MODULATED ELECTRIC ENERGY STIMULATORS

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Presented at the American Academy of Pain Management Conference Las Vegas, Nevada---September 1999

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I. Introduction:

Modulated Electric Energy Stimulators are devices which utilize the physics characteristics of the body to have a beneficial clinical effect on the human in reducing pain, and symptoms of depression, anxiety, and insomnia and are authorized by the FDA for these indications. Researchers have already reported that they have already used these devices to reduce spasticity, enhance alertness and increase attention span in the normal and increase the cognitive performance of neuronally deficient children. One researcher even developed safety information for use on the heads of children from 2.5 to 7.5 years of age. The authors conceived this application of the stimulator technology by analyzing the physics characteristics of the body and attempted to match the dynamic electrical impedance of the body with a stimulation pattern which the body could then convert into an internal signal that it could use constructively to help the body help itself.

II. Principles of Operation:

A. Using the electrical characteristics of the body:
Modulated Electric Energy Stimulators utilize the principles of carrier frequency penetration which places very low electrical Charge on the bulk capacitance of the body or head of an individual in such a manner that when the current from the said stimulator is turned off for 33.3 microseconds, the charge can leak from the bulk capacitance into the resistance of the tissue. This activity causes a current to flow inside the body, which apparently has been able to alter the level of certain neurobiochemicals as will be described subsequently. A modulating waveform, which philosophically turns the carrier waveform off and on, and has been found to have certain bio-active effects on the human physiology, is impinged on the carrier.

B. Physics of the Body:
The study of physics states that all matter (including the body) has electrical characteristics: resistive, capacitive, or inductive. There are some parts of the heart system that contain inductive characteristics but in the main, the body and head are mostly capacitive and resistive (including semiconductor like characteristics which are very special form of conducting or resistive circuits). For the record, resistive characteristics are those which impede the flow of current); capacitive characteristics include the ability to store an electrical charge. This has been observed in conjunction with the bulk capacitance of the body. If a researcher connected a capacitance meter or a power factor meter to measure the capacitance of the body, he/she will definitely find measurable capacitance associated therewith. The electrical equivalent circuit is shown in figure1. When two contacts are placed on the body from a LISS Cranial or Body Stimulator (LCS or LBS), we observe the effect of the contact impedance and the epidermis as a parallel network of both resistance and capacitance. The next series element in the body is the dermis, which looks electrically like a resistor; as does the nerve (also in series with the previous elements). The next item, also in series, the dermis (as the signals begin to exit from the body or head), likewise looks like a resistor. Finally, the exiting epidermis and contact impedance appear as the same type of resistance and capacitance network as seen in the initial part of this analysis. To test such a circuit, we must connect the stimulator in series both with the "Body or Head Circuit" and a "current reading resistor", across which we attach an oscilloscope. This in turn can display the pattern of current that flows thru the test system. Another oscilloscope, which should be connected above the stimulator and beyond the "current reading resistor" will present the pattern of the voltage,

which represents the "pressure" that pushes the "current" thru the "impedance" of the body (or head).

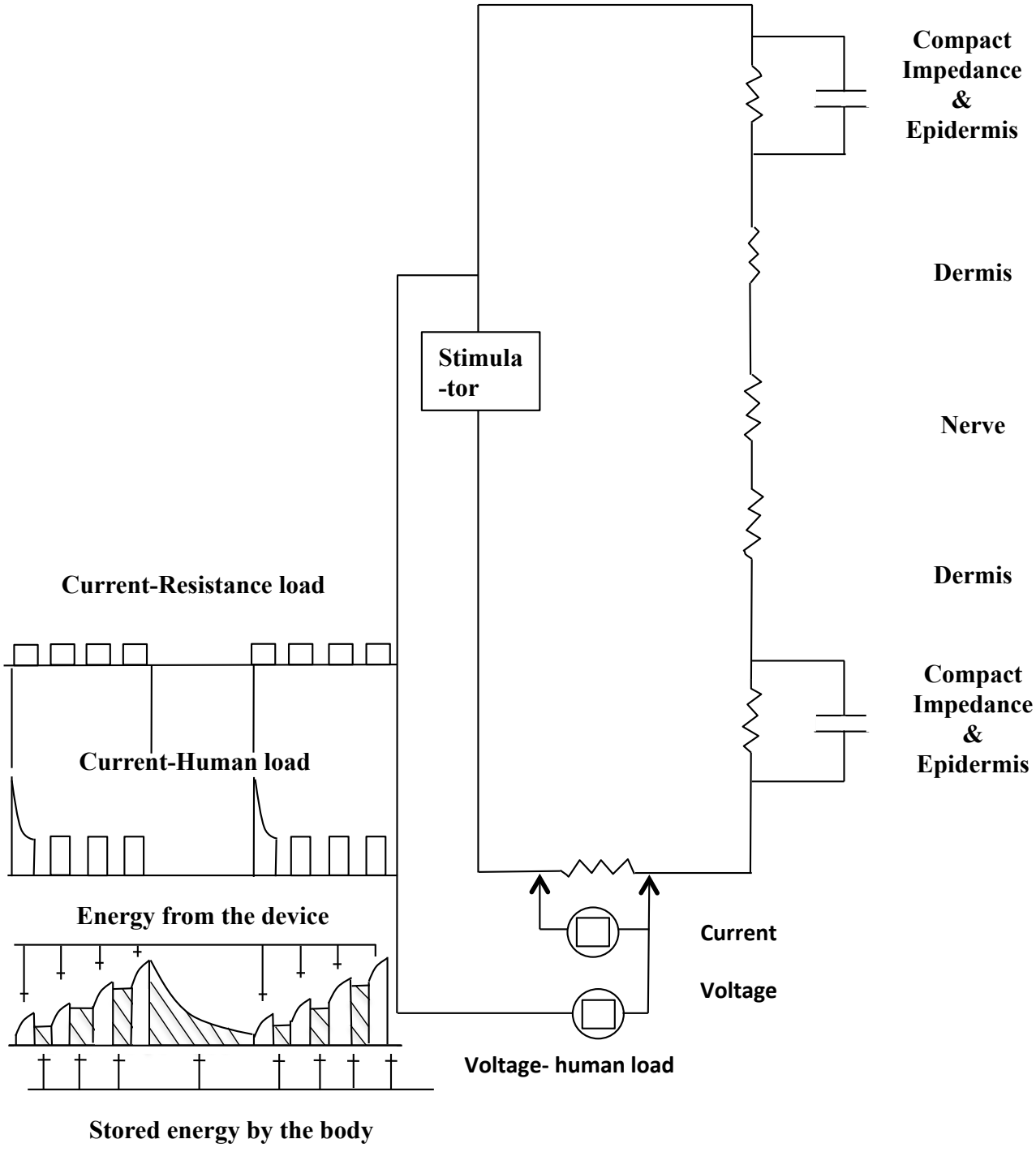


Figure 1. Equivalent circuit of the Body

C. The Gathering Effect:
Figure 2. shows the impact of the body's electrical circuit altering the wave shape of the LBS where the voltage rises from zero with the first pulse of energy in an exponential fashion but when the pulse attempts to return to zero, it does not do so, because the electrical charge from the device is stores on the "bulk capacitance of the body" and dissipates it when the high speed pulse (15,000hz) is momentarily turned off (for 33.3 microseconds). During the "off" time of 33.3 microseconds, the stores energy leaks off thru the body's own resistance (or equivalent), making a voltage "step" from which, the second pulse is initiated. Continuation of this process is called the "Gathering Effect", one pulse building on the level of the previous pulse---until an equilibrium is achieved.

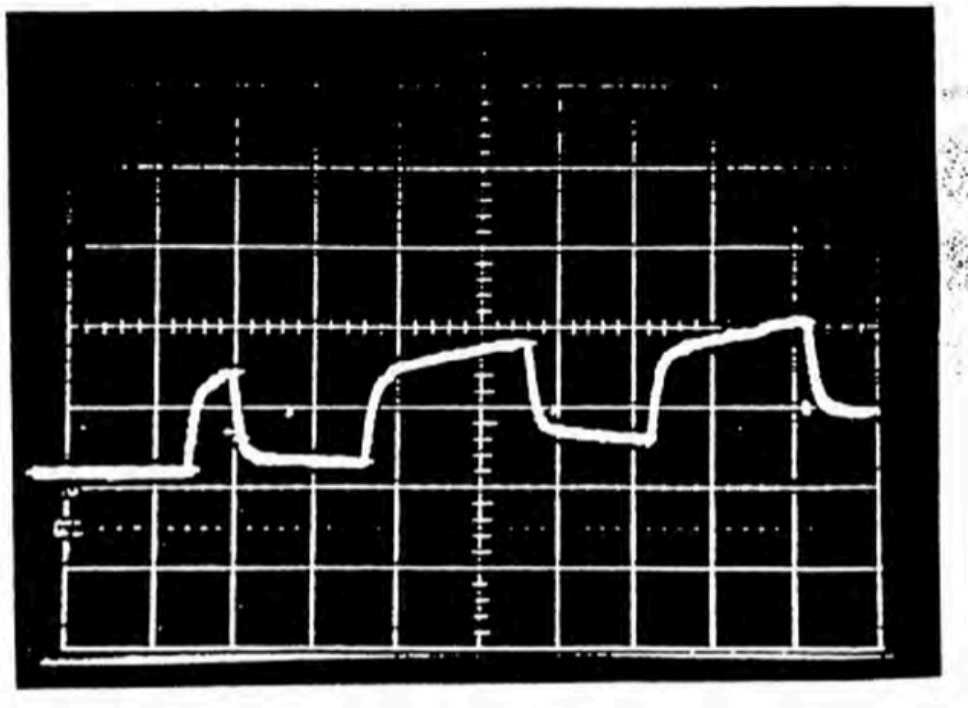


Figure 2. The Gathering Effect

D. The Triggering Phenomenon of the Body:
The triggering concept (Liss, 1996) is based on the assumption that it takes a certain amount of energy for a nerve signal to cross the synapse. When there is less than the required amount of energy present at the junction of the nerves under study, no signal will cross the synapse. When this occurs in a motor circuit the affected muscle will not function. Similarly in a sensory nerve or memory system there will be no consequent change in perception or transference of the memory information. The disturbance can also occur in the emotional systems of the brain and mind thus bringing a cloud over the individual's whole thought processes or behavior. Sir John Eccles was the first to demonstrate signal transmission across the synapse as it relates to intercellular resting potential in neurons. Sufficient energy at the synapse, therefore, appears to be essential for neurons that are involved in adaptive physiological mechanisms to function effectively and achieve homeostatic balance.

A research team at the Max Planck Institute of Biochemistry in Martinsried, Germany have built a new type of junction between a microscopic spot on a silicon chip and a corresponding spot on

the neuron of a leech and have demonstrated that "An electric voltage applied to the interior of the chip produces an electric field that induces a charge inside the cell (Fornherz, 1995). They showed, furthermore, that when this charge reaches a certain level, the cell fires, initiating the electro- chemical sequence by which nerve cells communicate with their neighbors."

The apparent requirement of an increment of "triggering energy" to be present for an event to transpire is well known in nature. In chemistry, for example, reactants must reach a "temperature of reaction" for an effect to take place. Similarly, in mechanics, "stiction" (static friction) must be overcome for motion to take place.

We hypothesize that in physiology, while the factors for an action may be present, if the "triggering energy" is absent or insufficient, no action will occur. We suggest that in some cases, introducing the current of the LCS or the LBS facilitates the physiologic action.

E. Demodulation:
Demodulation is the process of separating the audio frequency or the video signal from the "carrier" waveform in radio and television transmission, respectively. There is a circuit in radio and television that includes the lumped constant equivalent of resistors, capacitors, and semiconductors. Such a circuit separates the modulating frequency (or information) from the carrier frequency that transmits the signals through the atmosphere. We dial the radio to carrier frequency (~500,000 to1, 600,000 hz), but we listen to the radio transmitted audio frequency (~15 to 15,000 hz) and we see the video results of frequencies (~100,000 hz) while the television carrier frequencies can be 88,000,000 to 108,000,000 hz.

Granbard (1987) reported that the electrical characteristic of a lobster stomatogastric ganglion includes the property of "demodulation", normally the property of a semiconductor circuit in a "communication device". Thus, circuit rectification, which occurs in "demodulation" appears to be present in certain neural systems.

The modulated energy of the present and predecessor devices can be utilized in a variety of sites on the human head and body to provide the signal for the nervous system to "demodulate" the stimulator energy into the information which the organism needs to help alter the neurochemical levels of certain substances. Having learned how to bring energy into the anatomy, the real challenge lies in how to utilize it to enhance the body's ability to reduce its own disease symptoms.

Hence, contact placement, the combination of contacts, and integration into a complete treatment regimen, may need to take place at a particular time of day in the circadian cycle of the substance being targeted. Moreover, the sequence of treatments must be adapted to the disorder being treated.

F. Waveforms of the LCS and the LBS:
The low frequency oscillograph, figure 3, is that of the SBL202-B LCS and that of the SBLS02-B LBS.

Figure 4. shows the timing relationships among the various constituent waveforms. Please note that figure 4A, 15,000 hz carrier frequency, is modulated by both the first modulator of figure 4B, 15 hz, and the second modulator of figure 4C, 500 hz, to form the total waveform of both the SBL202-B LCS and the SBL502-B LBS.

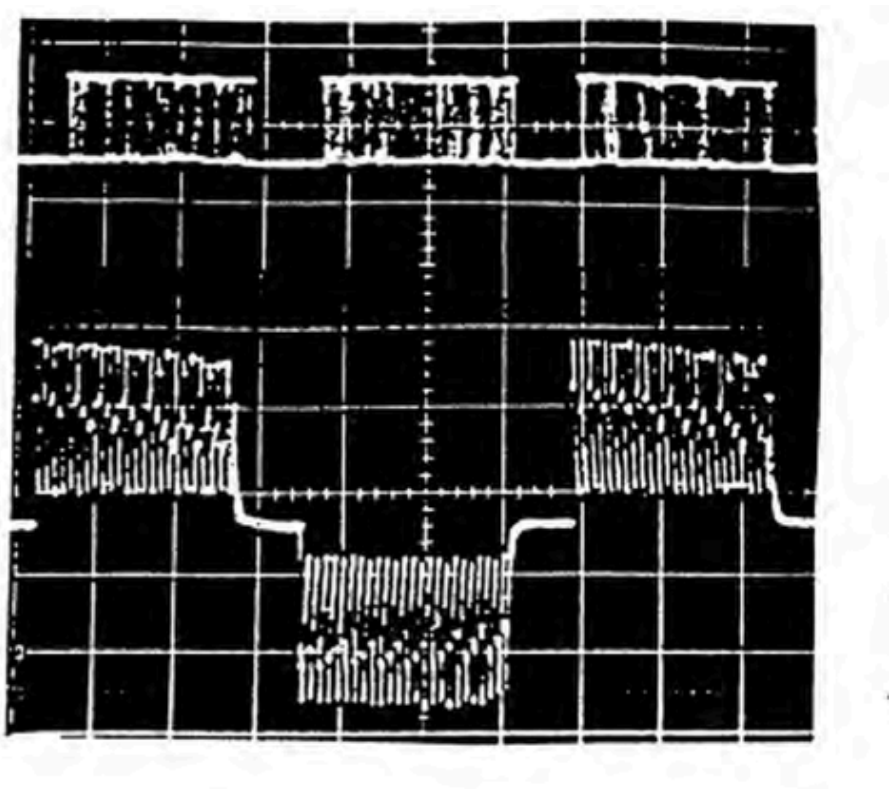


Figure 3. Output of LCS & LBS

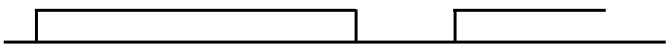
A. (Upper) Resistance Load (Monopolar)

B. (Lower) Human Load (Bipolar)

Figure A.

Carrier Frequency 15,000 Hz Monopolar

Figure B.

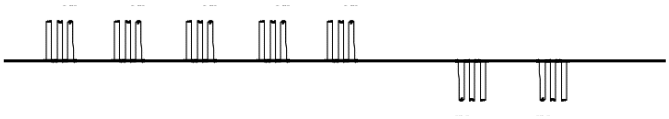


1st Monopolar 15 Hz

Figure C.

2nd Monopolar 500 Kz

Figure D.



Typical Combined Waveform (Bipolar)

Figure 4. LCS and LBS Constituent waveforms

III. Implications of Neurobiochemicals altered by Electrical Stimulation

The modulated electric energy stimulator technology, herein described is backed by 27 peer reviewed published studies, 27 patents, and six authorizations to market from the federal regulatory agency. These stimulators have been shown to alter the level of: Serotonin and Beta Endorphin in both the Cerebral Spinal Fluid (CSF) and the Blood Plasma as well as Cortisol, ACTH, GABA, DHEA, Neurotensin and Human Growth Hormone in blood plasma under certain specified conditions. (Shealy, Stress Medicine, 1995)

As a result of the alteration in the levels of these neurobiochemicals, the following clinical sequelae can be expected:

A. Pain Control and Management
B. Depression and Mood Management
C. Reduce the symptoms of Anxiety/Phobic disorder
D. Reduce the symptoms of Insomnia
E. Relaxation
F. Rebalance Hypothalamic/pituitary/Adrenal Axis
G. Reduce spasticity in the musculature
H. Enhance DeHydroEpiAndrosterone (DHEA)
I. Enhance the immune system.
J. Enhance Alertness, and increase Attention span.

Let us consider the mechanisms for drugs which effect serotonin, as compared to the action of the subject stimulator. Mood enhancing drugs and migraine headache drugs increase serotonin in a synapse by one of three mechanisms:

A. Reuptake Inhibition
B. MonoAmine Oxidase inhibitor
C. Bind to the particular sub receptor site.

The modulated energy stimulators have been shown to use the capacitance of the body to store an electrical charge temporarily. This causes a "Gathering Effect" by creating an electrical storage condition on the "Bulk Capacitance" of the Body. Thus, the authors have learned how to convert the energy from an external nine-volt battery into an internal current, which, we believe causes the alteration in the level of serotonin and the other neurobiochemicals, noted above.

Pain Control and Pain Management have been reported by Cassuto (1993), Graziano (1997), and Shealy (1976) and can be understood from the biochemical work of Shealy (1976), Closson (1985, 1986), LISS (1996) and Shealy (1999). Experience has shown that the rise in serotonin and beta-endorphin in both the Cerebral Spinal Fluid and the Blood plasma are likely responsible 'for the pain control and management benefit to the patients using the modulated energy stimulators.

Depression, Mood Management, Anxiety/Phobic Disorder and Insomnia are all classified as serotonergic dependent symptoms Therefore, if we can see the rise in serotonin, then it is easy to understand why these symptoms are reduced following an electrical treatment with the modulated energy stimulators.

Relaxation of the human is represented by the reduction in the plasma level of Cortisol. Cortisol is recognized as the "Fight or Flight" neurochemical in the body. Therefore, in order to relax the body, it is understandable why the reduction in cortisol indicates systemic relaxation.

Balancing the Hypothalamic/Pituitary/Adrenal Axis is the function of ACTH (which rises following electrical stimulation, with the modulated energy stimulators). However, there is a paradox when we analyze the biochemical level changes. In hundreds of assays following the electrical stimulation with the LISS Stimulators, Cortisol levels go down (representing systemic relaxation) while ACT H rises in the plasma measurements made to date. These two biochemicals normally rise and fall together but in this situation, that is not the case. We are at a loss at this time to explain this consistent paradox.

GABA is the neurobiochemical responsible for reducing spasticity in the body. It is one of two inhibiting neurobiochemicals and is thereby very important in balancing the action of complementary muscle actions (eg: agonist vs. antagonist).

DeHydroEpiAndrosterone (DHEA) is the leading neurobiochemical in the aging process and directly involved with enhancing the immune system. Dr. Shealy (Stress Medicine, Vol. 11:215-217 (1995) found that the use of 12 acupuncture sites in a specified order, once/day for a total of 15 to 20 minutes per day can enhance the level of DHEA an average of 225% within a twelve week period. Compare this statistic to the use of progesterone cream, used for 6 months, which resulted in an average enhancement of 60%. With the use of the LISS Body Stimulator on the "Ring of Fire" points for 12 weeks, one of eight people had a reduced level while seven of .the eight volunteers averaged 225% increase in that same time period. The characteristics of the waveform are critical to make this application work. The use of this technology for the enhancement of DHEA, by itself, can help the senior to a higher quality of life, and thereby enhanced independence.

It is apparent that with the cost of nursing home care averaging $50,000 per person per year, if we are able to save an average of only one month delay in entering a nursing home, the gross saving would be $4,000,000./every 1,000 people. If we saved each of the seniors over 65 during the 1993 census, society could be saved $132 Billion. Society, in this context, includes the individual, himself/herself, family, responsible organization like a union, major industry, or the appropriate government agency.

The clinical performance of the subject modulated energy stimulators has been documented in 27 peer reviewed published studies in various applications such as:

A. Depression
B. Pain
C. Headache
D. Cerebral palsy spasticity Reduction
E. Learning Disabilities
F. Enhancement of Dehydroepiandrosterone (DHEA)
G. Alteration of Serotonin and Beta-Endorphin in both the CSF and the blood plasma
H. Alteration in the blood plasma level of Cortisol, ACTH, and GABA
I. Dental Applications for:
    1. Restorative procedures without Novocain
    2. T M J Pain Control and Muscle Relaxation
J. Increasing the "Alertness" and "Attention Span" in Normal volunteers beyond the treatment time
K. Safety for transcranial use on children.

IV. Studies & Implications-Changes in Levels- Neurobiochemicals:

A. Double Modulated Carrier Frequency Stimulators:

Electrical Stimulation via Double Modulated Carrier Frequency Stimulators (DMCFS) can alter the level of certain neurotransmitters, such as: serotonin (Shealy 1979), beta-endorphin (Closson, 1986), cortisol (Closson 1986), ACTH (Closson, 1985), GABA (Closson, 1986), and even DHEA (Shealy, *1997;* Rosch 1998) without the use of drugs. Over the last twenty four years, research has been accomplished which indicates, in hundreds of normal volunteers and patients, that these neurobiochemical levels are altered after either transcranial stimulation with the LISS Cranial Stimulator or on the body with the LISS Body Stimulator (which are electrically identical).

Significant benefits have been demonstrated in Pain Control (Graziano, *1977;* Cassuto, 1993), Headache Management (Solomon, 1985,1989; Mac Gregor, 1993; Markovich, 1977; Romano, 1993; Terezhalmy, 1982; Morrison, 1994), reducing the need for amputating Diabetic legs (Wolf, 1995; Weinstein, 1987), Depression Symptom Reduction (Shealy, 1989, 1992,1994), and in the research mode, Cerebral Palsy and other Brain Injured Patients Spasticity Reduction (Malden, 1985; Logan, 1988; Sornson, 1985; Reilly, 1990, Hunt, 1986; Childs, 1993), and Relieving Symptoms of Learning Disabilities (Okoye, 1986).

LISS Cranial Stimulators (LCS) and LISS Body Stimulators (LBS) come in two different electrical characteristics:

1. Monopolar, where each positive burst of energy from zero to a plus value of four milliamperes is "on" for 50 milliseconds and "off" for 16.7 milliseconds. Each combination of “on” time and “off” time comprise 66.7 milliseconds which is the period of the 15 hz signal and is followed by the same burst of positive energy. Since this pattern of energy is only varying from zero to positive value, there is a modicum of direct current. We have observed increases in blood flow and alterations in the level of certain Neurobiochemicals, such as (See figure 1):

    a. Serotonin
    b. Cortisol
    c. ACTH
    d. Beta Endorphin

2. Bipolar LISS Cranial and Body Stimulators are devices where each positive burst of energy, varying from zero to a plus value of four milliamperes is “on” for 50 milliseconds and “off” for 16.7 milliamperes, is followed by a comparable negative burst of energy equal and opposite polarity to the initial burst. This “balance energy” method provides a net zero direct current. We have seen no blood flow increase from this waveform, but blood testing has shown almost twice the amount of neurobiochemical changes following bipolar stimulation, stimulation, compared to that of the monopolar. See Figure no. 5. The net frequency of this modulated device is 7.5 hz.

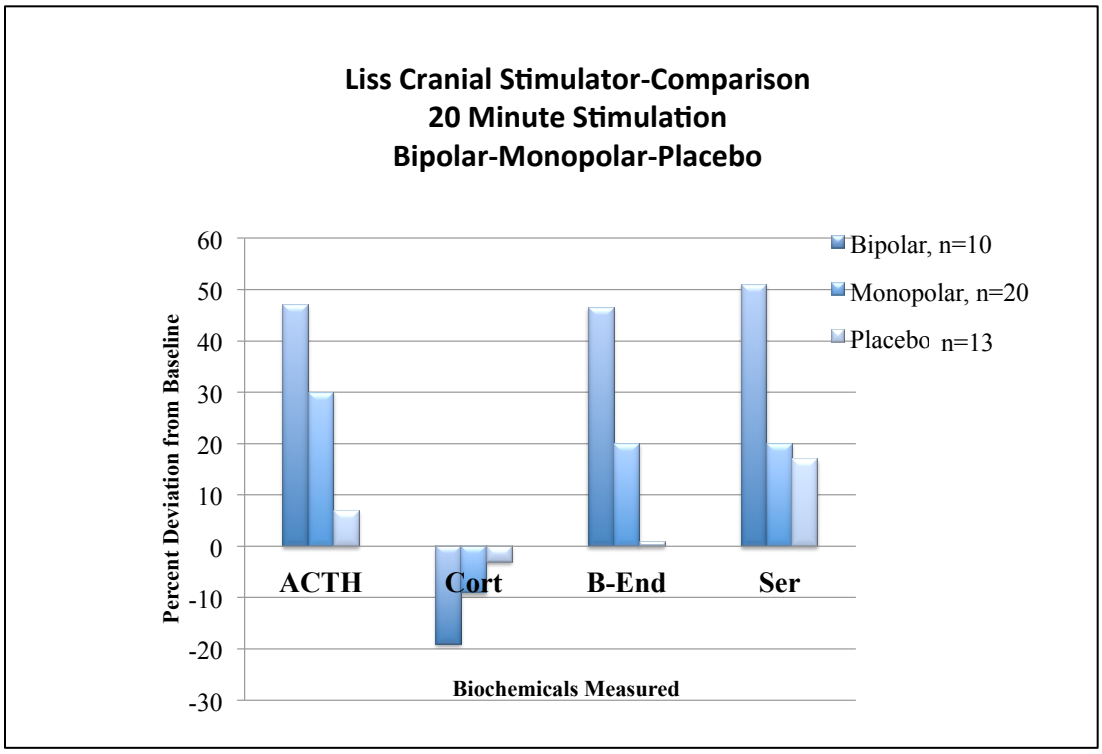


Figure 5. Baseline measurements following 20-minute transcranial stimulation vs. placebo testing.

Note that the monopolar device is able to increase blood flow toward the black contact and alters the level of certain neurobiochemicals, noted above. The bipolar version has not shown such increase in blood flow but it has shown alteration of the same neurobiochemicals approximately twice that of the monopolar device. Therefore, clinically, if there is a need to reduce pain through the increase of the flow of blood in the body, as in Diabetic Neuropathy, Raynaud's Disease, and Multiple Sclerosis, or out of the head, as in Migraine Headache, use the monopolar device. If there is a need to reduce pain by altering the level of neurobiochemicals, such as in chronic back and other musculoskeletal body pain, facial pain, or pain, secondary to neural dysfunctions, such as Reflex Sympathetic Dystrophy Syndrome (RSDS), then use the bipolar device.

The kinetics of the post transcranial stimulation blood plasma measurements, shown in Figure 6. indicate that during the first five minutes, there is no alteration in the level of cortisol. However, during the same time there is a 75% increase in ACTH, which over the rest of two hours reduces to 25% over baseline, while the Cortisol reduces to -12.5% (in the direction indicating relaxation). It takes twenty minutes for the serotonin to rise to its maximum of 50% over baseline which is maintained for the rest of the two hours. Beta Endorphin continued to increase over the two hour period. The only conclusion taken by the author is that this study must be replicated and extended to at least four or more hours. However, it certainly hints that 20 minutes stimulation with the LISS Cranial Stimulator likely triggers the body's long term neurobiochemical reactions.

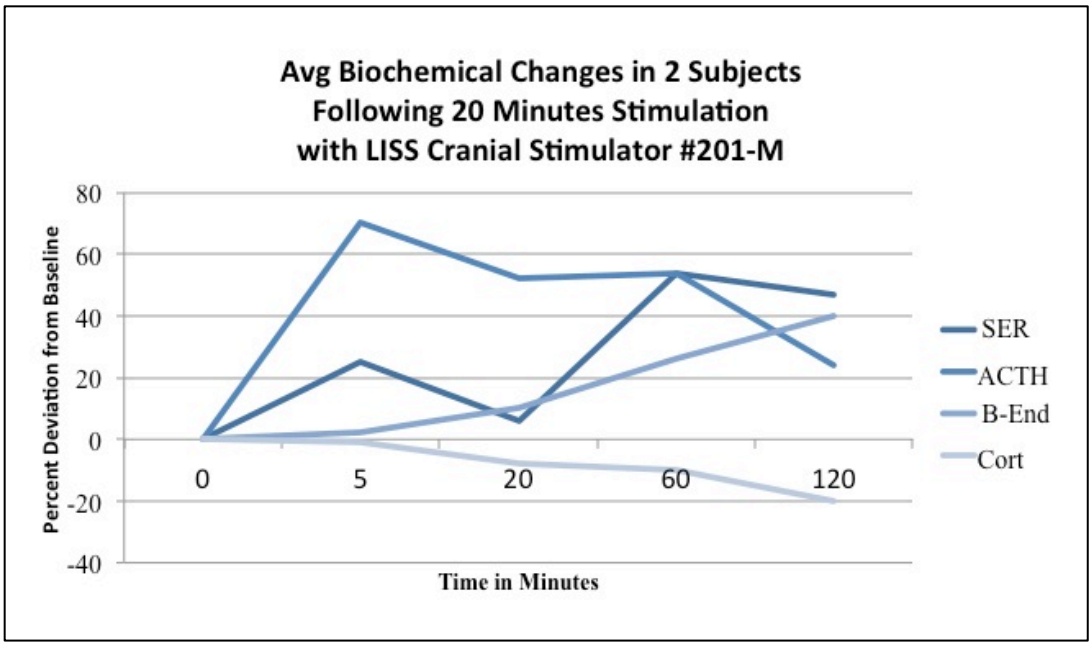


Figure 6. Kinetic Neurobiochemical Effects following Transcranial Stimulation (Liss, Malden, 1993)

Cerebral Spinal Fluid and Blood Plasma neurobiochemical measurements are shown in figure no. 7., (Cady, 1991)

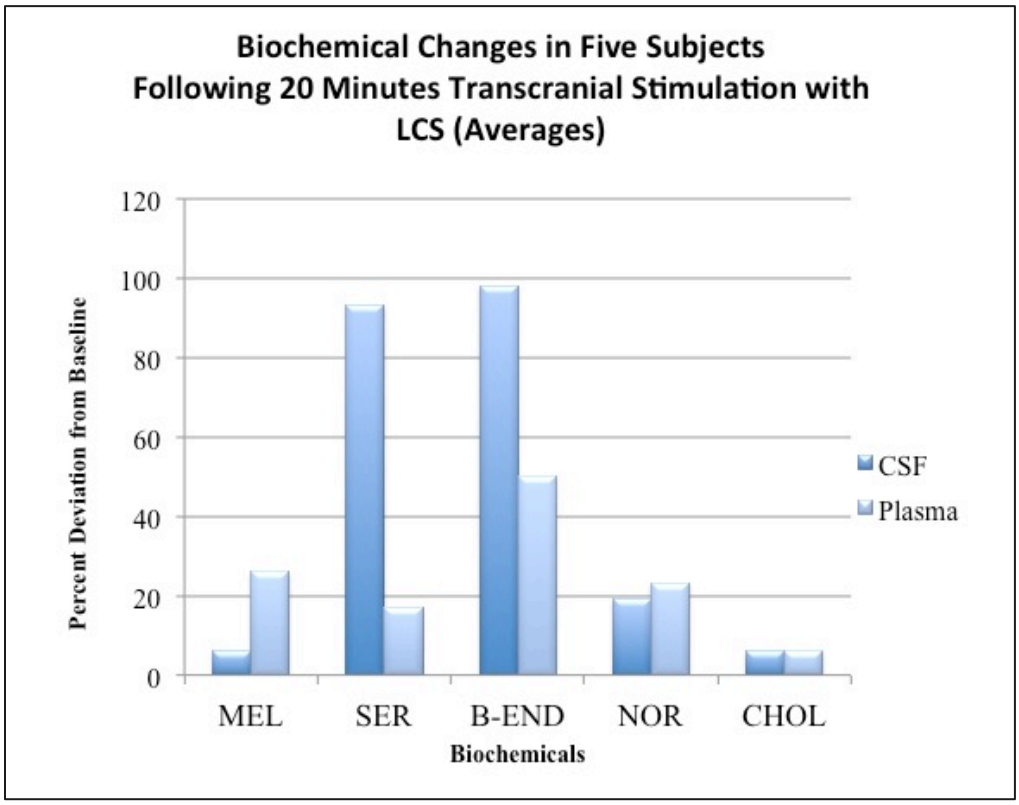


Figure 7. Cerebral Spinal Fluid & Blood Plasma Tests

A study was done in 1985 by William J. Closson, Ph.D., which indicated that the best conventional TENS device did not cause the significant changes in blood plasma neurobiochemical levels, noted above. These differences were presented at the Fourth International Montreux Congress on Stress, S. Liss-1992, (Closson, 1992) Figure No. 8.

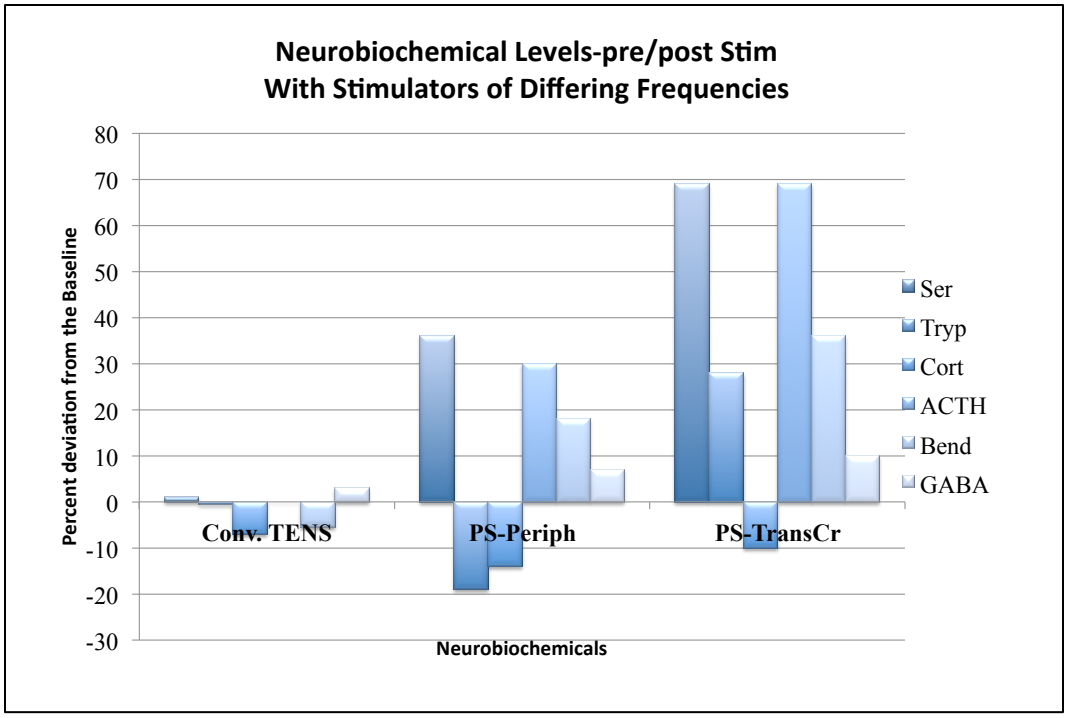


Figure 8. Neurobiochemical measurements following stimulation with devices of differing waveform.

The principal neurobiochemicals measured to date include:

	Substance	Alteration	Measured in Plasma	Measured in CSF
A.	Serotonin	Increases	x	x
B.	Beta Endorphin	Increases	x	x
C.	Tryptophan	Decreases	x	
D.	Cortisol	Decreases	x	
E.	ACTH	Increases	x	
F.	GABA	Increases	x	
G.	DHEA	Increases	x	

The implications for each of these neurochemicals are:

	Substance	Implications
A.	Serotonin	1. Mood management 2. Pain Tolerance 3. Insomnia Symptom Reduction 4. Cardiovascular Control
B.	Beta Endorphin	Endogenous Morphine-like biochemical
C.	Tryptophan	Precursor to Serotonin
D.	Cortisol	Systemic Relaxation
E.	ACTH	Hypothal./Pituitary/Adrenal Axis
F.	GABA	1. Neural Inhibitor 2. Involved w/ Spasticity Reduction
G.	DHEA	1. Principal Neurochemical in aging 2. Involved w/ Immune System 3. Involved w/ Endocrine System

Table 1. Neurobiochemical changes following Electrical Stimulation with the LISS Stimulators and implications thereof.

The next consideration in understanding the mechanisms of neurotransmitters in the body relates to the precursors of some of the critical neurobiochemicals:

	Neurobiochemical	Precursor Amino Acid
1.	Serotonin	Tryptophan
2.	Dopamine	Tyrosine
3.	Norepinephrine	Tyrosine (via Dopamine)
4.	Epinephrine	Tyrosine (via Norepinephrine)
5.	Acetylcholine	Lecithin

Table 2. Neurobiochemicals and associated precursors

V. Data summation and Analysis:

A. Standard screen:
The original intent of evaluating the neurobiochemical levels was Dr. Shealy's desire to explore the foundation of pain control. Therefore, the following screen was chosen:

1. Serotonin (Pain tolerance, depression, Insomnia)
2. Beta-Endorphin (Pain Control, Sense of Well Being)
3. Cortisol (Systemic Relaxation with decrease)
4. ACTH (Anti-inflammatory, Balance of HPA Axis)

Over the years, 92 normals have been measured for changes in Serotonin and Beta-Endorphin while 73 have been assayed for Cortisol and 78 for ACTH. Figure 9. shows the information noted herein.

Figure 10., Figure 11., and Figure 12. show patients with various pathologies also screened with the same protocol but with dysfunctions of Pain, Depression, Multiple Sclerosis, and Dental Restorative pain. Figure 10. Shows he effect of the modulated electrical stimulators on 23 Pain Patients, 11 Depressed Patients and 14 Normals, for comparison. Figure 11, shows the stimulators' effects in changing the plasma levels of ACTH for as Multiple Sclerosis Patients, and on 10 Normals (5-Active; 5- Placebo). Figure 12. shows the beneficial effects on 22 Dental patients who had been initially treated with transcranial stimulation to enhance the basic screen of neurobiochemicals prior to the restorative process. Please note that following the preparation for the cavities, the neurobiochemical levels basically were reduced from the effect of the procedure imposing pain on the patient. It is interesting to know that the neurochemical levels did not return to the original baseline but were considerable higher than the original baseline for both serotonin and beta-endorphin, the premier neurochemical s associated with the pain management process. We opine that the postoperative benefit in pain control (approximately 4 hours) was due to the fact that the pretreatment cranial application of the modulated electric stimulators created the elevated levels of both serotonin and beta-endorphin which gave rise to the prolonged benefit following the dental procedures.

Over the years 140 normals have been measured before and after active device stimulation with various neurobiochemical assays while 18 additional tests were made on normals before and after placebo device treatment. The same type of testing was done on patients with: Multiple Sclerosis, Pain, Depression, Headache, Diabetic Neuropathy, Dental Restorative procedures. 252 patients were treated with an active device and 14 patients were treated with a placebo device.

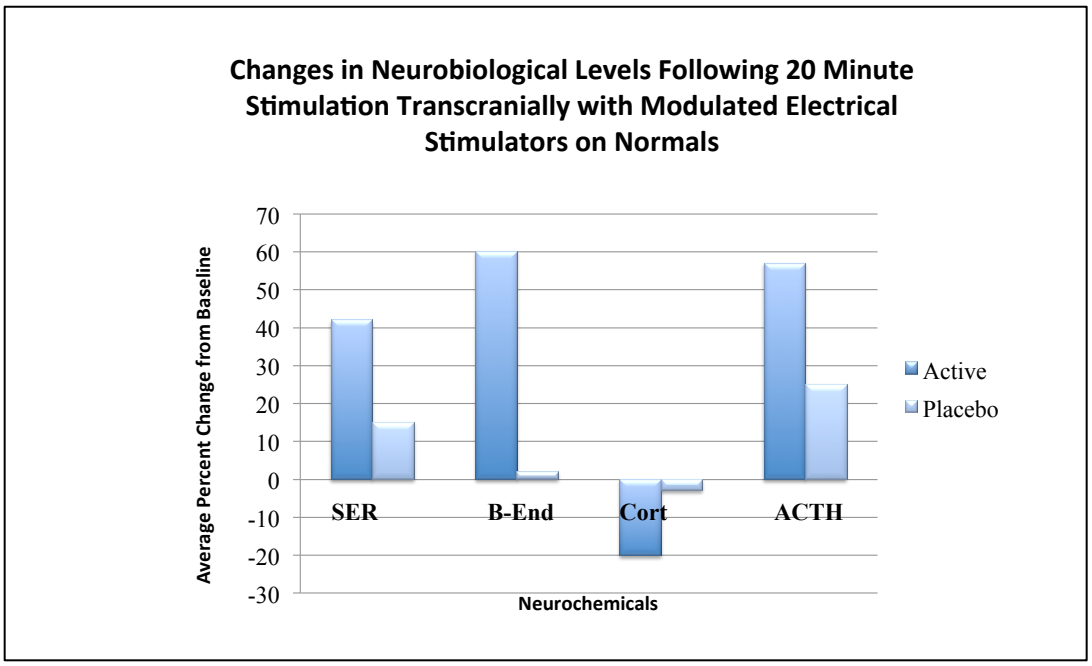


Figure 9. Analysis of normals tested with either active or placebo modulated electrical energy stimulators

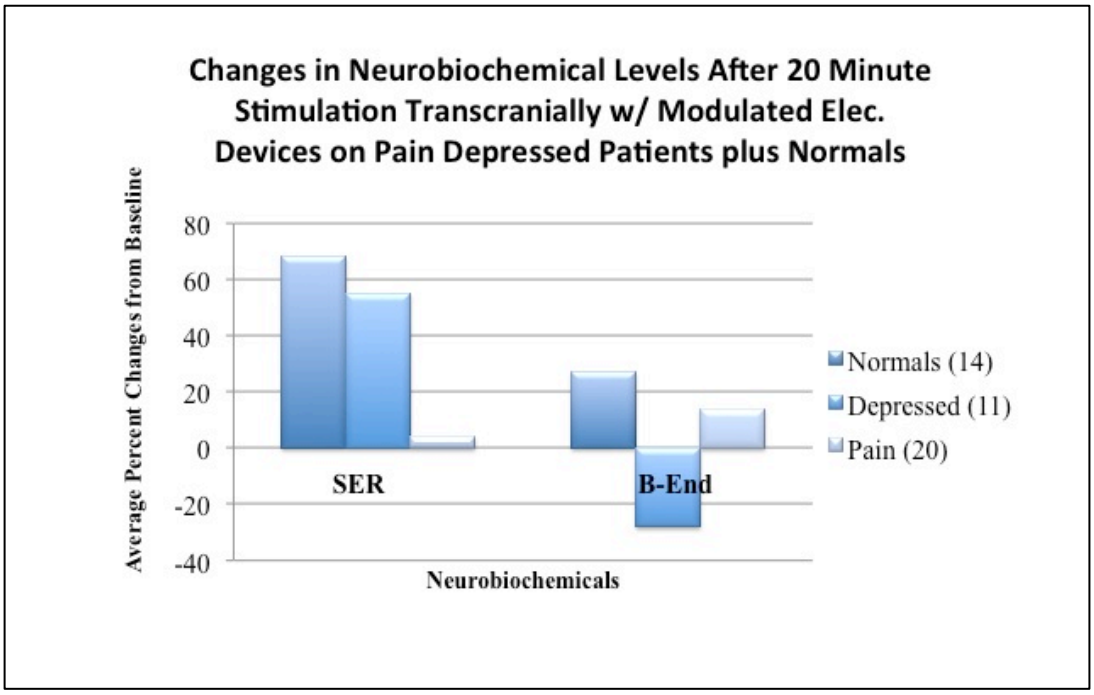


Figure 10. Showing stimulation with modulatd electric stimulators on patients with Pain and Depression compared to Normals.

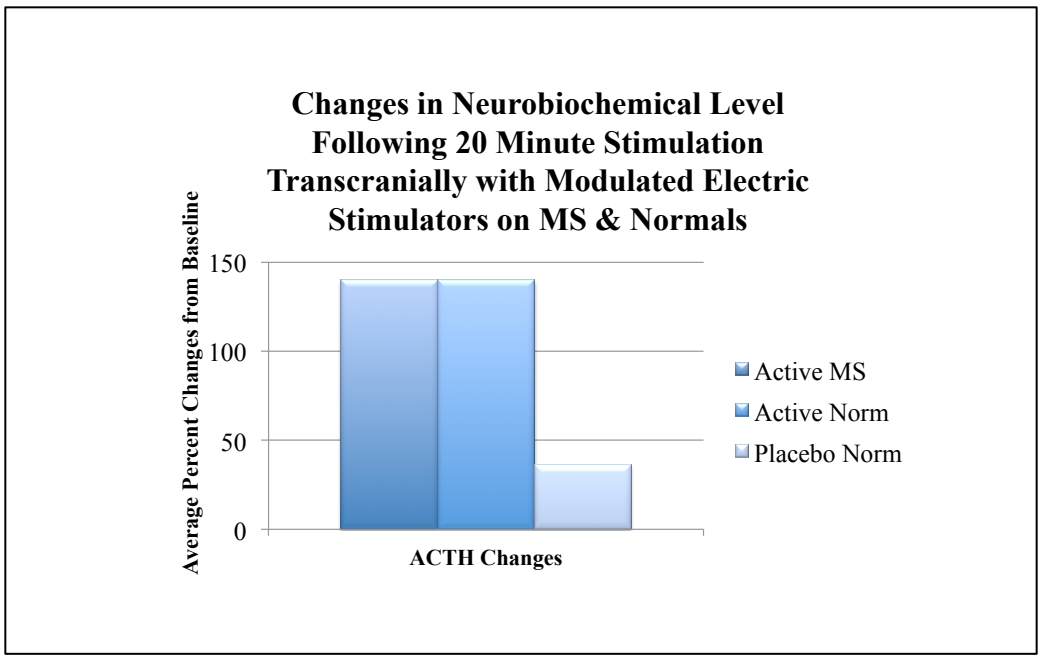


Figure 11. ACTH changes following stimulation with modulated electric stimulators on patients with Multiple Sclerosis compared to Normals.

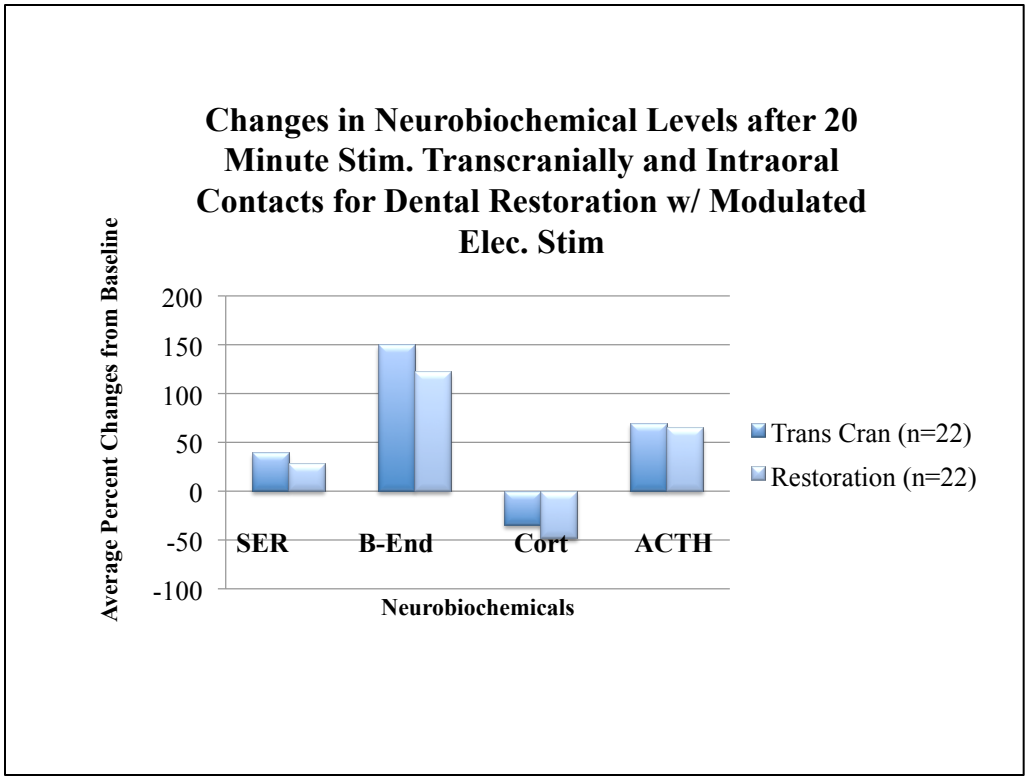


Figure 12. Comparison between the levels of neurobiochemicals resulting from transcranial pre-treatment with modulated electric stimulators compared to those levels following dental restorative procedures. Note that the imposed pain reduced the levels of serotonin, beta-endorphin and ACTH.

VI. Discussions

It has been shown that the tissue of the body contains electrical characteristics, which can be utilized to help the body help itself. Since the alteration of certain neurobiochemicals in the body and head can have a salutary impact on reducing the symptoms of depression, anxiety, insomnia, and pain the consideration of whether an electrical device can also alter the level of the same neurobiochemicals that specific drugs attempt to manage. If drugs work for the particular patient, then the physician in charged his/her patient would do well to use them. However, there are a significant number of patients with the pathology associated with depression, anxiety, insomnia, and pain for whom the drugs are not adequate. Their bodies and organic systems frequently are allergic or are overly sensitive to some of the side effects or drug inter- action dysfunctions unique to that particular person. For those types of patients, the capability of the modulated electric energy stimulators may be a viable alternative. It is for them and their responsible, caring physician that this presentation is dedicated.

VII. Conclusion:

The use of Double Modulated Cranial and/or Body Electrical Stimulators can utilize the body's bulk capacitance to cause an internal current to flow. That internal current, flowing through its own resistance, can increase a voltage, which may be able to facilitate triggering energy of a neural system. Tests have also confirmed that certain neurobiochemical levels have been altered following the use of the subject double modulated electrical nerve stimulators. Those measured include the following:

A. Serotonin
B. Beta-Endorphin
C. Cortisol
D. ACTH
E. GABA
F. DHEA
G. Neurotensin
H. Human Growth Hormone

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