Electromedicine

Electromedical Treatment of Headaches

By Daniel L. Kirsch, PhD, DAAPM, FAIS

Headaches are a common intermittent disorder experienced by most people at least some of the time. Chronic headaches of various etiologies are experienced by 1 in 6 Americans (16.54% of the population), which includes migraine headaches in 1 in 9 (10.29% of the population). Most headaches are of the tension-type which have been associated with muscle tension, stress, anger, anxiety and fatigue, and are characterized by mild to moderate, non-pulsating bilateral pain. The pain may begin in the front of the head or back of the neck, and may spread to involve the whole head. For occasional mild headaches, simply massaging the head and neck has proven effective.

Migraine pain usually presents unilaterally with a distinct pulsating quality often accompanied by nausea, vomiting, and sensitivity to light and sound. Migraine may be caused by intolerance to certain foods, such as red wine, chocolate, aged cheeses, nitrates, aspartame, beer, cured meats and Brewer's yeast. Migraine pain usually worsens with physical activity. These headaches are often preceded by an "aura" or visual disturbance and lasts an average of 4 to 72 hours.

Over-the-counter analgesics (e.g., aspirin, acetaminophen or NSAIDs) are the most common treatment for headaches. However, using analgesics more than three times a week may lead to rebound headaches; chronic daily headaches that require additional intervention and with it the iatrogenic risk of liver, kidney and gastrointestinal disease. Many prescription drugs are used to treat or prevent headaches. Among these are low-dose tricyclic antidepressants such as amitriptyline which may cause side effects (e.g., dry mouth, constipation, sexual dysfunction, blurred vision, dizziness, etc.).

Electromedical Treatment

Cranial electrotherapy stimulation (CES) reduces muscle tension, stress and anxiety—which are commonly accepted precipitating factors for many headaches—and treats the entire head and brain. CES uses between 100 microamperes and 4 milliamperes typically applied for 20 minutes to an hour daily or every other day. Microcurrent electrical therapy (MET)—which, by definition, uses a low level of current—is the only form of electromedicine safe enough to be used on the head for the treatment of headaches, along with any associated neck pain or temporomandibular disorder (TMD)—a contributing, if not causative factor for many headaches. Only those MET devices that have hand-held probes—rather than or in addition to self-adhesive electrodes—should be used on the head and neck. Pressure from the probes on the carotid sinus should be avoided.

FDA Survey Data

A survey was completed for the U.S. Food and Drug Administration in 1998 analyzing data on 500 patients as reported by 47 physicians.[1] There were 172 males and 326 females identified, ranging from 5 to 92 years old. Twenty-one of the two page forms were completed on inpatients, the balance on outpatients. While 41% of the patients were reported to have completed CES and/or MET treatment, 43% were still receiving treatment at the time of the survey. Ten patients discontinued treatment because it was not efficacious, three discontinued due to undesirable side effects, 13 because their insurance ran out, and 20 for other, unspecified reasons.

Physicians reported significant results of 25% or greater pain reduction in 260 out of 286 (90.91%) for pain relief, in 136 out of 151 (90.07%) for headache, and 245 out of 259 (94.59%) for muscle tension (see Table 1).

Self-reports from 1,949 pain patients who used CES for more than 3 weeks revealed an overall reduction of at least 50% of pain from various etiologies in 61%. Specifically, 55% of those reporting all headaches other than migraine, and 57% diagnosed with migraine, reported that their pain was reduced at least 50% (see Table 2).[2]

Research Study #1

A multicenter double-blind study was conducted of 112 people

PHYSICIANS' REPORTS • DEGREE OF IMPROVEMENT									
Condition	N	Worse	No Change	Slight <24%	Fair 25-49%	Moderate 50-74%	Marked 75-99%	Complete 100%	Significant >25%
Pain	286	1 0.35%	51 .75%	20 6.99%	48 16.78%	77 26.92%	108 37.76%	27 9.44%	260 90.91%
Anxiety	349	0 0.00%	8 2.29%	14 4.01%	39 11.17%	89 25.50%	181 51.86%	18 5.16%	327 93.70%
Depression	184	0 0.00%	8 4.35%	11 5.98%	31 16.85%	38 20.65%	82 44.57%	14 7.61%	165 89.67%
Stress	259	0 0.00%	6 2.32%	12 4.63%	37 14.29%	70 27.03%	124 47.88%	10 3.86%	241 93.05%
Insomnia	135	0 0.00%	16 11.85%	12 8.89%	17 12.59%	34 25.19%	45 33.33%	11 8.15%	107 79.26%
Headache	151	1 0.66%	8 5.30%	6 3.97%	25 16.56%	32 21.19%	63 41.72%	16 10.60%	136 90.07%
Muscle Tension	259	2 0.77%	6 2.32%	6 2.32%	42 16.22%	76 29.34%	111 42.86%	16 6.18%	245 94.59%

TABLE 1. *Physicians' survey of 500 patients presenting with multiple pain-related symptoms.*

with tension headaches.[3] Inclusion criteria were that all subjects had to have tension headaches requiring analgesic agents for at least one year, with at least four headaches per month. Subjects were excluded with diagnosis of migraine, cluster, or medication-rebound headaches, pregnancy, major physical, mental, or neurological problems, recent history of drug dependency, or implanted electrical devices. Participants were instructed on the use of CES and were told to treat each headache for 20 minutes and, if necessary, repeat 20 minutes after the first treatment (for another 20 minutes). The study lasted up to 10 weeks, but terminated after four headaches. Patient and physician global evaluations were the primary measures. Following active treatment (N=57), subjects reported an average reduction in pain intensity of approximately 35%. Sham treated subjects (N=55) reported a reduction of approximately 18%, a statistically significant effect (P=0.01).

Active CES was rated as moderately or highly effective by 40% of physicians, and by 36% of subjects. Both physicians and subjects scored sham CES moderately or highly effective in 16%. The difference in outcomes was statistically significant. Means of changes in headache severity of the two groups was 6.1 pretest to 4.0 post-test for the active group (-34.4%, P<0.001), and 6.4 to 5.2 for the sham group (-18.8%, P<0.001). 17 subjects left the study early due to adverse events (2 active, 2 sham), no effect (3 in each group), non-compliance (1 each), and five for other reasons. Six of 57 in the active group, and 7 of 55 in the sham group had one or more adverse events. The incidence of adverse events was not significantly different between the active and the sham treated groups for any of the reported symptoms.

The authors of the study concluded that it appears that CES is safe, and should be considered in the management of tension headaches as an alternative to the chronic usage of analgesics.

Research Study #2

Romano studied 100 consecutive fibromyalgia (FM) patients (23 males ages 22-58, mean=45, and 77 females ages 18-65, mean=46) in his rheumatology practice having severe chronic headache unresponsive to medications (NSAIDs, beta blockers, tricyclics, and ergots), biofeedback, low tyramine diet, local injections, and physical therapy.[4] They were provided CES devices and instructed to use them for 20 minutes, four times daily while continuing their medications. 75 completed the study. Dolimetry using a pressure algometer was performed at 6 active typical tender points just before CES and 1-2 months after. Patients were also asked to rate their headache severity on a 1-10 scale (1=no effect, 10=totally effective in relieving headaches) before CES, at a subsequent visit, and at follow-up.

CES proved to be effective in FM-related headache patients. Approximately 50% of FM patients using CES regularly reported a significant decrease in the frequency and intensity of their headaches. The mean pretreatment headache intensity score was 8.1 (7.8 for males, 8.4 for females). After 1-2 months of CES treatment, the mean score was 4.7 (4.5 for males, 4.8 for females). The difference in the mean scores was 3.4 (3.3 for males, 3.6 for females) and there was definite subjective improvement. Dolimetric testing of 450 sites (6 per patient) revealed that 42% (189) were improved (values increased greater than 1 kg/1.54 cm^2), 19% (86) were worse, and 39% (175) were

SELF-REPORTS • DEGREE OF IMPROVEMENT						
Condition	N	Slight <24%	Fair 25-49%	Moderate 50-74%	Marked 75-100%	Significant >25%
Pain (all cases)	1,949	136 6.98%	623 31.97%	741 38.02%	449 23.04%	1,813 93.02%
Migraine	118	2 1.69%	49 41.53%	30 25.42%	37 31.36%	116 98.31%
Headaches (all other)	112	20 17.86%	30 26.79%	24 21.43%	38 33.93%	92 82.14%

TABLE 2. *Self reports of 1,949 pain patients who used CES and/or MET for a minimum of 3 weeks. Note that while migraine patients experienced better relief overall, the differences were only significant in those who achieved less than 50% pain reduction.*

unchanged. Eight patients reported no benefit, six stated they were entirely free of headaches, while 15 (20%) reported CES efficacy as a "7", indicating moderate improvement in both frequency and severity of headaches. Thirty-eight (51%) rated improvement as a "7" or greater. The author concluded that CES is a helpful adjunct in the treatment of FM patients with headache previously unresponsive to conventional techniques. No side effects were reported.

Research Study #3

Brand studied 58 headache patients including migraine that were treated with CES and concluded that CES proved to be very useful.[5] In seven cases, CES was the only method that could prevent the onset of a migraine attack. In many cases, it was possible to prevent the occurrence of headaches without any additional medication. No side effects were reported.

Research Study #4

For his Ph.D. dissertation, Brotman conducted a double-blind study of 36 females, ages 18-40, suffering from classical migraine headaches (ICD-9 346.0), who were randomly assigned to Quieting Reflex Training (QR, a 6-second breathing and visualization exercise designed by the late Charles S. Stroebel, MD, PhD, to quickly shift neurophysiologic functioning to a parasympathetic dominant state) and sham CES (N=12), QR plus actual CES (N=12), or a CES only group (N=12).[6] All groups were measured for temperature changes using thermal biofeedback (TBF) via finger monitors on the dominant hand and temporalis muscle electromyogram (EMG). All received treatments twice weekly for one month, and had follow-up evaluations at 1, 2, and 3 month intervals. Medication levels dropped dramatically from the initial session to the eighth session. Fischer t-tests were employed separately for investigation of CES and QR. Results were calculated using the formula of frequency x intensity of headaches. The findings were that groups receiving TBF and QR, either with CES (pretreatment mean of 14.42 ± 6.26, post treatment of 4.50 ± 5.30) or with sham CES (pretreatment mean of 15.33 ± 6.62, post treatment of 4.33 ± 4.46), responded significantly better than did the TBF CES group alone (pretreatment mean of 14.00 ± 4.56, post treatment of 6.33 ± 4.38), but that the group receiving TBF, QR, and CES responded significantly better (mean of .08 ± 0.28) than the TBF, QR and sham CES group (mean of .58 ± 1.19) or the TBF and CES group (mean of 8.67 ± 6.60) at the 3 month follow-up period (Figure 1). Only the CES group showed significant carryover effects in finger temperature. Those groups that did not receive the CES treatment were subsequently treated with CES and they achieved headache reductions comparable to those obtained in the TBF, QR, and CES group.

Observations during the study suggested that CES may contribute to both a rapid rise of finger temperature during each session and to a homeostatic rise in finger temperature over

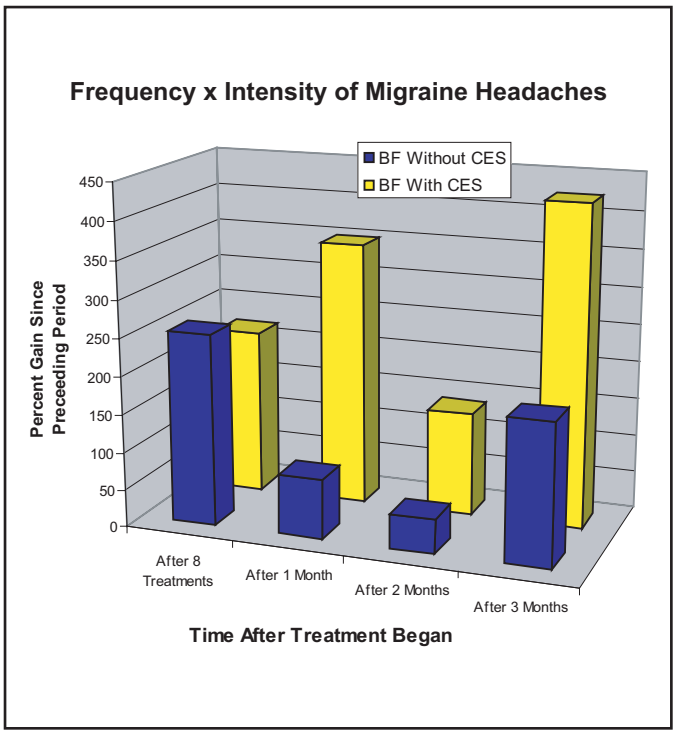

FIGURE 1. *CES potentiated biofeedback gain by more than 70% at the final follow-up period, 90 days after 8 treatment sessions.*

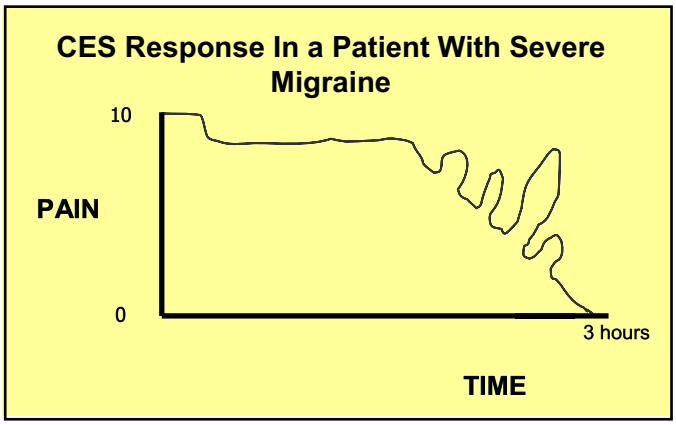

FIGURE 2. *Example of the course of treatment of CES in a patient with severe migraine. While the pain undergoes fluctuations, it is eliminated with 3 hours of ongoing CES treatment.* Courtesy of COL Michael T. Singer (Ret), Walter Reed Army Medical Center.

time. It was suggested that this was possibly due to a hypothalamic regulating mechanism. No subjects in the CES or sham CES groups reported side effects.

Research Study #5

England studied 18 migraine patients for his M.S. thesis, consisting of six males and 12 females ranging from 21 to 62 years old (mean of 37.9).[7] Three groups of six patients each were matched on the basis of headache intensity during a two week baseline period and divided into CES treatment, sham CES treatment, and waiting list control groups. CES was given 45 minutes per day for 15 days, Monday through Friday. A Wilcoxon matched-pairs, signed-ranks test was calculated for the difference in scores for each of the variables of headache frequency, intensity, and duration. The frequency of headaches had not changed significantly by the end of the study. There was no significant difference in intensity of headaches after the second week of treatment. However, when both baseline periods were compared to the results of the third week of treatment, the CES group was found to have significantly ($P<.025$) lower headache intensity ratings than the sham CES treated group.

There was also a significant ($P<.05$) reduction in duration of headaches among active CES over sham treated after the second week. The waiting list control group reported improvement also, but they were asked to recall their week's experience over the telephone on Friday only, while the treatment and sham treated groups were asked to keep a written record on a daily basis. It was noted that the recordings may not have been comparable and that the variable of medication usage tended to confound the results. The frequency, intensity, and duration of pain did not change in the sham treated patients during or following the study. The author of the study concluded that CES does consistently better than placebo. No side effects from CES were reported.

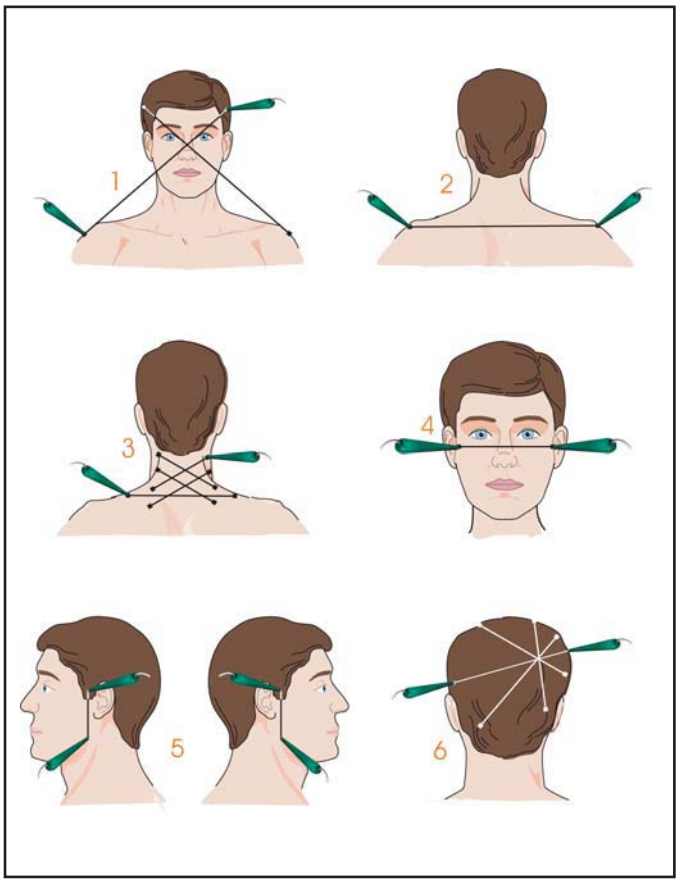

FIGURE 3. *Head Pain Protocol*

Course of Treatment in Severe Migraine

COL Michael T. Singer, a prosthodontist and former Director of the Craniofacial Pain Clinic at Walter Reed Army Medical Center in Washington, D.C., charted a severe migraine episode over the course of a 3 hour CES treatment.[8] As can be seen in Figure 2, after about 15 minutes of CES in a darkened room, the patient experienced a mild reduction in pain which then remained at that level for approximately 2 hours. At that point the pain began to diminish, but fluctuated where at times it appeared to return to the pretreatment level. After about 3 hours, the patient was pain free.

Microcurrent Electrical Therapy

At the Division of Otolaryngology of the Veterans Administration Medical Center in Cleveland, Ohio, Bauer reported on the use of microcurrent electrical therapy (MET) for severe intractable head and neck pain in cancer patients that failed to achieve adequate relief with "heavy medication" and surgery.[9] The author stated that the three cases he presented are representative of similar cases treated. Without exception, in every case there was a positive effect in decreasing pain. Objectively, these patients could be followed up by the amount of pain medication they required.

In Case 1, a 58 year old man had squamous cell carcinoma of the laryngeopharynx staged at T4N2M0, full course radiation therapy and radical neck dissection. After failing to achieve pain relief with 7mg of morphine sulfate every four hours along with various sedatives, he achieved complete relief without medication at all for one week following three daily, 10-minute MET treatments of 500 microamperes at 0.5 Hz, and was then maintained pain free with treatments every 3 days for 1 minute. In Case 2, a 54 year old man who also had a neck dissection and radiation for a T3N0M0 lesion of the larynx, and a primary squamous cell tumor of the left lung, was prescribed a combination of codeine, zomepirac sodium (Zomax), and amitriptyline hy-

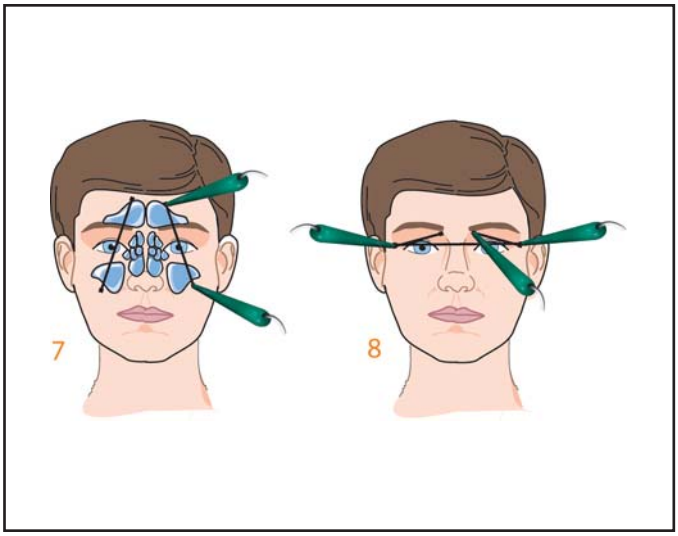

FIGURE 4. *Sinus and Ocular Pain*

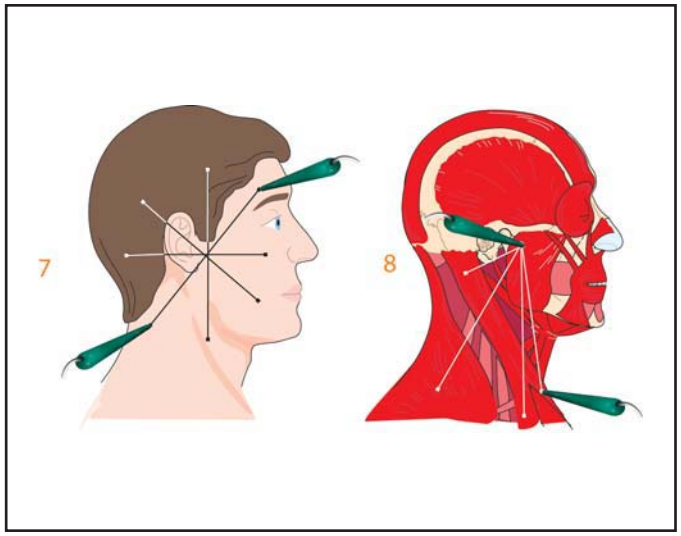

FIGURE 5. *Temporomandibular Disorder*

drochloride (Elavil), but provided little relief. After six minutes of MET treatment he had complete relief of pain for 50 hours, after which further treatment caused the pain to disappear again. Case 3 involved a 59-year-old man who had a T4N1M0 squamous cell carcinoma of the base of the tongue and supraglottis. Codeine and meperidine failed to completely control his severe pain that radiated to both ears. The pain was completely relieved for 8 hours after 12-minutes of MET treatment. The second treatment lasted 24 hours.

Bauer noted that the longevity of the results was especially encouraging. In every case pain relief lasted at least 8 hours and, in Case 2, the effect lasted more than 3 weeks. There was no indication of side effects, and usually there was no sensation of the electrical stimulus. He added that the positive results are unquestionable, and this form of electrical stimulation should not be confused with transcutaneous electrical nerve stimulation (TENS).

Microcurrent Electrical Therapy Protocols

In the previous issue of Practical Pain Management, this Electromedical Department provided a tutorial on microcurrent electrical therapy.[10] Following those basic guidelines, specific examples for treatment of head pain can be seen in Figure 3, 4, and 5. In Figure 3, at 10 seconds per site, the basic head pain protocol should take no more than 3 minutes. Figures 4 and 5 indicate electrode locations for head pain associated with sinus, ocular, or temporomandibular disorders which are to be added, when indicated, to the head pain protocol depicted in Figure 3.

Head Pain (See Figure 3)

Include the temporomandibular joint (TMJ), neck, and shoulders. Place probes:

1. At various angles above one ear to the tip of the contralateral shoulder. Then treat the contralateral side in the same manner.
2. Across the shoulders by treating bilaterally on the distal tips of the acromions.
3. In a few "X" patterns across back of neck.
4. From one TMJ to the other.
5. Temple to ipsilateral masseter muscle. Then treat the contralateral side.
6. At various angles for about 1 minute through the primary area of involvement.

Note: Reduce the current as necessary to avoid vertigo. Treating near the eyes may cause the patient to see flashing lights due to stimulation of the optic nerve. Some people may also taste metal fillings when treating across oral cavity. None of these conditions are harmful.

Sinus and Ocular Pain (See Figure 4)

Begin sinus and ocular pain treatment using the Protocol for Head Pain (steps 1 thru 6).

7. Treat sinuses when indicated, above and below eyes, or from side to side (see notes in Head Pain section). The patient should be able to breathe more clearly immediately following the treatment, although one treatment will have little residual effect on nasal congestion.
8. For ocular headaches treat behind eyes by placing probes on each temple, lateral to the lateral canthus of the eyes, and across each eye (ipsilaterally) at the bridge of the nose to the lateral canthus of the eye.

Temporomandibular Disorder (TMD) (See Figure 5)

Begin temporomandibular disorder treatment using the Protocol for Head Pain (steps 1 thru 6).

7. A star pattern across TMJ. Treat both sides.
8. Connect the TMJ with the sternocleidomastoideus (SCM) muscles, below the mastoid, and along the clavicular and sternal branches. Then treat the contralateral side in the same manner.

Conclusion

Cranial electrotherapy stimulation and microcurrent electrical therapy provides safe, efficacious and cost effective treatments for headaches of various etiologies, even in severe cases. Additional prospective randomized controlled trials are still needed to further verify the efficacy of these therapies and delineate the optimal course of treatment. However, enough data already ex-

ists to warrant practitioners' use of CES and MET for headache treatment in clinical settings, as well as prescriptive electromedical therapies for home use in relieving chronic pain. ■

Daniel L. Kirsch, PhD, DAAPM, FAIS is an internationally renowned authority on electromedicine with 33 years of experience in the electromedical field. He is a board-certified Diplomate of the American Academy of Pain Management, Fellow of the American Institute of Stress, Member of the International Society of Neuronal Regulation, and a Member of Inter-Pain (an association of pain management specialists in Germany and Switzerland). He served as Clinical Director of The Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center, New York City, and of The Sports Medicine Group, Santa Monica, California. Dr. Kirsch is the author of two books on CES titled, The Science Behind Cranial Electrotherapy Stimulation, 2nd Ed. published by Medical Scope Publishing Corporation, Edmonton, Alberta, Canada in 2002; and Schmerzen lindern ohne Chemie CES, die Revolution in der Schmerztherapie, Internationale Ärztegesellschaft für Energiemedizin, Austria 2000, in German. Best known for designing the Alpha-Stim CES and MET line of medical devices, Dr. Kirsch is Chairman of Electromedical Products International, Inc. of Mineral Wells, Texas, USA with additional offices in Europe and Asia.

References

1. Kirsch DL. *The Science Behind Cranial Electrotherapy Stimulation* (2nd Ed), Medical Scope Publishing Corporation. Edmonton, Alberta, Canada. 2002. pp 157-217.

2. Smith RB. Is microcurrent stimulation effective in pain management? An additional perspective. *American Journal of Pain Management*. 2001. 11(2):62-66.

3. Solomon S, Elkind A, Freitag F, Gallagher RM, Moore K, Swerdow B, and Malkin S. Safety and effectiveness of cranial electrotherapy in the treatment of tension headache. *Headache*. 1989. 29:445-450.

4. Romano T. The usefulness of cranial electrotherapy in the treatment of headache in fibromyalgia patients. *American Journal of Pain Management*. 1993. 3(1):15-19.

5. Brand J. Electrosleep therapy for migraine and headache. In Wageneder, F.M. and St. Schuy (Eds). *Electrotherapeutic Sleep and Electroanaesthesia*. Excerpta Medica Foundation, Amsterdam. 1970. pp 113-115.

6. Brotman P. Low-intensity transcranial electrostimulation improves the efficacy of thermal biofeedback and quieting reflex training in the treatment of classical migraine headache. *American Journal of Electromedicine*. 1989. 6(5):120-123.

7. England RR. *Treatment of migraine headache utilizing cerebral electrostimulation*. Master of Science Thesis. University of North Texas, Denton, Texas. 1976. pp 1-38.

8. Singer MT. *Central sensitivity syndrome: treating migraines without medication*. Presented at the Electromedical Track at the 14th annual clinical meeting of the American Academy of Pain Management. Denver, Colorado. September 4, 2003.

9. Bauer W. Electrical treatment of severe head and neck cancer pain. *Archives of Otolaryngology*. 1983. 109(6):382-383.

10. Kirsch, Daniel L. Microcurrent electrical therapy: A tutorial. *Practical Pain Management*. 2006. 6(7):59-64.