United Healthcare Exchange Plans

UnitedHealthcare® Value & Balance Exchange
Medical Policy

Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation

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➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements
- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)

Applicable States

This Medical Policy only applies to the states of Arizona, Maryland, North Carolina, Oklahoma, Tennessee, Virginia, and Washington.

Coverage Rationale

Functional electrical stimulation (FES) is proven and medically necessary as a component of a comprehensive rehabilitation program in members with lower limb paralysis due to spinal cord injury (SCI) when all of the following criteria are met:

- Demonstration of intact lower motor units (L1 and below) (both muscle and peripheral nerves)
- Muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently
- Demonstration of brisk muscle contraction
- Demonstration of sensory perception sufficient for muscle contraction
- Demonstration of a high level of motivation, commitment, and cognitive ability for device use
- Ability to transfer independently
- Demonstration of independent standing tolerance for at least three minutes
- Demonstration of hand and finger function to manipulate controls
- Post-recovery from SCI and restorative surgery of at least six months
- Absence of hip and knee degenerative disease
- Absence of history of long bone fracture secondary to osteoporosis

Neuromuscular electrical stimulation (NMES) is proven and medically necessary for treating the following indications:

- Disuse muscle atrophy if:
    - The nerve supply to the muscle is intact; and

    - The disuse muscle atrophy is not of neurological origin, but results from other conditions including but not limited to casting, splinting, or contractures
- To improve wrist and finger function and prevent or correct shoulder subluxation in persons with partial paralysis following stroke

The following are unproven and not medically necessary due to insufficient evidence of efficacy:
- Dorsal root ganglion (DRG) stimulation
- FES for treating any other indication not listed above
- Interferential therapy (IFT) for treating musculoskeletal disorders/injuries, or to facilitate healing of nonsurgical soft tissue injuries or bone fractures
- Microcurrent electrical nerve stimulation (MENS)
- NMES for treating any other indication not listed above
- Percutaneous electrical nerve stimulation (PENS), percutaneous electrical nerve field stimulation (PENFS) or percutaneous neuromodulation therapy (PNT)
- Percutaneous peripheral nerve stimulation (PNS)*
- Peripheral subcutaneous field stimulation (PSFS) or peripheral nerve field stimulation (PNFS)
- Pulsed electrical stimulation (PES)
- Scrambler Therapy (ST)

* For information regarding percutaneous peripheral nerve stimulation for occipital neuralgia and headache, refer to medical policy for Occipital Neuralgia and Headache Treatment.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0278T	Transcutaneous electrical modulation pain reprocessing (e.g., scrambler therapy), each treatment session (includes placement of electrodes)
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63664	Revision including replacement, when performed, of spinal neurostimulator electrode plate/paddle(s) placed via laminotomy or laminectomy, including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64999	Unlisted procedure, nervous system

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Coding Clarification: Transcutaneous electrical joint stimulation devices (E0762) are noninvasive devices that deliver low-amplitude pulsed electrical stimulation.

*Note: The following are the only FES devices verified by the Centers for Medicare & Medicaid Services (CMS) Pricing, Data Analysis, and Coding (PDAC) to be reported with HCPCS E0770:

- NESS L300 and H200 devices (Bioness)
- Odstock ODFS Pace FES System (Odstock Medical/Boston Brace)
- WalkAide (Innovative Neurotronics)

HCPCS Code	Description
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups 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
E1399	Durable medical equipment, miscellaneous
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8682	Implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
S8130	Interferential current stimulator, 2 channel
S8131	Interferential current stimulator, 4 channel

Description of Services

Electrical stimulators provide direct, alternating, pulsating and/or pulsed waveform forms of energy. The devices are used to exercise muscles, demonstrate a muscular response to stimulation of a nerve, relieve pain, relieve incontinence, and provide test measurements. Electrical stimulators may have controls for setting the pulse length, pulse repetition frequency, pulse amplitude, and triggering modes. Electrodes for such devices may be indwelling, implanted transcutaneously, or surface.

Functional Electrical Stimulation (FES)

FES is the direct application of electric current to intact nerve fibers in a coordinated fashion to cause involuntary but purposeful contraction. FES bypasses the central nervous system and targets motor neurons innervating either skeletal muscle or other organ systems. Electrodes may be on the surface of the skin or may be surgically implanted along with a stimulator. FES is categorized as therapeutic and functional. Therapeutic FES enables typically resistive exercise, with the goal of preventing muscular atrophy and promoting cardiovascular conditioning. Functional FES enables or enhances standing, ambulation, grasping, pinching, reaching, respiration, bowel or bladder voiding, or ejaculation. The two goals of FES are mutually supportive (Hayes, 2017).

Neuromuscular Electrical Stimulation (NMES)

NMES involves the use of transcutaneous application of electrical currents to cause muscle contractions. The goal of NMES is to promote reinnervation, to prevent or retard disuse atrophy, to relax muscle spasms, and to promote voluntary control of muscles in individuals who have lost muscle function due to surgery, neurological injury, or disabling condition.

Interferential Therapy (IFT)

IFT is a treatment modality that is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. Two medium-frequency, pulsed currents are delivered via electrodes placed on the skin over the targeted area producing a low-frequency current. IFT delivers a crisscross current resulting in deeper muscle penetration. It is theorized that IFT prompts the body to secrete endorphins and other natural painkillers and stimulates parasympathetic nerve fibers to increase blood flow and reduce edema.

Pulsed Electrical Stimulation (PES)

PES is hypothesized to facilitate bone formation, cartilage repair, and alter inflammatory cell function. Some chondrocyte and osteoblast functions are mediated by electrical fields induced in the extracellular matrix by mechanical stresses. Electrostatic and electrodynamic fields may also alter cyclic adenosine monophosphate or DNA synthesis in cartilage and bone cells.

Percutaneous Peripheral Nerve Stimulation (PNS)

PNS is a type of neuromodulation therapy where an electrode(s) are implanted near a peripheral nerve (i.e., nerve located outside of the brain and spinal cord) that subserves the painful dermatone. The electrode(s) deliver electrical impulses to the affected nerve to disrupt the transmission of pain signals thereby reducing the level of pain (International Neuromodulation Society, 2019). Implanted peripheral nerve stimulators include the StimRouter Neuromodulation System, SPRINT PNS System, and StimQ Peripheral Nerve Stimulator System.

Peripheral Subcutaneous Field Stimulation (PSFS)

PSFS, also known as peripheral nerve field stimulation (PNFS), is a technique used when the field to be stimulated is not well defined or does not fit exactly within the area served by any one or two peripheral nerves. Different from spinal cord stimulation (SCS) or peripheral nerve stimulation (PNS), the electrode arrays are implanted within the subcutaneous tissue of the painful area, not on or around identified neural structures, but most probably in or around cutaneous nerve endings of the intended nerve to stimulate (Abejon and Krames, 2009).

Microcurrent Electrical Nerve Stimulation Therapy (MENS)

MENS is intended for pain relief and to facilitate wound healing, delivering current in the microampere range. One micro amp (µA) equals 1/1,000th of a milliamp (mA). By comparison, TENS therapy delivers currents in the milliamp range causing muscle contraction, pulsing and tingling sensations. The microcurrent stimulus is subsensorial, so users cannot not detect it. Although microcurrent devices are approved in the category of TENS for regulatory convenience, in practical use they are in no way similar and cannot be compared to TENS in their effect (Curtis, et al. 2010; Zuim, et al. 2006). MENS is also referred to as microelectrical therapy (MET) or microelectrical neuro-stimulation. Examples of MENS devices currently in use include, but are not limited to, Algonix®, Alpha-Stim® 100, Microcurrent, and Micro Plus™.

Percutaneous Electrical Nerve Stimulation (PENS)

PENS, also known as percutaneous electrical nerve field stimulation (PENFS), is a conservative, minimally invasive treatment for pain in which acupuncture-like needles connected through a cable to an external power source are inserted into the skin. Needle placement is near the area of pain and is percutaneous instead of cutaneous (e.g., TENS). PENS electrodes are not permanently implanted as in SCS. The mechanism of action of PENS is theorized to modulate the hypersensitivity of nerves from which the persistent pain arises, potentially involving endogenous opioid-like substances. Examples of PENS/PENFS devices include, but are not limited to, IB-Stim and Neuro-Stim. The term percutaneous neuromodulation therapy (PNT) is sometimes used interchangeably with PENS. However, reports indicate PNT is a variant of PENS in which electrodes are placed in patterns that are uniquely different than placement in PENS (Hayes, 2019).

Dorsal Root Ganglion Stimulation

DRG stimulation therapy may be prescribed for pain that is limited to a specific area of the body that starts in a lower part of the body (e.g., foot, knee, hip and groin) following an injury or surgical procedure and grows worse over time. DRGs are spinal structures densely populated with sensory nerves that transmit information to the brain via the spinal column. Through the use of a neurostimulator system, (for example, Axium™ or the next-generation implantable pulse generator Proclaim™), physicians are able to directly treat targeted areas of the body where pain occurs (St. Jude Medical, 2018).

Scrambler Therapy

Scrambler Therapy (ST) (also referred to as Calmare Pain Therapy [Calmare Therapeutics Inc.] or transcutaneous electronic modulation pain reprocessing), is a noninvasive, transdermal treatment designed for the symptomatic relief of chronic pain. Treatment is performed by applying electrodes corresponding to the dermatome on the skin just above and below the area of pain. The device provides electrical signals via the electrodes presenting nonpain information to the painful area using continuously changing, variable, nonlinear waveforms (Hayes, 2018).

Clinical Evidence

Functional Electrical Stimulation (FES)

FES has been proposed for improving ambulation in individuals with gait disorders such as drop foot, hemiplegia due to stroke, cerebral injury, or incomplete SCI. Randomized controlled trials (RCTs) and case series have primarily included small patient populations with short-term follow-ups.

Nervous System Conditions

Spinal Cord Injury

Sadowsky et al. (2013) conducted a single-center cohort study to examine the effect of long-term lower extremity FES cycling on the physical integrity and functional recovery in people with chronic SCI. Twenty-five individuals with chronic SCI (at least 16 months following injury) who received FES during cycling were matched by age, gender, injury level, severity, and duration of injury to 20 people with SCI who received range of motion and stretching. The main outcome measure was change in neurological function, which comprised motor, sensory, and combined motor–sensory scores (CMSS) assessed by the American Spinal Injury Association Impairment scale. Response was defined as ≥1 point improvement. FES was associated with an 80% CMSS responder rate compared to 40% in controls. An average 9.6 CMSS point loss among controls was offset by an average 20-point gain among FES subjects. Quadriceps muscle mass was on average 36% higher and intra/inter-muscular fat 44% lower, in the FES group. Hamstring and quadriceps muscle strength was 30 and 35% greater, respectively, in the FES group. Quality of life and daily function measures were significantly higher in FES group. The authors concluded that FES during cycling in chronic SCI may provide substantial physical integrity benefits, including enhanced neurological and functional performance, increased muscle size and force-generation potential, reduced spasticity, and improved quality of life.

Harvey et al. (2010) conducted an RCT to determine the effectiveness of electrical stimulation (ES)-evoked muscle contractions superimposed on progressive resistance training (PRT) for increasing voluntary strength in the quadriceps muscles of people with SCI. A total of 20 individuals with established SCI (more than 6 months post injury) and neurologically induced weakness of the quadriceps muscles participated in the trial. Additional inclusion criteria were at least 90 degrees passive knee range of motion and moderate neurologically induced weakness in their quadriceps muscles of one leg responsive to ES. Patients with a recent history of trauma to the lower extremity, currently participating in a lower limb strength or ES training program or limited ability to comply were excluded. Participants were randomized to experimental or control groups. The experimental group received ES superimposed on PRT to the quadriceps muscles of one leg three times weekly for eight weeks. The control group received no intervention. Assessments occurred at the beginning and at the end of the eight-week period. The four primary outcomes were voluntary strength (muscle torque in Newton meters [Nm]), endurance (fatigue ratio), and performance and satisfaction items of the Canadian Occupational Performance Measure (COPM; points). The between-group mean differences (95% confidence interval [CI]) for voluntary strength and endurance were 14 Nm (1 to 27; p=0.034) and 0.1 (-0.1 to 0.3; p=0.221), respectively. The between-group median differences (95% CI) for the performance and satisfaction items of the COPM were 1.7 points (-0.2 to 3.2; p=0.103) and 1.4 points (-0.1 to 4.6; p=0.058), respectively. The authors concluded the results provide initial support for the use of ES superimposed on PRT for increasing voluntary strength in the paretic quadriceps muscles of individuals with SCI however, there is uncertainty about whether the size of the treatment effect is clinically important. They also stated that it is not clear whether ES was the critical component of the training program or whether the same results could have been attained with PRT alone.

Griffin et al. (2009) conducted a single-center case series study to evaluate body composition as well as metabolic and neurological profiles before and after 10 weeks of FES cycling in individuals with paralysis from SCI. Eighteen individuals with SCI received FES cycling 2–3 times per week for 10 weeks. Body composition was analyzed by dual X-ray absorptiometry. The American Spinal Injury Association (ASIA) neurological classification of SCI test battery was used to assess motor and sensory function. An oral glucose tolerance (OGTT) and insulin-response test was performed to assess blood glucose control.

Additional metabolic variables including plasma cholesterol (total-C, HDL-C, LDL-C), triglyceride, and inflammatory markers (IL-6, TNF-α, and CRP) were also measured. Total FES cycling power and work done increased with training. Lean muscle mass also increased however, bone and adipose mass did not change. The ASIA motor and sensory scores for the lower extremity significantly increased with training. Blood glucose and insulin levels were lower following the OGTT after 10 weeks of training. Triglyceride levels did not change following training. However, levels of IL-6, TNF-α, and CRP were all significantly reduced. The authors concluded that significant improvements in blood glucose control and inflammatory markers occurred in conjunction with an increase in lean muscle mass and motor and sensory ability following 10 weeks of FES cycling in persons with paralysis from SCI. They also stated that it is expected that continuous use would be required to maintain the observed health benefits across the life span.

Thrasher et al. (2006) conducted a single-center case series study to determine if direct muscle stimulation would have greater rehabilitative potential than the stimulation of reflexes. A convenience sample of five subjects with chronic, incomplete SCI trained for 12–18 weeks using a new multichannel neuroprosthesis for walking. The outcome measures, which were recorded throughout the training period, included walking speed, step frequency and average stride length based on a two minute walk test. Also identified were which walking aids and orthoses subjects preferred to use, and whether they employed a step-to or step-through gait strategy. Follow-up measurements of three subjects were made up to 10 weeks after treatment. All subjects demonstrated significant improvements in walking function over the training period. Four of the subjects achieved significantly increased walking speeds, which were due to increases in both stride length and step frequency. The fifth subject experienced a significant reduction in preferred assistive devices. Follow-up measurements revealed that two subjects walked slightly slower several weeks after treatment, but they still walked significantly faster than at the start of treatment. The authors concluded that the gait training regimen was effective for improving voluntary walking function in a population for whom significant functional changes are not expected and therefore, this application of functional electrical therapy is viable for rehabilitation of gait in incomplete SCI. Limitations of this study include its design and small sample size and therefore, further study is still needed to compare the effects of FES to conventional physiotherapy.

Additional evidence indicates that paraplegics can benefit from FES that exercises muscles without providing locomotion. In one study, electrically stimulated use of an exercise cycle by paraplegics restored muscle mass (Baldi, 1998). In another study, bone mineral density improved in some bones of patients with SCI after use of the FES bicycle (Chen, 2005). While most studies involved patients with many years of muscular atrophy, Baldi et al. utilized patients with less than four months of atrophy. Moreover, electrically stimulated isometric exercise stimulated bone remineralization that was not observed with electrically stimulated walking (Needham-Shropshire, 1997B). Even if the ambulation provided by devices such as the Parastep significantly improves, it will still only be usable by a subset of paraplegic patients such as those with T4-T11 SCIs (Klose, 1997). Stationary electrically stimulated exercise can be performed by a much larger group of patients including quadriplegics. To summarize, electrically stimulated ambulation cannot be considered safer or more beneficial than electrically stimulated stationary exercise unless the benefits of ambulation are shown to be superior in large-scale trials in which paraplegic patients are randomized to these two therapies. Further studies also need to be performed to confirm the benefits of electrically stimulated stationary exercise since the controlled trials conducted to date have used very small study populations and have assessed a limited set of outcome measures.

Cerebral Palsy

Moll et al. (2018) conducted a systematic review to assess the effect of FES of ankle dorsiflexors in children and adolescents with spastic cerebral palsy (CP) during walking. A search, using predetermined terms, was conducted using PubMed/MEDLINE, Embase, the Physiotherapy Evidence Database (PEDro), Web of Science, CINAHL, and the Cochrane Library. Outcomes were reported according to the International Classification of Functioning, Disability and Health (ICF). The ICF domains are classified by body, individual and societal perspectives by means of two lists: a list of structure and function and a list of domains of participation and activity. A total of 780 articles were identified and after review, 14 articles were included, including two small randomized controlled trials. In total, 127 patients received FES of the ankle dorsiflexors (14 bilaterally affected and 113 unilaterally affected). The participants' ages ranged from five to 19 years and the Gross Motor Function Classification System (GMFCS) level ranged from I to III. The authors concluded that: At the ICF participation and activity level, there is limited evidence for a decrease in self-reported frequency of toe-drag and falls; At the ICF body structure and function level, there is clear evidence (level I to III studies) that FES increased (active) ankle dorsiflexion angle, strength, and improved selective motor control, balance, and gait kinematics, but decreased walking speed. Adverse events included skin irritation and acceptance issues. The authors further stated that it cannot be concluded that FES (of the ankle dorsiflexors) improves functioning at the activity and participation level however, current evidence supports the potential role of FES as an alternative to classic orthotic treatment. The authors recommend that future studies should focus on the domain of activity and participation. The findings are limited by the study design of most of the included studies.

An 2016 RCT by El-Shamy and Abdelaal conducted an RCT to investigate the effects of the WalkAide FES on gait pattern and energy expenditure in children with hemiplegic CP. Seventeen children were assigned to the study group, whose members received FES (pulse width, 300 µs; frequency, 33 Hz, 2 hours/d, three days/week for three consecutive months). Seventeen other children were assigned to the control group, whose members participated in a conventional physical therapy exercise program for three successive months. Baseline and post-treatment assessments were performed using the GAITRite system to evaluate gait parameters and using an open-circuit indirect calorimeter to evaluate energy expenditure. Children in the study group showed a significant improvement when compared with those in the control group ($p < 0.005$). The gait parameters (stride length, cadence, speed, cycle time, and stance phase percentage) after treatment were (0.74 m,119 steps/min, 0.75 m/s, 0.65 s, 55.9%) and (0.5 m,125 steps/min, 0.6 m/s, 0.49 s, 50.4%) for the study group and control group, respectively. The mean energy expenditures after treatment were 8.18 ± 0.88 and 9.16 ± 0.65 mL/kg per minute for the study and control groups, respectively. The authors concluded that WalkAide FES may be a useful tool for improving gait pattern and energy expenditure in children with hemiplegic CP. The study was limited to a small sample size.

Chiu and Ada (2014) conducted a systematic review to determine the effectiveness of FES versus activity training alone in children with cerebral palsy (CP). Five RCTs met inclusion criteria. The experimental group had to receive FES while performing an activity such as walking. The studies used outcome measures of activity that best reflected the activity used in the study. When continuous data (e.g., walking speed) were not available, ordinal data (e.g., Gross Motor Function Measurement) were used. A statistically significant between-group difference in activity in the FES groups was reported for the three studies that compared FES with no FES. Improvements were seen immediately after the intervention period, but long-term follow-up was not reported. The two studies investigating the effects of FES vs. activity training reported no significant differences between the groups. The results reported that FES is better than no FES, but that FES is not more effective than activity training. The authors stated that they may be fairly confident that FES is effective given that all 3 trials reported between-group differences in favor of FES, but with no meta-analysis providing an effect size it is not possible to judge the clinical significance of the benefit. Limitations of the studies included the heterogeneous patient populations and the variations in the frequency, intensity and duration of the interventions.

Cerebrovascular Accident

A systematic and meta-analysis by Eraifej et al. aimed to evaluate the effectiveness of post-stroke upper limb FES on ADL and motor outcomes. Systematic review of randomized controlled trials from MEDLINE, PsychINFO, EMBASE, CENTRAL, ISRCTN, ICTRP and ClinicalTrials.gov. Twenty studies met inclusion criteria. Outcomes were ADL (primary), functional motor ability (secondary) and other motor outcomes (tertiary). Quality assessment was determined using GRADE (Grading of Recommendations Assessment, Development and Evaluation) criteria. In six studies, no significant benefit of FES was found for objective ADL measures (FES group participants = 67). A significant benefit on ADLs was demonstrated in an analysis of three studies where FES was initiated on average within two months post-stroke (n=32). No significant ADL improvements were seen in three studies where FES was initiated more than one year after stroke (n=35). Quality assessment using GRADE found very low-quality evidence in all analyses due to heterogeneity, low participant numbers and lack of blinding. Meta-analyses gave rise to certain limitations. including but not limited to the utilization of many different measurement instruments and only a minority were employed by more than a few studies, as well as inadequate participant blinding in most studies. The authors concluded that FES is a promising therapy which could play a part in future stroke rehabilitation. There is a need for high quality large-scale randomized controlled trials of upper limb FES after stroke in order to draw firm conclusions regarding its efficacy or its optimum therapeutic window (2017).

Jonsdottir et al. (2017) conducted a RCT assessing the efficacy of myoelectric continuous control FES (MeCFES) when used as a part of task-oriented therapy (TOT) in persons post-stroke. Eighty-two acute and chronic stroke victims were recruited and randomized to receive either the experimental (MeCFES assisted TOT (M-TOT) or conventional rehabilitation care including TOT (C-TOT). Both groups received 45 minutes of rehabilitation over 25 sessions. Outcomes were Action Research Arm Test (ARAT), Upper Extremity Fugl-Meyer Assessment (FMA-UE) scores and Disability of the Arm Shoulder and Hand questionnaire. Sixty-eight individuals completed the protocol, and 45 were seen at follow-up five weeks later. There were significant improvements in both groups on ARAT (median improvement: MeCFES TOT group 3.0; C-TOT group 2.0) and FMA-UE (median improvement: M-TOT 4.5; C-TOT 3.5). Considering subacute subjects (time since stroke < 6 months), there was a trend for a larger proportion of improved patients in the M-TOT group following rehabilitation (57.9%) than in the C-TOT group

(33.2%). This is the first large multicenter RCT to compare MeCFES assisted TOT with conventional care TOT for the UE. No AEs or negative outcomes were encountered. The authors concluded that MeCFES can be a safe adjunct to rehabilitation and could promote recovery of upper limb function in persons after stroke, particularly when applied in the subacute phase. Several study limitations were identified for example, the predicted sample size needed to make a definitive conclusion as to the efficacy of the MeCFES was not reached, there may have been differences in use of the device between centers, and missing data where 14 of 82 enrolled patients failing to provide follow-up data and of those, nine had a baseline assessment. Additional studies are still needed to clarify the utility of meCFES for patients who experience a stroke.

de Sousa et al. (2016) conducted a blinded, multi-institutional, RCT to determine whether active FES cycling as a supplement to standard care would improve mobility and strength more than standard care alone in individuals with a sub-acute acquired brain injury caused by stroke or trauma. The control group (n=20) received standard care, which consisted of a minimum of one-on-one therapy with a physiotherapist at least one hour per day. In addition, participants could join group exercise classes or have another hour of one-on-one therapy, if available. The study group (n=20) received an incremental progressive, individualized FES cycling program five times a week for four weeks, along with standard therapy. The primary outcomes measured were mobility and strength of the knee extensors of the affected lower limb. The secondary outcomes were strength of key muscles of the affected lower limb, strength of the knee extensors of the unaffected lower limb, and spasticity of the affected plantar flexors. On admission to the study, most participants could not walk or required a high level of assistance to walk/transfer. Only two individuals could ambulate without assistance at the end of four weeks. The mean composite score for affected lower limb strength was seven out of 20 points, reflecting severe weakness. The authors concluded that four weeks of FES cycling in addition to standard therapy does not improve mobility in people with a sub-acute acquired brain injury. Further studies could clarify the effects of FES cycling on strength, although the clinical significance may be limited without its accompanying impact on mobility.

Tan et al. (2016) performed an observational randomized study on 58 patients recovering from stroke to assess the effects of FES on walking function based on normal gait pattern. Participants were randomly divided into three groups: four-channel FES group (group A, n=29), single-channel FES group (group B, n=15) and placebo electrical group (group C, n=14) at the rate of 2:1:1. All received the standardized rehabilitation program. The four-channel and single-channel FES groups received treatment based on normal gait pattern. The placebo electrical group received the same ES as the four-channel FES group, but without current output when stimulating. After three weeks of treatment and statistically significant improvement in all three groups, the authors concluded FES based on normal gait pattern could improve walking function in individuals recovering from stroke.

The National Institute for Health and Clinical Excellence (NICE) published a guidance document for the use of FES for foot drop of central neurological origin. NICE concluded that the evidence on safety and efficacy appears adequate to support the use of FES for foot drop in terms of improving gait, but further publication on the efficacy of FES would be useful regarding patient-reported outcomes, such as QOL and ADL (2009, updated 2012).

In 2010, Weber et al. conducted a RCT to assess whether Onabotulinum toxin A injections and occupational therapy with or without FES improved upper limb motor function in 23 stroke patients with chronic spastic hemiparesis. 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 six and 12 weeks, no additional benefit was observed among patients treated with functional FES versus the comparison group, potentially due to small sample size.

Alon et al. (2007) conducted a randomized pilot study to evaluate if FES can enhance the recovery of upper extremity function during early stroke rehabilitation. The study included 15 individuals who survived a stroke and had mild-moderate upper extremity paresis during inpatient rehabilitation, which was continued at home. Participants were assigned to either FES combined with task-specific upper extremity rehabilitation (n=7) or task-specific therapy alone (control group, n=8) over 12 weeks. Outcomes were assessed via video recording on both upper extremities at baseline, 4, 8, and 12 weeks. Results demonstrated the study group experienced better functional recovery than the control group. Limitations include small study size and no long-term outcomes data post-therapy.

An RCT was conducted by Ring and Rosenthal to assess the effects of daily neuroprosthetic (NESS Handmaster) FES in 22 patients with moderate to severe upper limb paresis persisting 3-6 months post-stroke. Patients were clinically stratified to ‘no’ and ‘partial’ active finger movement groups, then randomized to the standard rehabilitation protocol (control) or standard rehabilitation plus neuroprosthesis at home (study) groups. Observer blinded evaluations occurred at baseline and at completion (six weeks). The use of the Handmaster system plus daily therapy showed significantly improved outcomes versus the control group. Because this treatment is performed by the patient at home, it may well be continued as needed to maintain the benefits. The intensive daily use of this therapy at home in patients receiving sub-acute stroke rehabilitation has proved to be safe and resulted in significantly improved outcomes with no AEs. Limitations include small study size and no long-term outcomes data post-therapy (2005).

Multiple Sclerosis

Broekmans et al. (2011) conducted an RCT involving 36 persons with MS to examine the effect(s) of unilateral long-term (20 weeks) standardized resistance training with and without simultaneous ES on leg muscle strength and overall functional mobility. The authors found that long-term light to moderately intense resistance training improves muscle strength in persons with MS, but simultaneous ES does not further improve training outcome.

A pilot study by Ratchford et al. (2010) evaluated the safety and preliminary efficacy of home FES cycling in 5 patients with chronic progressive MS (CPMS) to explore how it changes cerebrospinal fluid (CSF) cytokine levels. Outcomes were measured by: 2-Minute Walk Test, Timed 25-foot Walk, Timed Up and Go Test, leg strength, Expanded Disability Status Scale (EDSS) score, and MS Functional Composite (MSFC) score. QOL was measured using the Short-Form 36 (SF-36). Cytokines and growth factors were measured in the CSF before and after FES cycling. Improvements were seen in the 2-Minute Walk Test, Timed 25-foot Walk, and Timed Up and Go tests. Strength improved in muscles stimulated by the FES cycle, but not in other muscles. No change was seen in the EDSS score, but the MSFC score improved. The physical and mental health subscores and the total SF-36 score improved. The authors concluded that FES cycling was reasonably well tolerated by CPMS patients and encouraging improvements were seen in walking and QOL. The study is limited by small sample and lack of a comparison group. Larger studies are needed to evaluate the effects of FES for patients with MS.

Circulatory System Conditions

Kadoglou et al. (2017) performed a randomized, placebo-controlled study to investigate the effects of FES on the lower limbs as an alternative method of training in patients with chronic heart failure (HF). Participants deemed stable (n=120) (defined by New York Heart Association (NYHA) class II/III and mean left ventricular ejection fraction (LVEF) of 28 ± 5%), were randomly selected for either a 6-week FES training program or placebo. Patients were followed for up to 19 months for death and/or hospitalization due to HF decompensation. At baseline, there were no significant differences in demographic parameters, HF severity, or medications between groups. During a median follow-up of 383 days, 14 patients died (11 cardiac, three non-cardiac deaths), while 40 patients were hospitalized for HF decompensation. Mortality did not differ between groups, although the HF-related hospitalization rate was significantly lower in the FES group. The latter difference remained significant after adjustment for prognostic factors: age, gender, baseline NYHA class and LVEF. Compared to placebo, FES training was associated with a lower occurrence of the composite endpoint (death or HF-related hospitalization) after adjustment for the above-mentioned prognostic factors. The authors concluded that six weeks of FES training in individuals with chronic HF reduced the risk of HF-related hospitalizations without affecting the mortality rate. The beneficial long-term effects of this alternative method of training require further investigation.

Miscellaneous Conditions

Fossat et al. (2018) investigated whether early in-bed leg cycling plus ES of the quadriceps muscles added to standardized early rehabilitation would result in greater muscle strength at discharge from the ICU in a single center blinded RCT enrolling 314 critically ill adult patients. Patients were randomized to early in-bed leg cycling plus ES of the quadriceps muscles added to standardized early rehabilitation (n=159) or standardized early rehabilitation alone (usual care, n=155). The primary outcome was muscle strength at discharge from the ICU assessed by physiotherapists blinded to treatment group using the Medical Research Council grading system (score range, 0-60 points; a higher score reflects better muscle strength). Functional autonomy and health-related QOL were assessed at 6 months. Of the 314 participants, 312 completed the study and were included in the analysis. The median global Medical Research Council score at ICU discharge was higher in the usual care group than in the intervention group, scoring 51 and 48, respectively. There were no significant differences between the groups at six months. The authors concluded that adding early in-bed leg cycling exercises and ES of the quadriceps muscles to a standardized early rehabilitation program did not improve global muscle strength at discharge from the ICU.

Clinical Practice Guidelines

American Occupational Therapy Association (AOTA)

The AOTA practice guidelines for adults with stroke state that for improved occupational performance of individuals with motor impairments, there is high certainty based on evidence that the use of ES has a moderate net benefit. The guidelines also state that the evidence is weak regarding whether or not this therapy improves patient outcomes (Wolf and Nilsen, 2015).

Neuromuscular Electrical Stimulation (NMES) for Muscle Rehabilitation

Although the evidence is limited, NMES for the treatment of disuse atrophy in individuals where the nerve supply to the muscle is intactis supported by evidence. There is some evidence that the use of NMES may be an effective rehabilitative regimen to prevent muscle atrophy associated with prolonged knee immobilization following ligament reconstruction surgery or injury; however, controlled clinical trials are necessary to determine if the addition of NMES to the rehabilitation program will improve health outcomes.

Musculoskeletal System Conditions

Talbot et al. (2017) conducted a pilot RCT (NCT00942890) to compare the effects of a home-based NMES rehabilitation program plus the traditional military amputee rehabilitation program (TMARP) vs. the effects of TMARP alone on quadriceps muscle strength, functional mobility, and pain in military service members after a combat-related lower extremity amputation. In total, 44 participants with a unilateral transtibial amputation were randomly assigned to the TMARP plus NMES (n=23) or to TMARP alone (n=21). Both groups received 12 weeks of the traditional amputee rehabilitation, including pre- and post-prosthetic training. Those in the NMES group also received 12 weeks of NMES. Participants were tested at three-week intervals during the study for muscle strength and pain. For functional measures, they were tested after receiving their prosthesis and at study completion (weeks 6 and 12). In both groups, residual limb quadriceps muscle strength and pain severity improved from baseline to 12 weeks. The NMES plus TMARP group showed greater strength than the TMARP alone group at three weeks, before receiving the prosthesis. However, six weeks post-prosthesis, there was no group difference in the residual limb strength. Functional mobility improved in both groups between weeks six and 12 with no difference between the two treatment groups. The authors concluded that a home-based NMES intervention with TMARP worked at improving residual limb strength, pain, and mobility. While NMES seemed most effective in minimizing strength loss in the amputated leg pre-prosthesis, further research on amputation rehabilitation is warranted, as NMES may accelerate recovery.

De Oliveira Melo et al. (2013) conducted a systematic review to identify the evidence for NMES for strengthening quadriceps muscles in elderly patients with knee osteoarthritis (OA). Six RCTs met inclusion criteria. Four studies included ≤ 50 patients. Study designs and outcome measures were heterogeneous and comparators varied. NMES parameters were poorly reported. The trials scored extremely low on the allocation concealment and blinding items. In most of the trials, the randomization methods were not described. Due to the poor methodology of the studies and poor description of the strength measurement methods, no or insufficient evidence was found to support NMES alone or combined with other modalities for the treatment of elderly patients with OA. Due to the study limitations, no meta-analysis was performed.

In a prospective, longitudinal RCT, 66 patients, aged 50 to 85 years and planning a primary unilateral total knee arthroplasty (TKA), were randomly assigned to receive either standard rehabilitation (control) or standard rehabilitation plus NMES applied to the quadriceps muscle (initiated 48 hours after surgery). The NMES was applied twice daily at the maximum tolerable intensity for 15 contractions. Data for muscle strength, functional performance, and self-report measures were obtained before surgery and 3.5, 6.5, 13, 26, and 52 weeks after TKA. At 3.5 weeks after TKA, significant improvements with NMES were found for quadriceps and hamstring muscle strength, functional performance, and knee extension AROM. At 52 weeks, the differences between groups were attenuated, but improvements with NMES were still significant for quadriceps and hamstring muscle strength, functional performance, and some self-report measures. The authors concluded that the early addition of NMES effectively attenuated loss of quadriceps muscle strength and improved functional performance following TKA. The effects were most pronounced and clinically meaningful within the first month after surgery but persisted through one year after surgery. Further research focused on early intervention after TKA is warranted to continue to optimize patient outcomes (Stevens-Lapsley et al., 2012).

There are also studies that NMES can be effective when used for quadriceps strength training following anterior cruciate ligament (ACL) reconstruction or prior to TKA. In a small RCT of NMES for quadriceps strength training following ACL reconstruction, the group that received NMES demonstrated moderately greater quadriceps strength at 12 weeks and moderately higher levels of knee function at both 12 and 16 weeks of rehabilitation compared to the control group (Fitzgerald, 2003). Another small study by Walls et al. (2010) evaluated the effects of preoperative NMES for nine patients undergoing TKA. Five patients served as a control group. Preoperative quadriceps muscle strength increased by 28% in the NMES group. Early postoperative strength loss was similar in both groups; however, the NMES group had a faster recovery with greater strength over the control group at 12 weeks postoperatively.

Nervous System Conditions

Cerebral Palsy

A RCT by Pool et al. (2016) evaluated whether NMES applied to the ankle dorsiflexors during gait improves muscle volume and strength in children with unilateral spastic CP. The study involved 32 children (mean age of 10.5 years) and a Gross Motor Function Classification System of I or II. Participants were randomly assigned to either the eight-week daily NMES treatment group or control group (usual or conventional treatments). Outcomes at week eight (post-NMES) and week 14 (carryover) included magnetic resonance imaging for muscle volumes (tibialis anterior, anterior compartment, and gastrocnemius), strength (hand-held dynamometry for isometric dorsiflexion strength and heel raises for functional strength), and clinical measures for lower limb selective motor control. At week eight, the treatment group demonstrated significantly increased muscle volumes and dorsiflexion strength not only when compared to their baseline values but also when compared to the control group at week eight. At week 14, both tibialis anterior and lateral gastrocnemius volumes in the treatment group remained significantly increased when compared to their baseline values. However, only lateral gastrocnemius volumes had significantly greater values when compared to the control group at week 14. There were no between group differences in the clinical measures for lower limb selective motor control at weeks eight and 14. The authors concluded that eight weeks of daily NMES-assisted gait increases muscle volume and strength of the stimulated ankle dorsiflexors in children with unilateral spastic CP. These changes are use-dependent and do not carry over after the eight-week treatment period. Gastrocnemius volume also increased post-treatment with carryover at week 14.

Cerebral Vascular Accident

Knutson et al. (2016) evaluated whether contralaterally controlled FES (CCFES) or cyclic NMES (cNMES) was more effective for post-stroke upper limb rehabilitation in an interventional, phase II, randomized trial conducted at a single institution (NCT00891319). Stroke patients (n=80) with chronic (> 6 months) moderate to severe upper extremity (UE) hemiparesis were randomized into two groups, receiving 10 sessions/week of CCFES- or cNMES-assisted hand opening exercise at home plus 20 sessions of functional task practice in the lab over 12 weeks. The primary outcome was improvement in Box and Blocks Test (BBT) score at six months post-treatment, with UE Fugl-Meyer motor assessment (UEFMA) and Arm Motor Abilities Test (AMAT) also being measured. Evaluation of participants occurred at baseline, every three weeks during the treatment period, at end-of-treatment, and two, four, and six months post-treatment by a blinded assessor. At six-months post-treatment, the CCFES group had greater improvement than the cNMES group on the BBT, 4.6 versus 1.8, respectively, and a between-group difference of 2.8. No significant between-group difference was found for the UEFMA or AMAT. The authors concluded that 12 weeks of CCFES therapy resulted in improved manual dexterity compared to cNMES in stroke survivors experiencing chronic moderate to severe hand impairment, with advantage given to those whose impairment was moderate and were < 2 years post-stroke. The translatability of CCFES therapy to other research sites and to clinical practice still has not been established.

In a RCT by Shen et al. (2015), CCFES was compared to NMES as an innovative method to improve UE functions after stroke. Sixty-six patients were also treated with conventional medical treatment and rehabilitation training and were equally randomized into two groups. The treatments were administered in 20-minute sessions, five times per week for three weeks. Tools to assess results included the FMA, motricity index (MI), the Hong Kong version of functional test for the hemiplegic UE (FTHUE-HK) and active range of motion (AROM) of wrist extension. Patient status was measured before and after three weeks of treatment. Both groups showed significant improvements in all the measurements after treatment. Patients in CCFES group showed significantly higher UE FMA, FTHUE-HK scores and AROM of wrist extension than those in NMES group. The authors concluded that compared with the conventional NMES, CCFES provides better recovery of UE function in patients with stroke.

Lin et al. (2011) completed a single-blinded, RCT to investigate the long-term efficacy of NMES in enhancing motor recovery in the UEs of stroke patients. A total of 46 patients with stroke were assigned to a NMES group or a control group. Patients in the NMES group received the treatment for 30 min, five days a week for three weeks. Measurements were recorded before treatment, at the second and third week of treatment and one, three, and six months after treatment ended. The Modified Ashworth Scale for spasticity, the UE section of the FMA, and the Modified Barthel Index were used to assess the results.

Significant improvements were found in both groups in terms of FMA and Modified Ashworth Scale scores after the third week of treatment. The significant improvements persisted one month after treatment had been discontinued. At three and six months post-treatment, the average scores in the NMES group were significantly better than those in the control group. The authors concluded that three weeks of NMES to the affected UE of patients with stroke improves motor recovery. One limitation of this study was the absence of a sham stimulation group. Future studies using similar stimulation protocols with a larger sample are needed to gain further insight into the potential to induce functionally beneficial neuroplasticity in stroke patients.

Hsu et al. (2010) conducted a RCT to investigate the effects of different doses of NMES on UE function in acute stroke patients with severe motor deficit. Sixty-six acute stroke patients were equally randomized to 3 groups: high NMES, low NMES, or control. The treatment groups received NMES five days per week with the high-NMES group receiving 60 minutes of stimulation per day, and low-NMES group receiving 30 minutes per day for four weeks. The FMA, Action Research Arm Test, and Motor Activity Log (MAL) were used to assess the patients at baseline, four, and 12 weeks. Twelve subjects were lost to follow-up. Both NMES groups showed significant improvement on FMA and Action Research Arm Test scales compared with the control group at weeks four and 12. The high-NMES group showed treatment effects similar to those of the low-NMES group. The authors concluded that both higher and lower doses of NMES led to similar improvements in motor function.

Clinical Practice Guidelines

American Heart Association/American Stroke Association (AHA/ASA)

In its Guidelines for Adult Stroke Rehabilitation and Recovery, the AHA/ASA state that NMES combined with therapy may improve spasticity, but there is insufficient evidence that the addition of NMES improves functional gait or hand use. The AHA/ASA guidelines are endorsed by the American Academy of Physical Medicine and Rehabilitation and the American Society of Neurorehabilitation (Winstein et al., 2016).

Respiratory System Conditions

A 2018 Cochrane review by Hill et al. evaluated the effects of NMES, either alone or concurrently with conventional exercise therapy, to determine if this treatment might improve the overall physical condition and health-related QOL in people with chronic obstructive pulmonary disease (COPD). Nineteen studies met the inclusion criteria, of which 16 contributed data on 267 individuals with COPD. Of these 16 studies, seven explored the effect of NMES versus usual care. Nine explored the effect of NMES plus conventional exercise training vs conventional exercise alone. The reviewers concluded that NMES, when applied alone, increased quadriceps force and endurance, six-minute walking distance, time to symptom limitation exercising at a submaximal intensity, and reduced the severity of leg fatigue on completion of exercise testing. Evidence quality was considered low or very low due to risk of bias within the studies, imprecision of the estimates, small number of studies and inconsistency between the studies.

Miscellaneous Conditions

NICE guidance on transcutaneous NMES for oropharyngeal dysphagia found current evidence on efficacy to be limited in quality. They did not cite any major safety concerns, although they considered the safety evidence to be limited in both quality and quantity. NICE states that this technology should only be used with special arrangements for clinical governance, consent and audit or research; and encourages further research into transcutaneous NMES for this condition, which clearly documents indications for treatment and details of patient selection (2018).

Patsaki et al. (2017) studied the effects of NMES along with individualized rehabilitation on muscle strength of ICU survivors. Following ICU discharge, 128 patients were randomized to either daily NMES sessions and individualized rehabilitation (NMES group) or to the control group. Muscle strength was assessed by the Medical Research Council (MRC) score and hand grip at hospital discharge. Secondary outcomes were functional ability and hospital length of stay. The authors found that NMES and personalized physiotherapy in ICU survivors did not result in greater improvement of muscle strength and functional status at hospital discharge. However, they concluded that NMES may be effective in this subset of patients, and that the potential benefits of rehabilitation strategies should be explored in larger numbers in future studies.

Interferential Therapy (IFT)

Low Back Pain

Rajfur et al. (2017) conducted a pilot study to compare the effects of treating low back pain (LBP) using selected electrotherapy methods, assessing the influence of individual electrotherapeutic treatments on reduction of pain, improvement of the range of movement in lower section of the spine, and improvement of motor functions and mobility. Participants were assigned to six comparison groups: A - conventional TENS, B - acupuncture-like TENS, C - high-voltage ES, D - IFT stimulation, E - diadynamic current, and F - control group. Of the 127 qualified participants, 123 completed the three-week study. Authors determined that selected electrical therapies (IFT, TENS< and high voltage ES) appear to be effective in treating chronic LBP.

Franco et al. (2016) conducted a double-blind single institution RCT on 148 patients with chronic nonspecific low back pain (LBP) to determine whether IFT before Pilates exercises is more effective than placebo. The primary outcome measures were pain intensity, pressure pain threshold, and disability after six weeks of therapy. The study groups consisted of active IFT + Pilates group, and placebo IFT + Pilates group. Eighteen treatment sessions were offered three times a week for six weeks. Both groups showed significant improvement in outcomes after six weeks, with improvements in pain and disability being considered clinically significant as well. However, the authors concluded that active IFT combined with Pilates exercises is no better than placebo IFC plus Pilates. Further studies are suggested.

To assess the influence of TENS and IFT on pain relief and to compare the analgesic efficacy of the two modalities, Grabiańska et al. (2015) studied 60 patients with LBP. The participants were equally and randomly divided into two groups. Depending on the groups, patients were given a series of ten 20-minute sessions over a two-week period using either IFT or TENS currents. In all patients, VAS and Laitinen modified scale were taken before and after treatment. At the end of the two weeks, there was improvement in nearly all components of the VAS and Laitinen scale for both groups. There was no statistically significant difference between the groups in reducing the intensity and other aspects of pain (e.g., frequency, pain medication and activity limitation). The authors concluded that both IFT and TENS therapy are effective for pain relief in patients with LBP, as their study results demonstrated equal analgesic efficacy of both therapy modalities.

Hurley et al. (2004) investigated the outcomes of manipulative therapy and IFT used as sole modalities or in combination for treatment of acute LBP. Eighty patients received manipulative therapy, 80 received IFT, and 80 received a combination of both. The primary outcome was a change in functional disability on the Roland Morris Disability Questionnaire. Follow-up questionnaires were posted at discharge and at 6 and 12 months. At discharge, all interventions significantly reduced functional disability. At 12 months, there were no significant differences found between the groups for recurrence of back pain, work absenteeism, medication consumption, exercise participation or the use of healthcare. The authors concluded that there was no difference between the effects of a combined manipulative therapy and IFT package and either of the therapy modalities alone.

Hurley et al. (2001) conducted a single-blind, RCT on 60 subjects with LBP, evaluating whether the IFT applied to the associated spinal nerve is more efficacious than placing the current over the painful area. These investigators found a statistically significant reduction in functional disability scores for the spinal nerve therapy group compared with the control group or the painful area therapy group. However, no advantage was observed for the spinal nerve therapy group in pain or QOL scores. The authors' findings showed that IFT electrode placement technique affects LBP-specific functional disability, providing preliminary implications for future clinical studies.

Clinical Practice Guidelines

American College of Physicians (ACP)

In their clinical practice guideline addressing noninvasive treatments for acute, subacute, and chronic LBP, the ACP states clinicians and patients should initially select non-pharmacologic treatments including but not limited to exercise (e.g., tai chi, yoga, motor control exercise) and multidisciplinary rehabilitation (e.g., ES therapies) when managing chronic LBP (Qaseem et al., 2017).

Osteoarthritis of the Knee/Anterior Cruciate Ligament/Menisectomy/Knee Chondroplasty

Zeng et al. (2015) performed a systematic review and Bayesian network meta-analysis of 27 RCTs over a 30-year period, which compared different ES therapies (high-frequency TENS (h-TENS), low-frequency TENS (l-TENS), NMES, IFC, PES and noninvasive interactive neurostimulation (NIN)) with the control group (sham or no intervention) for relief of knee pain in 1253 patients with OA. The primary goal was to identify whether or not the different ES modalities offered pain management by measuring the degree of pain intensity and the change pain score at last follow-up time point. Of the six therapy modalities, IFT was the only significantly effective treatment in both pain intensity and changed pain score at last follow-up time point when compared with the control group. In addition, IFT was deemed the best probable option for pain relief among the six therapy modalities. The authors' conclusions were that IFT was the most promising for management of knee pain related to OA. The other ES therapies were considered safe for patients with knee OA, although some were considered inappropriate. Study limitations included a small number of included trials, heterogeneity of the evidence, and the indirectness of comparisons inherent to network meta-analyses.

A multi-center, single-blind, RCT by Burch et al. (2008) investigated the benefits of combined interferential (IF) and patterned muscle stimulation in the treatment of OA of the knee. The study randomized 116 patients to a test or control group. The test group received 15 minutes of IF stimulation followed by 20 minutes of patterned muscle stimulation. The control group received 35 minutes of low-current TENS. Both groups were treated for eight weeks. Subjects completed questionnaires at baseline and after two, four, and eight weeks. Primary outcomes included the pain and physical function subscales of the WOMAC OA Index and VAS for pain and QOL. Compared to the control group, the test group showed reduced pain and increased function. The test group showed a greater decrease in the WOMAC pain subscale (P=0.002), function subscale (P=0.003) and stiffness subscale (P=0.004). More than 70% of the test group, compared to less than 50% of the control group, had at least a 20% reduction in the WOMAC pain subscale. When analyzing only patients who completed the study (n=49 in test group, n=50 in control group), the test group had a nominally significant greater decrease in overall pain VAS. No significant differences were observed between groups related to incidence of adverse events (AEs). The authors concluded that in patients with OA of the knee, home-based patterned stimulation appears to be a promising therapy for relieving pain, decreasing stiffness, and increasing function. Study limitations included manufacturer sponsoring, 10% drop out rate and the treatment effect did not reflect a sufficient significant difference.

Jarit et al. (2003) conducted a randomized, double-blind, placebo-controlled trial of home-based IFT in 87 patients who had undergone ACL reconstruction, menisectomy, or knee chondroplasty. Patients were divided into three groups based on type of knee surgery and within each group randomized into treatment and placebo group. All patients were given home IFT devices. The treatment groups received working IFT units while the placebo groups received units set to deliver no current. At baseline, there were no statistically significant differences between IFT and control groups in edema or ROM. All IFT subjects reported significantly less pain and had significantly greater ROM at all postoperative time points. ACL and menisectomy IFT subjects experienced significantly less edema at all time points, while chondroplasty subjects experienced significantly less edema until four weeks postoperatively. The authors concluded that IFT may help to reduce pain, need for pain medication and edema as well as enhance recovery of function after knee surgery. The study is limited by subjective reporting of edema by patients, small treatment and control groups and lack of comparison to other treatment modalities. In addition, the control group may have been aware they were not receiving IFT, thereby confounding the results.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

In its clinical practice guideline on the treatment of OA of the knee, the AAOS cannot recommend for or against the use of physical agents (including electrotherapeutic modalities) due to inconsistent findings (2013).

Other Musculoskeletal Pain

Dissanayaka et al. (2016) compared the effectiveness of TENS and IFT in a single-blind RCT on individuals with myofascial pain syndrome (MPS). The aim of this study was to compare the effectiveness of these treatment modalities both in combination with hot pack, myofascial release, AROM exercise, and a home exercise program on MPS patients with upper trapezius myofascial trigger point. A total of 105 patients with an upper trapezius myofascial trigger point were randomly allocated to three groups, three therapeutic regimens-control-standard care (hot pack, AROM exercises, myofascial release, and a home exercise program with postural advice), TENS-standard care and IFT-standard care-were administered eight times during four weeks at regular intervals. Pain intensity and cervical range of motions (cervical extension, lateral flexion to the contralateral side, and rotation to the ipsilateral side) were measured at baseline, immediately after the first treatment, before the eighth treatment, and 1 week after the eighth treatment. Immediate and short-term improvements were marked in the TENS group (n=35) compared with the IFT group (n=35) and the control group (n=35) with respect to pain intensity and cervical range of motions. The IFT group showed more significant improvement on these outcome measurements than the control group did. The authors concluded that TENS with standard care facilitates recovery better than IFT does in the same combination.

To evaluate the effectiveness of passive physical modalities (which included IFT) on soft tissue injuries of the shoulder, Yu et al. (2015) conducted a systematic review of literature published between January 1, 1990, and April 18, 2013. RCTs and cohort and case-control studies were eligible. Of the 22 eligible articles, 11 studies were found to have a low risk of bias and so were analyzed, although the collective number of patients within the 11 studies was not cited. IFT was one of multiple modalities that were ineffective in reducing shoulder pain. The authors concluded that most passive physical modalities, including IFT, do not benefit patients with subacromial impingement syndrome.

In 2010, Fuentes and colleagues published a systematic review and meta-analysis of studies evaluating the effectiveness of IFS for treating pain. A total of 20 studies met the following inclusion criteria: RCT; included adults diagnosed with a painful musculoskeletal condition; compared IFS (alone or as a co-intervention) to placebo, no treatment, or an alternative intervention; and assessed pain on a numeric scale. Fourteen of the trials reported data that could be included in a pooled analysis. IFS as a stand-alone intervention was not found to be more effective than placebo or an alternative intervention.

Tibial Fractures

Fourie and Bowerbank (1997) studied IFT as a treatment to accelerate healing of tibial fractures in a double blind, RCT. Forty-one men received IFT, 35 received sham, and 151 received no intervention. Outcomes were measured by the time to union or incidence of nonunion. IFTs were applied to the experimental group via suction electrodes for 30 minutes per day for 10 days. The placebo group had only suction electrodes applied producing a rhythmical massage effect. The control group received no intervention. The data analysis reflected no difference in the time for union in the three groups. The authors concluded that IFT did not reduce healing time for new tibial fractures or prevent nonunion, and that further investigation was recommended.

Pulsed Electrical Stimulation (PES)

Newberry et al. (2017) conducted a systematic review to assess the efficacy of a variety of noninvasive interventions (including but not limited to ES techniques [including TENS], NMES, and pulsed electromagnetic field therapy [PEMF]) for OA treatment of the knee. A search was conducted using PubMed, Embase, the Cochrane Collection, Web of Science, the Physiotherapy Evidence Database, ClinicalTrials.gov, and abstracts from professional practice society annual meetings (e.g., American College of Rheumatology, American Academy of Orthopaedic Surgery). Eligible studies were those that were RCTs that enrolled adults 18 years or over who were diagnosed with OA of the knee and compared any of the interventions of interest with placebo (sham) or any other intervention of interest that reported a clinical outcome (including pain, function, and quality of life). The investigators also included single-arm and prospective observational studies that analyzed the effects of weight loss in individuals with OA of the knee on a clinical outcome. Findings were stratified according to duration of interventions and outcomes: short term (4–12 weeks), medium term (12–26 weeks), and long term (>26 weeks). A total of 107 studies were included in the review and of those, three studies evaluated treatment with pulsed electromagnetic field therapy. Based on a pooled analysis, PEMF had a statistically nonsignificant beneficial effect on short-term pain. In addition, the investigators reported that the evidence is insufficient to assess the effects of PEMF on short-term or other outcomes, and that larger randomized controlled trials are needed.

Negm et al. (2013) conducted a systematic review and meta-analysis to determine if low frequency (≤100 Hz) pulsed subsensory threshold electrical stimulation produced either through pulsed electromagnetic field (PEMF) or pulsed electrical stimulation (PES) vs. sham PEMF/PES intervention is effective in improving pain and physical function at treatment completion in adults with knee OA blinded to treatment. A search was conducted using MEDLINE, CINAHL, EMBASE, CENTRAL and AMED as well as in three clinical trial registries including Clinical Trials Registry, Current Controlled Trials and the World Health Organisation International Clinical Trials Registry Platform. Eligible studies included those with: 1) participants with clinically and/or radiological confirmed knee OA; 2) PEMF/PES frequency was ≤100 Hz; 3) the comparator was sham PEMF/PES; 4) the primary outcome was pain and/or physical function; 5) the study design was RCT with blinded participants; 6) data for knee OA participants were reported independently pre- and post-treatment; and 7) participants were over 30 years of age. A total of seven RCTs (459 participants/knees) were included. PEMF/PES appeared to improve physical function (standardized mean difference [SMD]=0.22, 95% CI, 0.04 to 0.41, *p*=0.02), and did not reduce pain (SMD=0.08, 95% CI, −0.17 to 0.32, p=0.55). The strength of the body of evidence was low for physical function and very low for pain. The authors concluded that current evidence is of low and very low quality suggesting that low frequency (≤100 Hz) pulsed subsensory threshold electrical stimulation produced either through PEMF/PES vs. sham PEMF/PES is effective in improving physical function but not pain intensity at treatment completion in adults with knee OA blinded to treatment. The authors also stated that methodologically rigorous and adequately powered RCTs are still needed to confirm and extend the findings of this review.

Farr et al. (2006) reported on a prospective, cohort study examining the use of PES for the treatment of OA of the knee in 288 patients. The device was used for 16-600 days with a mean of 889 hours. Improvement in all efficacy variables was reported. A dose-response relationship between the effect and hours of usage was observed as cumulative time increased to more than 750 hours. Improvements in the patient's or physician's global evaluation of the patient's condition occurred in 59% of patients who used PES less than 750 hours and in 73% of patients who used it more than 750 hours. The lack of a control group weakens the evidence in this study.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

In its clinical practice guideline on the treatment of OA of the knee, the AAOS cannot recommend for or against the use of physical agents (including electrotherapeutic modalities) due to inconsistent findings (2013).

Percutaneous Peripheral Nerve Stimulation (PNS)

There is insufficient evidence to support the use of PNS for the treatment of pain. While some studies have compared the effectiveness of PNS to placebo, the overall quality of the evidence is weak and limited. Further robust studies are needed to evaluate the efficacy of PNS.

Hayes published the following reports for PNS for pain: Peripheral nerve stimulation with the SPRINT PNS System for chronic knee pain (2021), SPRINT PNS System (SPR Therapeutics) for chronic pain (2020), and StimRouter Neuromodulation System (Bioness Inc.) for treatment of chronic pain (2020). All of these reports conclude that there is an insufficient quantity of published, peer-reviewed, human clinical data to evaluate the use of these devices.

ECRI published the following reports for PNS for pain: Sprint Peripheral Nerve Stimulation System for Treating Peripheral Nerve Pain (2020), StimRouter Neuromodulation System for Treating Peripheral Nerve Pain (2020), and StimQ Peripheral Nerve Stimulator System for Treating Peripheral Nerve Pain (2018). All of these reports indicate that the evidence is inconclusive since there are too few data.

Ilfeld et al. (2021) conducted a multicenter randomized, sham-controlled pilot study to determine the feasibility and optimize the protocol for a subsequent clinical trial and estimate the treatment effect of percutaneous peripheral nerve stimulation on postoperative pain and opioid consumption. Preoperatively, an electrical lead was percutaneously implanted to target the sciatic nerve for major foot/ankle surgery (e.g., hallux valgus correction), the femoral nerve for anterior cruciate ligament reconstruction, or the brachial plexus for rotator cuff repair, followed by a single injection of long-acting local anesthetic along the same nerve/plexus. Postoperatively, participants were randomized to 14 days of either electrical stimulation ($n = 32$) or sham stimulation ($n = 34$) using an external pulse generator in a double-masked fashion. The dual primary treatment effect outcome measures were (1) cumulative opioid consumption (in oral morphine equivalents) and (2) mean values of the "average" daily pain scores measured on the 0 to 10 Numeric Rating Scale within the first seven postoperative days. During the first 7 postoperative days, opioid consumption in participants given active stimulation was a median (interquartile range) of 5 mg (0 to 30) versus 48 mg (25 to 90) in patients given sham treatment (ratio of geometric means, 0.20 [97.5% CI, 0.07 to 0.57]; $P < 0.001$). During this same period, the average pain intensity in patients given active stimulation was a mean ± SD of 1.1 ± 1.1 versus 3.1 ± 1.7 in those given sham (difference, -1.8 [97.5% CI, -2.6 to -0.9]; $P < 0.001$). The investigators concluded that percutaneous peripheral nerve stimulation reduced pain scores and opioid requirements free of systemic side effects during at least the initial week after ambulatory orthopedic surgery. The limitations of this study include a small sample size and a short follow-up period.

Xu et al. (2021) conducted a systematic review to assess the clinical evidence for PNS in the treatment of acute or chronic pain. Study selection criteria included randomized trials, observational studies, and case reports of PNS used for in acute or chronic pain. Data extraction and methodological quality assessment were performed using Cochrane review methodologic quality assessment and Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment (IPM-QRB) and Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM-QRBNR). The evidence was summarized utilizing principles of best evidence synthesis on a scale of 1 to 5. A total of 227 studies met inclusion criteria and were included in qualitative synthesis. Evidence synthesis based on randomized controlled trials (RCTs) and observational studies showed Level II evidence (evidence obtained from at least one relevant high-quality RCT or multiple relevant moderate- or low-quality RCTs) of PNS for postamputation pain, chronic pelvic pain, chronic low back pain, shoulder pain, and lower extremity pain; and Level IV evidence (evidence obtained from multiple moderate- or low-quality relevant observational studies) in peripheral neuropathic pain and postsurgical pain. A meta-analysis was not possible due to wide variations in experimental design, research protocol, and heterogeneity of study population. According to the authors, there is a lack of high-quality RCTs for the use of PNS. The authors indicated that rigorously designed RCTs are needed to further validate the use of percutaneous PNS for most indications in pain management.

Deer et al. (2020) performed a systematic review of PNS for pain. An international interdisciplinary work group conducted a literature search for PNS. Inclusion criteria included prospective RCTs with meaningful clinical outcomes that were not part of a larger or previously reported group. Excluded studies were retrospective, had less than two months of follow-up, or existed only as abstracts. Full studies were graded by two independent reviewers using the modified Interventional Pain Management Techniques-Quality Appraisal of Reliability and Risk of Bias Assessment, the Cochrane Collaborations Risk of Bias assessment, and the US Preventative Services Task Force level-of-evidence criteria. Peripheral nerve stimulation was studied in 14 RCTs for a variety of painful conditions (headache, shoulder, pelvic, back, extremity, and trunk pain). Moderate to strong evidence supported the use of PNS to treat pain. According to the authors, there was moderate evidence (Level II) that implanted PNS can be expected to provide at least modest improvements in mononeuropathic pain (Deer et al., 2016) and hemiplegic shoulder pain (Wilson et al., 2014; Wilson et al., 2017). The authors indicated that additional prospective trials could further refine appropriate populations and pain diagnoses.

Gilmore et al. (2019a) conducted a multicenter, double-blinded, randomized, placebo-controlled study to assess the safety and effectiveness of percutaneous PNS for chronic neuropathic pain following amputation. Twenty-eight lower extremity amputees with postamputation pain were enrolled in the study. Subjects underwent ultrasound-guided implantation of PNS leads and were randomized to receive PNS or placebo for four weeks. The placebo group then crossed over and all subjects received PNS for four additional weeks. The primary efficacy endpoint evaluated the proportion of subjects reporting ≥50% pain reduction during weeks 1-4. A significantly greater proportion of subjects receiving PNS (n=7/12, 58%, p=0.037) demonstrated ≥50% reductions in average postamputation pain during weeks 1-4 compared with subjects receiving placebo (n=2/14, 14%). Two subjects were excluded from efficacy analysis due to eligibility changes. Significantly greater proportions of PNS subjects also reported ≥50% reductions in pain (n=8/12, 67%, p=0.014) and pain interference (n=8/10, 80%, p=0.003) after eight weeks of therapy compared with subjects receiving placebo (pain: n=2/14, 14%; pain interference: n=2/13, 15%). The investigators concluded that this study demonstrates that percutaneous PNS therapy may provide enduring clinically significant pain relief and improve disability in patients with chronic neuropathic postamputation pain. Study limitations included small sample size, short follow-up period (four weeks.), no significant difference in opioid usage reductions between groups, even though the PNS therapy group had greater absolute and percent reductions in average opioid usage.

Gilmore et al. (2019b) evaluated changes in chronic pain and functional outcomes after amputation up to 12 months as a follow-up to a 60-day PNS treatment (Gilmore et al., 2019a). Significantly more participants in group 1 reported ≥50% reductions in average weekly pain at 12 months (67%, 6/9) compared with group 2 at the end of the placebo period (0%, 0/14, p=0.001). Similarly, 56% (5/9) of participants in group 1 reported ≥50% reductions in pain interference at 12 months, compared with 2/13 (15%, p=0.074) in group 2 at crossover. Reductions in depression were also statistically significantly greater at 12 months in group 1 compared with group 2 at crossover. The investigators concluded that this study suggests that percutaneous PNS therapy delivered over a 60-day period may provide significant carry-over effects including pain relief, potentially avoiding the need for a permanently implanted system while enabling improved function in patients with chronic pain. The investigators indicated that although the pain relief and pain interference outcomes were clinically meaningful and statistically significant, the sample sizes made some outcomes difficult to interpret, such as the trend in both group 1 and group 2 towards greater pain relief during follow-up compared with the end of treatment. The investigators indicated that it is possible that the loss of 4 participants to follow-up influenced the average pain relief at later time points.

Peripheral Subcutaneous Field Stimulation (PSFS) or Peripheral Nerve Field Stimulation (PNFS)

van Gorp et al. (2016) conducted a multicenter, RCT investigating the efficacy of subcutaneous stimulation (SubQ) as ADD-ON therapy to traditional spinal cord stimulation (SCS) in treating back pain in failed back surgery syndrome patients. Individuals with a minimal pain score of 50 on a 100 mm VAS for both leg and back pain were eligible. If pain reduction after trial SCS was ≥ 50% for the leg but < 50% for the back, patients received additional SubQ leads and were randomized in a 1:1 ratio in a study arm with subcutaneous leads switched on (SubQ ADD-ON), and an arm with subcutaneous leads switched off (Control). The primary outcome was the percentage of the patients, at three months post-implantation, with ≥ 50% reduction of back pain. A total of 97 patients were treated with SCS for leg and back pain. Of these, 52 patients were randomized and allocated to the Control group (n=24) or to the SubQ ADD-ON group (n=28). The percentage of patients with ≥ 50% reduction of back pain was significantly higher in the SubQ ADD-ON group (42.9%) compared to the Control group (4.2%). Mean VAS score for back pain at three months was a statistically significant 28.1 mm lower in the SubQ ADD-ON group compared to the Control group. The authors concluded that subcutaneous stimulation as an ADD-ON therapy to SCS is effective in treating back pain in failed back surgery syndrome patients where SCS is only effective for pain in the leg.

McRoberts et al. (2013) conducted a multi-site, 2-phase, crossover RCT evaluating the safety and efficacy of PNFS in 44 patients with localized chronic intractable pain of the back. During phase I, patients rotated through four stimulation groups (minimal, subthreshold, low frequency, and standard stimulation). If a 50% reduction in pain was achieved during any of the three active stimulation groups (responder), the patient proceeded to phase II, which began with implant of the permanent system and remained in place for 52 weeks. The primary endpoint was a reduction in pain, assessed by the VAS. Of the 44 patients enrolled, 30 completed phase I. Twenty-four patients were classified as responders in phase I, and 23 received permanent system placement. Significant differences in VAS scores were observed between baseline and all follow-up visits during phase II. The authors concluded that PNFS is safe and effective as an aid in the management of chronic, localized back pain. Limitations to this trial are small study group size.

Yakovlev et al. (2011) conducted a case series study to evaluate PNFS as an alternative treatment option for patients with post-laminectomy syndrome when conventional treatments did not provide adequate relief of intractable LBP. Eighteen patients underwent an uneventful PNFS trial with percutaneous placement of four temporary quadripolar leads. The leads were placed subcutaneously over the lumbar or thoraco-lumbar area. The temporary leads were removed when patients experienced excellent pain relief over the next two days. The patients were then implanted with permanent leads. All patients reported sustained pain relief 12 months after implantation. The authors concluded that PNFS may be more effective in treating intractable LBP than SCS in patients with post-laminectomy syndrome after multilevel spinal surgeries. The lack of a control group limits the validity of the conclusions of this study.

Verrills et al. (2011) evaluated the clinical outcomes of 100 consecutive patients receiving PNFS for chronic pain in a prospective, observational study. The patients received PNFS for the treatment of chronic craniofacial, thorax, lumbosacral, abdominal, pelvic, and groin pain conditions. Overall, 72% of patients reduced their analgesic use following PNFS. Patients receiving a lumbosacral PNFS for chronic LBP reported a significant reduction in disability following treatment, as determined by the Oswestry Disability Index. No long-term complications were reported. The authors concluded that PNFS can be a safe and effective treatment option for intractable chronic pain conditions. This study was not randomized or controlled.

To aid in alleviating symptoms associated with opioid withdrawal, a PNFS delivery system known as the NSS-2 Bridge is marketed for use as a non-pharmacologic component of an inpatient or outpatient detoxification treatment program. One single-arm retrospective pilot study has been published (Miranda and Taca, 2017), citing 64 of 73 patients successfully transitioning to medically-assisted treatment after using the device with no reports of AEs. While several guidelines on the management of opioid withdrawal are available, none addressed the use of this type of device for this indication. Prospects for the NSS-2 Bridge System are unclear at this time (Hayes, 2017). Another PNFS system similar to the NSS-2 Bridge is known as the DrugRelief® stimulator. This auricular neurostimulation device is also used to reduce the symptoms of opioid withdrawal during detoxification. At present, there are no studies or published literature relating to this device.

Evidence on PNFS is limited, consisting of small uncontrolled and case studies. Prospective controlled trials are needed to evaluate the efficacy of this treatment.

Microcurrent Electrical Nerve Stimulation Therapy (MENS)

A 2018 Hayes report evaluated the use of microcurrent electrical therapy (MET) for the treatment of musculoskeletal pain in comparison with usual care. The literature search identified six eligible studies that compared MET with an alternative treatment in patients with musculoskeletal pain (lateral epicondylitis, LBP, Achilles tendinopathy, temporomandibular joint pain, and masticatory pain associated with bruxism (teeth grinding)). Evidence was considered to be very low quality. The authors concluded that there is insufficient evidence to assess the efficacy of MET for the treatment of pain associated with any of these conditions due to the paucity of evidence evaluating MET in any one indication. Additionally, the report concluded that there is substantial uncertainty regarding whether MET provides reduction in pain compared with usual care in patients with lateral epicondylitis.

MET was also evaluated by Hayes for the treatment of postoperative pain in adults. The literature search identified only three studies that evaluated MET for post-TKA (two studies) and total hip arthroplasty (one study). The authors concluded that there is insufficient evidence to evaluate use of MET for this indication, and there is substantial uncertainty regarding whether this technology provides pain relief in adults undergoing total joint arthroplasty (2018).

Kwon et al. (2017) conducted a prospective, double-blinded, sham-controlled RCT to evaluate the effects of short-term MENS on muscle function in the elderly. A total of 38 healthy elderly participants aged 65 years and above were enrolled and randomly divided into a real MENS or a sham MENS stimulation group. Both groups received stimulation to the eight anatomical points of the dominant arm and leg during the course of 40 minutes. The authors report that their hypothesis was accurate that real MENS was superior to sham in enhancing muscle function in healthy elderly subjects following short term application. Limitations to this study included the lack of definition of the "healthy elderly", short application time of the MENS, and lack of follow-up evaluation. Long-term RCTs with follow-up assessments are needed to confirm these results.

Gossrau et al. (2011) conducted a single-blinded, placebo-controlled randomized trial to assess the efficacy of MENS for reduction of painful diabetic neuropathy (PDN) in 41 patients. Participants were divided into two groups: 22 treated with MENS therapy and 19 with placebo. Treatment plan was three therapy sessions per week for four weeks. Primary outcomes measured included pain intensity, pain disability, and QOL at baseline, and the end of treatment, and four weeks post-treatment using standardized questionnaires. Patients with a minimum of 30% reduction in neuropathic pain score (NPS) were defined as therapy responders. After four weeks, only six of 21 patients in the study group (30%) responded to MENS therapy versus 10 of 19 (53%) of the placebo group. The differences in Pain Disability Index (PDI) for both groups were not statistically significant. The authors concluded that MENS therapy for PDN is not superior to placebo.

Koopman et al. evaluated the efficacy of MENS in treating aspecific, chronic LBP in a double-blind, randomized, crossover pilot trial. Ten succeeding patients presenting with nonspecific, chronic LBP in the university setting were included. Patients started with two, nine-day baseline periods followed by a five-day treatment period. During the treatment periods, either a placebo or MCT (verum) patch was randomly assigned. Mean and worst pain scores were evaluated daily by VAS score. Analgesic use, side effects, and QOL were assessed after each period. Differences between the last four days of a treatment period and the baseline period were calculated. Differences between verum and placebo periods per patient were also compared. A 20-mm VAS score reduction was considered clinically relevant. All outcome measures demonstrated efficacy with the verum treatment, except for an increase in NSAID use. However, none of the findings were statistically significant. The authors concluded that a positive trend in MENS use for a specific, chronic LBP could be reported, but that further research is required to evaluate the significance and relevance of these findings (2009).

MENS therapy has been studied in other small RCTs and case series for conditions such as delayed onset muscle soreness (Curtis et al. 2010) and diabetes, hypertension, and chronic wounds (Lee, et al. 2009). None of these studies are large controlled trials designed to test the effectiveness of MENS therapy against a placebo device. Therefore, due to the limited evidence in the peer reviewed literature, conclusions cannot be reached regarding the safety, efficacy, or utility of MENS therapy to decrease pain and/or facilitate healing for any condition.

Zuim et al. (2006) evaluated the effect of MENS therapy compared with occlusal splint therapy in temporomandibular disorders (TMD) patients with muscle pain. Twenty TMD patients were divided into four groups: occlusal splint therapy and MENS (group I); occlusal splints and placebo MENS (group II); only MENS (group III), and placebo MENS (group IV). Sensitivity derived from muscle palpation was evaluated using a VAS. There was reduction of pain level in all groups: group I reported a 47.7% reduction rate; group II, 66.7%; group III, 49.7% and group IV, 16.5%. However, the differences between groups relating to TMD muscle pain reduction were not statistically significant after four weeks. The authors concluded that MENS was not statistically superior to occlusal splints in the treatment of masticatory muscle pain in TMD patients. Study limitations include small study group and short follow-up period.

Percutaneous Electrical Nerve Stimulation (PENS)

A Hayes report evaluated the peer-reviewed literature related to PENS for the treatment of chronic LBP and PNT for the treatment of LBP. Evidence from the available studies (which included three RCTs with a range of 34-200 participants and one pretest/posttest study) was considered to be fair, poor, or very poor quality. The three RCTs evaluated the efficacy and safety of PENS for chronic LBP in adults and remaining study evaluated PNT for subacute radiating LBP. The authors concluded that there was insufficient published evidence to assess the clinical validity of PENS alone or in combination with physical therapy or general conditioning exercise in patients with chronic LBP. Additionally, the report concluded that there is insufficient published evidence to assess the impact of PNT on health outcomes or patient management for the treatment of LBP (2019).

A Hayes evidence brief concluded that there is insufficient published evidence to evaluate the IB-Stim PENFS device (Innovative Health Solutions, Inc., Versailles, IN) for treatment of pain associated with irritable bowel syndrome (2019).

Meng et al. (2018) conducted a multicenter RCT to investigate the effects of electroacupuncture (EA) on reducing inflammatory reaction and improving intestinal dysfunction in patients with sepsis-induced intestinal dysfunction with syndrome of obstruction of the bowels. A total of 71 patients were randomly assigned to control group (n=36) and treatment group (n=35). Patients in the control group were given conventional therapies including fluid resuscitation, anti-infection, vasoactive agents, mechanical ventilation, supply of enteral nutrition, and glutamine as soon as possible. In addition to conventional therapies, patients in treatment group underwent 20 minutes of EA twice a day for five days. At baseline, day one, day three, and day seven after treatment, biomarkers assessing intestinal inflammation and dysfunction were measured and recorded, respectively. Additionally, days on mechanical ventilation (MV), length of stay in intensive care unit (ICU), and 28-day mortality were also recorded. The authors concluded that EA, as a supplement to conventional therapy, can reduce inflammatory reaction and has protective effects on intestinal function than conventional therapy alone in patients with sepsis-induced intestinal dysfunction with syndrome of obstruction of the bowels. However, there were no significant differences identified between the two groups relative to number of days on MV, length of stay in ICU, and 28-day mortality. Limitations to this study include small sample size and single-center investigation. Further studies are required.

Mi et al. (2018) conducted a randomized observational trial to evaluate the effect of transcutaneous electrical acupoint stimulation (TEAS) on dosages of anesthetic and analgesics as well as the quality of recovery during the early period after laparoscopic cholecystectomy. One hundred patients who underwent laparoscopic cholecystectomy with grade I and II of the American Society of Anesthesiologists criteria were evenly and randomly assigned into an observation group and a control group. The patients in the observation group were treated with TEAS from 30 minutes prior to anesthesia induction to the end of operation. The patients in the control group received stimulation electrode(s) in the corresponding points without ES for the same time period. Researchers concluded that TEAS can reduce the dosage of anesthetic and analgesic delivered intraoperatively, as well as improve the quality of recovery during the early period after laparoscopic cholecystectomy.

Kovacic et al. (2017) conducted a single center, blinded, sham RCT evaluating the efficacy of a PENFS device known as Neuro-Stim (Innovative Health Solutions, Versailles, IN) in adolescents with abdominal pain-related functional gastrointestinal disorders. Adolescents (aged 11-18 years) who met Rome III criteria with abdominal pain-related functional gastrointestinal disorders were enrolled and assigned to either PENFS (n=60) with an active device or sham (n=55). After exclusion of patients who discontinued treatment (one in the study group, seven in the sham group) and those who were excluded after randomization because they had organic disease (2 and 1 in the study and sham groups, respectively), 57 patients in the PENFS group and 47 patients in the sham group were included in the primary analysis. The primary efficacy endpoint was change in abdominal pain scores measured via the Pain Frequency-Severity-Duration (PFSD) scale. Patients in the PENFS group had greater reduction in worst pain compared with sham after three weeks of treatment. Participants from each group (n=10) discontinued the study due to side-effects, none of which were serious. Symptoms included ear discomfort, adhesive allergy, and syncope due to needle phobia. The researchers concluded that PENFS with Neuro-Stim is has sustained efficacy for abdominal pain-related functional gastrointestinal disorders in adolescents. Study limitations include small sample size and short follow up period and exclusions after randomization.

Rossi et al. (2016) conducted a multicenter, prospective, observational study to evaluate the short- and long-term efficacy of a single probe and single shot PENS approach to treat chronic neuropathic pain. Seventy-six patients affected by neuralgia were enrolled in the study and divided into three groups depending on the etiology of the neuralgia (21 herpes zoster infection, 31 causalgia, 24 postoperative pain). In the study, Numerical Rating Scale (NRS) and Neuropathic Pain Scale (NPS) were assessed at baseline, 60 minutes after PENS, one week, and one, three, and six months post-therapy. Perceived health outcome was measured with Euroqol-5 dimension (EQ-5D) questionnaire at baseline and at six months. Pain assessment ratings decreased significantly after 60 minutes of PENS therapy and the reduction remained constant throughout the follow up period. Perceived health outcome measured with EQ-5D increased significantly from baseline. The authors concluded that PENS therapy produced significant and long-lasting pain relief in chronic peripheral neuropathic pain of different etiologies. The study limitations included small sample size, non-randomized observational study, short follow up period, and high prevalence of post-herpetic and occipital neuralgias.

In 2013, NICE published guidance related to the use of PENS to control neuropathic pain. The guidance states, “The current evidence on the safety of PENS for refractory neuropathic pain raises no major safety concerns and there is evidence of efficacy in the short term.” Therefore, this procedure may be used with normal arrangements for clinical governance, consent and audit. The guideline also indicates that NICE encourages further research into PENS for refractory neuropathic pain, particularly to provide more information about selection criteria and long-term outcomes, with clear documentation of the indications for treatment.

In 2011, Wanich and colleagues conducted a RCT to study the use of the Deepwave PNT system in patients who underwent primary TKA. Trial participants (n=23) were categorized into two groups (experimental or control). Following surgery, patients underwent either Deepwave or sham treatments. A Brief Pain Inventory questionnaire and the amount of all pain medications taken were recorded. The study results demonstrated a significant reduction in patient’s subjective rating of pain and VAS score in the experimental group ($p < 0.05$), with a trend toward decreased opioid use but this was not statistically significant ($p = 0.09$). The authors concluded that the Deepwave device was effective in reducing the subjective measures of pain with a trend toward decreased opioid use in patients following TKA. Details regarding the duration of treatments or the length of follow up were not documented.

Raphael et al. (2011) conducted a randomized double-blind sham-controlled crossover trial on 31 patients suffering from chronic pain with surface hyperalgesia to investigate the efficacy of PENS. The study results demonstrated statistically significant improvements from pre-therapy ratings and assessment of pain in the PENS group versus the sham group using the numerical rating scale (NRS) and the pain pressure threshold (PPT). The authors concluded that PENS therapy appeared to be effective in providing short-term pain relief in chronic pain conditions; however, studies, involving larger sample sizes and longer follow-up were recommended.

While some studies have compared the effectiveness of PENS to placebo, the overall quality of the evidence is weak and quite limited. Further robust studies are needed to evaluate the efficacy of this therapy for chronic pain.

Clinical Practice Guidelines

American Academy of Neurology (AAN), American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), American Academy of Physical Medicine and Rehabilitation (AAPMR)

In a joint guideline report on the treatment of painful diabetic neuropathy (PDN), the AAN, AANEM, and AAPMR concluded that PENS should be considered for the treatment of PDN (Bril et al., 2011).

Dorsal Root Ganglion (DRG) Stimulation

Kretzschmar et al. (2020) conducted a single-center, retrospective case series study to evaluate safety and effectiveness outcomes of dorsal root ganglion (DRG) stimulation for peripheral nerve injuries (PNI). A total of 27 individuals with PNI received a five- to six-day trial of a DRG neurostimulation system. Trial success (defined as ≥ 50% pain relief) was 85% and 23 patients received a permanent stimulator. Outcomes included pain, quality of life, mental and physical function, and opioid usage and were assessed at baseline and at 3-, 6-, 12-, 18-, 24-, and 36 months post-permanent implant. Implant-related complications were also documented. Thirty-six months of follow-up data were available for 21 patients (67% female), mean (SD) age was 52.5 ± 14.2 years, and PNI was diagnosed in the upper extremity in four patients and in the lower extremity in 17 patients. Compared to baseline, there was significant pain relief ($p<0.001$) at 3 (58%), 12 (66%), 18 (69%), 24 (71%), and 36 months (73%), respectively. Mental and physical function showed immediate and sustained improvements. Participants reported improvements in quality of life. Opioid dosage reduced significantly ($p<0.001$) at 3 (30%), 12 (93%), 18 (98%), 24 (99%), and 36 months (99%), and 20 of 21 patients were completely opioid-free after 36 months. There were five electrode dislocations and two electrode fractures during the follow up (between two and 15 months after primary surgery); four leads were replaced during an additional surgery intervention without any complications, three leads could not be replaced and therefore, their position had to be changed to a neighboring foramen. One patient developed a superficial wound infection which was conservatively treated and controlled. Two patients asked for the device to be removed within the first year after complete implantation despite good pain relief under therapy due to subjective discomfort caused by the implant (pocket pain). The authors concluded that DRG neuromodulation appears to be a safe, effective, and a durable option for treating neuropathic pain caused by PNI. They also stated that the treatment allows cessation of often ineffective pharmacotherapy (including opioid misuse) and significantly improves quality of life. Caution should be used when interpreting the study results as there are several limitations. Those include the study design, a case series lacking randomization and contemporaneous comparison group, the study data, that was retrospectively collected survey data from a single provider, and its small sample size. Additional multi-center, prospective, randomized trials with longer follow-up are still needed to elucidate DRG's role in the treatment of PNI.

Hayes performed an evidence review from 3 studies that evaluated DRG stimulation for treatment of complex regional pain syndrome (CRPS) in adults. Overall, a very-low-quality body of evidence suggests that DRG stimulation may result in treatment success, reductions in pain, and improvements in QOL compared with baseline assessments or SCS treatment. However, this body of evidence is limited by individual study limitations, limited quantity of evidence, and the availability of a single study comparing groups of patients that received DRG stimulation or spinal cord stimulation (SCS). In addition, current evidence suggests a potential safety concern for procedure-related AEs with DRG stimulation. Currently, there is insufficient evidence to draw conclusions regarding the safety and effectiveness of DRG stimulation for the treatment of CRPS in adults (2020).

Deer et al (2017) conducted a prospective, multicenter, randomized comparative effectiveness trial (known as the ACCURATE trial) in 152 subjects diagnosed with CRPS or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or dorsal column SCS via the Axium™ DRG system. The primary end point was a composite of safety and efficacy at three months, and subjects were assessed through 12 months for long-term outcomes and AEs. The predefined primary composite end point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in VAS score from pre-implant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving ≥ 50% pain relief and treatment success was greater in the DRG arm (81.2%) than in the SCS arm (55.7%) at three months. Device-related and serious AEs were not different between the two groups. DRG stimulation also demonstrated greater improvements in QOL and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia and reduced extraneous stimulation in non-painful areas, indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. The researchers concluded that DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS. Additional prospective randomized trials with longer follow-up are still needed to clarify the safety and efficacy of DRG in patients with CRPS or causalgia.

Liem et al. conducted a multi-center prospective case series study to evaluate the clinical performance of a new neurostimulation system designed to treat chronic pain through the electrical neuromodulation of the DRG neurophysiologically associated with painful regions of the limbs and/or trunk. The first publication (Liem 2013) reported outcomes from 32 subjects who were implanted with a novel neuromodulation device. Pain ratings during stimulation were followed up to six months and compared with baseline ratings. Subjects also completed two separate reversal periods in which stimulation was briefly stopped in order to establish the effects of the intervention. At all assessments, more than half of subjects reported pain relief of 50% or better. At six months post-implant, average overall pain ratings were 58% lower than baseline, and the proportions of subjects experiencing 50% or more reduction in pain specific to back, leg, and foot regions were 57%, 70%, and 89%, respectively. When stimulation was discontinued for a short time, pain returned to baseline levels. Discrete coverage of hard-to-treat areas was obtained across a variety of anatomical pain distributions. Paresthesia intensity remained stable over time and there was no significant difference in the paresthesia intensity perceived during different body postures/positions (standing up vs. lying down). The authors concluded that this trial demonstrated that neurostimulation of the DRG is a viable neuromodulatory technique for the treatment of chronic pain. Additionally, the capture of discrete painful areas such as the feet combined with stable paresthesia intensities across body positions suggest that this stimulation modality may allow more selective targeting of painful areas and reduce unwanted side-effects observed in traditional SCS.

Acknowledging their earlier research, Liem et al. (2015) reported on the maintenance of pain relief, improvement in mood, and QOL over 12 months. Subjects with intractable pain in the back and/or lower limbs were implanted with an active neurostimulator device. Up to four percutaneous leads were placed epidurally near DRGs. Overall pain was reduced by 56% at 12 months post-implantation, and 60% of subjects reported greater than 50% improvement in their pain. Pain localized to the back, legs, and feet was reduced by 42%, 62%, and 80%, respectively. Measures of QOL and mood were also improved over the course of the study, and subjects reported high levels of satisfaction. Importantly, excellent pain-paresthesia overlap was reported, remaining stable through 12 months. There were 86 safety events reported across 29 subjects; approximately half were judged by the investigators to be related to the device. The most common adverse events were temporary motor stimulation (12 events; 14.6%), cerebrospinal fluid leak with associated headache (7 events; 8.5%), and infection (7 events; 8.5%). The authors concluded that improvements in ratings of pain, mood, and quality of life with DRG-SCS have been demonstrated through 12 months of therapy. They also noted that there was good agreement in pain–paresthesia overlap and high levels of user satisfaction. Caution should be use when interpreting these study results as there are several limitations. Those include the study design as a case series lacking randomization and contemporaneous comparison group, the number of safety events that investigators deemed to be related to the device, and lack of long-term outcomes. Additional prospective randomized trials are needed to evaluate the utility of DRG stimulation in patients with back and/or lower limb pain.

Schu et al. (2015) conducted a retrospective review of data from patients with groin pain of various etiologies treated using neuromodulation of the DRG. Twenty-nine patients with neuropathic groin pain were reviewed. Patients underwent trial therapy where specifically designed leads were implanted at the target DRGs between T12 and L4. Patients who had a successful trial (> 50% improvement) received the fully implantable neuromodulation system. Pain scores were captured on a VAS at baseline and at regular follow-up visits. Twenty-five patients (86.2%) received fully implantable neurostimulators, and the average follow-up period was 27.8 ± 4.3 weeks. The average pain reduction was 71.4 ± 5.6%, and 82.6% (19/23) of patients experienced a > 50% reduction in their pain at the latest follow-up. Individual cases showed improvement with a variety of etiologies and pain distributions; a subanalysis of post-herniorrhaphy cohort also showed significant improvement. The authors concluded that early findings suggest that neuromodulation of the DRG may be an effective treatment for chronic neuropathic pain conditions in the groin region. This technique offers a useful alternative for pain conditions that do not always respond optimally to traditional SCS therapy. Neuromodulation of the DRG provided excellent cross-dermatomal paresthesia coverage, even in cases with patients with discrete pain areas. The therapy can be specific, sustained, and independent of body position. Study limitations include non-randomization and small sample size.

Several clinical trials studying DRG stimulation in patients with various conditions are active or recruiting. For more information, go to www.clinicaltrials.gov. (Accessed November 18, 2020

Scrambler Therapy (ST)

Kashyap and Bhatnagar (2020) conducted a systematic review to detect possible gaps in the literature regarding the efficacy of ST for cancer pain and formulate recommendations for research. Using predetermined terms, a search was conducted in PubMed and Embase. A total of 27 studies were retrieved. Ten were articles that were categorized as literature reviews, including seven narrative reviews, one editorial, and two systematic reviews. Seventeen were original studies, including two single-arm trials, one randomized controlled trial, four pilot trials, four case reports, two retrospective studies, and four prospective studies. The authors state that in general, the available literature supports the use of ST as an effective therapy for the management of refractory cancer pain. However, the level of evidence for its application to cancer pain is not particularly strong, and improvement in pain with ST may even be due to a placebo effect. The authors concluded that methodologically sound, large randomized control trials are needed in this area however, ST may be considered a good option for patients with cancer who are suffering from pain that does not respond to pharmacologic treatment.

A Hayes (2020) conducted a systematic review to evaluate evidence on the use of Scrambler Therapy (ST), also referred to as Calmare Pain Therapy and transcutaneous electrical modulation pain reprocessing, for the management chronic pain not related to cancer or cancer treatment. The literature search identified nine relevant clinical studies that met inclusion criteria: two RCTs, one quasi-RCT, and six single-arm studies, including one repeated measures time series, three pretest/posttest studies, and 2 retrospective database reviews. The findings included that the body of evidence, which was considered low or very low quality, is insufficient to draw conclusions regarding the effectiveness, efficacy, and safety ST for the management of chronic pain not related to cancer or cancer treatment in adults and as a result, there is a need for additional large, well-designed clinical studies to evaluate the comparative and long-term effectiveness and safety of ST, and to delineate patient selection criteria.

Compagnone and Tagliaferri (2015) conducted a multicenter, retrospective analysis on the safety and efficacy of ST after 10 sessions. All the patients (n=201) were suffering from chronic neuropathic pain of multiple etiologies. The mean number of sessions per patient was 10, but 39 subjects had complete absence of pain sooner and used fewer sessions. Seven patients stopped treatment due to lack of results, and two withdrew for personal reasons not ascribable to the treatment. Stimulation pain score of 0 during treatment, and not just pain reduction, is believed to be a predictor of long-term effectiveness. The authors concluded that ST is an efficient and safe alternative for several different types of refractory chronic neuropathic pain, with a very rare possibility of adverse events. Further studies are needed to optimize electrode positioning and correct fine-tuning of stimulation intensity.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Functional Electrical Stimulation (FES) Devices

Products used for FES are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 28, 2021)

Neuromuscular Electrical Stimulation (NMES) for Muscle Rehabilitation Devices

Products used for NMES for muscle rehabilitation are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 28, 2021)

Interferential Therapy (IFT) Devices

Products used for IFT are extensive. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed November 30, 2020)

Pulsed Electrical Stimulation (PES) Devices

There are multiple products used for PES. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 28, 2021)

Percutaneous Peripheral Nerve Stimulation (PNS)

There are several devices used for PNS such as the StimRouter Neuromodulation System, SPRINT PNS System, and StimQ Peripheral Nerve Stimulator System. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 5, 2021)

Peripheral Subcutaneous Field Stimulation (PSFS) or Peripheral Nerve Field Stimulation (PNFS) Devices

PSFS or PNFS using a fully implantable system is not currently approved by the FDA.

The NSS-2 System, a PNFS system marketed as an aid to reduce the symptoms of opioid withdrawal, was FDA approved on 11/15/17 (Product Code PZR). For more information, refer to: https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170018.pdf. (Accessed April 28, 2021)

The DrugRelief® auricular stimulator, a PNFS system marketed as an aid to reduce symptoms of opioid withdrawal, was FDA approved on 5/2/18 (Product Code PZR). For more information, refer to: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K173861. (Accessed April 28, 2021)

Microcurrent Electrical Nerve Stimulation Therapy (MENS) Devices

MENS devices are categorized as TENS devices intended for pain relief. They are regulated by the FDA's premarket approval (PMA) process.

Percutaneous Electrical Nerve Stimulation (PENS)or Percutaneous Electrical Nerve Field Stimulation (PENFS)

The FDA regulates PENS stimulators as class II devices (Product Code NHI). Several PENS devices have been approved by the FDA. Refer to the following website for more information and search by product name in device name section: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed April 28, 2021)

The IB-Stim, a PENFS system intended for use with functional abdominal pain associated with irritable bowel syndrome (IBS) in patients 11-18 years of age, was FDA approved on 6/7/19 (Product Code QHH). For more information, refer to: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN180057. (Accessed April 28, 2021)

Dorsal Root Ganglion (DRG) Stimulation Devices

There are several devices used for DRG stimulation. Refer to the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed April 28, 2021)

Scrambler Therapy (ST)

The Calamare/ST MC-5A TENS Device was initially approved by the FDA on February 20, 2009. A second 510(k) clearance was issued on May 22, 2015, for the ST MC-5A Device (Product Code GZJ). For more information, refer to the following websites:

- https://www.accessdata.fda.gov/cdrh_docs/pdf8/K081255.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf14/K142666.pdf

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Policy History/Revision Information

Date	Summary of Changes
08/01/2021	• Updated list of related policies to reflect title change for *Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)* (previously titled *Occipital Neuralgia and Headache Treatment*)
07/01/2021	**Template Update** • Removed *CMS* section **Coverage Rationale** • Added language to indicate percutaneous peripheral nerve stimulation (PNS) is unproven and not medically necessary due to insufficient evidence of efficacy; for information regarding percutaneous peripheral nerve stimulation for occipital neuralgia and headache, refer to Medical Policy titled *Occipital Neuralgia and Headache Treatment* **Applicable Codes** • Added CPT code 64555

Date	Summary of Changes
	Supporting Information - Updated *Description of Services, Clinical Evidence, FDA,* and *References sections* to reflect the most current information - Archived previous policy version IEXT0126.01

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.