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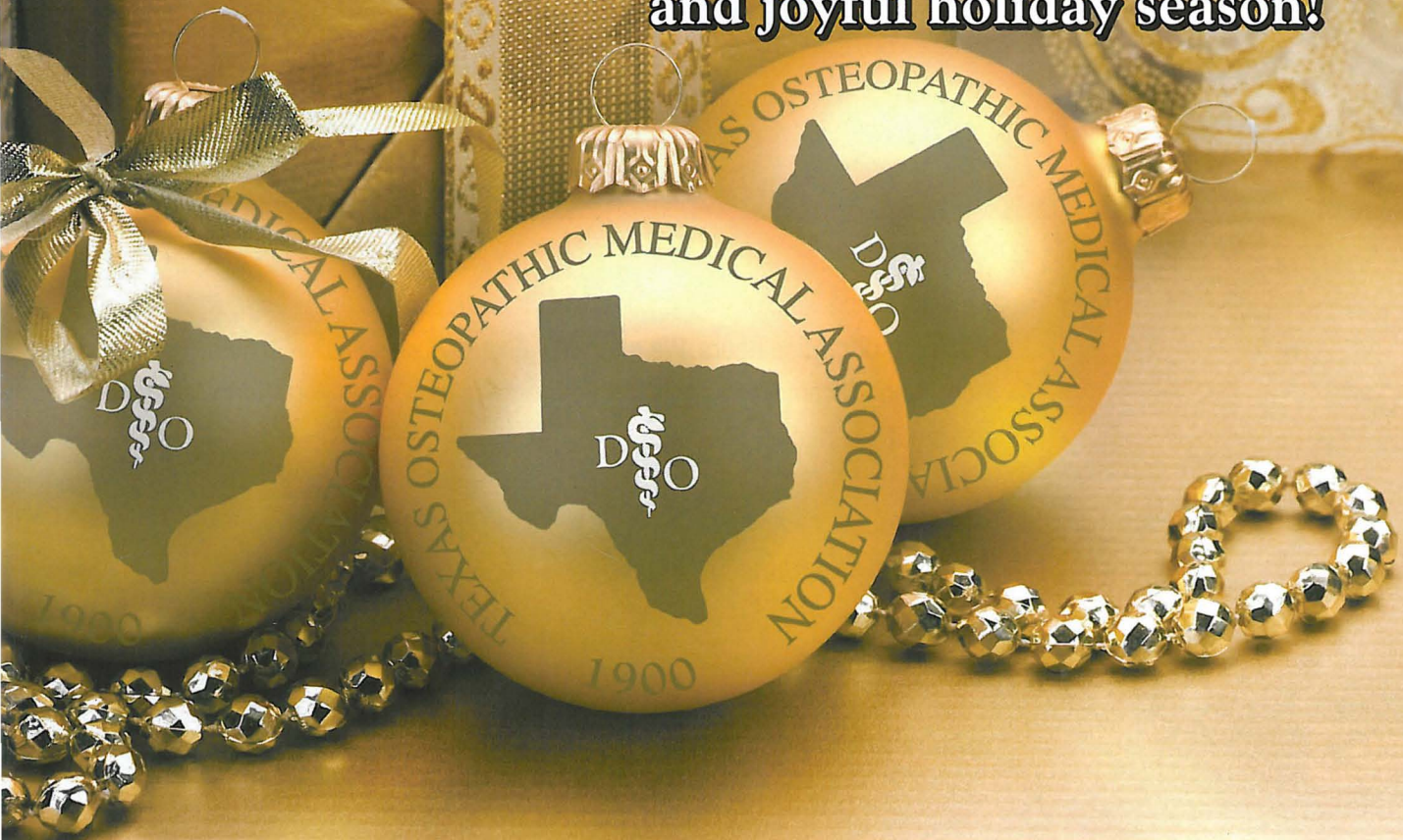
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*“Be filled with the wonder,
Be touched by the peace,
Be brightened by all those in your life.”*

**From our family to yours, a happy
and joyful holiday season!**



Alpha-Stim® Cranial Electrotherapy Stimulation (CES): Prescribing Electrons for Insomnia

Daniel L. Kirsch, PhD, DAAPM, FAIS

Cranial electrotherapy stimulation (CES) is a category of prescriptive medical devices using microcurrent levels of electrical stimulation delivered directly to the brain via transcutaneous electrodes for the treatment of anxiety, insomnia and depression. It is also achieving acceptance for pain management based on a growing body of research.¹ CES was included as a Tier II modality in the most recent standardized approach to pain management by the Office of the Army Surgeon General.²

When CES first came to the USA in the 1960s it was called "electrosleep." The intent of electrosleep was to put patients to sleep when the current was turned on. That rarely occurred regardless of the waveform parameters. However, subsequent findings have confirmed the robust effect of CES for sleep related disorders.

The procedure is simple: ear clip electrodes, moistened with an appropriate conducting solution, are applied at a comfortable current level for 20 minutes to an hour. Initially it should be used on a daily basis for a week or two, followed by a reduced schedule of two or three treatments a week until the insomnia is resolved, and then further reduced to an as-needed (PRN) basis.

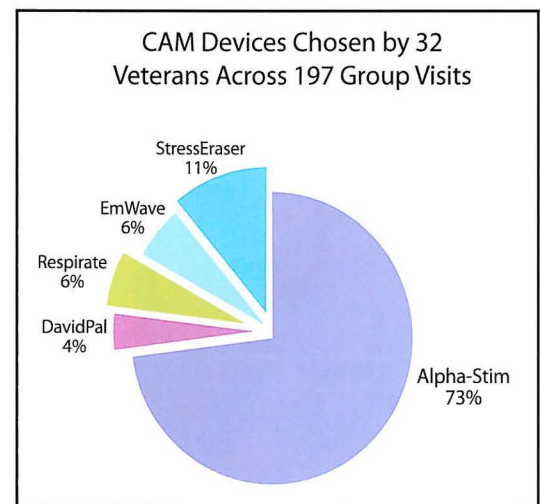
The United States Army uses cranial electrotherapy stimulation (CES) for insomnia at many Army medical centers and currently has two major studies underway in the USA and Germany researching CES for sleep related disorders. The Army Reserve Psychology Consultant to the Chief, Medical Service Corp. recently wrote the following letter to the Food and Drug Administration: "... I have utilized cranial electrotherapy stimulation since 1991, in hospital-based pain management programs, private practice, and the wartime theaters of both Iraq and Afghanistan. In each and every case, with unequivocally positive results and no less than negligible exceptions. Almost every single one of my private practice patients is now in possession of their own personal Alpha-Stim SCS device after years of battling the insurance industry and the Bureau of Workers' Compensation to assure that each of my patients received the most effective and beneficial treatment available to date anywhere in the world, as an adjunct to both traditional and holistic treatment approaches. Without exception, there is very simply, no more powerful form of therapeutic intervention, either as an adjunct or a stand alone form of treatment, than CES. This device is one of the most researched medical devices in today's market and has stood the test of time in that it has been on the market in continuous distribution for 30 years with a flourishing research base and growing utilization by the Department of Defense because it works so rapidly and so effectively.

The very same holds true in my own practice and during my three overseas deployments in support of Operations Iraqi Freedom and Enduring Freedom. In the latter case, this was under the worst possible conditions that any human being should ever be forced to tolerate. When productive sleep or any degree of sleep was elusive, Alpha-Stim CES was the answer in every case, with one single exception. When anxiety and panic prevented Soldiers from being able to perform critical missions, the response to CES was rapid and entirely effective, acting as an unequivocal force multiplier. In the face of desperately depressed Soldiers consumed with overwhelming misery and despair, the rapid and progressive effects of CES made it possible for these Soldiers to perform their missions and to exceed standards and expectations. Most importantly, with respect to PTSD, often rampant in the wartime theater, Soldiers were enabled to remain on mission, avoiding medevacuation to higher levels of care and to be returned to home station in the U.S., with exceedingly negative and dire consequences."³

The Colonel's letter was supported by a recent survey of patients conducted by mail between 2006 and August 2011 where 1,745 out of 4,590 respondents provided adequate data for analysis.⁴ Overall, 99.9% reported that they considered Alpha-Stim CES to be effective (*i.e.*, either yes or no) for their identified indication for use which could be anxiety, insomnia, depression and/or pain. Respondents were also asked to rate their perceived improvement since beginning treatment. Improvement was measured according to a low of no improvement = 1% to a high of complete recovery 100%. One percent of respondents reported complete recovery. Fifty-nine percent of respondents reported having either moderate (50–74%) or marked improvement (75–99%) from baseline or starting treatment. Twenty-three percent of respondents reported only fair improvement while 16% of respondents reported slight improvement. One percent reported no change in improvement. The final question asked was whether CES was more effective than anything else they had used for their reported indication. Thirty-six percent of respondents reported that it was more effective than anything else they had used for anxiety, 35% for pain, 17% for depression and 11% for insomnia.

In a recent government study veterans were trained in and offered use of five CAM modalities at a walk-in pain clinic at the Michael E. DeBakey Veterans Affairs Medical Center Pain Management Program in Houston. Of the five choices, they chose Alpha-Stim CES 73% of the time and reported an overall improvement in their sleep of 54%.⁵ As an added benefit, a paired t-test indicated an average decrease of 1.02 units (SD = 1.10) on the 0–10 Numerical Rating Scale of pain intensity during the study period, which was statistically significant ($p < .001$), exhibiting a large effect size of .93.

Cranial Electrotherapy Stimulation is among the most researched category of medical devices available and has proven safe and effective for sleep disorders for nearly 50 years.⁶ As a durable medical device that is protected with a multi-year warranty, it is inexpensive to use over time, with breakeven against most insomnia pharmaceuticals occurring over a period of less than six months. Accordingly it is worth a trial for patients with sleep-related disorders, especially to avoid polypharmacy effects in medicated pain patients.



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