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WHAT IS TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS)?

Transcutaneous electrical nerve stimulation is a portable, inexpensive and low risk form of electrostimulation, typically delivered via self-adhesive pads or carbon rubber pads with conducting gel which are attached over the area of pain. TENS has been defined as “the delivery of pulsed electrical currents across the intact surface of the skin using a ‘standard TENS device’ to stimulate peripheral nerves principally for pain relief.”¹ Within this definition, a “standard TENS device” is a “portable, battery-powered generator of monophasic or biphasic pulsed electrical current delivered in a repetitive manner, with a maximum peak-to-peak amplitude of approximately 60 milliamperes (mA) into a 1 kilohm load.”¹

TENS stimulation has one of two intentions: either to activate low-threshold, large-diameter afferent nerve fibers in the skin (known as conventional TENS and perceived as a tingling sensation) or to use lower frequency, higher intensity pulses to generate strong, non-painful skeletal muscle twitching in order to activate deep-seated peripheral afferents (known as acupuncture-like TENS, or AL-TENS).¹

TENS devices allow the user to adjust a number of settings that alter the pattern of electrical pulses. This normally includes the duration of each pulse (labelled “duration,” “width” or “ μ s”); the number of pulses applied each second (labelled “frequency,” “rate,” “Hz” or “pps” –pulses per second); and the strength of each pulse (labelled “intensity” or “amplitude”). TENS devices may also allow the user to deliver pulses in a regular continuous pattern or in what are termed “burst” (high frequency pulses delivered in low frequency packages) or “modulated” (pulses vary in intensity or frequency) patterns.

TENS is the most common form of electrotherapy used to treat low back pain: devices are available to members of the public at low cost and can be self-administered. Guidance from an informed health care professional regarding TENS use is, however, likely to optimize outcomes.

TENS OPERATIONAL MECHANISMS

Conventional TENS activates myelinated large-diameter low-threshold peripheral afferents (A- β fibers). It uses a pulse frequency of between 10–200 pulses per second, adjusted to an amplitude perceived by the user as “strong but comfortable.” The pulse width can be varied by the user, between 50–200 μ s. The afferent pathways activated influence interneurons in the medulla to release inhibitory neurotransmitters, which in turn inhibit activity in peripheral nociceptive afferents (presynaptic inhibition) and central nociceptive transmission cells (postsynaptic inhibition).¹ This is known as segmental inhibition. Evidence from animal studies indicates that conventional TENS can reduce activity in dorsal horn neurons which can transmit noxious information^{2,3} and that this effect is independent of descending inhibition.⁴

In contrast to conventional TENS, acupuncture-like TENS (AL-TENS) is intended to activate small-diameter A- δ myelinated afferents indirectly by stimulating large-diameter myelinated efferent A- α motor neurons, which produce muscle twitches. It should be noted that cutaneous stimulation also occurs.¹ It typically uses a pulse frequency under 5 pulses per second, adjusted to an amplitude which stimulates skeletal muscle contractions. The pulse width can be varied by the user, between 100–200 μ s. Mechanisms within the CNS are complex, but with AL-TENS, muscle afferents influence central transmission pathways, including the periaqueductal grey and nucleus raphe magnus, activating descending pain inhibitory pathways.¹

Conventional (high frequency) TENS increases release of Gamma-Amino Butyric Acid (GABA) in the deep dorsal horn of the spinal cord.⁵ High and low frequency TENS reduce primary hyperalgesia by activation of GABAA receptors spinally.⁵ TENS analgesia produced by stimulation of supraspinal sites (periaqueductal grey and rostral ventrolateral medulla) involves serotonin.⁵ TENS generates an opioid-mediated analgesia as a result of its effects on the periaqueductal grey and subsequently the rostral ventrolateral medulla.⁶

Distraction from pain may be a direct benefit of TENS stimulation, independent from pain relief achieved via other mechanisms. Qualitative research with experienced TENS users indicates that the sensation experienced when using TENS can act as a useful distraction from the pain.⁷ This aspect of TENS use does not seem to have been evaluated.

Improving the sensations of muscle tension and spasm associated with back pain may be an additional benefit of TENS use. Qualitative research with experienced TENS users indicates that sensations associated with muscle tension and spasm can be improved by TENS use.⁷ It is not clear whether this benefit relates to the experience of the sensations or to the state of the muscles themselves, and this possible benefit of TENS use does not seem to have been evaluated.

CONTRAINDICATIONS TO TENS USE

Contraindications to TENS use are summarized below as a list for clarity. For a detailed discussion of risks and related evidence to support complex treatment decisions, refer to the recommended text by Johnson.¹

Absolute Contraindications

1. Impaired communication or cognition such that the patient cannot understand TENS and communicate their experience of it or control the settings
2. Infection close to area of TENS stimulation
3. Treatable malignancy
(TENS can however be considered for pain relief in a palliative care setting)
4. Active or suspected deep vein thrombosis (DVT) may be treated with conventional TENS with caution, following successful anticoagulation

Local Contraindications

Local contraindications refer to those areas of the body where TENS should not be used and include:

1. Anterior neck due to risk of vasovagal syncope or laryngeal spasm
2. Temples/forehead due to thin tissue
3. Over impaired skin, e.g., infection, broken skin
(TENS can however be placed adjacent to impaired skin, e.g., to control pain from a wound.)
4. Eyes
5. Reproductive organs
6. Pregnancy: around low back, pelvis and abdomen
(A potential hazard of some TENS stimulation patterns may be uterine contraction, which may risk miscarriage or early labor. It should be noted that a review of the evidence⁸ found no published evidence of harm during pregnancy, but it is wise to avoid TENS treatment should problems occur which may then be attributed to TENS, especially given the seriousness of such problems. TENS can however be used during labor.)
7. Cardiac failure/dysrhythmia
(TENS should not be used at intensities above motor threshold over the anterior chest for any patient. It should not be used to treat pain in the thorax for patients with cardiac failure or arrhythmias. However, it can be used to treat angina at intensities below motor threshold, provided the patient has been assessed as being suitable for TENS by a cardiologist.)
8. Tissue subject to recent radiotherapy
9. Cardiac pacemakers
(TENS could interfere with the behavior of some forms of pacemaker and should not be used if there is any doubt about risk. A detailed exploration of this issue has been presented by Johnson.¹⁾
10. Implanted cardiac defibrillator
(TENS can interfere with the normal operation of a cardiac defibrillator.)
11. Recent fracture
(AL-TENS is contraindicated, as it causes muscle contraction and potential movement of the fracture site.)

Precautions

Precautions describe situations whereby TENS can be considered by experienced clinicians, taking into account the risks of non-treatment, and also the risks of other treatment options.

Treatment may be considered if it is agreed with the patient's awareness of the balance of risks and benefits, and treatment should be monitored carefully.

1. Epilepsy

(A detailed exploration of this issue has been presented by Johnson.¹⁾

2. Chronic wounds

3. Chronic skin conditions, e.g., eczema

4. Impaired sensation

5. DVT following successful anticoagulation

6. Bleeding disorders (e.g., hemophilia) following successful management

7. Implanted but superficial metal

HAZARDS OF/PROBLEMS WITH TENS USE

Driving and Operating Machinery

An unexpected increase in the TENS sensation, for example if the controls are inadvertently touched, can cause surprise. This surprise could be hazardous if the user is operating machinery, driving or performing other hazardous activities. Drivers should be advised to switch off the device and store it away, for example in a car glove box, so that the user would not be blamed in the case of an accident. The device can easily and safely be reattached during breaks from driving.

Problems with Connectivity

Some users report problems in maintaining connectivity between the electrodes and the skin.⁹ This can be influenced by skin type, body hair and perspiration. This problem can be managed to some extent by using additional tape or specialized belts with integral electrodes. Some users report problems in maintaining connectivity between the lead and the electrodes, particularly if they are treating leg pain, because of the larger movements involved with the legs, for example when climbing stairs.⁹ As a result of these problems with connectivity, TENS users have to decide whether the activities they plan are suitable for TENS use, taking into account these problems with connectivity and the movement involved with the activity.⁹ More sedentary activities might be suitable for TENS use, but more dynamic activities such as gardening and sport might not be appropriate for some users.

Problems with Fitting TENS

Some patients may not be capable of fitting the electrodes, depending upon their flexibility and dexterity and may therefore require help to fit and remove the electrodes.⁹

Problems with Availability

TENS devices are relatively lightweight, and typically have integral clips which allow the user to fit the device to a belt or clothing when in use, but intermittent TENS users would need to carry the device around with them if they are to use it when required. If they are unable or unwilling to

carry it at all times, it may be unavailable when required. As TENS devices are less portable than pain medication, this may influence the choices that users make about TENS use compared with pain medication.⁹

Problems with the TENS Sensation

Users report that certain TENS sensations can be unpleasant and that this experience varies over time, dependent partly upon the behavior of their pain at that time.⁹ This problem can be managed by varying the TENS settings over time, so that different sensations can be chosen by the user as required.

Problems with the Visibility of TENS

Some users are able to conceal their TENS device with clothing. If this is not possible, then others might notice the device and ask questions, resulting a conversation about the TENS user's pain that he or she may prefer not to engage in.⁹

PATIENT EDUCATION AND SUPPORT CAN OPTIMIZE TENS USE

The patient needs to gain confidence in self-administering TENS and overcome any fears regarding its use. A clear explanation of the mechanisms of TENS, appropriate to the patient's level of education, is important. The patient needs to be reassured that TENS can be used safely and that any contraindications have been considered.

Realistic expectations of TENS benefits can set the scene for a supervised first trial of TENS. The patient should understand that TENS is not a cure for their pain, but that it could be a useful management tool to improve their quality of life. The patient should understand that TENS may be more helpful in some contexts than others (see below).

It is important to familiarize the patient with TENS operation and the sensations associated with different settings. An explanation of the controls of the specific TENS device will help the patient to understand that they can gain control of the sensations. Following the explanation of the controls, the patient should fit the TENS device and experience the different sensations available as he or she slowly adjusts the controls.

A continuous pattern (conventional TENS, see above) should be selected for the supervised first trial, with a mid-range frequency (approximately 100 Hz) and a short pulse duration (approximately 100 μ s). The patient should be advised to slowly increase the amplitude (intensity) so that a sudden, strong sensation does not cause surprise. The user should be encouraged to increase the amplitude to a "strong, but comfortable" tingling sensation. He or she should be encouraged to then slowly adjust the pulse frequency (rate) and pulse duration (width) to explore the way in which these settings affect the sensation. The patient should be given clear guidance about moving the controls slowly and on how to reduce the intensity, so that he or she does not lose confidence as a result of inadvertently turning up the intensity in a mistaken

attempt to turn the device off. There should be time allowed for the patient to ask any questions, to troubleshoot any problems with the sensations and for the fitting of TENS.

There is no consensus about optimal pad positioning, and it is likely that each user will need to explore different options. These include:

1. Using two pads, either covering an area of pain or one to either side of the pain.
2. Positioning one pad over a painful area and placing a second pad nearby.
3. Using four pads to cover a larger area of pain.
4. If the patient has two areas of spinal pain, using two sets of pads to treat each pain at the same time.
5. For unilateral spinal pain, putting both pads on the painful side.
6. For both back pain and leg pain, putting two pads on the back and another two pads positioned over the leg pain.

Book a review appointment as an opportunity for troubleshooting TENS use and to review the TENS strategies tried (see below). It may take several weeks for the patient to gain sufficient experience to confidently use TENS, and this should influence the timing of the review.

STRATEGIC USE OF TENS, CONTEXT AND OUTCOMES

TENS can be used strategically, depending on the context of use, leading to different outcomes.

Strategy 1: To Manage a Flare-up of Pain

The context of use might be an episode of increased pain, which may also be associated with reduced function. The outcome of this strategic use would be to help with symptoms, but also to mitigate incapacity during the flare-up (rather than an increase in function as such).⁹

Strategy 2: At Rest

TENS may be used while resting, either after activities that have increased pain or pre-emptively before a pain-inducing activity. The outcomes of this strategic use could include help with symptoms and facilitation of activity, as well as a shorter period of rest enhanced by the use of TENS.⁹

A specific example of use at rest is the use of TENS before sleep to reduce initial insomnia associated with pain. Similarly, if the user is woken after sleep onset and finds it difficult to fall asleep again because of pain, they could try TENS. Users should ensure that their skin tolerates prolonged TENS use if they are at risk of falling asleep with TENS still attached and operating. Some devices have an automatic timer that switches the device off, which may be helpful in this context.⁹

Strategy 3: To Support General Activities

Users may be able to wear TENS for prolonged periods during the day to assist them in managing everyday activities. The outcome of this strategic use would be help with symptoms and increased function, although these two benefits may be offset against each other to achieve the most useful balance of pain relief and enhanced function for the patient at that time.⁹ As an example, the pain relief offered by TENS may allow the user to increase the duration of painful activities to the extent that any pain relief gained is then “traded off” or offset against the increased function.

Strategy 4: To Support a Specific Activity

The context of use is that the user sets a goal to achieve a particular activity which they could not manage as well without TENS (e.g., sitting in a theater). The outcome of this strategic use would be help with symptoms and an enhanced specific function, although these two benefits may be offset against each other.⁹ As an example, the pain relief offered by TENS may allow the user to increase the duration of a specific painful activity such as sitting or walking to the extent that any pain relief gained is then “traded off” or offset against the increased function.

Strategy 5: To Help with Morning Stiffness and Pain

The context of use would be a period of increased pain or difficulty with mobility on rising. The outcome of this strategic use would be help with symptoms and improved mobility earlier in the day.⁹

EVIDENCE OF EFFECT AND EFFECTIVENESS

There is evidence to support the hypoalgesic effect of TENS from laboratory studies on healthy humans using experimentally induced pain models.¹⁰⁻¹² The hypoalgesia attained can be increased by increasing TENS amplitude.¹²

There is no consensus regarding the effectiveness of TENS for chronic low back pain.^{13,14} These reviews identified problems with the number and/or quality of TENS trials, and recommended that further, high quality evaluation of TENS be undertaken in order to reach a conclusion about its effectiveness.

The Cochrane review¹³ identified only four high quality randomized controlled trials (RCTs) (585 patients), two of which included patients with prior surgery. Significant group baseline differences were noted in three studies. Limitations identified by the review were the small number of studies and variability in outcome measures that limited comparison. The review concluded that there was inconsistent evidence regarding the effectiveness of TENS for low back pain.

The NICE guideline¹⁴ found a limited number of RCTs so analysis was extended to non-randomized controlled trials. The evidence for outcomes from the included studies were evaluated using an adaptation of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox developed by the international GRADE working group. Eleven studies were included which evaluated TENS against placebo as a single intervention, three studies compared TENS versus usual care, and three studies compared TENS with another intervention. No strong GRADE recommendations were possible. Compared to sham TENS or usual care in a mixed population of people with or without sciatica, no clinical benefit was noted for any of the outcomes reported (pain, function or quality of life). However, for those without sciatica a clinically important benefit in favor of TENS compared to sham was observed for all of the quality of life domain scores, but there was conflicting evidence for pain and function for sham and usual care comparisons.

In conclusion, there is a paucity of good quality evidence, rather than evidence of no benefit, and it should be noted that for conditions such as osteoarthritis and rheumatoid arthritis where sufficient evidence is available, the evidence supports the use of TENS.¹⁵

A recent review of the methodologies of TENS RCTs for acute, chronic and cancer pain¹⁶ identified significant problems with elements of implementation fidelity such as limited duration of TENS application, insufficient stimulation and limited instruction in TENS use that could explain the negative findings of some trials. This review provides a detailed framework for appraising the design and reporting of TENS trials, and it would be valuable to use this same framework to appraise low back pain studies.

There is some uncertainty regarding the choice of primary outcome in a TENS trial, whether it should be pain relief or function and which measure of function should be used. A recent, large RCT of TENS (n = 236) compared to sham TENS for low back pain¹⁷ found no improvement in function as indicated by the Roland and Morris Disability Questionnaire (RMDQ)¹⁸ at six weeks which was selected as the primary outcome measure. However, a significantly greater number of participants in the active TENS group reported pain relief of more than 50% (numbers needed to treat, NNT = 5). As pain relief was selected as a secondary outcome in this study, the study is reported as indicating no benefit from TENS. The choice of primary outcome can clearly affect the interpretation of the trial results.

Patient-reported outcome measures (PROMs) can be judged against a range of eight criteria¹⁹ including validity and responsiveness. A further criterion of “appropriateness” describes the “match” of a measure to the “purpose and questions of a trial.”¹⁹ The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)²⁰ recommended core outcome measures for chronic pain clinical trials, including the Brief Pain Inventory,²¹ the Multidimensional Pain Inventory²² and the Short Form 36.²³ The Roland and Morris Disability Questionnaire¹⁸ was recommended as an additional disease-specific PROM for low back pain. The risk of a poorly matched PROM was highlighted by a clinical audit of long-term users of TENS²⁴ which indicated that improved sitting tolerance was one important reported benefit of TENS. None of these four IMMPACT-recommended measures include items related to sitting tolerance, so a possible benefit of TENS could be overlooked if these measures were used: a “sin of omission.” A comparison of four qualitative datasets reporting on the benefits of TENS

reported by TENS users indicated that out of 18 reported benefits, the RMDQ would capture only 4 of these, indicating that the RMDQ had a match of 22%: a considerable “sin of omission,” indicating that it is unlikely to be appropriate for TENS studies.²⁵

FUTURE RESEARCH CHALLENGES

There is currently no consensus regarding the duration and timing of TENS use that a TENS evaluation protocol should recommend to participants. Evidence from qualitative research^{7,9} suggests that individuals develop their own optimal approach through trial and error, hence a trial protocol that expects adherence to a standard pattern of use may inadvertently introduce a sub-optimal protocol for a number of study participants.

As discussed above, there is no consensus regarding the choice of outcome measures to be used for a TENS study. As indicated above, TENS can be considered as a complex intervention, depending upon the strategies of use⁹ chosen by each user, and each of these strategies has a different set of potential outcomes (see above). It is possible that a context-specific outcome may be required, e.g., to evaluate the usefulness of TENS in specific contexts such as assistance with sleep, sitting or different types of work.

The outcome of TENS use in a specific functional context may result in pain relief, increased function or a combination of both of these outcomes, if they are traded off against each other by the user. It is possible that a Clinical Global Impression of Change score may capture these contextualized, combined benefits more effectively than either a pain scale or a functional scale.²⁵

It should be noted that the questions that a patient wishes to be answered by TENS evaluation may be different than a researcher’s questions. A patient may be willing to accept less than 50% pain relief as a positive outcome of TENS use. Buchmuller et al.¹⁷ reported on the proportion of patients that achieved 50% pain relief,²⁶ but patients may be interested to know how likely it is that they might achieve a lower level of pain relief (e.g., 20%), which could still improve quality of life.⁷

A patient may have a specific functional difficulty, for example pain-related insomnia or sitting for journeys, with which they are struggling to cope. A problem-focused outcome regarding TENS effectiveness may be more informative for patients. This would allow potential users to identify whether their specific pain-related problems might be helped by TENS.

SUGGESTED READING

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This is a comprehensive, evidence-based book which was highly commended in the Medicine category in the 2015 British Medical Association Book Awards.

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