Reid Laurence Winick, DDS

Cranial electrotherapy stimulation (CES): A safe and effective low cost means of anxiety control in a dental practice

Abstract
A double-blind placebo-controlled study was performed on 33 randomly selected dental patients to evaluate whether cranial electrotherapy stimulation (CES) is a viable procedure for reducing anxiety during routine dental procedures. The active CES treatment group was significantly less anxious than the placebo group at the conclusion of various dental procedures.

Received: October 13, 1998
Last Revisions: February 13, 1998
Accepted: April 14, 1998

Reducing patient anxiety always has been a concern in the practice of dentistry. Today, dentists have a variety of modalities available to reduce patients' anxiety. Typical examples include medication, electronic anesthesia, acupuncture, hypnosis, air-abrasion dental handpieces, and nitrous oxide. Each has its advantages and disadvantages. Concerning disadvantages, some are too expensive, some are too time-consuming, and some have a long learning curve. Others are limited by patients' medical conditions, or have lingering side effects after treatment.

A popular dental anxiolytic is nitrous oxide, a gas of low anesthetic potency that is incapable of inducing deep levels of anesthesia if an adequate oxygen concentration is maintained.[1] Nitrous oxide induces a state of behavioral disinhibition, analgesia, and euphoria. Physicians and dentists have long considered nitrous oxide to be a safe pharmacological agent. Nevertheless, there is some evidence that its excessive or prolonged use can damage the bone marrow and nervous system by interfering with the action of vitamin B_{12}.[2]

There have been reports of immunological and reproductive disturbances in health care professionals who are chronically exposed to nitrous oxide.[3] An elevated risk of spontaneous abortion has been seen among women who worked with nitrous oxide for three or more hours per week in offices not using scavenging equipment (relative risk = 2.6, 95 percent confidence interval 1.3-5.0, adjusted for age, smoking, and number of amalgams prepared per week), but not among those using nitrous oxide in offices with scavenging equipment.[4]

It has been known for some time that electrical stimulation effects physiological changes. In the 1800s dentists reported excellent results using crude electrical devices for pain control. By the turn of this century, electrical devices were in widespread use to manage pain and to cure everything from cancer to impotency. The unrefined early electrical technologies and financial strength of the young pharmaceutical industry caused this form of therapy to fall into disrepute in the medical and dental professions. This left chemistry the "master science" and, as such, fully responsible for treating all of mankind's ills.

Now that we are approaching the turn of another century, armed with a new foundation of scientific data about the potential role of biophysics, scientists and practitioners are reexamining the use of electromedical modalities.[5] One of the results is that over the past 30 years, transcutaneous electrical nerve stimulation has become widely accepted by physicians and dentists as a means to control many forms of pain.

Alpha-Stim (Electromedical Products International Inc., Mineral Wells, TX) cranial electrotherapy stimulation (CES) technology appears to offer an easy to use, safe, and cost-effective treatment to reduce situational anxiety. Stanley et al. showed that CES

Table 1. Dental procedures.

Active Ss	Age	Sex	Dental procedures	Type, amount, and degree of local anesthesia
MS	38	F	Composite filling	No anesthesia
ABD	48	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 2 carps.
AR	25	F	Exam, cleaning, & bridge cementation	No anesthesia
SK	37	M	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
DA	32	F	X-rays & exam	No anesthesia
SF	65	F	Composite filling	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
IC	44	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
MS	46	M	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
RI	35	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
LR	73	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
FG	60	F	Crown cementation	No anesthesia
DH	39	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
LL	40	M	Composite filling	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
AB	50	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
AG	29	F	X-rays, exam, & cleaning	No anesthesia
AR	43	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
JC	27	M	Composite filling	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
Placebo Ss				
RK	35	F	Crown & bridge	No anesthesia
JC	27	M	X-rays, exam, & cleaning	No anesthesia
AR	43	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
GW	31	F	Crown & bridge	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 2 carps.
LL	26	F	X-rays, exam, & cleaning	No anesthesia
PG	39	M	X-rays, exam, & cleaning	No anesthesia
DD	30	F	X-rays, exam, & cleaning	No anesthesia
GS	30	M	Composite filling	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
AB	52	F	X-rays, exam, & cleaning	No anesthesia
BL	25	F	X-rays, exam, & cleaning	No anesthesia
EM	25	M	Root canal	2 percent polocaine with 1:20,000 levonordefrin 1.8 ml, 1 carp.
AG	29	F	Crown cementation	No anesthesia
PD	35	M	Periodontal treatment	No anesthesia
GH	54	F	X-rays, exam, & cleaning	No anesthesia
KF	36	F	X-rays, exam, & cleaning	No anesthesia
MA	21	F	X-rays, exam, & cleaning	No anesthesia

increases the potency of nitrous oxide and concluded that CES appears to be equivalent to 35–40 percent nitrous oxide.[6] Gibson showed that Alpha-Stim CES was as effective as relaxation training, but easier to administer.[7] Smith evaluated the same technology and found it to be effective in long-term phobic patients to the 0.0001 level of confidence.[8] In a series of electroencephalographic studies, Heffernan showed spectral smoothing consistent with pain reduction from this modality.[9,10] The efficacy of CES for anxiety has been confirmed through meta-analyses conducted at the University of Tulsa, and at the Department of Health Policy and Management, Harvard School of Public Health.[11,12] The present study evaluates CES for dental anxiety in anticipation of, during, and at the conclusion of various routine dental procedures.

Materials and methods

The Alpha-Stim 100 CES device was purchased for $595 plus $28 for ear clip electrodes. The Alpha-Stim is a microcurrent stimulator that produces a modified biphasic square waveform of varying pulse widths, at a 50 percent duty cycle. It attaches to the earlobes via ear clip electrodes. It was set at 0.5 Hz frequency, which produces a variable pulse width in this device. The current was standardized

Place a mark on the following line indicating your analysis of your anxiety at *this time*:

Not anxious _____ Very anxious

Fig. 1. VAS scale. The same scale was used six times with each patient. Both the patient and dentist marked the line prior to, during, and upon completion of the dental procedure.

Please note the degree of improvement of your anxiety from the Alpha-Stim (check one only):

❑ Worse	(negative change)
❑ None	(no change)
❑ Slight	(up to 24 percent less anxious)
❑ Fair	(25–49 percent less anxious)
❑ Moderate	(50–74 percent less anxious)
❑ Marked	(75–99 percent less anxious)
❑ Complete	(100 percent less anxious)

Fig. 2. Seven-point Likert scale. Higher numbers indicate less anxiety.

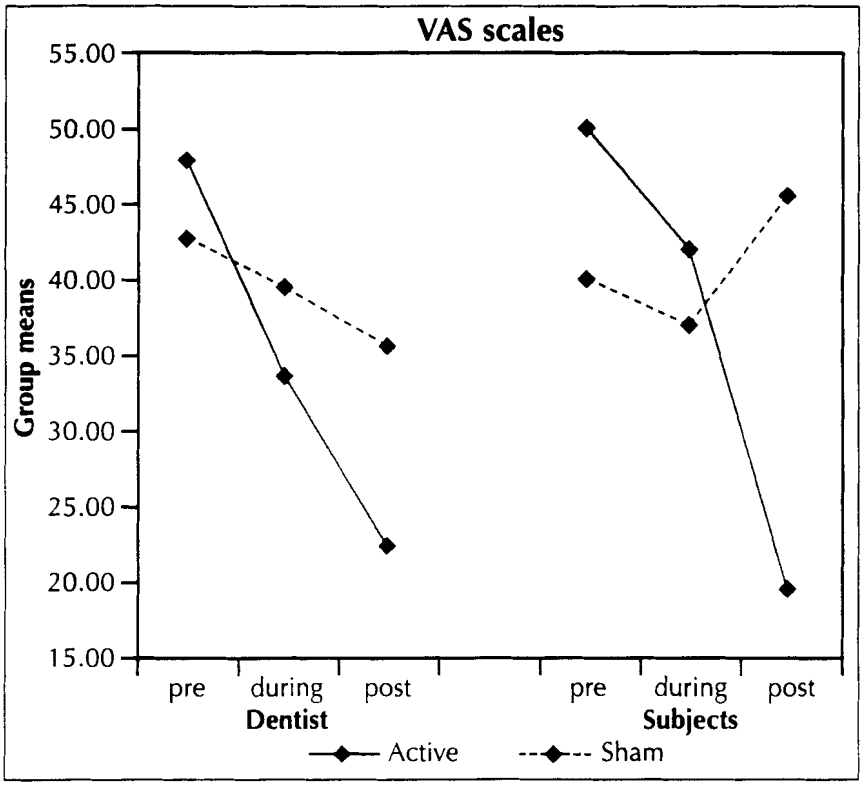

Fig. 3. VAS scale means.

below the normal recommended usage of "maximum comfortable level" to 200 uA because at that low level, the output is generally subsensory, allowing for double-blind research. The continuous time setting was used to encompass the entire dental procedure.

Thirty-three subjects were selected from the current author's active dental practice. Inclusion criteria were based on the subjects' willingness to participate in a double-blind study, and whether they reported anxiety about the dental procedures they were about to undergo. Patients who were pregnant or had a demand-type pacemaker were excluded; these conditions are contraindications for CES.[13] Those who reported no subjective anxiety, or did not want to take part in a double-blind study also were excluded. All other subjects were included in the study and signed an informed consent form explaining the purpose of the study and the possibility of their receiving a placebo treatment; 9 men and 24 women participated.

The dental subjects were randomly allotted to two groups based on the order of their arrival for dental treatment. Group A subjects received active CES treatment during the dental procedure; Group B subjects were connected to the CES device in exactly the same manner, but did not receive stimulation. Double-blinding of the dentist and subjects was ensured by the subsensory 200 µA setting, and a double-blinding box (provided by the manufacturer of the CES device) that uses separate jacks for each condition. All subjects were told that the Alpha-Stim uses a small amount of current and that they might or might not feel the current in their ear lobes. The code for the active and placebo conditions was released by the manufacturer after completion of the study.

The dental procedures included radiography, examinations, prophylaxis, periodontal treatment, anesthetic injections, operative procedures, and crown and bridge procedures (Table 1).

Subjects were given three 100 mm visual analogue scales (VAS) rated not anxious at the left end of the line to very anxious at the right end (Fig. 1). The scale was marked at the beginning before CES was initiated, at the middle, and again at the end of the procedure. The dentist-observer had a duplicate scale in which he indicated his observation of the subject's anxiety level at the same times. The ear clip electrodes use felt pads that were saturated with saline solution and placed on the subjects' ear lobes 5 minutes before starting the procedure. After the procedure, both the subjects

and dentist-observer completed a seven-point Likert scale (Fig. 2).

Less anxiety using the VAS is indicated by a falling score, while less anxiety on the Likert scale is indicated by an increasing score.

Results

The Student *t*-test (unpaired) analysis compared the active and placebo groups at specific times. The results are considered statistically significant at $p < 05$.

A total of 33 subjects in the study underwent dental procedures between September 28 and October 31, 1995. All subjects completed the study, and were randomly assigned to an active treatment group or placebo group. Both subjects and dentist were blinded to the treatment assignment. The treatment group had more subjects over 40 years of age (47 percent) than the placebo group (18.7 percent). However, perusal of the data showed no difference in effect of those over and under age 40 (Table 2).

Means for the VAS scales are shown in Fig. 3, with a decrease in the scale indicating a lessening of anxiety. The mean value for the dentist's and subject's evaluations tended to be higher in the treatment group at the start, probably due to the more severe procedures in that group compared to the placebo group (Table 1). Nevertheless, the overall feelings of anxiety were decidedly less in the treatment group when considering both the differences found in the dentist's and subject's evaluations: for the dentist treatment assessment by the VAS was -24 ± 6.4 (SEM) and for placebo was -7.2 ± 3.2 (SEM) ($p < .02$). The difference was even seen at the midpoint where the mean change was -13.5 ± 5.0 (SEM) for treatment and -3.4 ± 2.9 (SEM) for placebo ($p < .04$). At the conclusion of the study, the subject's evaluation by the VAS simulated the dentist's evaluation: differences were -30.1 ± 9.0 (SEM) for treatment and -4.2 ± 3.9 (SEM) for placebo ($p < .02$). However, no statistically significant differences were seen at the midpoint of the subjects' evaluations: -5.6 ± 9.7 (SEM) for treatment and -2.8 ± 3.2 (SEM) for placebo.

Table 2. Age and gender distribution.

Characteristics	N	Control percent	N	Treatment percent
Sex				
Male	5	31.2	4	23.5
Female	11	68.8	13	76.5
Age				
20-29	6	37.5	4	23.5
30-39	7	33.8	5	29.5
40-49	1	6.2	4	23.5
50-59	2	12.5	1	5.9
>59	0	0.0	3	17.6

Table 3. Results of the VAS and Likert scales.

Active	Dentist evaluation form				Patient evaluation form			
Ss	Pre Tx	During	Post Tx	Likert	Pre Tx	During	Post Tx	Likert
MS	44	42	37	4	52	5	0	7
ABD	44	35	14	3	19	47	4	3
AR	40	38	50	2	45	44	44	2
SK	17	9	7	5	34	63	28	6
DA	69	54	52	4	86	63	36	4
SF	47	53	22	4	48	65	0	7
IC	14	5	3	5	4	0	0	7
MS	87	32	6	6	100	0	0	7
RI	62	52	47	3	74	58	34	2
LR	26	15	14	2	3	3	3	2
FG	65	20	4	6	96	21	2	6
DH	37	51	49	2	7	50	45	2
LL	89	50	20	6	100	63	21	6
AB	58	12	9	6	52	29	27	5
AG	31	35	11	5	50	56	53	6
AR	30	14	12	6	44	70	14	5
JC	51	62	35	3	31	66	22	2
Placebo Ss								
RK	24	19	19	3	30	14	18	2
JC	34	34	29	2	14	17	19	2
AR	42	33	37	2	52	41	51	2
GW	66	75	69	2	93	87	71	2
LL	48	49	46	3	62	54	35	5
PG	38	44	47	2	4	18	29	1
DD	36	33	24	2	26	20	37	4
GS	47	26	17	3	19	14	1	4
AB	18	24	15	2	16	19	21	2
BL	75	38	32	3	35	0	0	4
EM	46	42	40	2	67	74	72	2
AG	24	24	24	2	34	40	39	2
PD	47	48	46	2	20	40	24	2
GH	14	16	11	2	19	20	18	2
KF	60	64	56	2	71	64	60	2
MA	64	60	54	2	74	70	74	2

The use of the Likert scale corroborated these findings (Fig. 4). The treatment group was less anxious, as indicated by an increase

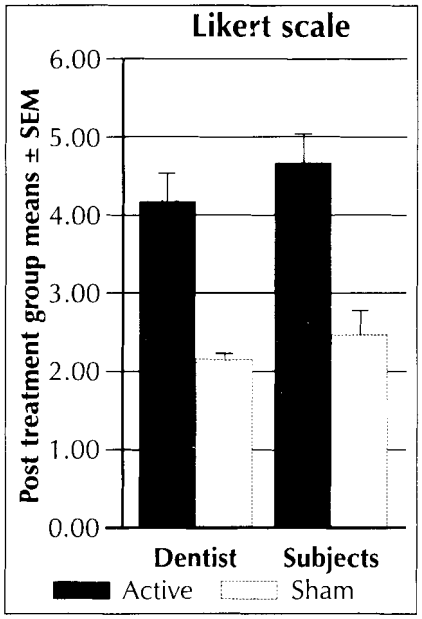

Fig. 4. Likert scale means.

in the scale values in both the dentist and subject evaluations: dentist 4.4 ± 0.4 (SEM) for treatment versus 2.3 ± 0.1 (SEM) for placebo ($p < .01$); subjects 4.8 ± 0.4 (SEM) for treatment versus 2.5 ± 0.3 (SEM) for placebo ($p < .01$). Table 3 shows the results obtained on the VAS and Likert scales.

Discussion

Although medicine based on chemical processes has enjoyed a near-monopoly throughout most of this century, the use of electrical stimulation for therapeutic effects is not new. Both Aristotle and Plato prescribed the Black Torpedo (electric ray fish) for a variety of medical conditions, from headaches to gout (head to toe).

Other cultures have based their entire medical systems on the concept of a controlling bioelectrical system. For example, Oriental medicine (acupuncture) is based on the idea of pathways analogous to electrical conductors, called meridians, that are predominantly positive (yang) or negative (yin).[14] Ayurvedic medicine has a similar concept, referring to bioelectricity as *prana*.

Two contemporary scientists have proposed new comprehensive models to explain how our physiology is controlled by bioelectrical control systems in addition to chemistry. Robert O. Becker, an orthopedic surgeon in New York, has performed more than 30 years of research into bioelectrical phenomena, which led him to conclude that all biological systems have a primitive electrical analogue data transmission and control system in addition to the better known digital nervous system.[15]

According to Becker, these electrical systems regulate all of life's processes. He was able to test his theories by studying regeneration. Using low-level electrical currents, he completely regenerated frog's limbs and achieved partial regeneration in rats. His book, *The body electric: electromagnetism and the foundation of life*, is the most important book in electromedicine. It includes a fascinating history of the development of science as it relates to the constant struggle between those limiting themselves to chemical physiology and those who also recognize bioelectrical control systems.

Björn Nordenström, a radiologist in Sweden, is another leading pioneer in electromedicine.[16] Nordenström, who served as Chairman of the Nobel Assembly in 1996, proposed a theory that a controlling bioelectric system is closely integrated both structurally and functionally with the circulatory system. He successfully treated terminal patients at the prestigious Karolinska Institute to prove his theories. His complete paradigm, including the experimental proof, is published in his book, *Biologically closed electric circuits: clinical, experimental and theoretical evidence for an additional circulatory system*.

No detectable adverse effects were noted in any of the subjects undergoing CES treatment. From the results obtained in this study, it appears that CES can induce short-term relief of anxiety during dental procedures. This study adds to the growing body of evidence that cranial electrotherapy stimulation is a safe and effective means of managing short-term situational anxiety.

Once the Alpha-Stim CES device is purchased, ongoing costs for the dentist are limited to replacement of a 9 volt battery after about 100 treatments, 4 felt electrodes per treatment at $8 per 200 retail cost, or $0.16 per patient visit, and saline solution.

Although the number of patients in this study was small, the differences obtained were clear. The evidence for determining that anxiety was less after CES therapy was gathered by two different techniques (VAS scales and Likert scales) and by two different observers (dentist and subjects). While more extensive studies need to be performed in the future, examination of the risk-benefits obtained in the present study warrant careful consideration of the usefulness of CES in dental practice.

Conclusion

Many dental patients experience extreme levels of anxiety. The results of this study, obtained by two different measurements, show that patients who experience anxiety are significantly comforted during various dental procedures through the use of CES. The results indicate a very significant improvement in patients' levels of anxiety at the completion of the procedure. Many members of the treatment group requested CES at subsequent visits, and none objected to it. In addition, the results show that the test method of using a 100 mm visual analog scale was confirmed as consistent in the subject and dentist-observer reports, and with the Likert scale. The low cost, safety, and ease of use of CES recommends its freer trial to enhance patient comfort during various routine dental procedures.

Author information

Dr. Winick is a general dentist who maintains a private practice in New

York City, and is co-founder and director of the TMD and Facial Pain Clinic at the New York Eye and Ear Infirmary.

Address correspondence to: Dr. Reid L. Winick, 405 Lexington Avenue, Suite 6900, New York, NY 10174; e-mail: www.info@reiddds.com.

References

1. Bourne JG. Nitrous oxide in dentistry: its danger and alternatives. Chicago: Year Book Publishers;1960.

2. Nunn JF. Clinical aspects of the interaction between nitrous oxide and vitamin B-12. Br J Anaesth 1987;59:3-13.

3. McMorrow A, et al. Combined system disease after nitrous oxide anesthesia: a case report. Neurology 1995; 45:1224-1225.

4. Rowland AS, et al. Nitrous oxide and spontaneous abortion in female dental assistants. Am J Epidemiol 1995; 141:531-538.

5. Kirsch DL, Lerner FN. Electromedicine: the other side of physiology. *In*: Weiner, ed. Pain management, a practical guide for clinicians. Boca Raton, Florida: St. Lucie Press;1998: 829-851.

6. Stanley T, et al. Transcutaneous cranial electrical stimulation increases the potency of nitrous oxide in humans. Anesthesiology 1982;57:293-297.

7. Gibson TH, O'Hare DE. Cranial application of low level transcranial electrotherapy vs. relaxation instruction in anxious patients. Am J Electromed 1987;4:18-21.

8. Smith RB, Shiromoto FN. The use of cranial electrotherapy stimulation to block fear perception in phobic patients. J Cur Ther Res 1992;51:249-253.

9. Heffernan M. Comparative effects of microcurrent stimulation on EEG spectrum and correlation dimension. Integr Physiol Behav Sci 1996;31: 202-209.

10. Heffernan M. The effect of variable microcurrents on EEG spectrum and pain control. Can J Clin Med 1997; 4:4-11.

11. Bianco F. The efficacy of cranial electrotherapy stimulation (CES) for the relief of anxiety and depression among polysubstance abusers in chemical dependency treatment. PhD dissertation. Tulsa, Oklahoma: The University of Tulsa; 1994.

12. Klawansky S, et al. Meta-analysis of randomized controlled trials of cranial electrostimulation: efficacy in treating selected psychological and physiological conditions. J Nerv Ment Dis 1995;183:478-485.

13. Kirsch DL. Cranial electrotherapy stimulation: a safe and effective treatment for anxiety. Med Scope Monthly 1996;3:1-26.

14. Story RT. Comprehensive meridian therapy. Seneca Falls, New York: NYCC;1995.

15. Becker RO, Selden G. The body electric: electromagnetism and the foundation of life. New York: William Morrow & Co.;1985.

16. Nordenström B. Biologically closed electric circuits: clinical, experimental and theoretical evidence for an additional circulatory system. Stockholm, Sweden: Nordic Medical Publishers; 1983.