Cranial Electrotherapy Stimulation as a Proven Effective Treatment for Fibromyalgia

by Daniel L. Kirsch, PhD, DAAPM, FAIS

Fibromyalgia (FM) has been reported to affect up to ten percent of the population.[1] In most cases, patients are living with the constant, unrelenting symptoms of the condition, including widespread pain in muscles and joints, stiffness, fatigue, sleep disturbances, irritable bowel syndrome, anxiety, depression, and cognitive disorders, to name a few of the more common symptoms in this largely idiopathic syndrome.

The central nervous system is implicated in FM based on the various systemic pain, mood, sleep, and cognitive disorders ubiquitous to the diagnosis. This type of widespread centrally mediated pain has been called Central Sensitivity Syndrome (CSS) by University of Illinois researcher Muhammad Yunnus, MD.[2] CSS diagnoses include FM, chronic fatigue syndrome, irritable bowel syndrome, tension and migraine headaches, primary dysmenorrhea, periodic limb movement disorder, restless leg syndrome, temporomandibular joint disorder, and myofacial pain syndrome. These share the common traits of pain, fatigue, poor sleep, and absence of structural tissue pathology, and they are all predominantly found in females. Gulf War syndrome and multiple chemical sensitivity has also been thought to be a similar, if not the same, condition.

Ronald Melzack became interested in central pain mechanisms from his studies of phantom limb pain, in which, for example, a left leg amputee could experience intense pain in his missing left foot.[3] He theorized the existence of an homunculus in the cortex that represented every part of the body. It was thought that neuromodules residing in a larger neuromatrix that comprised the homunculus normally send pain messages to the forebrain when sufficiently stimulated by afferent pain fibers ascending to the neuromatrix by way of the spinothalamic tract. Afferent fibers were thought to ascend from each given part of the body to its representative site on the homunculus. When the afferent input from a specific body site is cut off, the neuromodule involved then puts out dendrites to other neuromodules in an apparent attempt to make up for the new lack of stimulation. Referred pain can result from these new connections.[4]

It has long been known that other kinds of input can increase the tendency of a pain message to fire, thus lowering the pain threshold. Chief among these are stress,[5] especially stress in which the person senses a lack of personal control.[6] Emotional disturbance such as anger or fear can be a real source of stress, as can unwanted noises or lack of sleep, among many other things.

These findings combine to focus attention upon cranial electrotherapy stimulation (CES) as a possible way to effectively alter pain pathophysiology in the brain. Earlier studies, one on primates and one on a human seizure subject in which receptor electrodes were placed at different sites in the brain, showed that CES current applied across the head sent electrical impulses through every area of the brain, canalizing especially along the limbic system.[7,8] That meant that CES stimulates the brain's pain neuromatrix directly, and it also stimulates the limbic, or emotion center of the brain, either one or both of which could be important in altering or raising the threshold of the pain message.

Accordingly, the best treatment for FM might well be a general treatment of the brain rather than managing the myriad complex of individual symptoms. CES uses between 100 microamperes and four milliamperes typically applied for a duration of 20 minutes to an hour, daily or every other day. The prescription transcutaneous brain stimulator is authorized for interstate marketing and export by the Food and Drug Administration for the treatment of anxiety, depression, and insomnia, but physicians are also prescribing it to treat severe forms of chronic pain, since pain is processed and felt in the nervous system, which ➤

CES for Fibromyalgia

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is controlled by the brain. CES should not be confused with transcutaneous electrical nerve stimulation (TENS), which is a much stronger current delivered in a very different waveform. Positive results from recent studies suggest that CES may provide the relief from symptoms of fibromyalgia that nothing else has. Patients use CES by clipping electrodes to their earlobes, which transmit electricity directly through the brain.

Howard Rosen, MD; an anesthesiologist/pain specialist in Monterey, California, gave a lecture on fibromyalgia at the 2003 annual meeting of the American Academy of Pain Management. He said that he never uses narcotics because they don't work well enough for his patients, and once patients start narcotics, they never come off them. His prescription: a daily dose of mild electrical stimulation with CES.

Marilyn Lins, MD, of Utica Neuorological Surgery, Inc. in Tulsa, Oklahoma, said that the results she has been obtaining have been miraculous. A pain specialist, Dr. Lins reported on several fibromyalgia patients who have had sufficient pain relief to resume normal activities with as little as two 20-minute treatments per week. One of her patients stopped limping after only one treatment. Dr. Lins said, "[CES] has forever changed my treatment approach. I have never experienced results like I have had in the past two months."

Mitchell L., of Germantown, Tennessee, had suffered from fibromyalgia, arthritis, and a sleep disorder for over six years. His physical condition worsened in spite of nutritional supplements, diets, acupuncture, and hypnosis, none of which provided relief from his daily pain. He could not endure the prescribed exercise program. Medications would provide relief but cloud his mind, and eventually, they started to strain his liver function. Within two months of daily 20-minute treatment from a pocket-sized CES device, Mitchell's pain levels decreased, his sleep improved, and he was able to gradually increase his exercise while limiting his analgesics and anti-inflammatory medications. After six months, Mitchell was sleeping and exercising enough to reduce his medications further. By ten months, he only resorted to an occasional analgesic, usually after a particularly intense exercise session or a long drive. Mitchell said that CES technology helped him to reclaim his life. He is more alert and more active, with continuing signs of improvement.

Carole L. of Verdugo City, California, uses CES twice a day for her pain from lupus and fibromyalgia. It only took a few treatments for her to realize less frequent awakenings and a more rested feeling when she awoke. The fogginess gave way to a clear head, and she felt calm. When her pain increased, she was able to relieve it in minutes. She said, "If I had not experienced this myself, I would have difficulty believing it! I ended up having a pleasant evening instead

of being in bed with narcotic pain relievers and still feeling the pain."

Arun Kulkarni, MD, an anesthesiologist in Bombay, India, who conducted a microcurrent electrical therapy (MET) and CES study in pain patients[9] said that his fibromyalgia cases "respond extremely well and are getting 80 to 90% relief. I am highly convinced about CES technology now. A few of my colleagues want to own a CES for personal use after seeing its long-term results."

A study published in the *Journal of Clinical Rheumatology* found that CES technology significantly eased the pain of fibromyalgia.[10] The principal investigator, Alan S. Lichtbroun, MD, a board-certified rheumatologist in New Jersey, found CES was as effective as prescription drugs in relieving pain, but completely safe. After successful clinical use of CES in the his rheumatology practice, and IRB approval from Robert Wood Johnson Medical School, Lichtbroun undertook a double-blind, placebo-controlled study in which 60 randomly assigned patients who completed informed consent were given either three weeks of subsensation (100 microamperes) CES treatment at 0.5 Hz for one hour daily (N=20), sham treatment (N=20), or served as controls for any placebo effect in the sham-treated patients (N=20). All patients met the diagnostic criteria set forth by the American College of Rheumatology. The age range was from 23 to 82 years (mean of 50). There were two men and 58 women suffering from fibromyalgia, with ages ranging from one to 40 years (mean of 11 years).

Active CES-treated patients showed a significant improvement in tender point scores ($p<.01$), and a significant improvement in self-rated scores of general pain level ($p<.002$). The number of subjects rating their quality of sleep as poor dropped from 60% at the beginning of the study to five percent ($p<.02$). In addition, there were significant gains in the self-rated feeling of well-being ($p<.05$) and quality-of-life ($p<.03$), plus fairly dramatic gains in all six, stress-related, psychological test measures of the Profile of Mood States. No placebo effect was found among the sham-treated patients.

After the double-blind arm of the study, 23 of the 40 control patients opted for actual CES in an open clinical trial where they could increase the current in accordance with the standard clinical protocols for CES. They also showed a significant improvement in tenderpoint scores ($p<.001$) and in self-rated pain ($p<.005$), quality of sleep ($p<.001$), feeling of well-being ($p<.001$), and quality-of-life ($p<.001$). Overall, there was a 27% reduction in self-rated pain and a 28% decrease in the tenderpoint scores of the treated group.

According to a review of 34 studies of drug treatment for fibromyalgia, ➤

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adverse effects from drugs are seen in 20% of fibromyalgia patients who use them, and improvement from prescription drugs was reported as 28% at best.[11] In addition, unlike with the use of medication, there is no ongoing cost to the patient after purchase of the CES device. Accordingly, Lichtbroun concluded that CES is as effective as the drug therapies, with no negative side effects, and deserves further consideration as an additional agent for the treatment of fibromyalgia.

The results of the electrotherapy treatment were "very surprising," says Lichtbroun, an assistant professor at Robert Wood Johnson Medical School, in an interview for WebMD.[12] But most surprising, according to Lichtbroun, was that only five percent of the treated patients reported having sleep disturbances after treatment, compared with 60% who had sleep problems going into the study. And 90% of the treated patients reported that their quality of life had improved as a result of treatment, while 20% of the patients who were in the sham-treatment group said their quality of life had declined.

"This technique is gaining wide acceptance at chronic pain treatment centers," says Lichtbroun, "At first, I looked at this device very skeptically – and even now I am beginning to see [that] some patients who had a marked response at the beginning are gradually beginning to deteriorate – so again, I wondered if the machine had lost its power. But what I've found is that patients eventually lose their incentive to use the machine, and less frequent use appears to mean a return of symptoms."

For therapeutic use, patients are taught how to use the devices so that "they can undergo the treatment in their own homes, at a time that is convenient for them," said Lichtbroun. "That's a big advantage over some other approaches, such as massage, because it doesn't require special appointments or a trip outside the home," he points out.

Another double-blind, placebo-controlled study using CES technology for fibromyalgia was concluded at Louisiana State University Health Science Center in Shreveport.[13] Conducted by Randall Cork, MD, PhD, et al. in the Department of Anesthesiology, the results were similar to the Lichtbroun study. A total of 74 subjects participated: 39 were randomly assigned to the active CES treatment group and 35 to the sham-treated group. Seventy subjects were female, with an average age of 53 (range of 22 to 75 years old). Here again, 23 of the sham subjects crossed over to an open clinical trial after the double-blind arm of the study was completed.

Subjective pain intensity was the primary measured variable in this study. Pain intensity, McGill pain score, tenderpoint score, profile of mood states, and Oswestry Score measurements were taken at baseline and after three weeks. Three weeks after crossover of the sham group, all measurements were repeated. Significant CES effects were identified, revealing an improvement in pain intensity ($p<0.01$, compared to sham; $p<0.001$ in sham group after crossover), McGill Score (not significant in initial three-week trial; $p<0.001$ in sham group after crossover), tenderpoint score (($p<0.01$, compared to sham; $P<0.001$ in sham group after crossover), and profile of mood states ($p<0.01$, compared to sham; $p<0.001$ in sham group after crossover). No significant effect was observed on Oswestry Score, which is a quantitative disability scale rather than a functional assessment of pain. However, one might reasonably conclude that longer follow-up would be necessary to see changes in this subjective measure of disability among the population of this university-based, tertiary pain-management program.

Cork concluded that his study revealed that CES could play a significant role in the treatment of pain associated with fibromyalgia; however, the long-term effects on disability remain to be studied. He went on to suggest that CES appears to be an effective, well-tolerated treatment for fibromyalgia. Those involved in the treatment of fibromyalgia should include it in their clinical armamentarium, given the demonstrated safety of this non-invasive modality.

A peer-reviewed study published in the *American Journal of Pain Management* documented treatment outcomes from 2,500 patients who responded to a survey.[14] Of those, there were 363 fibromyalgia patients, 91% of whom reported significant results (>25% improvement) in their condition. These patients all used CES for a minimum of three weeks. Similar results were reported for other pains, including migraine and other headaches, back, and neck pain.

Stephen E. Plotnick, MD, a board-certified rheumatologist in Virginia Beach described the results he obtained in about 200 patients.[15] He wrote, "There's been variable acceptance regarding the safety of using opioid analgesics to treat

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noncancer pain. In FM patients, the risk-benefit ratio becomes even more complicated. Given that CES raises the serotonin and norepinepherine levels and has a neutralizing effect on somatic pain generators, I predict this therapy will become a mainstream modality for reducing medication reliance and enhancing function in patients with FM." Plotnick also presented the case report of a 40-year-old, disabled female patient with fibromyalgia complicated by chronic lumbar strain, ankle osteoarthritis, depression, and obstructive sleep apnea. She took escitalopram, celecoxib, and transdermal fentanyl in 150 mcg doses, every two days. After adding local microcurrent treatment and CES, her spinal pain went from 8 to 0, and her ankle pain went from 10 to 6. She was then able to reduce her opiod dose by half when she acquired a CES device for home use.

There are several models of CES depending on individual needs. Some insurance companies will pay for the device, but many won't because it is still not considered mainstream medicine, although the research has met the scientific standard of being successfully replicated more than once. There have been some well-designed pain studies in CES along with some fairly lax work by researchers, but the Lichtbroun and Cork studies rank among the most rigorously designed. As an initial reviewer of one of Lichtboun's studies stated, "This article is certainly intriguing. The results are so positive in such a difficult-to-treat population that one becomes skeptical. Nonetheless, positive results in a double-blind, controlled study need to be taken seriously."[16] This should certainly be taken seriously now that the study has been replicated. While more longitudinal studies need to be conducted, the best long-term management data to date is from the results supplied by patients in the aforementioned surveys, data that represents as much as two years of treatment with CES.[14]

It may be found that the low level stimulation of CES can be used to help people who have entered into a permanent stress homeostasis from various kinds of physical or psychological trauma, with the attendant symptoms such as pain, anxiety, insomnia, and depression. CES might do this by helping them regain a pre-stress homeostasis and, with it, the ability to direct their life without having to constantly expend energies on sustaining or regaining mental and emotional balance. Once their cortical neurophysiology is normalized, they might well experience a longer life in which to enjoy it. Many hypotheses have been proposed in the literature. These have primarily been theorized from the results obtained. Research has shown an increase in beta-endorphins, serotonin, and other neurotransmitters, and EEG and EMG studies as well as psychometrics all showed significant changes.[17] Studies are in place now at two medical schools to delineate the mechanisms through functional MRI imaging.

Additional, defining pain studies with CES are still needed, of course, but the quickly evolving evidence is growing ever more convincing. Unlike most pain medicines, such as Vioxx and Oxycontin, CES has not shown a single significant negative side effect in its treatment of pain. The only adverse events seen in 126 studies of CES involving 4,541 subjects who had actually received treatment were skin reactions at the electrode site (0.11%) and myogenic headaches (0.20%) due to the uneven relaxation of cervical muscles from the current traveling across the head.[17] These are both mild and self-limiting, and they round out the CES profile to compare it quite favorably with the other therapeutic options for the typically refractory FM patient.

Notes

1. Staud R. Abnormal pain processing in patients with fibromyalgia. *Fibromyalgia Aware*. 2003/4; 5(4):46-48.
2. Yunnus MB. What's new in fibromyalgia syndrome? A review of abstracts presented in the 1996 American College of Rheumatology Annual Scientific Meeting: Part 1. *The Fibromyalgia Times*. 1997;1(4):4.
3. Melzack R. Phantom limbs. *Scientific American*. 1992;266:120-126.
4. Coderre TJ, Katz J, Vaccarina AL. Contribution of central neuroplasticity to pathological pain: review of clinical and experimental evidence. *Pain*. 1993;52:259-285.
5. Schuster · JM. Antidepressants, anxiolytics, and antipsychotics in the treatment of pain. In: Weiner, R.S. (Ed). *Pain Management; A Practical Guide for Clinicians*. Boca Raton: St. Lucie Press. 1998: 156.
6. Averill JP Personal control over aversive stimuli and its relationship to stress. *Psychological Bulletin*. 1973;80:186-303.
7. Dymond AM, Coger RW, Serafetinides EA. Intracerebral current levels in man during electrosleep therapy. *Biological Psychiatry*. 1975; 10(1):101-104.
8. Jarzembski WB, Larson SJ, Sances, Jr. A. Evaluation of specific cerebral impedance and cerebral current density. *Annals of the N.Y. Academy of Science*. 1970;170:476-490.
9. Kulkarni AD, Smith R. The use of microcurrent electrical therapy and cranial electrotherapy stimulation in pain control. *Clinical Practice of Alternative Medicine*. 2001;2(2):99-102.
10. Lichtbroun AS, Raicer MC, Smith R. The treatment of fibromyalgia with cranial electrotherapy stimulation. *Journal of Clinical Rheumatology*. 2001; 7(2):72-78.
11. Leventhal LJ. Management of fibromyalgia. *Annals Internal Medicine*. 1999;131:850-8.
12. Peck P. These brain waves may tame fibromyalgia. WebMD. May 2, 2001.
13. Cork RC, Wood P, Ming N, Clifton S, James E, Price L. The effect of cranial electrotherapy stimulation (CES) on pain associated with fibromyalgia. *The Internet Journal of Anesthesiology*. 2004;8(2).
14. Smith R. Is microcurrent stimulation effective in pain management? An additional perspective. *American Journal of Pain Management*. 2001;11(2):62-66.
15. Plotnick SE. Finding hope: Alpha-Stim 100 may help clinicians yield better fibromyalgia treatment results. *Advance for Directors in Rehabilitation*. May 2005:82.
16. Katz RS. Commentary. *Journal of Clinical Rheumatology*. 2001;7(2):78.
17. Kirsch DL. *The Science Behind Cranial Electrotherapy Stimulation*. 2nd ed. Edmonton, Alberta, Canada: Medical Scope Publishing Corporation; 2002.

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