A controlled double blind study comparing the effects of strong Burst Mode TENS and High Rate TENS on painful osteoarthritic knees

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This double blind, controlled study compared the changes in pain, stiffness, circumference and range of movement, produced by one 30 minute application of High Rate TENS, or strong Burst Mode TENS on chronic osteoarthritic knees. Both TENS applications were applied at strong, tolerable intensities for 30 minutes, over four acupuncture points around the knee.

Pain, stiffness, circumference, and range of movement measurements were recorded immediately before and after the TENS applications.

Length of continuation of pain relief and alteration in stiffness was reported by subjects.

The study aimed to establish whether strong Burst Mode TENS produced significantly greater and longer lasting changes than those produced by High Rate TENS.

The only significant change produced by strong Burst Mode when compared with High Rate TENS was on knee circumference.

[K Grimmer: A controlled double blind study comparing the effect of strong Burst Mode TENS and High Rate TENS on painful osteoarthritic knees: *Australian Journal of Physiotherapy* 38: 49-56]

Key words: Transcutaneous Electrical Nerve Stimulation; Osteoarthritis; Knee; Double blind method

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Although pain and dysfunction from osteoarthritic joints trouble over 40 per cent of adults in the Western world (Darby 1983, Shane and Grant 1987, Stross et al 1986), no successful cure for osteoarthritis has been found to date (Altman 1986). Common methods of treatment for osteoarthritis of the knee include joint surgery, medication, electrotherapy, muscle strenghtening and external mechanical load reducing devices (Calabro 1986, Corrigan and Maitland 1986). In view of lengthening public hospital waiting lists, the development of quality, cost effective, self-managed treatment for osteoarthritic knees is a priority (Hadler 1985).

The benefits of Transcutaneous Electrical Nerve Stimulation (TENS) for chronic pain are well documented (Dougherty 1979, Duncan 1982, Mannheimer and Lampe 1984, Smith et al 1983, Taylor et al 1981, Wolf and Gersh 1985). Its ease of application, its safety, its cost, its non-addictive nature, and its suitability for self management are influencing factors in prescribing it to relieve the symptoms of osteoarthritis of the knee (Mannheimer 1987).

The most appropriate parameters for TENS applications, such as optimal stimulation levels, pulse frequencies, electrode placements and lengths of stimulation time are at present unresolved (Mannheimer 1987, Medtronic 1982, Nolan 1987, Taylor et al 1981, Wolf et al 1981, Wolf and Gersh 1985).

High Rate TENS (70 - 100Hz) has been shown to be effective on osteoarthritic knee pain (Smith et al 1983, Taylor et al 1981, Thurin et al 1980). Although High Rate TENS was originally considered to affect spinal gating mechanisms (Melzack and Wall 1965), and disrupt central pain patterns (Melzack and Loeser 1978), research has indicated that it may also stimulate particular endogenous opiates (Andersson et al 1976, Basbaum 1980, Basbaum and Fields 1978, Hughes et al 1984, Miller and Deyo 1980, O'Brian et al 1984, Sjolund and Eriksson 1979).

Current research into High Rate TENS continues, however, to establish it as producing sensory responses only (Lundberg 1984, Mannheimer 1987).

Although Mannheimer (1987) advocates the use of Strong Burst Mode TENS (three Hz trains of seven High Rate pulses) for chronic joint pain, there is little evidence that it reduces the symptoms of osteoarthritis of the knee. Strong Burst Mode TENS is thought to act similarly to Low Rate TENS in creating powerful intrinsic endogenous opiate stimulation (Sjolund and Eriksson 1978). It requires less intensity to produce the required sensations because it reduces skin impedance with its train of High Rate pulses (Mannheimer 1987). The protocol for a successful application of

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strong Burst Mode TENS mirrors that for Low Rate TENS, in that strong, rhythmic muscle contractions must be established for 30 minutes before the TENS application can be considered to be maximally effective (Lundberg 1984, Mannheimer and Lampe 1984, Wolf and Gersh 1985). Strong Burst Mode TENS is considered to produce both sensory and motor responses.

These regular, strong, muscle contractions around a swollen osteoarthritic joint may activate a pumping mechanism which may alter local fluid stasis (Garl and Cooper 1979, Wolf et al 1978), thus affecting joint stiffness and swelling. Lundberg (1984) suggests that local pain receptors may also be stimulated by a strong Burst Mode TENS application.

The changes produced by endogenous opiate stimulation have been shown to last longer than those produced by spinal gating (Lampe and Mannheimer 1984, Lundberg 1984). This is most readily explained by examination of the half life of the endogenous opiates (Clement-Jones 1983, Terenius 1979).

Although both High Rate and Burst Mode options are available in transcutaneous electrical nerve stimulators presently on the market, the most effective frequency for relieving the symptoms of osteoarthritis has not been demonstrated.

This study was conducted to test the hypothesis that strong Burst Mode TENS would produce greater and longer lasting reduction in pain, stiffness and swelling in osteoarthritic knees than would be produced by High Rate TENS.

Measurements

A vertical Absolute Visual Analogue Scale (AVAS) (Zusman 1986) was used for recording the pain measurement in this study because it has been demonstrated to be reliable, convenient and inexpensive (Melzack 1975, Scott and Huskisson 1976).

The measurement of stiffness by the AVAS had no precedent in the literature reviewed for this study. Stiffness is inherently a subjective measure, although change in stiffness may be related more to objective changes in the joint. Both Melzack (1975) and Stewart (1977) considered the AVAS a successful measuring device for any subjective assessment.

In this study, two parallel, vertical AVASs were used to measure immediate change in knee joint pain and stiffness.

Verbal reports of length of pain and stiffness relief have been used previously (Dougherty 1979, Mannheimer et al 1984, Smith et al 1983, Taylor et al 1981). Altman (1986) suggests that sufferers of chronic osteoarthritis of the knee can accurately report the diurnal variations of their pain, because of their experience with the nature of the disease.

A standard goniometer (Gifford 1914) was used to measure knee joint range of movement before and after the test. The goniometer is considered to be a reliable means of measuring linear joint movement if re-test reference points are marked (Dorinson and Wagner 1948, Leighton 1955). The goniometer was aligned with pen markings, indicating the line of the femur and the tibia for re-test reliability.

A non-elastic tape-measure was used to measure joint circumference. The protocol expounded by Amarasinghe (1966) for the measurement of a baby's head circumference was adopted, while marks were made around the knee joint line for re-test reliability. Tape measurements made in this fashion are considered reliable by De Boer (1975) and Tanner et al (1966).

Table 1.
Particulars of subjects participating in the study

	Males	Females	Age $\bar{X}$	Age (SD)	Years of osteoarthritis $\bar{X}$	Years of osteoarthritis (SD)
High Rate TENS	7	13	65.6	(16.2)	5.6	(6.6)
Strong Burst Mode TENS	8	12	65.7	(16.5)	9.9	(10.5)
Placebo	8	12	68.4	(11.3)	7.9	(9.0)
Total	23	37	66.5	(14.6)	7.8	(8.9)

Methods

Study sample

Sixty male and female subjects with ongoing, chronic osteoarthritic knee pain were randomly allocated (by dice) into three groups of 20, by a person independent of the study. Each group was tested with one application of either High Rate TENS, strong Burst Mode TENS or a placebo. The one researcher prepared the knee, and applied the TENS currents. All the measurements were made and recorded by another person who was blinded to the variables of the TENS applications and was independent of the study.

The study sample was drawn from 76 possible candidates, whose names were supplied by public and private outpatient records within the Hobart and Huon Valley environs.

The inclusion criteria for the study sample were:

1. Osteoarthritis as the only source of present knee pain, having been diagnosed by X-ray at least six months earlier (NH & MRC 1988),
2. Voluntary withholding of all analgesics, muscle relaxants and anti-inflammatory drugs for 48 hours prior to the test, and until

Table 2.
Pain, stiffness, circumference and range of movement measurements before and after the TENS test.

	Before the test		After the test		Difference	
	$\bar{X}$	(SD)	$\bar{X}$	(SD)	$\bar{X}$	(SD)
IMMEDIATE PAIN RELIEF (centimetres)						
High Rate TENS	7.1	(3.0)	2.2	(2.8)	4.9	(3.3)
Strong Burst Mode TENS	5.9	(2.3)	1.5	(1.8)	4.4	(1.8)
Placebo	6.3	(2.4)	3.5	(2.9)	2.8	(3.2)
LENGTH OF PAIN RELIEF (hours)						
High Rate TENS					15.8	(9.9)
Strong Burst Mode TENS					17.7	(8.0)
Placebo					10.2	(10.2)
IMMEDIATE STIFFNESS MEASUREMENT (centimetres)						
High Rate TENS	6.0	(3.9)	1.6	(2.6)	4.4	(3.8)
Strong Burst Mode TENS	5.7	(3.6)	2.1	(2.8)	3.6	(3.3)
Placebo	4.6	(3.8)	2.4	(3.1)	2.2	(2.3)
LENGTH OF STIFFNESS RELIEF (hours)						
High Rate TENS					16.3	(10.6)
Strong Burst Mode TENS					15.9	(9.1)
Placebo					7.0	(9.2)
KNEE CIRCUMFERENCE (centimetres)						
High Rate TENS	39.3	(3.1)	38.9	(3.2)	0.4	(0.3)
Strong Burst Mode TENS	40.6	(4.5)	39.8	(4.5)	0.8	(0.7)
Placebo	39.8	(3.3)	39.4	(3.2)	0.4	(0.4)
KNEE RANGE OF MOVEMENT (degrees)						
High Rate TENS	103.4	(10.2)	110.3	(9.6)	6.9	(7.9)
Burst Mode TENS	97.8	(9.2)	108.0	(9.3)	10.2	(12.9)
Placebo	105.9	(9.7)	108.9	(7.4)	3.0	(6.4)

normal pain returned,

3. The subject had no previous experience of TENS current,
4. The subject was able to independently complete the AVASs,
5. In the case of multijoint involvement, the subject could distinguish the most painful knee,
6. The subject did not wear a hearing aid or pacemaker during the TENS application, and
7. The subject's doctor considered the person to be fit to take part in the study.

Of the 76 potential candidates, one suitable man died before the test was conducted, two women refused to take part, one man and one woman had had previous experience of TENS current, five men and three women had no present knee pain, and three women were considered too ill to participate, by their doctors.

Skin testing and preparation

Prior to the TENS application, all subjects were skin tested for sharp prick, (using a tooth pick), and heat, (using a heated metal spoon), over the entire knee area. All subjects were found to have normal sensation.

The skin around the knee was then washed with warm water and a small amount of soap, rinsed with warm water, and dried with a towel, before testing took place.

Transcutaneous Electrical Nerve Stimulation parameters

Electrode placements

Acupuncture points were chosen for this study because they were likely to maximise intrinsic opiate response (Andersson et al 1973, Andersson and Holmgren 1975, Mann et al 1973, Melzack 1976, Melzack et al 1977), and were convenient and reproducible (Mann 1987, Mannheimer et al 1984, Smith et al 1983, Thurin et al 1980).

Four carbon/rubber/silicone electrodes of two by three centimetres were used in parallel dual channel placement, illustrated in Figure 1, over

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areas associated with the acupuncture points on the medial (Spleen 9), lateral (Gall Bladder 33), posterior (Urinary Bladder 40) and anterior (Spleen 10) aspects of the knee.

Apparatus

A Medtronic Neuromod Selectra TENS was used which produced a High Rate current of 80Hz, and Burst Mode current of three Hz trains of seven 80Hz pulses. New batteries were used every 10 hours of operation, and the output of the machine was checked by an independent medical electrician at the same time. Nonfunctioning leads were used with the same machine to create the placebo application.

A thin coating of Sealsystems Gel (Page Medical) was smeared over the entire surface of each electrode prior to TENS current being applied. This gel is low irritant, and consists of a neutral hypoallergenic base with added low chloride ionic species. Its density is 1100kg per cubic metre and its velocity (at 3.5MHz), is 1500m^{-1} (Specifications 1989).

Stimulation intensity

Group 1 (High Rate TENS):

The desired intensity was a strong, tolerable tingling paraesthesia throughout the area of pain.

Group 2 (strong Burst Mode TENS):

The desired intensity was a strong, tolerable, tingling sensation producing visible, comfortable muscle contraction.

Group 3 (Placebo):

The placebo subjects were told that a very high frequency current was being tested, and that no skin sensation would be felt.

The adaptation speed of hairy dermis, epidermis and C fibres (Willis and Grossman 1973) necessitates regular increases in High Rate TENS current to maintain perceived stimulation (Bloom 1981). Lampe and Mannheimer (1984) suggest that a decreasing strength of stimulation is perceived every five to 10 minutes during both High Rate and Burst Mode TENS application. Thus, to maintain a strong, comfortable, constant stimulation, all subjects were asked to increase the intensity of their TENS stimulation by three to five points (on visual display) every five minutes throughout the test. This protocol was also considered to reinforce the placebo application. The TENS currents were applied for 30 minutes.

Test position

For the duration of the test, the subject lay comfortably with the painful knee supported by a foam roll approximately 15 degrees from full extension. To evaluate knee stiffness before and after the test, subjects were asked to assess non-weight bearing rhythmic flexion and extension of their painful knee.

Outcome factors

The changes produced by the TENS applications were measured by:

- pain change on AVAS: immediately pre and post-test,
- stiffness change on AVAS: immediately pre and post-test,
- pain relief time (in hours) taken up to 24 hours after the test,
- stiffness relief time (in hours) up to 24 hours after the test,
- change in knee circumference: immediately pre and post- test,
- change in knee range of movement: immediately pre and post-test.

Results

The age and osteoarthritis history of the subjects who took part in the study are reported in Table 1. The means and standard deviations of the measured outcomes are presented in Table 2.

Pooled variance two-tailed *t*-tests were used to calculate the significance of the outcomes of this study. The results demonstrated several important points.

There was no significant difference between the strong Burst Mode TENS, High Rate TENS and placebo TENS in reducing the immediate pain.

Only Burst Mode TENS produced a significant length of pain relief, when compared with the placebo ($t_{(38)} = 2.58$, $p = 0.014$).

Only High Rate TENS produced a significant amount of immediate stiffness relief when compared with the placebo ($t_{(38)} = 2.22$, $p = 0.03$).

There was a significant difference between the length of stiffness relief produced by Burst Mode TENS and the placebo ($t_{(38)} = 3.96$, $p = 0.005$), and between High Rate TENS and the placebo ($t_{(38)} = 3.08$, $p = 0.004$)

Burst Mode TENS produced a significantly greater change in circumference than High Rate TENS ($t_{(38)} = -2.15$, $p = 0.04$).

Burst Mode TENS produced a significantly greater change in range of movement than the placebo ($t_{(38)} = 2.23$, $p = 0.03$).

Discussion

The results of this study do not support the hypothesis that strong Burst Mode TENS produces significantly greater changes in osteoarthritic knee pain, stiffness and range of movement, than those produced by High Rate TENS.

Three notable findings resulted from this study:

1. There was a greater than expected length of pain and stiffness relief produced by both High Rate and strong Burst Mode TENS.
2. There was a significant decrease of immediate post-test stiffness produced by High Rate TENS.
3. There was a large placebo response in immediate pain and stiffness relief.

Each of the measured outcomes is discussed briefly.

Immediate pain relieving effects

Although the measurements of immediate pain relief produced by High Rate TENS, strong Burst Mode TENS and the placebo were not significant when compared with each other, both the High Rate TENS and the strong Burst Mode TENS

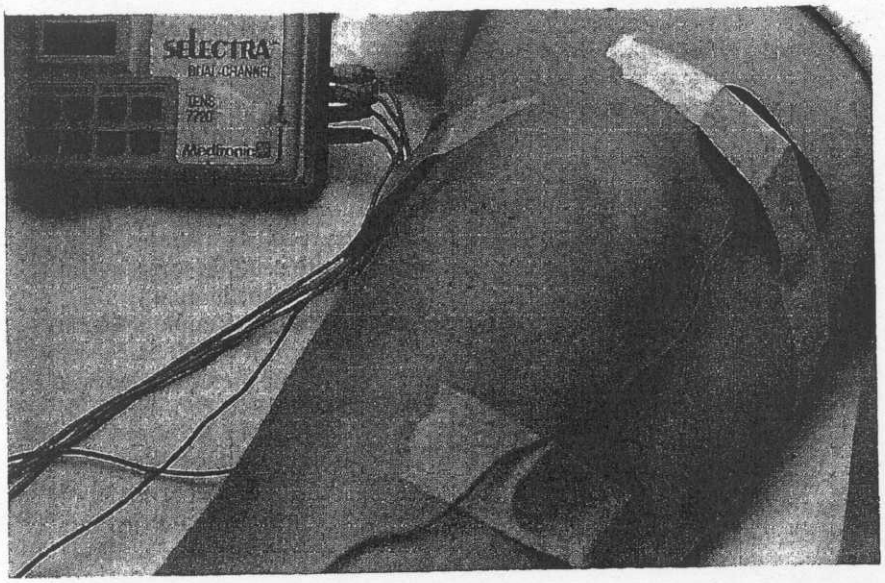

Figure 1.
Electrode positions used for all TENS appliations.

application relieved the average pre-test pain by more than 50 per cent, (20 per cent and 30 per cent respectively, greater than the placebo), suggesting that both active TENS applications had been successful (Hansson and Ekblom 1983, Salar et al 1981). Randomly assigning the subjects into the three groups was reasonably expected to distribute important differences in pre and post-test pain appreciation which may have confounded this result.

The length of pain relief after the TENS test

Strong Burst Mode TENS compared with the placebo produced the only significant result, although with greater numbers it could be argued that the High Rate TENS result, compared with the placebo, may have been significant ($t_{(38)} = 1.77$, $p = 0.085$). Both the High Rate TENS mean (15.8 hours) and the strong Burst Mode TENS mean (17.6 hours) are in excess of the pain relief suggested in the literature (Mannheimer et al 1984, Smith et al 1983, Taylor et al 1981, Thurin et al 1980). Both active TENS applications could be assumed to be superior to the placebo application.

It could reasonably be expected that the mechanical pain processes of an osteoarthritic knee would be stimulated, immediately weightbearing was resumed. The pain relief demonstrated in this study may have had several explanations.

It was anticipated that placing the electrodes over the areas associated with acupuncture points would maximise pain mediation by both active TENS applications. Whether the acupuncture point alone was stimulated, however, is debatable, given the size of the electrodes used in this study.

Alternatively, the effect of the different applied current frequencies needs to be considered. The High Rate signal was a constant 80Hz, while the strong Burst Mode signal was an interrupted flow of 80Hz signal. The sensory only nature of the High Rate TENS would be considered to have a different effect on circulatory and neurological systems than that produced by the combined sensory/motor nature of the strong Burst Mode current. The motor effects of muscle contraction, alteration in blood flow and increased joint lubrication due to the tolerable, rhythmic contractions produced by strong Burst Mode TENS may have mediated additional pain relief.

In addition, it could be argued that because hormones, such as Adrenocorticotrophin and B-lipotropin, are known to be released as a result of stress (Clement-Jones 1983, Tseng et al 1976, Wilkes et al 1980), the strain of attending an appointment, withdrawing medication, subsequent increasing pain, and focusing on the behaviour of the painful knee may have mediated additional pain relief mechanisms.

Immediate post-test stiffness relief

High Rate TENS produced the only significant result with respect to the placebo. Given the means of the pre-test stiffness measurement, it must be suggested that by chance the placebo group was less stiff than the other groups. The placebo group also had a greater mean pre-test range of movement.

Although the concept of stiffness is abstract, the causal factors may well be mechanical and measurable. Although there was a consistent correlation between stiffness measurements, circumference measurements and range of movement, there was no correlation between pain and stiffness measurement. Muscle tone and strength, blood supply, concentration of toxins within the joint, joint swelling and ligament dysfunction may all affect joint stiffness, independent of their causal relationship with pain.

No subject had any difficulty differentiating between stiffness and pain. In verbal reports of length of pain and stiffness relief, the answer was often different. Eight subjects, (four in High Rate Group, two in Burst Mode Group, two in Placebo Group) had no problem with stiff knees, while seven subjects experienced more stiffness than pain.

Length of stiffness relief lasting after the test

As has already been noted, the length of stiffness relief was greater than expected (Smith et al 1983, Taylor et al 1981). Both High Rate TENS and strong Burst Mode TENS produced

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significant lengths of stiffness relief when compared with the placebo. Again, the superiority of the active TENS applications with respect to the placebo can be assumed.

High Rate TENS may produce local tissue and joint changes that are not fully explained by the current theories about its action. In addition, the endorphin response to this application of strong Burst Mode TENS may not have peaked immediately after the test. Maximum stiffness relief from strong Burst Mode TENS may thus not have occurred until some time later.

Further investigation into the local biochemical response to both strong, tolerable High Rate TENS and strong Burst Mode TENS is indicated.

Circumference change

Strong Burst Mode TENS produced a significant result with respect to High Rate TENS, and approached a significant result with respect to the placebo ($t_{(38)} = 1.96$, $p = 0.06$). The knees subjected to the High Rate TENS application showed the smallest mean decrease in circumference immediately after the test. This may support the already discussed contention that High Rate TENS produces local changes in tissue behaviour, possibly a short-term increase in blood supply. The significant strong Burst Mode result was anticipated, due to the documented objective changes in joint performance created by Low Frequency TENS current (Garl and Cooper 1979, Wolf et al 1978).

Given the experimental design, joint circumference was unable to be measured any later than immediately post-test. Had this been done, other trends in both High Rate and strong Burst Mode TENS action may have become more apparent over time.

Change in range of movement

The significant change in circumference produced by strong Burst Mode TENS anticipated the significant change in range of movement with respect to the placebo. Because of the pumping action produced by strong Burst Mode TENS, a decrease in fluid around the joint could be expected to create greater freedom of movement within the joint. The correlations between overall stiffness change, change of circumference and the change in range of movement support the theory that stiffness is related more to objective changes than it is to pain. It also suggests that stiffness may have other causes than simply fluid stasis in the joint.

Given the significance of the High Rate TENS immediate post-test stiffness result, it is not surprising that it also appears to affect immediate change in range of movement ($t_{(38)} = 1.73$, $p = 0.09$).

Placebo TENS result on pain and stiffness relief

Placebo studies have been conducted since TENS was developed (Hansson and Ekblom 1983, Long (1974), Smith et al 1983, Thorsteinsson et al (1977, 1978). It has been suggested, that a placebo TENS application may itself stimulate endomorphins (Chen 1980, Levine et al 1978, Skrabanek 1978). The effect of placebo TENS on chronic pain is reported by Thorsteinsson et al (1977) as 33 per cent. Assuming this is based on mean pain relief, the effect in this study is 40 per cent. Reasons for this response may be an unreasonable expectation of success created by being invited to participate in a study of this nature, enhancement of the placebo effect by the use of the flashing light and digital display on the Selectra TENS, and giving the subject active control over their own pain relief. The placebo response in the length of stiffness relief (mean 7.0 hours) also invites comment. The mean length of placebo stiffness relief is higher than could be anticipated from an application that should have only the effect of rest on joint performance. Given that stiffness change did not correlate with pain change, any changes generated by personality and expectation cannot be expected to have lasting effects on stiffness.

Representativeness of the results

The question of external validity must be considered. Given the lack of medical, financial and clerical support, the study sample was drawn from a limited population area. Such a limited population may not have yielded a totally representative sample of subjects with painful osteoarthritic knees. Despite the limited geographical areas sampled, the ratio of women to men was similar to that suggested in the literature reviewed for this study.

Possible causes of bias

Age and the length of time the subject suffered from osteoarthritis may have confounded the results, despite randomisation. The variations in age of subjects was large, as reported by the standard deviation. There was a significant correlation between age and the length of time the subject had suffered from osteoarthritis, both overall and in the group tested with strong Burst Mode TENS.

An expectation of a result, despite information to the contrary, (verbally at the time of initial contact, and in the written test information sheet) may have been created because of disappointment in ongoing pain relief measures currently available for chronic osteoarthritis of the knee. The personal attention received by the subjects when participating in this trial may also have enhanced well-being, and consequently altered pain thresholds.

The amount of rest or exercise undertaken by each subject after the test, was an uncontrolled variable in this study. Subjects were asked to continue their normal daily routine, but as many of the subjects had journeyed some distance to participate, more exercise than normal may have occurred simply by attending the test venue.

In addition, inadequate diet in some subjects may have confounded the results. Dietary intake of tryptophan directly affects the production of serotonin, an amino acid involved in regulation of temperature, pain, sleep,

mood and appetite (Bowsher 1978, Messing and Lytle 1977, Seltzer et al 1981). Adequate tryptophan intake is ensured by including eggs, meat, poultry and dairy products in the diet (Wurtman 1982). No attempt was made by this author to investigate the dietary habits of the subjects.

Conclusions

This study suggests that strong Burst Mode TENS does not produce universally greater changes in pain, stiffness and range of movement, than those produced by High Rate TENS, when both are applied at a strong, tolerable intensity for 30 minutes to the same acupuncture points on painful osteoarthritic knees. The results from both active TENS applications are similar, and, despite the size of the placebo response, must be considered to be superior to the placebo.

Further study is indicated to establish other parameters relevant to this form of treatment. These include the High Rate TENS effect on joint stiffness, whether the use of acupuncture points for High Rate TENS electrode placements enhances the response, whether the responses from High and Burst Mode TENS endure past 24 hours, and whether the same responses from High Rate TENS, strong Burst Mode TENS and the placebo can be reproduced over time.

The legal, ethical, financial, therapeutic and social ramifications of home use TENS units indicate the urgent need for better understanding of TENS action.

Acknowledgements

The author acknowledges the support, advice and encouragement of Prof Terry Dwyer and Mr Michael Jones, during the preparation of this paper. The assistance of Imbros, Hobart in providing equipment is also acknowledged.

The paper was completed in association with The Menzies Centre for Population Health & Research, Clinical School, Royal Hobart Hospital, Hobart. The study was undertaken to complete the requirements of a Masters Degree in Medical Science from the University of Tasmania in 1989.

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