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By Steve Tyers, D.C., and Ray B. Smith, Ph.D.

## A Comparison of Cranial Electrotherapy Stimulation Alone or with Chiropractic Therapies in the Treatment of Fibromyalgia

The diagnosis of fibromyalgia has been on the rise in the past 15-to-20 years. Its incidence was rated as high as 4.8% of the population as of 1995, and is still climbing<sup>1</sup>. Numerous drug trials with these patients have been reported, with one reviewer noting that the pain reduction found in

34 such medication studies has averaged no more than 28%, and the medications have often been accompanied by sometimes serious side effects, in up to 20% of the study patients<sup>2</sup>.

Because it is known that psychological stress tends to augment the pain message<sup>3,4</sup>, we at the Integrated Medical Centers of California, La Jolla, decided to do a clinical trial of cranial electrotherapy stimulation (CES) alone, compared with a group of patients who received CES plus physical medicine.

CES is an FDA accepted, non-drug treatment for depression, anxiety and insomnia, all stress producing dysfunctions<sup>5</sup>. In an earlier study reported at an international conference in 1999, CES had been shown to reduce the perception of pain at the tender points significantly<sup>6</sup>.

We decided to attempt a replication of earlier CES treatment findings in fibromyalgia patients, and compare them with a second group of patients who would receive indicated chiropractic care along with CES therapy. This would allow us to evaluate any effect of the combination treatment on fibromyalgia pain.

### Method

Sixty patients with a prior diagnosis of



fibromyalgia signed voluntary consent forms to be in the study. Every third patient was assigned to receive CES alone, while the others were to receive both CES and chiropractic treatment. All patients were between the ages of 25 and 57 (mean 45). Five were male, and three were Latin American.

All patients were pre-tested on the Profile of Mood States (POMS), a standardized psychological test. In addition, all were asked to rate their overall pain level, their quality of sleep, their feeling of well being and their quality of life, on ten-point scales. Finally, their pain level on nine bilateral tender point sites and three bilateral sham tender point sites were evaluated by the senior author. The tender point scores were self-reported, on a 10-point scale, for each point probed, with any scores obtained on the sham points subtracted from the total.

All patients were given portable CES units and asked to treat themselves, via ear clip electrodes, one hour each day for the three weeks of the study. The devices were preset to provide 0.5 Hz, bilaterally symmetrical pulses with no direct current bias. The current intensity could be adjusted from 0 to 500 microamperes, with the majority of the patients choosing to

treat themselves at a level between 100 and 300 microamperes.

In addition to CES, the second two thirds of the patients were given chiropractic treatment. The specific combination of therapy to be utilized in the study would be aimed at restoring a balance between the muscles, the spine, and the nervous system as a whole, with proper posture thought of as being a key element in reducing the physical forms of stress.

Each patient in the second group was asked to come to the clinic three times a week, during the three weeks of the study, to receive hands-on treatment. On their last visits, they were given the final treatment followed, 20 minutes later, by the final tender point evaluations, POMS testing and final ratings on the self rating scales.

No attempt was made to adjust or change any medications the patients may have been on.

### Procedure

Each study participant was analyzed for postural imbalances when he/she came for the first treatment. Their primary trigger points were established and correlated with their aberrant biomechanics. The patient then received therapy, consisting of specific chiropractic adjustments to the axial skeleton, with specific trigger point therapy to affected musculature. Repetitive Postural Reflex analysis was used to fine-tune the application of myofascial therapies. Reflex muscle work was applied, while the trigger points were worked on. Specific stretches were performed after the manual therapy session. This consisted of cervical Posture Pump therapy and postural movement exercise. CES was performed during the same visit to relax the patient, and facilitate the home-

ostasis between body and brain.

### Results

One of the CES patients (Group I) and three of the CES plus chiropractic patients (Group II) did not complete the final paper work, leaving two groups of 19 and 37 patients, respectively.

Figure 1 shows how the two groups fared on percent improvement on the items measured by the self-rating scales and, also, on their tender point pain scores. (See Fig. 1 below)

It is of interest that, while CES alone obtained an average 26% gain in pain improvement—which compared favorably with the maximum of 28% improvement found in medication studies as reported above—Group II obtained a self-rated pain gain of 34%, and a tender point improvement of 32%—which is better than that found in medication studies in fibromyalgia patients. Not shown in the table, but perhaps of more significance in the current study, is that, while 63% of the patients treated by CES alone improved during the three weeks of the study, 37% stayed the same or even worsened, by as much as 11%. In marked contrast, every one of the Group II patients (100%), in which chiropractic treatment was added to the CES, improved during the three weeks.

Figure 2 shows a comparison of the percent improvement on five of the psychological measures, where members of Group II can be seen to have clearly experienced a greater percent gain than did Group I on all the major

mood factors measured: anxiety, depression, anger, fatigue and cognitive confusion. (See Fig. 2 below)

On the overall sleep self-rating scales, 87% of the patients, at the beginning of the study, rated their sleep as moderate to very poor. At the end of the study, 80% rated their sleep as moderate to excellent, an almost mirror image turn around in quality of sleep.

No negative side effects from treatments given in the study were reported from either group of patients, when asked at the end of the study.

### Discussion

One of our surprises was the difference in the two groups on percent gains in self-measured feelings of well being and quality of life at the end of the study. It is interesting to speculate that these ratings, coming only 20 minutes following their final treatment manipulations, could have been made while they were still feeling some of the physical discomforts of the treatments themselves.

On the other hand, the study evaluations ended at three weeks, and many therapists would expect ongoing gains from the new postural adjustments over the weeks to come, so that the post testing scores may not reflect the final gains the patients will experience from either CES therapy or the combination treatment.

### Conclusions

While this study is yet another positive finding of the benefits of CES as a

non-medicated treatment of fibromyalgia, it also points up additional benefits of combining CES with chiropractic care. This was especially true in terms of the total percentage of patients improving when chiropractic was added, as well as on the five psychological stress measures reported.

We conclude that CES is a valuable adjunct to chiropractic management of fibromyalgia patients.

*Dr. Steve Tyers currently serves as Director of Rehabilitation for Integrated Medical Centers of California, La Jolla. In that capacity, he oversees the Rehabilitation Department, directs the Nutrition Counseling Program, and coordinates the clinical work of the medical and chiropractic physicians on staff. He is also involved in research projects, including the fibromyalgia study reported here. He can be reached at [drtyers@hotmail.com](mailto:drtyers@hotmail.com).*

*Dr. Ray B. Smith is Vice President for Science at Electromedical Products International (manufacturers of the Alpha-Stim CES device used in the above study), in Mineral Wells, TX, and beginning his 29<sup>th</sup> year of CES research. He assisted with the development of the research protocol and study write up. He can be reached at [ray@epii.com](mailto:ray@epii.com). [www.epii.com](http://www.epii.com) ◊*

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Fig 1. Comparison of CES Alone or CES Plus Chiropractic Care in Fibromyalgia Patients

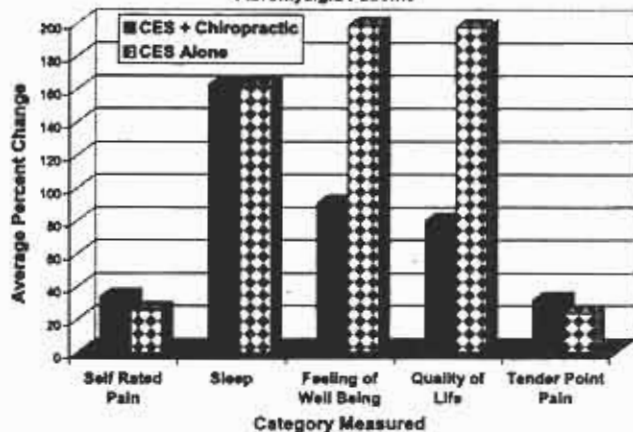
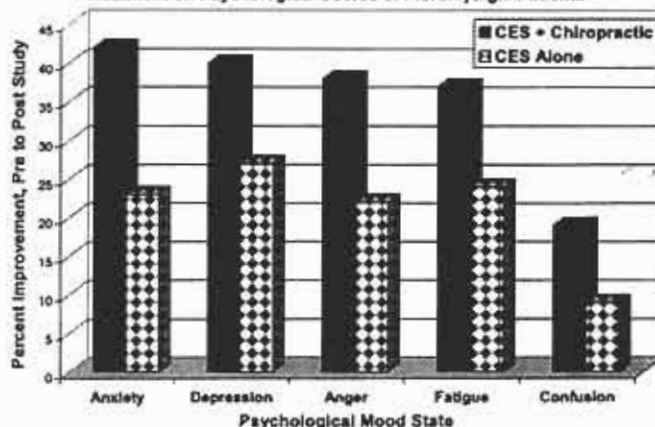


Fig 2. The Effects of CES Treatment Alone or CES Plus Chiropractic Treatment on Psychological Scores of Fibromyalgia Patients



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Pain	288	1 0.35%	5 1.75%	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 20.85%	82 44.57%	14 7.61%	165 89.87%
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%	138 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%

\*Total N = 500 patients with multiple symptoms.

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