

Clinical Experience with TENS and TENS Combined with Nitrous Oxide-Oxygen

Report of 371 Patients

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Transcutaneous electrical nerve stimulation (TENS) alone or TENS combined with nitrous oxide-oxygen (N₂O) was administered for restorative dentistry without local anesthesia to 371 adult patients. A total of 55% of TENS alone and 84% of TENS/N₂O visits were rated successful. A total of 53% of TENS alone and 82% of TENS/N₂O patients reported slight or no pain. In multivariable analyses, pain reports were related to the anesthesia technique and patient fear and unrelated to sex, race, age, tooth, or depth of preparation.

METHODS

Patients

TENS alone or TENS combined with N₂O was administered for restorative dentistry without local anesthesia to 371 adult patients. This report is confined to the effect of these modalities for one visit per patient. A total of 62 patients received TENS alone, and 309 received the combination. All patients were regular patients in a single urban practice. The first 20 patients received TENS alone. The second 20 patients received TENS/N₂O. The remaining patients were assigned to treatments, using a coin toss until 62 had been treated in TENS-alone group. The remaining patients received the combined treatment. The number of refusers was not recorded, although it was small. A total of 57% of the patients were male. Racially, the sample was 53% white, 27% black, and 20% Asian. TENS-alone patients were slightly older (mean = 41.7 years, SD = 14.3) than TENS/N₂O patients (mean = 36.5, SD = 11.3), $p = 0.011$. There was no significant difference in race between groups ($p = 0.09$). Table 1 records the fear reported for patients in the two treatment groups.

Nitrous Oxide. Four different N₂O machines were used: Ormco™ and Veriflow™ machines that measure gas flows with two flow tubes and Bird™ and Nitrox™ machines that are calibrated to deliver a variable percentage of mixed gasses at variable flow rates. All machines were attached to a circle breathing system and CO₂ absorbers with scavenging attachments to minimize gas use and simplify scavenging of waste gas. The gas was delivered to patients via an altered pedo mask until the patient reported an effect. The percentage of N₂O used varied from 35% to 45%.

TENS. The electrical signal, a balanced biphasic exponentially decaying signal (H-wave), at frequencies of 2 to 120 Hz was produced by four different machines: a

In a recent report,¹ the Council on Dental Materials, Instruments and Equipment of the American Dental Association reviewed the status of electronic dental anesthesia (TENS) devices. The report concluded that the clinical dental literature consisted primarily of anecdotal reports and that research was needed to determine the effectiveness of TENS. Nonetheless, other reports suggest that TENS may be an effective alternative for some patients where local anesthesia drugs are not warranted or desired.²

This clinical report examines the use of TENS alone and TENS combined with N₂O. Its purpose was to examine the effectiveness of pain control employing the two approaches and to begin to investigate clinical factors associated with successful/unsuccessful anesthesia.

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Table 1. Proportions of Patients with Different Levels of Dental Fear

<i>Fear</i>	<i>TENS (N = 62)</i>	<i>TENS/N₂O (N = 308)</i>
Relaxed	59%	75%
Apprehensive	31%	17%
Agitated, upset	10%	7%

$X^2 = 6.8, p = 0.03.$

Comfort machine™ produced by M.D. Products™, an H-wave™ button machine, and an H-wave™ dial machine produced by the Electric Waveform Labs.™ All of the machines purportedly deliver the same signal form, amplitude, frequencies, and voltages. The manufacturers' instructions were followed, but no further calibration was carried out.

The signals were delivered to patients via a variety of electrode systems. Disposable sponges and conductive cloth electrodes were used to contact the tissue. H clips, plastic clamps, cotton rolls with plastic inserts, and surgical tubing were used to hold the electrodes in place. The electrodes were wetted with water, diluted green mint mouthwash, or a fluoride mouthwash. Patients, who were ASA I or II, had electrodes placed bilaterally in the maxillary or mandibular buccal vestibule or unilaterally in the maxillary and mandibular vestibule over the roots of the tooth being treated and over the cuspids' roots or first premolar roots when treating anterior teeth. All treatment was performed by a single clinician.

Measures

Clinical success was a dichotomous (yes, no) measure of whether the patient would permit drilling. The pain measure, obtained after the procedure was completed, was a four-point scale ranging from none to severe. For analysis the pain scale was condensed to two points combining slight and no pain and moderate and severe pain. The dental fear measure was a three-point scale ranging from relaxed to agitated and upset. The fear measure was a global assessment by a single clinician before treatment.

Dental treatment characteristics included the tooth (grouped as mandibular posterior, maxillary posterior, all premolars, and all maxillary anteriors); depth of preparation was judged by the single clinician on a three-point scale ranging from ideal to requiring a base. Procedures studied included amalgams, composites, and crown preparations. The procedures were combined in analysis because there was little difference in results between them.

Data Analysis

Analysis was carried out using the statistical procedures of the SAS system. Contingency analysis was used to generate chi-square statistics to examine differences between TENS alone and TENS/N₂O. Unconditional logistic regression was used to evaluate models where the dependent measure was pain/no pain or success/no success, and the independent variables were age group, sex, race, tooth group, depth, and fear. The clinical literature had suggested that such variables might be related to outcomes, but little multivariable work had been carried out.

RESULTS

A total of 55% of TENS-alone and 84% of TENS/N₂O visits were rated as successful ($X^2 = 26.1, p < 0.001$). There were no differences in clinician-perceived success by age, sex, or race. Table 2 gives the distribution of the pain responses. Overall, more patients reported pain with TENS alone than with the combined treatment.

Variables Related to Pain with TENS

Fear and pain are strongly associated ($X^2 = 7.7, p = 0.02$). There was no relationship between age, sex, or race and pain reports. Table 3 gives the proportion of subjects reporting pain by tooth for subjects receiving TENS alone. In univariate analysis, mandibular molars have the highest proportion of patients reporting pain, and upper incisors have the lowest proportion reporting pain. There was no difference in the proportion reporting pain by depth of preparation. Similar analyses were conducted on the data for the subjects receiving TENS/N₂O, and the results are qualitatively similar.

In order to test the best predictor variables in a combined analysis, a multivariable model was evaluated where pain was the dependent measure. The results suggest (Table 4) that both the treatment condition and fear are independent and significant predictors of pain. In the combined model, neither age group nor tooth grouping were significant.

Table 2. Proportions of Subjects Reporting Pain for TENS Alone and TENS/N₂O

<i>Pain Level</i>	<i>TENS (N = 62)</i>	<i>TENS/N₂O (N = 309)</i>
Slight/none	53%	82%
Moderate/severe	47%	18%

$X^2 = 23.8, p < 0.001.$

Table 3. Proportion of Subjects Reporting Pain by Tooth Restored for Subjects Receiving TENS Alone

Level of Pain	Tooth Type				
	Lower Molars	Upper Premolars	Upper Molars	Lower Premolars and Incisors	Upper Incisors
None/slight	29%	46%	60%	63%	82%
Moderate/severe	71%	54%	40%	36%	18%

$$X^2 = 8.4, p = 0.07. N = 62.$$

DISCUSSION

This clinical report highlights the importance of having a broad range of pain control modalities that can be applied in individual cases. Clinician-perceived success was higher and self-reported pain was less in the TENS/N₂O strategy than with TENS alone. Moreover, nearly one-half the subjects in the TENS-alone group reported moderate or severe pain on drilling.

Much research remains to be done to evaluate these strategies. Note the pain reports of no pain/slight pain in the TENS group were a smaller proportion (53%) of subjects in this study than the 61.9% in the placebo group who reported with no pain in a previous study.³ In another study, only 15% of the placebo TENS group was successful without local anesthesia.⁴

In the univariate analyses of these clinical data, pain reports appeared to be related to tooth grouping. However, in the multivariate analysis, the predictors of pain were the technique used (TENS versus TENS/N₂O) and patient fear. Tooth grouping was not a significant predictor. The analysis demonstrates that while clinicians may believe there to be differences by tooth, the present data suggest that differences in the responses of patients were due to the effect of fear.

Few of the studies in the literature thus far carefully characterize subjects; many do not include potent psychological concomitants of pain, such as fear.^{5,6} Fear, in

this study, was associated with greater pain regardless of technique. A similarly important variable to include would be dental anesthetic efficacy history. There is considerable clinical evidence that a surprisingly high proportion of patients have had multiple restorative experiences with inadequate anesthesia and may anticipate considerable pain.⁷ Experiments controlling for expectation and chairside manner may be warranted. In addition a history of alcohol or drug use may affect study results.⁶

There are many limitations in interpreting the clinical data in this case report. The variations in TENS units, problems with blinding, and choice of pain and fear measures all limit generalization. On the other hand, the measures were all carried out by the same experienced clinician, and the results in the two treatment groups are considerably different. Therefore, the results may be helpful to clinicians and researchers interested in further work with TENS.

Effective local anesthesia employing anesthetic drugs is remarkably effective and safe. Nonetheless, alternative pain control strategies for patients who prefer not having these drugs and for those who are medically unable to tolerate them or are afraid of their effects need to be pursued. This paper suggests that the combination of TENS/N₂O may be a more effective strategy for many patients than TENS alone. Further, it suggests psychological factors, such as fear, need to be included in future studies.

Table 4. Unconditional Logistic Regression Model of Factors Related to Pain* with TENS Alone or TENS/N₂O

Variable	Beta	STD Error	P
Intercept	4.328	1.815	0.0171
Treatment	0.626	0.157	0.0001
Fear	0.637	0.191	0.0009
Age Group	0.037	0.138	NS
Tooth Group	0.003	0.018	NS

N = 371

* Pain dichotomized is none/slight or moderate/severe.

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