

Kirsch, Daniel L. **Postmarketing survey of Alpha-Stim CES patients.** Summarized here and presented in detail in the book *The Science Behind Cranial Electrotherapy Stimulation*, 2nd Ed., Medical Scope Publishing Corporation, Edmonton, Alberta, Canada, 2002.

A postmarketing survey was originally conducted for the FDA during October, 1995 of all known health care practitioners using Alpha-Stim CES technology. A total of 313 individual patient report forms were received. Another survey was conducted in 1998 and ended in April 1998 when 187 more forms were received providing combined data on a total of 500 patients. 174 males and 326 females were identified, ranging from 5 to 92 years old. 21 of the forms were completed on inpatients, and 423 on outpatients. 197 (41%) of the patients were reported to have satisfactorily completed CES treatment, and 207 (43%) were still receiving treatment at the time of the survey. Ten patients discontinued treatment because it was not efficacious, 3 discontinued due to undesirable side effects, 13 because their insurance ran out, and 20 for other reasons.

The most important aspect of this survey was the results reported as a degree of improvement in the seven symptoms present in most patients for which CES is prescribed; i.e., pain, anxiety, depression, stress, insomnia, headache, and muscle tension. A degree of improvement of 25% or greater was considered to be clinically significant. The combined data for all 500 patients reporting on multiple symptoms is summarized below:

Condition	N	Worse	No Change	Slight	Fair	Moderate	Marked	Complete	Significant
Pain	286	1 0.35%	5 1.75%	20 6.99%	48 16.78%	77 26.72%	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%

Negative side effects were all mild and self-limiting: 472 (94.4%) reported none. 6 (1.2%) reported dizziness as a side effect, and 2 (0.4%) reported nausea, both of which normally occur when the current is set too high or in patients with a history of vertigo, 3 (0.6%) reported skin irritation, and 1 each (0.2%) reported anger, a metallic taste, a heavy feeling, or intensified tinnitus.

The complete report contains comprehensive summary data detailing the findings and results of this postmarketing survey. The first data set is an overview of the 500 individual patient reports. Tables and graphs are provided for the results of prior treatment plotted against the efficacy of Alpha-Stim CES on pain, anxiety, depression, and insomnia. Following that are two sub-categories, one for primary psychiatric and psychological diagnoses, and the other reporting on the efficacy of Alpha-Stim CES on symptoms of anxiety, depression, stress, and insomnia in primary pain-related disorders and other diagnoses. Then the data is further broken down into 22 diagnostic sub-categories. Several observations were evident from this data. Overall, the results of Alpha-Stim CES are highly significant and consistent for all seven symptoms in all diagnostic categories. While Alpha-Stim provides consistently safe and effective results well beyond the previous therapies

used, it works slightly better for patients with primary psychiatric and psychological diagnoses. The efficacy is greatest for anxiety and stress patients, and then for depression and insomnia. The results also indicate that Alpha-Stim actually works best for muscle tension, and it is at least as efficacious for relieving headaches as it is for the other indications.

The majority of people used the Alpha-Stim for 10-60 minutes, with only 6.74% reporting using it for more than one hour. The recommended frequency setting of 0.5 Hz was used 92% of the time. It is no surprise that a variety of current strengths were used as people have varying afferent tolerances.

Far more people reported that their anxiety relief lasted days (67.93%) than those who said it only lasted hours (18.87%). While 12.26% of 106 reports stated their anxiety was relieved for more than a week, half that many (6.60%) stated it never returned. 68.42% of the people who reported said that they would use Alpha-Stim again, and 48.87% said it was the most efficacious treatment for their diagnosis. Quality of life measures were also significantly improved with 85% reporting it helped overall.

Alpha-Stim CES eliminated or at least reduced the need for some medications in more than half the people who use it.

Medical doctors wrote most of the prescriptions for Alpha-Stim, although a lot of dentists use it in-office for situational dental anxiety. Chiropractors, psychologists, physical therapists, and nurses also use Alpha-Stim.

There were 22 diagnostic sub-categories for which Alpha-Stim CES was analyzed. These may be useful in evaluating the potential outcome in a given patient population, and they also provide additional confirmation of the consistency in which Alpha-Stim technology is able to control pain, anxiety, depression, insomnia, and other symptoms in any patient population. The 22 sub-categories are:

Psychiatric/Psychological Diagnoses		Pain-Related and Other Diagnoses	
76	anxiety	50	back pain
61	dental anxiety	35	joint pain
18	depression	24	cervical pain
7	mixed anxiety depressive disorder	38	headache (including migraines)
21	stress	32	fibromyalgia and chronic fatigue syndrome
48	mood disorder due to a medical condition	5	complex regional pain syndrome (a.k.a. RSD)
14	insomnia disorder due to a medical condition	4	closed head injury
20	substance abuse and withdrawal	3	temporomandibular disorder
1	post traumatic stress disorder	3	carpal tunnel syndrome
1	attention deficit disorder	17	chronic pain and pain not otherwise specified
3	other	19	not specified

