



# PPM

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# ELECTROMEDICINE

Its Many Uses in Pain Management

## Also In This Issue

- Legacy Pain Patients
- Guided Imagery and Meditation
- Wake-Up Call: Avoiding Burn Out

# Cranial Electrotherapy Stimulation: Treatment Of Pain and Headache In Military Population

In this study, service members and veterans reported that cranial electrotherapy stimulation (CES) was a safe and effective treatment for pain and headache. The most striking finding was that subjects in the CES-only (no medication) group consistently reported higher pain relief from CES than those individuals in the group that received CES and medication.

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**A** critical aspect of treatment for virtually every trauma-related battlefield injury is the management of pain.<sup>1-4</sup> An increasing amount of research indicates that persistent pain can change brain circuitry, including the brain's endogenous mechanisms for controlling pain, and make it more difficult to control pain as it becomes chronic (lasting >3 months).<sup>5</sup> More acutely, survival rates among combat soldiers are greater today than in previous wars as a result of improvements in battlefield medicine.<sup>2,6</sup> However, the physical injuries are more severe than in the past, making modern soldiers more difficult to treat.<sup>2,7</sup>

Typically, battlefield injuries affect multiple organ systems and involve blast injuries from improvised explosive devices and roadside bombs, which often result in traumatic brain

injury (TBI), the signature injury of Operation Enduring Freedom in Afghanistan and Operation Iraqi Freedom.<sup>8</sup> The most common major physical injuries suffered by service members who served in the Afghanistan and Iraqi theaters of operations were complex musculoskeletal limb deformities, major extremity amputations, and TBIs.<sup>8,9</sup>

Chronic pain and headaches are a common problem following a combat injury, especially a TBI.<sup>10</sup> In a 3-year study of veterans, approximately 10% were diagnosed with TBI, 30% with post-traumatic stress disorder (PTSD), and 40% with pain. Approximately 6% of veterans had all 3 diagnoses, also known as the polytrauma triad.<sup>11</sup>

In a review of 12 studies that included 1,670 patients, Theeler and Erickson reported that that 58% of patients with TBI of any severity experienced chronic headaches.<sup>12</sup> In US service members, after a concussion the incidence of

Continued on Page 60 >>

Continued from Page 57 &gt;&gt;

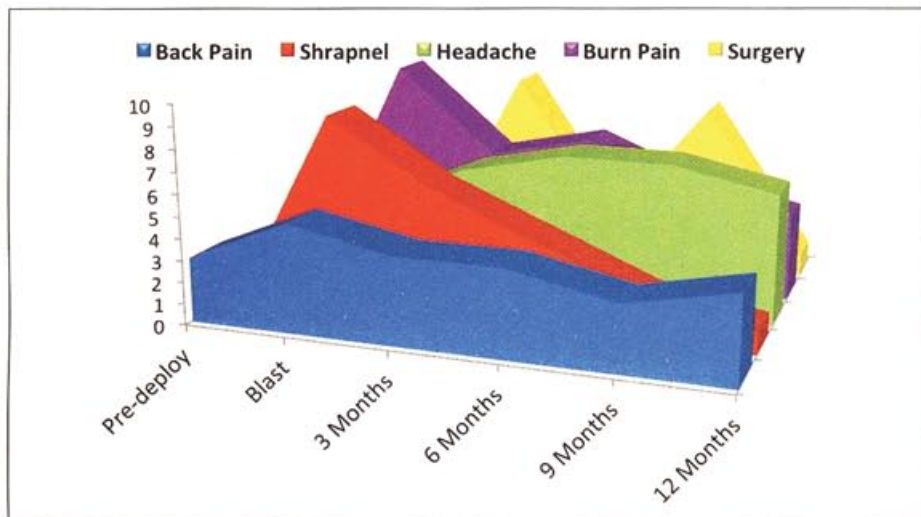


**Figure 1.** Combined course of polytrauma pain.

Source: Clark ME. Chronic Pain Issues: Physical and Psychological Aspects. The Military Family Research Institute at Purdue University. Battlemind To Home II Symposium, Nov. 2011, [https://www.mfri.purdue.edu/Clark\\_Battlemind\\_2011.pptx](https://www.mfri.purdue.edu/Clark_Battlemind_2011.pptx).

acute post-traumatic headache (PTHA) ranged from 31% to 96%. PTHA persists in 32% to 78% of patients at 2 to 3 months, 8% to 35% at 1 year; and approximately 20% at 3 to 4 years.<sup>12</sup>

The US Department of Veterans Affairs defines the term polytrauma as the condition of injuries to multiple body parts and organ systems that often, but not always, result from exposure to a blast.<sup>13</sup> The combined course of pain following polytrauma from the time of injury to 12 months is shown in Figure 1. Although the incidence of most types of pain decreased over time, pain from blast-related headache continued to increase for up to 6 months after injury, remained high, and decreased only slightly by 12 months, resulting in significant morbidity.<sup>14</sup>

The Department of Defense (DoD) and Veterans Affairs Medical Center (VAMC) providers prescribe cranial electrotherapy stimulation (CES) for the treatment of pain and headaches. Reports from clinical observations of DoD and VAMC practitioners on the effectiveness of CES for pain and headache are consistently positive. However, a search of the literature revealed no research about how service members

and veterans perceived the effectiveness of CES for the treatment of pain and headache. The purpose of this study was to address this gap in the literature and to explore perceptions of the safety and effectiveness of CES for pain and headache in this population of patients.

### The CES Device

In this study, the Alpha-Stim CES device (0.5 Hz, 100-600  $\mu$ A, 50% duty cycle, biphasic asymmetrical rectangular waves) was used. About the size of a smartphone, the stimulator sends a mild electrical current to the brain using ear clip electrodes. CES, a noninvasive brain stimulation modality,<sup>15</sup> is cleared by the Food and Drug Administration (FDA) for the treatment of anxiety, insomnia, and depression. Clinical observations revealed that CES also reduced pain and headache.

Four clinical trials that examined the effect of CES on pain found that the therapy significantly decreased pain.<sup>16-19</sup> Based on research from functional magnetic resonance imaging, EEG, and clinical neurotransmitter studies, the treatment mechanisms of CES include:

- Deactivating brain regions associated with hyperactivity consistent

with various disorders, such as pain, anxiety, insomnia, depression, and sleep problems.

- Increasing alpha-wave activity that induces relaxation and a pleasant state of well-being; decreasing delta-wave activity, which increases attention and alertness; and decreases beta activity, which decreases compulsive, ruminative thoughts.
- Increasing the concentration of neurochemicals such as beta-endorphin, serotonin, and melatonin, and decreasing cortisol in the brain, which reduces pain, insomnia, and the response to stress, while improving mood.<sup>20</sup>

All participants in this survey received an Alpha-Stim CES device prescribed by either a DoD or VAMC medical provider. Each individual was instructed in how to use the stimulator at home following a DoD or VAMC protocol. Patients were told to perform CES for 20 to 60 minutes daily, with the current adjusted to a comfortable level. They could administer additional CES treatments as needed to control pain and headaches. Observations in clinical practice show that extended use of CES is well tolerated. No side-effects from prolonged use have been reported.

### The Survey

Data for this article were taken from the Alpha-Stim Service Members and Veterans Survey on the safety and effectiveness of CES.<sup>21</sup> The study was conducted by Electromedical Products International, Inc., as an Alpha-Stim CES post-marketing surveillance survey for the FDA.

The data from the survey revealed that the majority of participants reported CES was effective ( $\geq$  25% improvement) for the treatment of anxiety (66.7%), insomnia (65.2%), PTSD (62.5%), and depression (54%). The majority of these individuals reported

at least a 50% improvement in each outcome. This article includes results from the data for pain and headache from the Alpha-Stim Service Members and Veterans CES Survey.

The survey included questions about demographic and background information; use of prescription medication; improvement from using CES for anxiety; PTSD; insomnia; depression; pain; headaches; and safety of the treatment.

Questions about safety and effectiveness were taken from previous surveys of CES users that included 5,171 civilian participants. The questions had content validity and established utility for this population. The 7-point Likert scale included the following answer options to questions that asked participants to rate their improvement from using CES: A, Worse (negative change); B, No change (0%); C, Slight improvement (1% to 24%); D, Fair improvement (25 to 49%); E, Moderate improvement (50% to 74%); F, Marked improvement (75% to 99%); and G, Complete recovery (100%).

E-mail addresses were obtained from DoD and VAMC prescription information on file at Electromedical Products International, Inc., manufacturer of the Alpha-Stim CES device. Delivery of the online survey was conducted by [www.surveymonkey.com](http://www.surveymonkey.com). Respondents could choose not to participate in the survey or to complete the questionnaire online. Of the 1,514 persons invited to participate in the survey, 152 submitted the on-line questionnaire, yielding a response rate of 10%. Web-based surveys have a typical response rate between 15% and 40%.<sup>22,23</sup>

## Results

Prior to statistical analyses, the data were screened for missing and out-of-range values. The survey responses were analyzed using descriptive statistics; 145 participants completed the questions on the safety and effectiveness

of CES. We used Dworkin and colleagues criteria for determining improvement of clinical importance.<sup>24</sup> Improvement of substantial clinical importance ( $\geq$  50%) was considered substantial clinical improvement, and improvement of moderate clinical importance (25%-49%) was termed moderate clinical improvement.<sup>24</sup>

The primary benefit of using the Dworkin criteria is that, in addition to the "gold standard" of a group that improved by at least 50%, an improvement of 30%-49% is categorized as a gain of moderate clinical importance. In a severely injured population, even a lesser amount of improvement than the established standard of at least 50% has the potential to improve pain and headache outcomes.

## The Study Participants

The majority of participants were male active duty service members (72%). The mean age was 38 years (standard deviation  $\pm$ 10). At the time of the survey, 82% of participants were still using CES. The mean

length of time using the device was 12.1 months (range, 3-36 months). Fifty percent of participants reported using CES once per day while 24% reported using CES twice daily, and 7% reported using the treatment at least 3 times per day. Eighty-two percent of participants who responded to the question about pain were taking pain medications. Of those participants who responded to the question about headaches, 75% were taking anti-migraine medication, pain medication, or both.

## Pain

Seventy-three participants who used CES for pain responded to the question: "If you are using Alpha-Stim CES for pain, since starting CES rate your improvement as...?" In the total group, 45.1% of participants reported that CES was effective for pain. In the CES-only group ( $n=13$ ), 19.9% reported greater improvement in pain than those in the CES-plus medication group ( $n=60$ ). The findings appear in Figure 2.

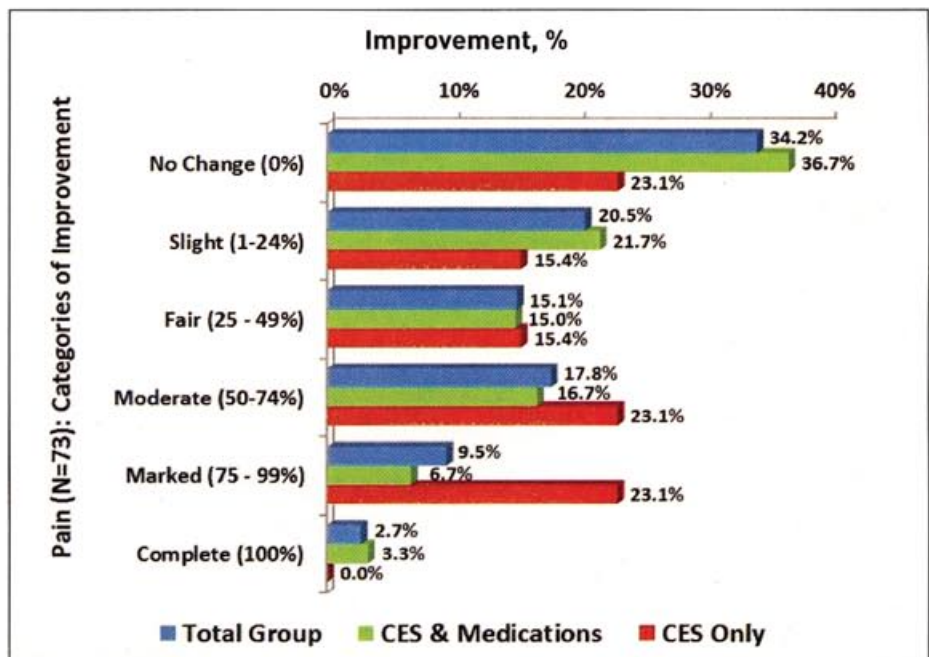


**Figure 2.** Perceived improvement in pain by category and group. CES, cranial electrotherapy stimulation

## Headaches

Seventy participants using Alpha-Stim for headaches responded to: "If you are using Alpha-Stim CES for headaches, since starting CES, rate your improvement as..." The findings from the total group, CES plus medication group (n=53) and CES only group (n=17) appear in Figure 3. In the total group, 58.5% of participants reported that CES was effective for headache. The CES-only group reported a 64.7% greater improvement than the CES plus medication group.

## Evaluating Important Clinical Improvement

On the 7-point Likert CES Clinical Improvement scale, the moderate (50%-74%), marked (75%-99%), and complete improvement (100%) categories were collapsed into a single category defined as substantial clinical improvement of at least 50%. The fair improvement category (25%-49%) was designated moderate clinical improvement.

There was a marked difference between the CES-only and CES plus medication

groups. Participants in the CES-only group consistently rated their improvement from using the device higher for both pain and headache. For example, 100% of participants in the CES-only group reported either substantial or moderate clinical improvement for headache (Figure 4).

All respondents reported that Alpha-Stim was safe, and none reported any adverse events from using CES.

## Discussion

This cross-sectional study explored the perceptions of combat injured active duty service members and veterans about the effectiveness of CES for pain and headache. A purposive sampling strategy was used to acquire information from respondents. The study has several limitations. The results are based on self-reported data and may have been affected by recall bias. The response rate was lower than usual for a Web-based survey and participants may not be representative of the total group of service members and veterans who used CES. Finally, findings from this type of study

cannot be generalized or used to infer causation. However, they do provide important information and insights not before available. These results can serve as a basis for the development of a randomized, sham-controlled clinical trial of CES for pain and headache.

The low response rate to the survey has several possible explanations. The persons asked to participate in the survey by email were injured active duty service members and veterans who had received a prescription for the Alpha-Stim CES device through the DoD or VA in the prior 6-year period. The email addresses of potential respondents may no longer have been valid. Potential respondents who were no longer using Alpha-Stim CES may not have chosen to respond to the questionnaire. Finally, some potential respondents may not have responded because of health or family issues. In contrast to the current study that includes subjects from a 6-year period, a survey of service members and veterans who obtained a CES device through the DoD or VA during the previous 12 months would most likely have an increased response rate.

The prevailing clinical belief is that CES can potentiate pain medications. Contrary to expectations, respondents who used prescription medication for pain and migraine headaches reported less improvement from CES than did the group that used CES alone. The most striking finding was on the headache variable, where 100% of the respondents in the CES-only group reported improvement of clinical importance (greater than or equal to 25%), with more than two-thirds of these individuals reporting at least a 50% improvement. In contrast, 45.3% of those individuals who were taking prescription medication for headache reported improvement from using CES for headache.

It is possible that the CES plus medication group had more serious injuries

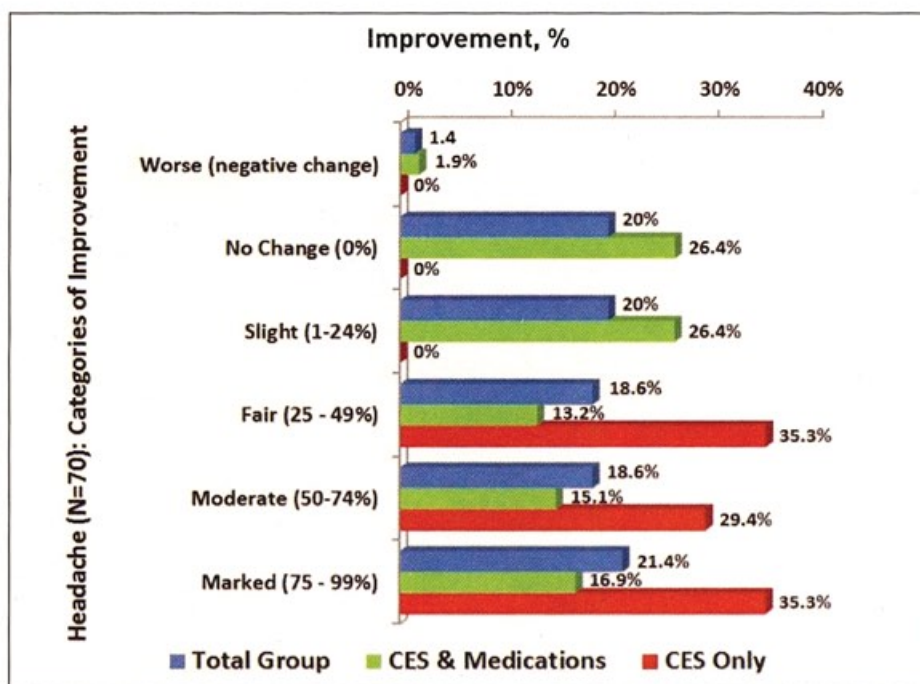


**Figure 3.** Perceived improvement in headache pain by category and group. CES, cranial electrotherapy stimulation

or medical problems than the CES-only group, which could account for the findings in this study. The finding that the CES-only group reported better outcomes for both pain and headache raises new questions. In future studies, the effects of severity of injury or medical condition, and the type and dose of medication on CES outcomes, warrant investigation. The differences between the CES-only group and the CES-plus medication group indicate the importance of controlling for medication in future studies.

All subjects in this survey considered CES to be safe and none reported side effects from the therapy. The findings of this study are consistent with an analysis of 14 CES studies that showed it to have an excellent safety profile. Side effects (all less than 1%) reported from CES include vertigo, headache, and skin irritation at the site of the electrodes. Vertigo and headache usually occur when the intensity of current is too high for the individual. These symptoms will resolve when the current is decreased. Alternating sites for placement of electrodes will decrease irritation at the electrode site that may occur.

No serious adverse effects have been reported during the 34 years Alpha-Stim CES has been on the market.<sup>25</sup> A safety benefit of CES is that the user is alert and relaxed after treatment, unlike drugs that can have serious adverse side effects and can hamper the ability of service members to function during rehabilitation and reintegration into family and community life.<sup>26-28</sup>

The CES-only group was relatively small, and included 13 and 17 participants for pain and headache, respectively, whereas the CES plus medication group included 53 and 60 participants for headache and pain, respectively. This disparity in cohort size could account for the differences in improvement ratings between the CES

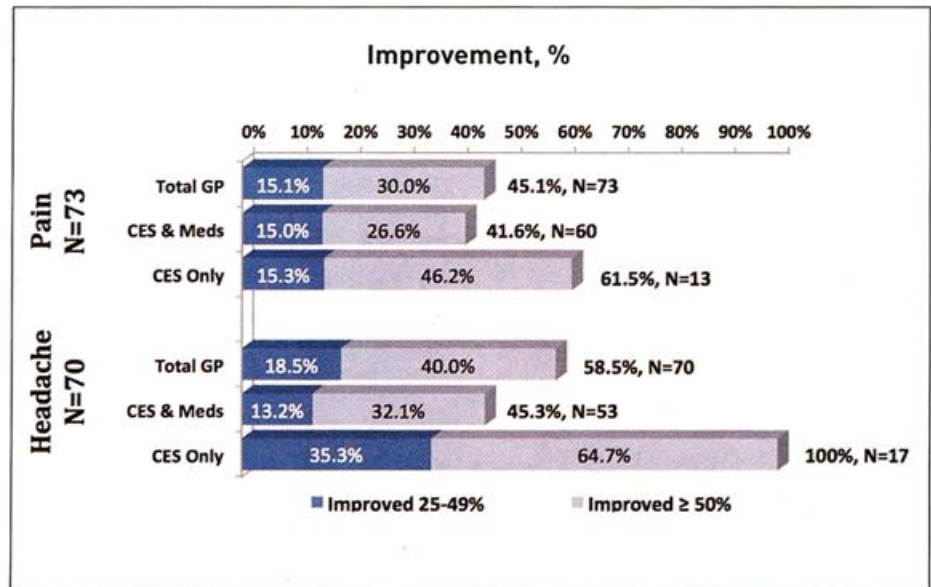


**Figure 4.** Clinical improvement of at least a 50% (substantial clinical improvement) and 25%-49% (moderate clinical improvement) for pain and headache, by group.

**CES**, cranial electrotherapy stimulation alone; **CES + Med**, CES plus medication; **TG**, total group

plus medication and CES-only groups.

The Army Surgeon General Pain Management Task Force, Army Pain Management Task Force, comprising representatives from all branches of the Armed Services, recommended a comprehensive approach to pain management that includes the use of complementary modalities such as acupuncture, CES, and mind-body therapies to augment conventional treatments.<sup>29</sup>

A multimodal approach to pain management often is recommended for service members and veterans. However, Galloway et al noted that many times, the typical approach includes only intervention-centered (eg, nerve blocks) or pharmacologic-centered treatment.<sup>30</sup> Usual treatment for pain ranges from non-prescription analgesics to powerful opioids and regional nerve blocks.<sup>4</sup> Addiction to opioids is a significant concern for the military.<sup>26,27</sup> This information further supports the need for including non-pharmaceutical approaches in a pain management program. The reports of service members and veterans suggest that they were able to use CES at home, following a DoD or VA protocol without difficulty. When

CES is used to treat pain and headache, it also can decrease common comorbidities such as anxiety, depression, and insomnia.<sup>21,31</sup>

## Conclusions

The findings of this study provide additional evidence that CES is a safe and effective treatment for pain and headache. Results in this study are consistent with the findings of randomized, sham-controlled trials on the use of CES for the treatment of pain in a military population. Making CES an essential component of a pain management program, either as an adjunct to traditional treatment or as a stand-alone option based on the severity of pain, has the potential to improve pain and headache treatment outcomes. ■

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Kathy Platoni, PsyD, has been a practicing clinical psychologist for more than 33 years and maintains her private practice in Centerville, Ohio. In service and as an Army Reserve clinical psychologist, she has deployed on 4 occasions in time of war, including Operation Desert Storm, Operation Iraqi Freedom, and Operation Enduring Freedom (both Joint Task Force, Guantanamo Bay Cuba and Afghanistan). Dr. Platoni has written and edited 2 landmark books with Dr. Raymond Scurfield on the subject of war trauma, *Expanding the Circle of Healing—Trauma in Its Wake* and *Healing War Trauma—A Handbook of Creative Approaches*. She was awarded Diplomate status by the American Academy of Pain Management.

Dr. Kirsch has disclosed that he is a major shareholder and officer of Electromedical Products International, Inc.

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## The findings of this study provide additional evidence that cranial electrotherapy stimulation is a safe and effective treatment for pain and headache.

working with the mental health teams for the survivors of the great earthquake in Sichuan, and he was keynote lecturer at the First Colloquium on the International Progress of Non-Pharmaceutical Intervention in Mental and Emotional Disorders at the Affiliated Brain Hospital of Nanjing Medical University in 2011. 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, and was the guest of the Minister of Health of Kuwait in 1992 where he taught pain and stress management for physical and mental trauma from the first Persian Gulf War.

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Jeff A. Marksberry, MD, serves as the

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