

attributed the high incidence of skin morbidity to the low-energy neutron beam (7.5 MeV) with its poor physical characteristics. Griffin *et al.*⁴ found an increase in complications of about 30% with low-energy compared with high-energy neutrons. Complications are also related to the volume treated.

It is hoped that with high-energy machines and well-collimated beams, the incidence of late effects will be reduced.

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Oral and Maxillofacial Surgery

Transcutaneous electrical nerve stimulation in the treatment of myofascial pain dysfunction

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Summary

The effect of transcutaneous electrical nerve stimulation (TENS) plus conservative therapy (ibuprofen, bite plate, self-physiotherapy) on myofascial pain dysfunction (MPD) was determined. A single-blind trial was done in 10 patients with MPD with subthreshold TENS (frequency 35 Hz, pulse width 100 milliseconds, modulation 50%) compared with sham TENS at 8 visits over 14 weeks. Pain was assessed on a visual analogue scale before and after TENS at each visit and the data were analysed with the analysis of variance (ANOVA) for repeated measures. A highly significant effect was seen for time ($F = 4.80$, $P = 0.0003$) but not for TENS. Subthreshold TENS did not increase the symptom relief produced by conservative treatment with the protocol used.

Chronic pain syndromes have been defined as persistent pain that lasts more than 6 months and are associated with behavioural and psychosocial factors.¹ Chronic facial pain may be atypical and reported prevalence varies. Two recent studies, for example, have reported chronic pain syndrome prevalences of 86%² and 12%,³ a large proportion of which was directly associated with the temporomandibular joint (TMJ) and adjacent tissues.

It is clear that chronic facial pain is an important problem. A common form of chronic facial pain is myofascial pain dysfunction (MPD), the broad concept of which was first described by Schwartz.⁴ In this syndrome complex diagnostic features vary slightly from clinician to clinician but common features are TMJ noise associated with mandibular movement, myalgia and arthralgia resulting in limitation of movement of the mandible, pain radiating from the pre-auricular area to local muscles, aching of the head and neck, and trigger spot: which are nodular areas of muscle which elicit pain if palpated. The pain is usually unilateral, and it is often worse on rising in the morning although it may intensify during the day.⁵ There are usually no clinical, biochemical or radiographic changes in the TMJ, since the primary site of the problem is not in the joint. Gelb⁶ stated that all patients with MPD have the following three factors: compromised neuromuscular, skeletal or dental tissues, emotional stress, and bruxing or clenching of the dentition (parafunction). In many individuals these factors are subclinical. In those individuals in whom one or more of the symptoms increase, MPD will become clinically evident.⁶

Treatment of the condition is usually conservative, consisting of elimination of parafunctional habits like grinding or clenching of teeth, physiotherapy, anti-inflammatory drugs or a bite plate. Response to conservative treatment varies from patient to patient and is not always ideal, and additional treatment modalities are constantly being tested in order to improve results.

One proposed modality has been transcutaneous electrical nerve stimulation (TENS) in which electrical impulses of a

defined frequency and wavelength are applied transcutaneously via electrodes on the surface of the skin to produce local analgesia. The technique was used as early as 1858 for tooth extraction⁷ but was abandoned until the 'gate control theory' of pain control was formulated by Melzack and Wall.⁸ Since then several studies of TENS in MPD have been done. Some authors felt that the method had promise^{2,9-12} but others disagreed.¹³ The use of the TENS in the management of chronic facial pain has been documented. For example, Bremerich and colleagues' study² evaluated the efficacy of TENS in the treatment of various diverse forms of chronic facial pain. They concluded that TENS is a simple, safe and effective method of treating chronic facial pain. Most of the literature reviewed did not stipulate specific settings for the frequency, pulse width or modulation settings of TENS, an omission that makes comparative studies difficult.

The present study was done to evaluate the efficacy of TENS in the treatment of MPD through standardisation of 11 independent variables: the type of TENS unit, the type and composition of the electrodes, the type and make of electrode, the site of placement of the electrodes, the number of electrodes, the frequency of the electric impulse, the pulse width (wavelength) of the generated pulse, the intensity of the generated pulse, the modulation of the electric impulse, the duration of the TENS treatment, the number of treatment sessions and the time period between treatment sessions.

Material and methods

Prior to the commencement of the study the protocol was scrutinised by the University of the Witwatersrand's Committee for Research on Human Subjects. Clearance was granted provided that no patient would be denied the benefit of accepted modes of conservative treatment. The trial design therefore consisted of a normal conservative management programme with TENS as an adjunct to this treatment.

The study was done at the TMJ clinic in the Division of Maxillofacial and Oral Surgery, University of the Witwatersrand. Patients were selected for the study after completion of a detailed TMJ questionnaire (available from the authors) and clinical examination. Only patients who presented with pure MPD, or those with MPD and an associated anterior dislocation of the meniscus with spontaneous reduction, were requested to join the study. Over an 18-month period 10 patients fulfilled the inclusion criteria and all consented to participate in the study knowing that a sham treatment was possible. The first patient was randomly allocated to a group by drawing lots, thereafter patients were alternated into treatment groups. All patients received standard conservative management for MPD. In addition the control group was given sham TENS treatment while the test group received active TENS treatment.

At the first visit, after diagnosis and recruitment into the study, each patient received a brief explanation of the problem, and was counselled about possible parafunctional habits; a soft diet and a home physiotherapy programme were recommended. In addition, ibuprofen 400 mg 3 times a day was prescribed for 1 week. Impressions of mandibular and maxillary teeth were taken for the construction of a bite plate — an upper Hawley type which allowed occlusion of only the lower incisors with the plate while separating the premolar and molar teeth by approximately 2 - 3 mm. The first TENS treatment was given at this visit. The pain level was quantified on a pre- and post-TENS treatment visual analogue scale (VAS) from 0 (no pain) to 10 (unbearable pain). The VAS system was chosen because Shipton¹⁴ has termed it the best 'paper and pencil instrument' for clinically assessing pain intensity. At the second visit the occlusal splint was fitted and an even contact flat plane occlusion of the patient's lower

incisors with the splint was provided by spot grinding using Bausch BK01 blue articulation paper (Bausch KG, Köln, West Germany). The second TENS treatment followed. The articulation of the lower incisors to the splint was checked at each visit and adjusted if necessary. The third to the seventh visit comprised TENS treatment while the eighth and final visit consisted of TENS treatment, clinical evaluation and final explanation of the problem and discharge from the study. At each of the visits where TENS treatment was provided, pre- and post-TENS pain values were recorded using the VAS.

The clinical evaluation was repeated at this point using the TMJ clinic questionnaire to evaluate muscle tenderness. This was an indication of the patient's response to treatment and determined whether the patient needed to continue treatment outside the scope of the study. If the latter was the case then the patient was referred back to the TMJ clinic for further management.

A Medimod TENS Unit # 44105 (Medical Devices Incorporated, St Paul, Minn., USA) (Fig. 1) was used. This is a dual channel machine which allows both left and right TMJs to be treated simultaneously and permits the frequency, wavelength and intensity to be varied. There is also a modulation facility which modulates the frequency and pulse width in a cyclical manner in order to minimise the possibility of tachyphylaxis to the generated pulse.

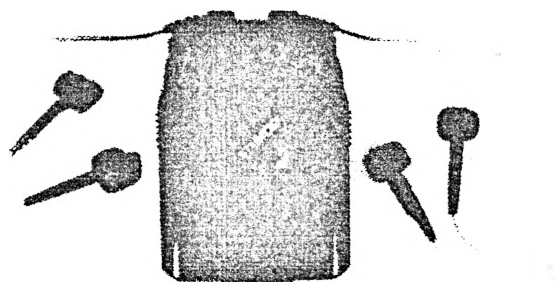


Fig. 1. The TENS unit.

Reasoning for the selection of definitive frequency, pulse width and modulation values was twofold, the first being the success rates reported in previous studies and the second a desire for an easily reproducible method for further studies. Shipton¹⁴ describes a 'low frequency high intensity stimulation pattern' to be effective in the treatment of chronic pain. Linzer and Long reported a 74% success rate in pain relief with the use of frequencies of 14 - 60 Hz.¹⁵ Tulgar *et al.*¹⁶ reported that TENS frequencies of 20 - 80 Hz produced the greatest analgesic effect and used pulse widths ranging from 50 to 200 microseconds in their study. Also reported in Tulgar's study is that frequency-modulated stimulation seemed to be more effective than conventional constant-mode stimulation.

The frequency setting used in this study was one of a relatively low frequency of 35 Hz, with reported success rates obtained using frequencies between 14 and 80 Hz. A pulse width of 110 microseconds was chosen also within the ranges used in prior studies. As frequency-modulated stimulation has been reported to be desirable, a modulation setting of 50% was selected for the study.

Placement of electrodes involved the identification of trigger point areas in the masseter and temporalis muscles by eliciting tenderness to palpation. Rubber electrodes 10 mm in diameter (Medical Devices Incorporated, St Paul, Minn., USA) were then placed with an adhesive electrode gel bilaterally on the masseter and temporalis trigger point areas (Fig. 2). The TENS unit was switched on and the intensity was increased until the patient was aware of a sensation. The



Fig. 2. Placement of electrodes.

intensity was then decreased to subthreshold levels after which the patient was treated for 30 minutes. A threshold level was determined at each treatment session in order to adjust the intensity to the subthreshold level at that particular appointment.

The TENS units for the control patients had electrode leads severed internally to ensure that the control TENS unit remained operative — with the red indicator light flashing, but the impulse generated did not reach the patient. No threshold was set with these patients, and they were unaware of the use of threshold sensation to set subthreshold treatment levels in the treatment patient group.

The data were then entered into the IBM 3083J24 main-frame computer at the University of the Witwatersrand and analysed using SAS[®] with an analysis of variance (ANOVA) for repeated measures test. The critical level for statistical significance was set at $P < 0.05$.

Results

Details of the patients are given in Table I. The gender ratio was 6 women to 4 men; the youngest patient was aged 21 years and the oldest 58. In the control group the mean age was 40.2 years (SD 14.6) and in the treatment group the mean age was 36.8 (SD 15.6). The duration of symptoms varied between 5 and 60 months. The mean duration was longer in the control group (mean 26.2 months, SD 22.1) than in the treatment group (mean 16.8 months, SD 10.7) because of the very long history of patient 3.

The overall results of the study are summarised in Table II as mean pain scores. When the grouped values are examined greater fluctuation in pain scores can be seen in the control group. The TENS group shows a clear reduction in pain score over the 8 visits.

The repeated ANOVA results showed a highly statistically significant result for time ($F = 4.80, P = 0.0003$), but treatment and time interaction was not statistically significant ($F = 0.58, P = 0.77$), which indicates that TENS had no significant effect in the trial.

TABLE I. DETAILS OF PATIENTS

Group	Patient	Gender	Age (yrs)	Duration of symptoms (mo.)
Control	1	F	52	18
	2	M	50	12
	3	F	28	60
	4	M	50	5
	5	F	21	36
Treatment	6	M	27	12
	7	F	58	12
	8	F	24	12
	9	F	26	12
	10	M	49	36

Discussion

All the participants in the trial were enthusiastic, ready to try any additional treatment to alleviate their distress, and able to use the VAS to describe their pain. In this trial the patient was blind to the treatment but bias was minimised because each patient, and not the therapist, measured the pain score. Examination of the individual results of each patient (Table

TABLE II. MEAN (SD) PAIN SCORES BY GROUP, VISIT AND TIMING

Visit	Control group			Treatment groups		
	Pre-TENS	Post-TENS	Difference	Pre-TENS	Post-TENS	Difference
1	55.6 (33.4)	41.6 (28.7)	14.0 (13.9)	60.8 (35.8)	44.8 (35.7)	16.0 (10.3)
2	44.8 (26.7)	35.8 (31.6)	9.0 (7.4)	48.6 (34.8)	41.6 (35.2)	7.0 (7.4)
3	22.0 (19.3)	19.0 (18.3)	3.0 (2.5)	37.4 (27.6)	32.0 (25.4)	5.4 (6.6)
4	20.4 (16.0)	20.8 (16.9)	-0.4 (1.7)	21.4 (17.2)	17.8 (12.7)	3.6 (6.9)
5	17.0 (7.6)	13.6 (7.9)	3.4 (6.4)	21.2 (13.7)	17.2 (11.1)	4.0 (9.1)
6	20.6 (11.5)	16.8 (14.5)	3.8 (4.8)	19.8 (17.2)	20.0 (18.3)	-0.2 (1.6)
7	22.4 (20.6)	17.6 (12.0)	4.8 (9.1)	22.2 (21.9)	21.2 (23.1)	1.0 (2.0)
8	17.8 (12.4)	14.8 (11.5)	3.0 (3.2)	15.4 (13.0)	16.4 (15.8)	1.0 (3.5)

II) reveals that most patients, whether they were control or active treatment patients, responded well to the treatment that they received over the 14 weeks of the trial. This is shown by a reduction in pain compared with that at the initial presentation. Comparison of pre-and post-treatment pain values within the trial groups shows little difference between the response of the control and the treatment groups, an effect confirmed by the lack of statistical significance for TENS.

Possible reasons for the favourable response to the routine conservative programme could be attributed to the following factors. A major consideration is that of time being the predominant correcting factor. Would the patients have experienced a significant improvement with increasing time no matter what therapy they were given? This theory is unlikely because most of the patients had been symptomatic for long periods before the treatment. Had time been the only factor to consider, they would have undergone spontaneous improvement long before presenting to the clinic for treatment.

A second possibility is that the conservative regimen over the time of the study provided the patient with a satisfactory treatment combination. If this is true then TENS had little influence on the pain values that were recorded by the patients. It can also be concluded that the conservative programme is a most effective mode of therapy for MPD. This is supported by the results of the statistical analysis of this study.

TENS may have played a passive role in the improvement of the patients' pain. This would mean that the effect of TENS in this study was limited to a placebo effect and that the only benefit of this treatment modality was to address the psychological aspect of the MPD, i.e. that patients were being recognised as needing care and that they were receiving treatment.

While the sample size was large enough to detect a significant effect of time, it may have been too small to detect subtle improvement due to TENS. A larger sample size possibly would have shown a significant effect, but this is difficult to obtain if pure MPD is to be treated. Inclusion of patients with mixed conditions will add confounding variables. Another important factor is that the TENS therapy may not have been applied to the patient long enough per treatment session, and consultations may not have been frequent enough. The TMJ clinic operates once a week. This limiting factor resulted in visits being confined to the times made available at the clinic.

Shipton¹⁴ advocates the use of supra-threshold levels, i.e. the intensity setting to be used is set at the highest intensity that the patient can comfortably tolerate. Literature studied prior to the initiation of the clinical trial recommended a TENS intensity that was increased to a level where the patient just became aware of a sensation and was then reduced to a subthreshold level.^{18,19} This method was chosen for the present investigation. Since completion of the study, the trend seems to have changed to favour the use of supra-threshold levels. Whether this method as described by Shipton would have produced better results is possibly a consideration for a further study and needs to be tested before TENS is eliminated as a treatment for MPD.

A large proportion of patients with clinically overt MPD present with signs and symptoms of contributory emotional stress. This significant emotional stress may have reduced the efficacy of TENS since Meyler *et al.*²⁰ have reported that TENS is less effective in patients with prominent psychological and social distress.

Ideally a study to evaluate TENS in MPD without any other masking factors is needed. The problem is that it is ethically unjustifiable to withhold successful treatment from a patient.

A direct comparison between the present study and other studies is difficult. Most other studies did not standardise their TENS settings as well as other variables so that subjective

opinions rather than objective measurements have been given. This makes comparison inaccurate and inappropriate.

Conclusion

Results of this study showed no statistically significant effect of TENS, delivered at a subthreshold level, on a weekly 30-minute treatment session, as an adjunct to conservative treatment of MPD.

Opsomming

Die effek van transkutane elektriese senuwee-stimulasie (TESS) plus konserwatiewe behandeling (ibuprofen, bytplate, self-fisioterapie) op miofasiale pyndisfunksie (MPD) is bepaal. 'n Enkele blinde proef is gedoen in 10 pasiënte met MPD met behulp van subdrempelwaarde TESS (frekwensie 35 Hz, pols-tydte 100 millisekondes, modulatie 50%) in vergelyking met vals TESS tydens 8 besoeke oor 14 weke. Tydens elke besoek is pyn voor en na TESS op 'n visuele analogooskaal gemeet en die data is met die variansie-analise vir herhaalde metings geanaliseer. 'n Hoogs betekenisvolle effek vir tyd is gesien ($F = 4.80$, $P = 0.0003$), maar nie vir TESS nie. Subdrempel TESS het nie die simptoombelasting vermeerder wat met konserwatiewe behandeling met die gebruikte protokol verkry is nie.

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