this patient population, frequency should be selected based on the location of the body part being stimulated. Upper extremity muscle groups tend to respond better to frequencies below 30 Hz.⁵ Any stimulation above this level can lead to a functional

decline in the amount of force that is able to be produced.⁵ However, when working with upper extremity muscles, frequencies between 12-16 Hz tend to be the most effective at eliciting strong contractions.⁶

When working with the lower extremities, the general rule of thumb is to use higher frequencies to elicit stronger contractions. The target range is 20-50 Hz, with most muscles responding well to 30-35 Hz.⁵ Anything below 16 Hz will not be sufficient enough to elicit a strong contraction.⁵ But, frequencies of 50 Hz or above tend to fatigue the muscle and can reduce the amount of force produced.⁵ Therefore, we should try to work within a range of 20-50 Hz, and only raise the frequency above that if the patient is not responding well to frequencies within that range.

The duration that is recommended for use in this patient population is 300-600 µs, however, some research shows that longer durations between 500-1000 µs, and decreased frequency, can lead to less muscle fatigue.^{5,9} Therefore, for a patient who is just beginning the FES treatment protocol, it may be beneficial to try a lower frequency and longer duration to allow the patient to slowly adapt to the stimulation. If our only goal with FES is to increase the amount of force being produced, then we can utilize shorter durations and higher frequencies.¹⁰ Shortening duration and increasing frequency can produce contractions involving recruitment of more fast-twitch muscle fibers, but this sacrifices endurance.^{5,10} In summary, when using FES with this patient population, intervention goal(s) should be considered as part of the process of selecting duration and frequency, because different combinations of parameter values can change the overall effect of the treatment.

Finally, intensity is another FES parameter which must be determined. There is no evidence that supports one level of intensity over another. Therefore, intensity should be gauged based on patient comfort. In the situations in which sensation is compromised in a limb, intensity should be tested on a non-affected limb to help determine a baseline. If stimulation of the affected limb elicits an appropriate contraction at a lower intensity than is seen with the non-affected limb, then the lower intensity should be used.

Benefits and Contraindications

FES has been shown to benefit patients with incomplete spinal cord injury in a number of ways. For patients who have intact or partially intact innervation, and therefore, resultant muscle function, FES can improve muscle strength and increase the bulk of muscle groups.⁷ FES also has the potential to affect the neurological system. When combined with physical therapy, it can induce reorganization of central nervous system circuits to improve functional capabilities.¹¹

For patients who rely on a therapist or care-provider to assist with transfers, FES can increase level of independence.⁷ For individuals with difficulty with standing balance or ambulation, beneficial effects of FES for improving kinematics and sequencing of gait have been demonstrated.^{2,7} In patients with bowl and bladder issues, functional electrical stimulation systems have been designed to help reduce incontinence.⁷ These come in the form of superficial or implanted units. Finally, for individuals exhibiting depressive symptoms as a result of decreased independence, decreased functional capacity, or reduced endurance, FES may improve quality of life by helping to alleviate these deficits.^{7,12} Given all of these potential benefits, FES is a promising tool for selected patients with incomplete spinal cord injury.

Appropriate patients for use of FES to facilitate gait training are patients with incomplete lesions between T4 and T12 who have some innervation to their lower extremity musculature.⁷ Lesions above this level place the patient at risk for autonomic dysreflexia, and lesions below this level place the patient at risk for bowel and bladder issues. The patient should also be motivated and willing to participate in this type of treatment. They should also have enough upper extremity function to be able to manage an assistive device. Finally, they should not have any spasticity that could hinder the gait sequence or their ability to maintain standing balance.⁷

Not every patient meeting all of these criteria is appropriate for FES. There are many absolute and relative contraindications that also need to be considered. Patients with electronic implants (pacemakers, DBS systems, etc.) can be at risk for serious bodily damage when FES comes in contact with their implanted device.¹³ FES should not be placed over the heart, face or head, or damaged skin, as the stimulation unit can interfere with cardiac rhythm, neural relay, and the body's innate recovery processes, respectively.¹³ Other common conditions to take into account are skin infection, deep vein thrombosis, pregnancy, bladder fibrosis, and hemorrhage.^{7,13} If a patient has any of these conditions, FES should not be used on or near the involved region of the body.

Evidence surrounding the use of FES and Incomplete SCI

As shown in the accompanying evidence table, there are numerous studies that compare functional electrical stimulation with the gait training modalities or physical therapy treatment protocols. Among these studies, there is a general consensus that gait training with functional electrical stimulation has a variety of benefits for patients with incomplete spinal cord injury, regardless of whether treadmill training is involved.^{14–16} However, when treadmill training is performed, the improvements in gait speed and and carryover effects tend to not be as large as when gait training with functional electrical simulation is performed over ground.¹⁷ Furthermore, ambulating on a treadmill demands less force production from muscle groups when compared to gait training over ground.¹⁷ When a patient who participated in gait training on a treadmill translates their learned gait motor program to the ground, they tend to have reduced performance due to the new force and energy demand. Therefore, if a patient is able to tolerate over-ground gait training, the therapist should opt for this over gait training on a treadmill, as it translates better to functional movement in the household and throughout the community.

It is also important to consider how gait training with FES affects outcomes in comparison to other gait training devices or techniques. Three different systematic reviews have addressed this, providing high-level evidence on how effective FES is when compared to other devices. Although each of these systematic reviews assessed different forms of gait training in different capacities, each of them came to a similar conclusion: functional electrical stimulation is equally as effective as other forms of gait training. In some outcome measures, such as the 6-minute walk test, both the over-ground gait training + FES and body weight supported treadmill training + FES groups had significant improvements when compared to the Lokomat and BWSTT only groups.¹⁸ Also, with the population of patients with acute incomplete spinal cord injury, the groups receiving FES had significant increases in their stride lengths.¹⁸ However, for other outcome measures, no significant differences were found between groups receiving FES and not receiving FES .^{18–20} Therefore, when implementing gait training into treatment, our goal for the patient is to improve gait speed, FES may be a good treatment tool. However, the results we will see this treatment strategy may depend on the patient's stage of recovery and prior level of function.²¹

If a patient's goal is to be able to be able to be able to go shopping at their local mall, we may make a goal for them related to distance and assess by using the 6-minute-walk-test (6MWT) as our outcome measure. With both of these patient goals, we need to consider different gait training strategies. Current research suggests that FES may be the best option to achieve a goal for improving distance travelled during the 6MWT.^{18,20} Comparatively, it is also suggested that the therapist should avoid using a robotic orthosis.^{18,20} If the goal for the patient is to be able to safely walk around their community, we could assess that using the 10m walk test. FES may be able to significantly increase gait speed, especially if it is used combined with an AFO.²² This would help the patient achieve the cutoff score of .4 m/s for limited community ambulation or .8 m/s for community ambulation on the 10m walk test.²³ If the patient's goal is to improve their lower extremity and upper extremity strength, moderate-level evidence suggests that combining FES with upper and lower extremity cycle ergometry using reciprocal movements may be the best option.²⁴

It is also important to consider the potential effects of FES will have on a patient prior to administering it. For example, patients with active muscle contraction below the level of the lesion in the acute setting, and who are able to perform some level of ambulation at initial evaluation are likely to experience greater benefits from the implementation of FES than patients with little muscle function or ambulation ability.¹⁸ In the chronic setting, this phenomenon is reversed. A patient with minimal muscle function and a lower functional level may have a greater change in function with FES implemented than a patient who is functioning at a higher level.^{15,18}

Conclusion

In conclusion, FES can be an effective treatment tool for patients with incomplete spinal cord injury. The therapist must ensure that the patient meets the inclusion criteria, does not have any absolute contraindications, and is otherwise appropriate for the intervention and likely to benefit from it. One of the most important criteria to consider when deciding whether or not to use FES is: how will implementing this affect the patient's goal attainment? This should be considered because certain outcomes are more influenced by FES than others. However, once the potential costs and benefits are weighed and the plan for FES is established, the patient may experience improvements in outcomes that are similar to, or greater than, those achieved with use of other forms of gait training.

References

- 1. Springer S, Vatine J-J, Lipson R, Wolf A, Laufer Y. Effects of dual-channel functional electrical stimulation on gait performance in patients with hemiparesis. *ScientificWorldJournal* 2012;2012:530906. doi:10.1100/2012/530906.
- 2. Springer S, Vatine J-J, Wolf A, Laufer Y. The effects of dual-channel functional electrical stimulation on stance phase sagittal kinematics in patients with hemiparesis. *J Electromyogr Kinesiol* 2013;23(2):476-482. doi:10.1016/j.jelekin.2012.10.017.
- Durand M. Consumer Alert: Two new devices for foot drop. *Momentum* 2008. Available at: https://f1000.com/work/item/6745510/resources/5912942/pdf. Accessed March 28, 2019.
- Bioness. Setting up your NESS: NESS L300. Available at: https://www.bioness.com/Documents/TechSupport/L300/I300_setting_up_your_ness_I3 00.pdf. Accessed March 28, 2019.
- 5. Doucet BM, Lam A, Griffin L. Neuromuscular Electrical Stimulation for Skeletal Muscle Function. *Yale J Biol Med* 2012;85:201-215.
- 6. Pons JL, Raya R, Gonzlez J. *Emerging Therapies in Neurorehabilitation II*. (Pons JL, Raya R, González J, eds.). Cham: Springer International Publishing; 2016. doi:10.1007/978-3-319-24901-8.
- 7. Sisto SA, Druin E, Sliwinski M. *Spinal Cord Injuries*. St. Louis: Mosby Elselvier; 2009.
- 8. Baker LL, Bowman BR, McNeal DR. Effects of waveform on comfort during neuromuscular electrical stimulation. *Clin. Orthop. Relat. Res.* 1988;(233):75-85.
- 9. Kralj A. Functional Electrical Stimulation: Standing and Walking After Spinal Cord Injury. 1st ed.; 1989.
- 10. Grill WM, Mortimer JT. The effect of stimulus pulse duration on selectivity of neural stimulation. *IEEE Trans. Biomed. Eng.* 1996;43(2):161-166. doi:10.1109/10.481985.
- Craven BC, Giangregorio LM, Alavinia SM, et al. Evaluating the efficacy of functional electrical stimulation therapy assisted walking after chronic motor incomplete spinal cord injury: effects on bone biomarkers and bone strength. *J Spinal Cord Med* 2017;40(6):748-758. doi:10.1080/10790268.2017.1368961.
- 12. Hitzig SL, Craven BC, Panjwani A, et al. Randomized trial of functional electrical stimulation therapy for walking in incomplete spinal cord injury: effects on quality of life and community participation. *Top. Spinal Cord Inj. Rehabil.* 2013;19(4):245-258. doi:10.1310/sci1904-245.
- ELECTROPHYSICAL AGENTS Contraindications And Precautions: An Evidence-Based Approach To Clinical Decision Making In Physical Therapy. *Physiother. Can.* 2010;62(5):1-80. doi:10.3138/ptc.62.5.
- 14. Field-Fote EC. Combined use of body weight support, functional electric stimulation, and treadmill training to improve walking ability in individuals with chronic incomplete spinal cord injury. *Arch. Phys. Med. Rehabil.* 2001;82(6):818-824. doi:10.1053/apmr.2001.23752.
- 15. Field-Fote EC, Lindley SD, Sherman AL. Locomotor training approaches for individuals with spinal cord injury: a preliminary report of walking-related outcomes. *J Neurol Phys Ther* 2005;29(3):127-137.

- 16. Postans NJ, Hasler JP, Granat MH, Maxwell DJ. Functional electric stimulation to augment partial weight-bearing supported treadmill training for patients with acute incomplete spinal cord injury: A pilot study. *Arch. Phys. Med. Rehabil.* 2004;85(4):604-610. doi:10.1016/j.apmr.2003.08.083.
- Field-Fote EC, Roach KE. Influence of a locomotor training approach on walking speed and distance in people with chronic spinal cord injury: a randomized clinical trial. *Phys. Ther.* 2011;91(1):48-60. doi:10.2522/ptj.20090359.
- 18. Morawietz C, Moffat F. Effects of locomotor training after incomplete spinal cord injury: a systematic review. *Arch. Phys. Med. Rehabil.* 2013;94(11):2297-2308. doi:10.1016/j.apmr.2013.06.023.
- 19. Lam T, Eng JJ, Wolfe DL, Hsieh JT, Whittaker M, the SCIRE Research Team. A systematic review of the efficacy of gait rehabilitation strategies for spinal cord injury. *Top. Spinal Cord Inj. Rehabil.* 2007;13(1):32-57. doi:10.1310/sci1301-32.
- Mehrholz J, Kugler J, Pohl M. Locomotor training for walking after spinal cord injury. Cochrane Database Syst. Rev. 2012;11:CD006676. doi:10.1002/14651858.CD006676.pub3.
- 21. Lam T, Noonan VK, Eng JJ, SCIRE Research Team. A systematic review of functional ambulation outcome measures in spinal cord injury. *Spinal Cord* 2008;46(4):246-254. doi:10.1038/sj.sc.3102134.
- 22. Kim CM, Eng JJ, Whittaker MW. Effects of a simple functional electric system and/or a hinged ankle-foot orthosis on walking in persons with incomplete spinal cord injury. *Arch. Phys. Med. Rehabil.* 2004;85(10):1718-1723.
- 23. Middleton A, Fritz SL, Lusardi M. Walking speed: the functional vital sign. *J. Aging Phys. Act.* 2015;23(2):314-322. doi:10.1123/japa.2013-0236.
- Zhou R, Alvarado L, Ogilvie R, Chong SL, Shaw O, Mushahwar VK. Non-gait-specific intervention for the rehabilitation of walking after SCI: role of the arms. *J. Neurophysiol.* 2018;119(6):2194-2211. doi:10.1152/jn.00569.2017.