

Functional Neuromuscular Electrical Stimulation

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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. [Electrical Stimulation Devices Index](#), Durable Medical Equipment, Policy No. 83
2. [Interferential Stimulation for the Treatment of Pain](#), Durable Medical Equipment, Policy No. 83.07
3. [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. An example of a cycle ergometer that has 510k FDA approval is the RT300 (Restorative Therapies, Inc.). Rowing devices have also been devised for exercise.

EVIDENCE SUMMARY

Treatment with functional neuromuscular stimulation 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 (RCT) 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.

Among patients with spinal cord injury, 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 spinal cord injury. 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.

FUNCTIONAL NEUROMUSCULAR ELECTRICAL STIMULATION (NMES) OF THE UPPER EXTREMITY

Systematic Reviews

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.^[2] 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 an SR evaluating the efficacy of NMES on shoulder subluxation.^[3] 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 an 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.^[4] The authors stated none of the modalities evaluated improved subluxation and upper limb function effectively.

A systematic review by Gu evaluated electrical stimulation for hemiplegic shoulder function.^[5] 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

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.^[6] 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.

A 2017 RCT by Jonsdottir randomized acute and chronic stroke patients to receive myoelectric controlled functional electrical stimulation (MeCFES) or task-oriented therapy (TOT) for 25 sessions.^[7] Of the 82 enrolled patients, 68 completed the protocol and 45 were seen at the five-week follow-up. There was significant improvement in both groups on two measures of arm function (Action Research Arm Test and the Upper Extremity Fugl-Meyer Assessment), but the groups were not significantly different. However, the study did not meet the planned sample size.

Wilson (2016) published 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.^[8] Participants received treatments for 40 minutes, two times every weekday for eight weeks. Evaluations occurred at baseline, end of treatment, and one, three, and six months after treatment ended. The authors concluded all treatments provided significant improvement, with no difference in efficacy between groups.

Harvey (2016) published an 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.^[9] 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).^[10] 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.^[11] 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.^[12] 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 CCRES 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.^[13] 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 week, 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 upper extremity conditions, including but not limited to stroke and spinal cord injury is limited. The available evidence from RCTs is suggestive that functional neuromuscular electrical stimulation provides no added benefit. Additional RCTs comparing outcomes with and without the device are still needed.

FUNCTIONAL NMES OF THE LOWER EXTREMITY

Systematic Reviews

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 studies on cost-effectiveness were identified. 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.

An SR by Prenton (2018), included in the CADTH review above, reported a meta-analysis of FES or ankle foot orthoses for foot drop caused by central nervous system conditions. 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 ($p=0.54$).

Yue (2018) performed an SR of RCTs examining the use of NMES, transcutaneous electrical stimulation (TENS), and electroacupuncture (EA) after total knee arthroplasty.^[14] 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. 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. Follow-up was through 12 or 13 months in three studies and six months or less in the remainder. Five of the included studies found that TENS provided superior analgesia than control and both EA studies found that the treatment offered satisfactory pain release immediately and five days after surgery.

Wonsetler (2017) published an SR (part 1) that evaluated the impact of different therapies on gait, by measuring spatiotemporal variables and asymmetry ratios.^[15] 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.

Miller (2017) published an SR to evaluate the efficacy of FES on gait speed for patients with multiple sclerosis.^[16] 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.

Springer (2017) published an SR to determine if FES is therapeutic and improves gait for patients with multiple sclerosis.^[17] Twelve studies were evaluated. Most of the studies showed a positive orthotic effect during stimulation on walking speed. Three studies showed a therapeutic effect, but not significant. The authors concluded more studies need to address the therapeutic effects of FES on gait, for patients, with multiple sclerosis.

Moll (2017) published an SR that assessed FES of ankle dorsiflexors in young patients with cerebral palsy.^[18] Fourteen documents were evaluated, but only five were considered level I – II evidence. The authors stated there is not enough evidence to support that FES improves activity function or participation level, but it may play a role as an alternative to orthosis in children with cerebral palsy.

Gatewood (2017) published an SR evaluating efficacy of different devices after arthroscopic knee surgery, one of which was NMES.^[19] Twenty-five studies were included in the review. The authors stated that NMES is recommended in addition to rehabilitation, but the SR level of evidence was II.

Langeard (2017) published an SR evaluating how NMES impacts lower limb function in the elderly.^[20] 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.

Bistolfi (2017) published an SR that evaluated the effects of NMES following total knee arthroplasty.^[21] Six studies, with 496 participants were included. The authors concluded NMES, with a rehabilitation program can slightly improve function better than a rehabilitation program alone, especially in patients who do not have good muscle activation. Including NMES, with rehabilitation does not increase function better than rehabilitation alone in the mid and long-term.

Cherian (2016) published an SR that evaluated non-operative treatments for osteoarthritis of the knee. Six of the 30 studies included were for NMES. The authors noted that pain improvement from NMES was similar to TENS, there was heterogeneity amongst NMES studies and long-term follow-up was not evaluated.

An SR published in 2016 compared FES with ankle foot orthoses (AFO) for the treatment of foot drop after stroke.^[22] Seven published studies were included, which represented five different trials with a total of 815 participants. The included trials were judged to be of medium-methodologic quality by the reviewers. Meta-analyses of study data showed similar improvements for both groups in 10m walking speed, functional exercise capacity, perceived mobility, and timed up-and-go. The authors concluded that both treatment modalities appeared to be equally effective and stated that “While combining data from different types of AFO/FES does not allow a detailed look at the possible different effects of each individual sub-type, assuming the prescription of devices within each trial was provided on the basis of clinical judgement and complies with current guidelines, this allows for a clinically relevant comparison.” Another systematic review evaluated peroneal stimulation for foot drop in stroke patients, with similar conclusions.^[23]

Cauraugh (2010) conducted a meta-analysis of 17 studies on NMES and gait in children with cerebral palsy.^[24] Fourteen of the studies used a pretest-post-test, within-subjects design. A total of 238 participants had NMES. Included were studies on acute NMES, functional NMES

and therapeutic NMES (continuous subthreshold stimulation). Five of the studies examined functional NMES, and one of these studies examined percutaneous NMES. There were three outcome measures for impairment; range of motion, torque/moment, and strength/force. There were six different outcome measures for activity limitations; gross motor functions, gait parameters, hopping on one foot, six-minute walk, Leg Ability Index, and Gillette gait index. Moderate effect sizes were found for impairment (0.616) and activity limitations (0.635). The review is limited by a lack of blinding in the included studies and the heterogeneity of outcome measures. The review did not describe if any of the included studies used a commercially available device.

Randomized Controlled Trials

In 2016, a small pilot RCT was published that assessed the effects of NMES in combination with mirror therapy in stroke survivors with hemiplegia.^[25] 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.^[26] 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.

Bethoux (2014) conducted a large multicenter industry-affiliated RCT to compare a foot-drop stimulator (WalkAide) with an ankle-foot orthosis (AFO) in 495 Medicare-eligible individuals who were at least six months poststroke.^[27] A total of 399 individuals completed the six-month study. Primary outcome measures were the 10-Meter Walk Test (10MWT), a composite measure of daily function, and device-related serious adverse events (AEs). There were 7 secondary outcome measures that assessed function and quality of life. Intention-to-treat analysis found that both groups improved walking performance over the 6 months of the study, and the NMES device was noninferior to the AFO on the primary outcome measures. Only the WalkAide group showed significant improvements from baseline to six months on several secondary outcome measures, but there were no significant between-group differences for any of the primary outcomes.

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.^[28] 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.

Kluding (2013) conducted an industry-sponsored single-blind multicenter trial that randomized 197 patients to 30 weeks of a foot drop stimulator (NESS L300) or a conventional ankle-foot orthosis (AFO).^[29] The AFO group received transcutaneous electrical nerve stimulation at each physical therapy visit during the first two weeks to provide a sensory control for stimulation of the peroneal nerve in the NESS L300 group. Evaluation by physical therapists who were blinded to group assignment found that both groups improved gait speed and other secondary outcome measures over time, with similar improvement in the two groups. There were no between-group differences in the number of steps per day at home, which were measured by an activity monitor over a week.

In 2013, a small multicenter within-subject crossover trial was published that compared the WalkAid footdrop stimulator versus conventional AFO.^[30] Patients who had a stroke within the previous 12 months and residual footdrop but no prior experience with an orthotic device were randomly assigned to WalkAide followed by AFO (six weeks each, n=38), AFO followed by WalkAide (n=31), or AFO for 12 weeks (n=24). Walking tests were performed both with and without a device at 0, 3, 6, 9, and 12 weeks. Both devices had significant orthotic (on-off difference) and therapeutic (changes over time when off) effects. The AFO had a greater orthotic effect on walking speed (figure 8 and 10MWT), while the WalkAide tended to have a greater therapeutic effect. The orthotic effect on PCI was significantly higher with an AFO than the WalkAide. Users felt equally safe with the two devices. Seventy percent preferred to keep the WalkAide after the 12-week study.

Knutson (2013) conducted a randomized trial 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.^[31] 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.^[32] Measures of function, but not activities of daily living, were reported. Patients were a convenience sample and concurrent physical therapy was not applied.

A randomized controlled trial of functional NMES to improve walking performance in patients with multiple sclerosis (MS) was published by Barrett (2009).^[33] 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 6, 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 3-minute walk test have not been confirmed (fatigue prevented use of the validated 6-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.^[34]

The National Institute of Health and Care Excellence (NICE) (2008) published a literature review on functional electrical stimulation for foot drop of neurological origin.^[35] The review included SRs, RCTs, and case series. NICE reported there is limited evidence on the impact of improved quality of life. In addition, there was variation in how the procedure was performed and several studies did not report absolute numbers.

Section Summary

These studies do not demonstrate that use of a neuromuscular stimulator device provided clinically significant improvements for any lower extremity condition. The lack of methodologically sound studies limits comparisons between groups. Duration of treatment effects is also unknown. Additional RCTs comparing outcomes with and without the device are still needed.

FUNCTIONAL NMES FOR OTHER CONDITIONS

Systematic Reviews

Intiso (2017) published an SR evaluating electrical stimulation as an adjunct to botulism toxin type A, for adult spasticity.^[36] 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 an SR that evaluated the impact on health outcomes for NMES versus rehabilitation for patients with moderate-to severe COPD.^[37] 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 an SR that evaluated several non-invasive treatments for PAD, to improve circulation.^[38] 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 Trial

Maddocks (2016) published a double-blinded RCT that evaluated the effect of home-based NMES on functional exercise capacity for patients with severe COPD.^[39] Patients received self-administered NMES (n=25) or placebo NMES (n=27) over six weeks. Follow-up evaluations occurred at six and 12 weeks. The authors stated that six weeks of NMES improves functional exercise capacity in patients with severe COPD, by enhancing quadriceps muscle mass and function, but the study had methodological limitations including limited follow-up, inability to mask staff who recorded adverse event data, and the inability to determine if the placebo itself was an effective comparison tool. More long-term studies are needed.

Section Summary

The current studies do not demonstrate improved health outcomes from NMES for other conditions, including but not limited to COPD, peripheral artery disease, or spasticity. Based on

the available published evidence, additional RCTs comparing this therapy to standard treatment are still required.

FES CYCLE ERGOMETERS AND ROWING MACHINES

More recently there has been interest in electromyography (EMG)-triggered functional neuromuscular electrical stimulation as a therapy for patients with lower extremity paresis. Available studies on this topic include one RCT^[40] and several case series.^[41-48]

Randomized Controlled Trial

Johnston (2009) reported on an RCT conducted on 30 children with spinal cord injury aged 5 to 13 years.^[40] 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 (VO_2), 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.

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. 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) AND THE AMERICAN HEART ASSOCIATION/ AMERICAN STROKE ASSOCIATION

The Department of Veterans Affairs (VA), Department of Defense (DoD) and The American Heart Association/ American Stroke Association (2010) published a Clinical Practice Guideline for the Management of Stroke Rehabilitation, recommending the use of functional electrical stimulation for shoulder subluxation and as an adjunctive treatment for gait training.^[49]

Specifically, they stated, “FES has been used for several years as a therapy modality for post-stroke patients, but has not been a routine standard of care. FES is a time-limited intervention, generally used during the first several weeks after the acute stroke.” The guideline found that use of FES was linked to intermediate health outcomes, but that high-quality evidence did not exist linking it to primary health outcomes.

NATIONAL INSTITUTE OF HEALTH AND CARE EXCELLENCE (NICE)

NICE (2009) published a guidance on functional electrical stimulation for foot drop of central neurological origin.^[50] NICE stated FES is safe and effective in improving gait for patients with foot drop of neurological origin, but patient selection should be made by a multidisciplinary team and further information would be useful on the efficacy and functional improvements that occur.

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. 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.

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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

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