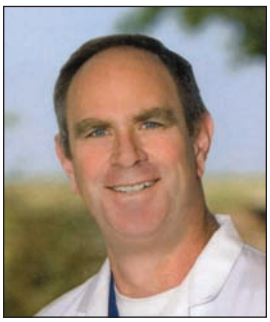
Cumulative Response from Cranial Electrotherapy Stimulation (CES) for Chronic Pain

Results from five CES sessions—administered over the course of treatment to 525 consecutive chronic pain patients—confirmed that an initial decrease in pain after the first session was typically followed by further decreases in pain from the cumulative effects of this modality.

Daniel L. Kirsch, PhD, FAIS

This is a welcome addition to the literature on electromedicine because it looks not only at the immediate effect but on the cumulative effect as well. No intervention controls chronic pain in one treatment so it is good to see Dr. Holubec prove that cranial electrotherapy stimulation persists and adds up to more pain relief over a series of treatments. While this may be obvious to practitioners, this study proves the observation that a series of electrical treatments directed to the brain are necessary to, and indeed can achieve, a clinically significant effect in pain management.

—Daniel L. Kirsch, PhD



By Jerry T. Holubec, DO

Cranial electrotherapy stimulation (CES) is an FDA-approved technology by physician prescription for the treatment of anxiety, depression and insomnia. While the use of electric currents in medical practice dates back more than 2,000 years, today's interest in CES, originally called electrosleep, originated in France in 1902 by Leduc and Rouxeau. Leduc's student, Robinovitch, made the first claim for inducing sleep from electrical treatment in 1914.[1]

Subsequent research interest revolved around electronarcosis and then electroconvulsive shock treatments through the late 1930s.[2] Interest in the smaller amounts of electric currents involved in CES did not begin in earnest until 1958 when Gilyarovski published a book titled, Electrosleep.[3]

When American researchers started to study CES about 40 years ago, they soon found that while it did not necessarily induce sleep, it achieved significant clinical effects for mood disorders.[4,5] Accordingly, the FDA changed the generic terminology from electrosleep to CES in 1978. A recently revised annotated bibliography of CES research summarized 126 human studies, 29 animal studies, and 31 review articles in the English language literature.[6]

The pain threshold has been found to be lowered when accompanied by the stress-related disorders for which CES has historically been prescribed.[7] CES has previously been studied in conjunction with other aspects of microcurrent electrical therapy (MET) applied to the body via handheld probes or self-adhesive electrodes in a pain management practice.[8] Results of that study of 20 patients revealed that those who continued at least two weeks of daily treatments exhibited an average of 73% improvement in their self-rated visual analogue pain scales and correlates well with this present study. CES has also been proven successful in double blind research for treating specific types of pain, such as fibromyalgia, reflex sympathetic dystrophy (RSD), and spinal pain.[9-12] This present study is the first evaluation of the cumulative effects from multiple sessions of CES in the treatment of the wide range of pain diagnoses found in a typical pain clinic.

The Regional Pain Care Center of North Texas is a specialty clinic that receives referrals of patients with unresolved pain from other physicians. Because the effects of CES on these patients were unknown, it was determined to conduct an open clinical evaluation of the response of these refractory patients to 20 minutes of CES when the patients first entered the facility.

Materials and Methods

The devices used for CES in this study were the Alpha-Stim SCS (Electromedical Products International, Inc, Mineral Wells, Texas, www.alpha-stim.com). It produces a bipolar modified square waveform of 0.5 Hz at a maximum current of 500 microamperes. Clip electrodes are placed on each ear lobe. Patients were allowed to set the current to a comfortable level. Most choose between 200 and 300 microamperes.

During the study, each patient was offered CES treatment upon entering the facility. Fewer than 1% refused the treatment. The remaining participants were asked to complete a pain questionnaire in which they described their area of pain and rated its intensity on a scale of 1 to 10—with 10 being the most severe pain they have experienced. Following the treatment, the patients received further evaluation and treatment prior to discharge. Patients who received other forms of electrotherapy in addition to CES were excluded.

A total of 525 patients were treated, 261 returned for a second treatment, 160 returned for a third, 57 returned for a fourth, and

Table 1. Response of pain patients to one to five 20-minute treatments with CES

Treatment Number	Patients Not Responding	Patients Responding	Percent Improvement	Patients Pain Free
First, N = 525 Initial Pain Level	20.19% 5.41	79.81% 6.21	42.40%	5.14% 3.26
Second, N = 261 Initial Pain Level	12.64% 5.33	86.21% 5.75	49.80%	10.73% 4.32
Third, N = 160 Initial Pain Level	15% 4.91	86.00% 6.31	53.99%	12.5% 4.45
Fourth, N = 57 Initial Pain Level	28.57% 3.08	71.43% 6.66	64.25%	10.52% 6.5
Fifth, N = 26 Initial Pain Level	38.46% 4.2	61.54% 7.25	70.64%	15.38% 6.5

26 returned for a fifth treatment. Patients were not specifically selected for additional CES treatments following the first but were offered the additional treatment if they were required to return to the clinic for other types of follow up. In general, the most severe cases were most likely to return. Treatments were spaced one day apart, except for patients who came on Thursday as the clinic is closed on Friday through the weekend. Those patients received treatment on the following Monday. Of the 525 initial patients treated, 343 (65.33%) were female, ages ranged from 9 to 91 years with a mean of 44.49 +/– 12.25.

Table 1 shows the results from the CES treatments. It can be seen that there is a percentage of patients who did not respond to CES treatment—as is the case in any treatment modality. The large group of patients (79.81%) who did respond to the initial CES treatment exhibited an impressive improvement of 42.40% from only one 20-minute dose. In subsequent visits, the number of patients grew smaller. However, the improvement was greater even though there was a higher initial pain level in these groups. The cumulative effect of CES was demonstrated by the increasing percent of patients becoming pain-free on consecutive visits.

The cumulative treatment effect can be seen in Figure 1. As the number of sessions progressed, there was a rising percentage of those not responding by the fourth and fifth treatments. This was due to the fact that the patients suffering with the most severe pain continued for additional treatment sessions. Even so, the percent improvement among the most severe group was still rising, as was the percent of patients achieving pain free status subsequent to the increasing number of treatments.

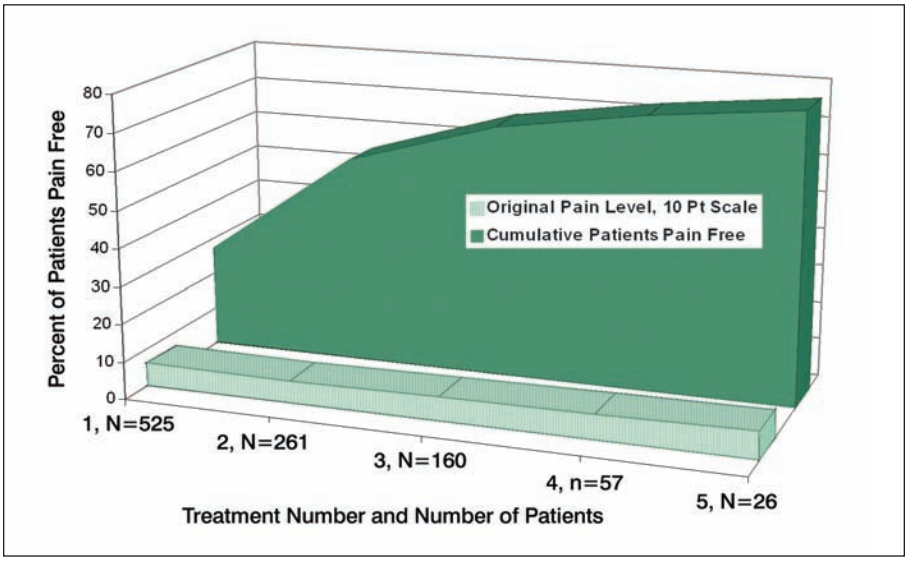


Figure 1. *Patients who report being pain free after one to five 20-minute CES treatment sessions.*

Table 2 shows the types of pain responding and not responding to CES treatment. There was no specific type of pain that would or would not respond to CES treatment. The distribution of pain areas were similar in the two groups except in patients diagnosed with RSD and fibromyalgia. It is known that CES is an effective treatment for RSD and fibromyalgia when longer treatment periods are utilized, but five treatments are not enough to establish control of these pathologies.[10,11]

Since not all of the patients were given the same number of treatments, this study cannot be definitive regarding the cumulative effects of CES treatments. The results of treatment in all sessions subsequent to the first, however, were subtracted from the initial pain level when the patients first entered the facility for treatment. The fact that the patients continued to exhibit improvement following each subsequent treatment gives strong support to the claim of a cumulative effect from this treatment.

Discussion

While this study gave strong support for the cumulative effectiveness of CES in the treatment of a wide variety of pain related disorders found in a busy pain management clinic, it should be acknowledged that many other types of pain management were also being employed with these patients as well. Many, though not all, patients who are referred to the clinic are taking prescribed pain medications upon arrival, and the initial self-evaluation of their pain level took any medication effect into consideration, with the improvements following CES rising over and above it. It is unlikely that the significant

drop in pain levels after a 20-minute CES treatment would be due to the medications. Prior research has shown that CES has the ability to potentiate the uptake and utilization of some medications, and that effect could have contributed an unmeasured treatment effect to these findings.[13,14] However, CES still showed a significant treatment effect—either as the sole treatment among the incoming patients, or as a treatment in addition to medications.

There are several mechanisms by which CES might be expected to have an effect in raising the pain threshold. It is known that at least 47% of the electricity applied to the head in CES penetrates the cranium and passes through all areas of the brain, while tending to canalize especially along the limbic system.[15] There is a growing theoretical interest in a pain neuromatrix in the cerebral cortex which, when stimulated sufficiently, sends pain messages to the frontal cortex where pain is perceived.[16,17] While a direct role of CES stimulation of the pain matrix has not been postulated, theorists assume that stress can add sufficient noxious input to the neuromatrix to raise it above an action threshold. CES has a history of successfully treating stress in pain patients.[6,9]

Another important part of the brain is the hypothalamic-pituitary axis which controls much of the body's hormone regulatory process. CES has also been shown to stimulate the increased production of serotonin, beta-endorphins, norepinephrine and cholinesterase in pain patients.[18] These hormonal changes could be expected to have an impact on the perceived level of pain.

Summary

Cranial electrotherapy stimulation (CES) is the application of microcurrent electrical stimulation of the brain and is authorized by the FDA for the treatment of anxiety, depression, and insomnia (by doctor's prescription). CES has also been studied for the treatment of fibromyalgia, reflex sympathetic dystrophy, and other pain related disorders. In this study, 525 consecutive pain patients in a pain management clinic were administered 20 minutes of CES treatment. Of those, 261 were given a second treatment at their next visit, 160 were given three treatments, 57 were given four treatments, and 26 were given five treatments. The 79.81% who responded to the first treatment experienced a 42.40% reduction in self-rated pain, with 5.14% of the patients declaring themselves pain free. Cumulative results were seen among those subsequently treated. There was a 70.64% reduction in pain after five treatments, including 15.38% of the remaining patients reporting no pain, a 300% increase. CES was shown to be a valuable addition to a multifaceted pain treatment program. No adverse side effects were noted.

Table 2. Pain areas of patients not responding vs. those becoming pain free following CES treatments

Area of Pain	Percent of Non-Responders	Percent of Those Becoming Pain Free
Spinal (Cervical to L4, L5)	43%	48%
Shoulder, Arm, Hand	28%	21%
Hip, Leg, Foot	9%	15%
Headaches, Migraines	8%	18%
RSD, fibromyalgia	12%	0%

Conclusions

One to five 20-minute CES treatment sessions produced a reduction in pain ranging from 42% to 71% in the approximately 80% of patients who responded. No negative side effects were observed by any member of the clinic staff or reported by the patients. Accordingly, this study gives credence to the claim that CES has a positive cumulative effect in refractory patients with a wide range of pain-related disorders. ■

Acknowledgement

The author appreciates the assistance of Mike Nichols with this study.

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