Cranial Electrotherapy Stimulation: Treating the Brain with Electrons for Pain and Stress-Related Disorders

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¾ Fellow, American Institute of Stress
¾ Member, International Society for Neuronal Regulation
¾ Consulting Editor, Journal of Neurotherapy
¾ Electromedicine Dept. Editor, Practical Pain Management
¾ Honorary Member, Inter-Pain (Germany/Switzerland)
¾ Member, Presidents Council, University of North Texas
¾ Pain, Stress and PTSD Consultant to US Army and VA

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Cranial Electrotherapy Stimulation (CES)

Easy 4-Step Procedure:
1. Wet Electrodes
2. Place on Ear Lobes
3. Turn on CES Device
4. Set to Comfortable Current for 20 Minutes to One Hour

The application of low level current, (usually <1 mA) applied across the head for medical or psychological conditions, or just as an aid in relaxation
FDA authorized by Rx for anxiety, depression and insomnia
Also used for fibromyalgia, ADD/ADHD, PTSD, CRPS (RSD), phantom limb pain, other pain syndromes

Qualitative Results
“What to Expect from CES”
Most people report feeling:

Happier,
Their Bodies are
More Relaxed,
Their Minds are
More Alert,
and They Feel Younger, More Energetic

Dr. Saul H. Rosenthal
Psychiatrist and CES Researcher Reported:
Calm, Relaxed Sensation
Activation of Alertness
Euphoric Tranquility
Not Worrying
Bright and Happy
Increased Energy
Improved Sleep
No Confusion, Memory Loss or Disorientation

Dr. Saul H. Rosenthal
Typical Comments from Patients:
“As if I have been given a happy pill.
Sort of a floaty, smiley feeling, very pleasant.
This is quite a change of moods.”
“Anxiety about capability seems reduced.”
“Smiling for no reason.”
“As though I have almost been conditioned not to worry.”
“Although I feel depressed, it is nothing like
I would expect from past experience,
even though the problem is large.”
Michael Hutchison  
Author of the book Megabrain Wrote:  
“My body immediately felt heavier,  
as if I was sinking down into myself.  
[Then] I realized I was becoming extremely relaxed.  
...Things are very, very clear.  
My body was no longer heavy, but very light, full of energy.  
The feeling was one of openness, clarity,  
as though I had been wearing sunglasses for weeks  
and had suddenly taken them off.  
I couldn’t help but feel that  
this is the way we’re supposed to be all the time.”

Proposed Mechanisms of Actions of CES

James Giordano, PhD  
Georgetown University

QEEG Changes in 30 Subjects Treated with 20 Minutes of CES.  
There is an Increase in Alpha and a Decrease in Delta Activity.  
Blue = decrease Red = increase  
Courtesy of Richard Kennerly, University of North Texas Ph.D. dissertation

Adverse Effects from CES

From 126 human studies  
encompassing 6,007 people  
with 4,541 receiving active CES treatment:

9 myogenic headaches (0.20%, 1:506)  
5 cases of skin irritation (0.11%, 1:910)

These are mild and self-limiting.

Primary Contraindications

Embryofetal Effects on Rats

Little and Patterson, 1996

844 fetal rats had 1 hour/daily CES throughout their pregnancy  
at 10, 100, or 1,000 Hz, 1 volt, 125 µA via ear tag electrodes.  
Autopsy revealed no congenital anomalies.

✓ More pregnancy resorptions and fewer offspring in all groups,  
  but only significant in the 1,000 Hz group.  
✓ Average fetal weight and brain weight were inversely  
  proportional to frequency.  
✓ Behavior resembled CES in humans, even in this aggressive  
  species; treated rats were not as active as the controls, so the  
  decrease in fetal weights may be because their food intake was  
  lowered.

Conclusion: CES may be embryolethal in the very early stages  
of pregnancy and might cause some miscarriages, but there is  
no evidence of fetotoxic effects.
Topics of Scientific Research on CES

Number of Pivotal Scientific Studies:

<table>
<thead>
<tr>
<th>CES is FDA approved for</th>
<th>Number of Pivotal Scientific Studies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>anxiety, depression, and insomnia</td>
<td>42 Anxiety + 1 Phobia</td>
</tr>
<tr>
<td></td>
<td>26 Depression</td>
</tr>
<tr>
<td></td>
<td>27 Insomnia</td>
</tr>
<tr>
<td></td>
<td>10 stress</td>
</tr>
</tbody>
</table>

Research Methodology of
86 Pivotal (out of 126) Studies of CES

- 35 Double-Blind Placebo-Controlled
- 9 Single-Blind
- 15 Controlled Study
- 6 Crossover
- 22 Open Clinical Trial
- 2 Retrospective Study
- 3 Case Study
- 13 Follow-up

Beta-endorphins

- 98% in plasma
- 219% in CSF

Serotonin

- 15 – 40% in plasma
- 50 – 200% in CSF

Electromyogram (EMG):

- ↑ with recovery to normal in 15 minutes
- ↓ in Mm spasticity in pts with hemiplegia and paraplegia
- ↓ frontalis Mm
- ↓ maintained 1 week post treatment
- ↑ relaxation
- ↓ involuntary movements in pts with Parkinson’s and dystonia musculorum were changed during treatment and eventually completely eliminated
- ↓ 15.8 µV to 4.5
- ↓ 38 µV to 3.2
- ↓ 10.4 µV to 3.8
- ↓ 8.4 µV to 4.0
Experimental Animal Studies on CES

- Rat studies showed as much as a threefold increase in β-endorphin concentration after just one CES treatment (Kroupsky, 1991).
- Blind tests of tail-flick latency (TFL) in rats show a significant increase in analgesic effect of opiates. (Stinus, 1990).

TFL as a % of baseline with drug, and with drug plus CES:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Drug Alone</th>
<th>Drug Plus CES</th>
</tr>
</thead>
<tbody>
<tr>
<td>morphine</td>
<td>174%</td>
<td>306%</td>
</tr>
<tr>
<td>fentanyl</td>
<td>176%</td>
<td>336%</td>
</tr>
<tr>
<td>alfentanil</td>
<td>169%</td>
<td>215%</td>
</tr>
<tr>
<td>dextromoramide</td>
<td>267%</td>
<td>382%</td>
</tr>
</tbody>
</table>

Results were also obtained after intracerebroventricular injection of morphine (10 micrograms; analgesic effect increase from 152% to 207% with CES) suggesting that CES potentiation of opiate-induced analgesia is centrally mediated.

The Use of CES to Potentiate Anesthesia in Surgery

The Effects of 7 to 10 Days of CES Treatment on Depression

The Effects of 2 and 3 Weeks of CES Treatments on Depression

CES Review: A Safer Alternative to Psychopharmaceuticals in the Treatment of Depression

Marshall Gilula, MD and Daniel L. Kirsch, PhD


Anxiety Scores Before and After CES Treatment
Two Meta-Analyses Reconfirmed the Significance of CES Research for Treating Anxiety:

- **University of Tulsa** (O'Connor, Presented at the 12th annual meeting of the Bioelectromagnetics Society, 1991)

  **Both Found CES Significantly Effective for Anxiety (P<.05)**
**Results Achieved with CES Technology**

Based on a Survey of Patients Reporting Psychological Disorders

<table>
<thead>
<tr>
<th>Condition (all cases)</th>
<th>N*</th>
<th>Slight &lt;24%</th>
<th>Fair 25-49%</th>
<th>Moderate 50-74%</th>
<th>Marked 75-100%</th>
<th>Significant &gt;25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological (all cases)</td>
<td>723</td>
<td>91</td>
<td>117</td>
<td>229</td>
<td>324</td>
<td>343</td>
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<tr>
<td>Anxiety (alone)</td>
<td>120</td>
<td>13</td>
<td>16</td>
<td>32</td>
<td>36</td>
<td>42</td>
</tr>
<tr>
<td>Anxiety (with other)</td>
<td>370</td>
<td>30</td>
<td>35</td>
<td>25</td>
<td>25</td>
<td>25</td>
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<tr>
<td>Depression/Anxiety</td>
<td>58</td>
<td>17</td>
<td>17</td>
<td>17</td>
<td>17</td>
<td>17</td>
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<tr>
<td>Depression (alone)</td>
<td>53</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Depression (with other)</td>
<td>265</td>
<td>34</td>
<td>34</td>
<td>34</td>
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<tr>
<td>Stress</td>
<td>123</td>
<td>34</td>
<td>34</td>
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<tr>
<td>Chronic Fatigue</td>
<td>55</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Incontinence</td>
<td>163</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
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</tr>
</tbody>
</table>

Depression: 66% >50 or 23 -31 >75% improved

(Pain: 6% >50 or 23 -31 >75% improved)

*Total N = 2500 patients with multiple symptoms. Results of those using Alpha-Stim™ at least 3 weeks before mailing warranty card. Warranty cards are shipped to 2500 consecutive patients received as of July 2000.

**Results Achieved with CES Technology**

Based on a Survey of 2,500 Patients

<table>
<thead>
<tr>
<th>Condition (all cases)</th>
<th>N*</th>
<th>Slight &lt;24%</th>
<th>Fair 25-49%</th>
<th>Moderate 50-74%</th>
<th>Marked 75-100%</th>
<th>Significant &gt;25%</th>
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</thead>
<tbody>
<tr>
<td>Pain (all cases)</td>
<td>1069</td>
<td>120</td>
<td>130</td>
<td>230</td>
<td>340</td>
<td>413</td>
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<tr>
<td>back Pain</td>
<td>604</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Cervical Pain</td>
<td>345</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Hip/Leg/Foot Pain</td>
<td>189</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Shoulder/Arm/Hand Pain</td>
<td>130</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Carpal Tunnel</td>
<td>20</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Arthritis Pain</td>
<td>168</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Pain: 61% >50% improved

*Total N = 2300 patients with multiple symptoms. Results of those using Alpha-Stim™ at least 3 weeks before mailing warranty card. Warranty cards are shipped to 2300 consecutive patients received as of July 2000.

**Results Achieved with CES Technology**

Based on a Survey of 2,500 Patients (continued)

<table>
<thead>
<tr>
<th>Condition (all cases)</th>
<th>N*</th>
<th>Slight &lt;24%</th>
<th>Fair 25-49%</th>
<th>Moderate 50-74%</th>
<th>Marked 75-100%</th>
<th>Significant &gt;25%</th>
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</thead>
<tbody>
<tr>
<td>TMJ Pain</td>
<td>158</td>
<td>17</td>
<td>18</td>
<td>18</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Myofascial Pain</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>RSD</td>
<td>50</td>
<td>10</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Fibromyalgia (alone)</td>
<td>142</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Fibromyalgia (with other)</td>
<td>363</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Migraine</td>
<td>118</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Headaches (all cases)</td>
<td>112</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Fibromyalgia: 54% - 50% >75% improved

*Total N = 2300 patients with multiple symptoms. Results of those using Alpha-Stim™ at least 3 weeks before mailing warranty card. Warranty cards are shipped to 2300 consecutive patients received as of July 2000.
Changes in Fibromyalgia Patients Following 3 Weeks of CES Treatment
Tyers, 2001 (N=19)

Change in Mood Scores of Fibromyalgia Patients Following CES Treatment
Tyers, 2001 (N=19)

CES Double Blind Fibromyalgia Study
Rheumatology
Lichtbroun et al. 2001 (N=60)

Response of Patients on Various Measures

Change in Fibromyalgia Tender Point Pain Scores from Pre to Post Study
Lichtbroun et al., 2001 (N=60)

CES Double Blind Fibromyalgia Study
Rheumatology
Lichtbroun et al. 2001 (N=60)

Sleep Pattern of Study Groups

Fig 2. Change in Mood Scores of Fibromyalgia Patients Following Alpha-Stim CES Treatment
CES Double-Blind Fibromyalgia Study
LSU Dept of Anesthesiology
Cork et al. 2004 (N = 74)

1. Pain Intensity (0-5)

2. Tenderpoint Score

3. McGill Score

4. Oswestry Score

VA Houston Spinal Cord Injury CES Study
Example of the CES Response in a Patient with Severe Migraine

Courtesy of COL Michael Singer, Walter Reed Army Medical Center

So, stay with it!

Improvement in RSD Symptoms and Function Following CES Treatment

FROM PIVOTAL SCIENTIFIC STUDIES:

<table>
<thead>
<tr>
<th>First Author</th>
<th>Subject Description</th>
<th>Authors’ Comments on Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpher, K.</td>
<td>classical migraine pts</td>
<td>CES group responded significantly better than the other 2 groups over the 3 month follow-up.</td>
</tr>
<tr>
<td>Brower, A.</td>
<td>cocaine abusers</td>
<td>No CES patients had returned for treatment, while 50% of the CES refusers and 39% of the controls recidivated in 6 to 8 months.</td>
</tr>
<tr>
<td>Flemenbaum, A.</td>
<td>anxiety, depression, insomnia, outpatients unresponsive to medication</td>
<td>Those who had beneficial results maintained them throughout the 6 month follow-up.</td>
</tr>
<tr>
<td>Hearst, E.D.</td>
<td>psychotherapy outpatients</td>
<td>3 patients showed continued improvement for 2 weeks to 2 months.</td>
</tr>
</tbody>
</table>
Overcash, Stephen
1999
197 anxiety outpatients
On 6 - 8 month follow-up, 73% of the patients were “well satisfied with their treatment and had no significant regression or other anxiety disorder.

Patterson, M.
1984
186 hospitalized alcohol and polysubstance abusers
78.5% were addiction-free (80.3% of drug addicts) 1 to 8 years after CES, with an average time in rehabilitation of only 16 days.

Smith, Ray
1999
23 psychiatric outpatients with anxiety, depression, ADD
On 18 month follow-up the patients performed as well or better than in the original study.

Weiss, Marc
1973
10 insomnia patients
All differences found were maintained at the 2 week and 2 year follow-up.

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Comparison of Anti-Depressant Drugs with Alpha-Stim SCS (at $495) CES First Year

Breakeven is at 4 to 6 Months

Cumulative 5 Year Savings Using CES Instead of Drugs

5-Year Device Warranty and Assuming No Drug Price Increases

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Why Not Try CES?
Questions? email: dan@epii.com
www.alpha-stim.com