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GOOD PRACTICE STATEMENT

Safety and best practice in neuromuscular electrical stimulation for pelvic floor muscle dysfunction

Introduction

This statement is based on a synthesis of the best available evidence, and the clinical knowledge of experienced healthcare professionals. It will be subject to periodic review as the evidence base evolves. This statement offers guidance, and should not be regarded as prescriptive; such advice will always require to be modified in accordance with the needs of the individual patient, and the clinician's skills and knowledge.

The aim of this statement is to outline best practice and safety considerations for clinician-led neuromuscular electrical stimulation (NMES) for adult male and female pelvic floor muscle (PFM) dysfunction. It includes the use of vaginal and anal electrodes, and also portable, battery-powered NMES devices and mains-powered machines. Indwelling and implanted electrodes, and percutaneous posterior tibial nerve stimulation (PTNS), transcutaneous electrical nerve stimulation (TENS) and magnetic electrical stimulation for pelvic floor dysfunction are not covered in this statement. The document provides short summaries of the evidence for the use of NMES when the desired physiological outcome is muscle strengthening or neuromodulation in people with symptoms of stress urinary incontinence (SUI), overactive bladder (OAB) and/or faecal incontinence (FI). Most of the data cited in this statement are derived from clinical trials involving female participants; there have been very few studies of NMES for men. Recommendations on how to achieve optimal results and safe practice are made.

Background

The International Continence Society defines urinary incontinence (UI) as the "[c]omplaint of involuntary loss of urine" (Haylen *et al.* 2010, p. 6; D'Ancona *et al.* 2019, p. 436). Faecal incontinence is the "involuntary loss of flatus, liquid or stool that is a social or hygiene problem" that has lasted for at least 1 month (Chatoor *et al.* 2007, p. 134; D'Ancona *et al.* 2019). Both of these symptoms of dysfunction are typically caused by damage to the nerve supply to the PFMs leading to weakness, or trauma to the muscular structures and fascia of the pelvic floor. This may adversely affect urethral and anal sphincter support, and muscle contraction. The National Institute for Health and Care Excellence (NICE) has recommended pelvic floor muscle training (PFMT) as the first-line treatment in the management of UI and female pelvic organ prolapse (NICE 2019). This approach has been demonstrated to improve the strength and efficacy of PFM contractions (Jha *et al.* 2018). It has been suggested that PFMT is also suitable in the management of FI (Woodley *et al.* 2017).

In this statement, NMES refers to therapy that applies a low- to medium-frequency electrical current to the motor fibres of the pudendal nerve and sacral nerve roots of the PFMs. When a neuromuscular unit is stimulated, electrical signals travel towards the peripheral and central nervous systems, which may be used to induce a desired clinical response based on the stimulation parameters. The clinical response may be a muscle contraction or a change in the sensation perceived (Nussbaum *et al.* 2017; Stewart *et al.* 2017). Several studies of NMES as an adjunctive treatment for pelvic floor dysfunction have been published, but the optimal stimulation parameters for PFM rehabilitation have not yet been established because of considerable variations in the methodologies of these studies. The primary objectives of NMES are to increase muscle strength, inhibit reflex bladder contractions, modify PFM vascularity and improve continence (Fall & Lindström 1991; Berghmans *et al.* 2002; Brown & Sharples 2014; Jha *et al.* 2018). A critical review of the application of NMES in musculoskeletal conditions suggested that NMES can improve collagen regeneration (Nussbaum *et al.* 2017).

Specialist physiotherapists use clinical reasoning to interpret the objective findings of a vaginal or rectal examination in the context of the

patient's symptoms and preferred goals of treatment. If an appropriate active voluntary contraction is present, then PFMT can commence. In patients with a weak or absent voluntary PFM contraction, NMES may be required as an adjunctive therapy to strengthen or activate it. Significant PFM weakness often results in patients having little sensation of a voluntary PFM contraction, and one of the objectives of using NMES is to improve their awareness of this. It should be noted that NICE (2019) recommends that NMES is not routinely used in combination with PFMT; however, it should be considered for patients who are unable to actively contract their PFMs in order to provide them with motivation and encourage adherence to therapy. Depending on an individual's dysfunction, NMES can be an appropriate form of exercise with or without patient participation.

Stimulation parameters

Frequency of stimulation

Frequency refers to the number of electrical pulses produced in 1 s during stimulation, and this is measured in hertz (Hz). The frequency of stimulation influences the type of muscle contraction, and the force of the motor response produced in the tissues. In order to avoid fatigue or discomfort, this should be adjusted to meet the desired treatment goals and/or to the patient's level of tolerance:

- (< 20 Hz) muscle twitches, tremors or a tapping sensation are perceived by the patient; and
- (20–50 Hz) a fused tetanic muscle contraction occurs that produces movement.

Studies have been conducted on physiological responses to different levels of stimulation frequency, and the consensus is that low-frequency NMES (≤ 10 Hz) is effective in producing benefits for detrusor overactivity (OAB), whereas a higher frequency (35–50 Hz) is required to elicit an involuntary muscle contraction in order to strengthen very weak PFMs.

Pulse duration

The time span during which a single electrical pulse is active is known as the pulse duration. This is measured in milliseconds (ms) or microseconds (μs). In order to depolarize a tissue membrane, an electrical pulse needs to be applied for a sufficient period of time at an adequate intensity. Many NMES units have an adjustable pulse duration range of 50–450 μs. It should be noted that the pulse duration range of 200–250 μs is likely to produce the most comfortable sensation during treatment, which will allow the patient to tolerate sufficient intensity for a therapeutic effect. The pulse duration has an inverse relationship with the stimulation intensity, which means that the shorter the pulse duration, the higher the current intensity required to excite the muscle tissue membrane.

Stimulation intensity or amplitude

The current intensity, which is also referred to as current amplitude, is the flow of charged particles over a specific period of time (≥ 1 s). The current intensity can also be described as the size of the stimulus, and this is measured in milliamperes (mA). When the current intensity is of adequate strength, it will lead to cell membrane excitation and the generation of an action potential. The numerical value of stimulation intensity varies between patients, and this should be set according to each individual's level of comfort. In practice, it is advisable to increase the intensity gradually. Initially, the patient may report a sensory stimulation, but the intensity may still be too low to elicit a muscle contraction. Continue to increase the current until there is a visible and/or palpable muscle contraction, and ensure that the patient is comfortable throughout. Emphasize that higher intensity is not necessarily better; rather, the objective is to find the optimal dose that produces a muscle contraction.

Duty cycle (on:off ratio)

The duty cycle is the period of time over which the stimulation is actively on and off, and is expressed as a ratio. This is also referred to as "work/rest" ratio. Following an internal digital assessment, the strength and endurance of the muscle being stimulated should be taken into consideration when setting the duty cycle. The order of motor unit recruitment elicited by NMES is not the same as voluntary muscle contraction, and in order to minimize fatigue and maintain the quality of muscle contraction during stimulation, a rest period should be included to enable complete relaxation between contractions (Doucet *et al.* 2012). The minimum stimulation (on:off) ratio for active muscle contraction is 1:2.

Ramp up and ramp down

Ramp up refers to the period of time taken for stimulating current intensity to rise from zero to maximum strength. Conversely, ramp down

refers to the time taken for this to fall from maximum intensity to zero. A gradual increase (ramp up) in stimulating current strength is more comfortable and tolerable for some patients. Some stimulation devices may include the ramp time as part of the total "on/work" phase of the duty cycle. There is no research base to support optimal ramp timings, but these are often set between 0.5 and 2 s.

Waveform

The waveform is a descriptive term that is used to denote the schematic or visual representation of how current pulses vary with time. Waveform properties are described as:

- the number of phases in a waveform (e.g. monophasic, biphasic or polyphasic);
- the symmetry of the phases (e.g. symmetric or asymmetric);
- the balance of the phase change (e.g. balanced or unbalanced); and
- the shape of the waveform (e.g. rectangular, square, triangular or spiked).

In the application of NMES, symmetrical or asymmetrical biphasic waveforms have no heating effect on tissues, and therefore, pose the least risk of causing a skin reaction (Robinson & Snyder-Mackler 2008).

Neuromuscular electrical stimulation for incontinence

Stress urinary incontinence

The proposed primary objectives of using NMES in the management of people with SUI are to: increase PFM strength; reinforce structural support of the urethra and bladder neck; and increase sensory feedback in weak PFMs (Sand *et al.* 1995; Yamanishi *et al.* 1997; Li *et al.* 2020). It has also been suggested that, via the application of internal or external surface electrodes, NMES contracts the PFMs directly, which strengthens the muscles and can improve collagen regeneration (Brown & Sharples 2014; Nussbaum *et al.* 2017; Jha *et al.* 2018).

Many randomized trials have been published on the use of NMES in the treatment of SUI; however, optimal stimulation parameters and treatment protocols have not yet been established. A systematic review by Stewart *et al.* (2017) assessed 56 studies of the role of NMES in the treatment of SUI. These authors reported that the evidence was of low quality and inadequate, and no firm conclusions could be made about the impact of NMES on quality of life (QoL) and rates of cure. Furthermore, Stewart *et al.* (2017) could not draw any conclusions about whether NMES adds additional benefit to PFMT, but they did find that it was better than no active treatment or a sham intervention.

Overactive bladder

The theoretical and physiological basis of how NMES works in the management of people with OAB symptoms remains unclear. The proposed mechanism of action is neuromodulation, which involves applying a variety of stimulation parameters via an intravaginal or intra-anal probe. Reflex inhibition of the detrusor muscle via sensory-level stimulation of pudendal nerve afferent fibres subsequently inhibits detrusor contraction and decreases the frequency of micturition (Jezernik *et al.* 2002; Van Balken *et al.* 2004; Abdelbary *et al.* 2015; Lucas *et al.* 2015; Zhu *et al.* 2016).

A Cochrane Review by Stewart *et al.* (2016) concluded that there was moderate-quality evidence to suggest that electrical stimulation with non-implanted electrodes is more effective than no active treatment, placebo or sham treatment in improving OAB symptoms. Despite this result, there was no conclusion drawn about the optimal stimulation parameters for the treatment of OAB. However, the most recent European guidelines on UI (Lucas *et al.* 2015) state that NMES is as effective as PFMT in the conservative management of mixed UI and SUI.

Faecal incontinence

Numerous trials investigating electrical stimulation in FI employ a combined approach to treatment, and this most frequently involves biofeedback. If the symptoms of FI are a result of a weak anal sphincter, the primary objective is to strengthen the external anal sphincter muscle. Four trials examining the use of NMES in FI were reviewed by Hosker *et al.* (2007). This Cochrane Review determined that there was a suggestion of therapeutic benefit, but insufficient data were available to allow consistent conclusions to be drawn about the efficacy of NMES in the management of FI. A systematic review by Vonthein *et al.* (2013) identified three high-quality trials. Although efficacy was not demonstrated, these authors reported that there is a risk of causing pain and local tissue damage around stimulation site with low-frequency NMES. Vonthein *et al.* (2013) determined that there was sufficient evidence for the efficacy

and safety of combined NMES and biofeedback in the treatment of FI.

In conclusion, studies of NMES in the management of people with symptoms of SUI, OAB and FI are considered to be of low to moderate quality, with poor comparability and a great deal of variability in terms of stimulation parameters, treatment regimens and outcome measures. The modes of delivery of NMES via non-implanted electrodes also vary considerably, and researchers often combine these with other forms of conservative therapy (e.g. PFMT and biofeedback). The available evidence does point towards some benefits associated with individual patient assessment of pelvic floor dysfunction, good clinical reasoning and treatment prescription for a specific patient's needs. Expert opinion suggests that the absence of a voluntary PFM contraction or the presence of a poor contraction [Modified Oxford Scale (MOS) grade < 2], or detrusor overactivity resulting in symptoms of bladder urgency, frequency or nocturia, are recognized indicators for the selection of NMES as a treatment modality.

Although no specific evidence was found for the role of electrical stimulation in the management of women with pelvic organ prolapse (POP), it could be argued that NMES may be beneficial if significant weakness of the PFMs is present.

Clinical application

It is vital that each NMES intervention is based on an individual patient's subjective symptoms, an objective assessment, and a review of the relevant precautions and contraindications (Table 1). Thorough clinical reasoning that takes the assessment of the pelvic floor muscle function into consideration is required for best-practice management of all patients. Although many NMES devices come with preset options to treat specific diagnoses or symptoms (e.g. SUI and urgency UI), it is essential to clinically reason the optimal parameters for each individual patient in order to achieve the best results.

Contraindications and precautions

There is a lack of reliable evidence and poor consensus about the specific contraindications and precautions for NMES when using intravaginal and intra-anal probes. Side effects that have been reported during trials include vaginal irritation, infection and bleeding, urethral pain, and urinary tract infections (Stewart *et al.* 2017). These reactions are usually attributable to the known physiological effects of NMES, and are reversible. The summary of recommendations (Table 1) is based on published general guidelines on contraindications and precautions in the application of NMES (Houghton *et al.* 2010; Watson & Nussbaum 2020).

In the absence of any clear and substantive evidence of efficacy, it is recommended that clinicians should consider all options for a specific patient, and clinically reason whether NMES is the most suitable treatment for that individual. In complex cases, it is recommended that the physiotherapist consults with the wider multidisciplinary team for that individual patient. It is essential that clinicians refer to the manufacturer's instructions for use for the device being considered. When NMES is applied externally using a crossfire technique, there are different contraindications with regard to metal implants in the field of stimulation. This will not be discussed in this statement, and it is suggested that clinicians should refer to the literature for further guidance.

Clinical documentation

Table 2 provides guidance on how to document the stimulation parameters used in treatment. This guidance has been complied on the basis of the terminology report published by the International Urogynecological Association and International Continence Society (Bø *et al.* 2017), and a recent article on how to report electrotherapeutic parameters in pelvic health rehabilitation (Barbosa *et al.* 2018). Accurate clinical documentation is an essential component of good clinical practice, and will facilitate better reproducibly of the clinical methods used in NMES for pelvic floor dysfunction.

Frequently asked questions

Can I use NMES in the presence of an intrauterine contraceptive device?

With a biphasic waveform current, there is no heating effect. Therefore, NMES can be used in the presence of an *in situ* intrauterine contraceptive device such as a coil (e.g. Mirena, Bayer AG, Leverkusen, Germany).

Can I use NMES in the presence of a metal implant such as a hip or knee replacement?

As mentioned above, a biphasic current has no heating effect, which means that NMES may be used in the presence of local joint replacements.

Table 1. Contraindications and precautions for neuromuscular electrical stimulation (NMES)

Contraindications and precautions	Rationale
Contraindications	
No valid consent	If valid consent is not obtained, the clinician should not proceed with the treatment
Implanted cardiac pacemaker	Stimulation may cause an implanted cardiac device to malfunction, but NMES may be used with other types of implanted pacemakers (see below)
Pregnancy/actively trying to conceive (i.e. may be pregnant)	Pelvic floor muscle contractions could result in the release of endorphins, which may lead to unwanted uterine contractions, and potentially, to miscarriage or premature labour in the first and third trimesters (the effect of NMES on foetal development is unclear; however, because the potential effects of an adverse reaction could be devastating, it is advisable not to use it); women of childbearing age should be counselled that they should stop treatment immediately if they become pregnant while using NMES
Recent trauma or haematoma in the area (e.g. immediately postpartum)	Stimulation promotes regional blood flow, causes the release of inflammatory mediators and vasoactive substances, and reduces platelet aggregation, which could cause bleeding
Less than 12 weeks after childbirth, or surgery in the perineal, pelvic or abdominal area	Forceful muscle contraction could disturb the incision site; an increase in local blood flow may provoke bleeding, exacerbate inflammation or heighten the risk of local infection; electrically induced contractions in denervated muscle may adversely affect the reinnervation process by altering the neurotransmitter
Active malignancy in the pelvic or abdominal area that is currently being treated	Stimulation may stimulate the growth and promote the spread of cancer cells
Abnormal recent smear test*	There is uncertainty about the level of risk associated with NMES; therefore, this modality should be delayed until a patient has been treated and returned to routine cervical cytology screening, and the most-recent screening result is negative
Broken skin in the area where the electrode is to be placed (e.g. anal hypersensitivity, or anal fissure or fistula)	Skin damage causes uneven current flow under the electrodes, increasing the risk of sensory disturbance; treatment can be reconsidered when the tissues have healed
Atrophic vaginitis	This depends on the severity of the condition, and should be treated before commencing NMES
Excessive, unexplained vaginal or anal bleeding, undiagnosed severe pain, swollen/bleeding haemorrhoids or fistula, or peripheral vascular disease	Stimulation is likely to cause an increase in local blood flow, and therefore, may provoke bleeding, increase inflammation or elevate the risk of local infection (N.B. If irritation and bleeding occur following use, discontinue NMES and seek medical advice)
Precautions	
Lack of physical competence with the device	The patient must be able to apply the device correctly, and have the manual dexterity to insert a vaginal or anal probe; this is important if the patient is to use a unit independently at home
Non-cardiac pacemaker (e.g. sacral nerve stimulator)	Stimulation may interfere with the functionality of a pacemaker; discuss treatment with the patient's multidisciplinary team, who may be able to temporarily turn off the pacemaker
Allergic reaction to electrode materials or gel	In particular, ensure that the patient has no known nickel allergy; most standard electrodes are made of stainless steel, which contains this alloy (gold-plated electrodes are now widely available and should be sourced, if required)
Severe pelvic organ prolapse	This condition may prevent the correct positioning and retention of an electrode, which would reduce the likelihood of a significant clinical change in muscle strength
Vaginal pessary	Such devices may adversely affect the positioning of an electrode (if a patient is self-managing a pessary, ask her to remove it prior to treatment)
Recently irradiated tissues (in previous 6 months)	Recently irradiated tissues may respond atypically because of the presence of radiation-induced inflammation or scar tissue, and/or the cellular or circulatory effects of radiation therapy (seek advice from an oncologist)
Scar tissue	Scars have increased electrical resistance, and therefore, the current may travel around the fibrous tissue; greater density at the edges may cause pain or sensitivity (increase the current intensity slowly while gaining feedback from the patient); in women with vaginal scarring or reduced vaginal capacity, consider using a smaller size of electrode
Haemophilia or blood-clotting disorders	It is necessary to ensure that the patient's condition is being controlled with medication; stress careful application of internal electrodes in order to avoid skin damage

Continued/

Table 1. (*Continued*)

Contraindications and precautions	Rationale
Epilepsy	Consult with an appropriate medical practitioner to find out if the patient is a stable epileptic; there is an unquantifiable theoretical risk that using NMES could trigger an epileptic fit
Diabetes	Assess sensation, and the degree to which neurological function is or is not affected
Sexual abuse	Advise the patient that the application of the internal electrode or the sensation of the stimulation may give her a flashback or cause distress
Menstruation	Patient choice dictates whether the treatment session should be continued, and this may depend on the level of bleeding (e.g. heavy versus light spotting); ensure that valid consent to proceed is given, if applicable, or postpone the intervention if the patient is not comfortable
Within 1 m of a transmitting mobile phone or two-way radio, or 3 m of high-energy electromagnetic radiation (e.g. diathermy units or welding/cutting equipment)	Proximity may cause NMES equipment to malfunction

*The POGP good practice statement (GPS) on the use of electrical stimulation of the pelvic floor muscles in women with recent abnormal cervical cytology (POGP 2016) is due for review. That update will be incorporated into the first review of the present GPS.

Table 2. Documentation of the treatment aims and stimulation parameters of intravaginal or intra-anal neuromuscular electrical stimulation (NMES) for pelvic floor dysfunction: (Hz) hertz; (ms) milliseconds; (μs) microseconds; and (mA) milliamperes

Aims and parameters	Description
Aims of treatment	Improve sensation (sensory-level stimulation) Improve reflex inhibition of the detrusor muscle (neuromodulation) Improve voluntary muscle contraction (motor-level stimulation)
Client position	Supine crook-lying is a common position; document any others used
Stimulation frequency	Magnitude of pulse frequency (Hz)
Pulse duration	Magnitude of pulse duration (ms or μs)
Current intensity	Magnitude (mA) Sensory-level stimulation is the sensation of electrical pulses reported by the patient Motor-level stimulation is indicated by indrawing of the perineum or anal wink
Duty cycle	Documented in the ratio of the on:off time of stimulation
Duration of treatment	Time of a single treatment episode (min)
Frequency of treatment	How often NMES should applied in a day over a 1-week period
Current polarity/waveforms	Monophasic or biphasic Describe the geometric shape of the pulse (e.g. rectangular or square) Symmetrical or asymmetrical Pulsed or continuous current Reciprocal or synchronous stimulation
Electrode	Document the brand of the electrode Intravaginal or intra-anal application Single or dual channel
Client's adherence to treatment	Some NMES units have a lock button to monitor how many times clients use their units as prescribed
Duration of treatment sessions	The whole duration of treatment episodes (weeks or months)

Can I use NMES in the presence of a mesh implant?

There should not be any issue with the fact that a patient has undergone surgery involving mesh unless there are complications or changes to the vaginal wall. For example, if the mesh has eroded through the vagina, the tissue impedance will be different in the scar tissue, as compared to the endovaginal mucosa, which may mean that the stimulation is intensified on the scar tissue. This could become uncomfortable.

How many sessions of NMES are needed?

The number of sessions should be determined by the clinician on the basis of an individual patient assessment. Subjective reporting of symptoms, QoL, objective examination and clinically significant change ought to be considered. Clinical reasoning should suggest continuing the treatment, with relevant progression, or perhaps, adopting a different approach as required. The patient may need to use a portable home unit if there is limited access to the clinic. The

suggested frequency of treatment sessions varies widely from daily use to three times a week, with each treatment lasting from 10 to 30 min in duration.

How long should each session be?

Patient tolerance to treatment and comfort, and the clinical reasoning for the optimal dose needed to achieve change should all be considered following assessment of the PFMs.

What is the optimal position for a patient?

A patient should be comfortable, and able to retain the electrode in any given position. It can be helpful to adapt the position of a patient in order to improve awareness of the muscle response to the NMES. Common postures used in a clinical setting are the crook- or side-lying positions. In a patient with mild or moderate POP, certain postures may allow for better positioning and retention of vaginal electrodes. A change in position may be used as a method of progressing the load in PFMT.

Can NMES be used with vaginal moisturizers, lubricants and topical oestrogen?

The use of a water-based lubricant gel allows for the transmission of energy via NMES. It also makes electrode insertion more comfortable for the patient. The use of vaginal moisturizers, topical oestrogen or other lubricants by the patient should have no adverse effect on the treatment, and in fact, may make it more comfortable.

Practice points

In summary, before using NMES as an adjunctive treatment in pelvic floor rehabilitation, the following points should be addressed:

- Complete a thorough subjective and objective assessment for each individual patient. This must include a digital vaginal or anorectal examination if intravaginal or intra-anal NMES is being considered.
- Apply clinical reasoning to identify the indications for NMES.
- Screen for any contraindications, potential risks or specific considerations, as guided by clinical reasoning and good practice.
- Discuss any specific considerations with your patients, and if required, ask their permission to confer with their consultant or general practitioner, or other members of the wider multidisciplinary team.
- Clinically reason the best options for each individual and the symptoms reported, including the duration of each session and the optimal position for the patient.
- Clearly document the stimulation parameters and other appropriate information in your clinical notes.
- Patients who are loaned NMES units should be fully instructed on how to use these devices. It is advisable to give patients written instructions, and document these in your clinical records.
- Reassess the patient at each session, and progress your clinical reasoning to ensure that your treatment planning/progression is individualized and relevant.
- Always work within your scope of practice, and adhere to any local policies.

Conclusion

There is insufficient current evidence to recommend that NMES should be used solely or routinely as a treatment for SUI and FI in pelvic health rehabilitation. However, it may be useful when a patient cannot perform an active PFM contraction, or can only manage a poor one (MOS grade < 2/5). There is also some evidence that NMES may be useful in the management of OAB symptoms. The available evidence from randomized controlled trials is inconclusive as a result of poor documentation and variation in stimulation parameters, and therefore, drawing definitive conclusions for clinical practice is problematic. Practitioners should consider the evidence available for the presenting pelvic floor dysfunction in conjunction with the individual patient assessment, and clinically reason the best treatment plan in each case.

Disclaimer

While POGP good practice statements are written by experienced clinicians and informed by evidence-based research, anyone referring to this resource must use independent judgement with regard to applying the suggestions made herein.

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