

Cranial Electrical Stimulation

Eric Braverman, M.D.¹

Cranial electrical stimulation has a long history. The use of electricity in therapeutic disorders dates back in scientific history to Mesmer, who tried to use magnetism for a variety of medical problems. Allen Child, M.D., Assistant Professor of Pharmacy at the University of Texas at Austin, suggests that electrical therapies actually date back to ancient Egypt. Currently acceptable electrical therapies include the TENS or Transcutaneous Electrical Nerve Stimulation device, which is an acceptable treatment for pain, and variations on the TENS (FES or fine electrical stimulators) which are used for treating some stroke patients. Electrical currents have been experimented with for hard-to-heal bone fractures. There are also now brain or cranial TENS devices (CES) which seem to impact brain chemistry in may significant ways. Cranial electrical stimulation (CES) devices are thought to raise alpha waves, raise blood levels of endorphins and increase conversion of amino acids into the brain's neurotransmitters. The FDA has approved CES devices for anxiety, depression, insomnia and stress. The usual treatment can be 15, 30, or 60 minutes twice daily for stress; often individuals wear it overnight with a timer. In the first few sessions, comfort levels may be exceeded within ten minutes. A poor connection or too high a dose can be discomfoting and should be avoided. Poor electrode placement with reapplication can suddenly give a slight but uncomfortable shock. The device does possess an automatic shut-off switch. The intensity of current should be set a comfortable level and the electrodes can be placed firmly on the mastoid process, forehead or arm.

New studies suggest the best placement of electrodes will be near the left

hand over the wrist or the forehead and the nose. We are collecting data to evaluate precise location. If headache occurs or any side effect the CES is discontinued. Pacemakers are contraindications for use of the device.

Other possible applications of the CES are menstrual cramping, stiff neck, allergic reactions, headache, temporal lobe disorders, etc. The bioelectrical approach may be useful to modulate neurotransmitters in the brain such that they may rebalance the immune system and help with aspects of all depression and anxiety type symptoms. Patients who first use the cranial electrical stimulation (CES) device can often experience benefit in the first 30 minute session. Often a good marker of its benefits is that it will produce good relaxation and even improve sleep. For other individuals an appropriate trial may be concurrent use with amino acids or antidepressants, which require at least three weeks to reach their full effect, and sometimes as much as two months to reach the full benefit.

The voltage of the CES device is one milliamp (mA) at 100 Hertz (cycles/second) and 20% duty cycle. TENS units are 2-50 mA. To put this in perspective, wall sockets have 10 amps, or ten times voltage, 60 Hertz (cycles/second), 110 volts.

Cranial electrical stimulation may be a very useful alternative to drug treatments in individuals that have treatment resistant anxiety and/or depression. Furthermore, CES used in combination with the natural amino acids may convert the amino acids more rapidly to neurotransmitters resulting in greater effectiveness. The TENS device in combination with amino acids is also more effective than amino acid augmentation alone. Therefore, there is hope that this new approach,

1. P.A.T.H. 212 Commons Way, Building 2, Princeton, NJ 08558

or brain bioelectrical approach, can be extremely successful and may actually become a first line therapy for psychiatric disorders because of its noninvasiveness and low level of side effects. It should be noted that individuals using this device may initially feel a tingling sensation. This is normal and good reaction. It has been noted that the device has been experimented with by many individuals and it has also been called cerebral electrical therapy or CET, which started in the USSR in 1947. Double-blind studies were done, with a treatment duration 30 minutes, with a frequency of 100 cycles per second and pulse duration of 1 millisecond. There were changes in 24-hour urinary free catecholamines and 17 ketosteroid levels. Researchers have experimented with other cranial electrical devices and called them neurotone therapy or neuroelectrical therapy (NET). Many researchers all around the country are actively studying the device and our ability to use it to full effectiveness will continue to grow in time.

In summary, Cranial Electrotherapy Stimulation (CES) is the FDA's term for any application of 1.5 mA or less of electricity across the head for medical purposes. Its use requires a prescription. Currently, all approved devices give 1000 hertz, 0.5-1 mA, on a 20% duty cycle. Following recommendations of the National Research Council and over 20 years of medical experience with CES in America, the FDA now considers the side effects of CES to be nonsignificant. For that reason their policy is to not require an Investigational Device Exemption prior to experimental studies of CES.

CES began in Europe in the 1950s under the rubric "Electrosleep". Eastern nations soon picked it up as a treatment modality and its use had spread worldwide by the late 1960s when animal studies of CES began in the U.S. at the University of Tennessee and at what is now the University of Wisconsin Medical School.

These were soon followed by human clinical trials at the University of Texas Medical School in San Antonio, the University of Mississippi Student Counseling Center, and the University of Wisconsin Medical School. As of April, 1990, there were over 100 published CES studies in the American literature.

Open marketing of CES devices began in the early 1970s in the U.S. for the clinical conditions of anxiety, depression and insomnia. Under the 1976 Medical Devices Amendment, the FDA grandfathered CES devices, which are currently marketed as previously, but limited to the earlier treatment claims until such time as Premarket Approval Application is submitted to FDA for these and/or any additional treatment claims.

To date, several thousand Americans are treated with CES annually and more than eleven thousand persons own CES devices, which have been prescribed for their home use. Possibly the most exciting application of the CES is for drug addiction. Further studies are needed to fully document use of the device for these purposes. In this technological age when we are surrounded by electromagnetic fields and currents, CES treatment may be necessary as an antidote and for maintenance of fully optimum health. Electromagnetic "pollution" from video screens, televisions, stereophonic equipment, microwaves and phone lines may be destroying our health and may require a device of this type to counter these negative effects. In addition, CES probably incorporates some of the benefits of electroconvulsive shock therapy (ECT) without the damaging effects of high amounts of current. CES may provide natural levels of supplementary current to keep the brain healthy in the electrical age.