

Functional Neuromuscular Electrical Stimulation

Effective: April 1, 2022

Next Review: November 2022

Last Review: March 2022

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Functional neuromuscular electrical stimulation is a method being developed to restore function to patients with damaged or destroyed nerve pathways through use of an orthotic device with microprocessor controlled electrical neuromuscular stimulation (neuroprosthesis).

MEDICAL POLICY CRITERIA

Functional neuromuscular electrical stimulation, also known as Neuromuscular Electrical Stimulation (NMES), Functional Neuromuscular Stimulation (FNS), Functional Electrical Stimulation (FES), Electrical Neuromuscular Stimulation (ENS), or electromyography (EMG)-triggered neuromuscular stimulation, using any device is considered **investigational** for all indications, including but not limited to the following: as a technique to provide ambulation in patients with spinal cord injury, to restore upper or lower extremity function in patients with nerve damage (e.g., spinal cord injury or post-stroke), to improve ambulation in patients with foot drop caused by congenital disorders or nerve damage (e.g., post-stroke or in those with multiple sclerosis), or as a treatment of pain.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Interferential Stimulation for the Treatment of Pain](#), Durable Medical Equipment, Policy No. 83.07
2. [Transcutaneous Electrical Modulation Pain Reprocessing](#), Medicine, Policy No. 143

BACKGROUND

Functional neuromuscular electrical stimulation is also known as Neuromuscular Electrical Stimulation (NMES), Functional Neuromuscular Stimulation (FNS), Functional Electrical Stimulation (FES), Electrical Neuromuscular Stimulation (ENS), or electromyography (EMG)-triggered neuromuscular stimulation. Neural prosthetic devices consist of an orthotic and a microprocessor-based electronic stimulator with one or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce functionally useful movements that allow patients to sit, stand, walk, and grasp. Functional neuromuscular stimulators are closed loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters which are required for complex activities such as walking. These are contrasted with open loop systems, which are used for simple tasks such as muscle strengthening alone, typically in healthy individuals with intact neural control.

REGULATORY STATUS

Functional neuromuscular electrical stimulation devices have received 510(k) or pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA) for the following indications:

- Providing stimulation to trigger action potentials to allow spinal cord injured patients the ability to stand and walk.

To date, Sigmedics' Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive PMA from the FDA. The Parastep device is approved to "enable appropriately selected skeletally mature spinal cord injured patients (level C6-T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury." Other devices include ReWalk™, by ReWalk™ Bionics research Inc., a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a hip-knee-ankle-foot device linked together with a cable at the hip joint.

- Restoring upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadraplegia).

Examples of these devices include: the Neurocontrol Freehand® system (no longer available), which received approval from the FDA through the PMA process and the NESS H200® (previously known as the Handmaster NMS I system), which received 510(k) clearance to provide hand active range of motion and function for patients with stroke or C5 tetraplegia.

- Improving dorsiflexion and ambulation in foot drop caused by stroke or multiple sclerosis.

Functional electrical stimulation of the peroneal nerve has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation. In these devices, a pressure sensor detects heel off and initial contact during walking. A signal is then sent to the stimulation cuff, initiating or pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of devices used for treatment of foot drop are the Innovative Neurotronics' (formerly NeuroMotion, Inc.) WalkAide®, Bioness' radio-frequency controlled NESS L300™, MyGait (Otto Bock HealthCare), and Odstock Medical Limited's Foot Drop Stimulator. All have received 510(k) marketing clearance from the FDA and are intended to be used in patients with drop foot by assisting with ankle dorsiflexion during the swing phase of gait.

- Allowing patients with impaired function of the extremities to passively and actively exercise using cycle ergometry.

Cycle ergometers consist of motorized leg ergometer, optional motorized arm crank, and leg and optional arm electrical stimulation. Examples of cycle ergometers that have 510k FDA approval are the RT300 (Restorative Therapies, Inc.) and the Myocycle (Myolyn). Rowing devices have also been devised for exercise.

EVIDENCE SUMMARY

Functional neuromuscular electrical stimulation is also known as Neuromuscular Electrical Stimulation (NMES), Functional Neuromuscular Stimulation (FNS), Functional Electrical Stimulation (FES), Electrical Neuromuscular Stimulation (ENS), or electromyography (EMG)-triggered neuromuscular stimulation. Treatment with NMES devices must be evaluated in general groups of patients against the existing standard of care for the condition being treated. Data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from a functional neuromuscular stimulation device provides a significant advantage over the placebo.

The principal outcome associated with use of functional neuromuscular stimulation devices includes a clinically significant improvement in functional ability, such that there is an improved ability to complete activities of daily living. As a secondary outcome, positive changes in the patient's quality of life may result from improved functional ability. Physical therapy is an important component of clinical treatment of loss of neuromuscular function. Therefore, comparisons between physical therapy with and without neuromuscular stimulation from adequately powered, blinded, RCTs are required to determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the standard of care.

NMES devices are not designed to be an alternative to a wheelchair and offer, at best, limited, short-term ambulation.^[1] Final health outcomes, such as improved functional performance and ability to perform activities of daily living, have not been reported. Without randomized comparisons, it is not known whether similar or improved results could be attained with other training methods.

Concomitant use of NMES with exercise equipment has been proposed to counteract the health consequences of paralyzed limbs, including prevention of muscle atrophy, reduction of muscle spasms, improvement of circulation, improvement in range of motion, improvement in cardiopulmonary function, reduction in pressure sore frequency, and improvements in bowel and bladder function. It is not clear that the health benefits of EMG-triggered NMES exercise cannot be realized through standard passive range of motion exercise.

FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION OF THE UPPER EXTREMITY

Systematic Reviews

A systematic review (SR) and meta-analysis published by Monte-Silva (2019) evaluated the effects of electromyogram-triggered neuromuscular electrical stimulation (EMG-NMES) on restoring wrist and hand movement in poststroke hemiplegia.^[2] Twenty-six studies (N=782) were included from clinical trials comparing the effect of EMG-NMES versus no treatment or another treatment on stroke upper extremity motor recovery. Fifty percent of the studies were considered to be of high quality. Outcomes were each of the International Classification of Functioning, Disability, and Health (ICF) domains. The meta-analysis showed that EMG-NMES had a robust short-term effect on improving upper limb motor impairment in the Body Structure and Function domain. No evidence was found in favor of EMG-NMES for the Activity and Participation domain. EMG-NMES had a stronger effect for each ICF domain in chronic (greater than or equal to 3 months) compared to acute and subacute phases. This SR included data from a 2017 RCT comparing myoelectric controlled functional electrical stimulation (MeCFES) or task-oriented therapy (TOT) in 68 participants for 25 sessions^[3] and a multicenter, single-blind, multi-arm parallel-group study that evaluated participants with upper limb hemiplegia receiving cyclic NMES (n=39), electromyography (EMG) triggered NMES (n=41), or sensory stimulation (n=42) for motor impairment and activity limitations.^[4] Additional RCTs are needed to show that EMG-NMES provides additional long-term improvement in upper limb motor impairment in individuals with chronic stroke.

Eraifej (2017) published a systematic review (SR) of RCTs to evaluate the efficacy of FES on upper limb function (activities of daily living and motor function) post-stroke.^[5] Twenty studies were included, with a total of 91 patients. The authors stated there is a lack of high-quality evidence to support FES at this time, but when applied within two months after stroke FES may be beneficial.

Lee (2017) published a SR evaluating the efficacy of NMES on shoulder subluxation.^[6] Eleven studies with 432 participants were included. The authors concluded NMES may have a positive effect on shoulder subluxation for patients with acute or subacute shoulder subluxation, but all studies were fair to good quality.

Arya (2017) published a SR that included 14 RCTs and eight pre- post-single group studies that evaluated several treatments, one of which was FES/electrical stimulation for shoulder subluxation.^[7] The authors stated none of the modalities evaluated improved subluxation and upper limb function effectively.

A SR by Gu (2016) evaluated electrical stimulation for hemiplegic shoulder function.^[8] This review included 15 RCTs, and the results of a meta-analysis showed that FES improved shoulder subluxation, but only if it was applied early after stroke. There were no significant effects seen for pain, upper arm motor function, daily function, or quality of life measures.

Randomized Controlled Trials

Khan (2019) published an RCT to determine the efficacy of theta burst stimulation (TBS) or functional electrical stimulation (FES) when combined with physical therapy (PT) after stroke. Sixty patients were randomized into three groups of 20 each: TBS+PT; FES+PT; and PT alone. The TBS group received intermittent TBS of ipsilesional hemisphere and continuous TBS of contralesional hemisphere while the FES group received FES of paretic limb, both for four weeks. All groups received supervised physical therapy for four weeks followed by home physiotherapy for one year. The primary outcome was the Fugl Meyer Assessment upper limb score (FMA-UL) which was assessed at baseline and at one, three and six months and one year. Compared to the PT group, mean FMA-UL scores were higher in TBS and FES

groups at all follow-ups ($p < 0.001$). From baseline to one year, mean (SD) FMA-UL scores increased from 14.9(2.1) to 55.55(2.46) in the TBS group, 15.5(1.99) to 55.85(2.46) in FES group, and 14.3(2.2) to 43.3(4.22) in the PT group. There was no difference between the FES and TBS groups. The authors conclude that this four-week intervention with TBS or FES combined with PT produces better long-term arm functions as compared to PT alone in patients with acute stroke. However, future RCTs are required due to small sample size and the lack of a sham stimulation in the control groups.

Uswatte (2018) reported a small RCT that compared an expanded form of Constraint-Induced Movement Therapy (eCIMT; $n=10$) which included electromyography-triggered functional electrical stimulation to a placebo control procedure ($n=4$) or usual care ($n=7$) for the treatment of severe hemiparesis.^[9] The patients who received usual care were crossed over to eCIMT at four months after enrollment. Both the original and crossover eCIMT groups showed short- and long-term improvements in the Grade-4/5 Motor Activity Log and the Canadian Occupational Performance Measure. This study was limited by extremely small sample sizes.

Harvey (2016) published a RCT to determine the effect of adding a task-specific hand-training program with functional electrical stimulation to a combination of usual care plus three 15-minute sessions per week of one to one hand therapy in patients with sub-acute hand tetraplegia, related to spinal cord injury.^[10] Patients in the experimental group ($n=37$) received intensive training with functional electrical stimulation on one hand for one hour per day, five days a week for eight weeks. The control group ($n=33$) and the experimental group received 15 minutes of one to one hand therapy three times a week without functional electrical stimulation for eight weeks. Measurement date was evaluated at baseline, 11 weeks and 26 weeks after randomization. The authors concluded adding an intensive task-specific hand training program with functional electrical stimulation does not improve hand function for sub-acute tetraplegia.

Popovic (2011) reported on the use of the Compex Motion electric stimulator device as a supplement to conventional occupational therapy (COT) to improve voluntary grasping among 24 patients with spinal cord injury (SCI).^[11] The patients were randomized to either functional electrical stimulation therapy device and COT, or COT alone for 40 hours over the course of 8 weeks. The primary outcome of interest was improvement on the Functional Independence Measure (FIM), a scale of ability to provide self-care in daily living. After 8 weeks, the functional neuromuscular electrical stimulation group had significantly higher scores on the FIM instrument and several other secondary outcomes (other scales of activities of daily living) after controlling for differences in degree of impairment between the groups. However,

durability of treatment effects was not able to be compared as 18 of the original 24 subjects were lost to follow-up at 6 months.

Weber (2010) reported on the use of the Bioness H200 device for use as a supplement to treatment with onabotulinumtoxinA and occupational therapy among 23 stroke patients with spasticity after stroke.^[12] The primary outcome was progression in upper limb motor function, as measured by improvement in the Motor Activity Log instrument after 12 weeks of therapy. Although improvements in motor activity were seen among all patients after 6 and 12 weeks, no additional benefit was observed among patients treated with functional neuromuscular electrical stimulation versus the comparison group, potentially due to small sample size.

Some recent RCTs have compared different types of NES. For example, a study published in 2016 compared the effects of contralaterally controlled functional electrical stimulation (CCFES) with cyclic neuromuscular electrical stimulation (cNMES) in 80 stroke patients with chronic upper extremity hemiparesis.^[13] Treatment was given over 12 weeks, and consisted of 10 sessions per week of either CCFES- or cNMES-assisted hand opening exercise at home and 20 sessions of functional practice in the laboratory. For the CCFES group, the task practice was stimulation assisted. Outcomes assessed were the change in Box and Block Test, upper extremity Fugl-Meyer and Arm Motor Abilities Test. At six months follow-up, the CCFES group showed greater improvement in the Box and Block test, but there were no significant difference in the other outcomes. There were no non-stimulation control groups in this study, which limits the conclusions that can be drawn.

In addition, a small pilot study evaluated task-oriented electromyography (EMG)-triggered electrical stimulation for shoulder subluxation in participants with subacute hemiparetic stroke.^[14] There were 10 patients randomized to the EMG-triggered stimulation group and 10 to the control group that received cyclic FES. The treatments were given five times a week for four weeks, and all patients additionally received four weeks of conventional physical therapy. There were significant improvements in shoulder subluxation, muscle activation, and pain (by Visual Analogue Scale) in the EMG-triggered stimulation group compared to the control FES group, but no differences in the Fugl-Meyer assessment.

Section Summary

Evidence for the use of NMES to restore upper extremity function in conditions including but not limited to stroke and spinal cord injury is limited. The studies reported do not consistently demonstrate significant improvement in function with NMES over control treatments, particularly in the long-term. Additional RCTs with and without NMES are needed to show that NMES provides additional improvement over established treatments as well as demonstration of long-term improvement in upper limb motor impairment.

FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION OF THE LOWER EXTREMITY

Systematic Reviews and Technology Assessments

The effectiveness of FES applied to the paretic peroneal nerve to improve post-stroke gait speed was evaluated in a systematic review (SR) published by da Cunha (2020).^[15] The search was limited to randomized controlled trials or crossover trials on the effects of FES alone or combined with other therapies in individuals with foot drop after stroke. Fourteen studies providing data for 1115 participants were included in the review, however only two of

the studies used conventional FES on the peroneal nerve. In three studies, FES was paired with conventional physiotherapy and compared with ankle-foot orthotics (AFO) or with other types of stimulation (TENS and NMES). Two studies combined FES with treadmill gait training and compared to sham plus treadmill gait training. The quality of evidence was low for all outcomes and serious risk of bias was noted according to the GRADE system. In the twelve studies (n = 1077) that evaluated gait speed and were included in the meta-analysis, FES was not found to enhance gait speed as compared with conventional treatment [SMD = 0.092 (95% CI: -0.34 to 0.53; I2 89%, p=0.68)]. Data from four studies were included in a sensitivity analysis, which showed that FES combined with physiotherapy could increase gait speed as compared with physiotherapy alone (n=133) [SMD = 0.51 (95% CI: 0.16 to 0.86; I2 0%, p=0.0042)]. A sensitivity analysis in data from four studies that combined FES with unsupervised home exercises (n=355), and three studies that used FES in regular activities at home (n=589), did not reveal a significant difference between groups [SMD = 0.02 (95% CI: -0.23 to 0.19; I2 0%, p=0.849) and SMD=-0.28 (95% CI: -1.53 to 0.96; I2 95%, p=0.653)]. Analysis of data from three studies (n=151) that assessed the effect of FES on active ankle dorsiflexion mobility of the paretic limb found that FES could improve active ankle dorsiflexion as compared with conventional treatment [MD=3.30 (95% CI: 1.48 to 5.12; I2 0%, p=0.0007)]. Data from five studies (n=780) were available for analysis of balance and functional mobility. Across these studies, it was found that FES could improve balance and functional mobility compared with conventional treatments [MD = 2.76 (95% CI: 0.64 to 4.88; I2 90%, p=0.011), MD = -3.19 (95% CI: -5.76 to -0.62; I2 84%, p=0.015), respectively]. Heterogeneity was high for both of these outcomes. Overall, the SR found positive effects of FES on the peroneal nerve for improving gait speed when combined with supervised exercises, but not with unsupervised home exercises. However, the high heterogeneity in the available data preclude determination of the benefits of FES combined with regular activities at home for improving gait speed. There was low quality of evidence for positive effects of FES on active ankle dorsiflexion mobility. The authors conclude that future research with adequate methodological quality is necessary to determine the exact effects of FES on gait speed, ankle dorsiflexion mobility, balance, and functional mobility.

A systematic review and meta-analyses of RCTs evaluating the efficacy of AFO and FES on walking speed and balance after stroke was published by Nascimento (2020).^[16] Eleven parallel, randomized trials (N=1135) of AFO or FES in ambulatory post-stroke patients were included. The methodological quality and reporting assessed by the Physiotherapy Evidence Database (PEDro) score of the trials ranged from 4 to 7, with a mean of 5.8, which is considered fair to good on a scale that ranges from 0 to 10. Significant increases in walking speed compared with no intervention/placebo was found for both AFO (MD 0.24m/s; 95% CI 0.06 to 0.41) and FES (MD 0.09m/s; 95% CI 0.03 to 0.14). AFO and FES were not significantly different for improving walking speed (MD 0.00m/s; 95% CI -0.06 to 0.05) or balance (MD 0.27 points on the Berg Balance Scale; 95% CI -0.85 to 1.39) after stroke.

A SR with meta-analysis by Salazar (2019) evaluated the effectiveness of NMES as an adjuvant therapy to improve gross motor function in children with spastic cerebral palsy.^[17] Six RCTs (N=174) were included in the meta-analysis. Medium effect size to improve gross motor function was found with NMES combined with other therapies in children with cerebral palsy in comparison with conventional physical therapy or neurodevelopmental therapy. Gross motor function was assessed by the Gross Motor Function Measure (GMFM) and its functional dimensions. Sensitivity analysis showed NMES combined with other therapies was effective to improve GMFM-sitting and standing dimensions but not GMFM-walking dimension. The

authors conclude that low-quality evidence suggests that NMES may be used as adjuvant therapy to improve sitting and standing dimensions of GMFM in children with spastic cerebral palsy. A previous SR by Moll (2017) that assessed FES of ankle dorsiflexors in young patients with cerebral palsy concluded that there is not enough evidence that FES improves activity function or participation level, but it may play a role as an alternative to orthosis in children with cerebral palsy.^[18] Similarly, a meta-analysis conducted by Cauraugh (2010) which evaluated NMES on gait in children with cerebral palsy found moderate effect sizes for impairment (0.616) and activity limitations (0.635).^[19] The review is limited by a lack of blinding in the included studies and the heterogeneity of outcome measures.

A SR by Renfrew (2019) evaluated the effect of FES for foot drop on health-related quality of life (HRQOL) in people with multiple sclerosis.^[20] Eight studies were eligible for review; seven were of moderate-to-strong methodological quality and one was weak. Seven studies demonstrated significant positive effects of FES on different aspects of HRQOL as measured by the 29-item Multiple Sclerosis Impact Scale, 36-item Short Form Health Status Survey, Canadian Occupational Performance Measure, and Psychosocial Impact of Assistive Devices Scale. While the authors concluded that FES has a positive effect on aspects of HRQOL in people with MS, this is considered preliminary given the limitations of the variety of HRQOL outcomes used.

In 2018, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a Rapid Response report that reviewed the clinical-effectiveness and cost-effectiveness nerve stimulation for foot drop. Four publications met the inclusion criteria and were reviewed. Two publications were systematic reviews and two were RCTs. No differences in functional outcomes were found between FES and ankle foot orthosis. However, FES combined with rehabilitation was more effective than rehabilitation alone for improving walking speed for patients with stroke-related foot drop in one RCT and FES was found to statistically reduce perceived exertion and several related measures in one cross-over RCT.

A SR by Prenton (2018), included in the CADTH review above, reported a meta-analysis of FES or ankle foot orthoses (AFO) for foot drop caused by central nervous system conditions^[21]. Eight RCTs met inclusion criteria. One RCT examined patients with cerebral palsy while the rest included stroke patients. The meta-analysis showed equal improvement in walking speed for both devices for stroke patients ($p=0.54$). A previous SR by the same authors which included many of the same studies reached similar conclusions; comparable improvements for AFO and FES groups was found in 10m walking speed, functional exercise capacity, perceived mobility, and timed up-and-go.^[22] This SR included a large multicenter RCT in 495 Medicare-eligible individuals,^[23] an industry-sponsored single-blind multicenter trial that randomized 197 patients to 30 weeks,^[24] and a small, multicenter within-subject crossover trial.^[25] An additional SR evaluating peroneal stimulation for foot drop in stroke patients^[26] also concluded that more studies are needed to evaluate the clinical effectiveness of FES on foot drop.

Miller (2017) published a SR to evaluate the efficacy of FES on gait speed for patients with multiple sclerosis.^[27] Nineteen studies were evaluated with 490 patients with multiple sclerosis. The studies were rated weak to moderate. The authors stated FES impacts foot drop and gait speed in a positive way, but more RCTs are required comparing FES with other treatment options. Similar findings are reported in a SR by Springer (2017).^[28]

Wonsetler (2017) published a SR (part 1) that evaluated the impact of different therapies on

gait by measuring spatiotemporal variables and asymmetry ratios.^[29] Two of the 46 studies included were for FES. The authors concluded measuring spatiotemporal variables and asymmetry ratios may provide information on functional improvement, but more studies are needed to evaluate different measures that can determine FES impact on gait.

Yue (2018) performed a SR of RCTs examining the use of NMES, transcutaneous electrical stimulation (TENS), and electroacupuncture (EA) after total knee arthroplasty.^[30] High risk of some type of bias was present in over 50% of studies on NMES, mostly in the category of blinding. For TENS and EA, high risk of bias was present in a lower percent of studies, although 75% and 100%, respectively, still had high or unclear risk of bias for blinding of participants and personnel present. Follow-up was through 12 or 13 months in three studies and six months or less in the remainder. Eight studies met the inclusion criteria for NMES, seven for TENS, and two for EA. Six of the studies showed a significant improvement in muscle strength and functional recovery following NMES while two found no significant differences in functional outcomes between the NMES and control groups. In contrast, in a SR evaluating efficacy of different devices after arthroscopic knee surgery, one of which was NMES,^[31] the authors stated that NMES is recommended in addition to rehabilitation, however level of evidence was II. Relatedly, Bistolfi (2017) published a SR with meta-analysis that evaluated the effects of NMES following total knee arthroplasty.^[32] Six studies with 496 participants were included. The authors concluded that while NMES with a rehabilitation program can slightly improve over a rehabilitation program alone, especially in patients who do not have good muscle activation, these effects were not present in mid and long-term outcomes. Utilization of NMES for osteoarthritis of the knee also was evaluated in a SR by Cherian (2016). The authors noted that while pain improvement from NMES was similar to transcutaneous electrical nerve stimulation, there was heterogeneity amongst NMES studies and long-term follow-up was not evaluated. Additional RCTs are needed to determine the effectiveness of NMES on the functional outcomes.

Langeard (2017) published a SR evaluating how NMES impacts lower limb function in the elderly.^[33] Ten studies were retrieved for the review. The authors concluded some of the studies noted that NMES improves function and molecular muscular physiology, but because there is a correlation between gait, balance and risk of falls more research is needed to evaluate if NMES can reduce fall rates in this group.

Randomized Controlled Trials

Hachisuka (2020) published the results of a multicenter, prospective, randomized, open-label trial comparing the effectiveness of gait training with or without a peroneal nerve stimulation device on improving gait ability and ankle-specific body functions in stroke patients.^[34] In total, 119 stroke patients with foot drop were randomly assigned to the experimental (n=56 gait training + WalkAide device) or control (n=59, gait training only) group. At four weeks, there was no significant difference between groups in the primary endpoint of change from baseline in six-minute walk test (6MWT). In addition, no significant difference between groups was found in several secondary endpoints. In sum, no significant impact of peroneal nerve stimulation on gait or body function in stroke patients were observed.

Prokopiusova (2020) published the results of a randomized trial that compared FES (combined with postural correction) and neuroproprioceptive facilitation and inhibition physiotherapy for two months in patients with multiple sclerosis and foot drop.^[35] Primary outcomes were: gait (two-Minute Walk Test; Timed 25-Foot Walk test; Multiple Sclerosis Walking Scale-12) and

balance (by e.g. Berg Balance Scale [BBS], the Activities-Specific Balance Confidence Scale [ABC], Timed Up-and-Go Test [TUG]) assessed immediately after and two months after program completion. While the group treated with FES experienced significant improvements immediately after program completion in Activities-Specific Balance Confidence Scale and Berg Balance Scale (all $p < 0.05$), none of these outcomes significantly differed between FES and physiotherapy groups at either time point. The study was limited by a lack of blinding of patients and clinicians.

Berenpas (2019) compared the effectiveness of implanted FES versus ankle-foot orthotics (AFO) in helping stroke patients with foot drop avoid obstacles while walking (“gait adaptability”).^[36] Two cohorts were studied: the first ($n=10$) were followed for 26 weeks; the second ($n=12$) were followed for 52 weeks. All study participants had experienced stroke more than six months prior and regularly used an AFO. A within-subjects repeated measures design was used. Gait adaptability was tested by having participants walk on a treadmill while obstacles were suddenly dropped in front of the paretic leg. Before implantation of the device, participants were tested using only the AFO (at 2 or 3 km/h). Patients were then implanted with a 4-channel peroneal nerve stimulator (ActiGait). Testing was then conducted with FES and with AFO at two weeks postimplantation, then at eight weeks, 26 weeks, and, for the second cohort, 52 weeks. Available response time (ART) was calculated “as the time between obstacle release and the moment the toe would have crossed the front edge of the obstacle in the case of an unaltered step.” ART was stratified into three categories based on at what point in the gait cycle the obstacle was dropped: 450-600 ms (mid stance), 300-450 ms (late stance/early swing), and 150-300 ms (mid swing). Results showed FES success rates were an average of 4.7% higher than with AFO (55.4% vs. 50.7%; $p=0.03$). Significant differences were seen between the three ARTs ($p < 0.001$), with higher success rates with longer ARTs. The individual results ranged widely in differences between devices: at 26 weeks they ranged from -29% to 85%. The small sample size and absence of control group limit the study’s generalizability, but larger controlled studies would be difficult given the requirements of the intervention.

A non-blinded randomized trial published by Renfrew (2019) evaluated the effectiveness of FES versus ankle-foot orthoses in 85 treatment-naïve people with multiple sclerosis with persistent (greater than three months) foot drop. Participants were randomized to receive a custom-made orthotic ($n=43$) or FES device ($n=42$) and multi-domain outcomes were assessed at zero, three, six, and 12 months. The authors concluded that ankle-foot orthotic and FES treatment have comparable effects on walking performance and patient-reported outcomes. The high drop-out rate for the study introduced uncertainty in the study findings.

In 2016, a small pilot RCT was published that assessed the effects of NMES in combination with mirror therapy in stroke survivors with hemiplegia.^[37] There were 14 patients randomized to NMES plus mirror therapy and physical therapy, and 13 patients randomized to the control treatment of physical therapy alone. Balance, muscle strength and tone, and gait were evaluated at baseline and after four weeks of treatment. The authors reported significant improvements in strength, balance, and walking tests following the intervention.

Another RCT compared locomotor training fast walking plus FES to locomotor training at self-selected or fast speeds without FES in 50 poststroke participants.^[38] While fast walking plus FES resulted in larger reductions in energy expenditure with walking than non-FES locomotor training, there were no differences between groups in the six-minute walk test.

Taylor (2013) conducted a small RCT to evaluate FES and physiotherapy exercise for dropped foot and hip instability in 28 patients with secondary progressive multiple sclerosis.^[39] Authors reported that both physiotherapy and FES improved mobility; however, these findings should be interpreted with caution due to the small sample size and cross-over study design whereby all patients received FES.

Knutson (2013) conducted a RCT of 26 stroke patients with chronic (greater than six months) foot drop comparing the effects of contralaterally controlled neuromuscular electrical stimulation (CCNMES) to cyclic neuromuscular electrical stimulation (NMES) on lower extremity impairment, functional ambulation, and gait characteristics.^[40] The authors reported no significant differences between groups. In addition, the study is limited by a lack of control group with which to compare the NMES treatment group outcomes.

Embrey (2010) conducted a randomized crossover trial on the efficacy of the Gait MyoElectric Stimulator for improvements in gait among 28 post-stroke patients after three months of use.^[41] Measures of function, but not activities of daily living, were reported. Patients were a convenience sample and concurrent physical therapy was not applied.

A RCT of functional NMES to improve walking performance in patients with multiple sclerosis (MS) was published by Barrett (2009).^[42] Fifty-three patients with secondary progressive MS and unilateral dropped foot were randomized to an 18-week program of either NMES of the common peroneal nerve using a single channel Odstock Dropped Foot Stimulator or a home exercise program, and assessed at six, 12, and 18 weeks. The primary outcome measure was walking speed over a 10-meter distance followed by secondary outcome measures of energy efficiency based on increase in heart rate during walking and walking distance in three minutes. Outcomes related to activities of daily living were not measured. In the NMES group, mean changes between baseline and 18-week measures were non-significant for all three outcome measures, both with and without stimulation. However, within the NMES group, when mean values for walking speed and distance walked were compared with and without stimulation, outcomes were significantly better with stimulation. In the exercise group, increases in walking speed over 10 meters and distance walked in three minutes were also significant ($p=0.001$ and $p=0.005$ respectively). At 18 weeks, the exercise group walked significantly faster than the NMES group ($p=0.028$). The authors note a number of limitations of their study: power calculations were based on the 10-meter walking speed measure only and indicated that 25 subjects would be required in each group, patients were highly selected, clinical assessors also provided treatment assignments (issues with blinding), and the validity and reliability of the three-minute walk test have not been confirmed (fatigue prevented use of the validated six-minute test). In addition, subjects in the exercise group were told they would receive a stimulator at the end of the trial which may have impacted adherence to the exercise regimen as well as retention in the trial. A second publication on this RCT states that it is not known how much time was spent with the devices each day and that the lack of standardized use of the NMES device is another potential confounder for these findings.^[43]

Section Summary

There have been numerous studies investigating the use of NMES in improving lower limb function in conditions including cerebral palsy, multiple sclerosis, and in post-stroke recovery. These studies do not demonstrate that use of a neuromuscular stimulator device provides clinically significant improvements for any lower extremity condition. The lack of methodologically sound studies limits comparisons between groups. Duration of treatment

effects also is unknown. Additional RCTs comparing outcomes with and without the device are still needed.

FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION FOR OTHER CONDITIONS

Systematic Reviews

The effect of NMES on upper and lower limb strength in patients with chronic kidney failure on hemodialysis was evaluated in a systematic review (SR) with meta-analysis published by Schardong (2020).^[44] Ten studies were included, totaling 242 patients. Some concern or high risk of bias was found in RCTs and moderate or critical risk of bias was found in nonrandomized studies. Random-effects meta-analysis showed that NMES increases quadriceps muscle strength (standardized mean difference [MD]=1.46; 95% confidence interval [CI], 0.86-2.07; $p<0.0001$ moderate quality of evidence), upper limb strength (MD=10.02kgF; 95% CI, 0.78-19.27; $p=0.03$ low quality of evidence), and functional capacity (MD=30.11m; 95% CI, 15.57-44.65; $p<0.0001$ moderate quality of evidence). Additional RCTs that address the risks of bias are needed.

Waldauf (2020) published a SR with meta-analysis investigating NMES, cycling exercises or protocolized physical rehabilitation as compared to standard of care in critically ill adults.^[45] Forty three RCTs (nine on cycling, 14 on NMES alone and 20 on protocolized physical rehabilitation) including 3,548 patients were reviewed. Reduced duration of mechanical ventilation (MD= -1.7 d [-2.5 to -0.8 d], $n = 32$ RCTs) and length of stay in ICU (MD= -1.2 d [-2.5 to 0.0 d], $n=32$ RCTs) were observed for treatment groups, however these effects were only significant for the protocolized physical rehabilitation subgroup. No impact of exercise interventions on mortality (odds ratio 0.94 [0.79-1.12], $n=38$ RCTs) or days in the hospital (MD=-1.6 [-4.3 to 1.2 d], $n=23$) was found.

The available data from RCTs evaluating the effect of NMES on swallowing function in dysphagic stroke patients were reviewed Alamer (2020).^[46] Eleven RCTs involving 784 patients were included in the analysis and the overall quality of the evidence was moderate to high. The PEDro score of all included studies was ranged from 5 to 9, with the mean score of seven. The treatment duration ranged from 10 to 60 minutes for each session, 2 to 5 times per week for a 2 to 6 week period. The primary outcome measures of the review were functional dysphagia scale (FDS), video fluoroscopy dysphagia scale (VFDS) and standardized swallowing assessments (SSA). Only two studies blinded the participants and therapists and four studies blinded the assessor. Of 11 studies, 10 ($n=748$) found that NMES groups had improved swallowing function in post-stroke dysphagia patients compared to the control, whereas one study ($n=36$) reported no differences between the experimental and control groups. No meta-analysis was possible due to heterogeneity of the available data.

Sun (2020) published a SR with meta-analysis evaluating the effectiveness of NMES in swallowing disorders across eight RCTs and three quasi-randomized controlled trials (studies in which the method of allocation is not considered strictly random).^[47] The quality of evidence was low to very low; all eight studies had small sample sizes, ranging from 18 to 57 contributing to high risk of bias, and only two studies had low risk of bias in allocation concealment. A significant, moderate pooled effect size (MD = 0.62; 95% CI=0.06 to 1.17) was found across all studies for NMES. Analysis of data from studies evaluating stimulation of the suprahyoid muscle groups revealed a negative MD of 0.17 (95% CI=-0.42, 0.08), whereas a large effect size was observed in studies stimulating the infrahyoid muscle groups (MD = 0.89;

95% CI = 0.47 to 1.30) and stimulating the suprahyoid and infrahyoid muscle groups (MD = 1.4; 95% CI = 1.07 to 1.74). Stimulation lasting 45 mins or less showed a large, significant pooled effect size (MD = 0.89; 95% CI = 0.58 to 1.20). Across all studies, no serious adverse events associated with NMES were reported. Larger and well-designed RCTs are needed to reach robust conclusions on the efficacy of NMES on swallowing disorders.

A SR by Novak (2020) provided an evaluation of optimal electrical stimulation parameters for adults with osteoarthritis (OA).^[48] The authors found that studies using NMES had a 77% decrease in pain and 72%-218% increase in quadriceps femoris strength. No evaluation of statistical significance in these percentages were reported. The concurrent use of other modalities, such as low-level laser therapy, with NMES in these studies do not permit the conclusion that the effects observed are due to the use of NMES. Heterogeneity in the treatment parameters across studies precluded meta-analysis.

The clinical outcomes of NMES applied during hemodialysis in people with end-stage renal disease was evaluated in a SR published by Valenzuela (2020).^[49] The authors included eight studies (N=221) and functional capacity, muscle strength, muscle mass, psychological outcomes, cardiovascular outcomes, biochemical variables and adverse events were the outcomes of interest. Differences between NMES-treated and control groups were analyzed by pooled mean difference between groups with a 95% confidence interval. Improvements were observed in the NMES group in functional capacity as assessed by the 6-minute walk distance test (MD 31 m, 95% CI 13 to 49), peak workload attained in incremental exercise (MD 12.5 W, 95% CI 3.2 to 21.9), knee extensor muscle strength (MD 3.5 kg, 95% CI 2.3 to 4.7) and handgrip strength (MD 2.4 kg, 95% CI 0.4 to 4.4). No clear effects on cardiovascular outcomes or biochemical variables (dialysis efficiency, urea and creatinine) were identified. No major adverse events related to NMES were observed. Although the quality of the included studies was fair to good, two studies followed a quasi-randomized design and the sample size of all included studies was low (consistently < 23 participants in NMES arms). In addition, blinding of participants or investigators was not commonly done, so a placebo effect and potential performance and detection bias cannot be ruled out. Future RCTs, especially long-term trials, are needed to confirm the effectiveness and safety of NMES in dialysis patients.

The effects of electrical stimulation in treating dysphonia were reviewed by Almeida.^[50] Eleven publications evaluating the effects of NMES or TENS on dysphonia caused by vocal fold paralysis, spasmodic dysphonia, behavioral dysphonia, or vocal fold nodules were included. The studies were classified as either high quality (three studies) or fair quality (eight studies). Although the authors found evidence that electrical stimulation may have a therapeutic effect in dysphonia, they conclude that due to the high risk of bias and data heterogeneity, the effectiveness of electrical stimulation in treating dysphonia cannot be established.

A broad SR evaluating interventions aimed at ameliorating reductions in physical performance, muscle strength and muscle quantity in hospitalized adults was published by Welch 2020.^[51] Although 44 studies (N=4,522) were included, only three were NMES studies (N=206), all of which combined the intervention with exercise. Findings were inconsistent across studies; a trial in a geriatric medicine population found no change in gait speed, a trial in a respiratory medicine population showed less decline in knee extension strength, and a third trial in a general medicine population found improvements in physical performance with NMES treatment. No meta-analysis was provided. Additional research, particularly regarding adherence, physical activity impact, and treatment protocol is needed before the effectiveness of NMES on preventing or treating sarcopenia in hospitalized adults can be established.

The effects of NMES on exercise capacity, functional performance, symptoms, and health-related quality of life (HRQoL) in patients with chronic obstructive pulmonary disease (COPD) was assessed in a SR with meta-analysis by Wu in 2020.^[52] Thirteen RCTs (N=447) were analyzed. Outcome measures included the 6-min walking distance (6MWD), peak rate of oxygen uptake (VO₂ peak), St George's Respiratory Questionnaire (SGRQ), and self-reported symptoms of dyspnoea and fatigue. Pooled estimates showed a significant increase in 6MWD the NMES group compared with the control group (mean difference (MD)=27.05, 95% confidence interval (CI): 8.46–45.63, $p<0.001$). No statistically significant difference was observed in VO₂ peak, peak power, or SGRQ. The quality of the evidence was very low, largely limited by poor methodology, which was noted as a primary limitation in the meta-analysis. The authors concluded that NMES is not to be recommended as an effective alternative training modality in the rehabilitation of stable COPD patients.

Zayed (2019) performed a SR and meta-analysis on RCTs comparing NMES plus usual care versus usual care in adult ICU patients on prevention of critical care myopathy.^[53] The primary outcome was global muscle strength and secondary outcomes included ICU mortality, duration of mechanical ventilation (MV), and ICU length of stay. Six RCTs were included. There was no significant difference between NMES plus usual care on global muscle strength, ICU mortality, duration of MV, or ICU length of stay in comparison with the usual therapy alone in critically ill patients. The authors conclude that further RCTs are needed to determine patients with maximum benefit and to examine NMES safety and efficacy.

A SR by Burgess (2019) reported the effectiveness of NMES for reducing edema.^[54] The seven studies meeting inclusion criteria included three RCTs and four non-randomized clinical trials. Within the studies sourced, there was a wide variation in the parameters utilized, but, in general, NMES was applied for 20–30 min. Stimulation occurred once a day in five studies, five times per week in one study, and reduced from three times to two times, to once per month, in one study. Although all studies reported a reduction in edema with NMES, variance in methodologies prevented the authors from providing a detailed comparison of this primary outcome. This variation in clinical presentations, methodologies, equipment, and rehabilitation settings of the included studies limited the generalizability of the review. Appropriately powered RCTs are required to determine the utility of NMES in the treatment of edema.

Intiso (2017) published a SR evaluating electrical stimulation as an adjunct to botulism toxin type A, for adult spasticity.^[55] Nine studies were included, for either neuromuscular stimulation or functional electrical stimulation. The authors concluded evidence does not support a combined treatment of electrical stimulation and botulism toxin type A, for spasticity. Additional high quality trials are needed.

Chen (2016) published a SR that evaluated the impact on health outcomes for NMES versus rehabilitation for patients with moderate-to severe COPD.^[56] Nine RCTs with 276 participants were included. The authors concluded NMES may be effective in improving quadriceps strength and exercise capacity in moderate to severe COPD, but more research is needed to evaluate the effect of NMES on other outcomes including quality of life.

Williams (2016) published a SR that evaluated several non-invasive treatments for peripheral arterial disease (PAD), to improve circulation.^[57] Four of the 31 studies included evaluated NMES. The authors concluded there only low-level evidence is available to support the use of electrical stimulation for PAD.

Randomized Controlled Trials

Hyer (2021) published the results of a RCT evaluating the impact of NMES on calf muscle volume and patient reported outcome measures following Achilles tendon surgery.^[58] A total of 40 patients followed a standardized postoperative protocol after surgical repair of the Achilles tendon. Group 1 (n=20) received protocol specific NMES and Group 2 (n=20, "sham device" control group) received subtherapeutic electrical stimulation. Preoperative and postoperative calf circumference (two, six, and 12 weeks) and magnetic resonance imaging (MRI) scans (two and six weeks), and patient-reported functional outcome scores were measured. No statistically significant difference was found between active NMES and sham control group.

The effectiveness of NMES in patients with postoperative complications after cardiovascular surgery was studied in a RCT published by Sumin (2020).^[59] In this trial, 18 patients underwent daily NMES starting postoperative day three until discharge in addition to standard rehabilitation program (NMES group), and 19 patients underwent standard rehabilitation program only (control group). Knee extensor strength at discharge, the primary outcome, was significantly higher in the NMES group (28.1 [23.8; 36.2] kg on the right and 27.45 [22.3; 33.1] kg on the left) than in the control group (22.3 [20.1; 27.1] and 22.5 [20.1; 25.9] kg, respectively; $p < 0.001$). No significant difference between groups was found in secondary outcomes of handgrip strength, knee flexor strength, quadriceps size, and 6-minute walk distance at discharge. Additional RCT trials are needed to overcome limitations of this study including small sample size and lack of long-term outcome data.

Dos Santos (2019) published the results of an RCT evaluating the effectiveness of NMES, either alone or in combination with exercise on reducing the duration of mechanical ventilation (MV) in critically ill patients.^[60] Participants were prospectively recruited within 24 hours following admission to the intensive care unit and randomly assigned to NMES (n=11), exercise (EX, n=13), combined therapy (NMES + EX, n=12), or standard of care (control, n=15). Duration of MV (days) was shorter in the combined therapy (5.7 ± 1.1) and NMES (9.0 ± 7.0) groups in comparison to control (14.8 ± 5.4). The small sample size of this study limits the ability to draw generalizable conclusions regarding NMES in critically ill patients.

Zhang (2019) published the results of a two-arm (RCT) of NMES for chronic urinary retention (CUR) following traumatic brain injury (TBI).^[61] Patients were randomly allocated to a treatment group (n=43) or a sham group (n=43) for an eight-week period treatment and four-week period follow-up. All primary (post-voiding residual urine volume) and secondary outcomes (voided volume, maximum urinary flow rate, and quality of life) were measured at baseline, at the end of eight-week treatment, and four-week follow-up. At the end of eight-week treatment as well as at the end of the four-week follow-up, the patients in the treatment group did not achieve better outcomes in any of the metrics than patients in the control group. The findings of this study showed that NMES therapy does not benefit patients with CUR following TBI.

Feil (2011) published the results of a randomized controlled study of NMES in highly-selected patients from a single clinical rehabilitation site undergoing endoscopically assisted reconstruction of the anterior cruciate ligament (ACL).^[62] Participants were randomized to a control group (performed volitional isometric quadriceps muscle contractions but did not use NMES), a group receiving NMES by the Polystim (PS, Biomedical Research Ltd) device, in which electrodes attached to a lead wire are placed on the skin for each treatment, or a group receiving NMES by the Kneehab (KH, Biomedical Research Ltd) device, which integrates the electrodes and wiring into a garment. Although 131 patients were randomized, 35 (26.7%) patients were later excluded from study participation for reasons that included deviation from the course of rehabilitation. An intention-to-treat analysis was performed to compare the

estimated treatment effect (pairwise comparison between KH and CO group only), using imputed values for missing data. The data analyzed included observations from 96 subjects as follows: KH group (n = 33 at completion), the PS group (n = 29 at completion), and control group (n = 34 at completion). These sample sizes included in the final dataset did not consistently meet the minimum needed per group (32) to achieve 80% power at a significance level of $p < 0.05$ according to *a priori* power calculations. Outcomes in all groups were improved across the study period and average strength and functional performance measures for the KH group were more improved than PS and control groups. This study is limited by considerable attrition, lack of an active control (sham) group, and lack of longer-term (beyond 24 weeks) follow-up.

Section Summary

The current studies do not demonstrate improved health outcomes from NMES for other conditions, including but not limited to COPD, edema, peripheral artery disease, or spasticity. Based on the available published evidence, additional RCTs comparing this therapy to standard treatment are still required.

NEUROMUSCULAR ELECTRICAL STIMULATION CYCLE ERGOMETERS AND ROWING MACHINES

More recently there has been interest in electromyography (EMG)-triggered functional neuromuscular electrical stimulation with exercise as a therapy for patients with lower extremity paresis. Available studies on this topic include two SRs, one RCT,^[63] and several comparative studies.^[64-73]

Systematic Reviews

van der Scheer (2021) published the results of a systematic review (SR) of data on the use of functional electrical stimulation (FES) cycling exercise after spinal cord injury (SCI) with a specific focus on health and fitness-related outcomes.^[74] Studies were included if they were in populations of participants that were at least 50% adult (≥ 16 years) with traumatic or non-traumatic SCI who were eligible and responsive to FES cycling. Studies in populations with a congenital condition (e.g., spina bifida) or a progressive disease (e.g., multiple sclerosis with spinal cord involvement) were excluded. Ninety-two studies (N=999) adults were included in the review. Study quality was appraised using Cochranes' Risk of Bias or Downs and Black tools; of the 92 studies reviewed, two were classified as Level 1 studies, seven as Level 2 studies, 65 as Level 3 studies, and 18 as Level 4 studies. Several outcome categories were defined, including muscle health, power output, aerobic fitness, fat mass, cardiovascular/metabolic, bone health, subjective well-being, and functional/neurological outcomes. For muscle health (36 studies), the one Level 1 study reported non-significant findings, while the four Level 2 studies and over 80% of Level 3 or 4 studies reported significant improvements ('Moderate' certainty in the evidence for *any* adult with SCI, and 'High' certainty in evidence for young to middle-aged adults with SCI). For power output and aerobic fitness, data from Level 1 or 2 studies were not identified, however, Level 3 and 4 studies reported significant improvement in these categories ("Low" certainty in evidence). Limited evidence was available for the other outcomes ('Very Low' certainty in evidence due to an absence of Level 1 or 2 studies, effects being inconsistent across the studies, imprecision, and/or indirectness).

A SR with meta-analysis by Fang (2021) was conducted to investigate the effect and dose-response of FES cycling on spasticity in individuals with SCI.^[75] The primary outcome measure

was spasticity assessed by Modified Ashworth Scale (MAS) or Ashworth Scale for lower limbs. Secondary outcome measures were walking abilities assessed by 6 Min Walk Test (6MWT), Timed Up and Go (TUG), and lower limbs muscle strength (LEMS). Twelve studies (one RCT and 11 nonrandomized or uncontrolled studies) were included in the qualitative assessment and data from eight of these were included in the meta-analysis (N=99). Time since injury ranged from less than four weeks to 17 years and participant age ranged from 20 to 67 years. Spasticity decreased significantly (95% CI=- 1.538 to - 0.182, $p = 0.013$) in favor of FES-cycling. Subgroup analysis showed that spasticity decreased significantly only in groups with more than 20 training sessions (95% CI=- 1.749 to -0.149, $p = 0.020$). Inclusion of a single RCT is a limitation of the available data. In addition, MAS of different lower extremities joints were pooled for the analysis, and factors such as level of injury, time since injury, frequency of FES, treatment duration could not be analyzed by subgroup.

The safety and effectiveness of ergometer training, including the use of FES in ergometer training, in stroke rehabilitation was evaluated in a SR published by Veldema (2020).^[76] The review included total of 28 studies (N=1115), however only six trials tested the effects of simple ergometer training in comparison to ergometer training with the assistance of FES in stroke rehabilitation. The meta-analysis found improved balance and postural control ($d=1.26$; 95% CI, 0.31-2.20; $I^2=95%$) as well as improved motor function and muscle force of lower limbs ($d=1.96$; 95% CI, 0.92-3.05; $I^2=100%$) in neuromuscular FES-assisted ergometer training over ergometer training alone. No significant effects were detected for cardiorespiratory fitness, walking ability, spasticity and hypertonia, or independence in activities of daily living. There was considerable heterogeneity in study populations, intervention protocols, and outcomes across trials. No adverse events were reported. The authors conclude that current data are too limited to recommend ergometer training in evidence-based rehabilitation. Additional research is needed to overcome the limitations of existing studies.

A SR with meta-analysis published by Ambrosini (2020) evaluated the effects of FES cycling, alone or in addition to usual care on walking, muscle power and tone, balance and activities of daily living in subacute stroke (less than six months) survivors.^[77] Seven RCTs (N=273) set in inpatient rehabilitation centers were included. The duration of the intervention ranged from three to eight weeks, and frequency of treatment ranged from three to six sessions per week. Four of the studies had low risk of bias, and the most frequently noted source of bias overall was lack of blinding. One study was adequately blinded with a placebo stimulation. Data from six studies (N=221) were included in the meta-analysis. A significant effect of treatment over placebo was found for walking short distances (SMD [95% CI] = 0.40, [0.13, 0.67]; $p=0.004$), which was the primary outcome. Secondary outcomes had mixed results, including improvement in the treatment group for capability to maintain a sitting position (MD [95% CI] = 7.92 [1.01, 14.82]; $p=0.02$; N=118). A moderate quality of evidence supported these findings. No significant differences were found between treatment and control groups for including muscle power functions of the lower limb, capability to maintain a standing position, or to perform activities of daily living. The authors conclude the current evidence of the effect of FES cycling in subacute stroke patients is limited, and that it cannot be recommended over usual care.

A 2019 SR published by Scally examined the outcomes of people with multiples sclerosis (MS) with mobility impairment following FES cycling intervention.^[78] Nine studies met the full inclusion criteria including five pre-post studies with no control group, two RCTs, one retrospective study and one case study. Outcome data was available for 76 unique participants, with 82 completing a FES cycling intervention. Two papers reported non-

significant improvements in aerobic capacity following a FES cycling intervention. Four papers reported no change in lower limb strength and two papers reported significant reductions in spasticity post training. The authors conclude that the low quality of the literature precludes any definitive conclusions regarding FES cycle training in treating spasticity or reducing cardiovascular disease risk in people with MS.

Shariat (2019) published a meta-analysis evaluating effects of cycling with and without FES on lower limb dysfunction in patients post-stroke.^[79] A total of 14 trials satisfied eligibility criteria and were included. Cycling had a positive effect on the six-meter walking test performance (standardized mean difference [SMD], 0.41; 95% confidence interval [CI], 0.11 -0.71; I²=0%) compared with no or placebo intervention (control). Compared with control, cycling had a positive effect on 10-meter walking speed (SMD, 0.30; 95% CI, 0.05 -0.55; I²=0%), and on balance based on the Berg score (SMD, 0.32; 95% CI, 0.06 -0.57; I²=49%). Cycling with functional electrical stimulation had a positive effect on balance (SMD, 1.48; 95% CI, 0.99 - 1.97; I²=91%) compared with cycling alone. The authors conclude that cycling has a positive effect on walking speed, walking ability and balance. While functional electrical stimulation combined with cycling had positive effects on balance beyond cycling alone, this additional benefit of FES to cycling alone on other outcomes, including walking, was not determined.

Randomized Controlled Trials

Johnston (2009) reported on an RCT conducted on 30 children with spinal cord injury aged 5 to 13 years.^[63] Children were randomly assigned by block randomization to one of three groups: cycling, with or without functional electrical stimulation (FES), or a control group receiving only electrical stimulation therapy at home three times a week for six months. Primary outcomes included improvements in oxygen uptake (VO₂), resting heart rate, forced vital capacity (FVC), and fasting lipid profile. Clinically relevant outcomes, such as those relating to activities of daily living or quality of life, were not investigated.

Neuromuscular Electrical Stimulation Cycling Adherence

Kressler (2019) published an analysis of functional electrical stimulation (FES) cycle usage data from 314 users with spinal cord injury (SCI) who engaged in 20,183 activity sessions.^[80] Usage patterns and energy expenditure were compared with authoritative exercise guidelines of 150 minutes of moderate-intensity aerobic activity per week over at least two days per week for a total of 1,000 kcals. Seven percent of participants were classified as high- (greater than or equal to five days per week), 11% as medium- (two to five days per week), and 82% as low-frequency users (less than two days per week). None of the users satisfied authoritative energy expenditure recommendations for disease prevention with FES cycling alone.

Section Summary

It is not clear that the benefits accomplished with EMG-triggered NMES plus cycling cannot be realized through standard passive range of motion exercise. Further, the feasibility and long-term benefits of using NMES cycling is uncertain. Based on the available published evidence, additional RCTs comparing this therapy to standard treatment are still required.

PRACTICE GUIDELINE SUMMARY

DEPARTMENT OF VETERANS AFFAIRS (VA), DEPARTMENT OF DEFENSE (DOD)

The Department of Veterans Affairs (VA) and Department of Defense (DoD) (2019) published a Clinical Practice Guideline for the Management of Stroke Rehabilitation, which included feedback from the American Physical Therapy Association, the Association of Academic Physiatrists, and the Case Management Society of America.^[81] This guideline suggests offering the use of functional electrical stimulation for shoulder subluxation, although the quality of evidence for this recommendation was considered moderate. The guideline also states very low confidence in the quality of evidence for offering functional electrical stimulation, neuromuscular electrical stimulation, or transcutaneous electrical nerve stimulation as an adjunctive treatment to improve upper and lower extremity motor function. For patients with foot drop, the guideline “suggest[s] offering either functional electrical stimulation or traditional ankle foot orthoses to improve gait speed, as both are equally effective.”

THE AMERICAN HEART ASSOCIATION/ AMERICAN STROKE ASSOCIATION

The American Heart Association and American Stroke Association published a guideline for adult stroke rehabilitation in 2016.^[82] This guideline comments on the use of electrical stimulation for the treatment of hemiplegic shoulder pain, including NMES, with the conclusion that this modality has not been evaluated sufficiently and its efficacy for pain prevention and treatment remains inconclusive.

SUMMARY

There is not enough research to show that neuromuscular electrical stimulation (NMES) improves health outcomes for people with spinal cord injury, stroke, congenital disorders, nerve damage, pain, or other conditions. Further, the feasibility and long-term health benefits of using NMES cycling is uncertain. Based on the available published evidence, additional randomized controlled trials comparing this combined therapy to standard treatment are needed. Therefore, functional NMES is considered investigational for all indications, including but not limited to treatment of spinal cord injury, stroke, congenital disorders, nerve damage, or pain

REFERENCES

1. D Graupe, KH Kohn. Functional neuromuscular stimulator for short-distance ambulation by certain thoracic-level spinal-cord-injured paraplegics. *Surg Neurol.* 1998;50(3):202-7. PMID: 9736079
2. K Monte-Silva, D Piscitelli, N Norouzi-Gheidari, MAP Batalla, P Archambault, MF Levin. Electromyogram-Related Neuromuscular Electrical Stimulation for Restoring Wrist and Hand Movement in Poststroke Hemiplegia: A Systematic Review and Meta-Analysis. *Neurorehabil Neural Repair.* 2019;33(2):96-111. PMID: 30704366
3. J Jonsdottir, R Thorsen, I Aprile, et al. Arm rehabilitation in post stroke subjects: A randomized controlled trial on the efficacy of myoelectrically driven FES applied in a task-oriented approach. *PLoS One.* 2017;12(12):e0188642. PMID: 29200424
4. RD Wilson, SJ Page, M Delahanty, et al. Upper-Limb Recovery After Stroke: A Randomized Controlled Trial Comparing EMG-Triggered, Cyclic, and Sensory Electrical Stimulation. *Neurorehabil Neural Repair.* 2016;30(10):978-87. PMID: 27225977
5. J Eraifej, W Clark, B France, S Desando, D Moore. Effectiveness of upper limb functional electrical stimulation after stroke for the improvement of activities of daily

- living and motor function: a systematic review and meta-analysis. *Systematic reviews*. 2017;6(1):40. PMID: 28245858
6. JH Lee, LL Baker, RE Johnson, JK Tilson. Effectiveness of neuromuscular electrical stimulation for management of shoulder subluxation post-stroke: a systematic review with meta-analysis. *Clinical rehabilitation*. 2017;31(11):1431-44. PMID: 28343442
 7. KN Arya, S Pandian, V Puri. Rehabilitation methods for reducing shoulder subluxation in post-stroke hemiparesis: a systematic review. *Top Stroke Rehabil*. 2017:1-14. PMID: 29017429
 8. P Gu, JJ Ran. Electrical Stimulation for Hemiplegic Shoulder Function: A Systematic Review and Meta-Analysis of 15 Randomized Controlled Trials. *Arch Phys Med Rehabil*. 2016;97(9):1588-94. PMID: 27178095
 9. G Uswatte, E Taub, MH Bowman, et al. Rehabilitation of stroke patients with plegic hands: Randomized controlled trial of expanded Constraint-Induced Movement therapy. *Restor Neurol Neurosci*. 2018;36(2):225-44. PMID: 29526860
 10. LA Harvey, SA Dunlop, L Churilov, MP Galea. Early intensive hand rehabilitation is not more effective than usual care plus one-to-one hand therapy in people with sub-acute spinal cord injury ('Hands On'): a randomised trial. *Journal of physiotherapy*. 2016;62(2):88-95. PMID: 27008910
 11. MR Popovic, N Kapadia, V Zivanovic, JC Furlan, BC Craven, C McGillivray. Functional electrical stimulation therapy of voluntary grasping versus only conventional rehabilitation for patients with subacute incomplete tetraplegia: a randomized clinical trial. *Neurorehabil Neural Repair*. 2011;25(5):433-42. PMID: 21304020
 12. DJ Weber, ER Skidmore, C Niyonkuru, CL Chang, LM Huber, MC Munin. Cyclic functional electrical stimulation does not enhance gains in hand grasp function when used as an adjunct to onabotulinumtoxinA and task practice therapy: a single-blind, randomized controlled pilot study. *Arch Phys Med Rehabil*. 2010;91(5):679-86. PMID: 20434603
 13. JS Knutson, DD Gunzler, RD Wilson, J Chae. Contralaterally Controlled Functional Electrical Stimulation Improves Hand Dexterity in Chronic Hemiparesis: A Randomized Trial. *Stroke; a journal of cerebral circulation*. 2016;47(10):2596-602. PMID: 27608819
 14. SM Jeon, Y Kim, KS Jung, YJ Chung. The effects of electromyography-triggered electrical stimulation on shoulder subluxation, muscle activation, pain, and function in stroke patients - pilot study. *NeuroRehabilitation*. 2016. PMID: 27792019
 15. M Jaqueline da Cunha, KD Rech, AP Salazar, AS Pagnussat. Functional electrical stimulation of the peroneal nerve improves post-stroke gait speed when combined with physiotherapy. A systematic review and meta-analysis. *Ann Phys Rehabil Med*. 2020. PMID: 32376404
 16. LR Nascimento, LA da Silva, JVM Araujo Barcellos, LF Teixeira-Salmela. Ankle-foot orthoses and continuous functional electrical stimulation improve walking speed after stroke: a systematic review and meta-analyses of randomized controlled trials. *Physiotherapy*. 2020;109:43-53. PMID: 33120054
 17. AP Salazar, AS Pagnussat, GA Pereira, G Scopel, JL Lukrafka. Neuromuscular electrical stimulation to improve gross motor function in children with cerebral palsy: a meta-analysis. *Brazilian journal of physical therapy*. 2019;23(5):378-86. PMID: 30712812
 18. I Moll, JSH Vles, D Soudant, et al. Functional electrical stimulation of the ankle dorsiflexors during walking in spastic cerebral palsy: a systematic review. *Developmental medicine and child neurology*. 2017. PMID: 28815571

19. JH Cauraugh, SK Naik, WH Hsu, SA Coombes, KG Holt. Children with cerebral palsy: a systematic review and meta-analysis on gait and electrical stimulation. *Clinical rehabilitation*. 2010;24(11):963-78. PMID: 20685722
20. LM Renfrew, L Paul, A McFadyen, et al. The clinical- and cost-effectiveness of functional electrical stimulation and ankle-foot orthoses for foot drop in Multiple Sclerosis: a multicentre randomized trial. *Clinical rehabilitation*. 2019;33(7):1150-62. PMID: 30974955
21. S Prenton, KL Hollands, LPJ Kenney, P Onmanee. Functional electrical stimulation and ankle foot orthoses provide equivalent therapeutic effects on foot drop: A meta-analysis providing direction for future research. *Journal of rehabilitation medicine*. 2018;50(2):129-39. PMID: 29227525
22. S Prenton, KL Hollands, LP Kenney. Functional electrical stimulation versus ankle foot orthoses for foot-drop: A meta-analysis of orthotic effects. *Journal of rehabilitation medicine*. 2016;48(8):646-56. PMID: 27563700
23. F Bethoux, HL Rogers, KJ Nolan, et al. The effects of peroneal nerve functional electrical stimulation versus ankle-foot orthosis in patients with chronic stroke: a randomized controlled trial. *Neurorehabil Neural Repair*. 2014;28:688-97. PMID: 24526708
24. PM Kluding, K Dunning, MW O'Dell, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. *Stroke; a journal of cerebral circulation*. 2013;44:1660-9. PMID: 23640829
25. DG Everaert, RB Stein, GM Abrams, et al. Effect of a foot-drop stimulator and ankle-foot orthosis on walking performance after stroke: a multicenter randomized controlled trial. *Neurorehabil Neural Repair*. 2013;27:579-91. PMID: 23558080
26. K Dunning, MW O'Dell, P Kluding, K McBride. Peroneal Stimulation for Foot Drop After Stroke: A Systematic Review. *Am J Phys Med Rehabil*. 2015;94(8):649-64. PMID: 26035725
27. L Miller, A McFadyen, AC Lord, et al. Functional Electrical Stimulation for Foot Drop in Multiple Sclerosis: A Systematic Review and Meta-Analysis of the Effect on Gait Speed. *Arch Phys Med Rehabil*. 2017;98(7):1435-52. PMID: 28088382
28. S Springer, S Khamis. Effects of functional electrical stimulation on gait in people with multiple sclerosis - A systematic review. *Multiple sclerosis and related disorders*. 2017;13:4-12. PMID: 28427700
29. EC Wonsetler, MG Bowden. A systematic review of mechanisms of gait speed change post-stroke. Part 1: spatiotemporal parameters and asymmetry ratios. *Top Stroke Rehabil*. 2017;24(6):435-46. PMID: 28220715
30. C Yue, X Zhang, Y Zhu, Y Jia, H Wang, Y Liu. Systematic Review of Three Electrical Stimulation Techniques for Rehabilitation After Total Knee Arthroplasty. *The Journal of arthroplasty*. 2018;33(7):2330-37. PMID: 29530519
31. CT Gatewood, AA Tran, JL Dragoo. The efficacy of post-operative devices following knee arthroscopic surgery: a systematic review. *Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA*. 2017;25(2):501-16. PMID: 27695905
32. A Bistolfi, J Zanovello, R Ferracini, et al. Evaluation of the effectiveness of neuromuscular electrical stimulation after total knee arthroplasty: a meta-analysis. *Am J Phys Med Rehabil*. 2017. PMID: 29016401
33. A Langeard, L Bigot, N Chastan, A Gauthier. Does neuromuscular electrical stimulation training of the lower limb have functional effects on the elderly?: A systematic review. *Experimental gerontology*. 2017;91:88-98. PMID: 28216413

34. K Hachisuka, M Ochi, T Kikuchi, S Saeki. Clinical effectiveness of peroneal nerve functional electrical stimulation in chronic stroke patients with hemiplegia (PLEASURE): A multicentre, prospective, randomised controlled trial. *Clinical rehabilitation*. 2021;35(3):367-77. PMID: 33103916
35. T Prokopiushova, M Pavlikova, M Markova, K Rasova. Randomized comparison of functional electric stimulation in posturally corrected position and motor program activating therapy: treating foot drop in people with multiple sclerosis. *Eur J Phys Rehabil Med*. 2020;56(4):394-402. PMID: 32383574
36. F Berenpas, AC Geurts, J den Boer, R van Swigchem, F Nollet, V Weerdesteyn. Surplus value of implanted peroneal functional electrical stimulation over ankle-foot orthosis for gait adaptability in people with foot drop after stroke. *Gait Posture*. 2019;71:157-62. PMID: 31071538
37. D Lee, G Lee, J Jeong. Mirror Therapy with Neuromuscular Electrical Stimulation for improving motor function of stroke survivors: A pilot randomized clinical study. *Technology and health care : official journal of the European Society for Engineering and Medicine*. 2016;24(4):503-11. PMID: 26890230
38. LN Awad, DS Reisman, RT Pohlig, SA Binder-Macleod. Reducing The Cost of Transport and Increasing Walking Distance After Stroke: A Randomized Controlled Trial on Fast Locomotor Training Combined With Functional Electrical Stimulation. *Neurorehabil Neural Repair*. 2016;30(7):661-70. PMID: 26621366
39. P Taylor, C Barrett, G Mann, W Wareham, I Swain. A feasibility study to investigate the effect of functional electrical stimulation and physiotherapy exercise on the quality of gait of people with multiple sclerosis. *Neuromodulation : journal of the International Neuromodulation Society*. 2014;17(1):75-84; discussion 84. PMID: 23601128
40. JS Knutson, K Hansen, J Nagy, et al. Contralaterally controlled neuromuscular electrical stimulation for recovery of ankle dorsiflexion: a pilot randomized controlled trial in patients with chronic post-stroke hemiplegia. *Am J Phys Med Rehabil*. 2013;92:656-65. PMID: 23867888
41. DG Embrey, SL Holtz, G Alon, BA Brandsma, SW McCoy. Functional electrical stimulation to dorsiflexors and plantar flexors during gait to improve walking in adults with chronic hemiplegia. *Arch Phys Med Rehabil*. 2010;91(5):687-96. PMID: 20434604
42. CL Barrett, GE Mann, PN Taylor, P Strike. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. *Mult Scler*. 2009;15(4):493-504. PMID: 19282417
43. JE Esnouf, PN Taylor, GE Mann, CL Barrett. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. *Mult Scler*. 2010;16(9):1141-7. PMID: 20601398
44. J Schardong, C Stein, R Della Mea Plentz. Neuromuscular Electrical Stimulation in Chronic Kidney Failure: A Systematic Review and Meta-analysis. *Arch Phys Med Rehabil*. 2020;101(4):700-11. PMID: 31877308
45. P Waldauf, K Jiroutkova, A Krajcova, Z Puthuchear, F Duska. Effects of Rehabilitation Interventions on Clinical Outcomes in Critically Ill Patients: Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Crit Care Med*. 2020;48(7):1055-65. PMID: 32345834
46. A Alamer, H Melese, F Nigussie. Effectiveness of Neuromuscular Electrical Stimulation on Post-Stroke Dysphagia: A Systematic Review of Randomized Controlled Trials. *Clin Interv Aging*. 2020;15:1521-31. PMID: 32943855

47. Y Sun, X Chen, J Qiao, et al. Effects of Transcutaneous Neuromuscular Electrical Stimulation on Swallowing Disorders: A Systematic Review and Meta-Analysis. *Am J Phys Med Rehabil.* 2020;99(8):701-11. PMID: 32209833
48. S Novak, G Gueron, Z Zou, G Cheung, JP Berteau. New Guidelines for Electrical Stimulation Parameters in Adult Patients With Knee Osteoarthritis Based on a Systematic Review of the Current Literature. *Am J Phys Med Rehabil.* 2020;99(8):682-88. PMID: 32167955
49. PL Valenzuela, JS Morales, LM Ruilope, P de la Villa, A Santos-Lozano, A Lucia. Intradialytic neuromuscular electrical stimulation improves functional capacity and muscle strength in people receiving haemodialysis: a systematic review. *Journal of physiotherapy.* 2020;66(2):89-96. PMID: 32291224
50. ANS Almeida, DAD Cunha, SLS Ferreira, BTL Guimaraes, PMM Balata, HJD Silva. Effect of Electrical Stimulation on the Treatment of Dysphonia: A Systematic Review. *J Voice.* 2020. PMID: 32868145
51. C Welch, Z Majid, C Greig, J Gladman, T Masud, T Jackson. Interventions to ameliorate reductions in muscle quantity and function in hospitalised older adults: a systematic review towards acute sarcopenia treatment. *Age Ageing.* 2020. PMID: 33098419
52. X Wu, X Hu, W Hu, G Xiang, S Li. Effects of neuromuscular electrical stimulation on exercise capacity and quality of life in COPD patients: a systematic review and meta-analysis. *Biosci Rep.* 2020;40(5). PMID: 32368783
53. Y Zayed, B Kheiri, M Barbarawi, et al. Effects of neuromuscular electrical stimulation in critically ill patients: A systematic review and meta-analysis of randomised controlled trials. *Aust Crit Care.* 2019. PMID: 31160215
54. LC Burgess, T Immins, I Swain, TW Wainwright. Effectiveness of neuromuscular electrical stimulation for reducing oedema: A systematic review. *Journal of rehabilitation medicine.* 2019;51(4):237-43. PMID: 30834452
55. D Intiso, A Santamato, F Di Rienzo. Effect of electrical stimulation as an adjunct to botulinum toxin type A in the treatment of adult spasticity: a systematic review. *Disability and rehabilitation.* 2017;39(21):2123-33. PMID: 27764971
56. RC Chen, XY Li, LL Guan, et al. Effectiveness of neuromuscular electrical stimulation for the rehabilitation of moderate-to-severe COPD: a meta-analysis. *International journal of chronic obstructive pulmonary disease.* 2016;11:2965-75. PMID: 27932876
57. KJ Williams, A Babber, R Ravikumar, AH Davies. Non-Invasive Management of Peripheral Arterial Disease. *Advances in experimental medicine and biology.* 2017;906:387-406. PMID: 27638628
58. CF Hyer, G Berlet, T Philbin, et al. Does Functional Neuromuscular Electrical Stimulation (NMES) Influence Calf Atrophy Following Achilles Tendon Surgery? Prospective Double-Blind Randomized Controlled Trial on the Use of Immediate Postoperative Electrical Muscle Stimulation to Preserve Muscle Function and Volume. *J Foot Ankle Surg.* 2021;60(4):683-88. PMID: 33736944
59. AN Sumin, PA Oleinik, AV Bezdenezhnykh, AV Ivanova. Neuromuscular electrical stimulation in early rehabilitation of patients with postoperative complications after cardiovascular surgery: A randomized controlled trial. *Medicine (Baltimore).* 2020;99(42):e22769. PMID: 33080746
60. FV Dos Santos, G Cipriano, Jr., L Vieira, et al. Neuromuscular electrical stimulation combined with exercise decreases duration of mechanical ventilation in ICU patients: A randomized controlled trial. *Physiother Theory Pract.* 2020;36(5):580-88. PMID: 30321084

61. YB Zhang, YN Cheng. A randomized controlled trial of neuromuscular electrical stimulation for chronic urinary retention following traumatic brain injury. *Medicine (Baltimore)*. 2019;98:e14106. PMID: 30633223
62. S Feil, J Newell, C Minogue, HH Paessler. The effectiveness of supplementing a standard rehabilitation program with superimposed neuromuscular electrical stimulation after anterior cruciate ligament reconstruction: a prospective, randomized, single-blind study. *Am J Sports Med*. 2011;39(6):1238-47. PMID: 21343386
63. TE Johnston, BT Smith, MJ Mulcahey, RR Betz, RT Lauer. A randomized controlled trial on the effects of cycling with and without electrical stimulation on cardiorespiratory and vascular health in children with spinal cord injury. *Arch Phys Med Rehabil*. 2009;90(8):1379-88. PMID: 19651272
64. PB Arnold, PP McVey, WJ Farrell, TM Deurloo, AR Grasso. Functional electric stimulation: its efficacy and safety in improving pulmonary function and musculoskeletal fitness. *Arch Phys Med Rehabil*. 1992;73(7):665-8. PMID: 1622323
65. JC Baldi, RD Jackson, R Moraille, WJ Mysiw. Muscle atrophy is prevented in patients with acute spinal cord injury using functional electrical stimulation. *Spinal Cord*. 1998;36(7):463-9. PMID: 9670381
66. LA Bremner, KE Sloan, RE Day, ER Scull, T Ackland. A clinical exercise system for paraplegics using functional electrical stimulation. *Paraplegia*. 1992;30(9):647-55. PMID: 1408342
67. SF Figoni, MM Rodgers, RM Glaser, et al. Physiologic responses of paraplegics and quadriplegics to passive and active leg cycle ergometry. *J Am Paraplegia Soc*. 1990;13(3):33-9. PMID: 2230794
68. SP Hooker, SF Figoni, MM Rodgers, et al. Physiologic effects of electrical stimulation leg cycle exercise training in spinal cord injured persons. *Arch Phys Med Rehabil*. 1992;73(5):470-6. PMID: 1580776
69. T Mohr, JL Andersen, F Biering-Sorensen, et al. Long-term adaptation to electrically induced cycle training in severe spinal cord injured individuals. *Spinal Cord*. 1997;35(1):1-16. PMID: 9025213
70. T Mohr, J Podenphant, F Biering-Sorensen, H Galbo, G Thamsborg, M Kjaer. Increased bone mineral density after prolonged electrically induced cycle training of paralyzed limbs in spinal cord injured man. *Calcif Tissue Int*. 1997;61(1):22-5. PMID: 9192506
71. KT Ragnarsson. Physiologic effects of functional electrical stimulation-induced exercises in spinal cord-injured individuals. *Clin Orthop Relat Res*. 1988(233):53-63. PMID: 3261220
72. KE Ralston, L Harvey, J Batty, et al. Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial. *Journal of physiotherapy*. 2013;59(4):237-43. PMID: 24287217
73. CL Sadowsky, ER Hammond, AB Strohl, et al. Lower extremity functional electrical stimulation cycling promotes physical and functional recovery in chronic spinal cord injury. *J Spinal Cord Med*. 2013;36:623-31. PMID: 24094120
74. JW van der Scheer, VL Goosey-Tolfrey, SE Valentino, GM Davis, CH Ho. Functional electrical stimulation cycling exercise after spinal cord injury: a systematic review of health and fitness-related outcomes. *J Neuroeng Rehabil*. 2021;18(1):99. PMID: 34118958
75. CY Fang, AS Lien, JL Tsai, et al. The Effect and Dose-Response of Functional Electrical Stimulation Cycling Training on Spasticity in Individuals With Spinal Cord

- Injury: A Systematic Review With Meta-Analysis. *Front Physiol.* 2021;12:756200. PMID: 34867459
76. J Veldema, P Jansen. Ergometer Training in Stroke Rehabilitation: Systematic Review and Meta-analysis. *Arch Phys Med Rehabil.* 2020;101(4):674-89. PMID: 31689416
 77. E Ambrosini, M Parati, G Ferriero, A Pedrocchi, S Ferrante. Does cycling induced by functional electrical stimulation enhance motor recovery in the subacute phase after stroke? A systematic review and meta-analysis. *Clinical rehabilitation.* 2020;34(11):1341-54. PMID: 32613859
 78. JB Scally, JS Baker, J Rankin, L Renfrew, N Sculthorpe. Evaluating functional electrical stimulation (FES) cycling on cardiovascular, musculoskeletal and functional outcomes in adults with multiple sclerosis and mobility impairment: A systematic review. *Multiple sclerosis and related disorders.* 2019;37:101485. PMID: 31706166
 79. A Shariat, MG Najafabadi, NN Ansari, et al. The effects of cycling with and without functional electrical stimulation on lower limb dysfunction in patients post-stroke: A systematic review with meta-analysis. *NeuroRehabilitation.* 2019;44:389-412. PMID: 31227660
 80. J Kressler, H Ghersin, MS Nash. Use of functional electrical stimulation cycle ergometers by individuals with spinal cord injury. *Topics in spinal cord injury rehabilitation.* 2014;20(2):123-6. PMID: 25477734
 81. Department of Veterans Affairs and Department of Defense Clinical Practice Guideline For The Management Of Stroke Rehabilitation. Last updated July, 2019. [cited 12/7/2021]. Available from: <https://www.healthquality.va.gov/guidelines/Rehab/stroke/VADoDStrokeRehabCPGFinal8292019.pdf>.
 82. CJ Winstein, J Stein, R Arena, et al. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke; a journal of cerebral circulation.* 2016;47:e98-e169. PMID: 27145936

CODES

Codes	Number	Description
CPT	None	
HCPCS	E0731	Form fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)
	E0744	Neuromuscular stimulator for scoliosis
	E0745	Neuromuscular stimulator, electronic shock unit
	E0764	Functional neuromuscular stimulator, transcutaneous stimulation of muscles of ambulation with computer control, used for walking by spinal cord injured, entire system after completion of training program
	E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
	K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application
	K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply

Date of Origin: July 2000