Transcutaneous Electrical Nerve Stimulation (TENS)

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Introductory article

Article Contents

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Transcutaneous electrical nerve stimulation (TENS) is a noninvasive, self-administered technique to relieve pain. During TENS, pulsed electrical currents are administered across the intact surface of the skin to generate strong nonpainful TENS sensations or mild muscle twitching at the site of pain. TENS inhibits onward transmission of nociceptive (pain-related) information in the central nervous system and appears to be beneficial for acute and chronic pain. Large meta-analyses suggest positive outcomes for the relief of musculoskeletal and post-operative pain, although many systematic reviews are inconclusive. Evidence suggests that some investigators have used small study sample sizes and TENS techniques that are unlikely to be effective based on the findings of studies that have evaluated optimal TENS settings using healthy volunteers. The national institute of health and clinical excellence (UK) recommend TENS for rheumatoid arthritis, osteoarthritis and musculoskeletal pain associated with multiple sclerosis but not for nonspecific low back pain and labour pain. TENS is inexpensive, safe and popular with patients and for this reason practitioners continue to offer patients TENS until better quality evidence emerges.

Introduction

Chronic pain is a major health care problem and many patients are dissatisfied with analgesic medication (Breivik *et al*., 2006). Administering electricity across the intact surface of the skin to relieve pain is an age-old technique dating back to the ancient Egyptians (2500 BC). In early times, electrogenic fish were placed onto the skin of painful body parts to 'numb pain' until electrostatic generators were developed, which enabled electricity to be administered with better precision. Electric stimulation therapy (electrotherapy) was popular until the late nineteenth century when pharmacological treatments began to dominate. In 1965, the publication of Melzack and Wall's 'gate control theory of pain' rekindled interest in electrotherapy leading to the introduction of transcutaneous electrical nerve stimulation (TENS).

TENS is the delivery of pulsed electrical currents across the intact surface of the skin to activate underlying peripheral nerves. TENS is an easy to use, noninvasive and inexpensive technique used to relieve pain. TENS is popular because users can self-administer treatment and titrate dosage without fear of overdose, serious adverse effects or drug interactions. Pain relief during TENS is rapid in onset and optimal when the user experiences a strong but nonpainful TENS sensation beneath the electrodes, so users administer TENS on an as-needed basis. TENS is inexpensive when compared with drug treatment, and in many countries TENS devices can be purchased over the counter or via the internet and without the need for a medical prescription. Nonetheless, it is wise to have a practitioner who is experienced in the principles and practice of TENS to supervise new users. A point of contact to troubleshoot any problems should also be provided.

TENS is used throughout the world because clinical experience suggests that it is beneficial for acute and chronic pain of nociceptive, neuropathic and musculoskeletal in origin. There is strong evidence from animal and human studies that TENS inhibits ongoing transmission of pain related information in the nervous system. Interestingly, clinical practice guidelines are inconsistent because high quality research evidence from randomised controlled clinical trials is either inconclusive or conflicting. For example, in the UK, the National Institute for Health and Clinical Excellence (NICE) recommended that TENS should not be offered for the early management of persistent nonspecific low back pain because there was insufficient quality evidence (National Institute for Health and Clinical Excellence, 2009). By contrast, the North American Spine Society recommended that TENS should be offered for chronic low back pain because it provided immediate short-term reductions in pain intensity (Poitras and Brosseau, 2008). NICE recommended that TENS should be offered for short-term relief of pain associated with osteoarthritis, rheumatoid arthritis and musculoskeletal pain associated with

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multiple sclerosis, but not for women in established labour. The purpose of this review is to critically evaluate the use of TENS for pain relief.

Definition

TENS is any technique that passes electrical currents across the intact surface of the skin to activate underlying nerves, although the term is generally used to describe currents delivered using a 'standard TENS device' to relieve pain. A standard TENS device consists of a small battery-powered stimulating device that generates pulsed electrical currents, which are delivered via lead wires to self-adhesive reusable electrode pads that are attached to the surface of the skin (**Figure 1**). The characteristics of the currents can be modified by the user according to what is available on the TENS device. Standard TENS devices produce biphasic pulsed electrical currents with pulse widths (durations) between 50 and 250 μs, pulse rates (frequencies) between 1 and 150 pulses per second (pps), pulse amplitudes between 1 and 60 milliamperes (mA) and a variety of pulse patterns (modes) including continuous (normal), burst (intermittent trains of pulses) and modulated amplitude and/or modulated frequency and/or modulated pulse duration (**Figure 2**).

A variety of TENS-like devices are also available on the market (**Table 1**) although detailed discussion lies outside of the scope of this review. Developments in technology rather than proven efficacy or a sound biological rationale appear to have driven the proliferation of many TENS-like devices. Evidence to support the effectiveness of TENS-like devices is very limited and therefore a standard TENS device should be tried in the first instance (Johnson, 2001).

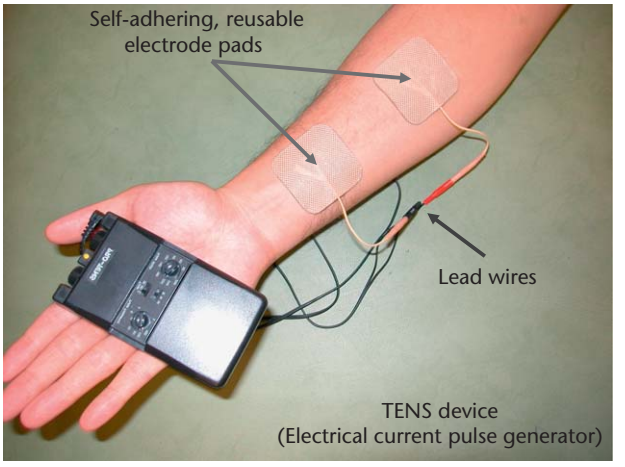

Figure 1 Transcutaneous electrical nerve stimulation.

TENS Techniques

The main TENS techniques are conventional TENS (low intensity and high frequency) and acupuncture-like TENS (high intensity and low frequency, **Table 2**).

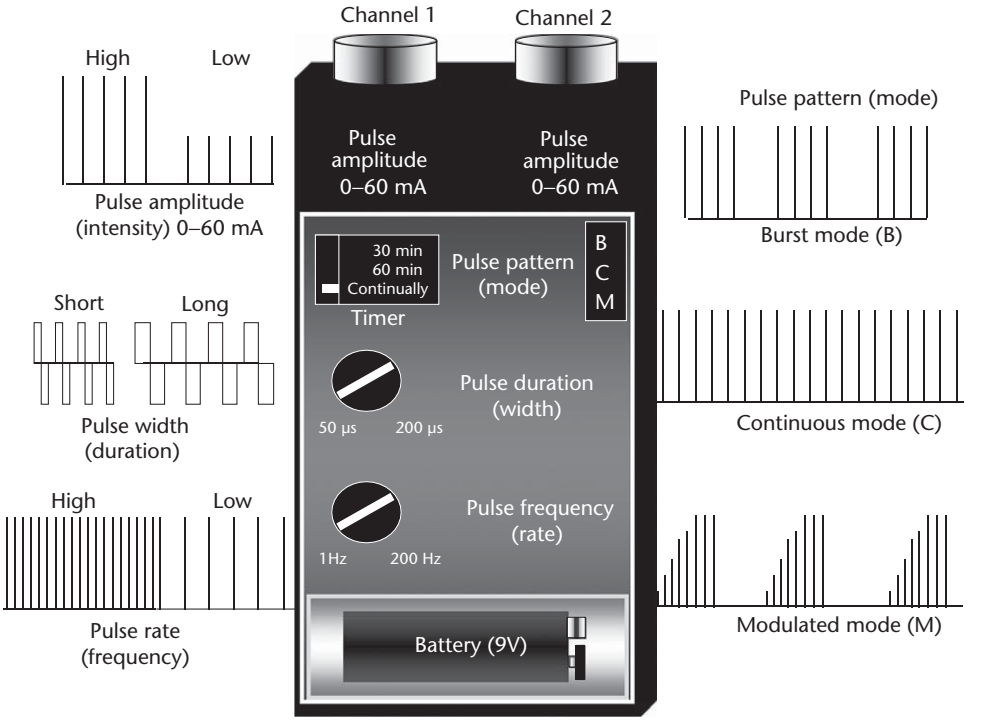

Figure 2 The electrical characteristics of a standard TENS device.

Table 1 The characteristics of various TENS-like devices

Device	Characteristics
Action potential simulation (APS)	Monophasic square pulse with exponential decay delivered by two electrodes. Pulse amplitude low (< 25 mA), duration long (800 μs–6.6 ms), frequency fixed at 150 pps.
Codetron	Pulsed square wave delivered randomly to one of 6 electrodes. Pulse amplitude low, duration long (1 ms), frequency low (2 pps).
H-wave stimulation	'Unique' biphasic wave with exponential decay delivered by two electrodes. Pulse amplitude low (< 10 mA), duration long (fixed at 16 ms), frequency low (2–60 pps).
Interferential therapy (Interference currents)	Two out of phase currents that interfere with each other to generate an amplitude modulated wave. Traditionally, delivered by four electrodes; some devices have amplitude modulated waves that are premodulated within the device (two electrodes). Pulse amplitude low, amplitude modulated frequency 1–200 Hz (carrier wave frequencies approximately 2–4 KHz).
InterX®	High amplitude, short pulse width, dynamic waveform delivered by closely spaced metal electrodes moved across the surface of the skin. Technology claimed to identify changes in tissue properties to identify optimal treatment locations.
Limoge current	High frequency pulses interrupted with repetitive low frequency cycle delivered by three electrodes (negative electrode between eyebrows and two positive electrodes in retro-mastoid region). Used to potentiate the effects of opiates.
MC5-A Calmare (Calmare® pain therapy treatment)	A large trolley based device that uses surface electrodes to simultaneously treat multiple pain areas using 'scrambler therapy'. Unable to find details of the output specifications of the device. Technology is claimed to substitute pain information with a synthetic nonpain information (Transcutaneous electrical modulation pain reprocessor).
Microcurrent, including transcranial stimulation and 'acupens'	Modified square direct current with monophasic or biphasic pulses changing polarity at regular intervals (0.4 s) delivered by two electrodes. Pulse amplitude low (1–600 μA with no paraesthesia), frequency depends on manufacturer (1–5000 pps). Many variants exist (e.g. transcranial stimulation for migraine and insomnia; acupens for pain).
Transcutaneous spinal electroanalgesia (TSE)	Differentiated wave delivered by two electrodes positioned on spinal cord at T1 and T12 or straddling C3–C5. Pulse amplitude high yet no paraesthesic sensation generated, duration very short (1.5–4 μs, frequency high (600–10 000 pps).
Pain®Gone	Hand held pen device using piezoelectric elements to deliver a low ampere high voltage single monophasic spiked pulse (e.g. 6 μA/15 000 V). Delivered by giving 30–40 individual shocks at the site of pain or on acupuncture points to generate non-noxious to mild noxious pin-prick sensation – repeated whenever pain returns.
Salutaris TENS	Dual channel stimulator delivering high (95 Hz) and low (4 Hz) frequency pulsed currents delivered by two electrodes using pulse widths of 100 us or 280 us and current output up to 70 mA (into a 1K ohm load). Uniqueness appears to be the use of a rising edge correction circuit 'to reduce the ramp time of each impulse and improve the therapy results'.

Conventional TENS

The aim of conventional TENS is to activate low threshold afferents (e.g. A-beta) that transmit information related to non-noxious (nonpainful) events without simultaneously activating high threshold afferents (A-delta and C fibres) that transmit information related to noxious (painful) events. This is achieved by titrating pulse amplitude to generate a strong, comfortable, nonpainful sensation of TENS beneath the electrodes and in the distribution of the nerve that has been activated. A continuous pulse pattern and frequencies greater than 10 pps are commonly used so that the sensation of TENS is akin to tingling (electrical paraesthesiae). TENS users learn to titrate current amplitude to achieve the appropriate intensity and then experiment with other stimulator settings to maintain the most

Table 2 The characteristics of conventional and acupuncture-like TENS

Characteristics	Conventional TENS	AL-TENS
Goal of stimulation	Activate peripheral low threshold cutaneous afferents (A-beta fibres).	Activate peripheral high threshold cutaneous (A-delta) and muscle (Group III) afferents.
Electrode positions	Straddle site of pain so that TENS sensation permeates painful area (dermatomal). In presence of hyper or hyposensitive skin electrodes should be placed over nerve bundles proximal to site of pain or in contralateral (mirror) positions.	Over muscle belly at site of pain or over motor nerves innervating site of pain (myotomal). In presence of hyper or hypo sensitive skin electrodes should be placed over main nerve bundle or in contralateral positions. Trigger points or acupuncture points are sometimes used.
Pulse amplitude (TENS sensation and intensity)	To generate a strong nonpainful TENS sensation (paraesthesiae) with minimal muscle activity). Usually no more than 60 mA (low intensity).	To achieve a strong pulsating TENS sensation with simultaneous muscle twitching, at or just below pain threshold. Usually no more than 70 mA (high intensity).
Pulse pattern (mode)	Continuous in first instance but determined by patient preference.	Burst or amplitude modulated usually used in first instance. If delivering low frequency single pulsed currents then continuous mode is used.
Pulse frequency (rate)	High (usually >10 pulses per second) determined by patient preference.	Low (<10 pulses per second). Usually <5 bursts (trains) per second of high frequency pulses) or <5 pulses per second if delivered using low frequency single pulsed currents.
Pulse width (duration)	Usually between 50–250 μs determined by patient preference.	Usually between 50–250 μs. Smaller pulse widths generate a weaker TENS sensations yet can still create muscle twitching.
Dose	Stimulate whenever pain relief is required. Can be used throughout the day with a break every hour or so.	Stimulate for no more than 30 min at a time as muscle fatigue may develop resulting in delayed onset muscle soreness the following day. Usually 2–3 treatments each day.
Time course of pain relief	Rapid onset and offset of effects. Pain relief tends to be via segmental mechanisms (i.e. spinal gating).	Rapid onset and delayed offset of effects. Pain relief tends to be a combination of segmental (i.e. spinal gating) and extrasegmental mechanisms (i.e. descending pain inhibitory pathways).

comfortable TENS sensation for their pain at that moment in time.

Acupuncture-like TENS (AL-TENS)

The aim of AL-TENS is to activate high threshold afferents in skin and in deeper (muscular) structures (A-delta). Thus, AL-TENS is a form of hyperstimulation. Low frequency single pulsed currents (<5 pps) or low frequency intermittent trains (bursts at <5 Hz) of high frequency pulses (˜100 pps) are commonly used and this generates a strong, nonpainful pulsating sensation beneath the electrodes and in the distribution of the nerve that has been activated. AL-TENS is administered at the site of pain, on acupuncture points, and over muscles, motor points and trigger points. Whether muscle twitching is a prerequisite for AL-TENS is a matter of debate and as a consequence clinical practice tends to be variable (Francis and Johnson, 2011). The presence or not of muscle twitching depends in part on whether electrodes are positioned over muscles or motor nerves. AL-TENS is used for patients with radiating neurogenic pain, pain associated with altered skin sensitivity, pain arising

from deep structures and when patients do not respond to conventional TENS (Johnson, 1998).

Other TENS techniques

Intense TENS is high intensity (i.e. painful) and high frequency currents delivered for short periods of time. Intense TENS is a counter irritant and used for painful wound-dressing changes, suture removal and venepuncture. Acu-TENS is the delivery of low frequency pulsed currents on acupuncture points although a variety of electrical characteristics of TENS have been used in clinical practice (Brown *et al*., 2009). Sequential TENS is strong nonpainful TENS punctuated with intense TENS and may be useful for background pain with incidents of breakthrough pain (Sandkühler, 2000). Sequential TENS is commonly used during childbirth where a boost button enables the user to increase the intensity of TENS during contraction pain.

Practical Application of TENS

Because TENS is a technique, it is important that it is administered safely (**Table 3**).

Contraindications, precautions and adverse events

Pacemakers, ventricular assist devices (artificial hearts) and internal cardiac defibrillators are contraindicated for TENS. Occasionally, medical specialists have indicated the use of TENS in these situations, providing electrode positions are distant from the chest. Recommendations for the use of TENS with pacemakers and implantable cardioverter defibrillators have been published (Burri and Piguet, 2009). TENS should not be administered close to the uterus for individuals who are pregnant or on the neck or head for individuals with epilepsy (Coldron *et al*., 2007). Likewise, TENS should not be applied close to bleeding tissue, over an active tumour for a patient whose tumour is treatable, or over active epiphysis (Chartered Society of Physiotherapy, 2006). TENS can be administered in individuals with metal implants, stents, percutaneous central catheters or drainage systems and close to transdermal drug delivery systems, providing progress is carefully monitored. Individuals with cognitive impairment may not be able to comprehend instructions. Adverse events from TENS are rare and usually consist of skin irritation beneath the electrodes and nausea and feeling faint due to a vasovagal response. TENS worsens pain in some individuals and produces artefacts on electrocardiograms, electroencephalograms and fetal monitoring equipment. TENS should not be used while operating motorised vehicles and can be used while going to sleep, providing the device has a timer so that it automatically switches off. Children as young as 4 years can use TENS under supervision. Decisions are left to the discretion of the medical practitioner.

Table 3 Protocol for TENS treatment

1. Check contraindications and test skin for normal sensation
2. With device switched off adjust TENS settings to:
   - Pulse pattern (mode) = continuous (normal)
   - Pulse frequency (rate) = mid range (80–100 pps)
   - Pulse duration (width) = mid range (100–200us)
   - Timer (if available) = continuous
3. Connect electrode lead wires to electrodes
4. Position electrodes on skin at appropriate site
5. Connect electrode lead wires to TENS device
6. Switch TENS device on
7. Slowly increase intensity until patient reports first TENS 'tingling' sensation. Ask patient whether the sensation is acceptable
8. Slowly increase intensity until patient reports a strong but nonpainful TENS sensation
9. Check that the sensation is acceptable and monitor patient for any signs of an autonomic response
10. Allow patient to experiment with settings by:
    - Reducing amplitude so TENS barely perceptible
    - Change the setting
    - Increase pulse amplitude to a strong nonpainful level
11. Instruct patient to adjust duration of stimulation according to need

Adequate TENS technique

The critical factors affecting the adequacy of TENS technique are electrode position and pulse amplitude (intensity), with a strong yet nonpainful TENS sensation within the site of pain being a prerequisite for pain relief in most instances (Bjordal *et al*., 2003; Claydon and Chesterton, 2008).

Electrodes position

Reusable self-adhering electrode pads made of knitted stainless steel are used to deliver TENS currents through the skin. A variety of shapes and sizes are available although square electrodes 50 mm × 50 mm are most commonly used. The cathode excites the membrane of the axon, so when monophasic waveforms are used, the cathode (normally the black lead wire) is placed proximal to the anode. However, most modern TENS devices use biphasic waveforms with zero net current flow, and so the placement of red and black lead wires is of less importance. Glove, sock and belt electrodes are readily available (Cowan *et al*., 2009) and electrode arrays to spatially target stimulation more precisely are being developed (Kolen *et al*., 2012).

Whenever possible, TENS electrodes are positioned over the site of pain so that TENS sensation permeates the painful site (**Figure 3**). In some instances, this may not be appropriate, so electrodes are positioned on skin with normal sensation and over nerves proximal to the site of pain. For example, TENS may aggravate tactile allodynia and dysaesthesiae associated with neuropathic pain, and so it would be unwise to deliver TENS on such sites. Likewise, TENS should not be applied to areas of numbness

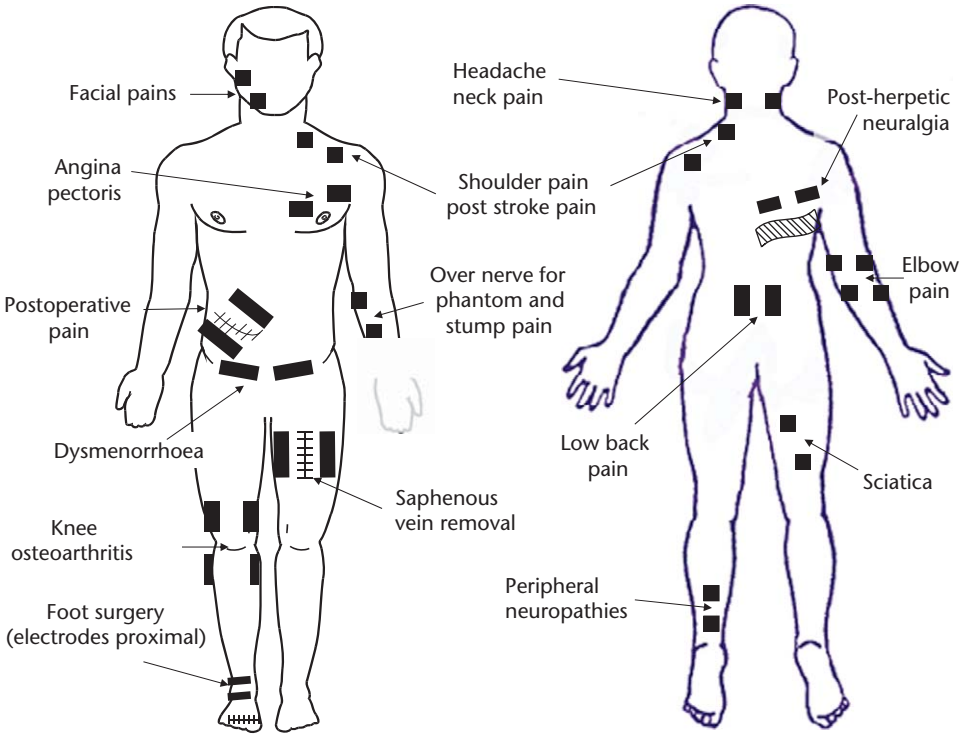

Figure 3 Electrode positions during TENS for painful conditions.

(e.g. following peripheral neuropathy) due to difficulty in achieving a TENS sensation. It is possible to project TENS sensations into extremities and phantom limbs by positioning electrodes over the appropriate nerves. There are very few studies that have systematically compared different electrode sites on outcome.

Electrical characteristics of TENS

Pulse amplitude is the key determinant of response to TENS because of its relationship to axonal activation. Individuals learn to titrate pulse amplitude to produce nonpainful TENS sensations indicative of low threshold cutaneous afferent activation (A-beta fibres). Muscle twitching during AL-TENS is indicative of higher threshold muscle afferent activation (A-delta fibres). Studies using models of non-injurious experimental pain on healthy pain-free human volunteers provide strong evidence that strong nonpainful TENS is superior to no current or barely perceptible TENS (Aarskog *et al*., 2007; Moran *et al*., 2011). If the pulse amplitude of TENS is left at the same level, the intensity of TENS will fade over time due to habituation, so it is important to increase amplitude to maintain a strong nonpainful TENS (Pantaleao *et al*., 2011).

Research using electrophysiological techniques and animal models of nociception has shown that different neurophysiological mechanisms are activated by different frequencies of TENS (DeSantana *et al*., 2008a). However, available evidence in human studies is inconsistent, and evidence of a relationship between frequency and the magnitude of analgesia and/or medical diagnosis has not been forthcoming. A systematic review of human studies concluded that hypoalgesia during strong nonpainful TENS was not influenced by pulse frequency (Chen *et al*., 2008), although most studies had small sample sizes. Since then, appropriately powered studies on healthy participants have shown that strong nonpainful TENS at 80 pps was superior to 3 pps at reducing ischaemic and mechanical pain (Chen and Johnson, 2010b, 2011). Interestingly, TENS at 3 pps was superior to 80 pps for reducing cold-pressor pain (Chen and Johnson, 2010a) suggesting that frequency effects may depend on the nature of the pain. Patients using TENS on a long-term basis show preferences for TENS frequencies although this appears to be based on the comfort of TENS sensation (Johnson *et al*., 1991; Oosterhof *et al*., 2008). Reducing pulse width (duration) aids passage of currents through the skin so that nerves lying in deeper tissue can be activated. This may be useful to stimulate muscles without causing a strong TENS sensation in the skin. Longer pulse durations are used during AL-TENS because they activate high threshold small diameter axons at lower pulse amplitudes.

Analgesic time course and dosing

Pain relief with conventional TENS is rapid in onset and offset with maximal benefit during stimulation. Successful long-term TENS users leave electrodes *in situ* and switch TENS on and off throughout the day paying attention to the condition of the skin beneath electrodes

(Johnson *et al*., 1991). Post-TENS effects may vary considerably between treatment sessions and may be due in part to natural fluctuations in symptoms and patient expectation. Higher intensities of TENS inhibit central nociceptive cell activity for up to 2 h post-TENS and activate descending pain inhibitory pathways (Sandkühler, 2000). Approximately 50% of chronic pain patients who try TENS gain short-term benefit although there is debate whether this benefit is superior to that achieved using placebo TENS (Oosterhof *et al*., 2012). TENS effects often decline in the long-term due to habituation to TENS, a worsening pain problem or because the effort to use TENS regularly is disproportionate to the amount of pain relief obtained (Koke *et al*., 2004). Repeated use of TENS has been shown to generate opioid tolerance via cholecystokinin (Desantana *et al*., 2010) and NMDA receptors (Hingne and Sluka, 2008) leading to a decline in pain relief (Liebano *et al*., 2011). Experimenting with electrode placements and TENS settings, using modulated patterns of TENS, or temporarily withdrawing TENS treatment may resolve the problem (Chen and Johnson, 2009).

Mechanism of Action

TENS currents tend to stay superficial and activate cutaneous afferents rather than motor efferents from the skeletal and autonomic systems. TENS causes orthodromic impulses travelling along an axon in their normal direction and antidromic impulses travelling along an axon in the opposite direction to normal. In sensory axons, impulses generated by TENS that are travelling toward the periphery (i.e. antidromic) will collide with and extinguish impulses arising from peripheral receptors travelling toward the central nervous system, thus causing peripheral blockade of impulses arising from tissue damage.

TENS-induced impulses in low threshold afferents cause synaptic inhibition of impulses arising from peripheral nociceptors when TENS is applied to the somatic receptive field (**Figure 4**). This inhibition occurs at the first synapse in the central nervous system (i.e. spinal cord or brainstem) and involves gamma-amino butyric acid (GABA) and met-enkephalin (Maeda *et al*., 2007). TENS also reduces the sensitised state of centrally sensitised dorsal horn neurons induced by peripheral inflammation in anaesthetised rats (Ma and Sluka, 2001).

TENS-induced impulses in high threshold afferents activate descending pain inhibitory pathways originating in the periaqueductal grey and ventromedial medulla causing inhibition of central nociceptor cells for up to 2 h after TENS has ceased (Sandkühler, 2000). Evidence suggests that TENS-induced activity in deep afferents produces greater inhibition than cutaneous afferents (Radhakrishnan and Sluka, 2005). It is likely that AL-TENS acts in part via activation of descending pain inhibitory pathways following input from high threshold, small diameter muscle

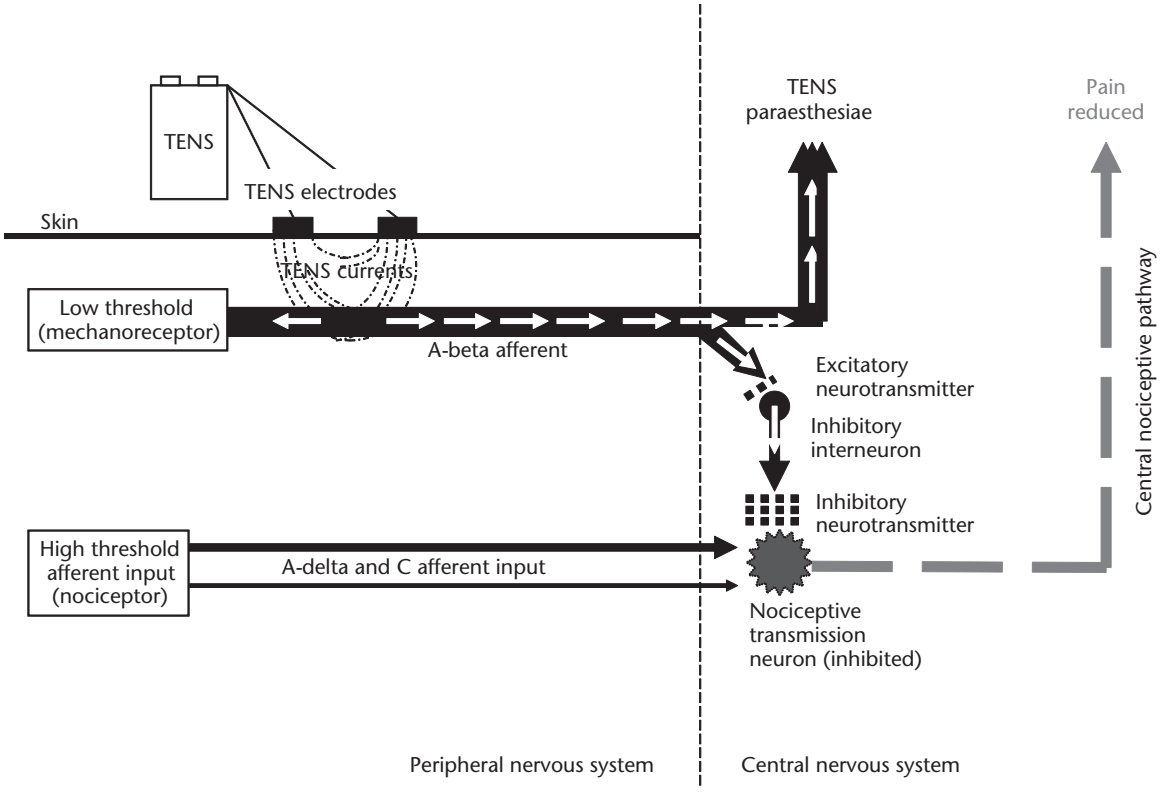

Figure 4 Mechanism of action of conventional TENS (white arrows indicate direction of nerve impulses).

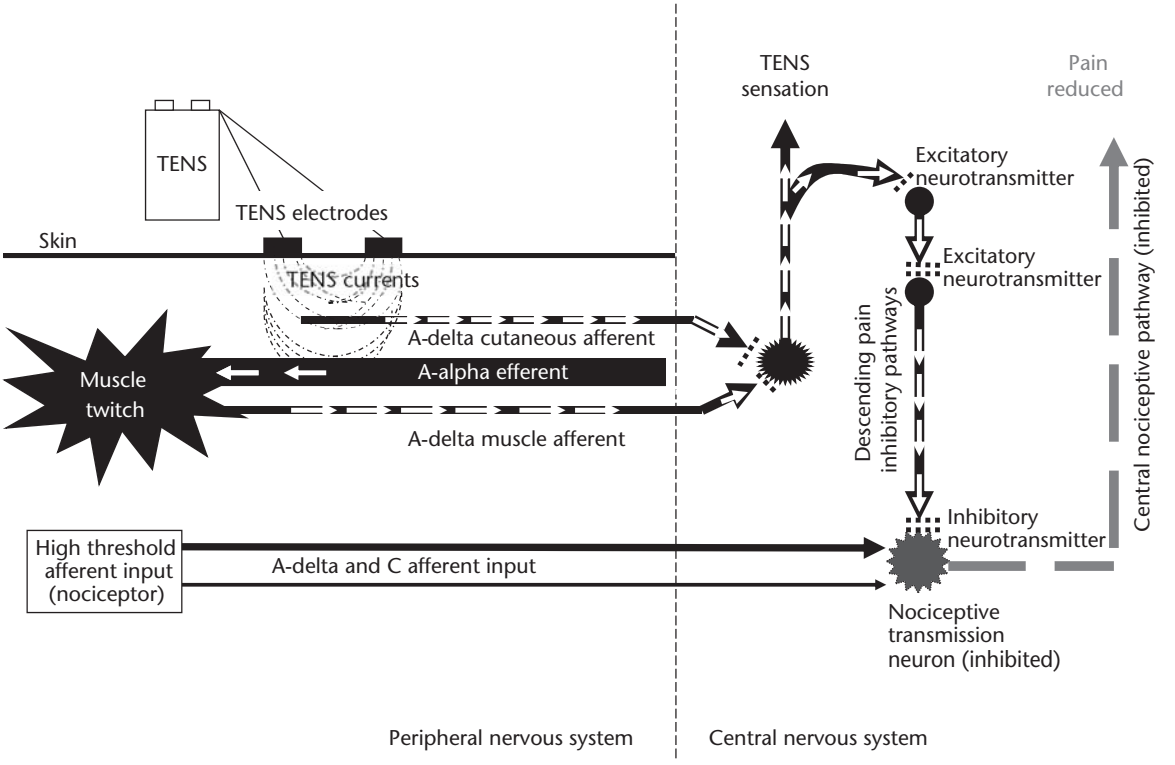

Figure 5 Mechanism of action of acupuncture like TENS (white arrows indicate direction of nerve impulses).

afferents activated by a TENS-induced muscle twitch (**Figure 5**). When the intensity of TENS becomes painful, it is probable that counterirritant mechanisms via diffuse noxious inhibitory controls contribute to pain relief achieved.

In the last decade, there has been much research comparing the neuropharmacology of high and low frequency TENS. This research has shown that low-frequency TENS acts via mu opioid receptors and high-frequency TENS acts via delta opioid receptors. However, a range of neurotransmitter systems have been implicated in TENS actions including cholinergic, adrenergic and serotinergic (DeSantana *et al*., 2008b).

Clinical Effectiveness of TENS

An unfiltered search on PubMed using the medical subject heading (MeSH) 'TENS' identified more than 800 hits for randomised controlled clinical trials (RCTs) (22 March 2012). However, uncertainty over the effectiveness of TENS for acute and chronic pain has remained for many decades because of methodological shortcomings in RCTs. A summary of the findings of systematic reviews is presented below (**Table 4**).

Acute pain

Cochrane Reviews have concluded that evidence was inconclusive for TENS as a stand-alone treatment for acute pain and for pain associated with childbirth and that there was weak evidence that TENS reduced pain associated with dysmenorrhoea (**Table 4**). Non-Cochrane systematic reviews on TENS for post-operative pain concluded that TENS was not effective in relieving pain, although subsequent meta-analyses found that TENS reduced post-operative analgesic consumption, was useful as an adjunct to analgesics for post-thoracotomy procedures producing moderate pain, and was very effective as a stand-alone therapy for post-thoracotomy procedures producing mild pain. TENS can reduce recovery room stay and improve tolerance to coughing and pulmonary ventilatory function. RCTs have found that TENS is effective for a range of acute pain conditions, including acute lower back pain, angina pectoris, orofacial pain, painful dental procedures and fractured ribs.

Chronic pain

A Cochrane review of TENS for chronic pain included 25 RCTs (1281 participants) and found that TENS was superior to an inactive TENS control in 13 out of 22 studies (Nnoaham and Kumbang, 2008). A large meta-analysis of TENS for chronic musculoskeletal pain included 32 RCTs on TENS and six studies on percutaneous electrical nerve stimulation (PENS) (1227 participants) and found that TENS was superior to an inactive TENS control (Johnson and Martinson, 2007). A Cochrane review of TENS for osteoarthritic knee pain included 18 RCTs (813

Table 4 Systematic reviews on TENS

Condition	Reference	Sample	Reviewers' conclusion
Acute Pain			
Acute pain	Walsh *et al*. (2009)	12 RCTs (919 participants) on TENS	Evidence inconclusive
Post-thoracotomy pain	Freynet and Falcoz (2010)	9 RCTs (645 participants) on TENS	Evidence of effect as an adjuvant
Post-operative analgesic consumption	Bjordal *et al*. (2003)	21 RCTs (964 participants) on TENS	Evidence of effect
Post-operative pain	Carroll *et al*. (1996)	17 RCTs (786 participants) on TENS	Evidence of no effect
Labour pain	Mello *et al*. (2011)	9 RCTs (1076 women) on TENS	Evidence inconclusive
Labour pain	Dowswell *et al*. (2009) and Bedwell *et al*. (2011)	19 RCTs (1671 women) on TENS	Evidence inconclusive
Labour pain	Carroll *et al*. (1997)	10 RCTs (877 women) on TENS	Evidence of no effect
Primary dysmenorrhoea	Proctor *et al*. (2002)	7 RCTs, (213 participants) on TENS	Evidence of effect
Chronic Pain			
Chronic pain (update of Carroll *et al*., 2001)	Nnoaham and Kumbang (2008)	25 RCTs (1281 participants) on TENS	Evidence inconclusive
Chronic pain	Carroll *et al*. (2001)	19 RCTs (652 participants) on TENS	Evidence inconclusive
Chronic musculoskeletal pain	Johnson and Martinson (2007)	38 RCTs (1227 participants) of any electrical nerve stimulation with 32 RCTs on TENS	Evidence of effect
Whiplash and mechanical neck disorders	Kroeling *et al*. (2009)	18 RCTs (1043 participants) of any electrotherapy with 7 RCTs (88 participants) on TENS	Evidence of effect
Low back pain	Dubinsky and Miyasaki (2010)	2 RCTs (201 participants) on TENS	Evidence of no effect
Low back pain	Khadilkar *et al*. (2008)	3 RCTs (197 participants) on TENS	Evidence inconclusive
Low back pain	Poitras and Brosseau (2008)	6 RCTs (375 participants) on TENS	Evidence of effect
Osteoarthritic knee pain	Rutjes *et al*. (2009)	18 RCTs (275 participants) on TENS	Evidence inconclusive
Osteoarthritic knee pain	Bjordal *et al*. (2007)	36 RCTs (2434 participants) of physical agents with 7 RCTs (414 participants) on TENS using adequate technique	Evidence of effect
Rheumatoid arthritis of the hand	Brosseau *et al*. (2003)	3 RCT (78 participants) on TENS	Evidence of effect
Neuropathic pain	Cruccu *et al*. (2007)	9 RCTs (200 participants) on TENS	Evidence of effect
Painful diabetic neuropathy	Jin *et al*. (2010)	3 RCTs (78 participants) on TENS	Evidence of effect
Painful diabetic neuropathy	Dubinsky and Miyasaki (2010)	2 RCTs (55 participants) on TENS	Evidence of effect
Phantom limb and Stump pain	Mulvey *et al*. (2010)	0 RCTs	No evidence available

(*continued*)

Table 4 Continued

Condition	Reference	Sample	Reviewers' conclusion
Post-stroke shoulder pain	Price and Pandyan (2001)	4 RCTs (170 participants) of any surface electrical stimulation with 2 RCTs on TENS	Evidence inconclusive
Chronic recurrent headache	Bronfort *et al*. (2004)	22 RCTs (2628 participants) of physical agents but no RCTs on TENS	Lack of available evidence
Cancer Pain (update of Robb *et al*., 2009)	Hurlow *et al*. (2012)	3 RCTs (88 participants) on TENS	Evidence inconclusive
Cancer pain	Robb *et al*. (2009)	2 RCTs (64 participants) on TENS	Evidence inconclusive

participants) and found that evidence was inconclusive although the standard mean difference between active and placebo TENS was approximately 20 mm on a 100-mm Visual Analogue Scale (VAS) (Rutjes *et al*., 2009). The VAS is a simple measurement instrument where respondents specify their level of agreement to a statement such as 'What is the intensity of your pain at present?', by indicating a position along a continuous line between two endpoints such as 0 mm = 'No pain' and 100 mm = 'Worst pain imaginable'. An earlier meta-analysis of seven RCTs delivering TENS at optimal doses found that TENS reduced pain by 22.2 mm (95% CI: 18.1–26.3) on a 100-mm VAS (Bjordal *et al*., 2007). A Cochrane review of TENS for rheumatoid arthritis of the hand included three small RCTs and found that evidence was inconclusive (**Table 4**).

The European Federation of Neurological Societies (EFNS) Task Force for neurostimulation therapy for neuropathic pain reviewed nine controlled trials (200 participants) and found TENS to be superior to placebo and recommended TENS as an add-on therapy (Cruccu *et al*., 2007). A meta-analysis of three RCTs (78 participants) on TENS for diabetic peripheral neuropathy found that TENS was superior to placebo (no current) TENS at reducing pain at 4- and 6-week follow-up, although the included studies did not use standard TENS devices (Jin *et al*., 2010). The Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology (AAN) concluded that TENS was 'probably effective' for painful diabetic neuropathy based on three small RCTs although there was only a total of 31 participants that received TENS and 24 that received placebo TENS (Dubinsky and Miyasaki, 2010). A Cochrane review on electrical stimulation for post-stroke shoulder pain included one RCT that found that TENS relieved hemiplegic shoulder pain although there was insufficient evidence to judge effectiveness of TENS for post-stroke shoulder pain (Price and Pandyan, 2001). Cochrane reviews on TENS for amputee pain (Mulvey *et al*., 2010) and cancer-related pain (Hurlow *et al*., 2012) failed to find sufficient RCTs to judge effectiveness.

A good example of the inconsistency of review outcomes for TENS is demonstrated for chronic low back pain. A Cochrane review of TENS for chronic low back pain included three RCTs (110 participants receiving TENS and 87 receiving placebo TENS) and was inconclusive (Khadilkar *et al*., 2008). Likewise, NICE reviewed three small RCTs (331 participants received TENS and 168 received placebo TENS) and concluded that there was insufficient evidence to judge effectiveness for persistent nonspecific low back pain. By contrast, The North American Spine Society reviewed six RCTs (375 participants receiving TENS and 192 receiving placebo TENS) and concluded that TENS reduced pain intensity in the short-term (Poitras and Brosseau, 2008). A meta-analysis of several therapies concluded that the effect size for TENS was small, but of a similar magnitude to analgesic medication, including NSAIDs and muscle relaxants (Machado *et al*., 2009). The Therapeutics and Technology Assessment Subcommittee of the AAN concluded that TENS was not effective for chronic low back pain based on level A evidence (i.e. good-quality RCTs) although there were only two small RCTs with a total of 114 participants receiving TENS and 87 receiving placebo (Dubinsky and Miyasaki, 2010). One of these RCTs was criticised at the time of publication for clinical heterogeneity, use of a suboptimal TENS technique and the concurrent use of hot packs, which could have masked the effects of TENS. The other RCT used participants with multiple sclerosis and some participants in the placebo TENS group were taking additional analgesics.

Challenges in TENS research

The majority of RCTs on TENS have insufficient sample sizes. Investigators have delivered TENS where the intensity of stimulation is weak and it is not possible to ascertain whether nerve stimulation had taken place. In some studies, electrodes have been positioned at body locations that do not have a clear physiological relationship to the site of pain. Often, TENS treatments are too short or too infrequent leading to under dosing. Failure to measure the effects of TENS while the participant experiences a strong nonpainful TENS sensation and allowing participants to take concurrent medication during the RCT are also

confounding factors. A methodological review that included 38 RCTs taken from the Cochrane reviews on acute, chronic and cancer pain demonstrated that these shortcomings bias trial outcome so that there is an underestimation of treatment effects (i.e. low implantation fidelity) (Bennett *et al.,* 2011).

In addition, it is not possible to fully blind TENS to participants because a strong nonpainful TENS sensation is a prerequisite of adequate TENS technique. Stating that some TENS devices generate 'tingling sensations', whereas others do not (e.g. microcurrent) in participant information sheets can help to conceal 'real' and 'fake' interventions. Furthermore, transient sham TENS devices that produce a short-lived TENS sensation before fading away to zero current have proved successful in blinding participants in laboratory situations (Rakel *et al*., 2010). In future, RCTs on TENS need to be designed with more consideration to these issues. There is a need for large scale multicentre pragmatic trials that include hundreds of participants, similar to that seen for acupuncture (Jena *et al*., 2008). Universally accepted practice guidelines for TENS should be developed to reduce variability in clinical practice and research, including guidelines on adequate technique and dosage. **See also**: Pain and Analgesia; Pain: Control

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