Cranial Electrotherapy Stimulation (CES): A Safe and Effective Non-Pharmacological Treatment for Anxiety

A Review of the Literature

by

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Electrical stimulation for therapeutic purposes is not new. At least two millennium ago, physicians used electric eels to relieve pain. Experimentation with low intensity electrical stimulation of the brain was first reported by Drs. Leduc and Rouxeau of France in 1902. Initially, this method was called electrosleep as it was thought to be able to induce sleep. Since then, it has been referred to by many other names, the most popular being transcranial electrotherapy (TCET) and neuroelectric therapy (NET). Research on using what is now referred to as cranial electrotherapy stimulation (CES) for treatment of anxiety began in the Soviet Union during the 1950's. Research conducted throughout this century has demonstrated that the nervous system works through a complex interaction of both chemical and electrical properties. Neuronal processes can be altered by electrical as well as pharmacological means.

Cranial Electrotherapy Stimulation is a simple treatment that can easily be administered at any time. The current is applied by easy-to-use clip electrodes that attach on the ear lobes, or by stethoscope-type
electrodes placed behind the ears. In the 1960's and early 1970's, electrodes were placed directly on the eyes because it was thought that the low level of current used in CES could not otherwise penetrate the cranium. This electrode placement has been abandoned over 20 years ago.

Anxiety reduction is usually experienced during a treatment, but may be seen hours later, or as late as one day after treatment. In some people, it may require a series of five to ten daily treatments to be effective.

Cranial electrotherapy stimulation leaves the user alert while inducing a relaxed state. Psychologists call this an alpha state. The effect differs from pharmaceutical treatment in that people usually report feeling that their bodies are more relaxed, while their minds are more alert. Most people experience a feeling that their bodies are lighter, while thinking is clearer and more creative. A mild tingling sensation at the electrode sites may also be experienced. The current should never be raised to a level that is uncomfortable. One 20 minute session is often all that is needed to effectively control anxiety for at least a day, and the effects appear to be cumulative. Cranial electrotherapy stimulation may also be used as an adjunct to anxiolytic medication and/or psychotherapy, behavioral modification, and other conservative methods of treatment. For people who have difficulty falling asleep, CES should be used at least three hours before going to bed or the increased alertness may interfere with sleep. A review article cannot adequately describe the CES experience. Only trying it or witnessing its use will do that.

After treatment, there are usually no physical limitations imposed so most people can resume normal activities immediately. Some people may experience a euphoric feeling, or a state of deep relaxation that may temporarily impair their mental and/or physical abilities for the performance of potentially hazardous tasks, such as operating a motor vehicle or heavy machinery, for up to several hours after treatment. At present, there are over 100 research studies on CES in humans and 18 experimental animal studies. No significant lasting side effects have been reported. Occasional self-limiting headache, discomfort or skin irritation under the electrodes, or lightheadedness may occur. Patients with a history of vertigo may experience dizziness for hours or days after treatment.

Cranial electrotherapy stimulators are generally limited to less than one milliampere (mA) of current. The Alpha-Stim 100 is an example of a CES device that employs very low intensity electrical current pulses (up to 600 microamperes) for the treatment of anxiety. To put this into perspective, it takes one-half of an ampere to light an ordinary 60 watt light bulb. To truly compare the work done per second by these two different currents, we must multiply the currents by the respective voltages that drive them. The product current x voltage is a measure of the rate of generation of energy, and is referred to as the power output. By definition, when a device outputs 1 ampere of current with a 1 volt driving force, the power output of the device is 1 watt. Therefore for the Alpha-Stim 100, the maximum output is (600/1,000,000)amperes x 9 volts = 0.0054 watts, or about 11,000 times less power than the light bulb. Many people do not even feel this amount of current.

The current state of knowledge of bioelectrical systems is limited, as it is in many areas of biology. At the present time there is no uniform agreement on the mechanisms of action of CES. Accordingly, the evidence of CES effectiveness is empirical. It is generally believed that the effects are primarily mediated through a direct action on the brain at the limbic system, the hypothalamus and/or reticular activating system (Brotman, 1989; Gibson, 1987; Madden, 1987). The primary role of the reticular activating system is the regulation of electrocortical activity. These are "primitive" brain stem structures. The functions of these areas and their influence on our emotional states were mapped using electrical stimulation. Electrical stimulation of the peri aqueductal gray matter (PAG) has been shown to activate descending inhibitory
pathways from the medial brainstem to the dorsal horn of the spinal cord, in a manner similar to (-endorphins (Salar, 1981; Pert, 1981; Ng, 1975). Cortical inhibition is a factor in the Melzack-Wall Gate Control theory (Melzack, 1975). It is possible that CES may produce its effects through parasympathetic autonomic nervous system dominance via stimulation of the vagus nerve (CN X) (Toriyama, 1975). Other cranial nerves such as the trigeminal (CN V), facial (CN VII), and glossopharyngeal (CN IX), may also be involved (Taylor, 1991). Electrocortical activity produced by stimulation of the trigeminal nerve has been implicated in the function of the limbic region of the midbrain affecting emotions (Fields, 1975). Substance P and enkephalin have been found in the trigeminal nucleus, and are postulated to be involved in limbic emotional brain factors (Hokfelt, 1977). The auditory-vertigo nerve (CN VIII) must also be effected by CES, accounting for the dizziness one experiences when the current is too high. Ideally, CES electrodes are placed on the ear lobes because that is a convenient way to direct current through the brain stem structures.

Animal studies of CES using monkeys reveal that 42% to 46% of the total applied current enters the brain, with the highest concentration in the thalamic region (Jarzembiski, 1970). Rat studies showed as much as a threefold increase in (-endorphin concentration after just one CES treatment (Krupisky, 1991). Mongrel dog research suggests that CES releases dopamine in the basal ganglia, and that overall physiological effects appear to be anticholinergic and catecholamine-like in action (Pozos, 1971). The size, location, and distribution of synaptic vesicles were all within normal limits after a series of ten, one hour treatments in Rhesus monkeys (Richter, 1972). Several studies in humans and stump-tailed macaques revealed a temporary reduction in gastric hypersecretion (Reigel, 1970; Reigel, 1971; Wilson, 1970; Kotter, 1975).

One hundred and three human studies involving 4,848 subjects (3,404 receiving cranial electrotherapy stimulation, while the remainder served as sham-treated or controls) reveal significant changes associated with anxiolytic relaxation responses, such as lowered electromyograms (Gibson, 1987; Forster, 1963; Hefferman, 1995; Overcash, 1989; Voris, 1995), slowing on electroencephalograms (Braverman, 1990; Cox, 1975; Krupitsky, 1991; McKenzie, 1976; Sing, 1971), increased peripheral temperature (an indicator of vasodilation) (Brotman, 1989; Hefferman, 1995), reductions in maximal acid output (Kotter, 1975), and in blood pressure, pulse, respiration, and heart rate (Hefferman, 1995; Taylor, 1991).

The efficacy of CES has also been clinically confirmed through the use of 28 different psychometric tests. The significance of CES research for treating anxiety has been reconfirmed through meta-analyses conducted at the University of Tulsa (O'Connor, 1991), and at the Department of Health Policy and Management, Harvard School of Public Health (Klawansky, 1995).

The authors reviewed all the aforementioned 103 CES studies for comments on side effects and safety. The most common area of complaint, reported in five studies, was transient blurring of vision lasting no more than one hour from the mechanical pressure caused by eye electrodes used in the 1960's and early 1970's. The incidence of this problem was seen equally in active CES groups and sham CES, indicating the problem was due to mechanical pressure over the orbits, and not electrically-induced. As stated previously, this problem does not apply to modern CES devices because none use eye electrodes. There was seven reports of headaches (0.2%), and three cases of skin irritation or electrode burns at the electrode sites (0.09%). Table One lists all comments on side effects and safety in the English language literature on CES.
## Table One

**COMMENTS ON SIDE EFFECTS AND SAFETY FROM ALL CES RESEARCH STUDIES**

<table>
<thead>
<tr>
<th>First Author, Year</th>
<th>N</th>
<th>Subject Description</th>
<th>Authors' Comments on Safety and Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achts, K.A. 1968</td>
<td>24</td>
<td>severe insomnia patients and drug abusers</td>
<td>Complications were discovered in 5 cases; 2 complained of headaches, 3 felt aching in the eyes, 1 had hysterical convulsions during the treatment. Too strong currents caused headaches in healthy persons. The currents were too weak to cause convulsions and too weak to bring about neurovegetative side effects.</td>
</tr>
<tr>
<td>England, Ronald R. 1976</td>
<td>18</td>
<td>migraine patients</td>
<td>1 patient in the placebo group developed a skin irritation at the location of the electrode. She suggested that sensations felt during the treatment were responsible.</td>
</tr>
<tr>
<td>Feighner, John P. 1973</td>
<td>23</td>
<td>long term psychiatric patients, unresponsive to medications, ECT, psychotherapy</td>
<td>4 of 8 long-term depressed patients were dropped from the study because of massive worsening of depressive symptoms.</td>
</tr>
<tr>
<td>Flamenbaum, A. 1974</td>
<td>28</td>
<td>anxiety, depression, insomnia outpatients unresponsive to</td>
<td>An insignificant trend towards worsening was seen by the 24th week. 5 of 25 patients were not improved or had become worse. The author added that side effects are virtually nonexistent.</td>
</tr>
<tr>
<td>Forster, Sigmund 1903</td>
<td>23</td>
<td>inducing sleep</td>
<td>Although as current amplitude was increased to 20 volts, a feeling of slight dizziness approaching a headache was noted, the authors concluded that the technique appears to be entirely safe.</td>
</tr>
<tr>
<td>Frankel, Bernard 1973</td>
<td>17</td>
<td>insomnia</td>
<td>A commonly reported norocuss side effect was mild blurring of vision lasting 15-30 minutes which resulted from sustained mechanical pressure of the electrodes on the eyeballs.</td>
</tr>
<tr>
<td>Gomez, Evaristo 1974</td>
<td>28</td>
<td>14 heroin patients, 7 placebo and 7 controls</td>
<td>It was noted that with a higher current the patients felt uncomfortable, but there were no skin burns.</td>
</tr>
<tr>
<td>Heast, E.D. 1974</td>
<td>20</td>
<td>psychotherapy outpatients</td>
<td>No patient with primary affective disorder was adversely affected by CES.</td>
</tr>
<tr>
<td>Hochman, Richard 1988</td>
<td>600</td>
<td>dental patients</td>
<td>From the results obtained during 1 year of treating a variety of patients requiring a broad scope of dental treatments, CES was found to provide a safe, noninvasive, readily acceptable, adjunctive analgesic modality to maintain patient comfort through the majority of dental procedures for most patients.</td>
</tr>
<tr>
<td>Koeplinger, R.F. 1971</td>
<td>14</td>
<td>insomnia patients</td>
<td>The only side effects noted were blood pressure losses during treatment, and a slight blurring of vision occurs due to eye electrodes, which stops within a few minutes.</td>
</tr>
<tr>
<td>Krupitsky, E.M. 1991</td>
<td>20</td>
<td>alcoholic patients with affective disorders</td>
<td>CES was not accompanied by side effects nor complications and was well tolerated by the patients. CES tends to avoid side effects and complications sometimes observed in antidepressant therapy and tranquilizers.</td>
</tr>
<tr>
<td>Levitt, Eugene 1975</td>
<td>13</td>
<td>psychiatric inpatients</td>
<td>Subjects in both groups reported slight blurring of vision lasting 30 - 45 minutes following treatments. This supports the findings of other researchers that the blunted vision effect is mechanically caused by pressure of eye electrodes, and not electrical current.</td>
</tr>
<tr>
<td>McKenzie, Richard 1976</td>
<td>12</td>
<td>8 chronic anxiety, depression and insomnia patients and 4 controls</td>
<td>Blurring of vision due to eye electrode pressure was fairly uniform over the small control sample and was not especially uncomfortable.</td>
</tr>
<tr>
<td>Magans, F. 1967</td>
<td>A: 20 B: 0</td>
<td>hospitalized poly substance abusers, and</td>
<td>No ill effects were noted on prolonged and repeated observations in deg. and in humans.</td>
</tr>
<tr>
<td></td>
<td>A: 20</td>
<td>asthma children</td>
<td></td>
</tr>
<tr>
<td>Magans, F. 1966</td>
<td>31</td>
<td>inducing sleep</td>
<td>No ill effects were observed after repeated experiments in the same and different individuals.</td>
</tr>
</tbody>
</table>
In addition, a search was conducted of United States Food and Drug Administration records through Freedom of Information Services. The search encompassed all complaints to FDA from May, 1976 through March, 1995 (latest available data). The search revealed only 3 entries. One was an implanted stimulator (which can hardly be considered a CES device) manufactured by Medtronic Neuro Division. The device apparently malfunctioned causing the need for it to be explanted. No death or serious injury occurred. The other two were both Pain Suppressor Model 112A malfunctions. Of these, one caused the patient to suffer extreme headache pain for about 10 hours, and lack of sleep for 48 hours. The patient discontinued use of the device, took a prescription sleeping pill and then felt better. The other was a patient who was two weeks pregnant and experienced the early signs of miscarriage. This patient was instructed not to use the device while pregnant and was referred to the instruction manual which expressly states "warning": the safety of the device during pregnancy has not been established. It should be noted that the output of the Pain Suppressor is up to 4 mA which is unusually high for a CES device.

A postmarketing survey was conducted during October, 1995 of health care practitioners using Alpha-Stim CES technology. A total of 313 individual patient report forms were received. 112 males, and 199 women were identified, ranging from 5 to 85 years old. Twenty of the forms were completed on inpatients, the balance on outpatients. 57.84% of the patients were reported to have completed CES treatment, and 42.16% were still receiving treatment at the time of the survey. 4 patients continued treatment because...
it was not efficacious, 3 discontinued due to undesirable side effects, and 24 for other reasons. Table Two provides the results of the survey.

**Table Two**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number Reported</th>
<th>Worse</th>
<th>No Change</th>
<th>Slight &lt;24%</th>
<th>Fair 25-49%</th>
<th>Moderate 50-74%</th>
<th>Marked 75-99%</th>
<th>Complete 100%</th>
<th>Significant &gt;25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety</td>
<td>207</td>
<td>0%</td>
<td>0.48%</td>
<td>1.93%</td>
<td>10.53%</td>
<td>28.02%</td>
<td>53.14%</td>
<td>5.80%</td>
<td>202</td>
</tr>
<tr>
<td>Stress</td>
<td>162</td>
<td>0%</td>
<td>0%</td>
<td>4%</td>
<td>26%</td>
<td>48%</td>
<td>78%</td>
<td>6%</td>
<td>158</td>
</tr>
<tr>
<td>Depression</td>
<td>102</td>
<td>0%</td>
<td>0%</td>
<td>3%</td>
<td>12%</td>
<td>28%</td>
<td>55%</td>
<td>4%</td>
<td>99</td>
</tr>
<tr>
<td>Insomnia</td>
<td>74</td>
<td>0%</td>
<td>2.70%</td>
<td>1.35%</td>
<td>9.48%</td>
<td>27.03%</td>
<td>44.59%</td>
<td>14.86%</td>
<td>71</td>
</tr>
<tr>
<td>Pain</td>
<td>125</td>
<td>0.60%</td>
<td>0%</td>
<td>1.50%</td>
<td>16%</td>
<td>26.40%</td>
<td>38.40%</td>
<td>16.80%</td>
<td>95.95%</td>
</tr>
<tr>
<td>Headache</td>
<td>74</td>
<td>0%</td>
<td>2.70%</td>
<td>0%</td>
<td>9.46%</td>
<td>21.62%</td>
<td>52.70%</td>
<td>13.51%</td>
<td>72</td>
</tr>
<tr>
<td>Muscle Tension</td>
<td>110</td>
<td>0%</td>
<td>0%</td>
<td>0.91%</td>
<td>18.18%</td>
<td>24.55%</td>
<td>46.36%</td>
<td>10.00%</td>
<td>99.09%</td>
</tr>
</tbody>
</table>

* Total N = 313 reported on multiple symptoms 6 (1.9%) reported dizziness as a side effect, which usually occurs when the current is set too high, or in patients with a history of vertigo, 1 (0.3%) reported a "singed" earlobe (electrode burn), 1 (0.3%) reported anxiety/nausea, and 1 (0.3%) reported a nger. The latter two problems most likely were a result of the underlying disease, not the CES treatments.

Fifteen studies conducted follow-up investigations from 1 week to 2 years after treatment. Thirteen of 13 (100%) reported a continued improvement after a single CES treatment, or a series of CES treatments. The other two of the follow-up reports only commented on safety (Forster, 1963, and Hochman, 1988). None of the 15 revealed any long term harmful effects. The author's comments on follow-up are listed in Table Three.
When restricted to anxiety populations or studies that measured for physiological and/or psychological changes in anxiety, there are 40 scientific studies of CES, involving 1,835 patients. 34 of the 40 (85%) studies reported efficacious results in the treatment of anxiety. Five of the studies on CES (all using the Alpha-Stim) support the effectiveness for managing anxiety during or after a single treatment (Gibson, 1983; Heffernan, 1995; Smith, 1993; Voris, 1995; Winick, 1995).

Of the 6 of 40 (15%) anxiety studies categorized by the authors as having negative results, 5 were done in the 1970's, and 1 in 1980. Three showed both actual treatment and sham groups to improve significantly, most likely because both groups were also taking medications (Levitt, 1975; Passini, 1976; Von Richtofen, 1980). One was a depression study in which the author noted that acute anxiety was not relieved and again, the study did not control for medications (Hearst, 1974). One reported no significant change on anxiety or depression scales, but subjective insomnia improved (P<.05) during active treatment (Moore, 1975). Only one study conducted on a population of insomniacs with an average duration of symptoms for almost 20 years did not show any significant change at all in any parameters (Frankel, 1973).
Table four provides a summary of all the CES research in the English language on anxiety patients, and on other populations that were tested for anxiety.

### Table Four

**CES RESEARCH ON ANXIETY: SCIENTIFIC STUDIES**

This table includes all known studies that were done on patients with diagnosis of anxiety or that utilized tests for anxiety.

Notes: Numbers in the Results column indicate means unless otherwise indicated. A list of psychometric tests abbreviated under methodology is provided following this table.

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Material/Methods</th>
<th>N</th>
<th>Subject</th>
<th>Results, Comments and Conclusions</th>
</tr>
</thead>
</table>
| Bianco, Faust    | double-blind, IRB approved, 6 - 14.45 minute treatments, Beck Anxiety and Depression Inventories, HAS; LB 2000 | 65 | polysubstance abuser inpatients with anxiety      | Hamilton Anxiety: CES pre: 24.44 ± 9.22  
                           → post: 7.09 ± 3.21  
                           placebo pre: 22.56 ± 9.95  
                           → post: 15.67 ± 7.92  
                           controls pre: 20.56 ± 6.21  
                           → post: 16.90 ± 9.06  
                           CES vs placebo or controls P<.05, placebo vs control P>.05  
                           There was no significant difference between variables at pretreat, however there was significant post test group differences.  
                           Although the self reports showed no statistical differences between groups, there was a trend towards significance. The author concluded that the active CES, when combined with the normal treatment regimen given at the treatment facilities was more effective in reducing anxiety and depression than the normal treatment regimen alone and the sham CES plus normal treatment regimen. |
| Flemenbaum, A.   | 5, 30 minute treatments, urinay free catecholamines & 17 ketosteroids; device not specified | 7  | 7 males: 4 normals and 3 psychiatric inpatients with neurotic anxiety | There was a 23.9 to 47.4 microgram increase in 24 hour urinary free catecholamines with the greatest rise in 2 anxiety patients and 1 volunteer who was slightly symptomatic; and an average gain of 6.0 mg in 24 hr urinary 17 ketosteroid. The authors suggested that these findings probably reflected change at the hypothalamic or pituitary level in the brain. |
| Flemenbaum, A.   | double-blind crossover, 10, 30 minute treatments, Zung and other tests; Electroson 50 | 23 | long term anxiety, depression and insomnia psychiatric patients, unresponsive to medications, psychotherapy, or ECT | CES → placebo group:  
                           4.5 in day 1 to 2.5 in day 15 (P <.02)  
                           4.4 on day 1  
                           placebo → CES group:  
                           4.4 in day 1  
                           4.0 on day 15 (N.S.)  
                           Scores on the Zung self rating depression scale improved significantly in both groups, but only after 10 days of active treatment, and never during the sham phase of treatment. Actively treated patients also improved significantly on other target symptoms, particularly anxiety and insomnia. 7 of 18 patients who exhibited significant improvement relapsed within the first month after treatment. 4 of 6 long term depressed patients were dropped from the study because of massive worsening of depressive symptoms, 2 of whom exhibited suicidal ideation. The remaining 2 depressed patients had an unremarkable course, but remained in the study. 3 patients benefited more from this therapy than any previous extensive psychiatric care. |
| Flemenbaum, A.   | 5, 30 minute treatments, Zung, global clinical ratings of 1-7; Electroson 50       | 28 | anxiety, depression, insomnia outpatients unresponsive to medications | By the 6th week the pathology for the 3 groups seemed to be reduced to approximately equal levels. Comparison of the final results with the pretreatment ratings shows improvement statistically significant at the .01 level. The author noted that at the end of the study 12 of the 25 patients were much, or very much improved, 8 had shown some effect, though minimal, and 5 were not improved or had become worse. Some of these chronic patients were practically asymptomatic, other psychophysiological symptoms like asthma and blood pressure had become controllable by regular medical treatment, andlor their target symptoms showed complete or nearly complete remission. Most remarkable of all, these changes occurred in patients who previously had not responded to extensive treatment. Although about 50% of the patients showed minimal improvement, or none at all, those who had beneficial results |
Cranial electrotherapy stimulation has been well researched and clearly proven to be the most effective, and safest method of treatment for anxiety, and anxiety-related disorders. It is also highly effective for depression and insomnia, muscle tension, and headaches. As an increasing number of patients seek alternatives to the side effects and potential addiction of pharmaceuticals, CES offers a viable solution. It is inexpensive to offer CES in a physician's office, clinic, or hospital, and chronically-stressed patients will find it cost-effective over time to own their own CES device.

About the Authors:

Dr. Daniel L. Kirsch is a neurobiologist and a Diplomate of the American Academy of Pain Management. He designed Alpha-Stim technology and is Chairman of the Board of Electromedical Products International, Inc. Dr. Kirsch is Dean Emeritus of the Graduate School of Electromedical Sciences at City University Los Angeles. He has served as Clinical Director of The Center for Stress and Pain Related Disorders at Columbia-Presbyterian Medical Center of the City of New York (in association with Kenneth Greenspan, M.D.), The Sports Medicine Group in Santa Monica, California (in association with Karlis C. Ullis, M.D.), and Electro-Acutherapy Medical Centers of Orange County (in association with F.P. Meyer, M.D.). He has been on the Board of Directors of the National Institute of Electromedical Information and the International Society for Bioelectricity. Dr. Kirsch is the author of three books published in the 1970's and numerous articles in the field of electromedicine, and is the First Editor of the American Journal of Electromedicine. Dr. Kirsch is a member of the American Preventive Medical Association, the National Pain Outreach Association and other professional organizations. He is listed in Who's Who in the World, Two Thousand Notable Americans, and the International Directory of Distinguished Leadership.

Dr. Lawrence Paros is an educator, writer, and neuroscientist. His background includes a distinguished career in education and Human services. He created and directed two experimental schools which gained widespread recognition and which were cited by the U.S. Office of Education as "exemplary" and which replicated at more than 125 sites nationwide. He also supervised the development of a nationwide network of neighborhood-based inner city group homes for the Department of Labor. At Yale University, headed up a unique project for talented poverty youth, and later directed a model anti-poverty agency, featuring an innovative community center for appropriate technology. A recognized authority on language, the author of three books, several articles on education, and a former columnist for the Seattle Post-Intelligencer and commentator for the NPR affiliate in Seattle, he has given over the past ten years to the study of neurotechnology, and specifically CES. He is the former Vice President of Well Test Instruments and Process Instruments, Inc, the founder and CEO of CES Labs, and was one of the feature speakers at the first Neurotechnology Forum. His experience in educational innovation and curriculum development, concern for social justice, and skill in language/communication joins his interest and knowledge of scientific instrumentation in his current efforts to broaden the public's understanding and appreciation of CES and other mind enhancement technology.

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