

The Discovery of Transcutaneous Spinal Electroanalgesia and Its Relief of Chronic Pain

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Key Words

Spinal cord stimulation, transcutaneous spinal electroanalgesia, unilateral tenderness.

Summary

Transcutaneous spinal electroanalgesia (TSE) is a new method employing brief pulse durations (10 μ sec or less) at relatively high voltage (50 V or more) that are designed to modulate processing of chronic pain when surface electrodes are placed on the skin overlying the spinal cord, without causing distress or side effects. In patients with chronic unilateral tenderness TSE significantly reduced tenderness as compared with the contralateral side ($p < 0.001$). A randomised, double-blind, cross-over clinical trial comparing the widespread analgesic effects of TSE with a control, showed the new method to be significantly superior ($p < 0.005$). TSE is well tolerated and can scarcely be felt. An advantage of TSE over peripheral nerve stimulation is that the surface electrodes are always placed over the spinal cord, regardless of the site(s) of pain.

Introduction

Spinal cord (dorsal column) stimulation has been practised for 28 years by means of neurosurgical implantation of electrodes in the spinal canal (Shealey, 1971). There are no reports that such stimulation produces side-effects; but there are long-term risks of infection associated with the implantation of wires and stimulator. Once the treatment is discontinued, the pain usually returns rapidly. If the method is ineffective, it requires further surgery to recover the apparatus.

To reduce the risks and costs of surgical implementation of electrodes and stimulator, we sought a non-invasive method of stimulating the spinal cord *via* surface electrodes. The problem we had to solve was to provide a current of enough amplitude to traverse the tissues that lie between the skin and the spinal canal, to elicit voltage gradients within the cord. The difficulty with existing electrotherapeutic devices, such as transcutaneous electrical nerve stimulation (TENS) is that they employ relatively broad duration pulses (50-200 μ sec) intended to excite peripheral nerves at low amplitude. Since current concentration is at its greatest in the skin immediately beneath the electrodes, cutaneous peripheral nerves are the

first to be excited as the amplitude is increased. We found a maximum tolerable amplitude of approximately 35 V when TENS was applied (2 cm radius electrodes, pulse duration 200 μ sec, and a frequency of 100 Hz). Ericson (1984) has measured TENS currents at various distances from electrodes in saline baths. When electrodes of 2 cm radius are employed, 10% of the applied current can be recorded at a distance of 5 cm, the approximate distance from the skin to the spinal cord.

We studied the effects of delivering brief duration pulses (10 μ sec or less) in order to produce a painless current of sufficient amplitude to cause changes in the spinal cord. Our rationale was that the minimum amplitude required to cause action potentials in any class of peripheral nerve is increased as the pulse width is reduced (Brinley, 1974). While maintaining a stimulation frequency of 100 Hz, we recorded amplitudes required to produce sensation at various pulse widths. Table 1 shows us the thresholds obtained in one subject (AM). Reducing the pulse width from 200 to 4 μ sec raised the amplitudes required to reach thresholds of tingling sensation and pain tolerance by a factor of approximately 8 and 5 respectively.

Table 1: Comparison of thresholds of sensation and pain tolerance obtained by pulses of 200 and 4 μ sec in one subject. In both cases the frequency was 100 Hz, the anode being placed on the skin over the spinous process of T1 and the cathode at T12

Modality	Pulse width (μ sec)	Spinal cord sensation (volts)	Tingling threshold (volts)	Pain tolerance (volts)
TENS	200	—	10	35
TSE	4	55	80	180

While employing brief pulses of 10 μ sec or less, with the electrodes placed on the mid-line of the back – the anode placed above the cathode – we observed that at a sub-threshold level for tingling, another sensation could be felt deeply in the spinal region. This is a painless feeling of continuous light pressure. This we have called *spinal cord sensation* as this deep feeling of light pressure cannot be obtained if electrodes are placed elsewhere, eg on the skin overlying the median nerve.

Table 2. Thresholds of sensations produced by 4 μ sec pulses at 100 Hz, with 4 x 4 cm electrodes placed on the mid-line of the back overlying various spinous processes

Electrode location		Threshold (volts)	
Anode	Cathode	Spinal cord sensation	Tingling threshold
T1	T2	Not obtainable	84
T1	T6	76	96
T1	T12	70	100

We discovered that when electrodes are placed on the mid-line of the back over the spinal cord, the closer they are placed together, the lower the voltage required to produce a tingling sensation; in contrast however, the higher the voltage required to elicit spinal cord sensation (table 2). Indeed, if the electrodes are placed side by side (1 cm apart), spinal cord sensation cannot be obtained.

Spinal cord sensation is rarely felt by patients in severe pain. We note their tingling thresholds are usually elevated. However we have shown analgesia is produced even when TSE is not perceived. It appears that this form of brief pulse duration stimulation produces analgesia without the necessity of peripheral nerve stimulation.

With this in mind we have explored the effects of frequencies in the region of 100 kHz, a repetition rate faster than any neurone can faithfully follow (Li and Bak, 1976). The higher the frequency, the more rapid the onset of analgesia. At 100 Hz, 40 minutes are usually required to produce analgesia; but at 150 kHz, eight minutes may be enough.

Provided electrodes are placed on the skin overlying the spinal cord, we have learnt that changes take place that produce widespread analgesia, even when the stimulation is sub-threshold so far as peripheral nerves are concerned. Thus we have called the new form of therapy *transcutaneous spinal electroanalgesia* (TSE) to distinguish it from other electrical methods that produce their effects by stimulating peripheral nerves.

We spent several months experimenting on ourselves to make sure no side effects were produced. Subsequently we performed (1) an open pilot study (N=100), (1a) a study of 16 out of these 100 patients, who presented with unilateral tenderness, and (2) a formal, randomised, double-blind, cross-over clinical trial on eight subjects not only to see what changes occur when TSE is employed, but also to provide a challenge to our hypothesis that this form of stimulation is an effective means of producing analgesia.

1. Pilot Study

Patients, Materials and Methods

Pilot studies of TSE were performed on 100 consecutive sufferers of pain (musculoskeletal, visceral and neurogenic in origin). The diagnoses included severe conditions such as osteoporotic collapse of vertebrae, post-operative pain, secondary deposits in the spine and pancreatitis (table 3). The average duration of pain was 4.7 years, and the average severity of pain before treatment was 5 on the visual analogue (VAS) scale: 0 = no pain; 10 = agony (Huskisson, 1983).

In all cases the anode was placed overlying T1 and the cathode over T12. A 4 μ sec square wave was employed at a nominal frequency of 600 Hz.

Table 3: Variety of diagnoses of patients treated by TSE in the pilot study

Achilles tendonitis; ankle pain; cervical spondylosis; osteoporotic collapse of vertebrae; degenerative changes in a variety of intervertebral discs; dysmenorrhoea; foot pain; fractures in humerus and scaphoid; heel pain; hip pain; knee pains; low back pain; migraine; migrainous neuralgia; neck pain; osteo-arthritic pains in many joints; pancreatitis; polymyalgia rheumatica; post-operative pains following Cloward's fusion of the cervical vertebrae, eye surgery and resection of the lower third of the oesophagus; post-herpetic neuralgia; post-radiotherapy pain to the larynx; post-viral fatigue pains in many regions of the body; posterior thoracic pain; pain caused by sarcoidosis affecting abdomen, shoulder and back; secondary deposits in the spine; shoulder pain; temporo-mandibular joint pain; tennis elbow; and trigeminal neuralgia.

Results

The pilot study showed that TSE produced long-term 60% or more relief after five or six weekly treatments in 63% of patients whose pain was of relatively recent origin (2.6 years).

However, 30% of patients whose pains were more persistent (on average 12 years duration) did not develop this cumulative effect, and required treatment daily to produce continuous comfort.

The remainder who failed to respond had severe anxiety, or pains of an on-going mechanical or inflammatory origin, such as severe osteoarthritis of the hip or knee, rheumatoid arthritis or ankylosing spondylitis. No side effects or interactions with drug regimens were reported.

1a. Patients in the Pilot Study who Presented with Unilateral Tenderness

Patients, Materials and Methods

Sixteen out of the 100 patients in the pilot study presented with a unilateral tender region; whereas in the remainder, tender regions were bilateral. In these 16 patients, observations in the tender region were compared with those on the

Table 4: Comparison before and after TSE treatment of the pain pressure thresholds and two-point discrimination expressed as a ratio of non-tender to tender and tender to non-tender regions respectively in 16 consecutive patients diagnosed as having unilateral nociceptive conditions in the pilot study. The contralateral (non-tender) side acted as control. The differences between pre- and post-treatment ratios are also shown in figs 1 and 2. (There was not enough time to complete the two-point discrimination test in patients k and l, who were examined in casualty)

Patient	Tender region	(N=16)				(N=14)				Relief (%)
		Pain pressure threshold ratios (non-tender/tender)				Two-point discrimination ratios (tender/non-tender)				
		Before		After		Before		After		
kg/cm ²	ratio	kg/cm ²	ratio	cm	ratio	cm	ratio			
a	(L) lumbar	3.5/2.5	1.40	4.5/4.5	1.00	9.0/5.0	1.80	6.0/5.4	1.11	80
b	(L) mid trapezius	4.5/3.0	1.50	4.1/4.0	1.03	8.7/4.2	2.07	7.0/8.0	0.88	75
c	(R) cervical	2.1/0.8	2.63	1.4/1.5	0.93	5.5/4.0	1.38	2.7/3.5	0.77	50
d	(L) mid trapezius	2.2/1.2	1.83	3.0/3.0	1.00	7.5/6.0	1.25	2.0/2.0	1.00	70
e	(L) upper trapezius	4.2/3.0	1.40	3.4/3.0	1.13	7.5/5.9	1.27	5.1/5.2	0.98	60
f	(L) sacro-iliac	2.2/1.1	2.00	3.6/3.4	1.06	7.2/4.2	1.71	3.5/3.4	1.03	50
g	(L) gluteal	2.6/2.0	1.30	2.6/2.6	1.00	8.0/7.2	1.11	7.0/10.0	0.70	80
h	(R) gluteal	5.5/1.5	3.67	7.5/8.5	0.88	9.5/4.0	2.38	6.5/6.0	1.08	75
i	(L) groin	2.0/0.8	2.50	1.8/1.8	1.00	5.5/2.0	2.75	5.0/4.0	1.25	50
j	(L) rectus abdominis	1.5/1.0	1.50	2.0/2.6	0.77	3.5/2.8	1.25	3.0/3.2	0.94	85
k	(L) scaphoid fracture	2.4/1.0	2.40	2.2/1.8	1.22	-	-	-	-	50
l	(R) rectus femoris rupture	4.0/0.5	8.00	1.8/1.8	1.00	-	-	-	-	75
m	(L) medial hamstring	1.6/0.8	2.00	1.1/1.2	0.92	10.5/6.0	1.75	8.0/7.0	1.14	25
n	(L) gluteal	0.7/0.2	3.50	0.5/0.5	1.00	9.2/8.0	1.15	4.0/4.0	1.00	50
o	(R) gluteal	2.0/0.2	10.00	0.6/0.5	1.20	10.0/6.0	1.67	5.0/4.0	1.25	75
p	(R) gluteal	4.5/3.0	1.50	4.0/4.0	1.00	5.5/3.5	1.57	6.0/6.2	0.97	100

opposite side before and after treatment with TSE. Several observations were made. Tenderness was measured in kg/cm² by a pressure threshold meter* (Fischer, 1988). A watch was attached to the device so that pressure could be increased at a steady rate of 0.1 kg/cm²/sec. An average of three observations was recorded on each occasion.

Cutaneous sensation was tested in the following ways: light touch (cotton wool), warmth (equally warm steel discs), pin-prick, and two-point discrimination.

Two-point discrimination was recorded as the least distance (cm) apart that two points of a divider could be distinguished from each other; the average of three observations was recorded on each occasion.

Results

Before treatment, in every case of uni-lateral nociceptive tenderness, the mechanical pain threshold was reduced as compared with the contralateral side.

Before treatment, however, there was an elevation of cutaneous threshold in tender regions. Patients were less able to feel cotton wool, heat or pin-prick on the tender side as compared with the contralateral non-tender side; furthermore the two-point discrimination test was increased (table 4) in all patients where it was recorded.

Following 60 minutes TSE (performed with 4 μ sec

pulses at 600 Hz), the ratios of observations made on the tender side as compared with the contralateral control, were found to be significantly reduced ($p < 0.001$) when analysed by Wilcoxon rank sum tests (table 4, figs 1, 2).

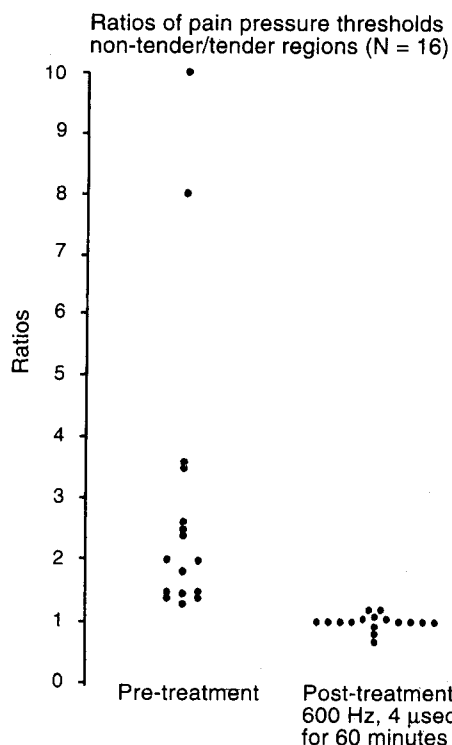


Fig 1: Before treatment, in patients presenting unilateral tender regions, the mechanical pain pressure thresholds were not as high as those obtained at the same site on the contralateral non-tender (control) side, see table 4. The ratios of thresholds of the non-tender (control)/tender regions observed before TSE are compared with those immediately afterwards

*Supplied by Pain Diagnostics and Thermography, 17 Wooley Lane East, Great Neck, NY11021, USA

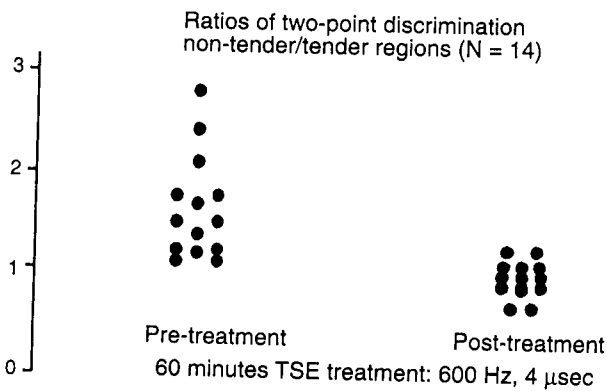


Fig 2: Before treatment in patients presenting unilateral tender regions, the minimum distance between the tips of a divider laid gently on the skin required to produce sensation of two separate points was greater on the tender region than that required on the same site in the contralateral non-tender (control) side, see table 4. The ratios of two-point discrimination of the tender/non-tender (control) regions are compared before and immediately after TSE

2. Clinical Trial

Patients, Materials and Methods

Ethical permission was granted by the United Bristol Hospital Trust Research Committee to perform a double-blind randomised cross-over study to compare the effects of one 20-minute treatment of the new method TSE (frequency 10 kHz, pulse duration 1.5 μ sec, requiring an approximate amplitude of 180 V to reach tingling threshold) with a 20-minute treatment of TENS (frequency 100 Hz, pulse duration 200 μ sec, requiring approximately 10 V to reach tingling threshold). In both cases, the anode was placed on the skin overlying the spinous process of T1 and the cathode over the spinous process of T12, regardless of the site(s) of pain.

Normally one would not apply TENS to these locations, or employ it for so short a time. We wished to use TENS in this trial as a control, to give the patient an opportunity to feel a minimal sensation on both occasions. (We avoided sham stimulation as a control, as this might have endangered the double-blind element in the trial. During sham stimulation patients might betray the fact they had no sensation, and as this was a cross-over trial they might reasonably assume this was the less active treatment.)

The trial was double-blind. On each occasion the patient was linked to both devices via a junction box designed to allow only one type of stimulation to be delivered on any particular occasion. Each junction box was coded by a trial co-ordinator who was not present during the investigation. As this was a cross-over trial, the coding ensured that every patient received each type of treatment one

after the other at a week's interval. Neither the patient nor the practitioner (AM) knew which type of treatment was administered. The junction box coding ensured that among each group of eight patients, in random fashion half received the control as their first treatment and the other half TSE. To prevent more patients than necessary becoming involved in the trial, interim statistical analysis of results by Wilcoxon rank sum tests were to be carried out independently by the trial co-ordinator when the results of each group of eight patients were made known to her. (A significant result was obtained in the first group of eight patients, so the trial was discontinued at this point).

As pain is difficult to quantify, we employed five measures of efficacy. Before and after each type of treatment, the short form McGill Questionnaire (Melzack, 1987) was completed by the patient. Physical sign scores – the total number of positive physical signs multiplied by their average severity (1 = mild; 2 = moderate; 3 = severe) were recorded by the practitioner (AM). The surface area of painful regions (an estimated percentage of total body surface) was established by the patient shading in such areas on a body outline chart. The surface area of the body occupied by abnormally tender regions found by the practitioner's palpation was recorded on another body outline chart. Finally, the average of three estimations of the mechanical pain threshold (kg/cm^2) was obtained from the most tender region by steadily increasing the pressure of 0.1 $\text{kg}/\text{cm}^2/\text{sec}$ by a pressure threshold meter (Fischer, 1988).

Patients rarely feel pain at the site of its source. As Kellgren (1977) has shown, pain is usually referred elsewhere from deep structures. So painful areas shaded in by the patients on the body outline charts have been called 'referred areas of pain'; whereas regions found to be abnormally tender to palpation by the practitioner are referred to as 'tender regions'. In these patients there was little overlap between the two on the body. It was interesting to note that on first examination the average 1.5% of the referred areas correlated well with that of the tender regions at 1.9%.

Inclusion and exclusion criteria ensured that all patients in the trial had suffered continuous musculoskeletal pain for a year or more. Of 19 consecutive patients entered for the trial, the criteria excluded 11. The duration of continuous pain, the degree of disability, the sites of the pain and diagnosis of each patient in the trial are shown in table 5. No patient reported distress or any side effect from the trial.

Table 5: Diagnoses and other parameters of the eight consecutive patients included in the clinical trial

Patient No	Sex	Age (yrs)	Duration of continuous pain (years)	Disability* %	GHQ†	Diagnosis
1	M	66	22	44.4	3	Back pain: spondylolisthesis and osteo-arthritis
2	F	53	1	44.0	3	L shoulder pain: post-injury
3	M	49	31	40.0	2	Neck pain: ankylosing spondylitis
4	M	59	17	74.0	11	Pain in neck, elbows and knees: osteo-arthritis
5	M	37	1	51.1	4	Back pain
6	F	52	14	48.9	3	Pain in L hip, groin and knee: osteo-arthritis and degenerative changes L3-S1
7	M	67	6	53.3	8	Pain in both legs: osteo-arthritis T12-L5 and spondylolisthesis of L3 on L4
8	M	59	7	66.7	7	Pain in both knees, neck, shoulders, R lumbar region and groin: post-injury and osteo-arthritis
Average		55	12	52.8	5	

*One of two types of questionnaire was chosen as the most appropriate for each patient to measure disability as a percentage score (0 = no disability; 100 = complete disability). One was designed for patients predominantly suffering upper thoracic or neck pain (Neck Pain Disability Index of Vernon and Mior, 1991); the other had a very similar format but was designed to assess the degree of disability suffered by patients with low back pain (Oswestry Low Back Disability Questionnaire of Fairbank *et al*, 1980).

†GHQ (General Health Questionnaire) is a self-administered screening test aimed at detecting psychiatric disorders in a non-psychiatric clinical setting (Goldberg, 1972). It consists of 30 questions. A score of 1 is granted if any question is answered in the affirmative, otherwise the score is zero. A total score of 6 or less is regarded by many pain clinics as an indication of a normal emotional state. So we may score depression in this way: 0 to 6 = no depression; 30 = very depressed.

Table 6: Reduction in pain scores measured by Short Form McGill Questionnaire, physical sign scores, surface areas of referred pain and tender regions, and elevation of pain pressure thresholds in a tender region, following one randomly assigned 20-minute treatment of TSE or control treatment during the clinical trial

Patients	TSE treatment								Average % change	Control treatment								Average % change
	1	2	3	4	5	6	7	8		1	2	3	4	5	6	7	8	
Short Form McGill Questionnaire																		
Before	12.90	9.80	9.00	5.00	11.00	17.00	13.00	11.50	12.40	5.50	8.40	9.00	13.00	14.30	14.20	9.50		
After	7.60	3.10	0.00	1.70	1.50	5.50	3.00	6.00	8.80	4.20	7.50	7.00	2.55	14.50	5.20	10.80		
% reduction	41.09	68.37	100.00	66.00	86.36	70.59	76.92	47.82	69.64	29.03	23.64	10.71	22.22	80.38	-1.40	63.38	-13.68	26.79
Physical sign score																		
Before	9.00	8.00	9.00	6.00	1.00	9.00	1.00	8.50	8.00	7.00	9.00	5.00	2.00	9.00	2.00	6.00		
After	3.00	4.00	6.00	2.00	1.00	5.00	0.00	4.50	8.00	7.00	9.00	5.00	1.50	9.00	2.00	6.00		
% reduction	66.67	50.00	33.30	66.67	0.00	44.44	100.00	47.06	51.02	0.00	0.00	0.00	0.00	25.00	0.00	0.00	0.00	3.13
Surface area (% body surface)																		
<i>Referred pain</i>																		
Before	1.60	2.80	0.40	2.20	1.90	0.40	1.10	2.90	1.60	0.70	0.60	3.80	1.60	0.70	0.90	3.40		
After	1.10	0.10	0.00	1.10	0.00	0.15	0.20	0.90	1.30	0.60	0.20	2.60	0.60	0.50	0.50	0.80		
% reduction	31.25	96.43	100.00	50.00	100.00	62.50	81.80	68.97	73.87	18.75	14.29	66.67	31.58	62.50	28.57	44.44	76.47	42.91
<i>Tender regions</i>																		
Before	1.00	0.80	0.40	1.40	0.90	1.30	1.40	2.25	1.60	0.50	0.80	2.20	1.00	1.20	0.90	1.45		
After	0.00	0.05	0.00	0.20	0.00	0.25	0.00	0.20	1.60	0.60	1.20	2.40	1.20	1.05	0.80	1.60		
% reduction	100.00	93.75	100.00	85.71	100.00	80.77	100.00	91.11	93.92	0.00	-20.00	-50.00	-9.09	-20.00	12.50	11.11	-10.34	-10.73
Mechanical pain pressure thresholds (kg/cm²)																		
Before	2.20	1.00	0.80	0.50	1.60	0.20	1.80	1.50	2.00	1.00	0.30	0.60	1.80	0.50	1.00	1.20		
After	3.00	2.00	1.50	0.60	5.50	0.50	3.80	3.00	2.50	0.90	0.20	0.50	1.80	0.30	1.00	2.00		
% increase	36.36	100.00	87.50	20.00	243.75	150.00	111.00	100.00	106.09	25.00	-10.00	-33.33	-16.67	0.00	-40.00	0.00	66.67	-1.04
Treatment*	T2	T1	T1	T2	T1	T1	T2	T2	T1	T2	T2	T1	T2	T2	T1	T1		

*T1 = 1st of the two randomly assigned treatment.
T2 = 2nd of the two randomly assigned treatments.

Table 7: A comparison of the mean percentage changes in five measures of efficacy (and all five combined) of the two treatments TSE and control, performed during the clinical trial (N = 8)

Treatment	Reduction in McGill pain score	Reduction in physical sign scores	Reduction in referred area of pain	Reduction in area of tender region	Increase in pain threshold	Combined average change
TSE	69.64	51.02	73.87	93.92	106.09	78.91
Control	26.79	3.13	42.91	-10.73	-1.04	12.21
Significance of difference: p <	0.005	0.01	0.01	0.005	0.005	0.005

*Assessed by Wilcoxon rank sum test.

Results

In table 7 the means of the five measures of success in the two groups are compared, and also the average reduction in all five measures combined. In every case the reduction caused by TSE was greater than that provided by the control (table 6). The differences between the effects of the two treatments were statistically significant when tested by Wilcoxon rank sum tests.

Discussion

The formal clinical trial shows unequivocal support for a beneficial effect of TSE in reducing five measures of chronic pain severity. This and the open study of patients presenting with unilateral tenderness suggests the effects of TSE are widespread, though the surface electrodes are located over the spinal cord.

To our surprise we found that those patients in our pilot study who had unilateral tenderness to deep palpation before treatment, had raised thresholds of cutaneous sensation as compared with the contralateral un-injured side. However, as expected, there was a reduced threshold to mechanical pressure, as compared with the contralateral control (table 4). Although we were not aware of their work at the time, our observations confirm the findings of Callaghan *et al* (1978) who also compared observations of unilaterally tender regions with the contralateral non-tender control side. In the tender region, they found comparatively impaired cutaneous perception not only to light touch but also to noxious heat and electric shock, co-existing with relatively increased awareness of joint position and proprioception.

It appears that the deep receptor input in the tender region is facilitated in favour of the cutaneous; while the reverse is present on the opposite side. This phenomenon may explain a commonly observed paradox: in regions that are exquisitely tender to deep palpation, patients often report a

partial numbness, and increased ability to tolerate repeated application of heat, which sometimes leads to mottled changes in the skin, *erythema ab igne*.

As the TSE surface electrodes are placed over the spinal cord, the only explanation we can provide as a cause of changes occurring in deep and cutaneous receptor thresholds on both sides of the body is that its effects are mediated *via* the central nervous system.

It has always been a mystery why so many disparate forms of treatment (some noxious and others not) such as ice, heat, liniments, massage and TENS applied peripherally to tender regions produce beneficial effects (Macdonald, 1980). Of these, acupuncture is the oldest form of peripheral stimulation recorded in detail (Lu and Needham, 1980).

We propose that peripherally applied stimulation produces analgesia by increasing cutaneous input in the tender region. This tends to offset the injury-induced changes in central activity, that before treatment had inhibited activity excited by cutaneous receptors in favour of the deep.

In treatments applied to the periphery, however, the practitioner's skills lie in knowing how to discover the location of tender regions that require cutaneous stimulation, as the phenomenon of referred pain often obscures the way (Kellgren, 1977). For example, in some patients pain in the wrist may be associated with a tender region in the lower cervical region.

On many occasions when treating patients by peripheral stimulation, another phenomenon may be observed. As one successfully reduces tenderness in one area, other regions become abnormally tender to palpation. Here again we can invoke mechanisms found within the central nervous system. These permit activities in central neurones in one region of the spinal cord to suppress those in the remainder (Le Bars *et al*, 1984).

One Advantage of TSE Over Peripheral Nerve Stimulators

The parameters of TSE stimulation are designed to avoid causing action potentials in peripheral nerves; thus the widespread analgesia we have observed cannot be explained by anything known about pain mechanisms.

The main advantage of TSE is that the stimulation is provided centrally. This allows the electrode location to be standardised regardless of the site or number of sites of tender regions or their associated referred areas of pain. It does not matter whether the pain is present in the knee, hip, spine or elbow or all four regions at once, the electrodes are always placed over the spinal cord.

TSE Does Not Mask Acute Pain

We and other practitioners have found the analgesic effects of TSE are markedly reduced when pain continues to arise from a noxious mechanical input, as may be found in severe osteo-arthritic changes in weight-bearing joints such as hip or knee, or where there is an active inflammation, eg ankylosing spondylitis, rheumatoid arthritis or gout. TSE relieves migraine, but not the pain of meningitis. This we have found to be of importance, when patients are continuing to use the method at home. To give an example: a war veteran who had suffered many years of severe post-injury pain to the abdomen derived relief from TSE applied daily, and was able to stop taking morphine; recently, however, he was able to feel the onset of angina. This caused him to report his new condition to his doctor and obtain relevant investigations and medication.

TSE appears to reduce the facilitation or sensitisation of spinal cord interneurons that remain a cause of chronic pain, when the original inflammation and peripheral nerve sensitisation has subsided. In cases where inflammation continues to provide an ongoing source of input from peripheral nociceptors, TSE does not act in any fashion as an anaesthetic. For example TSE does not relieve labour pain.

In this sense TSE may be used diagnostically: if it proves ineffective, a continuing source of inflammation or nociceptive mechanical input is likely to be present.

Anxiety associated with emotional disorder is another factor that has been found to reduce TSE's effectiveness.

Neurogenic Pain

With the anode placed on the skin overlying T1 and the cathode at T12 (fig 4), neurogenic pain (eg

sciatica, post-herpetic and trigeminal neuralgia) is temporarily made worse when TSE employs a rectangular wave form; but when the polarity of the electrodes is reversed, such hyperaesthesiae tend to be markedly relieved.

Wave Forms and Other Parameters

In our early studies, a rectangular wave form was always employed. The minimum time for the onset of analgesia was 40-60 minutes, unless high frequencies (2000 Hz or more) were employed. High frequencies place a considerable demand on the battery supply.

In our search for more rapid relief, we have discovered that when a capacitor is placed in series with the output, a differentiated wave form is produced. This wave form reduces sensation still further, yet the onset of pain relief is more rapid even at the comparatively low frequency of 600 Hz. This development allows pain relief to be produced in patients suffering frequently recurring pains such as migraine, tennis elbow, back or knee pain where no obvious signs of inflammation are present in eight to 20 minutes. However the differentiated wave form has no effect on neurogenic pain. To relieve neurogenic pain such as sciatica, trigeminal or post-herpetic neuralgia, the rectangular wave form with reversed polarity is still required. The battery operated device (fig 3) conforms to BS 5724 part 1 and produces either type of wave form as the condition requires with the following parameters: a nominal frequency of 600 Hz, a pulse width of 4 μ sec and a nominal amplitude of 120 V for square wave and 240V for the differential (\pm 10%).

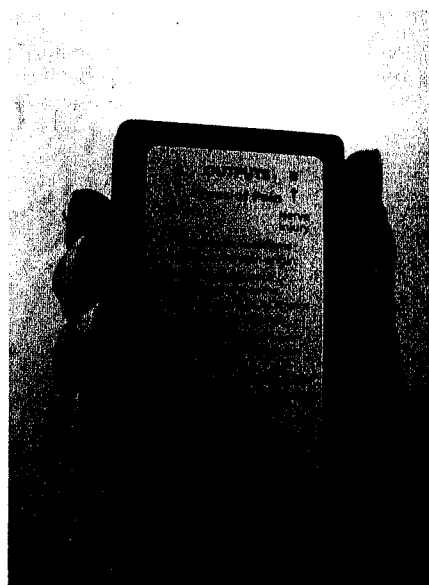


Fig 3: The TSE device capable of producing both types of wave form: (a) differentiated for treating chronic pain; and (b) rectangular wave form with reversed polarity for the treatment of paraesthesiae associated with neurogenic pains, eg trigeminal or post-herpetic neuralgia

Electrode Locations

There are two electrode locations: both overlie the spinal cord. In the usual arrangement one self-adhesive surface electrode (50 mm in diameter) is placed on the mid-line of the back at the level of T1, while the other lies over the spinous process of T12 where the spinal cord terminates (fig 4). If the lower electrode is placed over the *cauda equina*, the analgesic effects are lost. We would like to attach the upper electrode to the cervical region, but in practice it is difficult to keep it in this position for any length of time.

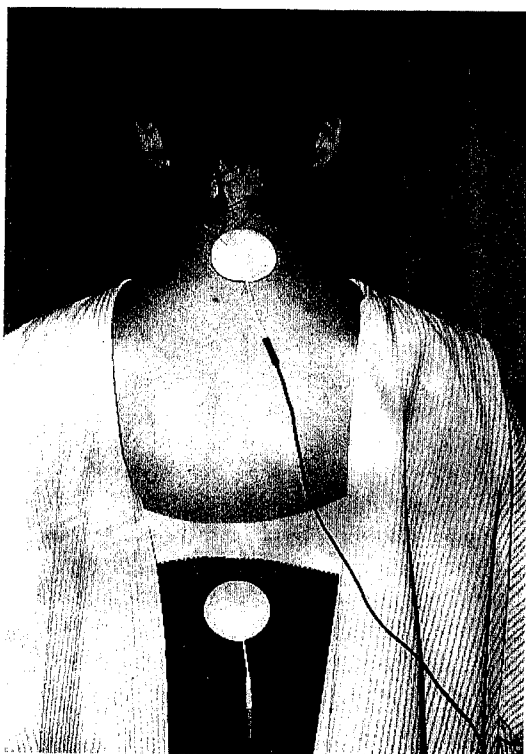


Fig 4: In order to treat pains arising in any region below the neck, the upper electrode is placed over the spinous process of T1, while the lower is placed just above the level of T12

However in order to treat pains arising in the cranium or neck, we have found that the electrodes have to be placed more rostrally: for this purpose it is sufficient to place on on either side of the neck overlying the transverse processes of C3-5 (fig 5).

Indications

The chief indication is to provide pain relief in that large group of chronic sufferers, who were injured in the past, but the original inflammation has subsided. Furthermore they have developed few mechanical changes that continue to excite peripheral nociceptors, or such changes have already been corrected by surgery. Ideally they present with little in the way of emotional disorder.

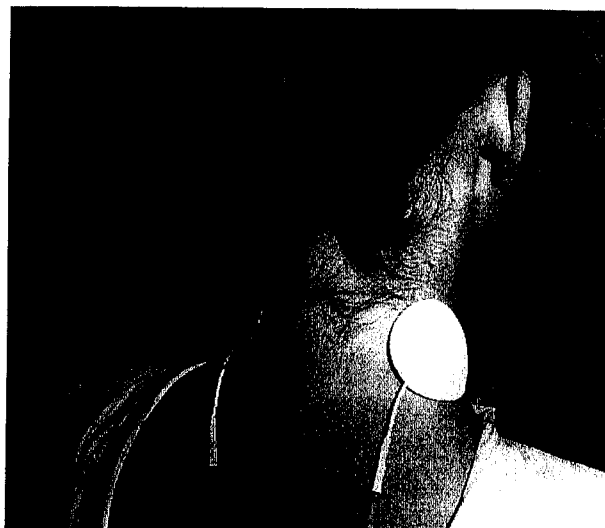


Fig 5: To treat pains arising in the cervical or cranial region, the electrodes are placed on either side of the neck over the transverse processes of cervical vertebrae

Conclusions and Recommendations

We have discovered a new method of relieving chronic pain by means of electrical stimulation applied *via* surface electrodes placed over the spinal cord, while employing brief pulses (in the region of 4 μ sec) at high voltage (in the region of 120 V or more). The higher the frequency the more rapid the onset of analgesia, but the greater the demands made on the battery supply. As a satisfactory compromise, the present device (fig 3) operates at a nominal frequency of 600 Hz.

In comparison with the usual electroanalgesic methods that are applied peripherally, the following advantages have been found: compliance is high as the stimulation can scarcely be felt; the electrode location is standardised (the electrodes are always placed on the skin overlying the spinal cord) regardless of the site(s) of pain; the minimum onset time of analgesia is eight minutes; the post-stimulation period of relief after the first treatment tends to be eight hours or more; the period of post-stimulation relief is cumulative and lasts longer after each successive treatment in those patients (63% of our pilot study), who have had an average duration of pain of two to three years, so that five or six treatments may produce relief lasting many months; however in those patients who have had pain for an average of 12 years, this cumulative effect does not occur, but the standardisation of electrode location permits them to use the device for half an hour or so a day at home to provide continuous comfort.

The disadvantages of the new method as a pain relieving system are as follows: it does not relieve acute pain, eg those pains arising from some on-going mechanical input such as a fracture or

obstetric pain, or when active inflammation is present, eg gout, rheumatoid arthritis or ankylosing spondylitis. However, this disadvantage may be regarded as an invaluable asset when patients are treating themselves at home, as the method does not mask the onset of some new disorder that requires active medical intervention such as angina, meningitis or appendicitis.

The long periods of post-stimulation relief and the ability to produce cumulative relief in non-segmental fashion suggests a similar mechanism found in electro-acupuncture (Macdonald, 1989). Its analgesic effects are as powerful as that provided by opioids, but without side effects. However with such brief pulse durations (usually 4 μ sec) action potentials are not excited in peripheral nerves. TSE is quite unlike any peripherally applied method of pain relief. We do not know why this form of stimulation should only affect pain modulation in the presence of chronic but not acute pain. Although we set out to simulate dorsal column stimulation, by chance we discovered something else, which may be more useful and practical in the relief of chronic pain as its analgesic effects are non-segmental and last longer after stimulation is discontinued. Certainly A β fibres within the dorsal columns are not stimulated by TSE, as there are no paraesthesiae.

A good deal of work is required over the next few years to discover the mechanisms of a new method that has been gradually developed since 1991. Such work may in turn lead us to a better understanding of the cause of so many distressing and disabling chronic pains.

The analgesic effects of TSE have been found to be significantly superior ($p < 0.005$) to a control in a formal randomised double-blind cross-over study in the relief of chronic musculoskeletal pain (table 7). Its effects are likely to be central in origin, as the investigations on patients in the pilot study who had unilateral tenderness have shown (table 4, figs 1, 2).

Four thousand patients have been treated without known side effects or interactions with drugs. At present 400 patients employ a portable battery-operated device at home. This device (fig 3) is being manufactured for clinics and patients as indicated.

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