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

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-ablation 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. 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.

There have been reports of immunological and reproductive disturbances in healthcare professionals who are chronically exposed to nitrous oxide. 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.

It has been known for some time that electrical stimulation affects 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 impotence. 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. One of the results is that over the past 30 years, transcranial 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., Memorial 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...
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<tr>
<td>JC 27</td>
<td>M</td>
<td>X-rays, exam, &amp; cleaning</td>
<td>No anesthesia</td>
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<td>Crown &amp; bridge</td>
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<tr>
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<tr>
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<tr>
<td>MA 21</td>
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<td>No anesthesia</td>
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</table>

Increases the potency of nitrous oxide and concluded that CES appears to be equivalent to 25-40 percent nitrous oxide. Gibson showed that Alpha-Stim CES was as effective as relaxation training, but easier to administer. Smith evaluated the same technology and found it to be effective in long-term phobic patients to the 0.0001 level of confidence. In a series of electroencephalographic studies, Heffernan showed spectral smoothing consistent with pain reduction from this modality. 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. 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 $998 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 earbobs 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.

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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 seven completion of the dental procedure.

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

Q Worse: (negative change)
Q None: (no change)
Q Slight: (up to 24 percent less anxious)
Q Fair: (25–44 percent less anxious)
Q Moderate: (55–74 percent less anxious)
Q Marked: (75–94 percent less anxious)
Q Complete: (100 percent less anxious)

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

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 procedures. Group $B$ subjects were connected to the CES device in exactly the same manner, but did not receive stimulation. Double-blinding of the dental and subjects was ensured by the sensory 200 $\mu$A 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 is 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, and at the end of the procedure. The dentist-of-server 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 below the normal recommended usage of ‘maximum comfortable level’ to 200 $\mu$A, because at that low level, the output is generally sensory, 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 contraindica-

Fig. 3. VAS scale means.

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and dentist-observer completed a seven-point Likert scale [Fig. 2].

Less anxiety using theVAS 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 < 0.05.

A total of 33 subjects in the study underwent dental procedures between September 26 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, the mean age 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, due to the more severe procedures in that group compared to the placebo group [Table 3].**

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 -2.5 ± 0.4 (SEM) and for placebo was -7.2 ± 3.2 (SEM) (p < 0.02). The difference was even more evident at the midpoint where the mean change was -13.5 ± 5.0 (SEM) for treatment and -3.4 ± 2.9 (SEM) for placebo (p < 0.04). 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 < 0.02). However, no statistically significant differences were seen at the midpoint of the subject's evaluations: 5.6 ± 9.7 (SEM) for treatment and -2.8 ± 3.2 (SEM) for placebo.

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

**Table 2. Age and gender distribution.**

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<tr>
<th>Characteristics</th>
<th>N Treatment percent</th>
<th>N Control percent</th>
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<td>Female 11</td>
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**Table 3. Results of the VAS and Likert scales.**

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<th>Pre Tx</th>
<th>Dentist evaluation form</th>
<th>During</th>
<th>Post Tx</th>
<th>Likert</th>
<th>Patient evaluation form</th>
<th>Pre Tx</th>
<th>During</th>
<th>Post Tx</th>
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**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      |
| AR        | 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      |
| KE        | 60     | 64                      | 56     | 2       | 71     | 63                      | 46     | 2      |
| MA        | 64     | 60                      | 54     | 2       | 74     | 70                      | 74     | 2      |

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in the scale values in both the dentis-
ty and subject evaluations: den-
tist 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 elec-
trical 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 (bioelec-
trical) 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). Ayu-
urvedic medicine has a similar
concept referring to bioelectricity
as prana.

Two contemporary scientists
have proposed new comprehen-
sive models to explain how our
physiology is controlled by bio-
electrical control systems in addi-
tion to chemistry. Robert O. Becker,
an orthopedic surgeon in New
York, has performed more than
30 years of research into bioelec-
trical phenomena, which led him
to conclude that all biological sys-
tems have a primitive electrical
duplicate data transmission and
control system in addition to the
better known digital nervous
system.11

According to Becker, these elec-
trical systems regulate all of life’s
processes. He was able to test his
theories by studying regeneration.
Using low-level electrical cur-
rents, he completely regenerated
frog’s limbs and achieved partial
regeneration in two. His book,
The body electric: electromagnets
and the foundation of life, is the
most important book in electric
medicine. It includes a fasci-
nating history of the development
of science as it relates to the con-
stant struggle between those limit-
ing themselves to chemical physi-
ology and those who also
recognize bioelectrical control
systems.

Bjorn Nordenström, a radiolo-
gist in Sweden, is another leading
pioneer in electromedicine.12
Nordenström, who served as Chair-
man of the Nobel Assembly in
1986, proposed a theory that a
controlling bioelectric system is
closely integrated both structurally
and functionally with the circula-
tory system. He successfully
treated terminal patients at the
prestigious Karolinska Institute to
prove his theories. His complete
paradigm, including the experi-
mental proof, is published in his
book, Biologically cycled electric cir-
cuits: clinical, experimental and the-
oretical evidence for an additional
circulatory system.

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

Once the Alpha-Stat CES de-
vice is purchased, ongoing costs
for the dentist are limited to re-
placement of a 9 volt battery after
about 100 treatments, 4 volt elec-
trodes per treatment at $8 per 200
retail cost, or $0.16 per patient
visit, and saline solution.

Although the number of pa-
tients 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 ob-
servers (dentist and subjects). While
more extensive studies need to be
performed in the future,
examination of the risk-bene-
fits 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 re-
results of this study, obtained by
two different measurements,
show that patients who experi-
ence anxiety are significantly
comforted during various dental
procedures through the use of
CES. The results indicate a very
significant improvement in pa-
tients’ levels of anxiety at the com-
blication of the procedure. Many
members of the treatment group
requested CES at subsequent vis-
its, and none objected to it. In ad-
dition, the results show that the
test method of using a 100 mm
visual analog scale was confirmed
to be consistent in the subject and
dentist-observer reports, and with
the Likert scale. The low cost,
safety, and ease of use of CES rec-
ommends its freer trial to enhance
patient comfort during various
routine dental procedures.

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References