

1 **Clinical Practice Guideline:** **Electric Stimulation for Pain, Swelling and Function**
 2 **in the Clinic Setting**

4 **Date of Implementation:** **June 16, 2016**

6 **Product:** **Specialty**

9 Related Policies: 10 CPG 121: Passive Physiotherapy Modalities 11 CPG 135: Physical Therapy Medical Policy/Guideline 12 CPG 155: Occupational Therapy Medical 13 Policy/Guideline 14 CPG 269: H Wave Electrical Stimulation
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15 **GUIDELINES**

16 I. Use of electric stimulation (e.g., TENS, EMS) is considered medically necessary in
 17 a clinic setting and under the direct supervision of a physical therapist or similar
 18 professional for an individual when prescribed as part of a comprehensive treatment
 19 program for pain and swelling, and only used short term (e.g., up to 2 weeks).
 20

21 Note: The medical records must document the response to the use of electrical stimulation,
 22 including specific parameters related to the type of electric stimulation (e.g., low or high
 23 frequency TENS, electrode placement).
 24

25 II. Neuromuscular Electrical Stimulation (NMES) is considered medically necessary
 26 for disuse atrophy where the nerve to the muscle is intact, and the individual has
 27 any of the following non-neurological reasons for the disuse atrophy and only in
 28 conjunction with active exercise:

- 29 • Major hip or knee surgery where there is failure to respond to basic therapeutic
 30 exercises as initiated in physical therapy/rehabilitation; or
- 31 • Previous immobilization (e.g., casting or splinting) of an extremity (arm or leg).
 32

33 III. Microcurrent electrical nerve stimulation (MENS) therapy is considered unproven
 34 for the treatment of chronic back pain and all other indications.
 35

36 IV. Microcurrent point stimulation is considered unproven for the treatment of chronic
 37 pain and any other indications.
 38

39 V. H-WAVE[®] stimulation is considered unproven for diabetic peripheral neuropathy
 40 and for all other indications including:

- 41 • To accelerate healing
- 42 • To reduce edema

- 1 • To reduce pain from causes other than chronic diabetic peripheral
2 neuropathy
3 • To treat chronic pain due to ischemia
4
- 5 VI. Threshold Electrical Stimulation is considered not medically necessary for any
6 condition.
7
- 8 VII. Pelvic floor stimulation (electric and magnetic stimulation is considered unproven
9 for the treatment of urinary or fecal incontinence except for the following
10 condition):
11 • Pelvic floor electrical stimulation with a non-implantable stimulator may be
12 covered as medically necessary for the treatment of stress and/or urge urinary
13 incontinence in cognitively intact patients who are a Medicare beneficiary and
14 who have failed a documented trial of pelvic muscle exercise (PME) training.
15 ○ A failed trial of PME training is defined as no clinically significant
16 improvement in urinary continence after completing 4 weeks of an ordered
17 plan of pelvic muscle exercises designed to increase periurethral muscle
18 strength.
19 ○ The patient's medical record must indicate that the patient receiving a non-
20 implantable pelvic floor electrical stimulator was cognitively intact,
21 motivated, and had failed a documented trial of pelvic muscle exercise
22 (PME) training.
23 ○ Stimulation delivered by vaginal or anal probes connected to an external
24 pulse generator may be billed as 97032. Stimulation delivered via electrodes
25 should be billed as G0283.
26 ○ Utilization of electrical stimulation may be necessary during the initial
27 phase of treatment, but there must be an improvement in function. These
28 modalities should be utilized with appropriate therapeutic procedures to
29 effect continued improvement.
30 ○ Medicare beneficiary has an intact nerve supply to the muscle, including
31 brain, spinal cord, and peripheral nerves, and other non-neurological
32 reasons for disuse are causing the atrophy (e.g., post-casting or splinting of
33 a limb, and contracture due to soft tissue scarring).
34 ○ Documentation must clearly support the medical necessity of electrical
35 stimulation if used more than 12 visits as an adjunctive therapy or for
36 muscle retraining.
37
- 38 VIII. Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous
39 Neuromodulation Therapy (PNT) are considered unproven for any indication.
40
- 41 IX. NMES/Electrical Stimulation (e.g., Guardian dysphagia dual chamber unit,
42 VitalStim Therapy device) is considered unproven for the treatment of dysphagia.

- 1 X. Deep Pharyngeal Neuromuscular Stimulation (DPNS) is considered unproven.
 2
 3 XI. RST-SANEXAS neoGEN® Electric cell-Signaling Treatments (EcST) is
 4 considered unproven for any indication (e.g. peripheral neuropathy).
 5
 6 XII. Hako-Med treatments are considered unproven for any indication (e.g. peripheral
 7 neuropathy).
 8

9 Note: Use should be to support an active care approach (i.e., therapeutic exercise, active
 10 self-care). Its use in the treatment of sub-acute or chronic conditions beyond the acute
 11 inflammatory response time frame requires demonstration of clinically meaningful and
 12 lasting improvements in function and pain, documentation of the anticipated benefit, as
 13 well as condition-specific rationale in order to be considered medically necessary.
 14

15 Electrical stimulation (except NMES) is contraindicated in areas of sensory deficits. A
 16 patient’s sensory deficits (decrease or loss) do not allow them to provide the correct
 17 feedback necessary for the safe and effective application to the affected area. Electrical
 18 stimulation in other related areas without sensory deficits may be appropriate.
 19

20 **Home Electrical Stimulation Devices (Electrical Stimulators)**

21 If coverage for an in-home electrical stimulation device is available, the following
 22 conditions apply. In-home electrical stimulation units are considered medically necessary
 23 for the following scenarios:
 24

- 25 • Neuromuscular electrical stimulation (NMES) (HCPCS Code E0745) and related
 26 supplies (HCPCS Code A4595) are considered medically necessary when used as
 27 a component of a comprehensive rehabilitation program for the treatment of disuse
 28 atrophy when the nerve supply to the atrophied muscle is intact.
- 29 • A transcutaneous electrical nerve stimulator (TENS) (HCPCS Code E0720, E0730)
 30 and related supplies (HCPCS Code A4595) are considered medically necessary for
 31 supervised or unsupervised, in-home use as an adjunct to conventional post-
 32 operative pain management within 30 days of surgery.
- 33 • Conductive Garment: A conductive garment (HCPCS Code E0731) is considered
 34 medically necessary when used in conjunction with a medically necessary in-home
 35 NMES or TENS device for ANY of the following clinical situations:
 - 36 • The use of conventional electrodes, tapes or lead wires is not feasible
 37 either because the individual has a large area requiring treatment or a large
 38 number of sites requiring stimulation.
 - 39 • The site(s) requiring stimulation (i.e., back) is/are difficult to reach with
 40 conventional electrodes, tapes or lead wires.
 - 41 • A co-existing medical condition (e.g., skin problems) precludes the use of
 42 conventional electrodes, tapes, or lead wires.

1 In-home electrical stimulation units for all other scenarios are considered unproven.

2
3 **CPT/HCPCS Codes and Descriptions**

4

CPT®/HCPCS Codes	CPT®/HCPCS Codes Description
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97032	Application of a modality to one or more areas; electrical stimulation (manual) each 15 minutes
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)

5
6 **BACKGROUND AND DESCRIPTION**

7 Electrical stimulation (ES) therapy involves the application of electrodes to the affected
8 area of the body for the purpose of delivering electrical current. There are several forms of
9 electrical current used in rehabilitation settings. Electrical stimulation is used for muscle
10 re-education (disuse atrophy), pain relief, reduction of swelling, and healing enhancement.
11 This CPG will focus on the use of electric stimulation for pain, swelling and function
12 (muscle re-education/disuse atrophy) when used in the outpatient clinic setting.

13
14 A TENS unit must be distinguished from other electrical stimulators (e.g., neuromuscular
15 stimulators) which are used to directly stimulate muscles and/or motor nerves.
16 Transcutaneous electrical nerve stimulation (TENS) is characterized by biphasic current
17 and selectable parameters such as pulse rate and pulse width. TENS uses a battery-operated
18 device that applies electrical stimulation via transmission of pulses of various
19 configurations at the site of pain by wired electrodes that are taped to the surface of the
20 skin. For example, conventional TENS or high frequency TENS delivers 40–150 hertz (Hz)
21 compared to acupuncture-like TENS that delivers a low frequency at 1–10 Hz. Pulsed
22 TENS uses low-intensity firing in high-frequency bursts at 100 HZ. Units often have preset
23 programs with variations and modulations of frequencies and durations of pulses. TENS
24 has been used for a number of applications. In theory, TENS stimulates sensory nerves to
25 block pain signals; it also stimulates endorphin production to help normalize sympathetic

1 function. TENS has been used to relieve acute or chronic pain related to musculoskeletal
2 conditions, pain associated with active or post-trauma injury, obstetrical pain, or
3 postoperative pain. TENS for pain control occurs via the gate theory or the endogenous
4 opiate theory. Conventional transcutaneous electrical stimulation (TENS) is an example of
5 the use of the gate theory to control or block pain. Low-rate TENS is an example of the use
6 of the endogenous opiate theory of pain control. TENS can also be delivered through the
7 use of a form-fitting conductive garment (for example, a garment with conductive fibers
8 that are separated from the individual's skin by layers of fabric). This garment is applied
9 when a condition exists that precludes conventional TENS electrode placement.

10
11 In an editorial by Johnson and Jones (2016), the contradictory nature of TENS research
12 evidence was noted, creating uncertainty for practitioners. For example, it is recommended
13 in NICE guidelines that TENS should be offered for short-term relief of osteoarthritis,
14 rheumatoid arthritis and musculoskeletal pain secondary to multiple sclerosis, but not for
15 nonspecific low back pain. Authors recommend that practitioners be mindful that
16 recommendations not to offer TENS are based on a paucity of evidence on which to make
17 a judgment rather than evidence of inferiority or equivalence to placebo. Trying to interpret
18 research on TENS is challenging because summarizing research findings is hindered by
19 inconsistent terminology, variability in clinical technique and poor study design. Current
20 research evidence suggests that it is reasonable to offer TENS as an adjunct to core
21 treatment for most painful conditions, especially because it is inexpensive and has a
22 favorable safety profile compared with long-term medication. However, it must be kept in
23 mind that it should be combined with an active exercise program.

24
25 Microcurrent Electrical Nerve Stimulation (MENS) involves the use of a device that
26 delivers small amounts of electrical current (millionths of an amp) to help relieve pain and
27 heal soft tissues of the body. The application of microcurrent stimulation to an injured area
28 is proposed to realign the body's electrical current and increase the production of adenosine
29 triphosphate, resulting in increased healing and recovery and blocking of perceived pain.
30 The electrical current is subsensory and usually not felt. MENS differs from TENS in that
31 it uses a significantly reduced electrical stimulation (i.e., 1,000 times less current than
32 TENS). The goal of TENS is to block pain, while MENS acts on naturally occurring
33 electrical impulses to decrease pain by stimulating the healing process (Frequency Specific
34 Microcurrent, 2014). Frequency specific microcurrent (FSM) is a type of microcurrent
35 therapy. The microcurrent device has two separate channels that allow both the frequency
36 and current to be set independently for each channel. FSM is proposed as a treatment option
37 for nerve and muscle pain, shingles, and herpes (Frequency Specific Microcurrent, 2011).

38
39 The H-WAVE[®] electrical stimulation device generates a biphasic, exponentially decaying
40 waveform with pulse-wide widths. Its waveform distinguishes it from TENS and other
41 forms of electrical stimulators. H-WAVE[®] is classified as a powered muscle stimulator.
42 The hypothesis that the H-WAVE[®] device (Electronic Waveform Lab, Inc., Huntington

1 Beach, CA), a small-diameter fiber stimulator, is a paradigm shift of electrotherapeutic
2 treatment of pain associated with human neuropathies and sports injuries is based on a
3 number of its properties. The primary effect of H-WAVE[®] device stimulation (HWDS) is
4 the stimulation of "red-slow-twitch" skeletal muscle fibers. The authors propose, based on
5 the unique waveform, that the H-WAVE[®] device specifically and directly stimulates the
6 small smooth muscle fibers within the lymphatic vessels ultimately leading to fluid shifts
7 and reduced edema. The H-WAVE[®] device was designed to stimulate an ultra-low
8 frequency (1-2 Hz), low tension, non-tetanzing, and non-fatiguing contraction, which
9 closely mimics voluntary or natural muscle contractions. The H-WAVE[®] device can
10 stimulate small fibers due in part to its exponentially decaying waveform and constant
11 current generator activity. The main advantage of these technologies over currently applied
12 electrical stimulators (e.g., TENS, interferential, NMES high-volt galvanic, etc.) is that H-
13 WAVE[®] small fiber contraction does not trigger an activation of the motor nerves of the
14 large white muscle fibers or the sensory delta and C pain nerve fibers, thus eliminating the
15 negative and painful effects of tetanzing fatigue, which reduces transcapillary fluid shifts.
16 Another proposed function of the H-WAVE[®] device is an anesthetic effect on pain
17 conditions, unlike a TENS unit which in the short term activates a hypersensory overload
18 effect (gate theory) to stop pain signals from reaching the thalamic region of the brain.
19 When the H-WAVE[®] device is used at high frequency (60 Hz), it supposedly acts
20 intrinsically on the nerve to deactivate the sodium pump within the nerve fiber, leading to
21 a long-lasting anesthetic/analgesic effect due to an accumulative postsynaptic depression.
22 The large pulse width theoretically enables contraction in the muscle for extended periods
23 of time at a low fatigue rate and increases circulation, muscle relaxation, pain relief and
24 wound healing. H-WAVE[®] stimulation has been used in the treatment of pain related to a
25 variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint
26 dysfunctions, or reflex sympathetic dystrophy. H-WAVE[®] electrical stimulation must be
27 distinguished from the H-waves that are a component of electromyography.

28
29 Other waveforms are used for pain modulation as well, including interferential current
30 (IFC), which is produced by two interfering alternating currents. Interferential stimulation
31 (IFS) is characterized by 2 alternating-current sine waves of differing medium frequencies
32 that combine together to produce an interferential current that is also known as a beat pulse
33 or alternating modulation frequency. One of the 2 currents is held at 4,000 Hz, and the
34 other can be held constant or varied over a range of 4,001 to 4,100 Hz. Interferential therapy
35 (IFT) delivers a crisscross current at 4000–4150 pulses per second, resulting in deeper
36 muscle penetration. It is theorized that IFT prompts the body to secrete endorphins and
37 other natural painkillers and stimulates parasympathetic nerve fibers to increase blood flow
38 and reduce edema. Interferential currents reportedly can stimulate sensory, motor, and pain
39 fibers. Because of the frequency, the interferential wave meets low impedance when
40 crossing the skin to enter the underlying tissue. This deep tissue penetration can be adjusted
41 to stimulate parasympathetic nerve fibers for increased blood flow. According to

1 proponents, interferential stimulation differs from TENS because it allows a deeper
2 penetration of the tissue with more comfort (compliance) and increased circulation.

3
4 High Voltage Galvanic Stimulation (HVGS) or high volt pulsed current (HVPC) is
5 characterized by high voltage pulsed stimulation and is proposed primarily for local edema
6 reduction through muscle pumping and polarity effect. High volt pulsed current (HVPC)
7 is used for tissue healing and edema control based on polarity principles. Edema is
8 comprised of negatively charged plasma proteins, which leak into the interstitial space. The
9 theory of HVPC is that the high voltage stimulus applies an electrical potential which
10 disperses the negatively charged proteins away from the edematous site, thereby helping
11 to reduce edema (Cameron, 2017).

12
13 Neuromuscular electric stimulation (NMES) is the application of electrical current through
14 electrodes on the skin to targeted muscles to elicit muscle contraction. NMES is proposed
15 to promote neuromuscular re-education, improve motor unit recruitment, and thus to
16 prevent or diminish muscle atrophy and is an established treatment modality for disuse
17 atrophy when the nerve supply to the muscle is intact. NMES is typically used as a
18 component of a comprehensive rehabilitation program. Compared to TENS, NMES
19 delivers a stronger current with a wider pulse width. Neuromuscular electrical stimulation
20 can be grouped into 2 categories: (i) stimulation of muscles to treat muscle atrophy due to
21 disuse (e.g., post-surgical, immobilization), and (ii) enhancement of functional activity in
22 neurologically impaired individuals. These devices within the second category use
23 electrical impulses to activate paralyzed or weak muscles in precise sequence and have
24 been utilized to provide SCI patients with the ability to walk (e.g., The Parastep I System).
25 Neuromuscular electrical stimulation used in this manner is commonly known as functional
26 electrical stimulation (FES).

27
28 Electric stimulated muscle contraction/neuromuscular electric stimulation (NMES) has
29 been found to enhance muscle function gains post-surgically. Patients who have received
30 an anterior cruciate ligament (ACL) reconstruction have demonstrated accelerated
31 recovery and greater muscle function when NMES is used in combination with exercise;
32 however, the impact on functional outcomes is inconsistent (Cameron, 2017). Similar
33 results were noted with knee OA patients and for other inflammatory conditions of the
34 knee. Most research studied the use of NMES on the quadriceps muscle, however clinically
35 NMES may be used for other joints and muscle groups (Cameron, 2017). Functional
36 electric stimulation (FES) is proposed for use in certain neurologic populations. As an
37 example, FES can be applied to the anterior tibialis muscle to assist in dorsiflexion during
38 gait for patients with foot drop. Several studies support the integration of FES for patients
39 with spinal cord injury or who have sustained a stroke for various activities. As long as the
40 peripheral nervous system is intact, any patients with central nervous system dysfunction
41 may benefit from FES use. In these situations, effectiveness of FES is thought to be most
42 likely due to the direct effect of muscle strengthening in addition to increased excitability

1 of the motor neuron pool produced by the motor level electrical stimulation (Cameron,
2 2017).

3
4 PENS and PNT combine the theories of electroacupuncture, and TENS and the terms are
5 often used interchangeably. PENS involves the delivery of an electrical current through the
6 insertion of a needle below the skin at the site of pain compared to acupuncture that places
7 needles based on energy flow. It is not the same as acupuncture. PENS is similar to TENS
8 except that the needles are inserted one to four centimeters around or adjacent to the
9 applicable nerve. Up to ten needles with five electrical channels may be used. PENS is
10 generally reserved for patients who fail to obtain pain relief from TENS. PENS may also
11 involve the application of electric stimulation to needles placed at the dermatomal levels
12 corresponding to the painful area. PNT is a variation of PENS which was developed as a
13 treatment for neck and back pain. This treatment involves insertion of very fine needle-like
14 electrodes into the skin of the neck or back to stimulate nerve fibers in the deep tissues.
15 The treatment regimen suggested by manufacturers typically consists of two to three, 30-
16 minute sessions per week, for two to six weeks.

17
18 VitalStim[®] Therapy is a type of NMES that uses a mild electrical current that is intended
19 to treat dysphagia by re-educating the muscles and improving swallowing. Guardian
20 dysphagia dual chamber unit is proposed for use for muscle re-education by application of
21 external stimulation for pharyngeal contraction. VitalStim[®] therapy was approved by the
22 US Food and Drug Administration in 2001 for the treatment of dysphagia through the
23 application of neuromuscular electrical stimulation to cervical swallowing muscles. To
24 date, however, aside from the developer's own studies, there are no peer-reviewed
25 publications supporting these claims. Deep pharyngeal neuromuscular stimulation (DPNS)
26 is an electrical stimulation therapy for people with dysphagia. DPNS stimulates the cranial
27 nerves by directly touching specific areas within the mouth and throat. This causes the
28 pharyngeal and lingual muscles to contract. Over time, this is postulated to strengthen the
29 patient's gag reflex and help to improve long-term swallowing functionality.

30 **Contraindications and Precautions**

31 **Contraindications for use of Electrical Currents include:**

- 32 • Demand pacemakers, implantable defibrillator, or unstable arrhythmia
- 33 • Placement of electrodes over carotid sinus
- 34 • Areas where venous or arterial thrombosis or thrombophlebitis is present
- 35 • Pregnancy – over or around the abdomen or low back

36
37
38 **Precautions for Electrical Current use include:**

- 39 • Cardiac disease
- 40 • Impaired mentation
- 41 • Impaired sensation

- 1 • Malignant tumors
- 2 • Areas of skin irritation or open wounds

3 **EVIDENCE AND RESEARCH**

4 **TENS**

5 There are many published reports regarding the use of TENS for various types of
 6 conditions such as low back pain (LBP), myofascial and arthritic pain, sympathetically
 7 mediated pain, neurogenic pain, visceral pain, diabetic neuropathy and postsurgical pain.
 8 While randomized controlled trials (RCTs) have focused on both high and low frequency
 9 TENS, all of the currently available studies have methodological flaws that limit
 10 interpretation, including inadequate blinding, lack of reporting of dropouts, lack of
 11 reporting of stimulation variables, and lack of proper outcome measures (Johnson et al.,
 12 2015). However, it is recognized that TENS is widely accepted in the physician and therapy
 13 community as a treatment of a variety of etiologies of pain in combination with
 14 comprehensive treatment program.
 15

16 According to the Philadelphia Panel Evidence-Based Clinical Practice Guidelines on
 17 Selected Rehabilitation Interventions for Low Back Pain publication (2001), TENS
 18 demonstrated no effectiveness for improvements in pain or function in subjects with
 19 chronic low back pain (LBP). Evidence was stated as good (level I). The Panel
 20 recommends that there is poor evidence to include or exclude TENS alone as an
 21 intervention for chronic LBP. According to The Cochrane Collaboration systematic review
 22 on TENS for chronic LBP (Khadilkar et al., 2005) there is limited and inconsistent
 23 evidence to support the use of TENS as an isolated intervention for chronic LBP. In 2010,
 24 the Therapeutic and Technology Assessment Subcommittee of the American Academy of
 25 Neurology (AAN) published a report finding TENS ineffective for chronic low back pain
 26 (Dubinsky and Miyasaki, 2010). The results indicated that there are conflicting reports of
 27 TENS compared to sham TENS in the treatment of chronic low back pain, with two Class
 28 II studies showing benefit, but two Class I studies and another Class II study not showing
 29 benefit. Because the Class I studies are stronger evidence, TENS is established as
 30 ineffective for the treatment of chronic low back pain. Their recommendations were that
 31 TENS is not recommended for the treatment of chronic low back pain (Level A) and further
 32 research into the mechanism of action of TENS is needed, as well as more rigorous studies
 33 for determination of effectiveness. Per ACOEM guidelines, TENS for acute or sub-acute
 34 LBP or acute radicular pain syndromes is not recommended given insufficient evidence
 35 (ACOEM, 2007). In a review by Poitras and Brosseau (2008), it was determined that
 36 globally, high- and low-frequency TENS appears to have an immediate impact on pain
 37 levels in subjects with non-specific chronic LBP, with high-frequency TENS achieving
 38 better results. Studies included were of relatively poor quality and the lack of consistent
 39 parameters from study to study makes comparisons difficult. Based on this review, TENS
 40 appears to be of no benefit for long term pain or perceived disability (Poitras and Brosseau,
 41 2008). Khadilkar et al. (2008) updated the 2005 Cochrane Review to determine whether
 42

1 TENS is more effective than placebo for the management of chronic LBP. Only
2 randomized controlled clinical trials (RCTs) comparing TENS to placebo in patients with
3 chronic LBP were included. Four high-quality RCTs (585 patients) met the selection
4 criteria. Clinical heterogeneity prevented the use of meta-analysis. There was conflicting
5 evidence about whether TENS was beneficial in reducing back pain intensity and
6 consistent evidence in two trials (410 patients) that it did not improve back-specific
7 functional status. There was moderate evidence that work status and the use of medical
8 services did not change with treatment. In general, patients treated with acupuncture-like
9 TENS responded similarly to those treated with conventional TENS. However, in two of
10 the trials, inadequate stimulation intensity was used for acupuncture-like TENS, given that
11 muscle twitching was not induced. Adverse effects included minor skin irritation at the site
12 of electrode placement. Authors concluded that the evidence from the small number of
13 placebo-controlled trials does not support the use of TENS in the routine management of
14 chronic LBP. Further research was encouraged.

15
16 The American Society of Anesthesiologists (ASA) and American Society of Regional
17 Anesthesia and Pain Medicine (ASRA) support the use of TENS in their revised guideline
18 recommending that "TENS should be used as a multimodal approach to pain management
19 for patients with chronic back pain and may be used for other pain conditions (e.g., neck
20 and phantom limb pain)" (ASA/ASRA, 2010). A Cochrane review that identified 25
21 eligible RCTs was not favorable in their analysis of the literature support of TENS for
22 various chronic pain conditions, primarily due to the quality of the available literature
23 (Nnoaham and Kumbang, 2008). These authors found positive results for pain relief in 13
24 out of 22 studies that compared TENS to a placebo or other inactive control group. In
25 studies that compared different TENS modes, seven of nine studies found no difference in
26 pain relief between high vs. low frequency TENS. Overall, the low methodological quality
27 and low power of the available literature did not allow the authors to make firm conclusions
28 regarding the effectiveness of TENS for chronic pain.

29
30 In 2013, Pivec et al. studied the clinical and economic impact of TENS in patients with
31 chronic LBP through analysis of a national database. This study evaluated patients who
32 were given TENS compared with a matched group without TENS prior to intervention and
33 at one-year follow-up. Patients who were treated with TENS had significantly fewer
34 hospital and clinic visits, used less diagnostic imaging, had fewer physical therapy visits,
35 and required less back surgery than patients receiving other treatment modalities. Jaurequi
36 et al. (2016) conducted a systematic review and meta-analysis of the efficacy of TENS for
37 the treatment of chronic, musculoskeletal low back pain. Thirteen studies, which included
38 randomized controlled trials, cohort studies, and randomized crossover studies ($n=267$),
39 met inclusion criteria. Follow-ups ranged from 2–24 weeks with a mean follow-up of seven
40 week. The duration of treatment ranged from 2–24 weeks (mean 6 weeks). The overall
41 standardized mean difference in pain from pre- to post-treatment with TENS showed a
42 significant improvement of TENS on pain reduction. When subdivided into treatment

1 duration, patients that were treated for less than five weeks ($n=8$ studies) had significant
2 effects on pain, while those treated for more than five weeks did not. The heterogeneity
3 among studies was substantially significant among the TENS groups. Limitations of the
4 studies included: small patient populations; variations in treatment times, TENS frequency
5 and length of follow-up; and conflicting outcomes. The authors noted that despite the
6 positive results, large multi-center prospective randomized trials are needed to develop the
7 appropriate treatment protocols for this patient population. According to the AHRQ
8 Comparative Effectiveness publication on Non-Invasive Treatments for Low Back Pain
9 (2016), additional evidence demonstrates that TENS is not effective versus sham TENS.
10 Effectiveness of TENS was previously classified as insufficient, and the strength of
11 evidence remains low because of methodological limitations in the trials and imprecision.
12 Evidence on harms associated with TENS was limited but suggests an increased risk of
13 skin site irritation without an increased risk of serious adverse events (AHRQ, 2016).
14 According to the American College of Physician's Noninvasive Treatments for Acute,
15 Subacute, and Chronic Low Back Pain clinical practice guideline (2017), evidence was
16 insufficient to determine the effectiveness of transcutaneous electrical nerve stimulation
17 (TENS).

18
19 Two practice guidelines support the use of TENS, one for rheumatoid arthritis based on
20 positive results in one (1) RCT (Ottawa Panel Evidence-Based Clinical Practice
21 Guidelines, 2004), and one for the treatment of knee osteoarthritis based on meta-analysis
22 of five (5) RCTs included in the analysis (Philadelphia Panel Practice Guidelines, 2001).
23 Johnson et al. (2015) assessed the analgesic effectiveness of TENS, as a sole treatment, for
24 acute pain in adults. Only RCTs of adults with acute pain (< 12 weeks) were examined
25 with TENS given as a sole treatment and assessed pain was with subjective pain scales.
26 The types of acute pain included in this Cochrane Review were procedural pain, e.g.,
27 cervical laser treatment, venipuncture, screening flexible sigmoidoscopy and non-
28 procedural pain, e.g., postpartum uterine contractions and rib fractures. There was a high
29 risk of bias associated with inadequate sample sizes in treatment arms and unsuccessful
30 blinding of treatment interventions. Seven trials reported minor adverse effects, such as
31 mild erythema and itching underneath the electrodes and participants disliking TENS
32 sensation. Authors concluded that this review offers tentative evidence that TENS reduces
33 pain intensity over and above that seen with placebo (no current) TENS when administered
34 as a stand-alone treatment for acute pain in adults. The high risk of bias associated with
35 inadequate sample sizes in treatment arms and unsuccessful blinding of treatment
36 interventions makes definitive conclusions impossible.

37
38 Jin et al. (2010) conducted a systematic review to evaluate the effectiveness of TENS on
39 diabetic peripheral neuropathy. Three randomized controlled trials ($n=78$) met inclusion
40 criteria. TENS was reported more effective than placebo in the reduction of mean pain
41 score at 4 and 6 weeks follow-up but not at 12 weeks. Pieber et al. (2010) conducted a
42 systematic review of the literature to evaluate electrotherapy, including TENS, for the

1 treatment of peripheral neuropathy in patients with diabetes. Three randomized controlled
2 trials ($n=76$) and one retrospective review ($n=54$) evaluating TENS met inclusion criteria.
3 The studies included short-term follow-ups and conflicting results. One study reported
4 significant improvement in pain and another study reporting recurrence of pain after
5 cessation of TENS. Due to the small patient populations, short-term treatment duration,
6 short-term follow-up and poor study methodology, large multi-center randomized
7 controlled trials are needed to further evaluate the long-term effect of TENS on diabetic
8 neuropathy. Hurlow et al. (2012) conducted an update review of the 2009 review by Robb
9 et al. One new study met inclusion criteria ($n=24$). There were significant differences in
10 participants, treatments, procedures and symptom measurement tools used in the studies.
11 The clinical utility of TENS for the treatment of cancer pain has not been established. Robb
12 et al. (2009) conducted a systematic review of the literature to evaluate TENS for the
13 treatment of cancer-related pain. Two randomized controlled trials ($n=64$) met inclusion
14 criteria. Meta-analysis was not conducted due to the disparities between patient population,
15 mode of TENS, treatment duration, and outcome measures prevented meta-analysis. There
16 is insufficient evidence to support TENS for the treatment of cancer-related pain.

17
18 Mulvey et al. (2010) conducted a systematic review of randomized controlled trials to
19 assess the effectiveness of TENS for the treatment of phantom pain and stump pain
20 following amputation in adults. No studies were identified. Johnson et al. (2015b)
21 conducted an update of this Cochrane review and found no new randomized controlled
22 trials evaluating TENS for the treatment of phantom pain and stump pain. Rheumatoid
23 Arthritis: In a systematic review of the literature, Brosseau et al. (2003) evaluated the
24 effectiveness of TENS for the treatment of rheumatoid arthritis of the hand. Three
25 randomized controlled trials ($n=78$) met inclusion criteria. Conventional TENS (C-TENS)
26 and acupuncture-TENS (acu-TENS) were compared to either placebo or each other. Pain
27 outcomes on the effect of TENS were conflicting. Acu-TENS was beneficial for reducing
28 pain intensity and improving muscle power scores compared to placebo. No clinical benefit
29 on pain was reported with C-TENS compared to placebo. C-TENS resulted in a clinical
30 benefit on the patients' assessment of change compared to acu-TENS. The authors
31 concluded that more well-designed studies with a standardized protocol and adequate
32 numbers of subjects were needed to fully identify the effect of TENS for the treatment of
33 RA of the hand.

34
35 Dissanayaka et al. (2016) compared the effectiveness of transcutaneous electrical nerve
36 stimulation and interferential therapy (IFT) both in combination with hot pack, myofascial
37 release, active range of motion exercise, and a home exercise program on myofascial pain
38 syndrome patients with upper trapezius myofascial trigger point. Following randomization
39 of patients into three groups (hot pack, active range of motion exercises, myofascial
40 release, and a home exercise program with postural advice), transcutaneous electrical nerve
41 stimulation-standard care and IFT-standard care-were administered eight times during
42 4 weeks at regular intervals. Pain intensity and cervical range of motions (cervical

1 extension, lateral flexion to the contralateral side, and rotation to the ipsilateral side) were
2 measured at baseline, immediately after the first treatment, before the eighth treatment, and
3 1 week after the eighth treatment. Immediate and short-term improvements were marked
4 in the transcutaneous electrical nerve stimulation group ($n = 35$) compared with the IFT
5 group ($n = 35$) and the control group ($n = 35$) with respect to pain intensity and cervical
6 range of motions ($P < 0.05$). The IFT group showed significant improvement on these
7 outcome measurements than the control group did ($P < 0.05$). Authors concluded that
8 TENS with standard care facilitates recovery better than IFT does in the same combination.

9
10 Page et al. (2016) completed a Cochrane Database Systematic Review on electrotherapy
11 modalities for rotator cuff disease. Examples included therapeutic ultrasound, low-level
12 laser therapy (LLLT), transcutaneous electrical nerve stimulation (TENS), and pulsed
13 electromagnetic field therapy (PEMF). These modalities are usually delivered as
14 components of a physical therapy intervention. Authors synthesized the available evidence
15 regarding the benefits and harms of electrotherapy modalities for the treatment of people
16 with rotator cuff disease. Randomized controlled trials (RCTs) and quasi-randomized
17 trials, including adults with rotator cuff disease (e.g., subacromial impingement syndrome,
18 rotator cuff tendinitis, calcific tendinitis), and comparing any electrotherapy modality with
19 placebo, no intervention, a different electrotherapy modality or any other intervention (e.g.,
20 glucocorticoid injection) were included. Trials investigating whether electrotherapy
21 modalities were more effective than placebo or no treatment or were an effective addition
22 to another physical therapy intervention (e.g., manual therapy or exercise) were the main
23 comparisons of interest. Main outcomes of interest were overall pain, function, pain on
24 motion, patient-reported global assessment of treatment success, quality of life and the
25 number of participants experiencing adverse events. Most trials ($n = 43$) included
26 participants with rotator cuff disease without calcification (four trials included people with
27 calcific tendinitis). Sixteen (34%) trials investigated the effect of an electrotherapy
28 modality delivered in isolation. Only 23% were rated at low risk of allocation bias, and
29 49% were rated at low risk of both performance and detection bias (for self-reported
30 outcomes). The trials were heterogeneous in terms of population, intervention and
31 comparator, so none of the data could be combined in a meta-analysis. Authors were
32 uncertain whether transcutaneous electrical nerve stimulation (TENS) was more or less
33 effective than glucocorticoid injection with respect to pain, function, global treatment
34 success and active range of motion because of the very low-quality evidence from a single
35 trial. Authors concluded that uncertainty exists as to whether TENS is superior to placebo,
36 and whether any electrotherapy modality provides benefits over other active interventions
37 (e.g., glucocorticoid injection) because of the very low quality of the evidence. Further
38 trials of electrotherapy modalities for rotator cuff disease should be based upon a strong
39 rationale and consideration of whether or not they would alter the conclusions of this
40 review.

1 In an article by Vance et al. (2014) titled “Using TENS for pain control: the state of the
 2 evidence,” transcutaneous electrical nerve stimulation (TENS) is described as a
 3 nonpharmacological intervention that activates a complex neuronal network to reduce pain
 4 by activating descending inhibitory systems in the central nervous system to reduce
 5 hyperalgesia. Within the article, authors describe the current mechanisms of TENS
 6 reduction on analgesia, which is thought to be more complex than previously described.
 7 More specifically, TENS activates a complex neuronal network to result in a reduction in
 8 pain. At frequencies and intensities used clinically, TENS activates large diameter afferent
 9 fibers. This afferent input is sent to the central nervous system to activate descending
 10 inhibitory systems to reduce hyperalgesia. Specifically, blockade of neuronal activity in
 11 the periaqueductal gray (PAG), rostral ventromedial medulla (RVM) and spinal cord
 12 inhibit the analgesic effects of TENS showing that TENS analgesia is maintained through
 13 these pathways. In parallel, studies in people with fibromyalgia show that TENS can restore
 14 central pain modulation, a measure of central inhibition. Therefore, TENS appears to
 15 reduce hyperalgesia through both peripheral and central mechanisms. Authors do report
 16 that the evidence for TENS efficacy is conflicting. Sluka et al. (2013) suggests that certain
 17 factors should be considered when evaluating the research. These include dosing of TENS,
 18 negative interactions with long-term opioid use, the population and outcome assessed,
 19 timing of outcome measurement, and comparison groups. Population-specific systemic
 20 reviews and meta-analyses are emerging, indicating both high frequency (HF) and low
 21 frequency (LF) TENS being shown to provide analgesia, specifically when applied at a
 22 strong, non-painful intensity. They conclude that additional research is necessary to
 23 determine if TENS has effects specific to mechanical stimuli and/or beyond reduction of
 24 pain and will improve activity levels, function and quality of life. These authors are
 25 considered experts in the area of TENS research, and they offer these interesting practice
 26 points:

- 27 • High frequency (HF) and low frequency (LF) transcutaneous electrical nerve
 28 stimulation (TENS) activate different opioid receptors. Both applications have been
 29 shown to provide analgesia specifically when applied at a strong, non-painful
 30 intensity. HF TENS may be more effective for people taking opioids.
- 31 • Effective analgesia for chronic pain conditions may be limited by the development
 32 of tolerance to TENS if repeated application of either LF or HF TENS at the same
 33 frequency and intensity is used daily (i.e., same dose). Strategies to prolong
 34 analgesia may include varying these parameters.
- 35 • Targeting the use of TENS during movement or activity may be most beneficial.
- 36 • TENS may be effective in restoration of central pain modulation, a measure of
 37 central inhibition.
- 38 • A clearer picture of TENS effectiveness will emerge as trials with attention to
 39 optimal dosing and appropriate outcome measures increase in numbers.

40
 41 Gibson et al. (2019) provided an overview of evidence from Cochrane Reviews of the
 42 effectiveness of TENS to reduce pain in adults with chronic pain (excluding headache or

1 migraine). They included nine reviews investigating TENS use in people with defined
 2 chronic pain or in people with chronic conditions associated with ongoing pain. The
 3 evidence reported within each review was consistently rated as very low quality. The
 4 authors considered the approach of combining sham and no intervention data to be
 5 problematic since these different comparisons may be estimating different true effects.
 6 Authors found the methodological quality of the reviews was good, but quality of the
 7 evidence within them was very low. They were therefore unable to conclude with any
 8 confidence that, in people with chronic pain, TENS is harmful, or beneficial for pain
 9 control, disability, health-related quality of life, use of pain-relieving medicines, or global
 10 impression of change. Pietrosimone et al. (2020) aimed to determine the effect of TENS +
 11 therapeutic exercise (TE) on patient-reported function, quadriceps strength, and voluntary
 12 activation, as well as physical performance compared with sham TENS + TE (Sham) and
 13 TE alone in individuals with symptomatic knee OA and quadriceps voluntary activation
 14 failure (QVAF). Ninety individuals participated in a double-blinded randomized controlled
 15 trial. Everyone received 10 standardized TE sessions of physical therapy. TENS + TE and
 16 Sham groups applied the respective devices during all TE sessions and throughout
 17 activities of daily living over 4 wk. Improvements in WOMAC subscales, quadriceps
 18 strength, and voluntary activation, 20-m walk times, chair-stand repetitions, and stair-climb
 19 time were found at post 1 and post 2 compared with baseline for all groups ($P < 0.05$).
 20 WOMAC Pain and Stiffness improved in the TENS + TE group compared with TE alone
 21 at post 1 ($P < 0.05$); yet no other between-group differences were found. Authors concluded
 22 that TE effectively improved patient-reported function, quadriceps strength, and voluntary
 23 activation, as well as physical performance in individuals with symptomatic KOA and
 24 QVAF but augmenting TE with TENS did not improve the benefits of TE.

25
 26 A Best Practices for Chiropractic Management of Patients with Chronic Musculoskeletal
 27 Pain: A Clinical Practice Guideline authored by Hawk et al. (2020), stated that for chronic
 28 low back pain, TENS or interferential current may be beneficial as part of a multimodal
 29 approach, at the beginning of treatment to assist the patient in becoming or remaining
 30 active. For chronic neck pain, they recommend TENS and interferential current in the same
 31 manner as for chronic low back pain.

32
 33 Rapazo et al. (2021) investigated the effectiveness of electrical stimulation (ES) for neck
 34 pain (NP). Main results showed evidence of moderate quality that ES combined with other
 35 intervention significantly decreases the pain intensity compared to other intervention
 36 immediately post-treatment and at short-term follow-up; evidence of low quality showed
 37 significant effects of ES combined with other intervention in decreasing neck disability
 38 compared to other intervention immediately post-treatment; evidence of very-low quality
 39 that ES increased the pressure pain threshold compared to placebo immediately post-
 40 treatment and that ES + other intervention also increased the pressure pain threshold
 41 compared to other intervention at short-term follow-up. Authors concluded that ES

1 combined with other intervention seems to be useful to relieve pain and to improve
2 disability in people with NP, however, more studies are needed.

3
4 Dias et al. (2021) compared the immediate analgesic effect of transcutaneous nerve
5 stimulation (TENS) and interferential current (IFC), with different combinations of
6 parameters, in individuals with chronic low back pain (CLBP). 280 individuals with CLBP
7 were included in the study, both genders, randomized in 8 groups, all individuals
8 underwent a single application of TENS or IFC for 30min. The assessments were carried
9 out prior to the intervention, as well as immediately after, with the following outcomes:
10 pain intensity (Numeric Pain Rating Scale-NPRS), qualitative pain characteristics (McGill
11 Pain Questionnaire-MPQ), and pressure pain threshold (PPT) by pressure algometry (PA)
12 in 4 points of the low back region. Authors concluded that both TENS and IFC presented
13 immediate analgesic effect in CLBP, with emphasis on the interferential current of 4 KHz
14 modulated at 100Hz.

15
16 According to the National Institute for Health and Care Excellence (NICE) review (2021),
17 they report the following for TENS:

- 18 • TENS versus sham TENS and usual care
 - 19 ○ Quality of life
 - 20 ▪ Moderate quality evidence from 1 study with 202 participants
 - 21 showed no clinically important difference between TENS and sham
 - 22 TENS at ≤ 3 months.
 - 23 ▪ Quality of life Moderate to low quality evidence from 1 study with
 - 24 202 participants showed no clinically important difference between
 - 25 TENS and usual care at ≤ 3 months.
 - 26 ○ Pain reduction
 - 27 ▪ Very low-quality evidence from 2 studies with 242 participants
 - 28 showed a clinically important difference for TENS compared to
 - 29 sham TENS at ≤ 3 months.
 - 30 ▪ Moderate quality evidence from 1 study with 40 participants showed
 - 31 a clinically important difference for TENS at > 3 months compared
 - 32 to sham TENS.
 - 33 ▪ Low quality evidence from 1 study with 202 participants showed
 - 34 no clinically important difference between TENS and usual care at
 - 35 ≤ 3 months.
 - 36 ○ Physical function
 - 37 ▪ High quality evidence from 1 study with 202 participants showed no
 - 38 clinically important difference between TENS and sham TENS at
 - 39 ≤ 3 months.
 - 40 ▪ High quality evidence from 1 study with 202 participants showed
 - 41 no clinically important difference between TENS and usual care at
 - 42 ≤ 3 months.

- 1 ○ Psychological distress
 - 2 ■ Moderate to low quality evidence from 1 study with 202
 - 3 participants showed no clinically important difference between
 - 4 TENS and sham TENS at ≤ 3 months.
 - 5 ■ Moderate to low quality evidence from 1 study with 202
 - 6 participants showed no clinically important difference between
 - 7 TENS and usual care at ≤ 3 months.
- 8 ○ Pain interference
 - 9 ■ Low quality evidence from 1 study with 202 participants showed no
 - 10 clinically important difference between TENS and sham TENS at
 - 11 ≤ 3 months.
 - 12 ■ Low quality evidence from 1 study with 202 participants showed
 - 13 no clinically important difference between TENS and usual care at
 - 14 ≤ 3 months.
- 15 ○ Pain self-efficacy
 - 16 ■ High quality evidence from 1 study with 202 participants showed no
 - 17 clinically important difference between TENS and sham TENS at
 - 18 ≤ 3 months.
 - 19 ■ High quality evidence from 1 study with 202 participants showed no
 - 20 clinically important difference between TENS and usual care at ≤ 3
 - 21 months.

22
 23 Reichenbach et al. (2022) sought to determine the effectiveness of TENS at relieving pain
 24 and improving physical function as compared to placebo TENS, and to determine its safety,
 25 in patients with knee osteoarthritis. 220 participants with knee osteoarthritis were recruited
 26 between October 15, 2012, and October 15, 2014. Patients were randomized to 3 weeks of
 27 treatment with TENS ($n = 108$) or placebo TENS ($n = 112$). The primary endpoint was
 28 knee pain at the end of 3-weeks treatment assessed with the WOMAC pain subscale.
 29 Secondary outcome measures included WOMAC physical function subscale and safety
 30 outcomes. There was no difference between TENS and placebo TENS in WOMAC pain at
 31 the end of treatment, nor throughout the trial duration. Subgroup analyses did not indicate
 32 an interaction between patient/treatment characteristics and treatment effect on WOMAC
 33 pain at the end of treatment (P -interaction ≥ 0.22). The occurrence of adverse events was
 34 similar across groups, with 10.4% and 10.6% of patients reporting events in the TENS and
 35 placebo TENS groups, respectively ($P = 0.95$). No relevant differences were observed in
 36 secondary outcomes. Authors concluded that TENS does not improve knee osteoarthritis
 37 pain when compared to placebo TENS. Therapists should consider other potentially more
 38 effective treatment modalities to decrease knee osteoarthritis pain and facilitate
 39 strengthening and aerobic exercise.

40
 41 Johnson et al. (2022) investigated the efficacy and safety of transcutaneous electrical nerve
 42 stimulation (TENS) for relief of pain in adults in a systematic review and meta-analysis.

1 The review included 381 RCTs (24, 532 participants). Pain intensity was lower during or
2 immediately after TENS compared with placebo (moderate-certainty evidence).
3 Methodological (e.g., sample size) and pain characteristics (e.g., acute vs chronic,
4 diagnosis) did not modify the effect. Pain intensity was lower during or immediately after
5 TENS compared with pharmacological and non-pharmacological treatments used as part
6 of standard of care (low-certainty evidence). Levels of evidence were downgraded because
7 of small-sized trials contributing to imprecision in magnitude estimates. Data were limited
8 for other outcomes including adverse events which were poorly reported, generally mild
9 and not different to comparators. Authors concluded that there was moderate-certainty
10 evidence that pain intensity is lower during or immediately after TENS compared with
11 placebo and without serious adverse events.

12
13 Wu et al. (2022) evaluated the effects of Transcutaneous Electric Nerve Stimulation
14 (TENS) on pain, function, walking ability and stiffness in people with Knee osteoarthritis
15 (KOA). Twenty-nine studies were found (1398 people, age range 54-85, 74% are female)
16 and fourteen were included in this review. Intervention duration was divided as short term
17 (immediately after intervention), medium term (<four weeks) and long term (\geq four
18 weeks). Active TENS showed greater improvement in Visual Analogue Scale (VAS) than
19 sham TENS. Combining TENS with other interventions produced superior outcomes
20 compared with other interventions for VAS in all the terms. In the meanwhile, TENS
21 combined with other interventions was superior to other interventions for the pain subgroup
22 of Western Ontario and McMaster Universities Arthritis Index in the medium term and
23 long term. TENS combined with other interventions was superior to other interventions for
24 function in the medium term and long term. Authors concluded that TENS could
25 significantly relieve pain, decrease dysfunction and improve walking ability in people with
26 KOA, but it is not effective for stiffness.

27
28 Beltran-Alacreu et al. (2022) determined if the use of PENS is more effective and should
29 be recommended when compared to TENS for the reduction of musculoskeletal pain
30 intensity. Nine RCTs were included in the qualitative analysis, with seven of them in the
31 quantitative analysis (n = 527). The overall effect of PENS on pain was statistically but not
32 clinically superior to TENS with a high level of heterogeneity. When only studies with a
33 lower risk of bias (n = 3) were analyzed, the heterogeneity decreased, and no difference
34 was observed between TENS and PENS with a moderate recommendation level according
35 to GRADE. There were no data concerning adverse effects. There is low-quality of
36 evidence for more pain intensity reduction with PENS, but the difference was not clinically
37 significant. However, when only studies with low risk of bias are meta-analyzed, there is a
38 moderate quality of evidence that there is no difference when TENS or PENS is applied
39 for pain intensity.

40
41 Evans et al. (2022) summarized the reported efficacy of transcutaneous single nerve
42 stimulators in management of migraine frequency and severity. Fourteen studies, which

1 treated 995 patients, met inclusion criteria, including 7 randomized controlled trials and 7
2 uncontrolled clinical trials. Transcutaneous nerve stimulators reduced headache frequency
3 in episodic migraines (2.81 fewer headache days per month, 95% CI 2.18-3.43, I² = 21%)
4 and chronic migraines (2.97 fewer headache days per month). Transcutaneous nerve
5 stimulators reduced headache severity in episodic headaches (2.23 fewer pain scale points).
6 Authors concluded that preventive use of transcutaneous nerve stimulators provided
7 clinically significant reductions in headache frequency in individuals with chronic or
8 episodic migraines. Individuals with episodic migraines also experienced a reduction in
9 headache pain severity following preventive transcutaneous nerve stimulation.

10
11 Fertout et al. (2022) assessed the efficacy of transcutaneous electrical nerve stimulation
12 (TENS) for the management of temporomandibular disorders (TMD) and to determine the
13 indications and most appropriate application modalities in a systematic review. Fourteen
14 articles were retained, corresponding to a total of 532 patients, among which, 285 had a
15 TMD. Immediately after a TENS session, significant relief of pain (19.2% to 77%),
16 significant functional improvement (mouth opening amplitude increased by between 8.7%
17 and 19.46%), and reduced electromyographic activity of the anterior temporalis and
18 masseter muscles were observed. However, studies comparing TENS to other physical
19 medicine modalities (ultrasound and laser) reported equivalent results. Authors concluded
20 that further randomized comparative clinical trials will be necessary to optimize the use of
21 TENS (program, duration of sessions, duration of treatment) for different types of TMD.

22
23 Vance et al. (2022) addressed the continued uncertainty about the clinical efficacy of TENS
24 to alleviate pain, despite years of research and note that this uncertainty is related to the
25 quality of the clinical trials included in systematic reviews. This summary of the evidence
26 includes only trials with pain as the primary outcome. In comparison with their 2014
27 review, there appears to be improvement in adverse events and parameter reporting.
28 Importantly, stimulation intensity has been documented as critical to therapeutic success.
29 Examinations of the outcomes beyond resting pain, analgesic tolerance, and identification
30 of TENS responders remain less studied areas of research. This literature review supports
31 the conclusion that TENS may have efficacy for a variety of acute and chronic pain
32 conditions, although the magnitude of the effect remains uncertain due to the low quality
33 of existing literature. In order to provide information to individuals with pain and to
34 clinicians treating those with pain, authors suggest that resources for research should target
35 larger, high-quality clinical trials including an adequate TENS dose and adequate timing
36 of the outcome and should monitor risks of bias. Systematic reviews and meta-analyses
37 should focus only on areas with sufficiently strong clinical trials that will result in adequate
38 sample size.

39
40 Davison et al. (2022) systematically reviewed and evaluated available literature examining
41 the effectiveness of using electrical stimulation to promote clinical outcomes after hip
42 fractures. Initial screening indicated 24 articles were appropriate for full-text review, and

1 four articles met the inclusion criteria. In included studies, electrical stimulation (i.e.,
 2 TENS) reduced pain (mean difference (MD) = 3.3 points on 10-point Visual Analogue
 3 Scale, $p < .001$), improved range of motion (ROM) (MD: 25.7°, $p < .001$), and accelerated
 4 functional recovery immediately after hip fracture ($p < .001$). Conflicting evidence existed
 5 when using neuromuscular electrical stimulation to improve muscle strength and other
 6 functional outcomes (e.g., mobility); however, nine experts advised that longer-term
 7 interventions might be necessary to achieve significant improvement in muscle strength.
 8 Authors concluded that the available evidence, albeit limited, supports the early application
 9 of noninvasive electrical stimulation (e.g., TENS) for improving clinical outcomes (i.e.,
 10 reducing pain, improving ROM, and accelerating functional recovery after hip fractures).
 11 They could not find conclusive evidence on the effectiveness of using electrical stimulation
 12 to improve muscle strength. This review establishes the need for future additional high-
 13 quality trials in this field.

14
 15 Leemans et al. (2022) estimated the effects of musculoskeletal rehabilitation interventions
 16 on movement-evoked pain and to explore the assessment methods/protocols used to
 17 evaluate movement-evoked pain in adults with musculoskeletal pain. Meta-analysis was
 18 conducted for outcomes with homogeneous data from at least 2 trials. The mean change in
 19 movement-evoked pain was the primary outcome measure. Thirty-eight trials were
 20 included, and 60 different interventions were assessed. There was moderate-certainty
 21 evidence of a beneficial effect of exercise therapy compared to no treatment on movement-
 22 evoked pain in adults with musculoskeletal pain. There was low-certainty evidence of a
 23 beneficial effect of transcutaneous electrical nerve stimulation compared to no treatment.
 24 There was no benefit of transcutaneous electrical nerve stimulation when compared to
 25 sham transcutaneous electrical nerve stimulation.

26 27 **Microcurrent Electrical Nerve Stimulation**

28 There is insufficient evidence in the published peer-reviewed scientific literature to support
 29 the safety and effectiveness of MENS including frequency specific microcurrent (FSM).
 30 Studies include small patient populations and short-term follow-ups with conflicting
 31 outcomes and in some cases reported outcomes were no better than placebo (Rajpurohit et
 32 al., 2010; Zuim et al., 2006). More recently, microcurrent, using very small electrical
 33 devices contained within wound dressings, has been evaluated as a therapy to speed the
 34 closure of chronic wounds. However, research published to date has not produced findings
 35 that suggest this form of ES can accelerate wound closure (Houghton, 2014). Nair (2018)
 36 did not have some positive findings for wound healing, however more research is needed to
 37 confirm results. Iijima and Takahashi (2021) summarized the level of knowledge regarding
 38 the effects of microcurrent therapy (MCT) on musculoskeletal pain in adults. Randomized
 39 controlled trials (RCTs) investigating the effects of MCT on musculoskeletal pain were
 40 included. Additionally, non-RCTs were included to assess the adverse events. The primary
 41 outcomes were pain and adverse events related to MCT. A comprehensive assessment of
 42 4 RCTs and 5 non-RCTs that met the inclusion criteria revealed that MCT significantly

1 improved shoulder pain (1 study, 40 patients) and knee pain (1 study, 52 patients)
 2 compared with sham MCT without any severe adverse events. MCT has clinically
 3 significant benefits for knee pain. This study also revealed a clinically significant placebo
 4 response in treating knee pain. This evidence highlights the substantial effect of placebo
 5 response in clinical care. Authors concluded that the findings of this meta-analysis
 6 highlight the effect of placebo response in treating knee pain. MCT is a potential, core
 7 nonpharmacologic treatment option in clinical care with minimal adverse events and
 8 should be further investigated.

9 **H-WAVE®**

11 There is insufficient evidence in the published peer reviewed scientific literature to support
 12 the safety and effectiveness of the H-WAVE® electrical stimulators. Blum et al. (2008)
 13 conducted a systematic review and meta-analysis of randomized and nonrandomized
 14 controlled trials to evaluate the safety and efficacy of H-WAVE® therapy. Five studies
 15 ($n=6535$) met inclusion criteria. H-WAVE® was shown to decrease pain across various
 16 chronic soft tissue inflammation and neuropathic pain conditions, decrease pain medication
 17 intake ($n=2$ studies) and increase functionality ($n=2$ studies). However, author-noted
 18 limitations of the studies included the heterogeneity of the studies, inconsistency of the
 19 effects (e.g., reduction in pain medication, functionality), data were obtained from cross-
 20 sectional studies, data were subjective in nature (i.e., there were no formal examination
 21 findings, test results and/or laboratory values), various outcome measures, potential
 22 selection bias of publications for this review, and due to a lack of reported data it was not
 23 possible to statistically evaluate the safety of the therapy. Williamson et al. (2021)
 24 systematically searched human clinical studies on H-Wave® device stimulation (HWDS)
 25 was conducted as well as a comprehensive review of articles articulating possible HWDS
 26 mechanisms of action. Studies unrelated to H-Wave® were excluded. Multiple clinical
 27 studies have reported significant benefits for diabetic and non-specific neuropathic pain,
 28 where function also improved, and pain medication usage substantially dropped. Authors
 29 concluded that low- to moderate-quality HWDS studies have reported reduced pain,
 30 restored functionality, and lower medication use in a variety of disorders, although higher-
 31 quality research is needed to verify condition-specific applicability. HWDS has enough
 32 reasonable evidence to be considered as an adjunctive component of non-opioid multi-
 33 modal pain management, given its excellent safety profile and relative low cost. It is
 34 important to consider that two authors have a conflict of interest as they are consultants for
 35 Electronic Waveform Lab Inc. and have an interest in a positive outcome.

36 **Interferential Current (IFC)**

38 Studies for IFC are primarily in the form of case reports, case series and some randomized
 39 controlled trials with small patient populations, short-term treatment sessions and short-
 40 term follow-ups. Randomized controlled trials with large patient populations and long-term
 41 follow-ups comparing IFT to established treatment options are lacking. The California
 42 Technology Assessment Forum (2005) evaluated the literature on IFT for the treatment of

1 musculoskeletal pain and concluded that this treatment modality has not been shown to be
2 as beneficial as alternative treatments such as nonsteroidal anti-inflammatory drugs and
3 exercise therapy. Although IFT was found to be a generally safe technique, it did not meet
4 the CTAF technology assessment criteria for the treatment of musculoskeletal pain.
5 Fuentes et al. (2010) conducted a systematic review and meta-analysis of randomized
6 controlled trials ($n=20$) to evaluate the pain-reducing effectiveness of IFC in the
7 management of musculoskeletal pain. Twenty studies met inclusion criteria. Seven studies
8 assessed IFC for joint pain (e.g., osteoarthritis), nine for muscle pain (e.g., low back pain,
9 neck pain), three for soft tissue shoulder pain (e.g., tendinitis) and one for postoperative
10 pain. Three studies were considered to be of poor methodological quality, 14 of moderate
11 quality and three of high quality. Methodological issues included small sample sizes,
12 heterogeneity of patient population, inappropriate handling of withdrawals and dropouts,
13 and lack of appropriate randomization, concealment of allocation and blinding of patients
14 and assessors. Fourteen studies ($n=1114$) were used for meta-analysis. Only three studies
15 reported adverse events (e.g., blisters, burns, bruising, swelling). The authors concluded
16 that the analgesic effect that IFC is superior to that of the concomitant interventions was
17 unknown; IFC alone was not significantly better than placebo or other therapy at discharge
18 or follow-up; the heterogeneity across studies and methodological limitations prevented
19 conclusive statements regarding analgesic efficacy; and the results should be viewed with
20 caution due to the limited number of studies that used IFC as a monotherapy. The American
21 College of Physicians and the American Pain Society Joint Clinical Practice Guideline for
22 the Diagnosis and Treatment of LBP (Chou and Huffman 2007) concluded that there was
23 not enough evidence to support the use of interferential therapy, TENS, traction,
24 ultrasound, or short-wave diathermy for acute or chronic LBP. These results were based
25 on systematic reviews and randomized trials of one or more of the aforementioned
26 therapies for treatment of acute or chronic LBP that reported pain outcomes, back specific
27 function, general health status, work disability or patient satisfaction. In a review by Poitras
28 and Brosseau (2008), they determined that due to limited studies of sufficient quality, no
29 recommendations could be made for the use of ultrasound, interferential current, or
30 electrical muscle stimulation for the treatment of chronic LBP.

31
32 Facci et al. (2011) compared the effects of TENS and interferential current among patients
33 with nonspecific chronic low back pain. One hundred and fifty patients were randomly
34 divided into three groups: TENS (group 1), interferential current (group 2) and controls
35 (group 3). The patients designated for electrotherapy received ten 30-minute sessions,
36 while the control group remained untreated. All patients and controls were evaluated before
37 and after treatment using a visual analog scale and the McGill Pain and Roland Morris
38 questionnaires, and regarding their use of additional medications. Results showed no
39 statistically significant difference between the TENS and interferential current groups. The
40 only difference was found between these groups and the controls, with noted improvement
41 in outcome measures for the treatment groups.

1 According to the AHRQ publication on Non-Invasive Treatments for Low Back Pain
2 (2016), insufficient evidence from four trials exists regarding the effectiveness of
3 interferential therapy versus other interventions, or interferential therapy plus another
4 intervention versus the other interventions alone for low back pain, due to methodological
5 limitations and imprecision. According to the American College of Physician’s
6 Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain clinical practice
7 guideline (2017), evidence was insufficient to determine the effectiveness of electrical
8 muscle stimulation and inferential therapy.

9
10 Rutjes et al. (2009) conducted a systematic review of randomized or quasi-randomized
11 controlled trials of electrical stimulation, including IFT ($n=4$ studies), for the treatment of
12 osteoarthritis of the knee. Due to the poor methodological and reporting quality of the
13 studies, the effectiveness of IFT could not be confirmed.

14
15 Zeng et al. (2015) investigated the efficacy of different electrical stimulation (ES) therapies
16 in pain relief of patients with knee osteoarthritis (OA). 27 trials and six kinds of ES
17 therapies, including high-frequency transcutaneous electrical nerve stimulation (h-TENS),
18 low-frequency transcutaneous electrical nerve stimulation (l-TENS), neuromuscular
19 electrical stimulation (NMES), interferential current (IFC), pulsed electrical stimulation
20 (PES), and noninvasive interactive neurostimulation (NIN), were included. IFC was the
21 only significantly effective treatment in terms of both pain intensity and change pain score
22 at last follow-up time point when compared with the control group. Meanwhile, IFC
23 showed the greatest probability of being the best option among the six treatment methods
24 in pain relief. However, the evidence of heterogeneity and the limitation in sample size of
25 some studies could be a potential threat to the validity of results. Authors also state that
26 although the recommendation level of the other ES therapies is either uncertain (h-TENS)
27 or not appropriate (l-TENS, NMES, PES and NIN) for pain relief, it is likely that none of
28 the interventions is dangerous.

29
30 Almeida et al. (2018) investigated the effects of transcutaneous electrical nerve stimulation
31 and interferential current on acute and chronic pain. Eight studies with a pooled sample of
32 825 patients were included. In general, both transcutaneous electrical nerve stimulation and
33 interferential current improved pain and functional outcomes without a statistical
34 difference between them. Authors concluded that transcutaneous electrical nerve
35 stimulation and interferential current have similar effects on pain outcome The low number
36 of studies included in this meta-analysis indicates that new clinical trials are needed.

37
38 In 2019, Kadi et al. (2019) evaluated IFS for treating pain after total knee arthroplasty
39 surgery. A total of 113 individuals were randomized to IFS ($n=57$) or sham treatment
40 ($n=56$). There were 98 individuals (87%) who completed the study. After 30 days, there
41 was no significant difference between groups in pain assessed by a VAS, 0.278. Pain
42 medication use (paracetamol) also did not differ significantly between groups after

1 treatment and neither did outcome measures assessing range of motion or edema. In this
2 study, IFS was not beneficial at improving outcomes after total knee arthroplasty.

3
4 Hussein et al. (2022) aimed to analyze the recently available information regarding the
5 efficacy of IFC in alleviating the pain of musculoskeletal origin. This review included 35
6 trials of variable methodological quality from which 19 trials were selected for the meta-
7 analysis. In general, IFC alone versus placebo demonstrated a significant pain-relieving
8 effect. On the other hand, IFC showed no significant difference when added to standard
9 treatment compared to placebo plus standard treatment or standard treatment alone.
10 Similarly, IFC showed no significant difference when compared to other single
11 interventions (laser, TENS, cryotherapy). Authors concluded that IFC alone is better than
12 placebo at discharge. However, the low number of studies raises suspicions about this
13 conclusion. IFC alone or added to other interventions is not more effective than
14 comparative treatments in relieving musculoskeletal pain.

15
16 Chen et al. (2022) conducted a systematic review and meta-analysis to assess the
17 effectiveness of interferential current therapy (IFC) in patients with knee osteoarthritis. Ten
18 RCTs with 493 patients met the inclusion criteria. Nine RCTs were included in the meta-
19 analysis. The IFC groups exhibited significant improvements relative to the control groups
20 for short-term pain scores, long-term pain scores, and short-term Western Ontario and
21 McMaster Universities Osteoarthritis Index scores. All included studies did not observe
22 any obvious adverse effects of IFC. IFC can be recommended as a treatment for knee
23 osteoarthritis because it improves short- and long-term pain and short-term function.
24 However, large-scale and high-quality RCTs with longer follow-up are required to
25 establish an appropriate standardized treatment.

26 27 **High Volt Galvanic Stimulation (HVGS)**

28 The few studies identified in the literature addressing HVGS were mostly randomized
29 clinical trials and case studies published before 1997 with small patient populations and
30 short-term follow-up. Patient selection criteria were lacking. More recently, Snyder et al.
31 (2010) systematically reviewed the basic-science literature regarding the effects of high-
32 voltage pulsed stimulation (HVPS) for edema control. Included studies investigated HVPS
33 and its effect on acute edema formation and included outcome measures specific to edema.
34 Eleven studies met the inclusion criteria. Studies were critiqued by electrical stimulation
35 treatment parameters: mode of stimulation, polarity, frequency, duration of treatment,
36 voltage, intensity, number of treatments, and overall time of treatments. According to
37 Snyder et al., (2010), the available evidence indicates that HVPS administered using
38 negative polarity, pulse frequency of 120 pulses/s, and intensity of 90% visual motor
39 contraction may be effective at curbing edema formation. In addition, according to authors,
40 evidence suggests that treatment should be administered in either four 30-min treatment
41 sessions (30-min treatment, 30-min rest cycle for 4 h) or a single, continuous 180-min
42 session to achieve the edema-suppressing effects. Often such treatment occurs in an athletic

1 training room for college athletes and may not be feasible in an outpatient clinical setting.
 2 Authors suggest that findings supported by the basic science research provides a general
 3 list of treatment parameters that may successfully manage the formation of edema after
 4 acute injury in animal subjects They believe this should facilitate further research related
 5 to HVPS and the effects on edema in humans. At this time, there is insufficient evidence
 6 in the published peer reviewed scientific literature to support the safety and efficacy of
 7 HVG/HVPS stimulation.

9 **PENS and PNT**

10 There is insufficient evidence in the published peer-reviewed literature to support the safety
 11 and effectiveness of PENS or PNT as a treatment option for chronic pain. Overall, studies
 12 have included small patient populations and short-term follow-ups. For low back pain,
 13 most of the literature is of poor quality with all trials evaluating chronic low back pain. In
 14 a technology brief, Hayes (2017) investigated the effectiveness of PENS for the treatment
 15 of low back pain (LBP). Three randomized controlled trials ($n=34$ to 200) evaluated the
 16 efficacy and safety of PENS for chronic LBP (CLBP) in adults and one study evaluated
 17 PNT for subacute radiating LBP. Hayes rated the studies as very low-quality of evidence.
 18 There was no clinically significant improvement with the use of PENS. When compared
 19 with other therapies, PENS monotherapy was favored over treatment with PENS followed
 20 by TENS or TENS alone at one month; however, the difference was not maintained at two
 21 months. Another study reported no difference in outcomes with PENS vs. sham. There is
 22 insufficient evidence to support PENS for the treatment of LBP. Weiner et al. (2008)
 23 conducted a randomized controlled trial ($n=200$) to evaluate the efficacy of PENS in adults
 24 with chronic low back pain. Patients were randomized to either 1) PENS, 2) brief electrical
 25 stimulation to control for treatment expectance (control-PENS), 3) PENS plus general
 26 conditioning and aerobic exercise (CGAE) or to 4) control-PENS plus CGAE. Treatment
 27 was delivered twice a week for six weeks to the 50 participants in each group. All groups
 28 reported significantly reduced pain (McGill Pain Questionnaire short form) and disability
 29 and improved gait velocity, which was sustained at six months. Significantly fewer fear
 30 avoidance beliefs were reported in the CGAE group compared to the non-CGAE group.
 31 Comparable reduced pain and function were reported by the PENS and control-PENS
 32 group, whether delivered for five minutes or 30 minutes. Thus, the exact dose of electrical
 33 stimulation needed for analgesia could not be determined. PENS and CGAE were more
 34 effective than PENS alone in reducing fear avoidance beliefs, but not in reducing pain or
 35 in improving physical function. There was a statistically significant improvement in chair
 36 rise time in the control-PENS plus CGAE compared to control-PENS alone. The overall
 37 drop-out rate was 8%. In the Agency for Healthcare Research and Quality (AHRQ)
 38 publication “Noninvasive Treatments for Low Back Pain” by Chou et al. (2016), the two
 39 studies on PENS that were of fair quality contradicted one another, as one found that PENS
 40 plus exercise was superior to sham plus exercise, while the other did not. Some studies
 41 looked at LBP with radicular signs while others did not or were unclear. Overall, the
 42 literature doesn’t support PENS for treatment of chronic low back pain without radicular

1 symptoms. There was insufficient evidence to determine effects of PENS versus sham,
2 PENS plus exercise versus exercise alone, or PENS versus other interventions (TENS),
3 due to methodological limitations and imprecision. Harms were poorly reported in trials of
4 PENS.

5
6 Kang et al. (2007) conducted a single-blinded, randomized study of 63 patients with knee
7 pain secondary to osteoarthritis. Twenty-eight patients were randomly assigned to the sham
8 group and 35 to the live treatment group. The study investigated the efficacy of PNT in
9 reducing knee pain and medication consumption during the first week following treatment.
10 Pain levels were rated on a 100-mm visual analog pain scale. The live group had greater
11 efficacy than the sham group in all time periods; however, only in the immediate post-
12 treatment period did it reach statistical significance ($p=0.0361$). The overall median pain
13 intensity difference over all periods was 14.5 for the live group and 6.5 for the sham group
14 and reached statistical significance. At one week follow-up, the live group reported
15 significantly less medication use than the sham group. Plaza-Manzano et al. (2020)
16 evaluated the effects of percutaneous electrical stimulation (PENS) alone or as an adjunct
17 with other interventions on pain and related disability in musculoskeletal pain conditions.
18 Sixteen studies were included and included heterogeneous musculoskeletal conditions with
19 short- or midterm follow-ups. The risk of bias was generally low; but the heterogeneity of
20 the results downgraded the level of evidence. Authors concluded that there is low level of
21 evidence suggesting the effects of PENS alone or in combination for pain, but not related
22 disability, in musculoskeletal pain.

23
24 Beltran-Alacreu et al. (2022) aimed to determine if the use of PENS was more effective
25 and should be recommended when compared to TENS for the reduction of musculoskeletal
26 pain intensity. Studies published until 31/12/2020, comparing the effectiveness of PENS
27 and TENS, were considered. The main outcome was pain assessed with a visual analog
28 scale or numerical pain rating scale. Nine RCTs were included in the qualitative analysis,
29 with seven of them in the quantitative analysis ($n = 527$). The overall effect of PENS on
30 pain was statistically but not clinically superior to TENS with a high level of heterogeneity.
31 When only studies with a lower risk of bias ($n = 3$) were analyzed, no difference was
32 observed between TENS and PENS with a moderate recommendation level according to
33 GRADE. There were no data concerning adverse effects. There was low-quality of
34 evidence for more pain intensity reduction with PENS, but the difference was not clinically
35 significant. However, when only studies with low risk of bias are meta-analyzed, there was
36 a moderate quality of evidence that there is no difference when TENS or PENS is applied
37 for pain intensity.

1 According to National Institute for Health and Care Excellence (NICE), regarding PENS:

- 2 ▪ PENS versus sham PENS
 - 3 ○ Quality of life
 - 4 ▪ Low quality evidence from 1 study with 89 participants showed a
 - 5 clinically important benefit of PENS compared to sham PENS at ≤ 3
 - 6 months.
 - 7 ▪ Very low to low quality evidence from 1 study with 24 participants
 - 8 showed a clinically important benefit of PENS compared to usual
 - 9 care at ≤ 3 months.
 - 10 ○ Pain reduction
 - 11 ▪ Low quality evidence from 1 study with 89 participants showed a
 - 12 clinically important benefit of PENS compared to sham PENS at ≤ 3
 - 13 months.
 - 14 ▪ Low quality evidence from 1 study with 24 participants showed a
 - 15 clinically important benefit of PENS compared to usual care at ≤ 3
 - 16 months.

17 **NMES and FES**

19 Electric stimulated muscle contraction/neuromuscular electric stimulation (NMES) has
 20 been found to enhance muscle function post surgically. Patients who have received an ACL
 21 reconstruction have demonstrated accelerated recovery and greater muscle function when
 22 NMES is used in combination with exercise; however, the impact on functional outcomes
 23 is inconsistent (Cameron, 2017). Similar results were noted with knee OA patients and for
 24 other inflammatory conditions of the knee. Most research studied the use of NMES on the
 25 quadriceps muscle, however clinically NMES may be used for other joints and muscle
 26 groups (Cameron, 2017). NMES has been shown to be part of an effective rehabilitative
 27 regimen for patients following ligament/knee surgery. It may help prevent muscle atrophy
 28 associated with knee immobilization, may enable patients to ambulate sooner, and may
 29 reduce the use of pain medication as well as length of hospital stay (Arvidsson, 1986; Lake,
 30 1992; Gotlin et al, 1994; Snyder-Mackler et al, 1991 and 1995). Bax et al (2005)
 31 systematically reviewed the available evidence for the use of NMES in increasing strength
 32 of the quadriceps femoris. The authors concluded that limited evidence suggests that
 33 NMES can improve strength in comparison with no exercise, but volitional exercises
 34 appear more effective in most situations. The authors' cautious conclusions reflect the
 35 general poor quality of the included studies. It is also important to understand that at the
 36 time NMES is used, it is to re-education the neuromuscular system and engage more motor
 37 units with muscle contraction. Given this, the mechanism of strength increase is likely due
 38 to improved neuromuscular action vs. a true strength increase of the muscle.

39
 40 Monaghan et al. (2010) completed a Cochrane review regarding the effectiveness of NMES
 41 as a means of increasing quadriceps strength in patients before and after total knee
 42 replacement. Only two studies were identified for inclusion in the review. No significant

1 differences were reported in either study for maximum voluntary isometric torque or
2 endurance between the NMES group and the control group, but significantly better
3 quadriceps muscle activation was reported in the exercise and neuromuscular stimulation
4 group compared with the exercise group alone in the second study. This difference was
5 significant at the mid training (six week) time point but not at the twelfth week post training
6 time point. Both studies carried a high risk of bias. Mean values were not given for strength,
7 endurance, cross sectional area or quality of life. Pain outcomes, patient satisfaction or
8 adverse effects were not reported in either study. The results were presented as percentage
9 improvements from baseline and the number of subjects in each group was unclear.
10 Authors concluded that the studies found in this review do not permit any conclusions to
11 be made about the application of neuromuscular stimulation for the purposes of quadriceps
12 strengthening before or after total knee replacement. At that time the evidence for the use
13 of neuromuscular stimulation for the purposes of quadriceps strengthening in this patient
14 group is unclear.

15
16 Kim et al. (2010) performed a systematic review of RCTs assessing the effects of NMES
17 on quadriceps strength, functional performance, and self-reported function after ACL
18 reconstruction. Eight randomized controlled trials were included. Authors concluded that
19 NMES combined with exercise may be more effective in improving quadriceps strength
20 than exercise alone, whereas its effect on functional performance and patient-oriented
21 outcomes is inconclusive. Inconsistencies were noted in the NMES parameters and
22 application of NMES. Imoto et al. (2011) systematically evaluated the effectiveness of
23 electrical stimulation on rehabilitation after ligament and meniscal injuries. Seventeen
24 studies evaluating ES after anterior cruciate ligament reconstruction and two studies
25 evaluating ES after meniscectomy were included. There was a statistically significant
26 improvement in quadriceps strength through ES and in functional outcomes six to eight
27 weeks after surgical reconstruction of the anterior cruciate ligament. Authors concluded
28 that there is evidence that ES coupled with conventional rehabilitation exercises may be
29 effective in improving muscle strength and function two months after surgery. Maddocks
30 et al. (2013) evaluated the effectiveness of NMES for improving muscle strength in adults
31 with advanced disease and to examine the acceptability and safety of NMES, and changes
32 in muscle function (strength or endurance), muscle mass, exercise capacity, breathlessness
33 and health-related quality of life. They included randomized controlled trials (RCTs) in
34 adults with advanced chronic obstructive pulmonary disease (COPD), chronic heart failure,
35 cancer or human immunodeficiency virus/acquired immunodeficiency syndrome
36 (HIV/AIDS) comparing a program of NMES as a sole or adjunct intervention to no
37 treatment, placebo NMES or an active control. Eleven studies involving a total of 218
38 participants met the inclusion criteria across COPD, chronic heart failure and thoracic
39 cancer. Authors concluded NMES appears an effective means of improving muscle
40 weakness in adults with progressive diseases such as COPD, chronic heart failure and
41 cancer. Further research is needed to confirm findings and determine most effective
42 parameters.

1 Bemner et al. (2016) completed a critically appraised topic on the effectiveness of
2 neuromuscular electrical stimulation in improving voluntary activation of the quadriceps.
3 Four randomized controlled trials (RCTs) met the inclusion criteria and were included. Of
4 the included studies, one reported statistically significant improvements in quadriceps
5 voluntary activation in the intervention group relative to a comparison group, but the
6 statistical significance was not true for another study consisting of the same sample of
7 participants with a different follow-up period. One study reported a trend in the NMES
8 group, but the between group differences were not statistically significant in three of the
9 four RCTs. Current evidence does not support the use of NMES for the purpose of
10 enhancing quadriceps voluntary activation in patients with orthopedic knee conditions.
11 There is level B evidence that the use of NMES alone, or in conjunction with therapeutic
12 exercise, does not enhance quadriceps voluntary activation in patients with orthopedic knee
13 conditions (e.g., anterior cruciate ligament injuries, osteoarthritis, total knee arthroplasty).

14
15 Jones et al. (2016) updated a Cochrane Database review on the effectiveness of
16 neuromuscular electrical stimulation for quadriceps muscle weakness in adults with
17 advanced disease. Programs of NMES appear to be acceptable to patients and have led to
18 improvements in muscle function, exercise capacity, and quality of life. However,
19 estimates regarding the effectiveness of NMES based on individual studies lack power and
20 precision. Randomized controlled trials in adults with advanced chronic respiratory
21 disease, chronic heart failure, cancer, or HIV/AIDS comparing a program of NMES as a
22 sole or adjunct intervention to no treatment placebo NMES, or an active control were
23 included. Eighteen studies (20 reports) involving a total of 933 participants with COPD,
24 chronic respiratory disease, chronic heart failure, and/or thoracic cancer met the inclusion
25 criteria for this update, an additional seven studies since the previous version of this review.
26 All but one study that compared NMES to resistance training compared a program of
27 NMES to no treatment or placebo NMES. Most studies were conducted in a single center
28 and had a risk of bias arising from a lack of participant or assessor blinding and small study
29 size. The quality of the evidence using GRADE comparing NMES to control was low for
30 quadriceps muscle strength, moderate for occurrence of adverse events, and very low to
31 low for all other secondary outcomes. The included studies reported no serious adverse
32 events and a low incidence of muscle soreness following NMES. NMES led to a
33 statistically significant improvement in quadriceps muscle strength. An increase in muscle
34 mass was also observed following NMES, though the observable effect appeared
35 dependent on the assessment modality used. Across tests of exercise performance, mean
36 differences compared to control were statistically significant for the 6-minute walk, but not
37 for the incremental shuttle walk, endurance shuttle walk, or for cardiopulmonary exercise
38 testing with cycle ergometry. Authors concluded that NMES may be an effective treatment
39 for muscle weakness in adults with advanced progressive disease and could be considered
40 as an exercise treatment for use within rehabilitation programs. Further research is very
41 likely to have an important impact on the confidence in the estimate of effect and may

1 change the estimate. Further research to understand the role of NMES as a component of,
2 and in relation to, existing rehabilitation approaches is needed.

3
4 Gatewood et al. (2017) aimed to investigate the efficacy of device modalities used
5 following arthroscopic knee surgery. Outcome measures included: muscle strength, range
6 of motion, swelling, blood loss, pain relief, narcotic use, knee function evaluation and
7 scores, patient satisfaction and length of hospital stay. Twenty-five studies were included
8 in this systematic review, nineteen of which found a significant difference in outcomes.
9 Authors concluded that NMES improve quadriceps strength and overall knee functional
10 outcomes following knee surgery. Yue et al. (2018) assessed the evidence relative to the
11 comparative effectiveness of neuromuscular electrical stimulation (NMES),
12 transcutaneous electrical nerve stimulation (TENS), and electroacupuncture (EA) for
13 improving patient rehabilitation following total knee arthroplasty (TKA). Data were
14 analyzed from 17 randomized controlled trials involving 1285 procedures: 8 NMES studies
15 (608 procedures), 7 TENS studies (560 procedures), and 2 EA studies (117 procedures).
16 Qualitative analysis suggested that NMES was associated with higher quadriceps strength
17 and functional recovery after TKA. Recovery benefits were maximal when the stimulation
18 was performed once or twice a day for 4-6 weeks at an intensity of 100-120 mA and
19 frequency of 30-100 Hz. The electrode should be sufficiently large (100-200 cm²) to
20 reduce discomfort. TENS at an intensity of 15-40 mA and frequency of 70-150 Hz provided
21 effective analgesia after TKA. EA at an intensity of 2 mA and frequency of 2 Hz may also
22 provide postoperative analgesia of TKA. Authors concluded that as adjunct modalities,
23 NMES and TENS can effectively improve rehabilitation after TKA without triggering
24 significant intolerance, and maximal benefits depend on optimized parameters and
25 intervention protocols. EA may be an effective adjunct modality for analgesia after TKA.

26
27 Novak et al. (2020) sought to provide guidelines for treatment parameters regarding
28 electrical stimulation by investigating its efficacy in improving muscle strength and
29 decreasing pain in patients with knee osteoarthritis. Nine randomized control trials were
30 included in the review. First, the review confirmed that neuromuscular electrical
31 stimulation is the most effective electrical stimulation treatment in the management of knee
32 OA, and its efficiency is higher when combined with a strengthening program. Second,
33 frequency of at least 50 Hz and no more than 75 Hz with a pulse duration between 200 and
34 400 μ s and a treatment duration of 20 mins is necessary for successful treatment. Peng et
35 al. (2021) evaluated the effect of neuromuscular electrical stimulation (NMES) on
36 quadriceps muscle strength, pain, and function outcomes following total knee arthroplasty
37 (TKA). Nine RCTs that involved 691 patients were included in the meta-analysis. Pooled
38 analysis showed that NMES improved quadriceps muscle strength after TKA within 1
39 month, 1-2 months, 3-4 months, and 12-13 months; pain between 1 and 2 months and
40 between 3 and 6 months, Western Ontario and McMaster Universities Osteoarthritis Index
41 (WOMAC) between 3 and 4 months, timed up and go test (TUG) within 1 month, 3 minute
42 walk test between 3 and 6 months, and SF-36 MCS between 3 and 6 months after TKA.

1 Authors concluded that as a supplementary treatment after TKA, postoperative NMES
2 could improve the short-term to long-term quadriceps muscle strength, mid-term pain, and
3 mid-term function following TKA. However, many outcomes failed to achieve statistically
4 meaningful changes and minimal clinically important difference (MCID), thus the clinical
5 benefits remained to be confirmed.

6
7 Labanca et al. (2022) investigated whether adding NMES to TKA rehabilitation leads to a
8 better quadriceps strength recovery in comparison with standardized rehabilitation. A
9 second aim was to investigate which are the most commonly used NMES pulse settings
10 and their effectiveness. Intervention studies evaluating the effects of a rehabilitation
11 intervention based on quadriceps NMES in patients undergoing TKA were retrieved. Four
12 studies met the inclusion criteria. Due to the limited number and the heterogeneity of the
13 selected studies, it was not appropriate to carry out a meta-analysis. All the studies reported
14 higher quadriceps strength in patients undergoing quadriceps NMES, particularly early
15 after TKA. The addition of NMES or traditional strength training shows similar long-term
16 effects. Short duration and low-intensity NMES have limited effects on quadriceps
17 strength. Heterogeneity was found on NMES methodologies and pulse settings. In
18 conclusion, NMES is effective for quadriceps strength recovery following TKA. NMES
19 intensity and duration are essential for good NMES outcomes on quadriceps strength.
20 Further studies on NMES methodologies, pulse features and settings are required to address
21 the gaps in knowledge on NMES following TKA.

22
23 Culvenor et al. (2022) synthesized the evidence for effectiveness of rehabilitation
24 interventions following ACL and/or meniscal tear on symptomatic, functional, clinical,
25 psychosocial, quality of life and reinjury outcomes. Authors included 22 systematic
26 reviews (142 trials of mostly men) evaluating ACL-injured individuals and none evaluating
27 isolated meniscal injuries. Authors synthesized data from 16 reviews evaluating 12
28 different interventions. Moderate-certainty evidence was observed for: (1) neuromuscular
29 electrical stimulation to improve quadriceps strength; (2) open versus closed kinetic chain
30 exercises to be similarly effective for quadriceps strength and self-reported function; (3)
31 structured home-based versus structured in-person rehabilitation to be similarly effective
32 for quadriceps and hamstring strength and self-reported function; and (4) postoperative
33 knee bracing being ineffective for physical function and laxity. There was low-certainty
34 evidence that: (1) preoperative exercise therapy improves self-reported and physical
35 function postoperatively; (2) cryotherapy reduces pain and analgesic use; (3) psychological
36 interventions improve anxiety/fear; and (4) whole body vibration improves quadriceps
37 strength. There was very low-certainty evidence that: (1) protein-based supplements
38 improve quadriceps size; (2) blood flow restriction training improves quadriceps size; (3)
39 neuromuscular control exercises improve quadriceps and hamstring strength and self-
40 reported function; and (4) continuous passive motion has no effect on range of motion.
41 Authors concluded that the general level of evidence for rehabilitation after ACL or
42 meniscal tear was low. Moderate-certainty evidence indicates that several rehabilitation

1 types can improve quadriceps strength, while brace use has no effect on knee
2 function/laxity.

3
4 The main goal of stroke rehabilitation is to improve function to allow patients greater
5 independence in their activities of daily living, resulting in an improvement in quality of
6 life. Typical treatment techniques of stroke rehabilitation comprise various combination of
7 range of motion (ROM) and muscle strengthening exercises, mobilization activities, and
8 compensatory techniques. Other key therapies include neurophysiological and/or
9 developmental based methods in which the treatment program incorporates neuromuscular
10 re-education techniques. It is in these situations that FES is used for stroke rehabilitation.
11 It has been utilized to manage contracture of joints, maintain ROM, facilitate voluntary
12 motor control, and reduce spasticity. However, there is insufficient evidence that FES is
13 effective as a rehabilitative tool for patients who suffered strokes. In particular, there are
14 little data supporting the long-term effectiveness of this modality for stroke rehabilitation
15 and other neurologic conditions. In a Cochrane review, Price and Pandyan (2000)
16 ascertained the effectiveness of any form of surface electric stimulation in the prevention
17 and/or treatment of pain around the shoulder at any time after stroke. These investigators
18 concluded that the evidence from randomized controlled studies so far does not confirm or
19 refute that ES around the shoulder after stroke influences reports of pain, but there do
20 appear to be benefits for passive humeral lateral rotation. A possible mechanism is through
21 the reduction of glenohumeral subluxation. The authors stated that further studies are
22 needed. Van Peppen et al (2004) determined the evidence for physical therapy
23 interventions aimed at improving functional outcome after stroke. 151 studies were
24 included in this systematic review; 123 were randomized controlled trials (RCTs) and 28
25 controlled clinical trials (CCTs). Researchers reported that while strong evidence was
26 found regarding use of NMES for glenohumeral subluxation, no or insufficient evidence
27 in terms of functional outcome was found for FES and NMES aimed at improving dexterity
28 or gait performance. Furthermore, in a review on therapeutic orthosis and electric
29 stimulation for upper extremity hemiplegia after stroke, Aoyagi and Tsubahara (2004)
30 stated that despite a number of studies suggesting the effectiveness of electrical stimulation
31 for reducing shoulder subluxation or improving the function of wrist and finger extensors
32 in the short term, the long-term effectiveness after discontinuation as well as the motor
33 recovery mechanism remains unclear. More research is needed to determine the evidence-
34 based effectiveness of electrical stimulation for stroke survivors. Koyuncu et al. (2010)
35 conducted a randomized controlled trial to evaluate FES for the treatment of 50 hemiplegic
36 patients with shoulder subluxation and pain secondary to stroke. All patients received
37 conventional rehabilitation and the study group also received FES stimulation to the
38 supraspinatus and posterior deltoid muscles on the hemiplegic side, five times a day, one
39 hour each for four weeks. Comparison of the resting AROM vs. PROM VAS value changes
40 showed no significant difference between the groups. There was a significant difference
41 between the two groups for the amount of change in shoulder subluxation in favor of the
42 study group, indicating increased stability of the shoulder. Authors suggest that that

1 applying FES treatment to the supraspinatus and posterior deltoid muscles in addition to
2 conventional treatment when treating the subluxation in hemiplegic patients is more
3 beneficial than conventional treatment by itself. Gu and Ran (2016) reviewed the evidence
4 for the effect of functional electrical stimulation (FES) on shoulder subluxation, pain, upper
5 arm motor function, daily function, and quality of life in patients with stroke when added
6 to conventional therapy. The results of this meta-analysis showed a significant difference
7 in shoulder subluxation between the FES group and the placebo group, only if FES was
8 applied early after stroke. And a significant difference was observed posttreatment in the
9 Fugl-Meyer Motor Assessment between the FES group and the placebo group. No effects
10 were found on pain, upper arm motor function, daily function, and quality of life outcomes.
11 Authors concluded that FES can be used to prevent or reduce shoulder subluxation early
12 after stroke. However, findings did not support the efficacy of use of FES for pain
13 reduction, improvement in arm strength, movement, functional use, daily function, or
14 quality of life after stroke.

15
16 FES has been proposed for improving ambulation in patients with gait disorders such as
17 drop foot, hemiplegia due to stroke, cerebral injury, or incomplete spinal cord injury. As
18 an example, FES can be applied to the anterior tibialis muscle to assist in dorsiflexion
19 during gait for patients with foot drop. Several small studies support the integration of FES
20 for patients with spinal cord injury or who have sustained a stroke for various activities.
21 As long as the peripheral nervous system is intact, any patients with central nervous system
22 dysfunction may benefit from FES use. Effectiveness of FES may be likely due to the direct
23 effect of muscle strengthening in addition to increased excitability of the motor neuron
24 pool produced by the motor level electrical stimulation (Cameron, 2017). Yan and
25 colleagues (2005) evaluated whether FES was more effective in promoting motor recovery
26 of the lower extremity and walking ability than standard rehabilitation alone. A total of 46
27 patients were assigned randomly to one of three groups receiving standard rehabilitation
28 with FES or placebo stimulation or alone (control). They received treatment for 3 weeks,
29 starting shortly after having the stroke. Outcome measurements included composite
30 spasticity score, maximum isometric voluntary contraction of ankle dorsi-flexors and
31 planter-flexors, and walking ability. After 3 weeks of treatment, those receiving FES plus
32 standard rehabilitation did better on several measures of lower limb functioning compared
33 to the other 2 groups. All patients in the FES group were able to walk after treatment, and
34 84.6 % of them returned home, in comparison with the placebo (53.3 %) and control (46.2
35 %) groups. However, these authors stated that generalization of the results from this study
36 should be performed with caution because of subject selection criteria, which did not cover
37 all stroke categories or subjects aged younger than 45 or older than 85 years. Randomized
38 controlled trials and case series have primarily included small patient populations ($n=14-$
39 64) with short-term follow-ups and heterogeneous treatment regimens and outcome
40 measures (Esnour, et al., 2010; Nooijen, et al., 2009; Everaert, et al., 2010; Stein, et al.,
41 2010; Barrett, et al., 2010; Postans, et al., 2004).

1 In a Cochrane review on electrostimulation for promoting recovery of movement or
2 functional ability after stroke, Pomeroy et al (2006) sought to find out whether
3 electrostimulation improved functional motor ability to do activities of daily living.
4 Twenty-four trials were included in the review. Authors reported that electrostimulation
5 improved some aspects of functional motor ability and some aspects of motor impairment
6 and normality of movement over no treatment. For electrostimulation compared with
7 placebo, this review found that electrostimulation improved an aspect of functional motor
8 ability. For electrostimulation compared with conventional physical therapy, they found
9 that electrostimulation improved an aspect of motor impairment. There were no statistically
10 significant differences between electrostimulation and control treatment for all other
11 outcomes. Authors caution that these results need to be interpreted with reference to the
12 following: (1) the majority of analyses only contained one trial; (2) variation was found
13 between included trials in time after stroke, level of functional deficit, and dose of
14 electrostimulation; and (3) the possibility of selection and detection bias in the majority of
15 included trials. Researchers conclude that data were insufficient to inform clinical use of
16 electrostimulation for neuromuscular re-training. Research is needed to address specific
17 questions about the type of electrostimulation that might be most effective, in what dose
18 and at what time after stroke. Pereira et al. (2012) conducted a systematic review of
19 randomized controlled trials to evaluate the effectiveness of FES in improving lower limb
20 function in chronic stroke patients (mean time since stroke ≥ 6 mos.). Seven RCTs
21 including a pooled sample size of 231 participants met inclusion criteria. Analysis revealed
22 a small but significant treatment effect in favor of FES on the 6-minute walk test. Authors
23 conclude that FES may be an effective intervention in the chronic phase post stroke.
24 However, its therapeutic value in improving lower extremity function and advantage over
25 other gait training approaches remains uncertain.

26
27 More recently, Howlett et al. (2015) conducted a systematic review and meta-analysis to
28 investigate the effectiveness of FES in improving activity following a stroke and to
29 determine if FES is more effective than training alone. Eighteen randomized and non-
30 randomized comparisons studies ($n=485$) met inclusion criteria. One study had three arms
31 which was counted as a separate comparison group ($n=19$ comparisons). Because of
32 incomplete data, all trials were not included in the meta-analysis. Only measures that
33 reflected the International Classification of Function domain of activity performance were
34 used in analyses. In some trials only one measure was available and in trials with more than
35 one measure the reviewers chose the measure that most closely reflected the task being
36 trained. Various outcome measures were used for lower-limb and upper-limb activity
37 assessments. FES had a small to moderate effect on activity compared to no FES or placebo
38 and had a moderate effect on activity compared to training alone. However, due to the lack
39 of available data, the authors were unable determine if FES improved subject participation
40 or if the benefits of FES are long-term. Author-noted limitations of the studies included:
41 the lack of blinding of therapist and participants; the potential of small trial bias with 25
42 being the average number of participants per trial; and combining data for the meta-analysis

1 that was collected using different outcome measures. There was also heterogeneity of
2 subject characteristics including time after stroke, the limb that was trained, and the
3 severity of stroke. In a randomized controlled study, Bethoux et al. (2015) compared
4 changes in gait quality and function between FES and ankle-foot orthoses (AFOs) in
5 individuals with foot drop post-stroke over a 12-month period. They completed a follow-
6 up analysis on a multi-center unblinded RCT that had been conducted at 30 rehabilitation
7 centers. Subjects continued to wear their randomized device for all home and community
8 ambulation for another 6 months to final 12-month assessments. Primary outcomes were
9 the 10 Meter Walk Test (10MWT) and device-related serious adverse event rate. Secondary
10 outcome measures were the 6-Minute Walk Test (6MWT), GaitRite Functional
11 Ambulation Profile, and the Modified Emory Functional Ambulation Profile (mEFAP). A
12 total of 495 subjects were randomized, and 384 completed the 12-month follow-up. Both
13 FES and AFO groups showed statistically and clinically significant improvement for
14 10MWT. No significant between group differences were found. At 12 months, both FES
15 and AFOs continue to demonstrate equivalent gains in gait speed. Results suggest that
16 long-term FES use may lead to additional improvements in walking endurance and
17 functional ambulation; further research is needed to confirm these findings.

18
19 Prenton et al. (2016) conducted a systematic review and meta-analysis of randomized
20 controlled trials to compare the effects of FES and ankle foot orthoses (AFO) for foot drop
21 of central neurological origin. Five synthesized randomized controlled trials ($n=815$) were
22 included. Orthotics included customized and off the shelf AFOs. Meta-analysis of the
23 outcomes of the 10-meter (m) walking speed (5 trials) ($n=789$) and functional exercise
24 capacity (3 trials) ($n=761$) showed between group comparable improvements which were
25 not significant ($p=0.79$; $p=0.31$, respectively). There were no significant differences in
26 meta-analysis for the 10-meter (m) walk test using data at short- (4 trials; $n=771$) and
27 longer-term (3 trials; $n=713$) time-points for FES vs. AFO. There was a significant
28 difference ($p=0.04$) in favor of the AFO for the medium-term 10-m test. Analyses revealed
29 between group comparable improvements in functional exercise capacity. The timed up-
30 and-go test was reported in two studies, and both reported between-group comparable
31 improvements ($p=0.812$ and $p=0.539$). The mobility domain of the Stroke Impact Scale
32 (SIS) was reported by three trials ($n=701$) and showed comparable between-group
33 improvements ($p=0.80$). This meta-analysis indicates that AFOs have positive combined-
34 orthotic effects on walking that are equivalent to FES for foot-drop caused by stroke
35 regardless of length of use. The fact that the reviewed trials only included subjects age 18
36 years and older who had experienced a stroke prevents the results from being generalized
37 to other populations. Other limitations of the analysis included the risk of bias in the studies
38 and the heterogeneity of the AFO and FES devices used.

39
40 Stein et al. (2015) conducted a systematic review ($n=29$ studies; 940 subjects) and meta-
41 analysis ($n=14$ studies; 383 subjects) of randomized controlled trials to evaluate the effect
42 of NMES on spastic muscles after stroke. The primary outcome was spasticity, assessed

1 by the Modified Ashworth Scale. The secondary outcome was range of motion ($n=13$
2 studies), assessed by a goniometer. Outcomes were conflicting. Some studies reported an
3 improvement in spasticity ($n=12$ studies) and range of motion ($n=13$ studies) with NMES
4 when used as an adjunctive therapy and some studies did not. Based on sensitivity analysis,
5 no effects on spasticity and range of motion were seen on wrists and no effect on spasticity
6 of elbows. The degree of spasticity and the criteria for spasticity assessment varied. Most
7 studies showed evidence of bias. Other study limitations included: heterogeneity of
8 outcome measures; time of treatment following stroke (1.5 months to more than 12
9 months); various degrees of chronic tissue changes; heterogeneity of conventional
10 therapies used (e.g., active leg cycling, occupational therapy, stretching, Botulinum Toxin
11 A), missing data; and heterogeneity of stimulation frequency and pulse duration. Large
12 scale and high-quality randomized controlled trials are needed to establish the true efficacy
13 NMES in this patient population. Sharififar et al. (2018) aimed to determine the effect on
14 motor function of extremities of adding an electrical sensory modality without motor
15 recruitment before or with routine rehabilitation for hemiparesis after stroke by a
16 comprehensive systematic review and meta-analysis. Authors concluded that electrical
17 sensory input could contribute to routine rehabilitation to improve early post-stroke lower-
18 extremity impairment and late motor function, with no change in spasticity. Prolonged
19 periods of sensory stimulation such as TENS combined with activity can have beneficial
20 effects on impairment and function after stroke.

21
22 Kristensen et al. (2021) sought to determine the effectiveness of neuromuscular electrical
23 stimulation (NMES) toward improving activities of daily living (ADL) and functional
24 motor ability post stroke and to investigate the influence of paresis severity and the timing
25 of treatment initiation for the effectiveness of NMES. The inclusion criteria were
26 randomized controlled trials exploring the effect of NMES toward improving ADL or
27 functional motor ability in survivors of stroke. The search identified 6064 potential articles
28 with 20 being included. Data from 428 and 659 participants (mean age, 62.4 years; 54%
29 male) for outcomes of ADL and functional motor ability, respectively, were pooled in a
30 random-effect meta-analysis. The analysis revealed a significant positive effect of NMES
31 toward ADL, whereas no effect on functional motor ability was evident. Subgroup analyses
32 showed that application of NMES in the subacute stage and in the upper extremity
33 improved ADL, whereas a beneficial effect was observed for functional motor abilities in
34 patients with severe paresis. Authors concluded that the results of the present meta-analysis
35 are indicative of potential beneficial effects of NMES toward improving ADL post stroke,
36 whereas the potential for improving functional motor ability appears less clear.
37 Furthermore, subgroup analyses indicated that NMES application in the subacute stage and
38 targeted at the upper extremity is efficacious for ADL rehabilitation and that functional
39 motor abilities can be positively affected in patients with severe paresis.

40
41 Johnston et al. (2021) provided evidence to guide clinical decision-making for the use of
42 either ankle-foot orthosis (AFO) or functional electrical stimulation (FES) as an

1 intervention to improve body function and structure, activity, and participation as defined
2 by the International Classification of Functioning, Disability and Health (ICF) for
3 individuals with poststroke hemiplegia with decreased lower extremity motor control
4 within this clinical practice guideline. A review of literature published through November
5 2019 was performed across 7 databases for all studies involving stroke and AFO or FES.
6 Data extracted included time post-stroke, participant characteristics, device types,
7 outcomes assessed, and intervention parameters. Outcomes were examined upon initial
8 application and after training. Recommendations were determined on the basis of the
9 strength of the evidence and the potential benefits, harm, risks, or costs of providing AFO
10 or FES. One-hundred twenty-two meta-analyses, systematic reviews, randomized
11 controlled trials, and cohort studies were included. Strong evidence exists that AFO and
12 FES can each increase gait speed, mobility, and dynamic balance. Moderate evidence exists
13 that AFO and FES increase quality of life, walking endurance, and muscle activation, and
14 weak evidence exists for improving gait kinematics. AFO or FES should not be used to
15 decrease plantarflexor spasticity. Studies that directly compare AFO and FES do not
16 indicate overall superiority of one over the other. But evidence suggests that AFO may lead
17 to more compensatory effects while FES may lead to more therapeutic effects. Due to the
18 potential for gains at any phase post-stroke, the most appropriate device for an individual
19 may change, and reassessments should be completed to ensure the device is meeting the
20 individual's needs. It is important to note that this CPG cannot address the effects of one
21 type of AFO over another for the majority of outcomes, as studies used a variety of AFO
22 types and rarely differentiated effects. The recommendations also do not address the
23 severity of hemiparesis, and most studies included participants with varied baseline
24 ambulation ability. Authors summarize that this CPG suggests that AFO and FES both lead
25 to improvements post-stroke. Future studies should examine timing of provision, device
26 types, intervention duration and delivery, longer term follow-up, responders versus
27 nonresponders, and individuals with greater impairments.

28
29 van der Scheer et al. (2021) summarized and appraise evidence on functional electrical
30 stimulation (FES) cycling exercise after spinal cord injury (SCI), in order to inform the
31 development of evidence-based clinical practice guidelines. Ninety-two studies met the
32 eligibility criteria, comprising 999 adults with SCI representing all age, sex, time since
33 injury, lesion level and lesion completeness strata. For muscle health (e.g., muscle mass,
34 fiber type composition), significant improvements were found in 3 out of 4 Level 1-2
35 studies, and 27 out of 32 Level 3-4 studies (GRADE rating: 'High'). Although lacking Level
36 1-2 studies, significant improvements were also found in nearly all of 35 Level 3-4 studies
37 on power output and aerobic fitness (e.g., peak power and oxygen uptake during an FES
38 cycling test) (GRADE ratings: 'Low'). Authors concluded that the evidence indicates that
39 FES cycling exercise improves lower-body muscle health of adults with SCI and may
40 increase power output and aerobic fitness. Mahmoudi et al. (2021) systematically reviewed
41 the effect of functional electrical stimulation (FES) on balance as compared to conventional
42 therapy alone in post-stroke. Nine papers were included in this review. The total number

1 of participants in this review study was 255. The age of participants ranged from 20 to 80
2 years. Stroke patients were in chronic phase ($n = 5$) and in subacute phase ($n = 4$). Various
3 parameters, including the target muscles, the treatment time per session (20 min-2 h),
4 number of treatment sessions (12-48) and FES frequency (25-40 Hz), were assessed.
5 Among the studies, significant between-group improvement favoring FES in combination
6 with conventional therapy was found on the Berg Balance Scale ($n = 7$) and Timed Up and
7 Go Scale ($n = 4$) when compared to conventional therapy alone. There was no adverse
8 effect reported by any studies. Authors concluded that FES was reported to be more
9 beneficial in balance improvement among stroke patients when combined with
10 conventional balance therapy. The studies were limited by low-powered, small sample
11 sizes ranging from 9 to 48, and lack of blinding, and reporting of missing data.

12
13 Ye et al. (2021) comprehensively and critically appraised the clinical benefits and
14 engineering designs of functional electrical stimulation (FES)-rowing for management of
15 individuals with spinal cord injury (SCI). Comparison of peak oxygen consumption
16 ($\dot{V}O_{2peak}$) rates showed that $\dot{V}O_{2peak}$ during FES-rowing was significantly higher than
17 arm-only exercise; FES-rowing training improved $\dot{V}O_{2peak}$ by 11.2% on average, with a
18 4.1% increase in $\dot{V}O_{2peak}$ per month of training. FES-rowing training reduced bone
19 density loss with increased time postinjury. The rowing ergometer used in 2 studies
20 provided motor assistance during rowing. Studies preferred manual stimulation control
21 ($n=20$) over automatic ($n=4$). Authors concluded that results suggest FES-rowing is a
22 viable exercise for individuals with SCI that can improve cardiovascular performance and
23 reduce bone density loss. Further randomized controlled trials are needed to better
24 understand the optimal set-up for FES-rowing that maximizes the rehabilitation outcomes.
25 Karamian et al. (2022) summarized the various forms of electrical stimulation technology
26 that exist and their applications for SCI. With regards to FES and NMES, authors report
27 positive findings for improvement in muscle function and functional activities.

28
29 Chiu et al. (2014) conducted a systematic review to determine the effectiveness of FES vs.
30 activity training alone in children with cerebral palsy. Five randomized controlled trials
31 met inclusion criteria. The experimental group had to receive FES while performing an
32 activity such as walking. The studies used outcome measures of activity that best reflected
33 the activity used in the study. When continuous data (e.g., walking speed) were not
34 available, ordinal data (e.g., Gross Motor Function Measurement) were used. A statistically
35 significant between-group difference in activity in the FES groups was reported for the
36 three studies that compared FES with no FES. Improvements were seen immediately after
37 the intervention period, but long-term follow-up was not reported. The two studies
38 investigating the effects of FES vs. activity training reported no significant differences
39 between the groups. The results reported that FES is better than no FES, but that FES is
40 not more effective than activity training. Outcomes could not be pooled for meta-analysis
41 due to incomplete data and the large difference in baseline scores. Due to the inability to
42 conduct a meta-analysis, the authors stated that firm conclusions could not be made.

1 Limitations of the studies included the heterogeneous patient populations and the variations
2 in the frequency, intensity and duration of the interventions. Bosques et al. (2016)
3 discussed the potential clinical applicability, while clarifying the differences in electrical
4 stimulation (ES) treatments and the theory behind potential benefits to remediate functional
5 impairments in youth in a comprehensive review. The synthesis of the literature suggests
6 that improvements in various impairments may be possible with the integration of ES. Most
7 studies were completed on children with cerebral palsy (CP). Electrical stimulation may
8 improve muscle mass and strength, spasticity, passive range of motion (PROM), upper
9 extremity function, walking speed, and positioning of the foot and ankle kinematics during
10 walking. Sitting posture and static/dynamic sitting balance may be improved with ES to
11 trunk musculature. Bone mineral density may be positively affected with the use of
12 Functional Electrical Stimulation (FES) ergometry. ES may also be useful in the
13 management of urinary tract dysfunction and chronic constipation. Among all reviewed
14 studies, reports of direct adverse reactions to electrical stimulation were rare. In conclusion,
15 NMES and FES appear to be safe and well tolerated in children with various disabilities.
16 Authors suggested that physiatrists and other healthcare providers better understand the
17 indications and parameters in order to utilize these tools effectively in the pediatric
18 population.

19
20 Springer and Khamis (2017) completed a systematic review on the orthotic and therapeutic
21 effects of functional electrical stimulation on gait in people with multiple sclerosis (MS).
22 Twelve relevant studies were reviewed. Eleven studies reported the effects of peroneal
23 stimulation. Most found a significant orthotic effect (measured during stimulation), mainly
24 on walking speed. Only three assessed the therapeutic effect (carry-over), which was not
25 significant. Authors concluded that the evidence suggests that FES has a positive orthotic
26 effect on walking in patients with MS. Yet, more robust trials are needed to substantiate
27 this finding. Therapeutic efficacy of FES was not demonstrated.

28
29 Ou et al. (2022) assessed the effects of neuromuscular electrical stimulation on the upper
30 limbs of patients with cerebral palsy. Eight randomized controlled trials (N = 294) were
31 included in the meta-analysis. Compared with traditional physical therapy, sensorimotor
32 training and task-oriented training, constraint-induced movement therapy, dynamic
33 bracing, and conventional robot-assisted therapy, neuromuscular electrical stimulation in
34 combination with these therapies resulted in significantly greater functional scale scores,
35 muscle strength of upper limbs, and spasticity of upper limbs but did not improve the wrist
36 range of motion. In addition, the effect of neuromuscular electrical stimulation on
37 functional scale scores remained after 3-mo follow-up. Authors concluded that
38 neuromuscular electrical stimulation effectively improved hand function, muscle strength,
39 and spasticity in patients with cerebral palsy.

40
41 Chen et al. (2023) investigated whether neuromuscular electrical stimulation improves
42 mobility in children with spastic cerebral palsy. A total of 14 randomized controlled trials

1 (2 crossover studies and 12 parallel studies including 421 patients) were included in this
2 meta-analysis. Compared with the control group (conventional physical therapy), the
3 treatment group exhibited greater improvement in walking speed and the standing,
4 walking, running, and jumping dimension of the Gross Motor Function Measure. Authors
5 concluded that neuromuscular electrical stimulation improved mobility in children with
6 spastic cerebral palsy, particularly in standing, running, and jumping function, and it is safe
7 for children with spastic cerebral palsy.

8
9 Zhu et al. (2022) summarized and analyzed the relationship between functional electrical
10 stimulation treatment and gait parameter changes in children with cerebral palsy. Nine
11 papers were included in the analysis, with a total of 282 children with cerebral palsy,
12 including 142 patients in the functional electrical stimulation treatment group and 140
13 patients in the comfort treatment, general nursing, or other physical therapy. The results
14 showed that functional electrical stimulation could increase the walking speed of children
15 with cerebral palsy and increase the walking step length of children with cerebral palsy.
16 Authors concluded that functional nerve stimulation treatment could increase the gait speed
17 and step length of children with cerebral palsy, which could improve the walking of
18 children with cerebral palsy. Furthermore, this study needs more research data to support
19 the authors' findings.

20
21 Ignácio et al. (2022) sought to determine what the effect is of an intravaginal electrical
22 stimulation regimen on their ability to contract the pelvic floor muscles and on self-reported
23 urinary incontinence in women who are unable to contract their pelvic floor muscles
24 voluntarily. Sixty-four women with pelvic floor muscle function assessed by bi-digital
25 palpation to be grade 0 or 1 on the Modified Oxford Scale. For 8 weeks, participants
26 randomised to the experimental group received weekly 20-minute sessions of intravaginal
27 electrical stimulation with instructions to attempt pelvic floor muscle contractions during
28 the bursts of electrical stimulation in the final 10 minutes of each session. The control group
29 received no intervention. The primary outcome was ability to voluntarily contract the
30 pelvic floor muscles, evaluated through vaginal palpation using the Modified Oxford Scale.
31 Secondary outcomes were prevalence and severity of urinary incontinence symptoms
32 assessed by the International Consultation on Incontinence Questionnaire on Urinary
33 Incontinence-Short Form (ICIQ-UI-SF) score from 0 to 21. Sixty-one participants provided
34 outcome data. After the intervention, the ability to contract the pelvic floor muscles was
35 acquired by 36% of the experimental group and 12% of the control. The experimental
36 group also improved by a mean of 2 points more than the control group on the ICIQ-UI-
37 SF score. Authors concluded that in women who are unable to contract their pelvic floor
38 muscles voluntarily, 8 weeks of intravaginal electrical stimulation with voluntary
39 contraction attempts improved their ability to contract their pelvic floor muscles and
40 reduced the overall severity and impact of urinary incontinence on quality of life. Although
41 the main estimates of these effects indicate that the effects are large enough to be

1 worthwhile, the precision of these estimates was low, so it is not possible to confirm
2 whether the effects are trivial or worthwhile.

3
4 Zhu et al. (2022) evaluated the efficacy and safety of pelvic floor muscle training (PFMT)
5 combined with biofeedback (BF), electrical stimulation (ES) therapy, or both for
6 postpartum lower urinary tract symptoms (LUTS). Seventeen studies were included. The
7 results of the meta-analysis showed that PFMT plus ES with or without BF was more
8 effective than PFMT alone. Patients receiving PFMT plus ES and BF achieved greater
9 improvement than controls receiving PFMT alone in incontinence quality of life scores,
10 pelvic floor muscle strength, and urodynamic parameters (maximum urethral closure
11 pressure, abdominal leak point pressure, and maximum urinary flow rate), and 1-h urine
12 leakage also decreased. Authors concluded that PFMT plus ES with or without BF
13 exhibited better efficacy and safety for early postpartum LUTS than PFMT alone.

14
15 Ali et al. (2022) sought to determine the effects of nonsurgical, minimally or noninvasive
16 therapies on urge urinary incontinence (UUI) symptoms and quality of life (QoL) in
17 individuals with neurogenic bladder (NGB). Randomized controlled trials that compared
18 therapies such as intravaginal electrical stimulation (IVES), transcutaneous electrical nerve
19 stimulation (TENS), neuromuscular electrical stimulation (NMES), transcutaneous tibial
20 nerve stimulation (TTNS), pelvic floor muscle training (PFMT), and behavioural therapy
21 (BT) to control were included. Meta-analyses revealed a significant effect of electrical
22 stimulation on UUI due to multiple sclerosis and stroke. The pooled analyses of TTNS and
23 revealed significant effects of these interventions on QoL in people with Parkinson's
24 disease. However, meta-analyses revealed nonsignificant effects for PFMT and BT on UUI
25 due to Parkinson's disease. Authors concluded that their meta-analyses found electrical
26 stimulation to be beneficial for improving the symptoms of UUI among people with
27 multiple sclerosis and those with stroke. The review also revealed that TTNS and BT might
28 improve QoL for people with NGB due to Parkinson's disease, although the effects of
29 PFMT and BT on UUI warrant further investigation.

30
31 Sarmiento et al. (2022) perform an updated and comprehensive literature review focused
32 on the effects of pelvic floor electrical stimulation. Regarding the studied populations, the
33 results demonstrated heterogeneity between human and animal populations. Articles
34 comprised studies that investigated the therapeutic effects of electrical stimulation on
35 pelvic floor dysfunctions in humans, totaling 1303 participants. From these, only the
36 research performed by 25 included men in the study population, which investigated 96
37 patients with urinary incontinence post-radical prostatectomy. Authors concluded that non-
38 invasive electrical stimulation has shown promise in the clinical improvement of disorders
39 associated with pelvic floor fragility. The vast majority of studies addressed in this review
40 showed that electrostimulation improves urination control and sexual quality, in addition
41 to providing greater collagen production and maintaining the effectiveness of sphincter
42 contraction.

1 Learnardo et al. (2022) compared biofeedback-assisted pelvic muscle floor training
 2 (PFMT) and pelvic electrical stimulation (ES) as an intervention group, with PFMT or
 3 bladder training (BT) as the control group, in women with an overactive bladder (OAB) in
 4 a meta-analysis. Eight studies involving 562 patients (comprising 204 patients with
 5 biofeedback-assisted PFMT, 108 patients with pelvic ES, and 250 patients who received
 6 PFMT alone or BT and lifestyle recommendations only, as the control group) were
 7 included. The ES group showed significant differences in terms of changes to QoL,
 8 episodes of incontinence, and the number of participants cured or improved, while the
 9 biofeedback group resulted in nonsignificant changes in QoL, episodes of incontinence,
 10 and the number of participants cured or improved, both compared to the control group
 11 respectively. Authors concluded that this meta-analysis shows that low-frequency pelvic
 12 ES appears to be sufficient and effective as an additional intervention for women with OAB
 13 in clinical practice according to improvements in the subjects' QoL and reduction of
 14 symptoms. Meanwhile, biofeedback-assisted PFMT does not appear to be a significant
 15 adjuvant for conservative OAB therapy.

16
 17 Todhunter-Brown et al. (2022) summarized Cochrane Reviews that assessed the effects of
 18 conservative interventions for treating urinary incontinence (UI) in women. The common
 19 types of UI are stress (SUI), urgency (UUI) and mixed (MUI). A wide range of
 20 interventions can be delivered to reduce the symptoms of UI in women. Conservative
 21 interventions are generally recommended as the first line of treatment. Authors included
 22 reviews that compared a conservative intervention with 'control' (which included placebo,
 23 no treatment or usual care), another conservative intervention or another active, but non-
 24 conservative, intervention. They included 29 relevant Cochrane Reviews. Seven focused
 25 on physical therapies; five on education, behavioural and lifestyle advice; one on
 26 mechanical devices; one on acupuncture and one on yoga. Fourteen focused on non-
 27 conservative interventions but had a comparison with a conservative intervention. There
 28 were 112 unique trials (including 8975 women) that had primary outcome data included in
 29 at least one analysis. For UUI, (five reviews): Conservative intervention versus control:
 30 there was moderate to high-certainty evidence demonstrating that PFMT plus feedback,
 31 PFMT plus biofeedback, electrical stimulation and bladder training were more beneficial
 32 than control for curing or improving UI. Women using electrical stimulation plus PFMT
 33 had higher quality of life than women in the control group. One conservative intervention
 34 versus another conservative intervention: for cure or improvement, there was moderate
 35 certainty evidence that electrical stimulation was more effective than laseropuncture. There
 36 was high or moderate certainty evidence that PFMT resulted in higher quality of life than
 37 electrical stimulation and electrical stimulation plus PFMT resulted in better cure or
 38 improvement and higher quality of life than PFMT alone. For all types of urinary
 39 incontinence (13 reviews): Conservative intervention versus control: there was moderate
 40 to high certainty evidence of better cure or improvement with PFMT, electrical stimulation,
 41 weight loss and cones compared to control. Specific to electrical stimulation and exercise,
 42 authors concluded that there is high certainty that PFMT is more beneficial than control for

1 all types of UI for outcomes of cure or improvement and quality of life and electrical
2 stimulation is beneficial for women with UUI. Most evidence within the included Cochrane
3 Reviews is of low certainty.

4
5 Stania et al. (2022) sought to determine the therapeutic efficacy of intravaginal electrical
6 stimulation (ES) in women with SUI. Of the 686 records identified, a total of 10 articles
7 met the inclusion criteria. A meta-analysis revealed significant differences between the ES
8 and no active treatment groups in the pooled objective cure rates and subjective cure or
9 improvement rates. No significant differences were found in the pooled number of
10 incontinence episodes per 24 h, the pooled Incontinence Quality of Life Questionnaire
11 scores or the pooled number of adverse effects between the ES and other conservative
12 treatment groups. Authors concluded that there was insufficient evidence for or against the
13 use of intravaginal ES therapy for women with SUI, partly due to the variability in the
14 interventions of the included trials and the small number of trials included.

15
16 Electrical stimulation (ES) has been examined for the treatment of dysphagia. However,
17 there is currently insufficient evidence to support the effectiveness of ES in treating this
18 condition. No peer-reviewed literature was found for DPNS specifically, but rather is
19 limited to electrical stimulation, FES, or NMES. In a non-concurrent cohort study,
20 Blumenfeld et al. (2006) assessed the effectiveness of ES in treating persons with
21 dysphagia and aspiration. The charts of 40 consecutive subjects undergoing ES and 40
22 consecutive persons undergoing traditional dysphagia therapy (TDT) were reviewed. The
23 swallow severity scale improved from 0.50 to 1.48 in the TDT group ($p < 0.05$) and from
24 0.28 to 3.23 in the ES group ($p < 0.001$). After adjusting for potential confounding factors,
25 persons receiving ES did significantly better in regard to improvement in their swallowing
26 function than persons receiving TDT ($p = 0.003$). The authors concluded that the findings
27 suggested that dysphagia therapy with transcutaneous ES is superior to traditional
28 dysphagia therapy alone in individuals in a long-term acute care facility. They also stated
29 that confirmation of these findings with a prospective, placebo-controlled, randomized
30 clinical trial is needed before a definitive determination regarding the effectiveness of ES
31 dysphagia therapy can be made. Kiger et al. (2006) compared the outcomes using
32 transcutaneous neuromuscular electrical stimulation (VitalStim[®] therapy) to outcomes
33 using traditional swallowing therapy for deglutition disorders. A total of 22 patients had an
34 initial and a follow-up video-fluoroscopic swallowing study or fiberoptic endoscopic
35 evaluation of swallowing and were divided into an experimental group that received
36 VitalStim[®] treatments and a control group that received traditional swallowing therapy.
37 Outcomes were analyzed for changes in oral and pharyngeal phase dysphagia severity,
38 dietary consistency restrictions, and progression from non-oral to oral intake. Results of
39 chi-square analysis showed no statistically significant difference in outcomes between the
40 experimental and control groups.

1 Huckabee and Doeltgen (2007) reviewed NMES as an emerging modality in an attempt to
2 advise the New Zealand medical community about the application of it as a treatment for
3 pharyngeal swallowing impairment (dysphagia). Authors conclude that there are potential
4 benefits of the use of this treatment but key concerns for patient safety and long-term
5 outcomes exist. Shaw et al. (2007) sought to evaluate the effectiveness of VitalStim®
6 therapy in a heterogeneous group of dysphagic patients. They performed a retrospective
7 analysis of 18 patients who received this therapy at an urban tertiary referral center. All
8 patients underwent pre-therapy evaluation by speech-language pathologists, including
9 modified barium swallow and/or functional endoscopic evaluation of swallowing and
10 clinical evaluation of swallowing that included assessment of laryngeal elevation, diet
11 tolerance, and swallowing delay, and were then assigned an overall dysphagia severity
12 score. After therapy, all patients underwent the same assessments. Twelve of the 18 also
13 underwent a functional swallowing telephone survey months (range, 1 to 21 months) after
14 their therapy to assess whether the improvement was worthwhile and sustained. Eleven of
15 the 18 patients (61%) demonstrated some improvement in their swallowing. Six of the 18
16 patients (33%) were improved enough to no longer require a feeding tube. However, of the
17 5 patients categorized as having “severe dysphagia” before therapy, only 2 showed any
18 improvement, and these patients still required a feeding tube for adequate nutrition.
19 Telephone surveys did confirm that those who improved with their therapy seemed to
20 maintain their progress and that most patients were satisfied with their therapy. Authors
21 concluded that VitalStim therapy seems to help those with mild to moderate dysphagia.
22 However, the patients with the most severe dysphagia in the study did not gain
23 independence from their feeding tubes but could potential help those with mild to moderate
24 dysphagia. Carnaby-Mann and Crary (2007) examined the evidence on neuromuscular
25 electrical stimulation for swallowing rehabilitation. A total of 81 studies were reviewed.
26 Seven were accepted for analysis. A significant summary effect size was identified for the
27 application of NMES for swallowing. Best-evidence synthesis showed indicative findings
28 in favor of NMES for swallowing. The analysis revealed a small but significant summary
29 effect size for NMES for swallowing. Because of the small number of studies and low
30 methodological grading for these studies, caution should be taken in interpreting this
31 finding. These results support the need for more rigorous research in this area. This is in
32 agreement with the observation of Steele et al (2007) who noted that although ES
33 approaches to the restoration and rehabilitation of swallowing is an exciting area of
34 research which holds promise for future clinically relevant technology and/or therapy,
35 implementation of ES in clinical swallowing rehabilitation settings still remains pre-
36 mature.

37
38 Clark et al. (2009) systematically reviewed the literature examining the effects of NMES
39 on swallowing and neural activation. The review was conducted as part of a series
40 examining the effects of oral motor exercises (OMEs) on speech, swallowing, and neural
41 activation. Out of 899 citations initially identified for the broad review of OMEs, 14 articles
42 relating to NMES qualified for inclusion. Most of the studies (10/14) were considered

1 exploratory research, and many had significant methodological limitations. Authors
2 concluded that the review revealed that surface NMES to the neck has been most
3 extensively studied with promising findings, yet high-quality controlled trials are needed
4 to provide evidence of efficacy. Surface NMES to the palate, faucial pillars, and pharynx
5 has been explored in Phase I research, but no evidence of efficacy is currently available.
6 Intramuscular NMES has been investigated in a single Phase I exploratory study.
7 Additional research is needed to document the effects of such protocols on swallowing
8 performance. Christiaanse et al. (2011) compared the change in swallowing function in
9 pediatric patients with dysphagia who received neuromuscular electrical stimulation
10 (NMES) to a control group who received usual oral motor training and dietary
11 manipulations without NMES. Children were classified into two groups based on the
12 etiology of their dysphagia (primary vs. acquired). Only the treatment group who had
13 acquired dysphagia improved more than the similar subgroup of control children. Authors
14 concluded that NMES treatment of anterior neck muscles in a heterogeneous group of
15 pediatric patients with dysphagia did not improve the swallow function more than that seen
16 in patients who did not receive NMES treatment. However, there may be subgroups of
17 children that will improve with NMES treatment. Geeganage et al. (2012) assessed the
18 effectiveness of interventions for the treatment of dysphagia and nutritional and fluid
19 supplementation in patients with acute and subacute stroke. Authors included 33 studies
20 involving 6779 participants. Swallowing therapies included the following: acupuncture,
21 drug therapy, neuromuscular electrical stimulation, pharyngeal electrical stimulation,
22 physical stimulation (thermal, tactile), transcranial direct current stimulation, and
23 transcranial magnetic stimulation. Authors conclude that there remains insufficient data on
24 the effect of swallowing therapy, feeding, and nutritional and fluid supplementation on
25 functional outcome and death in dysphagic patients with acute or subacute stroke.
26 Behavioural interventions and acupuncture reduced dysphagia, and pharyngeal electrical
27 stimulation reduced pharyngeal transit time.

28
29 Tan et al. (2013) assessed the overall efficacy by comparing the two treatment protocols in
30 a meta-analysis. Studies that compared the efficacy of treatment and clinical outcomes of
31 NMES versus traditional treatment (TT) in dysphagia rehabilitation were assessed. Seven
32 studies were eligible for inclusion, including 291 patients, 175 of whom received NMES
33 and 116 of whom received TT. Of the seven studies, there were two randomized controlled
34 trials, one multicentre randomized controlled trial and four clinical controlled trials. The
35 change scores on the Swallowing Function Scale of patients with dysphagia treated with
36 NMES were significantly higher compared with patients treated with TT. However,
37 subgroup analysis according to etiology showed that there were no differences between
38 NMES and TT in dysphagia post-stroke. No studies reported complications of NMES.
39 Authors concluded that NMES is more effective for treatment of adult dysphagia patients
40 of variable etiologies than TT. However, in patients with dysphagia post-stroke, the
41 effectiveness was comparable. Miller et al (2014) performed a systematic review of the
42 literature on the use of neuromuscular electrostimulation (NMES) in otorhinolaryngology

1 that have been published in German or English. The search identified 180 studies. These
2 were evaluated and relevant studies were included in the further evaluation. The authors
3 concluded that the evidence collected to date is encouraging; particularly for the treatment
4 of certain forms of dysphagia and laryngeal paresis. Terré and Mearin (2015) evaluated the
5 effectiveness of neuromuscular electrical stimulation (NMES) treatment in patients with
6 oropharyngeal dysphagia secondary to acquired brain injury. Twenty patients with
7 neurological oropharyngeal dysphagia (14 stroke and six severe traumatic brain injury)
8 were enrolled in a prospective randomized study, with patients and assessors blinded (to
9 group allocation): 10 patients underwent NMES, and conventional swallowing therapy and
10 10 patients underwent sham electrical stimulation (SES) and conventional swallowing
11 therapy. Both groups completed 20 sessions. Feeding swallowing capacity was evaluated
12 using the functional oral intake scale (FOIS). After treatment, the NMES group increased
13 by 2.6 points (4.5 points) compared with only 1 point (3.1 points) for the SES group. At 3
14 months of follow-up, mean scores were 5.3 and 4.6 respectively; thus, both groups
15 improved similarly. At that time point (3 months), tracheal aspiration persisted in six
16 patients in each group. However, a significant improvement in relation to the bolus
17 viscosity at which aspiration appeared was found in the NMES group versus the SES group.
18 Also, a significant increase in pharyngeal amplitude contraction was observed at the end
19 of treatment (1 month) in the NMES group compared with the SES group. Authors
20 concluded that NMES significantly accelerated swallowing function improvement in
21 patients with oropharyngeal dysphagia secondary to acquired brain injury.

22
23 Chen et al. (2016) evaluated whether swallow treatment with neuromuscular electrical
24 stimulation is superior to that without neuromuscular electrical stimulation, and whether
25 neuromuscular electrical stimulation alone is superior to swallow therapy. Eight studies
26 were identified. Authors concluded that swallow treatment with neuromuscular electrical
27 stimulation seems to be more effective than that without neuromuscular electrical
28 stimulation for post-stroke dysphagia in the short-term considering the limited number of
29 studies available. Evidence was insufficient to indicate that neuromuscular electrical
30 stimulation alone was superior to swallow therapy. Alamer et al. (2020) summarized the
31 latest best scientific evidence on the efficacy of neuromuscular electrical stimulation on
32 swallowing function in dysphagic stroke patients. Evidence of overall quality was graded
33 from moderate to high. Eleven RCTs involving 784 patients were analyzed. The primary
34 outcome measures of this review were functional dysphagia scale (FDS) and standard
35 swallowing assessment. This review found neuromuscular electrical stimulation (NMES)
36 coupled with traditional swallowing therapy could be an optional intervention to improve
37 swallowing function after stroke in rehabilitation department.

38
39 Liang et al. (2021) explored the clinical efficacy of VitalStim electrical stimulation
40 combined with swallowing function training for patients with dysphagia following an acute
41 stroke. Seventy-two patients with dysphagia following an acute stroke were admitted to the
42 hospital and were further divided into two groups using prospective research methods.

1 There were 36 cases in each group according to the random number table method. The
2 control group received conventional medical treatment and swallowing function training
3 while the experimental group received conventional medical treatment and VitalStim
4 electrical stimulation combined with swallowing function training. The overall response
5 rate of the experimental group (94.44%) was higher than that of the control group
6 (77.78%), and the difference was statistically significant. Compared with before treatment,
7 the upward and forward movement speeds of the hyoid bone, anterior movement speed,
8 the grading score of the Kubota drinking water test, Caiteng's grading score, serum
9 superoxide dismutase, 5-hydroxytryptamine, and norepinephrine levels, Fugl-Meyer
10 Assessment score, and multiple quality of life scores of the two groups showed
11 improvement after treatment. While the standard swallowing assessment score, serum
12 malondialdehyde level, and National Institutes of Health Stroke Scale score decreased, the
13 aforementioned indices showed a significant improvement in the experimental group.
14 Authors concluded that the results of this study indicate that VitalStim electrical
15 stimulation combined with swallowing function is effective for treating dysphagia
16 following an acute stroke. It can effectively improve swallowing, neurological, and limb
17 motor functions, reduce complications, promote physical recovery, and improve overall
18 quality of life of patients.

19
20 Miller et al. (2022) evaluated recent studies regarding a potential effectiveness of
21 transcutaneous NMES applied to the anterior neck as a treatment for dysphagia. Eighteen
22 studies were identified with varying patient groups, stimulation protocols, electrode
23 placement and therapy settings. However, 16 studies have reported of beneficial outcomes
24 in relation with NMES. It could generally be concluded that there is a considerable amount
25 of level 2 studies which suggest that NMES is an effective treatment option, especially
26 when combined with traditional dysphagia therapy for patients with dysphagia after stroke
27 and patients with Parkinson's disease, or with different kinds of brain injuries. Further
28 research is still necessary in order to clarify which stimulation protocols, parameters and
29 therapy settings are most beneficial for certain patient groups and degrees of impairment.

30
31 Literature does not support the use of NMES for the treatment of heart failure (Arena et
32 al., 2010) conducted a systematic review of the literature to evaluate the evidence
33 supporting NMES and inspiratory muscle training (IMT) for the treatment of systolic heart
34 failure. Thirteen NMES studies met inclusion criteria, ten were randomized controlled
35 trials. Although the studies reported improvement in aerobic capacity, peak oxygen uptake
36 and strength and endurance of muscle groups, the studies were limited by patient
37 population (i.e., mostly males), diverse NMES training protocols, variation in the type of
38 muscle contraction elicited (i.e., titanic vs. twitch), the use of different muscle groups and
39 different comparators. The percent improvement in peak oxygen uptake was consistently
40 greater with conventional therapy (i.e., bicycle/treadmill). Sillen et al. (2009) conducted a
41 systematic review of randomized controlled trials to analyze the role of NMES in strength,
42 exercise capacity, and disease-specific health status in patients with congestive heart failure

1 ($n=9$ studies) and chronic obstructive pulmonary disease ($n=5$ studies) with disabling
 2 dyspnea, fatigue, and exercise intolerance. The limited number of studies, heterogeneous
 3 patient populations and variability in NMES methodology prohibited the use of meta-
 4 analysis. Although some of the studies reported significant improvements with NMES
 5 compared to no exercise or usual care, outcomes, including adverse events, were
 6 conflicting. Additional studies are indicated to provide sufficient evidence to establish the
 7 clinical utility of NMES in this patient population.

9 **PRACTITIONER SCOPE AND TRAINING**

10 Practitioners should practice only in the areas in which they are competent based on their
 11 education, training and experience. Levels of education, experience, and proficiency may
 12 vary among individual practitioners. It is ethically and legally incumbent on a practitioner
 13 to determine where they have the knowledge and skills necessary to perform such services
 14 and whether the services are within their scope of practice.

15
 16 It is best practice for the practitioner to appropriately render services to a member only if
 17 they are trained, equally skilled, and adequately competent to deliver a service compared
 18 to others trained to perform the same procedure. If the service would be most competently
 19 delivered by another health care practitioner who has more skill and training, it would be
 20 best practice to refer the member to the more expert practitioner.

21
 22 Best practice can be defined as a clinical, scientific, or professional technique, method, or
 23 process that is typically evidence-based and consensus driven and is recognized by a
 24 majority of professionals in a particular field as more effective at delivering a particular
 25 outcome than any other practice (Joint Commission International Accreditation Standards
 26 for Hospitals, 2013).

27
 28 Depending on the practitioner’s scope of practice, training, and experience, a member’s
 29 condition and/or symptoms during examination or the course of treatment may indicate the
 30 need for referral to another practitioner or even emergency care. In such cases it is prudent
 31 for the practitioner to refer the member for appropriate co-management (e.g., to their
 32 primary care physician) or if immediate emergency care is warranted, to contact 911 as
 33 appropriate. See policy *Managing Medical Emergencies (CPG 159 – S)* for information.

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