

The American Institute of Stress

# HEALTH AND STRESS

Your source for science-based stress management information

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## **Brain Stimulation & Mind Manipulation Replace Drugs**





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# HEALTH AND STRESS

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# THE FUTURE



## PART II: BRAIN STIMULATION WILL REPLACE DRUGS

by Paul J. Rosch, MD, FACP

Editor-in-Chief

To summarize and add to the last Newsletter, prior to 1800, electrotherapy was limited to shocks from electric fish or static electricity generated by friction from rubbing glass or amber with a cloth. Gilbert showed in 1600 that this force, which could cause light objects like feathers to move, differed from a similar energy in magnets that attracted bits of iron. He read everything he could about magnets and was fascinated by the findings of Peter Peregrinus.

In 1269, the Italian city of Lucera was under siege by order of the Pope because its citizens had strayed from the faith. Pierre de Maricourt an engineer, was largely responsible for the success of this campaign, and the Pope renamed him Peter Peregrinus, which means "pilgrim." This was a papal title occasionally conferred to reward those doing "God's work." While planning about how best to breach the city's walls, Peregrinus was also trying

to make a perpetual motion machine using lodestones that he carved into spheres. In a lengthy letter, he described how a lodestone that he floated tended to line up in a north-south direction and returned to that position when he tried to change it. If he floated two lodestones so that their ends were close, they would come together, but when he turned one in the opposite direction, the reverse happened. He may have been the first to observe

that all magnets had a north-south end, and coined the term "pole" from the Greek *pólos* (axis or pivot) to refer to these. Gilbert later proposed that the earth itself was a giant magnet with North and South poles, and that its magnetic field somehow influenced our souls and provided a link to God. Eight decades later, Isaac Newton developed his theory of gravity and Three Laws of Motion. He also showed that planetary objects were governed by these same natural laws, and reconfirmed that the sun rather than the earth was the center of our solar system.

In the early 1500s, Paracelsus, a Swiss physician and alchemist, proposed that life came from an energizing force in the atmosphere called *archeus* that was similar to the mysterious power in magnets. Newton also believed that space was permeated with an invisible "aether" that acted as a medium to transmit gravitational or electromagnetic forces. Anton Mesmer later referred to this as a "universal fluid," which provided "animal magnetism" that he could use to cure disease. Benjamin Franklin,

who disproved this, also showed that lightning, although much more powerful, was the same as the static electricity from friction machines and that both could be stored in Leyden jars. In addition, he and others advocated administering electric shocks to the brain to treat depression and other emotional complaints. This met with mixed success, but, as noted in the concluding sentence, many theories changed when a different form of electricity became available after 1800.

#### **The Italian Connection: Luigi Galvani, Alessandro Volta And Giovanni Aldini**

Luigi Galvani, professor of medicine at the University of Bologna, was studying the anatomy and physiology of frog legs and the effect of electrical stimulation. His assistant had been dissecting a frog leg-spinal cord specimen, and was surprised to find that the leg contracted when he touched either the cord or the nerve with his scalpel. He reported this to Galvani, who reduplicated this phenomenon several times, but noted that if he was careful to hold the scalpel by its bone handle

to avoid touching any metal, nothing happened. The reaction was also much stronger when the electrostatic friction generator was being cranked up, and a leg placed in a glass container adjacent to the generator also contracted without any contact. If he suspended several frogs' legs from a wire around the machine while it was being turned, "*I was rewarded by the sight of all the legs jumping together.*" And when he attached a fresh spinal cord-frog leg dissection to the bottom of an iron bar that did not reach the ground and ran a wire from this into a deep well, the leg contracted when there was lightning before he heard any thunder. The leg would also twitch spontaneously when there was no lightning, and on a few occasions even when there were no clouds or rain. He was later able to cause muscular contraction by touching the nerve or leg with different metals in the absence of any possible electrostatic influence.

In his 1791 *De viribus electricitatis*, he concluded that muscle tissue contained an innate vital force that he termed "animal electricity," since it differed from the "natural"



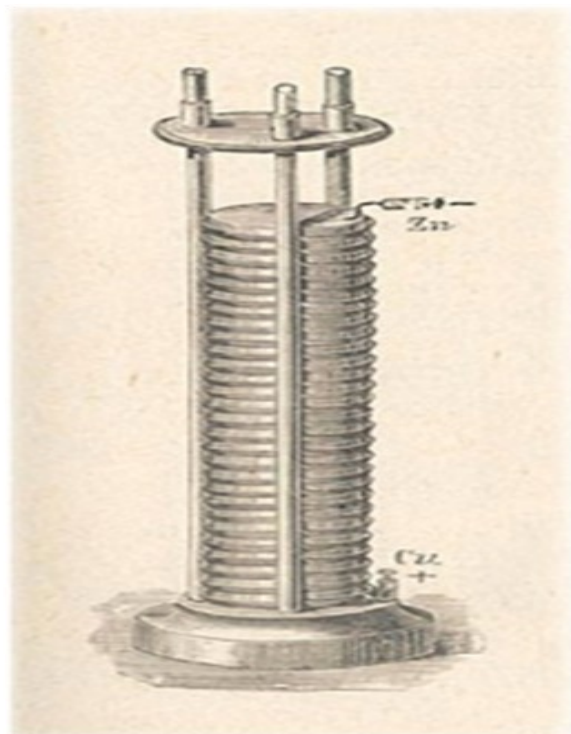
form that produced lightning and the "artificial" static electricity generated by friction machines. He also believed the brain secreted an "electric fluid" and that the flow of this fluid through a hollow in nerves was what stimulated muscle fibers to contract. When he touched the exposed muscle of one frog with the nerve of another, the muscle contracted, which established for the first time that bioelectric forces did exist in living tissue and supported his animal electricity theory. This was soon embraced by other leading researchers who duplicated his experiments and confirmed his results, initially including Alessandro Volta, a professor of physics at the University of Pavia. However, after further investigation, Volta began to challenge the existence of any specific electricity that was intrinsic to the legs or other body parts. While he did not dispute Galvani's results, he offered a different explanation, which led to a debate between the two, and eventually, the first electrical battery.

Volta was appointed professor of physics at the Royal School in Como in 1774 at the age of 29, and

was particularly interested in the physiological effects of electricity. The following year he developed the electrophorus, a friction device that produced static electricity that was stored not in a Leyden jar, but on a plate. This retained a much stronger charge for longer periods of time and some large plates could produce 15 inch sparks. He discovered methane after reading a paper by Benjamin Franklin on "flammable air" and eventually found it at Lake Maggiore. He was later able to isolate methane and study the effects of igniting it by an electric spark in a closed vessel. In 1779, he was appointed professor of experimental physics at the University of Pavia, a chair he occupied for almost 40 years. He devised experiments to measure both electrical potential and charge and found they were proportional for any given object. This is referred to as Volta's Law of capacitance and is why the unit of electrical potential is called the volt.

Following Galvani's 1791 publication, he began

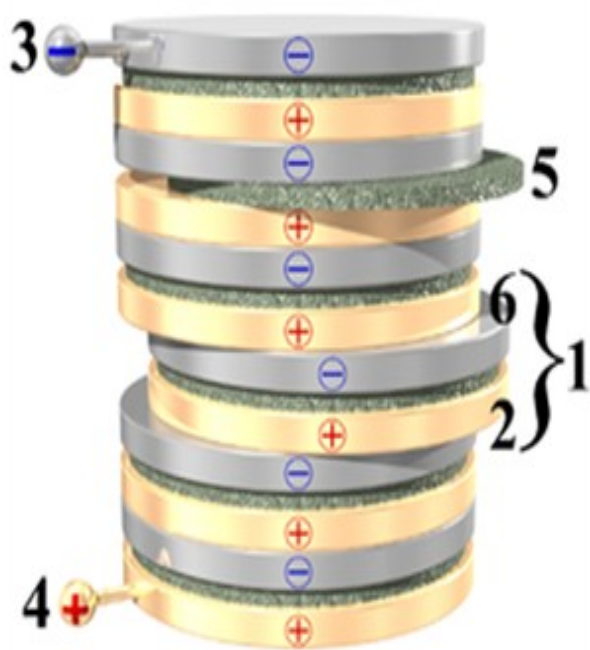
investigating "animal electricity" by repeating the original experiments and modifying them. Galvani showed that when two pieces of metal were connected on opposite ends of a frog's leg and electricity was applied, the leg contracted.



The Voltaic Pile

Volta found that when the two metals were different, an electrical current was generated that the moist frog's leg conducted. The "twitching" Galvani and his assistant observed was due to the two different metals - the steel knife and the tin plate upon which the frog was lying. The frog's leg merely

served as a conductor or electrolyte, and had nothing to do with "animal electricity." He subsequently proved this by substituting the frog's leg with brine soaked paper and demonstrating that it conducted electricity. He also discovered that this electrochemical force varied with different metals. This led him to invent the first electric battery, the voltaic pile, which he made from thin sheets of copper and zinc separated by moist pasteboard shown to the left, on the previous page. When the negative top was connected to the positive bottom with a wire, it created a new type of electricity that flowed steadily.



To replicate the electrochemical activities of living cells outside the body, Volta had initially experimented with individual cells in series, each cell being a wine goblet filled with brine into which the two dissimilar electrodes were dipped. Salt water was better than plain water and the best pair of dissimilar metals to produce electricity was zinc and silver, but this was unsafe to use in his pile and he found that its power declined more rapidly.

The pile was later modified to substitute an acid as the electrolyte. As shown to the left, 1, a cell, contains three discs. 2 is a disc made from copper, 5 is a cardboard or leather disc soaked in sulfuric acid, which lasts longer than brine, and 6 is a disc made from zinc. Connecting 3 and 4 with a wire produced a current of electricity and the higher the pile, the stronger the current.

In 1800, Volta wrote a letter to the Royal Society of London for publication. He reported on the construction of an

electric apparatus that could easily be assembled following his detailed instructions that concluded:

In this manner I continue coupling a plate of silver with one of zinc, and always in the same order, that is to say, the silver below and the zinc above it, or vice versa, according as I have begun, and interpose between each of those couples a moistened disk. I continue to form, of several of this stories, a column as high as possible without any danger of its falling.

In his letter, he explained that the advantages of his Pile over the Leyden jar were that it provided a "perpetuous flow" (steady current), did not need to be previously charged, and retained its charge for much longer periods. In addition, unlike Leyden jars that required an insulating separator, the Pile was made only of conductors, and could be considered the "artificial analogue of the natural electric organ of the torpedo fish."



Volta's invention quickly became a huge international success. One year after his letter was published, the *Institut de France* invited him to Paris, where he demonstrated his "electric column" to leading scientists as well as Napoleon, as shown in the painting above. Napoleon was so impressed, he awarded Volta with a gold medal and a pension. He later appointed him a Count, a Cavalier of the Legion of Honor, and senator for the kingdom of Lombardy.

Volta's invention seemed to settle the long but courteous controversy with Galvani and his colleagues

at the University of Bologna. The spokesperson for Galvani had been his nephew, Giovanni Aldini, a physicist who assisted him in numerous experiments and in writing his book. In 1798, the year Galvani died, Aldini became professor of experimental physics at the University of Bologna, the oldest medical school in Italy. When he learned of Volta's invention, he immediately began studying its effects on dismembered animals and even corpses with dramatic results. He traveled throughout Europe demonstrating these and defending Galvani's concept of animal electricity. He stimulated the heads and

trunks of cows, horses, sheep and dogs, which produced repeated spasmodic but very lifelike movements of the facial muscles, arms, and legs. Aldini soon became an accomplished showman and people flocked to see what was called "galvanism", which had now developed into a theatrical spectacle. An eyewitness reported:

Aldini, after having cut off the head of a dog, makes the current of a strong battery go through it: the mere contact triggers really terrible convulsions. The jaws open, the teeth chatter, the eyes roll in their sockets; and if reason did not stop the fired imagination, one would almost believe that the animal is suffering and alive again."

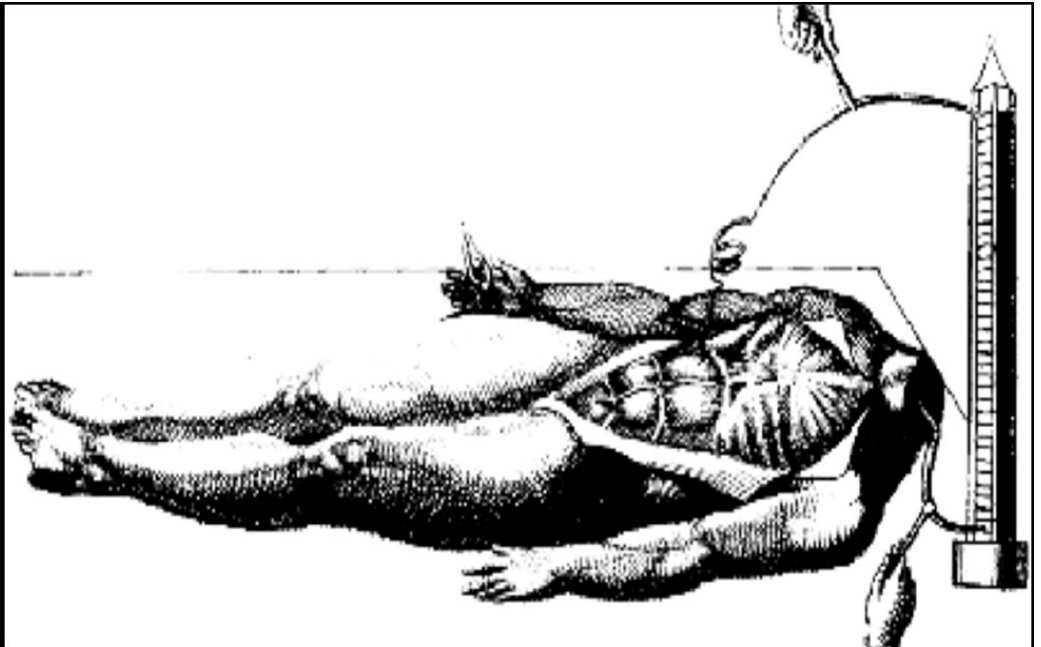
It was even thought that a corpse, head or other body part could be brought back to life if the electrical stimulus was strong enough. Aldini was the inspiration for Mary Shelley's *Frankenstein; or, The Modern Prometheus*,



written in 1816, when she was 18. She and her lover (later her husband) Percy Bysshe Shelley were visiting Lord Byron at his villa on Lake Geneva. The conversation turned to the feasibility of returning a corpse or assembled body parts to life and Byron suggested they have a contest to see who could write the best horror story based on this theme.

parts from fresh graves and the gallows and stitched them together to create his monster. He gave him life by harnessing the power of a lightning bolt. The book was published anonymously in 1818, but in the 1831 edition, she acknowledged her debt to Aldini in her Preface. Many mistakenly think Frankenstein is the monster's name.

with corpses for educational purposes, but also to insure that the condemned could not rise on Judgment Day since their bodies would no longer be intact. After the hanging on January 18, the body was quickly brought to Aldini, who took a pair of conducting rods linked to a powerful battery and touched them to various body parts with dramatic



After thinking about what the story line might be, she had a dream about a scientist who created life from a collection of body parts and was horrified by the results. In her novel, which may have been the first science fiction book, Dr. Frankenstein, the mad scientist, collected body

In 1803, Aldini was invited to London by the Royal College of Surgeons to conduct his experiments on George Forster, who was being hung for murdering his wife and child. Part of his sentence also stipulated that his body would be dissected not only to provide medicine

results. According to one report, when applied to Forster's mouth and ear, *"the jaw began to quiver, the adjoining muscles were horribly contorted, and the left eye actually opened. When one rod was moved to touch the rectum, the whole body convulsed: indeed, the movements were so much*

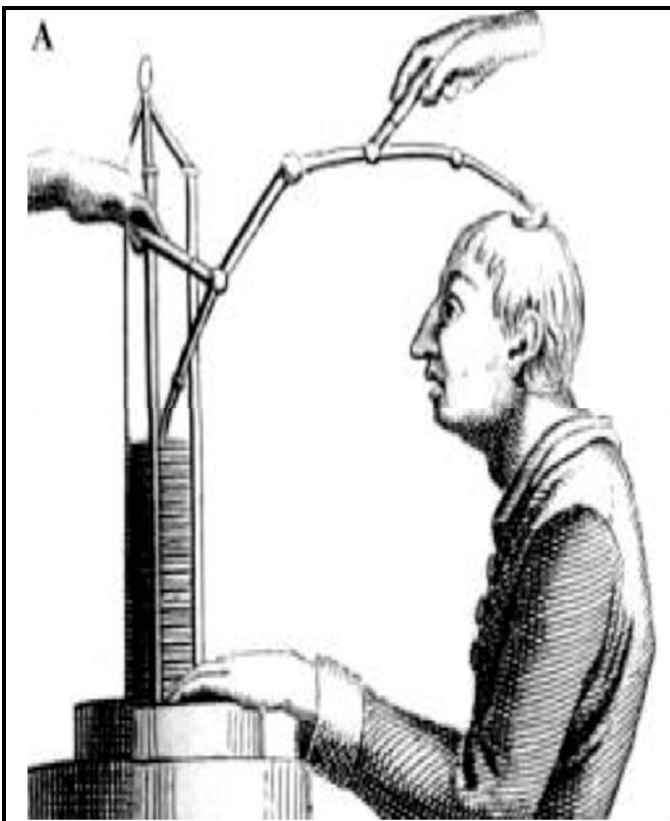


Later that year, Aldini published *An account of the late improvements in galvanism, with a series of curious and interesting experiments performed before the commissioners of the French National Institute, and repeated lately in the anatomical theaters of London*. However, the author was listed as John Aldini, possibly because it was published in London. It was an influential book on galvanism that presented for the first time multiple experiments in

which the principles of Volta and Galvani had been combined. It also contained the first description of how steel needles could be magnetized by connecting them to a voltaic circuit. Aldini was among the first to treat mentally ill patients with shocks to the brain, especially for "melancholic madness." This was also described in detail in a section entitled "Application of Galvanism on Madness, and Other Illnesses of a Different Nature" that described

two successful cases from Bologna.

Aldini's first patient, a 27-year-old farmer by the name of Louis Lanzarini, "fell into a state of deep melancholy" and was sent to the public hospital of St. Ursula in 1801. When questioned, he gave laconic and confused answers, and appeared withdrawn. After Aldini administered cranial electrical treatments, he began to improve and actually even looked forward to receiving them.



Cranial Electrotherapy Treatment of Louis Lanzarini  
Aldini *Essai théorique et experimental sur le galvanisme*, 1804

We conceived the idea of shaving the head above the suture of the parietal bone.... The patient then touched with one of his hands the bottom of the pile, and at the same time an arc was established from the summit of the pile to the metallic armature placed on the head. By this arrangement the action of the Galvanism was rendered more moderate; the patient endured it for a long time, and seemed to be greatly relieved by it.... On his leaving the hospital I carried him to my house, that he might be fitted by proper nourishment for resuming his former occupations. He remained with me eight days ... during which time he was exceedingly tractable, and performed his duty with great care and attention.... After this period, I obtained a regular report respecting his behavior and state of his health ... and I learned ... that he continued to enjoy good health, and to exercise his usual employment.

As Aldini explained:

Aldini also presented the case of a laborer with less severe symptoms, whose treatment and progress were similar to Lanzarini's. Nevertheless, Aldini was reluctant about making any claims, since two apparent cures were inadequate to draw any conclusions. He also reported several failures, and warned that cranial electrotherapy was of no value "in cases of raving madness," or mania. His book was superseded by *Essai théorique et expérimental sur le galvanisme*, a sumptuous two-volume, 680-page-long treatise published in Paris in 1804. It contained much more detailed descriptions of previous publications and included contributions from others in Europe and England. It also had more engravings and illustrations, some of which were in color.

He dedicated this book to Napoleon who had defeated the Austrian army in Northern Italy in 1796, and created the Cisalpine Republic in 1797, which included the duchy of Milan and Bologna. In it, Aldini explained:

It will be forever remembered in the splendor of the His-

tory of Galvanism the day when, just arriving in Italy, you allowed me to develop in front of you its main experiences, despite the vast military and politic activities that surrounded you. The memory of this honorable epoch emboldens me to dedicate this work to you. The support that you grant to all sciences also goes toward the progress of Galvanism: the monuments that you erected to its glory are great and worthy of your name. This homage is the expression of a public reconnaissance and a tribute that I render to the memory of Galvani, whose discovery, magnified by your auspices, will go, with your name, into immortality.

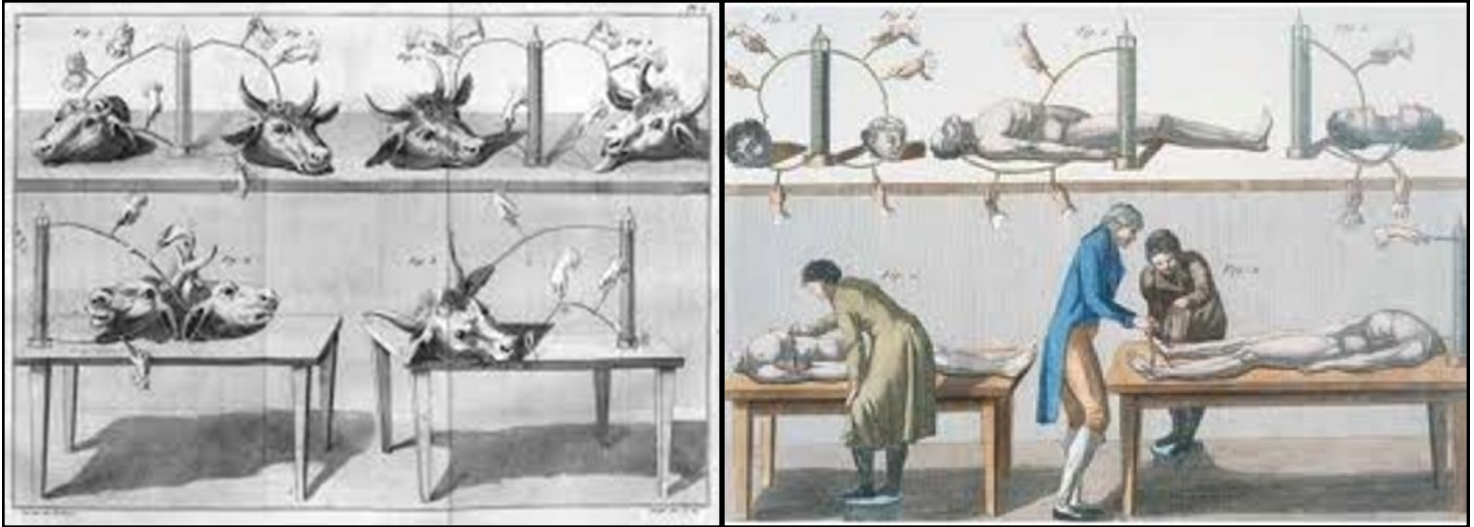
In return, Aldini was made a knight of the Napoleonic Order of the Iron Crown. and in 1807, was appointed a Councilor of the state of Milan.

Some idea of the numerous complicated experiments Aldini performed can be gained from the

magnificent engravings in this book. He electrified the decapitated heads of various warm blooded animals, including lambs and oxen, as seen to the left, as well as heads and other parts of corpses of criminals in Bologna in 1802 shown to the right. There was no illustration of his experiments on the body of George Forster in London, which had attracted so much publicity because of the possibility of bringing him back to life. Aldini had doubted this because the spinal cord had been severed, and provided a lengthy explanation to explain his position that ended with:

I think that this account will easily convince the readers that the experiments I did on the hanged criminal did not aim at reanimating the cadaver, but only to acquire a practical knowledge as to whether galvanism can be used as an auxiliary, and up to which it can override other means of reanimating a man under such circumstances. I only wanted to recommend galvanism as





From Aldini J. *Essai théorique et expérimental sur le galvanisme*. Paris: Fournier Fils, 1804.

the most powerful means to assist and augment the efficacy of all other stimulants.

### **Cranial Electrotherapy For Mental Illness In The 19th Century And Beyond**

Prior to Galvani's "animal electricity," it was thought that animal spirits stored in the ventricles of the brain circulated through hollow nerves to cause muscular contraction. Even Franklin and contemporaries, who first administered shocks to the head, thought electricity was a fluid due to the influence of Galen. However, their decision to apply this for depression and mental illness was based solely on accidental exposure that produced an improved mood and

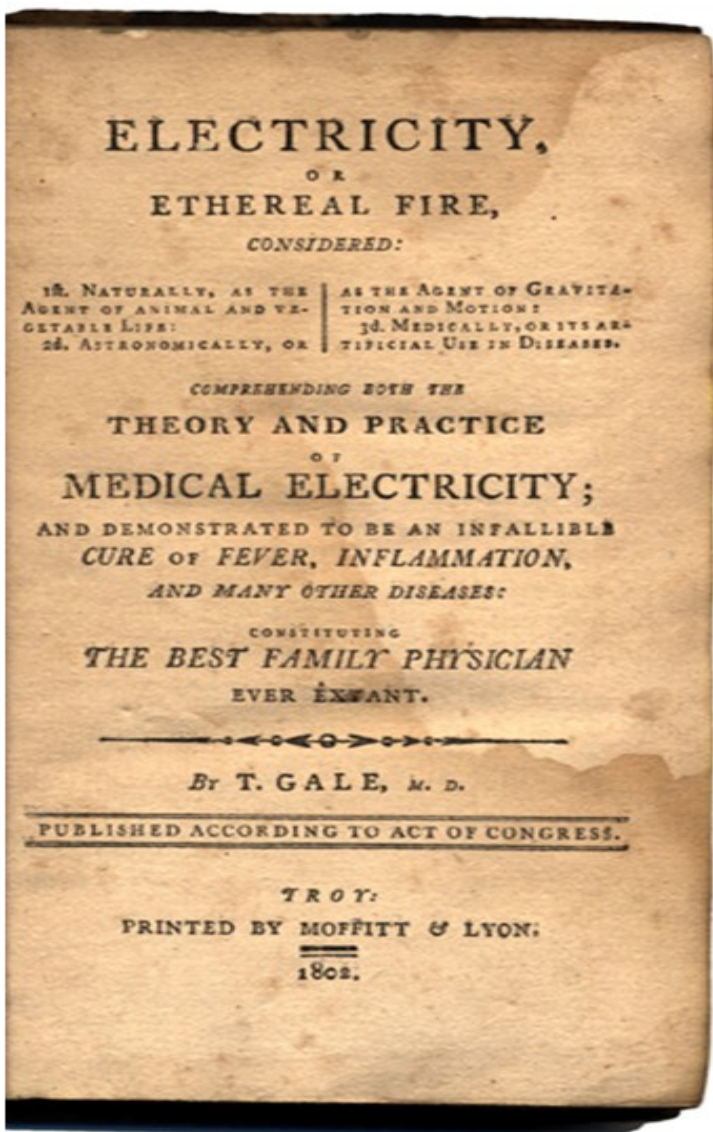
appeared to be safe. It was difficult to know the proper dose and how often or how long it should be since the source was a Leyden jar. There is no indication that Aldini was aware of any of this and he used a current of electricity from a voltaic pile that allowed more control. He also tested it on himself to gauge the correct dosage.

Others also independently began to use cranial electricity to treat a variety of mental and other illnesses including Dr. T. Gale, a relatively obscure evangelical physician who practiced in upper New York State. He believed that electricity was an "ethereal fluid" and "the means by which God gave spiritual and physical motion to his creation." In addition to

energizing all living creatures and plants it pervaded all space. As he explained in his 1802 *Electricity or Ethereal Fire, Considered*:

The electrical effluvia is far more subtile than air, is diffused through all space, surrounds the earth, and pervades every part of it; and such is the extreme fineness, velocity and expansiveness of this active principle, that all other matter seems to be only the body, and this the soul of the universe.

With respect to mental illness, *"If the electric*



restoring a person to the use of reason." He described three patients suffering from melancholia. The first was a young woman who was breast-feeding during the summer of 1795, when she began to ignore her baby and stopped eating. Gale noted that "her mother was the only person she would correspond with. She was terrified at the sight of her husband, with whom she had lived in perfect cordiality until she became insane.... She was emaciated almost to a skeleton; deep dejection of spirits, gloomy and

tum depression, he was also successful in treating a suicidal man who had been in a "delirium" for several years and had even cut his own throat. He exhibited excellent recovery after just two sessions with what Gale considered to be moderate to fairly strong electrical shocks. His third case was a man who became delusional after being cheated out of a large amount of money. Gale reported,

"His family had become much alarmed...he told them that the devil said he must kill a daughter of his. I charged the machine as high as I thought he could bear, and live through. I passed the shock upon him, which almost knocked him to the floor. Passed the shock from the top of his head to the feet. I gave six or seven more, but lighter. He went home, and was more composed in his mind the next day, as I was informed; but it was necessary to bring him again. I gave him a second electrification and they took him home, and it was not long before he had the right use of his mind, was composed and well."

*shock can be applied in the first stages of madness, before indirect debility takes place, it may be immediately removed; ... I have found, by experience, that gentle shocks through every part of the system upon the nerves, and through the stomach, and down the back of the head, upon the top of the head, through the brain to the feet, have assisted in*

*melancholy."* She was given some "very light shocks," which induced her to smile the next day. After four or five weeks of additional treatments, "all that gloominess of mind was dispelled, and she was able to unite with her husband again in keeping house."

In addition to this case of apparent post par-

Numerous advances in the nature of electricity and electromagnetic fields due to contributions by Faraday, Ampère and d'Arsonval followed. In 1871, Beard and Rockwell published their *Practical Treatise of the Medical and Surgical Uses of Electricity* promoting the use of alternating current. In 1896, d'Arsonval reported in his paper, "Apparatus for Measuring Alternating Currents of All Frequencies," that "an intensity of 110 volts, 30 amperes with a frequency of 42 cycles per

second, gives rise to, when one places the head into the coil, phosphenes and vertigo." Phosphenes are flashes of light seen when the eyes are closed due to stimulation of the retina or occipital lobe. Aldini and others had also described this.

In 1891, Sylvanus P. Thompson, a British electrical engineer and physicist, had published *The Electromagnet: Electro-magnetic & Magnetic Physics with Practical Applications*. He later became particularly interested in

the effects of electromagnetic fields and in his 1910 paper, "A Physiological Effect of an Alternating Magnetic Field," confirmed d'Arsonval's findings. He also demonstrated how he could produce phosphenes in anyone as well as affect their frequency and other features. He did numerous experiments to see the effects of electromagnetic field stimulation of the brain on

himself, as shown in this 1910 photograph to the left. As he was not a physician, he did not study patients, but was elected to serve as the first president of the British Radiological Society.

There were numerous textbooks on electrotherapy in the early 1900's, it was taught in medical schools, and like radiology, was considered a legitimate discipline. However there were so many quacks making worthless claims, it was banned as a treatment in the U.S. following the 1910 Flexner report. Research on electrical stimulation of the brain began with Leduc and Roux in France in 1902, although [Tesla](#) noted its soporific effects in 1898. Louise Robitnovitch was the first to recommend it for insomnia in 1914, and most subsequent studies were done by others from Russia who expanded its use to treat anxiety as well as sleeping disorders in 1949. Anan'ev published the first paper on cranial electrical stimulation in 1957 and the first book by Gilyarovski appeared a year later with the simple title, *Electrosleep*. This remained the popular term





for this approach until 1978, when the FDA decided to replace it with cranial electrotherapy stimulation (CES).

The first use of electricity to deliberately induce convulsions was in 1938 by Professor Ugo Cerletti, Director of the Clinic for Mental and Nervous Diseases in Rome. He thought that seizure disorders prevented or ameliorated schizophrenia based on previous studies with Metrazol, an epileptogenic stimulant that produced an immediate convulsion. He had been studying the effects of electroconvulsive seizures in dogs with his assistant, Lucino Bini, who had lessened their mortality rates by placing the electrodes on both temples rather than the mouth and rectum. Cerletti was anxious to try electroconvulsive therapy (ECT) on a patient, but was discouraged by his colleagues because "*the idea of submitting a man to convulsant electric discharges was considered as utopian, barbaric, and dangerous; in everyone's mind was the specter of the electric chair.*" In addition, transcranial electricity was used to kill

pigs in slaughterhouses. Cerletti and Bini investigated this, and found that the pigs were actually in an electrically induced epileptic coma when their necks were slashed. Further studies revealed that the pigs could tolerate much higher voltage doses delivered across the head without dying or permanent harm.

This was tested when a middle-aged male apprehended by the police was admitted. He "*expressed himself exclusively in an incomprehensible gibberish made up of odd neologisms and, since his arrival from Milan by train without a ticket, not a thing had been ascertainable about his identity.*" Cerletti described the procedure as follows:

As was our custom with dogs, Bini and I fixed the two electrodes well wetted in salt solution, by an elastic band to the patient's temples. As a precaution, for our first test, we used reduced tension (70 volts) with a duration of 0.2 seconds. Upon closing the circuit,

there was a sudden jump of the patient on his bed with a very short tensing of all his muscles; then he immediately collapsed on to the bed without loss of consciousness. The patient presently started to sing at the top of his voice, then fell silent. It was evident from our experience with dogs that the voltage had been held too low.

At this point, a heated controversy ensued among those present as to whether a repeat shock at a higher voltage should be attempted. During this debate, the patient suddenly yelled out in clear language "*Non una seconda! Mortifera!*" (not again it will kill me!). Although the majority of observers felt the experiment should be stopped, Cerletti continued with a stronger dose.

I had the electrodes reapplied, and a 110 volt discharge was sent through for 0.5 seconds. The im-



mediate, very brief cramping of all the muscles was once again seen; after a slight pause, the most typical epileptic fit began to take place. True it is that all had their hearts in their mouths and were truly oppressed during the tonic phase with dyspnea, ashy paleness, and cadaverous facial cyanosis and apnea which, if it be awe inspiring in a spontaneous epileptic fit, now seemed painfully never ending -until at the first deep, stertorous inhalation, and first chronic shutters, the blood ran more freely in the bystanders veins as well: and, lastly, to the immense relief of all concerned, was witnessed a characteristic, gradual awakening by step. The patient sat up of his own accord, looked about him calmly with a vague

smile, as though asking what was expected of him. I asked him "what has been happening to you?" He answered, with no more gibberish: " I don't know, perhaps I have been asleep."

The patient received thirteen more ECT treatments over the next two months, when he was discharged in complete remission. He remained symptom free for the next two years, after which he was lost to follow up.

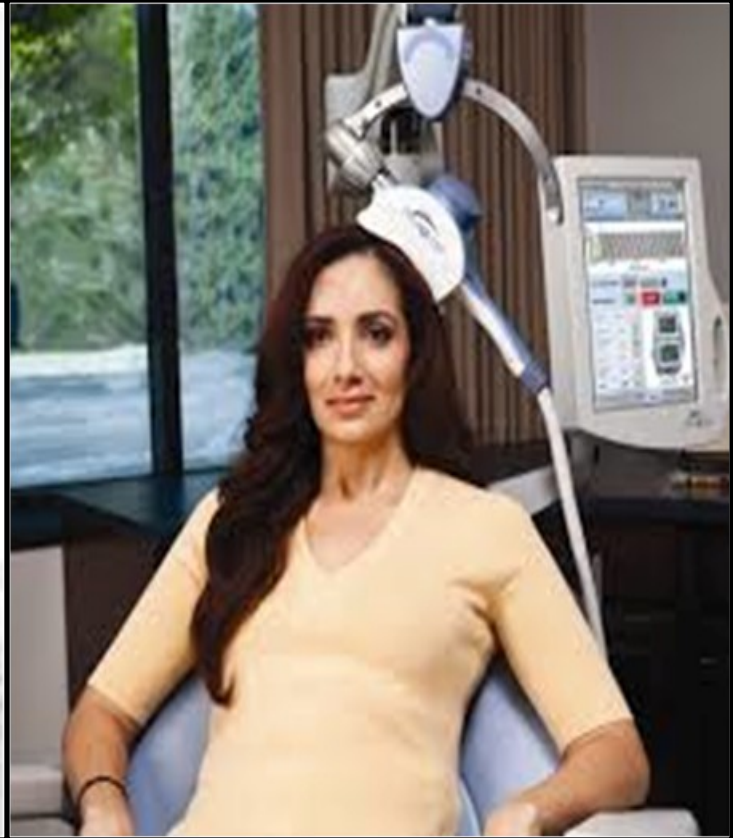
The improvement in this and subsequent patients was so dramatic that some Italian and other European physicians considered it a medical miracle, and by 1943, ECT had crossed the Atlantic to America. It was primarily used for schizophrenia but was soon tried for any psychiatric disorder and found to be particularly effective for severe depression. In a 1954 paper entitled "Prognosis of depression treated by electric convulsive therapy", H.F. Jarrie estimated that

one third of the 60,000 hospitalized patients in England and Wales would receive ECT. It's interesting that neither Jarrie nor Cerletti were apparently aware that Franklin, Aldini and other early investigators had recommended electric shocks to the head to treat melancholia. The first modern attempt at electrical stimulation of the brain took place in 1874 in a conscious patient being treated for osteomyelitis of the scalp. The brain was exposed during debridement and muscle contractions were apparent when the motor cortex was subjected to electrical but not mechanical stimulation.

However, it was not until 1948, that electrodes were successfully implanted in the brain to treat a psychiatric disorder. In the 1960's, researchers began experimenting with the use of weak DC currents applied directly to the exposed cortex of animals and showed that currents much lower than those necessary for the initiation of an action potential could still cause neuroexcitability. In 1976, Anthony Barker and col-



Figure- Barker demonstrating TMS [1].



leagues at the University of Sheffield overcame many of the earlier technical problems and developed a crude magnetic stimulator that produced responses without direct contact. This was progressively refined over the next decade and they introduced noninvasive Transcranial Magnetic Stimulation in 1985.

It has been modified several times since then as illustrated above. To the left is a photo of Barker treating a patient with his original device. The diagram to the right shows a variation of this called re-

petitive transcranial magnetic stimulation (rTMS) that is approved to treat patients resistant to antidepressant drugs and may have other applications. In addition to rTMS, TMS, CES and ECT, here has been an explosion of other cranial electrotherapies with an alphabet soup of acronyms, such as deep brain stimulation (DBS), transcranial direct current stimulation (tDCS), functional electrical stimulation (FES), magnetic seizure therapy (MST) vagus nerve stimulation (VNS), transcranial pulsed current stimulation (tPCS) and low energy emission therapy

(LEET). Modern cranial electrotherapy stimulation (CES) devices evolved or were preceded by electrosleep (ES), cranial electrostimulation therapy (CET), transcerebral electrotherapy (TCET), and neuroelectric therapy (NET). Others like transcutaneous cranial electrical stimulation (TCES) came from electroanesthesia (EA), and interferential current therapy (IFC). Variations of these for specific applications include galvanic vestibular stimulation (GVS), transcranial alternating current stimulation (tACS) and transcranial random noise stimula-

tion (tRNS).

All of the above come under the heading of transcranial electrical stimulation (TES) as well as cranial electrotherapy stimulation (CES). This has led to considerable confusion since although they are regulated by the FDA and require a prescription, much less expensive devices that purport to be equally effective are readily available directly to the public. These are not under the jurisdiction of the FDA, Federal Trade Commission or Federal Communications Commission unless they claim to be effective for the diagnosis or treatment of a disease. However, there are ways to avoid this by advertising their success in people complaining of memory loss, fatigue, difficulty in concentration, lack of

libido or sexual performance, irritability, despondency, smoking, other addictions, and especially stress.

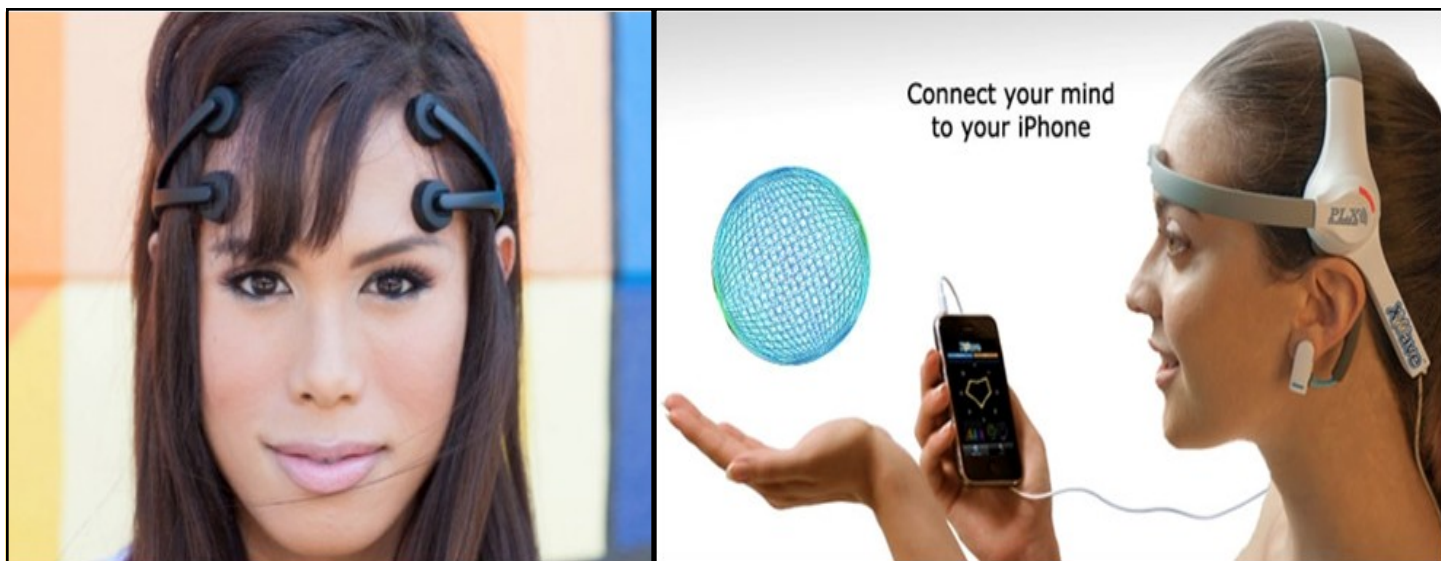
The \$249 Transcranial Direct Current Stimulation (tDCS) foc.us headset (below, left) claims to improve a gamer's abilities by stimulating specific areas of the brain with a "low electric current." The website states it "meets all regulatory safety standards" but "offers no medical benefits, is not a medical device, and is not regulated by the FDA." No studies are referenced.

To the right is the XWave Visualizer app and headset for under \$200. It detects "the faintest electrical impulses transmitted through the skull to the surface of the forehead and converts these analog signals into digital

signals." This "first brain-computer interface for Apple products" tells you how hard you're concentrating. The company also claims it can be used to treat ADHD.

It is obviously a violation to make any medical claims, but there are so many of these OTC devices that the FDA does not have the manpower to monitor all of them. Describing it as a tDCS device also implies that it is similar to tDCS products that have been approved for iontophoretic drug delivery, and others that are undergoing clinical trials for the treatment of depression and fibromyalgia whose results have been published in peer reviewed journals.

This is a particularly perplexing problem for non-prescription products that claim to be cranial



electrotherapy stimulation (CES) devices, such as this [advertisement](#). As can be seen, it goes into a lengthy discussion of the history of CES, how it is administered and indications that emphasize its greatest benefits will be "First and foremost, those suffering from stress in the form of depression, anxiety, and insomnia who seek an effective non-pharmacologic alternative. Secondly, those suffering from illnesses where stress constitutes a prime symptom. Among these are: "substance abuse withdrawal syndrome (alcohol, street drugs, nicotine, prescription drugs), chronic fatigue syndrome including fibromyalgia, pre-menstrual syndrome, attention deficit disorder and hyperactivity, migraine and tension headaches, TMJ dysfunction, chronic pain, pre-

competitive and performance anxiety, panic disorders, tic douloureux, bruxism, stress induced asthma, hives, gastrointestinal disorders, ulcers or gastritis, and irritable bowel syndrome, to name a few."

It cites legitimate research done with Alpha-Stim, a CES FDA cleared device, and implies that its studies apply to their products such as the Brain Tuner by linking the two. Thus, it explains that the current is delivered in two ways: "The traditional 100Hz unit utilizes pre-gelled electrodes that snap on or attach to the end of lead wire that plugs into jack of the unit. The Brain Tuner (BT-5 and 6) employs a stethoscope shaped device that sits beneath the ears. The 0.5 Hz unit (Alpha Stim) uses 'ear clips' with felt electrodes that adhere to the clips.

Saturate the felt electrodes with saline solution and then apply them to the superior aspect of the earlobes as close to the jaw as possible." In boasting about the "unblemished safety record" of CES it emphasizes that "The Alpha-Stim 100 is an example of a CES device that employs very low intensity electrical current pulses (up to 600 microamperes)," and that "The Alpha-Stim in particular uses a very broad band of frequencies collectively known as harmonic resonance. This insures that the right frequency will be delivered to reestablish homeostasis within the bioelectrical system. The other frequencies pass harmlessly." There is a link to a page containing references on safety, but the vast majority are from the 1970's and none are from the past 25 years,





most used Alpha-Stim and apparently no studies have been conducted on any of their CES devices, several of which are shown below at left. One of these costs more than \$1,000.00.

The problem is that most consumers are unaware that the FDA has not only redefined CES to satisfy certain arbitrary criteria, but considers that all devices in this classification are equally efficacious despite the fact that there are significant differences in hardware and software. In addition, some are constantly being improved. The Alpha-Stim 2000 that was sold in the early 1980s weighed 40 lbs. and the price was \$5,850.00 (equivalent to \$13,732.00 today). The current version of this is under 2 lbs. and costs less than \$800.00. It has been authorized by the FDA for the treatment of anxiety, depression, insomnia and pain for over 30 years, during which it has enjoyed an impeccable safety record. In point of fact, this and other CES devices that have demonstrated efficacy are so safe, that they do not require a prescription for use in almost every other

country.

Although they are also much more cost effective than pharmaceuticals, their wider use has been hindered by huge drug companies which have a powerful influence on the FDA, other regulatory authorities, the media, academia, prominent medical societies and physicians who are the recipients of their largesse. As a result, they still require a prescription and must periodically submit lengthy PMA (Premarket Approval) documents that cost millions to prepare and review but are frequently not responded to. The tragedy is that these funds are not available to explore the potential for CES in treating cancer, Parkinson's disease, fibromyalgia, tinnitus and other disorders in which pilot studies and anecdotal reports mandate the need for further research. This is particularly true for PTSD, where the first choice is antidepressants that are not only ineffective, but may be contributing to the unexplained epidemic of suicides in veterans that is not combat related.

There is much more that could be said,

such as the fact that consumers are unaware that the spurious CES products purchased without a prescription have no studies to validate their claims. As a consequence, customers will be dissatisfied with the results and will assume that reputable CES devices are also worthless. (Click [here](#) for another example). However, we have already devoted two lengthy Newsletters to just this one topic, which has prevented me from reporting on exciting developments in other areas in a timely fashion. As a result, future issues of *Health and Stress* will be much larger and issued quarterly rather than monthly. In order to keep current and inform you of the latest developments, weekly or periodic updates on important research findings and advances in stress medicine will be posted in the Chairman's interactive blog on our website —so be sure to check on this to provide your own comments and to stay tuned!

<http://www.stress.org/about/chairmans-blog/>

Paul J. Rosch, MD, FACP  
Editor-in-Chief

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# GET INSIDE OUR HEAD

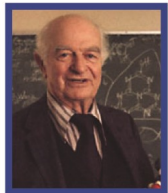


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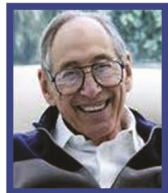
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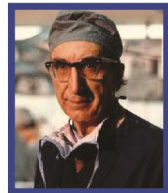
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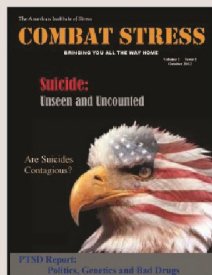
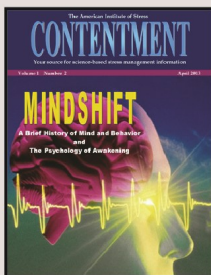
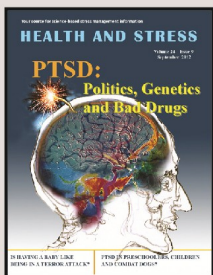
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