Varhope charging the batteries

WARNING!
This book contains provocative material not for children or the sexually immature

V oltage  | a mperage  | r esistance  | H ydration  | o xygenation

| pH - p roton pressure | Eh - e lectron pressure |

ISBN 978-615-5169-17-5 VARHOPE (Voltage, Amperage, Resistance, Oxidation, Hydration, Proton and Electron pressure, the body electric’s vital signs)
Clinical and Scientific Evaluation of 
Charge Stability and the SCIO 
by Dr Desiré Dubounet Professor Emeritus of IMUNE

INTRODUCTION

In 5th grade we are all taught a basic scientific fact, we are made of atoms. All things are made of atoms. Atoms are made of electrons, protons, neutrons, and other much less numerous subatomic particles. The electrons and protons make up by far most of things and thus most of our bodies. The electrons and protons are electrically charged. The electrons are so highly charged that they never touch but instead repel when they approach another. The electrons, protons, and neutrons are very small and they are held apart from each other by fields. If we condense the solid matter of the electrons, protons and neutrons together the human body would be so small it would take a microscope to see it. If the proton is the size of a golf ball, the electron is smaller than the size of the point of a pin and it is over a mile away. Between the electron and proton thus is electro-magnetic-static fields, held by Quantic forces. So our bodies are more than 99.99999999999999999999999 fields empty of matter. These Quantic electro-magnetic-static fields are what we are. This is 5th grade science.

Noone has yet to see the true nature of our existence. Noone can see the electrons, protons, or the fields they make. So we are only able to see a macro form of it. Our brains are trapped inside our skull and thus we cannot directly perceive anything. We are thus stuck with an indirect perception. A perception that comes thru the brain and is effected by our own internal brain state and personal bias. We project our own feelings, memories, psychic mental states onto our perceptions. It is difficult not to. So as humans developed we have made many assumptions of how the universe works, what is the nature of our bodies and lives, and our belief in a power greater than our own. And with a sense of history and knowing that we must project, and twist ideas, we should always be humble and recognize that we can never know. We are stuck making good guesses, better and better guesses, but always guesses. Science is the art of further developing the guess of our true nature.

In 9th grade we are taught about light. Light is made of photons. Photons are electro-magnetic radiation, particles in wave formations that can transfer energy. Quantum Electro-Dynamics QED tells us of how when a electron absorbs a photon the electron goes to a higher quantum energy state. When the electron releases a photon it goes to a lower state. QED tells us of virtual photons and just how all electron, proton, neutron movement is connected to the photon.

Voltammetry is the science of understanding how a substance's electro-magnetic field reacts with its environment. A hormone has electrons and protons and how they are placed in a 3 dimensional space will determine how it exchanges electro-magnetic action and this is measured by measuring the 3 dimensional effect of it voltammetric field. The amount of charged particles is the amperage, the pressure or potential of the charged particles is the volts. Basic 7th grade physics. Every compound having its own individual and distinct voltammetric signature field.

There are other forces such as the large atom force that when the extreme energy in a sun forces protons to overcome their need to repel and forces them together. Thus all atoms past hydrogen and helium are made in the stars. Gravity is the force that draws matter together. This is a weak force, as Newton once said "It takes a group of matter the size of the earth to make a liter of water weigh a kilo".

There is another weak force that is undeniable, the power of the mind. We know from Quantum theory that twin photons can be separated to any distance and when we tell one photon something, the other twin knows it instantly. At the birth of the universe there was a big bang where all of the matter of the universe came through a singularity in ten to the minus 43 of a sec. Thus at one point in our past history all things were conjoined and as such there is an ability of a quantic system to influence another. The observer effect of physics, the need for a double blind in medicine, subspace mathematics and other evidence proves this. There is not a law of Attraction as some have said but there is an effect of Attraction. There is a power of the mind (a known Quantic engine) to influence another Quantic system. Science has for a long time laughed at this and has purposefully avoided the proof of this true effect. And now science has become a search for funding not a search for truth. And since humiliation might interfere with funding most scientists still ignore the evidence.

So with some simple science taught in our schools let us analyze the development of biology. First our fifth grade science tells us we are mostly electro-magnetic-static and Quantic fields. Non-living things mostly obey the laws of thermodynamics. The laws of thermodynamics teach us that energy cannot be created or destroyed, and that heat must flow from a hot body to a cold body. The hot coffee must succumb to the colder room and the two gradually equate their temperature.
Biological systems outwardly disobey these laws by maintaining a temperature difference and not succumbing to the room temperature unless they die. Then as the Washington Post editor says, after death a person loses their battle with room temperature. Biology is using a slightly different system of laws with a more quantic system than thermodynamic.

A living thing must be able to metabolize and reproduce in some fashion to be considered alive. All of life is based on the transfer of energy from photons to electrons of atoms, acceptance of the free protons of water, oxidation and reduction of the electrical particles of life. Life is an electrical process. Metabolism is taking in nutrients, taking the photonic or electrical energy from them, and excreting the remainder as excretions of waste products. Reproduction is assembling new tissue for repair and also to propagate the species. The energy is Quantic electro-magnetic-static in nature as is everything. The basic energy of the electromagnetic radiation that is Visible light or Infrared heat. Plants take in low energy ionic bound minerals and use the energy of visible light to make high energy covalent bound plant compounds which are then food for the animals. This is the process of photosynthesis as shown in the Calvin Cycle.

Animals take in the high energy compounds of sugars / carbohydrates with electrons in high energy states. This electron energy is then gleaned in the cells via the Krebs Cycle to make ATP (Adenosine Tri-Phosphate) for energy. ATP is the key energy of most life. The master equation of life shows the key nature of the electrical / photonic energy exchange. The single cell systems such as bacteria set up a boundary layer such as a cell membrane to separate the thermodynamic world from the quantic interior. Entropy and thermodynamics dictate process in the non-living exterior versus the Quantic organized non random entropy interior. Metabolism and reproduction guided by an organized accounting of energy intake and outgo. Geared for metabolism and reproduction. Quantic Electromagnetic fields in cyclic organized fashion that is mostly dependent on the Quantic actions of DNA. DNA can only be described in the Quantic electromagnetic actions of the fields of it voltammetric structure.

Single celled organisms develop or evolve into multi celled organisms. This needs more complex DNA structures and the number of chromosomes needed grows. DNA acts as the chief accountant as it sends off RNA and messenger RNA to accomplish the goals of life. Life develops with tremendous diversification over 100,000,000 organisms have evolved with various and diverse functions. But all are Quantic electromagnetic exchange devices taking in energy, excreting waste products, and trying to reproduce. Everything having it’s own set of field intricacies, and a single reactive ever changing overall field signature. The Quantic Electro-magnetic-static field of an organism is reacting towards nutrition and away from toxins. To maximize metabolism. It reacts to mating signals and reproductive gesticulations to maximize reproduction.

The multi-celled organisms diversify and all have an innate non-verbal Quantic electro-magnetic drive for survival. Biology operates thru field interactions. The height of DNA diversification is presently the development of a word area of the brain, where we think in words. This allows for explicit verbal communication and explicit exchange of thoughts, feelings, desire, fears, etc. There are over one hundred trillion cells in the human body and all are sending signals to the brain via enervation and photon exchange. Making some ten to the 16 bits of data a sec. Or less. 1,000,000,000,000,000,000,000. The word area of the brain has developed as a small part of the human brain. About the size of a golf ball this Broca area is for words. Words coming in and words going out. The rest of the Brain is for life, metabolism and reproduction. Life is an unconscious process. Life is non-verbal. We do not have to think words to live. Words are for helping us function in social ways.

We have a reticular formation in the base of our brains that act as a filter to screen out unneeded data from our word area. The word area has the ability to assay about one million 1,000,000 bits of data at a time. More and the word area goes into overload. Below one thousand sensory bits and the system goes into sensory deprivation mode. It invents sensory data. This means that ten to the sixteenth bits of data minus the ten to the 6 bits of data for the word area and the word are of the brain gets one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of the data sent to the brain. The unconscious non-verbal body electric gets all of this data and much more.

The spiritual cultures of the world know this and all exercises in spiritual development revolve around diminishing the words in the brain and coming aware more of the unconscious process. Mantras, meditation, stillness, yoga, kundalini, and many others all say we must control and diminish to effects of the verbal word mind to get in touch with our body energetic-electric. The true self.

Much of the mistake of modern science and modern societies is to over value the words and the verbal process. Our society is presently over valuing the paper pushers and letting their need for words be more important than people. We need paper pushers and we need to have quality systems but there should be a requirement to try to minimize the over wordy and clarify the process of our society for everyone to understand not just the small minded paper pushers. This is especially true for biology and medicine.

The very process of life in an innate unconscious non-verbal Quantic electromagnet field interaction. Words have little to do with it. But so-called modern medicine has overvalued the words. They wait for the patient to verbally notice something is wrong, go to the doctor office and announce what is wrong, answer the doctors’ verbal questions, and receive verbal instruction. And yet this verbal exercise of medicine is only aware of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of the data. The body electric knows much more.
Patients’ words are influenced by their mood state. Patients all lie, at least that is what Dr. House tells us on TV. Patients sometimes say things they think the doctor wants to hear, they cover up things they don’t want the doctor to know and very often they are completely out of touch with their own feelings and symptoms. Once I asked a patient if they had regular bowel movements. She said of course once a week like clockwork. Words are often the only intervention given to a doctor. In ancient China the doctor was sometimes unable to see the patient if he was royal. So the Chinese doctors had to develop new skills. Words have been a hallmark of medicine but it is also one of the greatest limitations. You can be really sick and have no symptoms or any verbal awareness of your sickness. Many people have tended to not only over value words, but some assume falsely there are only words.

Dr. Hans Selye has developed a new style of medicine where stress (in it many forms) constitutes the cause and or aggravation of all disease. Our white paper on stress and Selye’s principles outlines this more thoroughly. Stress allows disease to form and weakens natural defenses against the development of disease. Stress complicates the electrical balance of the homeostasis of the body. All stress is electrical stress. (The White paper on stress reduction is published in the journal)

This little intro makes three valuable points for medicine and biology. First, all things are electrical in nature and so is biology. Thus medicine needs to pursue a more dramatic effort to use electrical measures and electrical therapies. And second, the word area of the brain is often over-valued when it is just a small small part of the system. Third, stress reduction is a major part of medicine and has been undervalued in the past. The ICD 10 list Acute Stress as a disease and gives it a diagnostic number 43. What is acute versus non-acute is not up to anal retentive regulators but only up to qualified medical field personal on an individual basis. Biofeedback devices such as the SCIO are listed in the CPT manual as therapy for stress.This edition of the International Journal of the Medical Science of Homeopathy is dedicated to the presentation and review of the recent articles on the SCIO system and its use in stress reduction. We will present articles on Kirlian photography, Charge Stability, Redox potential, Stress Reduction all on the SCIO system.

The basic body electric parameters of Voltage, Amperage, Resistance, Hydration (as a variance of capacitance), Oxidation (as a variation of inductance), Proton Pressure, and Electron Pressure constitute the VARHOPE. This is first reviewed in the 1995 article in the International Journal of the Medical Science of Homeopathy. The body needs these electrical parameters to exist and perform any function. The first study presented in this Journal is an article on the scientific review of the electro-physiological processes of the body and how they can be measured and corrected with simple biofeedback and micro-tens treatments.

The EPFX device was first registered in America and was designed to measure these electrical indices. As the technology shifts to the QXCI and then to the SCIO there is a constant development of increased speed, accuracy, and effectiveness of these biofeedback units to measure and correct the body electric. The first published studies done in the late eighties and early nineties all point to effectiveness. A therapist in Germany remarks how the SCIO can make changes in a patient visible in just one session. In his experience he can take most any patient and measure their basic wellness and after just one session see measurable improvement. This leads us to the following series of experiments.

Clinical Study 1 Kirlian photography as a Measure for VARHOPE

Dr. Radu Stefan

A Romanian doctor used a kirlian photograph unit to do a test of the electrical systems validity. This Kirlian imagery device immerses the patient in a safe electrical plasma that can accentuate the presence of free electrical energy. Thus a type of electrical aura can be seen. Whatever you think of this technique and it’s somewhat bizarre claims, it is undeniable that it is showing a reflection of the electrical field in certain areas of the body. He took pictures before and after chiropractic, acupuncture, and massage therapies. There was little change. But the pre post pictures of the SCIO system show an undeniable electrical change.

We report these findings and photos as preliminary speculative evidence of the proposed effect of the SCIO on the body electric.

In his pre and post pictures there are very astounding changes in the body electric shown by the Kirlian photography. This proves that the SCIO system is capable of producing and increased electrical field around the human. There was no double blind or use of a standard measure, so a new experiment was needed to be designed. We need to measure more critically the effect.
Varhope charging the batteries
Varhope charging the batteries
Varhope charging the batteries
Varhope charging the batteries
Varhope charging the batteries

Year of birth: 1938

10.02.2003 16:19

1L 10.02.2003 13:32
1R 10.02.2003 13:32
2L 10.02.2003 13:32
2R 10.02.2003 13:32
3L 10.02.2003 13:32
3R 10.02.2003 13:32
4L 10.02.2003 13:32
4R 10.02.2003 13:32
5L 10.02.2003 13:32
6 10.02.2003 13:32
7 10.02.2003 13:32
8 10.02.2003 13:32
9 10.02.2003 13:32

10.02.2003 16:16

1L 10.02.2003 15:16
1R 10.02.2003 15:16
2L 10.02.2003 15:16
2R 10.02.2003 15:16
3L 10.02.2003 15:16
3R 10.02.2003 15:16
4L 10.02.2003 15:16
4R 10.02.2003 15:16
5L 10.02.2003 15:16
6 10.02.2003 15:16
7 10.02.2003 15:16
8 10.02.2003 15:16
9 10.02.2003 15:16
Clinical Study 2

In Toronto, Canada a SCIO therapist did an evaluation of 100 patients of before and after VARHOPE readings. The results (published in this journal) showed significant changes after a two week therapy session.

Clinical Study 3

VARHOPE Large scale study.

This study demonstrates the safety and effective qualities of the SCIO device used in a large scale study. A large scale study of over 97,000 patients with over 320,000 patient visits reported their diseases. The SCIO measures global electrical measures of the body. When there are abnormal measures of the electro-physiological factors, the device allows a feedback loop between the Central Nervous System (CNS) of the patient and the device. Of the patient visits listed some 50 plus % (55,921) showed very low electro-physiological factors, below 30% normal. The cybernetic electro-physiological feedback loop was then used to help the patient reduce stress and thus improve the electro-physiological factors. There was improvement in over 95% of the electro-physiological measures at the end of the session (post test) versus the pre test. The average improvement in electro-physiological VARHOPE factors is 5%. These patients reported stress reduction and improved well being as well.

Clinical Study 4

Verbal report of stress reduction

As we reported in the introduction, many people over value and over rate the verbal mind. They might even think that it is all. At any rate a second test was designed to evaluate stress reduction over a three month period by using a verbal assay of the stress of the patient. The verbal mind is only aware of very little of the body’s activities and is easily confused and prone to suggestion.

A study of 240 patients, over a three month period started with a verbal questionnaire using the Beck’s Stress inventory. A placebo group was designed and the test sites of Speyer, Germany and 5 test sites in Italy were chosen. Under medical doctor supervision the intervention was a series of treatments with the SCIO or the placebo device.

This study had two main flaws. 1. There was no site study supervisor to properly determine that the placebo device was fully disabled from the active software. Later analysis determines that there was confusion and perhaps no placebo was used. 2. The study used only verbal subjective measures and was not properly designed to measure electro-physiological or medical data.

The study results showed no difference from placebo group to treatment group. There was 62.5 percent improvement in both groups. This is a significant improvement over no intervention. Most people do not improve such after 3 months of stress therapy. So there were results. But since there was no guarantee of an established placebo group a fourth study was conducted.
A double-blind placebo-controlled study of the application of Eclosion EPFX/SCIO therapy for stress reduction clinical study protocol

Dr. Gianfranco Amaduzzi  
Bologna, Italy

Luigi Maselli  
Bari, Italy

Rossella IanTorno  
Milano, Italy

Giuseppe Mauger  
Catanid, Italy

Dr. Rainer Mutschler  
Germany

Kathrin Sollner,  
Germany

2008 Ethics International

PURPOSE OF STUDY

The purpose of this clinical study is to determine the efficacy of the ECLOSION Electro Physiological Feedback Xroid (EPFX)/Scientific Consciousness Interface Operations System (SCIO) device, manufactured by ECLOSION KFT (the Company), in stress reduction by introducing low-level electromagnetic frequencies into an individual's body through electrodes attached to the person's wrists, ankles, and forehead to balance or harmonize and return to normal the optimal frequencies at which the body's cells and organs should resonate. This enables the body to strengthen, heal and expel the pathogens that propagate stress and its associated 'unwellness', consequently reducing stress and improving general health and function.

EXPECTED RESULTS

Following completion of the treatment phase with the ECLOSION EPFX/SCIO, it is anticipated that the subjects in the test group, relative to subjects in the control group, will show, where applicable:

• a reduction in systolic and/or diastolic blood pressure reading at rest.
• decreased resting heart rate (fewer beats per minute)
• a decreased score on the Perceived Stress Scale (PSS), implying a reduced level of overall stress.
• decreased scores on one or more of the six mood factors of the Profile of Mood States (POMS) Standard questionnaire, implying improved mood states.
• decreased scores on the State and/or Trait Anxiety scales on the Spielberger’s State-Trait Anxiety Inventory (STAI), implying reduced anxiety levels and/or improved reactions to anxiety.
• a decreased score on the Beck Depression Inventory-II® (BDI-II®) implying reduced levels of depression.
• some degree of satisfaction with the overall study outcome.
• maintenance in improved outcome measure ratings at the one-month post-treatment phase measurement time point.

For subjects in the control group, it is expected that there will likely be some improvement in measured variables. That is, subjects in the control group will likely report some of the positive changes listed above for test group subjects. However, on average, any positive change in post-treatment measures for control subjects is expected to occur to a significantly lesser degree than for subjects in the test group.

This study will be a double-blind, placebo-controlled, randomized clinical trial designed to demonstrate safety and effectiveness of the Eclosion EPFX/SCIO.

TREATMENT GROUPS

There will be two subject groups in this clinical study, with as close as possible to an equal number of subjects assigned to each of the two groups, as follows:

Test group: Subjects in the test group will receive the actual study treatment with an active, operational harness.

Control group: Subjects in the control group will receive a ‘fake’ study treatment with a placebo
The Perceived Stress Scale (PSS) is a global measure of perceived stress that assesses the degree of stress as indicated by a total score of 25 or greater on the Perceived Stress Scale. Individuals in this study will be males and females who present with elevated levels of perceived stress as indicated by a total score of 25 or greater on the Perceived Stress Scale.

**Population:** Individuals with Elevated Levels of Perceived Stress

Individuals in this study will be males and females who present with elevated levels of perceived stress as indicated by a total score of 25 or greater on the Perceived Stress Scale.

The Perceived Stress Scale (PSS) is a global measure of perceived stress that assesses the degree to which situations in an individual’s life are appraised as stressful. The subject is asked to indicate how often he or she felt or thought a certain way regarding 14 items, following a 5-point Likert scale from 0 to 4, as follows: 0 = never, 1 = almost never, 2 = sometimes, 3 = fairly often, 4 = very often. The PSS total score is obtained by reversing the scores on seven positive items and then summing across all 14 items, for a possible total of 56.

The PSS was designed for use with samples with at least a junior high school education. The items are easy to understand and the response alternatives are simple to grasp. The questions are general in nature such that they are relatively free of content specific to any sub-population group.

Validation data for the 14-item PSS was collected from three samples: two groups of college students and one group of individuals enrolled in a smoking-cessation program. Mean scores on the PSS complete samples ranged from 23.18 to 25.0. There was no statistically significant difference in mean PSS score between males and females, and age was found to be unrelated to PSS in all three samples.

Statistical evaluations found the PSS to have adequate internal and test-retest reliability and to be correlated in the expected manner with a range of self-report and behavioral criteria.

Additional information, including the complete PSS tool, can be found in Appendix C of this clinical study protocol. This includes the original article evaluating the scales, as follows: “Cohen, S., Kamarck, T., and Mermelstein, R. A Global Measure of Perceived Stress. Journal of Health and Social Behavior, 1983, Vol. 24 (December): 385-396.”

- Able and willing to maintain regular and consistent diet, exercise and lifestyle regimens throughout the study.
- Able and willing to maintain current medication regimes throughout the study.
- Able and willing to abstain from partaking in treatments – conventional or alternative (such as hypnotherapy, acupuncture, massage therapy, etc.) – or over-the-counter or prescription medications, including herbal remedies, designed to reduce stress throughout the study, other than the EPFX/SCIO treatment that is part of this study.
- Between 18 and 65 years of age.
- Male or female.
- Females on adequate birth control or not of child-bearing years.

**EXCLUSION CRITERIA**

A subject will be considered ineligible for participation in this clinical study if he or she satisfies any one or more of the following exclusive conditions criteria.

- Total score of less than 25 on the Perceived Stress Scale.
- Stage 2 Hypertension (elevated blood pressure), defined by a systolic blood pressure level of 160 mmHg (millimeters of mercury) or higher OR a diastolic blood pressure level of 100 mmHg or higher, measured using a sphygmomanometer and averaged across three seated (resting) blood pressure readings taken at 10-minute intervals. The first measurement will be recorded after the subject has been at rest (seated) for about 10 minutes. The source for the Stage 2 Hypertension criteria is the Seventh Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, American Heart Association.
• Subjects taking antihypertensive (blood pressure lowering) drugs.
• Tachycardia, Bradycardia or Irregular Resting Heart Rate, defined as follows:
  • Tachycardia: rapid or increased resting heart rate of greater than 100 beats per minute.
  • Bradycardia: abnormally slow resting heart rate of less than 60 beats per minute.
  • Irregular Resting Heart Rate: Irregular pattern of beats wherein beats are consistently missed across a 60-second period.

Resting Heart Rate - the number of times the heart beats per minute - will be measured at the wrist (radial artery), using the manual palpation method to feel the pulse - the rhythmic expansion and contraction (or throbbing) of an artery as blood is forced through it by the regular contractions of the heart. It is a measure of how hard the heart is working. Heart rate through measurement of the pulse at the wrist will occur as follows:

1. The palm side of the subject’s right hand is faced upwards.
2. The investigator places his or her index and middle fingers on the wrist, approximately ½-1 inch below the base of the hand.
3. The investigator presses his or her fingers down in the groove between the middle tendons and the outside bone until a throbbing sensation - the radial pulse – is felt.
4. The investigator counts the number of beats that occur in 60 seconds, using a watch with a second hand or digital second counter for accuracy.

Resting Heart Rate will be taken after the subject has been seated for 10 minutes. The subject’s final recorded pre-treatment heart rate will be the average of three consecutive measurements, each taken about 5 minutes apart.

• Generalized Obesity, defined by a Body Mass Index (BMI) of 30 kg/m² or greater, according to the World Health Organization (WHO) and Center for Disease Control (CDC) criteria.
• Significant major stressful life events in the past 3 months likely to impact not only emotional but also physical health and wellness, defined by a score of 200 or greater on the Life Events Questionnaire (LEQ). The LEQ is contained in Appendix D.
• Significant major stressful life events known or anticipated to occur during the course of the study (i.e. the upcoming 3 months), defined by a score of 200 or greater on the Life Events Questionnaire, answered for known upcoming events such as a wedding, retirement, home move, etc.

Type 1 diabetes.
• Any known heart condition(s), such as cardiac arrhythmias, congestive heart failure disease, myocardial infarction.
• Prior cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers.
• Seizure disorder or family history of seizure disorder.
• Serious medical illness or condition: cancer; HIV, anorexia/bulimia.
• Serious head trauma.

PRE-TREATMENT PHASE

The purpose of the pre-treatment phase is to record baseline measures against which post-treatment changes will be assessed, and to record demographic subject variables.

The following measures will be recorded during the pre-treatment administration phase:

Physiological Measures

1. Blood Pressure: Systolic and diastolic blood pressure will be measured in millimeters of mercury (mm Hg) using a sphygmomanometer. If the pre-treatment phase occurs on the same day as the study qualification evaluation phase, then blood pressure does not need to be measured again. If the pre-treatment phase occurs on a different day to the study qualification evaluation phase, then the subject’s blood pressure will be measured again at this time, three consecutive seated measurements, each ten minutes apart (as during the study qualification evaluation phase). Also as during the study qualification evaluation phase criteria, if the subject’s three-measurement blood pressure average falls into the category of Stage 2 elevated high blood pressure (defined by a systolic blood pressure level of 160 mmHg or higher OR diastolic blood pressure of 100 mmHg or higher), then the subject shall be disqualified from further participation in the study at this time.

Else, the subject’s blood pressure reading will be classified as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>Systolic (mm Hg)</th>
<th>Diastolic (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>less than 120</td>
<td>and</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120–139</td>
<td>or</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Stage1</td>
<td>140–159</td>
</tr>
</tbody>
</table>

2. Resting Heart Rate: Resting heart rate - the number of times your heart beats per minute - will be measured at the wrist (radial artery), using the manual palpation method to feel the pulse. The precise methodology is detailed in the study qualification evaluation section. If the pre-treatment phase occurs on the same day as the study qualification evaluation phase, then Resting Heart Rate does not need to be measured again. If the pre-treatment phase occurs on a different day to the study qualification evaluation phase, then the subject's Resting Heart Rate will be measured again at this time, three consecutive seated measurements, each five minutes apart, with the first measurement occurring after the subject has been seated at rest for about 10 minutes (as during the study qualification evaluation phase). Also as during the study qualification evaluation phase criteria, if the subject's three-measurement Resting Heart Rate average falls into the bradycardia, tachycardia or irregular categories, then the subject shall be disqualified from further participation in the study at this time. Else, the subject's Resting Heart Rate will be recorded as the number of beats per minute.

A Resting Heart Rate in the range of 60 - 90 beats per minute is considered in the normal range. The average Resting Heart Rate for a male is 70 beats per minute, and for a female is 75 beats per minute.

Quality of Life Assessment Measures

1. The Perceived Stress Scale (PSS): The 14-item PSS questionnaire will be administered during the pre-treatment assessment phase ONLY IF the study qualification evaluation phase has occurred on a different day. Else, the PSS score attained during the study qualification evaluation administration will hold at this time. If the PSS is re-administered during the pre-treatment assessment phase, also as per the study qualification evaluation phase criteria, if the subject's PSS total score is 25 or greater, indicative of excessively elevated levels of perceived stress, then the subject shall be disqualified from further participation in the study at this time.

Additional information about the PSS can be found in the study qualification evaluation section as well as in Appendix C of this clinical study protocol.

2. The Profile of Mood States (POMS) Standard: The POMS Standard is a factor-analytically derived inventory that measures six identifiable mood or affective states. The POMS is easy and quick to administer and score.

The POMS Standard is a self-report inventory that contains 65 items and takes about 10 minutes to complete. The items pertain to a series of mood states and the subject responds to each item based on how well each item describes his or her mood at the present time (right now). Each item is rated on a 5-point scale ranging from 'Not at all' to 'Extremely.' The complete POMS inventory is contained in Appendix E of this clinical study protocol document.

The POMS measures six identified mood factors:
- Tension-Anxiety
- Depression-Dejection
- Anger-Hostility
- Vigor-Activity
- Fatigue-Inertia
- Confusion-Bewilderment

The POMS Standard includes psychiatric norms derived from a sample of 100 individuals, college student norms derived from 856 undergraduates, adult norms derived from a group of 400 volunteers aged 18-94, stratified by age, gender and race according to the 1990 U.S. census. Since 1971, many research studies have provided evidence for the predictive and construct validity of the POMS Standard. Alpha coefficient and other studies have found the POMS Standard to exhibit a high satisfactory level of internal consistency, while product-moment correlations indicate a reasonable level of test-retest reliability. Factor analytic replications provide evidence of the factorial validity of the 6 mood factors, and an examination of the individual items defining each mood state supporting the content validity of the factor scores. Many recent studies continue to add to and affirm the validity of POMS normative sample. A bibliography of published research of almost 3000 research studies from 1964-2002 utilizing the POMS adds to and affirms the validity of the POMS normative sample and is available upon request.

3. Spielberger's State-Trait Anxiety Inventory (STAI): The State-Trait Anxiety Inventory (STAI) provides a reliable measure of both temporary and dispositional anxiety in adults. First developed by Charles D. Spielberger in the 1960s, the STAI was later revised in 1983. The revised STAI is typically referred to as the STAI-Y. The STAI is a self-administered test and it is the most widely used measure of anxiety worldwide, used in both clinical and research settings. It is suitable for adults at a 6th grade reading level or above.

The STAI consists of 40 items divided into two subscales or domains: State Anxiety and Trait Anxiety:

State Anxiety: assesses an individual's current level of anxiety – a more temporary state. The 20 items measuring State Anxiety ask subjects how they feel right now at this moment, and reflects situational factors that may influence anxiety levels. Subjects rate their feelings about each statement on a four-point intensity scale of 1=Not at all, 2=Somewhat, 3=Moderately So, and 4=Very Much So.

Trait Anxiety: assesses an individual’s anxiety proneness – a more general and long-standing quality of how an individual typically responds to stress. The 20 items measuring Trait Anxiety ask subjects how they “generally” feel. Subjects rate themselves on a four-point frequency scale of 1=Almost Never, 2=Sometimes, 3=Moderately So, and 4=Very Much So. Examples of items Trait Anxiety scale items are "I feel at ease;" "I feel upset;" "I lack self-confidence."

Scoring: State and trait anxiety are scored separately. Each item is scored from 1-4, for a total inventory score range of 20 to 80, where 20 equals ‘not feeling like that at all (state anxiety) or even (trait anxiety)’ and 80 equals ‘feeling like that very much (state anxiety) or always (trait anxiety).’ Essentially, the higher the score, the greater the level of anxiety. Both percentile ranks and standard (T) scores are available for male and female working adults and stratified by age.
There will be three during-study assessment time points, as follows:

- End of Month 1 (after the 8th study treatment)
- End of Month 2 (after the 12th study treatment)
- End of Month 3 (after the 14th study treatment)

At end of Months 1 and 2 assessment time points, the following measures will be recorded:

- Blood pressure: three-reading average
- Resting Heart Rate: three-reading average
- Perceived Stress Scale (PSS)

At end of Month 3 assessment time point, all of the measures recorded during the pre-treatment phase will again be recorded, as follows:

- Blood pressure: three-reading average
- Resting Heart Rate: three-reading average
- Perceived Stress Scale (PSS)
- Profile of Mood States (POMS) Standard
- Spielberger’s State-Trait Anxiety Inventory (STAI)
- Beck Depression Inventory-II (BDI-II)
- Analyzing Stress in the Body Subject Questionnaire

Regarding validity, correlations between the STAI and other common measures of trait-anxiety are as follows: the Taylor Manifest Anxiety Scale: .80; the IPAT Anxiety Scale: .75; and the Multiple Affect Adjective Check List: .52.

The STAI is contained in Appendix F of this clinical study protocol document. The STAI Manual is available upon request.

4. Beck Depression Inventory®—II (BDI®—II):

The Beck Depression Inventory®—II (BDI®—II) is in line with the depression criteria of the Diagnostic and Statistical Manual of Mental Health Disorders—Fourth Edition (DSM–IV). This new edition of the Beck Depression Inventory® is the most widely used instrument for detecting depression. It takes about five minutes to complete and is demonstrated to be highly clinically sensitive to measurement and change.

The BDI–II consists of 21 items that assess the intensity of depression in clinical and normal patients. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression, evaluated over the period of the past two weeks. It has been validated for samples aged 13-80 years.

Reliability: Internal consistency (Cronbach’s alpha) is .92 for clinical patients and .93 for non-clinical individuals. Test-retest reliability is .93.

Validity: Concurrent validity: two comparisons between BDI-II and its previous version resulted in correlations of .93 and .84, the latter using the take-home form. Other tests found BDI-II to be correlated with the Beck Hopelessness Scale (.68), Scale for Suicide Ideation (.37), Beck Anxiety Inventory (.60), Hamilton Psychiatric Rating Scale for Depression-Revised (.71), and Hamilton Rating Scale for Anxiety—Revised (.47).

Scoring: Most items on the BDI-II are rated on a 4-point scale ranging from 0 to 3. Several items have seven response options to discern differences in behavior or motivation. The BDI-II is scored by adding the ratings for the 21 items. The maximum total score is 63.

Clinical interpretation of total scores uses the following guidelines: 0 to 13 (minimal depression), 14 to 19 (mild depression), 20 to 28 (moderate depression), and 29 to 63 (severe depression).

The BDI-II is contained in Appendix G of this clinical study protocol document.
A subject adverse reactions and events sheet will be completed by the Principal Investigator. Any necessary action will be taken. More detailed information on this process can be found in the section below titled: "REPORTING OF ADVERSE REACTIONS AND EVENTS."

- **Additional Comments:** A subject or investigator may record any comments related to study participation at any time, as desired.

**POST-TREATMENT PHASE**

The post-treatment phase will occur two weeks (14 days) following the final treatment administration with the ECLOSION EPFX/SCIO at the end of month three.

The purpose of the post-treatment assessment phase is to gain a sense of duration of treatment effect beyond the cessation of the treatment administration period.

At the end of the two-week follow-up period, the following measures will be recorded:

- Blood pressure: three-reading average
- Resting Heart Rate: three-reading average
- Perceived Stress Scale (PSS)
- Profile of Mood States (POMS) Standard
- Spielberger’s State-Trait Anxiety Inventory (STAI)
- Beck Depression Inventory (BDI-II)
- Analyzing Stress in the Body Subject Questionnaire

**Discussion**

**Clinical Study 5**

A double-blind placebo-controlled study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO’s ability to increase Body Wellness after one 45-minute session

Gage Tarrant, Bart Keough, Jane Summers, Jill Caravalho, Gene Helton, Lynn Smith and Julie Craker in Seattle, U.S.A.;
Jacqueline Jacques, Jean-Pierre Turblin, Adrian Muresan and Anne Préau in Paris, France;
Dr. Codruta Bacean and Dr. Onut Bacean in Timisoara, Romania;
Dr. Rainer Mutschler and Kathrin Sollner in Speyer, Germany.
Dr. Danis in Budapest, Hungary

In this study there were conclusive results of electro-physiological improvement. This study was conducted at five sites of approximately 40 subjects in each.

Under medical supervision the study was conducted in Budapest, Hungary, Timisoara, Romania, Seattle Washington, Speyer Germany, and Paris, France. Thus there were over 200 patients in this medical study.

The SCIO can undo the damage by regulating and balancing the Body Electric’s Regulatory Processes + increasing VARHOP

If you need more information on the SCIO and purchase details please get in touch with us
Maitreya Kft.
tel: +3613036043 | web: www.qspubspace.com | e-mail: info@qspubspace.com
A host of wellness tests and electro-physiological tests were performed. The results showed significant results with the electro-physiological factors of the VARHOPE. Thus the SCIO was proven to have significant action in improving the electro-physiological field of a patient.

In a review of the results. Patients with dysfunctional wellness of flexibility, blood pressure, and other factors can be improved with just one session. This was a tendency that was not statistically shown at a 5 alpha level, but was seen in the data.

So after this series of experimental tests and evaluation we can conclusively conclude that the SCIO is

1. Safe (no report of any significant risk)
2. Effective at long term stress reduction
3. Effective at short term electro-physiological, charge stability and stress reduction
4. Effective at making short term wellness changes


Introduction

BACKGROUND: Stress is known to have many negative effects on multiple aspects of an individual’s life. Stress can affect an individual’s physical, cognitive, emotional and social well-being. We hypothesized that within one 45 minute biofeedback session, a measurable improvement in Body Wellness indicators can be achieved.

OBJECTIVE: To evaluate whether a 45 minute session with the SCIO biofeedback device affects an individual’s Body Wellness.

DESIGN: Randomized, double-blind, placebo controlled trial.

SETTING AND PATIENTS: 192 individuals with awareness of levels of perceived stress as well as injuries/pain, between 18 and 65 years of age, male or female, randomized into placebo and SCIO test groups, at private clinics at multi centered sites.

INTERVENTION: Subjects were randomized to the test group (a 45 minute SCIO biofeedback system session) or placebo (SCIO, Maitrey Kft. www.qxsubspace.com)

MEASURES: Pre and post measures as follows: Quality of Life Questionnaire, Energy Index Factor (systolic blood pressure left arm sitting + diastolic blood pressure left arm sitting x pulse), Grip Strength Test (measured in kilograms), Oxygenation Test, Flexibility Test (measured in inches in The USA and centimeters everywhere else), Memory Test, pH Test, VARHOPE scores (electrical measures within the device, as follows: voltage (V), amperage (A), resistance (R), hydration (H), oxygenation (O), proton pressure (P) and electron pressure (E)).

RESULTS: Patients in SCIO group had greater VARHOPE scores than those in placebo group (p<0.005). The other indicators of Body Wellness were not statistically significant, but there are trends in the improvement levels between the Test and Control (Placebo) groups.

CONCLUSIONS: The electrical parameters of VARHOPE can be improved by a 45 minute SCIO biofeedback session. However, it may require more SCIO biofeedback sessions for the other Body Wellness Indicators to be increased. Further studies are suggested.

Stress is known to have many negative effects on multiple aspects of an individual’s life. Stress can affect an individual’s physical, cognitive, emotional and social well-being.

Different applications of biofeedback have been shown to be effective on stress management and health. Biofeedback is usually combined with a relaxation technique, applied before, during or after the biofeedback training. Studies have evaluated the effectiveness of biofeedback combined with a relaxation technique, EEG Biofeedback, EMG Biofeedback, and HRV Biofeedback and found them to have positive results on reducing the stress burden and alleviating the conditions.

In the fifth grade we learned that our bodies are made of atoms. And atoms are made mostly of protons, neutrons and electrons. There are great spaces between these electrons and protons and other atoms. Our bodies are made up mostly of electrons and their electromagnetic fields. Here is a Hydrogen Atom.

In Hydrogen if the protons are like marbles, the electron is over a kilometer away the next atom’s electron is over 2 kilometers away, the next proton is over 4 kilometers away. So there is more than 99.999999999999% empty space. This space is filled with energetic fields. The electrons never touch each other so what we are made of is interacting electromagnetic fields.

Atoms are 99.999999999999% empty space and the empty space between atoms is just as or emptier 99.9999999999999999999% empty space. This space is filled with energetic fields. The electrons repel each other. Why don’t things pass right through things?

Things don’t fall through other things because they are levitating on an energetic electrostatic fields. When you sit on a chair, you are not really touching it. You see, every atom is surrounded by a shell of electrons. This electron cloud presents a rather negative face to the world. Remember that like charges repel each other. When two atoms approach each other, their electron shells push back at each other, despite the fact that each atom’s net charge is 0.

When two atoms come together and have empty spaces in their electron quantum shells, they will share electrons to fill in the spaces in both of their shells. The electrons really do go back and forth between atoms and they do so pretty fast. Outer Electrons tend to be kind of mobile, which is also a very nice feature of nature, since without it your walkman would not work or you would...
The SCIO is designed to correct the manifestation of stress and/or electro-stress patterns within the individual at the most primal of physiological levels. The device works on the theory that stress disrupts the inherent electromagnetic frequencies at which the body's cells, organs, etc. resonate and that by returning these frequencies to their natural state, the stress and any subsequent illness that occurred because of the disruption can be corrected.

The objective of the study was to determine if one 45-minute treatment with the SCIO would show a change, and hopefully an improvement, on a person's Body Wellness indicators.

Methods

- Study design

The study was designed as a randomized, double blind, placebo controlled study. The goal of the study was to analyze the changes in Body Wellness Indicators after one 45-minute SCIO session, so there was no follow up necessary days or weeks after the treatment.

All study personnel and participants were blinded to treatment assignment for the duration of the study. Only the study statisticians and the data monitoring committee unblinded data after the study sites are completed, but none had any contact with study participants, nor will they ever have contact with future participants.

Randomization was assured at each testing site by the one person organizing the subject scheduling prior to the study. As people called to schedule their appointments based on the Subjects availability, the Scheduler would randomly assign the subject to one group or the other depending on which room was available. None of the staff members involved in the clinical trial process were aware of what group/device was placebo and what group/device was real.

Each testing site was given two pieces of equipment - placebo equipment and actual equipment. The software operating the placebo devices is designed to look exactly as the one operating the real device, with no distinguishing differences. The difference is that the placebo harness was not equipped internally with functional electrodes and the programming for the placebo device output only blank matrices. Neither the actual (test) nor the placebo harness produced any detectable noise, heat, light or other sensation output, so this also wasn't a distinguishing factor for subjects or the investigator between the actual (test) and placebo devices.

To evaluate blinding, at the end of the session, both subject and investigator were asked to indicate which group they believed the subject to be assigned to (SCIO Test, placebo) and what led to that belief.

The study was completed in five testing sites on the following dates: Budapest, Hungary, 5-10 August 2009, Timisoara, Romania from 2-4 September 2009, Seattle, Washington, from 23 – 25 October 2009, Paris, France from 17-20 November 2009 and Speyer, Germany from 23 – 27 November 2009.

The investigation was initiated on the 2nd of September 2009, in Timisoara, Romania, and completed on the 27th of November 2009 in Speyer, Germany.

- Patients

A sample size of 40 patients per site was calculated. The sample size of 45 subjects per group (test and control, separately) has been determined using Table A.3. Sample sizes per group for a two-tailed test on proportions. P1 = .20, on page 266 of the textbook, Statistical Methods for Rates and Proportions, Second Edition, Joseph L. Fleiss, Division of Biostatistics, School of Public Health, Columbia University, 1981, John Wiley & Sons, Inc. Publishers, New York, NY. To apply the values in this table to a one-tailed test, the alpha value of 2*alpha (0.05) was used.

From here, it was anticipated that about one-twelfth of subjects overall may withdraw from the study prior to completion for various reasons, including the length of the treatment period.

Final sample size = sample size X 1/(1-d); where d = # expected dropouts/# subjects enrolled.

Final sample size = 45 X 1/(1-0.089); where d = 4/45

Final sample size = 45 X 1/0.911 = 45 X 1.098 = 49 subjects per group.

Therefore, a minimum starting sample size of 49 subjects in each treatment group was needed to insure that a sufficient number remains at the end of the trial (40 subjects per group) for any significant differences found between groups to be considered statistically valid and representative of the general population being sampled. For ease of division between the test sites, the number has been rounded up to 50 subjects per treatment group.

Patients were locally recruited in Speyer, Seattle, Paris, and Timisoara, from the pool of potentially suitable patients who normally attend the test sites for various services or form nearby consenting and suitable medical offices and other such suitable locations. Respondents were invited to the
session. After giving written Informed Consent forms, patients were screened by investigators. Inclusion criteria were perceived levels of high stress, injury and/or pain (based on a Quality of Lifestyle Questionnaire), age between 18 and 65. Exclusion criteria included extremely sick patients on more than 5 prescribed drugs, crippled and handicapped patients, diagnosed heart conditions, prior head traumas, pregnancy, breastfeeding or planning pregnancy, pacemaker use, serious mental illnesses, prior cardiac surgeries, seizure disorders, developmental disability or cognitive impairment, participation in other medical research in the past 30 days. At some sites, Inclusion/Exclusion Criteria were evaluation via email or phone in advance.

Participants deemed eligible based on baseline assessment were randomly assigned to either the test (SCIO) group or the control (placebo) group. Subjects in the test group received the actual study treatment with an active, operational harness, and those in the control group received a ‘fake’ study treatment with a placebo harness that does not contain any active electrodes. The investigators follows the same protocol for all subjects. None of the participants could discern if they were in one group or the other as the devices and equipment looked and felt the same. Levels of stress were assessed by self-report questionnaires. Body Wellness Indicators were evaluated through physiological measurements and electrical device measurements.

The potential for adverse reactions were monitored at each test site according to the Freiburger Ethics Committee International, Germany, which approved the study protocol. However, no adverse reactions were reported during the study or after the study.

**Outcome measures**

The study was designed to determine the device’s efficacy by recording baseline measures in the pre-treatment phase, against which post-treatment changes were assessed. There were 8 types of tests performed pre- and post – treatment, for both test group and placebo group.

First, the levels of stress and pain/injury were assessed using a self-report Quality of Life Questionnaire. The questionnaire had 10 questions to be answered on a scale from 1 to 10 (the higher the stress, the higher the value).

Then physiological measurements were taken for the assessment of Body Wellness Indicators, defined as follows: Energy Index Factor, Strength Test, Oxidation Test, Flexibility Test, Memory Test, pH Test, VARHOPE test.

**Energy Index Factor was calculated using the formula:**

Systolic BP left arm sitting + the diastolic BP left arm sitting x pulse = energy index factor.

The Energy Index Factor indicates parasympathetic control below 9,000, balance at 14,000 and sympathetic nervous control at 18,000+

The strength test was performed using a hand-held Dynamometer. Subject held the Dynamometer in one hand, gave one big squeeze with one hand on the Dynamometer while the investigator documented how many kilograms of strength the patient was able to exert.

The same procedure was repeated for the other hand.

For the anaerobic oxidation test, the patients started in a seated position, relaxed and breathed at a normal breath rate for 1 minute. The subject took a deep breath at the same time that the investigator started a stop-watch counting minutes, seconds and tenths-of-a-second. Subject stood up at a normal speed and sat down again at a normal speed while still holding their breath as long as possible. As soon as the subject stopped holding breath and took a new breath then investigator stopped the stop-watch. Investigator documented the length of time that the subject held breath during Anaerobic Oxgenation Test.

To evaluate flexibility, there were three types of flexibility tests performed. Low back flexibility was measured with the subject sitting down on the floor with legs stretched out in front, heels approximately 20.32 cm (8 inches) apart. The subject extended both hands, outstretched fingers towards their heels keeping legs straight. Subjects were asked to do a maximum stretch and touch the floor as far as they can, even going past the heels, if they could. The distance in centimeters (or inches in The USA) from where their fingers touched the floor to the heels, with Zero at the heels, positive if they can extend past the heels, minus if they are before the heels. Normal scores are anywhere from -7.62 centimeters (-3 inches) to 0 centimeters (0 inches), scores below -7.62 centimeters (-3 inches) indicate low back difficulty. Ideal score should be 17.78 centimeters (7 inches) past the heels.

Side to Side Flexibility was measured with subject standing on their knees without bending forward or backward at the waste, and leaning to the left side, trying to touch their left palm to the floor. Normal readings are touching fingers or knuckles to floor. An advanced subject would be able to touch their palm. If they cannot touch their fingers it indicates a lack of flexibility. A protractor was used to determine the angle of flexibility.

Neck flexibility is measured with the subject trying to touch their ear to their shoulder without raising their shoulder to their ear. A protractor was used to determine the angle of flexibility.

The suggested method for the memory test was to choose a first set of 5 random numbers. If the subject remembered these numbers in the proper sequence (either forward or backward depending on the memory test), then the investigator added 2 to the existing digit and one more digit to the end to increase the sequence by one digit. This method was continued until the end. The investigators recorded the number of memorized digits (forward and backward).

An Over-The-Counter pH (acidity-alkalinity) Test Kit was purchased and used for pre-test and post-test measurements of pH.

VARHOPE is an acronym coined by the manufacturer in which V = Voltage, A = Amperage, R = Resistance, H = Hydration, O = Oxygenation, P = Protons and E = electrons.

The VARHOPE numbers are measured by the biofeedback device, during a 1,5 minute Calibration process and they are measured again at the end of the session.

The VARHOPE numbers are separated into two (2) categories where VARHO is one category and PE and the second category. The VARHO readings are set on a scale, determined by the manufacturer, from 0-110. Changes in the readings are shown on the scale where an increase in number shows improvement.

The PE readings are set on a scale, determined by the manufacturer, where the closer the P reading to 75 the more the client’s state of wellness has stabilized, and the closer the E reading to 65 the more the client’s state of wellness has stabilized. This scale was chosen to make it easier for the layperson to accept readings on a simpler scale rather than electrical readings.

**Voltage** is derived directly from the skin electro-potential amplitude. Amperage is the amount of
charged particles flowing and Voltage is the pressure behind the flow. All biofeedback instruments measure voltage which is the electro-potential of the skin underneath the electrode. Amplitude disorders in EEC or ECG, refer to the voltage vector.

**Amperage** is calculated from the volume of current over a short period of time coming off of the body. Knowing the skin’s electro-potential and impedance using Ohm law of \( V = A \times R \) (Voltage equals Amperage times Resistance), the current or amperage at a transcutaneously measured point can be calculated. This is referred to in the industry as a virtual measured variable. Using simple collective mathematics global measures of our patient’s Voltage, Amperage and Resistance can now be established. Amperage is the amount of charged particles flowing and Voltage is the pressure behind the flow.

**Resistance** is a measure of how a substance resists current flow. In a complex situation of multiple liquids acting as electrolytes and multiple membranes, there are induction and capacitance enhancements to the flow (magnetic and capacitance). Resistance is measured in Ohms.

**Hydration** The active stability of water concerning the amount of free water and its ability to permeate osmotic membranes. The electrical pulse of the SCIO stimulates osmosis. It is measured as the range of voltage scores over a period with the aberrant signals and cardio-signals filtered out give us a Hydration index. Voltage changes observed during the Calibration process give us a Hydration index (based on the free proton effect).

**Oxygenation** is given through the range of amperage scores over a period of time, with the aberrant signals and cardio-signals, which, when filtered out give an Oxygenation index. The range of scores, between maximum and minimum, reflects oxygenation giving an Oxygenation index. As the changing Voltage and Amperage is measured we get inductance and capacitance virtual scores and this allows us to find a Hydration and Oxygenation index. As Amperage changes slightly with each breath, we get an Oxygenation index from comparing maximum and minimum values. We need to observe several normal breaths to establish an Oxygenation index during the Calibration procedure.

**Proton balance** (in relation to Electron balance) The polarity of the signal and the collective global readings give us a proton-electron balance. Thus the system has an index which can be compared to established norms of patients based on age, stress, metal implants in teeth, smoking and disorders in EEC or ECG, refer to the voltage vector.

**Proton balance** can now be calculated. This is referred to in the industry as a virtual measured variable. Using the paired t-test, the percentage differences between the mean differences in final post-treatment Body Wellness score minus pre-treatment Body Wellness score for subjects in the test group versus subjects in the control group was evaluated.

For the primary efficacy outcome measure, an intent-to-treat analysis (including all randomized patients), and a per-protocol analysis (subjects without major protocol deviations, incompletes excluded) were performed.

Handling of missing data in the per-protocol analysis was according to the multiple imputation method.

For the evaluation of the secondary efficacy outcome measures an ANOVA was used to evaluate the change in total Body Wellness score across the measurement time points of pre-treatment and post-treatment, comparing test and control group subjects. It was expected that more test group subjects will demonstrate an improvement in Body Wellness in one or more tests from pre-treatment to treatment to post-treatment than will control group subjects. There were made correlations between scores on the various inventories and a z-test was used to evaluate differences in outcome satisfaction ratings between test and placebo group subjects. Changes recorded on the VARHOPE readings during treatment and comments provided by subjects were also evaluated. A safety outcome evaluation of any reported adverse events and reactions was performed.
Analysis of results was performed by individual test site and pooled across test sites. Application of a balanced test-control group study design incorporating a block by test site randomization procedure contributed to statistical justification of pooling data across the different test sites.

The baseline covariates of age, gender and pre-treatment score were adjusted for in the analysis through use of an ANCOVA analysis.

**Results**

The study flow chart, based on the Consolidated Standards of Reporting Trials recommendations, is shown in Figure 1. Subjects were recruited through local contacts on a voluntary basis. Some were screened beforehand via phone or e-mail and others were screened upon arrival. Potential candidates were excluded or deemed ineligible for the following reasons: a) did not meet inclusion criteria (n=3), b) scheduling problems (n=2), c) missed appointments (n=7). 192 subjects were enrolled and randomly assigned to either the SCIO Test Group (n=100) or Placebo Group (n=92). The subjects not included in analysis were those from whom no pre and/or post measurements were recorded at the end of the session. Reasons for not obtaining data were scheduling problems.

![Flowchart of the study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session](image)

**Table 1. Baseline demographics of both groups (Data are numbers or percentages)**

The first 41 subjects (Budapest, Hungary) the demographics scores did not transfer to the database. Results are shown in Figure 2. There was no statistical difference between groups in the following outcomes: Quality of Life Questionnaire, Energy Index Factor, Strength Test, Flexibility, Memory and pH.
<table>
<thead>
<tr>
<th></th>
<th>SCIO Treatment group (Test group)</th>
<th>Placebo group (Control group)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>N</td>
</tr>
<tr>
<td>x Flexibility Side to Side</td>
<td>-0,6588</td>
<td>85</td>
</tr>
<tr>
<td>x Flexibility Neck</td>
<td>0,8706</td>
<td>85</td>
</tr>
<tr>
<td>x Memory Test (Forward)</td>
<td>-0,2706v</td>
<td>85</td>
</tr>
<tr>
<td>x Memory Test (Backward)</td>
<td>-0,1624</td>
<td>85</td>
</tr>
<tr>
<td>x pH level</td>
<td>0,6012</td>
<td>84</td>
</tr>
<tr>
<td>x Voltage</td>
<td>-14,4286</td>
<td>84</td>
</tr>
<tr>
<td>x Amperage</td>
<td>-15,8333</td>
<td>84</td>
</tr>
<tr>
<td>x Resistance</td>
<td>-16,9167</td>
<td>84</td>
</tr>
<tr>
<td>x Hydration</td>
<td>-16,6071</td>
<td>84</td>
</tr>
<tr>
<td>x Oxygenation</td>
<td>-18,7381</td>
<td>84</td>
</tr>
<tr>
<td>x Proton pressure</td>
<td>-2,3214</td>
<td>84</td>
</tr>
<tr>
<td>x Electron pressure</td>
<td>3,6548</td>
<td>84</td>
</tr>
</tbody>
</table>

Table 2. Summary results for the SCIO Treatment (Test) group

<table>
<thead>
<tr>
<th></th>
<th>Placebo group (Control group)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
</tr>
<tr>
<td>x Quality of life Questionnaire 1</td>
<td>0,4462</td>
</tr>
<tr>
<td>x Quality of life Questionnaire 2</td>
<td>0,2000</td>
</tr>
<tr>
<td>x Energy Index Factor</td>
<td>885,7077</td>
</tr>
<tr>
<td>x Left Hand Strength (Kg)</td>
<td>-0,0615</td>
</tr>
<tr>
<td>x Right Hand Strength (Kg)</td>
<td>0,0769</td>
</tr>
<tr>
<td>x Oxygenation</td>
<td>-1,2500</td>
</tr>
<tr>
<td>x Flexibility Low Back</td>
<td>-2,0580</td>
</tr>
</tbody>
</table>

Table 3. Summary results for the Placebo (Control) group
Figure 2. Outcomes of 146 subjects analyzed in the study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session.

There was significant difference between groups in the VARHOPE measures (p < 0.005). The results were as follows:

- 86.90% of subjects had a V improvement of more than 5%,
- 90.47% of subjects had an A improvement of more than 5%,
- 88.09% of subjects had an R improvement of more than 5%,
- 88.09% of subjects had an H improvement of more than 5%,
- 89.28% of subjects had an O improvement of more than 5%,
- 47.61% of subjects had a P improvement of more than 5%,
- 48.80% of subjects had an E improvement of more than 5%.

There were no adverse events reported during or following the study.

Discussion

We conducted a double blind, randomized study with a placebo controlled design to evaluate an intervention comprising of a 45 minute SCIO Biofeedback session. We looked at the impact of this session on electrical scores (VARHOPE), perceived levels of stress and pain/injury, blood pressure, strength, memory, flexibility and pH in subjects with high levels of stress. Significant effects associated with the intervention were observed in VARHOPE scores. The biofeedback session had no risks associated with the study. Compliance to the study protocol was maintained during the study.

The body is an electrical process requiring volts and amps which conduct through resistance circuits to operate. All muscles are activated by electrical impulse (e.g. action potential). Muscles themselves are magnetic using volts and amps for their operation. The brain is a massive collection of cells that have electrical activity that can be measured via the EEG. The heart itself is the largest electro-magnetic engine and uses electrical impulses to influence the muscles of the heart to circulate blood. Most EEG, ECG and EMG measures are only concerned with oscillatory properties and not so concerned with the volume or basic amperage of the circuit. The collective baseline of the circuit of EEG, ECG, EMG and GSR measurements can give us a rating of the global body voltage, body amperage and skin resistance (V, A and R respectively). There are norms of the V, A and R and certain people, due to stress or other factors, can have low V, A and/or R.

The collective inductance and capacitance changes in the body are a reflection of redox potential and can reflect hydration (H) and oxygenation (O) indexes.

Irregularities in EEG, EMG, ECG and GSR can be corrected through guided electro-stimulation. The V and A are also greatly affected by the charge stability of the free protons and electrons, (negative charges and positive charges in the body), which collectively make up the proton pressure (P) and electron pressure (E). The acidity-alkalinity balance is an electrical measure of the amount of positive versus negative charged particles. This can be measured by the carbon based electrodes of the SCIO through electro-stimulation biofeedback.

This Clinical Study was developed in the context of substantiating the Indication for Use for the SCIO biofeedback device of rectifying charge stability imbalance and rectifying redox potential, two of the factors that influence Body Wellness. One study objectives was to determine if one 45-minute treatment with the SCIO would show a change on a person’s Body Wellness indicators as defined by the study hypothesis, which is now proven valid.
The other indicators of Body Wellness (Quality of Life Questionnaire, Energy Index Factor, Strength, Anaerobic Oxygenation Test, Flexibility, Memory and pH) were not statistically significant, although these results are highly valuable. A closer analysis shows that there are trends in the improvement levels between the Test and Control (Placebo) group. As per the hypothesis defined in the Clinical Study protocol it was expected that any positive change in post-treatment measures for control subjects is expected to occur to a significantly lesser degree than for subjects in the test group.

The subjects were not equally assigned to the placebo versus test group, but as follows:
- Budapest, Hungary
  - Control Group n=27
  - Treatment Group n=14
- Timisoara, Romania
  - Control Group n=17
  - Treatment Group n=21
- Seattle, Washington, U.S.A.
  - Control Group n=20
  - Treatment Group n=20
- Paris, France
  - Control Group n=20
  - Treatment Group n=20
- Speyer, Germany
  - Control Group n=8
  - Treatment Group n=25

Because the test/placebo assigned ratio was not equal, in order to determine trends of improvement per the study hypothesis, we have analyzed subjects from Seattle, USA and Paris, France (40 subjects in test group, 40 subjects in placebo group).

Strength test results analysis showed that 60% of the subjects in the test group had a 5% or more improvement in left hand strength, as opposed to only 35% of the placebo group which had a 5% or more improvement. In the case of the right hand strength, difference is smaller, however, 47% of the test group subjects improved more than 5%, and 37.5% of the placebo group improved more than 5%. The results show that there is definitely a possibility of improving strength with the SCIO biofeedback device, the question that remains is how many SCIO sessions would have a statistically significant result. Also, another thing to consider while analyzing the results is that the protocol followed included mostly general stress reduction therapies, as opposed to using specific muscle strengthening treatments, which could have a greater impact on strength.

It is interesting how the anaerobic oxygenation test had a greater improvement for the placebo group (68.42%). Test group had an 55.26% of subjects that had a 5% or more improvement. The question this rises is whether the improvement occurred because the subjects had a chance to relax during the 45 minute protocol or because of the biofeedback session. The anaerobic oxygenation test requires a clear mind and a rested body. So whether or not the results are due to the relaxing 45 minute session is unclear.

Analysis of flexibility back shows that 60% of the subjects in test group had a 5% or more improvement versus 55% of the placebo group that showed a 5% or more improvement. 10% more of the subjects in the test group had a 5% or more improvement of flexibility side versus subjects in placebo group. In Seattle, side to side flexibility showed statistically significant improvement. Even though the overall analysis does not support these findings, it is a strong basis for future studies. Also, evaluating pathological versus non-pathological data revealed that, for one site (Paris) subjects with pathological reactions to the low back flexibility test had non-pathological reactions after the biofeedback session.

Flexibility of the neck has again quite similar results. 25% of the test group and 27.5% of the placebo group had a 5% or more improvement. It would be interesting to find out whether flexibility would be significantly improved by specific muscle therapies with the SCIO device. Considering the relaxation therapies that were applied in this study, it is definitely worth finding out how many specific SCIO treatments would have a considerable effect on flexibility measurements.

Memory test did not suggest any trends, but showed improvement of more than 5% being observed at an exactly the same percent of the test group subjects as the placebo group subjects.

Energy Index Factor, a variable based on blood pressure measurements did not show statistical significance. However, a study that evaluated the effects of GSR Biofeedback and Progressive Muscle Relaxation (PMR) showed that PMR induced a significant decrease in blood pressure whereas GSR biofeedback training showed a decrease in respiratory rate. The GSR treatment was administered for 20 minutes daily, for 10 consecutive days. This provides a strong basis for a further analysis of the SCIO device sessions and the effects it might have on blood pressure.

This study has limitations, primarily among them the lack of repeat sessions that require follow-up to compare results over prolonged time and repeat sessions. Nevertheless, the results obtained after one session provided valuable data on feasibility and plausibility. Another limitation was the short duration of the study. An alternative design would provide data obtained over a significantly longer period of time, which may also influence the results of the study and offer better understanding of the efficacy of a sequence of sessions with the SCIO device.

Conclusions

The SCIO device appears to be a valuable tool in improving Body Wellness. One 45 minute session had significant results improving the natural electrical parameters of the body. The results also showed trends of improvement in other body variables, therefore providing a basis for future studies. The fact that there were no adverse events reported shows device safety.

The electrical factors of the body electric are perhaps more important than any other. The device used in this study was able to have a positive effects on slightly but significantly increasing the VARHOPE indices in just one 45 minute study thus increasing the wellness of the body.
Healthy membrane potential and adequate body voltage makes all of the functions of the cell work better.

Low Body Voltage leads to weak membrane potential, weak osmosis, trapped toxins, premature aging, and increased susceptibility to virus.

Factors that influence the body voltage and membrane potential are fatty acids in the cell membrane, minerals, especially salts, hydration water, oxygenation, stress, toxins and life style.

The SCIO has been proven in tests to increase the electrical potential of the body. Increased cellular membrane potential makes osmosis increase, which increases detoxification, nutrient transfer and absorption, hydration, oxidation, and all cellular functions in general.

Acknowledgements

The study was funded by Maitreya Ltd., manufacturer of the SCIO Universal Electrophysiological Biofeedback System. Maitreya Ltd. was involved in the design and conduct of the study and provided logistical support during the trial. Employees of the sponsor worked with the investigators, but the analyses were performed by two independent statisticians. The manuscript was prepared by Dr Rainer Mutschler. Maitreya Ltd. was permitted to review the manuscript and suggest changes, but the final decision on content was exclusively retained by the author, Dr. Rainer Mutschler.

Disclosure Policy

Let it be known under the Disclosure Policy, that Dr. Rainer Mutschler uses the SCIO Universal Electrophysiological Biofeedback System in his clinic, CFI Center for Integrative Medicine, Speyer, and therefore has the financial benefit of supporting his business with the publication of this study. Also, Maitreya Ltd., manufacturer of the SCIO Universal Electrophysiological Biofeedback System has the benefit of scientific support of its product with the publication of this study. Furthermore, Maitreya Ltd. has contracted with Dr. Rainer Mutschler for a total of 12,000 EUR for his work as Principal Investigator on the study.

Ethical Guidelines

The Experiment was conducted in accordance with the Declaration of Helsinki (1964). All human subjects who were involved in the study fully understood and consented to the study. The Freiburger Ethics Committee (feki) approved the study.

References

Varhope charging the batteries

 reviewer of EEG biofeedback training on children with attention deficit hyperactivity disorder

These are exciting times. The Quantum family of devices has a strong history of science with the first trivector subspace studies done at Youngstown State University in the 1970s. The sports studies are strong and the recent help we were able to give Novak Djokovic helped him to beat Roger Federer and go back to the world number 2 in tennis. I have written a new series of books to help you all learn more about our exciting science.

Our recent studies have prove just how safe and effective our device is. We have shown scientifically that our device can charge your batteries and improve your body electric. We have put VARHOPE onto the scientific map. Over a hundred medical science articles on our technology have been published in peer reviewed medical journals.

Now we are facing the next challenge of the QC and TVEP work. The Quantum Quality Control (QQC) world patent has been accepted and the technology scientifically validated as a proper Voltammetric process. We can detect the electrical signature of an item with this equipment, amplify the signature signal and send it into the patient and see the reactivity. This is done on top of the skin (Transcutaneous), using Voltammetric signals, to get reactivity scores or what is scientifically known as Evoked Potential. So the TVEP is Transcutaneous Voltammetric Evoked Potential. This is called the Xrroid first registered with the FDA in 1989.

In 1994 the study was done comparing the TVEP reactions of all of the AIDS patients of Hungary in the Semmilvies hospital in Budapest.

"Electrical Reactivity as a Pre-screen of HIV Infections" by Nagy K., Nelson W., Barabas E., Balazs E. Horvath A. done at the National Institute of Dermato-Venerology, Budapest Hu. 1994

The scientific conclusions were unveiled at a world congress on Sexually transmitted diseases in Singapore, 1996 the World Congress of AIDS and Sexually Transmitted Disease. This showed a reactivity pattern of AIDS patients and lead to developing herbal remedies for AIDS. The major research project NARINGA in Africa has had great results and success from this basic research.

In 1995 a research project at the Szent Janos Hospital in Budapest on cataracts with the Xrroid reactivity patterns lead to the discovery of the way excess dextrose sugar is the main cause of cataracts and a homeopathic process to treat the cataracts resulted with great success.

"Xrroid Reactivity Patterns of Cataract Patients" by Nelson W, Nagy J. Szent Janos Hospital 1995

Now the world of doing studies has become very complicated and extremely regulated. So much so that the FDA is trying to help make it a little easier. They have written an article enclosed with this letter to get people like you to help do some science. We at Maitreya have procured an American approved Institutional Review Board (IRB), medical supervision, and a study for any of you to help do science.

We have everything ready we need you. You pick a disease or condition you want to treat, like autism as just one example. You line up some patients. Even as little as six patients will do. You officially join our study project as an investigator. We review your credentials to see what kind of supervision you will need. If you require such supervision it is supplied on line. You set up two days for treatment with about half on one day and half on the next. If you have a large group it might take more than two days.

We teach you what to do and how to get informed consent from your study participants.

Our placebo study supervisor goes onto your computer online and sets it randomly to placebo setting. Then neither you nor the patients know what day is placebo and what day or days are normal. This is called double blind. You treat the patients with one session no more than one hour and you send the data to us on line. Very simple indeed, easy for you and us. All of this officially registered for acceptable research parameters.

You may help find the next cure for a major disease. You may be putting your name into the history books. Very simple and very easy, and our data gets published in an ISSN peer reviewed medical journal which is good for your CV resume’.

So please help us to help the world help us to do the next step of science in getting our technology out to the masses. If you have questions and or would like to get started please tell us. Write
Thus there are definitely electrical values of each patient at multiple globally placed electrodes that make up a VARHOPE profile. These factors are most often controlled by lifestyle behaviors and stress. Slight regulatory balancing from the guided electro-stimulation of the SCIO can also make changes.

Early Volt-Ammetry research noted a connection of body Voltage with the catecholamines of the body, and Amperage to the indolamines. The catecholamines are the hormones associated with the adrenal system, our fight flight system. Hypoadrenia is epidemic in our stress filled society. Stress unmanaged is weakening our adrenals and lessening our body Voltage. The indolamines are brain hormones associated with love and other high brain function.

Resistance measured in Ohms is perhaps the greatest variant. Normal skin resistance is 40 to 50 thousand Ohms. Our normal of 100 is based on there being not too much or too little Resistance. Inflammation diseases will make Resistance go up and conductance go up. Degenerative diseases will make Resistance go up and conductance down. This is well documented in the literature. There are other things that effect Resistance that must be ruled out. But as we pass a current thru a limb or quadrant a decreased Resistance will reflect possible inflammation and an increased Resistance possible degeneration. Soft tissue will respond to lower frequencies below 100 and the bone to frequencies of 300 to 600. There can be degeneration and inflammation in the same quadrant. But the cybernetic pulse is designed to systematically thru stimulation measure and re-stimulation produce a guided auto-focusing pulse to treat any aberrant electrical profile. This is the SCIO.

Volts times Amps is Power. This is measured in Watts. The Volt-Ammetric research showed that giving catecholamines such as adrenalin made voltage go up. Giving indolamines like serotonin made Amperage go up. When body the body Amperage falls to low it signals the end of life. Adrenalin is associated with fear and anger. Serotonin is associated with love. We see reports of a small 100 pound mother picking up a car to save her child. An act of love. We do not hear reports of her picking up a car to throw at her husband. So love with indolamines power Amperage are more powerful. Increasing the Amperage of a circuit is more effective in power than Voltage.

Glen Rein and others have reported seeing an increase of adrenalin with a stimulation of the body of a 500 hz signal. Indolamines were found to increase with a 1000 hz signal. The SCIO system can act to increase low Voltage and Amperage thru electro-stimulation. There is much volt-ammetric research on the effects of certain frequencies on the parts or hormones of the body. Electro-stimulation is shown to increase osmosis thereby freeing minerals to stabilize pH. Cranial Electro Stimulation (CES) is used for treating stress, insomnia, depression, etc. and the use of MENS is found to have positive effects on pain, wound and trauma treatment. Once a body is subjected to low pulsed micro-current therapy the benefits are manifest in many ways. But the greatest value is improving the bodies resistance to stress. Stress and stressors are the cause of all disease.

The SCIO sends in a micro-current stimulation and measures response. We can determine if the body responds harmonically or positively or negatively to the stimulation by analyzing the response. Thus a guided cybernetic loop pulse can help to increase the effects of the electro-stimulation. The body can be improved electrically and all regulatory procedures in the body can be improved with an increased VARHOPE profile.
The charge stability or Proton Electron pressure pH is a measure of the relative amount of charged particles in a system. We measure this globally as a measure of the whole body. Acids accept electron since they have an excess of protons. Hence the HCl, HS, HN, or the H means hydrogen which is a proton. Bases donate electrons since they have an excess of negative charge.

Most of our patients (over 80%) are sick because they are extra acid from stress, diets of meat and potatoes. They need electrons. The SCIO can shift from a sine wave to a square wave. This supplies more electrons. The body electric can divert the electrons to where they are needed.

If the patient is more alkaline, a spike wave is designed to help siphon off the excess through the device ground. The micro-current system can assist in correcting pH irregularities.

An Alarm response to a signal is produced by an unnatural increase in voltage on all electrode points. Harmonic reaction show little reaction. And resonant reactions show positive. So we can monitor the body electric and let the system auto-focus the safe micro-current to help correct functions of VARHOPE.

There are oscillation functions in the body such as brain wave, heart action, and muscles. The SCIO can help to stabilize regulation of these processes with electro-stimulation as well. It is well shown in the literature how electro-stimulation of the body can have beneficial effects in these areas. The SCIO simply uses a cybernetic biofeedback loop to sharpen the auto-focusing effects of the safe micro-current device.

The next discussion is of the basic nature of electrical charge in biology.

Life must keep Potassium inside the cell and Sodium outside of the cell. The natural thermodynamic balance is for them to gravitate to be equal. So potassium has a natural pull to go out and sodium to go into a cell. Because the concentration gradient for potassium is directed out of the cell, while the concentration gradient for sodium is directed into the cell, there is a need for a sodium pump to stabilize the life of the cell. This takes the energy of ATP to operate the sodium pump. The sodium-potassium pump transports 2 potassium ions inside and 3 sodium ions outside at the cost of 1 ATP molecule. There should be twice as much potassium as sodium in the healthy human body.

Membrane potentials are defined relative to the exterior of the cell; thus, a potential of −70 mV implies that the interior of the cell is negative charge relative to the exterior. Life is electrical.

Electrons never touch, so atoms never touch, molecules never touch. Not much ever touches anything. It is all an interaction of their fields. Research has shown that when we apply even a weak current or electro-potential across a cell, membranes become more osmotic. Osmosis increases with small electro-potential stimulation. The membranes shown above have different electro-potentials across them. The main factors of membrane potential are membrane consistency which implies that the interior of the cell is negative charge relative to the exterior. Life is electrical.

Slight electro-stimulation is shown to not only increase osmosis, but to have pain reducing qualities (MENS), relaxation effects, mood stabilization (CES), and charge stability. When you charge your car battery you use a trickle tickle charger. It supplies a similar charge to the battery over a long period to tickle and trickle the needed electrons into the battery. The SCIO works this way as well. In the picture of the two cells we see that the sad cell has less electro-potential or is a weak battery. The SCIO sense the proper frequency the patient’s body electric responds to and the trickle tickles the charge into the cells. This increases osmosis and charges the cells back to proper cellular membrane potential.

Just like the tickle trickle battery charger, too much current will not be accepted. The body is especially designed to not accept large charges. A small charge that is much like the body’s own level of volts, amps resistance and oscillation resonance is best to use for charging the body’s cell membrane batteries. The SCIO having measured the body electric factors then applies a stimulus to charge or balance the system and monitors it’s progress with a feedback loop.

Our experimental research shows an increased VARHOPE score after the SCIO treatment proving it effectiveness and safety. The short term effects will be better and longer lasting if they are coupled with life style changes. REF STUDIES

POTASSIUM AND SODIUM

As we have said there should be twice as much potassium as sodium in the healthy human body. But people like salt and producers put more salt into foods to sell and satisfy customers. Potassium occurs mostly in fruit and vegetables. Potassium makes foods turn Orange. So oranges, pumpkin, paprika, squash etc have the most. Most people get too much sodium and too little potassium. This puts pressure on the potassium-sodium pump. This wastes ATP needed for other cellular functions and stress the body electric. The excess sodium makes the body go acid with excess positive charge. This drives the charge stability of the body to the acid state and is reflected in the measurements made from the SCIO. There are many other factors that can upset this electrical balance.
The electro-potential of the cell membrane must be kept inside some strict limits to assure proper electrical activity for life. The cell is an electrical dynamo needing energy for activity. This energy comes from hot electrons (high quantum state energy of electrons in food). The food has gotten its energy from the sun’s visible light photons energizing the electrons to higher quantum states. The quantum energy is broken down in Krebs cycle to make ATP. Photons of heat are released. The cells will have electrical activity that is of a tight range and thus electro-medicine will need to decipher the code of the types of variations in the body electric that hallmark disease states. The cell must fight thermodynamics to live.

The factors of mineral balance especially sodium to potassium is largely a nutritional issue. Too much sodium versus potassium is one of the greatest single health risks today. Oxygenation is also key. Smoking and lack of exercise is epidemic and killing millions. Over use and improper use of doctor prescribed medicines is also killing millions. Too much animal fat, trans-fatty acids, dextrose sugar, processed foods, food additives, environmental toxicity, mercury amalgams, and uncontrolled stress are life style factors that are killing millions of people. So the first place to start with health care is the behavior. Behavioral medicine is a ever growing issue of responsibility in health care. The SCIO devotes its first level of use and design to the education and possible correction of life style issues. It is important to point out the value and importance of correcting these issues for health.

Correlations between whole-body impedance measurements and various bio-conductor volumes, such as total body water and fat-free mass, are experimentally well established; we can measure many different factors of the body electric. First there is skin electro-potential.

Each of these small little batteries we call cells blend in harmony to make the multi-cellular organism we call the human. The hundred trillion cells in the human body act both in series and in parallel to make the electro-potentials of the human body. Most of these cells are surrounded by fluid (interstitial, lymph, blood etc.). Theses fluids are mostly water with lots of free protons, electrons and minerals which further enhance the electrical factors. The normal cell has a resting voltage potential across the membrane of 70milli-volts (-70mv). The brain cell will fire at peak voltage of +30mv so as to create a difference of 100 milli-volts.

Thus the body has a measureable voltage and amperage while living. This electro-potential is oscillating and or pulsing. Cells charge and discharge electricity at varying speeds. Global measures reflect trends of the cells in the area to be measured. There are norms of these measures.

The amperage and voltage coming off of the body’s skin is of a range of zero to 5 milliamps and 1.5 volts. Zero is obvious as we all have seen the flat line in a movie telling us the person is dead. Normal people put off micro-amperage and milli-volts, the extreme can be seen at over a volt. The criteria of these potentials are derived from their location and oscillation.
The brain cell will fire with a process called action potential. An action potential is a very rapid change in membrane potential that occurs when a nerve cell membrane is stimulated. Specifically, the membrane potential goes from the resting potential (typically -70 mV) to some positive value (typically about +30 mV) in a very short period of time (just a few milliseconds).

What causes this change in potential to occur? The stimulus causes the sodium gates (or channels) to open and, because there’s more sodium on the outside than the inside of the membrane, sodium then diffuses rapidly into the nerve cell. All these positively-charged sodium ions rushing in causes the membrane potential to become positive (the inside of the membrane is now positive relative to the outside). The sodium channels open only briefly, and then close again. This difference makes a potential at the skin measured by the SCIO system, as with all biofeedback systems.

The SCIO measures electro-potential at the 12 harness points in the clear, then applies a voltammetric signal into any or all of the points, then measures the harness points with the applied signal. The amperage and voltage coming off of the non stimulated body's skin is usually of a range of zero to 5 milliams and 1.5 volts. Zero is obvious as we all have seen the flat line in a movie telling us the person is dead. Normal people put off micro-amperage and milli-volts, the extreme can be seen at over a volt. The criteria of these potentials are derived from their location and oscillation. Thus we can calculate the base body voltage, amperage and resistance from our readings.

If we measure on the scalp or the forehead as in the case of the SCIO, we can measure the transcutaneous correlate of the activity of brain cells firing in the brain below the point of measure. This is called EEG or electroencephalography. We can ascertain the Brain wave from the oscillation pattern. The pattern or rhythm of the brain wave is from 4 hertz as delta waves, 4-8 Hz for theta, 8 to 20 for alpha, and 20 to 100 for beta waves. If we measure the electro potential of the skin and filter out these waves we can get the EEG.

If we measure on the forehead, wrists and ankles as in the case of the SCIO, we can measure the transcutaneous correlate of the activity of muscle cell activity between the points of measure. This is called EMG or electromyleography. We can ascertain the muscle activity from the oscillation pattern. The pattern or rhythm of the muscle waves is from 2 to 20 normally with variant spindles up to 1000 Hz. If we measure the electro potential of the skin and filter out these waves we can get the ECG. The heart signal is the largest in potential and smallest in time measured in biofeedback.

To measure skin resistance, we must apply a known voltammetric signal as an input and then see how much of it is resisted by the body, most applicably by the skin. The measure the galvanic skin resistance or impedance we need to be able to input a voltammetric signal into the electrode points. This is a variant signal in the SCIO of variant wave forms, and wave potentials. The measured output of resistance is usually non hertzian. Pulsations in resistance reactivity are fractal and non repeating.

The voltammetric signal of the SCIO is of a micro-current nature. The applied signal strength is derived from the base signal strength of the patient body natural. We are of the philosophy that signals exceeding twice the body norm will be considered invasive and the body will react adversely to such signals. We wish to just tickle the body with electro-stimulus near the natural. Thus the upper limits of the SCIO body stimulation output will be 5 volts, and 50 micro-amps. All of this is under the regulatory safety criteria specified.

Thus as seen in the EPFX FDA 1989 registration the SCIO is registered to measure volts and amps at 12 points of forehead, wrist and ankles. Input a voltammetric signal to these points, and then measure the reaction of resistance at these points. The SCIO then can acts as a frequency generator sending out voltammetric waveforms and a frequency counter measuring frequency response.

From these simple criteria a host of electrophysiological data can spin out to assist the SCIO in correcting aberrant electrophysiological functioning. Electro-stimulation is helpful in osmotic stimulation, transcutaneous electro-nerval-stimulation for pain control and injury or wound healing, redox stimulation, and others. The SCIO uses a cybernetic loop of analysis to use this electro stimulation to adjust electro-physiology of the patient.

Smooth muscle intracellular pH: measurement, regulation, and function

Smooth muscle performs many functions that are essential for the normal working of the human body. Changes in pH are thought to affect many aspects of smooth muscle. Despite this, until recently little was known about either intracellular pH (pHi) values or pHi regulation in smooth muscle. Recent work measuring pHi with either microelectrodes or nuclear magnetic resonance spectroscopy is now providing some of this much needed information for smooth muscles. From these studies, it can be concluded tentatively that pHi is the same in different smooth muscles, approximately 7.06 (37 degrees C).

This value is very close to those obtained in cardiac and skeletal muscle. It is clear that pH is not in equilibrium across the smooth muscle membrane; i.e., pHi is regulated. Preliminary results in smooth muscle suggest that certain aspects of this regulation are different from that described for other muscle types. Changes in pH have been found to produce marked effects on contraction in smooth muscle. Of particular interest is the fact that, unlike striated muscles, some smooth muscles can produce more force during an intracellular acidification.
Michael Linden, Thomas Habib and Vesna Radojevic
Mission Psychological Consultants, 30270 Rancho Viejo Road, Suite C, 92675 San Juan Capistrano, California

Abstract Eighteen children with ADD/ADHD, some of whom were also LD, ranging in ages from 5 through 15 were randomly assigned to one of two conditions. The experimental condition consisted of 40 45-minute sessions of training in enhancing beta activity and suppressing theta activity, spaced over 6 months. The control condition, waiting list group, received no EEG biofeedback. No other psychological treatment or medication was administered to any subjects. All subjects were measured at pretreatment and at posttreatment on an IQ test and parent behavior rating scales for inattention, hyperactivity, and aggressive/defiant (oppositional) behaviors. At posttreatment the experimental group demonstrated a significant increase (mean of 9 points) on the K-Bit IQ Composite as compared to the control group (p<.05). The experimental group also significantly reduced inattentive behaviors as rated by parents (p<.05). The significant improvements in intellectual functioning and attentive behaviors might be explained as a result of the attentional enhancement affected by EEG biofeedback training. Further research utilizing improved data collection and analysis, more stringent control groups, and larger sample sizes are needed to support and replicate these findings.

Page 3. EEG Biofeedback for ADD 37 Research efforts into new treatment options are vital considering the extent and intractability of these disorders. ... This finding of underarousal correlates with low amplitude in EEG beta frequencies found in this population.

Descriptor Key Words EEG biofeedback - attention deficit disorder - attention deficit hyperactivity disorder - intelligence - learning disabilities

This research was supported by an equipment grant by Autogenics Systems. Portions of this paper were presented at the annual convention of the Association of Applied Psychophysiology and
years developing a rationale for the diagnosis of attention-deficit/hyperactivity disorder (ADHD) and treatment of ADHD employing EEG biofeedback techniques. The article first briefly reviews the history of research and theory for understanding ADHD and then deals with the development of EEG and event-related potential (ERP) assessment paradigms and treatment protocols for this disorder, including our work and that of others who have replicated our results. Illustrative material from our current research and child case studies is included. Suggestions for future experimental and clinical work in this area are presented and theoretical issues involving the understanding of the neurophysiological and neurological basis of ADHD are discussed.

This disorder is primarily found in boys (James and Taylor, 1990), with the ratio of boys ... (1992), in a study of children with ADHD, found an increase in absolute amplitude in the ... The ADHD children were found to have EEG frequency distributions that resembled profiles typical of

**Physiological studies of the hyperkinetic child:**

- JH Satterfield, DP Cantwell, Li Lesser ... - American Journal of ... 1972 - Am Psychiatric Assoc ... We feel that in the absence of known etiology or pathogenesis, as in the more common psychiatric disorders, marked differences in response to adequate trials of the same ... The mean resting EEG amplitude and the range of the mean resting EEG amplitudes were also computed ... Event-related EEG/MEG synchronization and desynchronization: basic principles G Pfurtscheller, FH Lopes da Silva - Clinical Neurophysiology, 1999 - Elsevier ... In addition it was also shown that visual stimuli can reduce the amplitude of the ongoing EEG amplitude (Vijn et al., 1991), thus demonstrating that the model assuming that an ERP can be represented by a signal added to correlated noise does not hold in general ...

Brain and human pain: topographic EEG amplitude and coherence mapping ACN Chen, PRappelsberger - Brain Topography, 1994 - Springer ... awake states, sensory ac- tivation, cognitive processing, learning, stress and emotionality, mental disorders, effects of ... and pain, the tasks of this study were: (a) to employ both amplitude and coherence analysis in pain study, (b) to expand the EEG recording channels ...

- ... CT scan and sensorimotor EEG rhythms in patients with cerebrovascular disorders
- ... Electroencephalography and Clinical ..., 1981 - Elsevier ... Fifty subjects with cerebrovascular disorders and motor deficits, all able to perform a voluntary ... From the mu rhythm, the hemispheric asymmetry in amplitude and ERD during movement (ERD ... Comparisons of CT scan data and EEG findings indicate a high correlation between ...

EEG biofeedback training and attention-deficit/hyperactivity disorder in an ... DP Carmody, DC Radvanski, S Wadhwani ... - Journal of ..., 2000 - informaworld.com ... on the most frequent methods of treatment of Attention Deficit Hyperactivity Disorder (ADHD) over ... either by inhibiting high-ampli- tude theta activity or by rewarding high-amplitude beta activity.

Evaluation of the effectiveness of EEG neurofeedback training for ADHD in a ...

- JF Lubar, MO Swartwood, JN Swartwood, PH O’ ... - Applied ..., 1995 - Springer ... aspect of the electrical activity of the brain such as the frequency, location, amplitude, or duration of ... or to enhance certain types of EEG activity and decrease other types of EEG activity

Biofeedback, March 1993 in Los Angeles and at the annual meeting of the Biofeedback Society of California, November, 1992 in Monterey, California. The authors gratefully acknowledge Todd Fischer and Paul Clopton for their valuable assistance in statistical analysis for this article.

**Human EEG gamma oscillations in neuropsychiatric disorders**

Clinical Neurophysiology, Volume 116, Issue 12, Pages 2719-2733 C. Herrmann, T. Demiralp

**Abstract**

Due to their small amplitude, the importance of high-frequency EEG oscillations with respect to cognitive functions and disorders is often underestimated as compared to slower oscillations. This article reviews the literature on the alterations of gamma oscillations (about 30–80Hz) during the course of neuropsychiatric disorders and relates them to a model for the functional role of these oscillations for memory matching. The synchronous firing of neurons in the gamma-band has been proposed to bind multiple features of an object, which are coded in a distributed manner in the brain, and is modulated by cognitive processes such as attention and memory. In certain neuropsychiatric disorders the gamma activity shows significant changes. In schizophrenic patients, negative symptoms correlate with a decrease of gamma responses, whereas a significant increase in gamma amplitudes is observed during positive symptoms such as hallucinations. A reduction is also observed in Alzheimer’s Disease (AD), whereas an increase is found in epileptic patients, probably reflecting both cortical excitation and perceptual distortions such as déjà vu phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes. A hypothesis of a gamma axis of these disorders mainly based on the significance of vul phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes. A hypothesis of a gamma axis of these disorders mainly based on the significance of vul phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes. A hypothesis of a gamma axis of these disorders mainly based on the significance of vul phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes. A hypothesis of a gamma axis of these disorders mainly based on the significance of vul phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes. A hypothesis of a gamma axis of these disorders mainly based on the significance of vul phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes. A hypothesis of a gamma axis of these disorders mainly based on the significance of vul phenomena frequently observed in epilepsy. ADHD patients also exhibit increased gamma amplitudes.
when ... above) and the inhibition of theta activity in the case of Attention Deficit Disorders or the...

Sleep bruxism: an oromotor activity secondary to micro-arousal
- T Kato, P Rompke, JY Montplaisir, BJ ... - Journal of Dental ..., 2001 - jdr.sagepub.com

... frequent and the burst amplitudes are higher in SB patients than in normals ... abrupt change in the frequency of cortical EEG that is occasionally ... snoring, apnea, periodic leg movement syndrome, or insomnia) or medical disorders (eg, psychiatric, neurological, or movement ... EEG and human psychopharmacology
- M Fink - Annual review of pharmacology, 1969 - Annual Reviews

... In some rigorous EEG quantitative studies, threshold drug effects were ob served when a simple reaction-time task was periodically introduced with the EEG frequency and amplitude changes measured immediately after correct performance of the task (46, 47, 50). ... EEG changes with benzodiazepine administration in generalized anxiety disorder
- MS Buchsbaum, E Hazlett, N Sicotte, M Stein, J Wu, ... - Biological ..., 1985 - Elsevier

... Day 0 predrug minus day 0 Benzodiazepine EEG in Anxiety Disorder BIOL PSYCHIATRY 835 1985;20:832-842 postdrug (2 hr) and day 0 predrug minus day 14 group means and t-tests for the ... 1985 ;20:832-842 Figure 1. Change in EEG amplitude with drug administration. ...

The application of EEG sleep for the differential diagnosis of affective disorders
- DJ Kupfer, FG Foster, P Coble, RJ ... - American Journal of ..., 1978 - Am Psychiatric Assoc

... Page 2. EEG SLEEP AND AFFECTIVE DISORDERS Am J Psychiatry 135:1, January 1978 70 ... schizo-affective disorder. All EEG sleep records were scored independently and without knowledge of the patient's clinical diag-nosis. The sleep values for each of the 95 patients rep- ...

A cross-national EEG study of children with emotional and behavioral problems: A ... 
- M Matsura, Y Okubo, M Toru, T Kojima, Y He, Y ... - Biological ..., 1993 - Elsevier

... 8.3 (1.0) 41 (36, 5) 8.6 (1.2) 26 (17, 9) 8.2 (1.6) 87 (55, 32) 8.1 (1.5) 29 (19, 9) 8.0 (1.9) aADDH: attention deficit disorder with hyperactivity, amplitude theta with 30 p,V or more, and consecutve alpha with three or more waves). Calculation of Hypothetical EEG Maturation Material ...

Individual reliability of amplitude distribution in topographical mapping of EEG
- A Burgess, J Gruzelier - Electroencephalography and Clinical ..., 1993 - Elsevier

... L., Ahn, H., Easton, P., Fridman, J. and Kaye, H. Neurometric evaluation of cognitive dysfunction and neurolog-i cal disorders in children. ... Pollock, V.E, Schneider, L.S and Lyness, SA Reliability of topo-graphic quantitative EEG amplitude in healthy late-middle-aged and elderly ...
Demographic
- Male
- Born – 1960
- Age - 46
- Diagnosed with HIV and AIDS
- Prescription drug for AIDS
- Lifestyle – altered and healthy
- Water consumption – fair
- Employment – High school teacher

Case
With this particular client it was a life and death situation right from the beginning. The patient’s digestive system was compromised due to years of unhealthy eating, without the use of digestive enzymes. On our first session together, we helped each other to balance the emotional issues and help to build the immune system. Through stress management and organ stimulation, we worked with the lymphatic system, adenoids, appendix, tonsils, thymus, liver and spleen. These organs were gently stimulated through biofeedback therapy and the spiritual healing was balanced. NLP (Neuro Linguistic Programming) techniques were used to work with guilt and self esteem issues and in addition, I added Autops zaps for AIDS and “feel good”. I told the patient that if I were in his situation I would take a “detox bath”, containing baking soda, Epsom salts, and hydrogen peroxide 3%, to help detox the skin. After a bath I would take a shower and rub my skin with coconut oil, to help bring back the moisture and oils to my skin.

He saw the benefit this would have for him, the patient mentioned that he was getting colonics done 1-2 times a week, but I noticed that he was neglecting to replace to vital digestive enzymes (probiotics) that his body was desperately searching for, this information was concluded from the beginning of his first session it was clear there was an issue with blood, environmental, immune, inflammation, liver, and fungus.

It was determined at that time that we would have a 2 hour session once a week and if there was a concern of any kind, he could call and be seen right away. What I noticed after the first session with the patient is that his skin colour returned and he had a look in his eye of confidence, as if he found his path to wellness.

Continuing
The patient returned once a week for 7 months. Over this time we worked through the layers of stressors on the body and helped supply the proper nutrients needed. I had the patient bring several types of supplements from his nutritionist and checked the resonance according to his meridian flow and reaction. It was not long after the first session that the patient’s skin began to clear up and he could return to work. His digestion and bowel movements improved greatly. This was a great relief to him, for the goal seemed to be in sight! As we proceeded through the process his body was now ready to start detoxing. At first I told him in this situation, I would do a lymphatic cleanse for 2 weeks, and then begin a liver cleanse that was supplied from a Hulda Clark website. Over 100 stones were released within his stool and lots of internal bowel congestion, that was blocking his main detox outlet.

Throughout this entire time I noticed that his VARHOPE scores were improving greatly per session, with the odd slip. The more we worked together the longer the varhopes would stay in tune. This whole process was very exciting for both of us, since at the outset of our meeting he had been sent home by his doctor to die. This alone was a traumatic event. It was a coaching and confidence building conversation, which was critical throughout the entire process.

Since I am not a doctor, I was strongly recommending that he see his doctor for check ups and routine blood checks. During this time his doctor would “forget to get his blood test done” and would not disclose his information. We couldn’t figure it out. Then the patient became angered by this and demanded that another blood test be taken and reported to him immediately. This alone was a feat of emotional confidence that was not the same the patient I first met, frail and scared of the unknown and what the future held. Two weeks passed and the patient arrives in my office with a giant smile on his face. I ask him what he was so happy about. He handed me his blood test, not only from the recent blood test but also the “lost” blood results.

It read:
HIV count –
- 327,021 copies/mL, T-cell count 30 February, 2006
- 200,000 copies/mL, T-cell count 120 May, 2006
- 70,000 copies/mL, T-cell count 449 July, 2006

This was a very exciting time for both of us since the marker for HIV activity is 50,000. It meant that we have almost reached our goal! We then continued throughout the next couple months with more biofeedback sessions.

Review
In reviewing this case I feel very confident in the direction of the therapy sessions. Other than the minor set backs, which is natural in the healing process. The body needs time to heal and to detox as well. Over the 7 months that I was working with the patient, I saw a great improvement in his spiritual, physical and emotional state. This was a great joy to see that we can help with such a fatal dis-ease.

I watch as his confidence and feeling of self worth improved. This was a very good thing, since now he was able to enjoy life to the fullest. I am looking forward to seeing the patient again in the future and see if there is any decline in overall state.

My advice to all new practitioners coming into the field of biofeedback is that we must listen to the body and not the “standard protocols”. In my experience it is relevant that balancing the person instead of the dis-ease. This alone causes for less therapy sessions and more productive results. We must understand that every individual is different and special in their own way and it would be unfair to treat every person the same as the last.
Our job and duty as biofeedback therapist is to assist the body in balancing stressors, in turn making it easier for the body to heal itself. We make suggestions of lifestyle changes and coach them through their emotional issues, so that they can make their own decisions. I find it much easier to work with clients when you have them create their own conclusions and help them to learn about themselves on an even deeper level. We need to educate, so that when our clients leave us, they are able to maintain a state of health and not fall back into their previous lifestyle that brought them to us.
Varhope charging the batteries
Varhope charging the batteries
The patient
This particular client was sent by a past client that found very good results working with me and the system. The patient was diagnosed with lung cancer at the age of 74. He had decided that chemo therapy and radiation were not the answer for him. Over the course of five months we only saw the patient five times. This is not a lot of sessions, but this was the only time that the patient could fit into his very busy schedule. The patient was very hard to communicate with due to his small understanding of the English language. He was always accompanied by his daughter, who translated everything in to his native tongue. (Italian)

Demographics
- Born – 1931
- Male, Diagnosed with lung cancer
- Six different Prescription drugs
- Water Consumption – fair
- Employment – Retired
Case
As I looked into the patient’s case, it was prevalent that virus, fungus and parasite activity was high within his body. One of the first things I noticed with the patient besides the large amount of pathogens present, was his pH levels were acidic. Making it a perfect home for all pathogens to mutate and duplicate. These pathogens were highly concentrated within the lungs and bowels of the client. This is also where he was diagnosed with cancer. Was it possible the parasites were mistaken for tumors? Very possible, I then decided to work with this concern because cancer was not in high levels, compared to pathogen activity.

the patient’s organs were also highly under stress due to his age and lack of previous care to his body. Degeneration was present, and he had a high reactance speed. His high reactance speed was telling me that his body did not recognize the pathogens as a threat; another good sign there was a possible wrong diagnoses.

Continuing
Over the five months that I saw the patient I worked with what his body needed for that day, balancing all stresses one by one. In turn this would allow his body to heal itself much quicker, and understand what was happening. The sessions were also mostly centered around Rife therapy and zapping for pathogens.

Since there were a lot of emotional issues coming to the surface, it was clear that there were some things that need to be balanced within the NLP program as well. It was very exciting to see as the weeks and months pass, the patient responding very well and balanced on all levels.

Near the end of month five the patient went missing. I didn’t hear from him for at least three (3) to four (4) weeks. It was making me worried, I decided to call his daughter and see what was happening. I was hoping for the best.

The answer was, “we didn’t tell you?” my father went to get some radiation done and before the treatment they did another MRI scan. The “cancer” was gone! Gone!

Review
To sum it all up, the patient was pleased with the sessions he received. It was amazing to see the traumatic things that were told to this particular client from his medical doctor without the proper research being gathered. Maybe if the medical world would be more accepting of biofeedback we could put an end to this “medicate or operate” system.

With a few lifestyle changes and a coaching process to deal with unspoken emotions, the results are amazing a significant. This technology of biofeedback is truly a leap towards a more productive medical system.

A few weeks after seeing the patient last, I decided to call his daughter. She had a tear in her eye and a frog in her throat. Her father went to the hospital for radiation. Before they perform the treatment it is standard protocol to administer another MRI, to find… THE TUMOR WAS GONE! How exciting is that! I was very impressed. Another person helped from biofeedback.
Varhope charging the batteries

Chart

November 2, 2005

Chart

November 7, 2006

Chart

November 11, 2005

Chart

January 9, 2006
The patient

The patient was recommended to me by his brother. His brother found us on the internet. The patient had been diagnosed with Parkinson disease. He had experienced troubles with gambling and money management due to the side effects from the medications that he was currently taking and he had “the shakes”.

When I first met the patient, he was in a very negative state. He could not hold still. Kicking and hand twitches were common. He was on three (3) different medications and was emotionally stressed. The patient is a retired hardware store owner, and had worked very hard with several highly toxic chemicals on a regular basis.

Demographics

- Male
- Born – 1942
- Age - 65
- Diagnosed with Parkinson’s
- Prescription drug for Parkinson’s
• Lifestyle – fragile
• Water consumption – fair
• Employment – retired hardware store owner

Case
The patient had been diagnosed with Parkinson’s when I first met him. Sent to me by his brother, the patient did not know what to expect on his first visit. His thoughts were scattered and his emotions were high.

I did my best to guide the patient through the initial process in explaining what biofeedback was and how it works. The patient seemed to catch on quickly, and he was ready to try it out.

There was a high amount of heavy metals present, which told me that the nerves would be damaged and the myelin sheath would be gone for the most part. Chemical toxins were also high with in his blood. On the first session I always like to go through what the body is trying to say, nutrition, spinal, NLP, nelson report, all charts and patient super conscious reduction. This gives me a good idea of what is causing the most stress within the body and what the body is ready to deal with first.

Once I had my information it was very easy to find the path to wellness and the thread to dis-ease. With the patient it was all about the toxins running everywhere in his body. The homotoxicology screen was filled with red and endless supplies of toxins were present.

Continuing
With this information I asked the patient how often his bowels movements were and if there was any pain. Once I had that information it was evident that his bowels needed to be detoxed before any toxins were released.

Most sessions were centered on detoxing the body, repairing the nerves and bringing back mental clarity, although every session was different than the last. After our first session with the patient, he held out his hands. Which were not shaking! He then said “I haven’t been able to do this in 20 years”! I was amazed.

With more talking and coaching it was obvious the 30 years of working with toxic materials was the cause of his diagnosis of Parkinson’s. And the side effects of his medications were the cause of his gambling addiction. Working with his doctor, the patient was able to come completely off his medications and the nutrition profile allowed the patient to have a nutritious lifestyle. Increasing the amount of water in his diet and using a cilantro pesto for heavy metal detox was essential to the patient regaining health and reversing the aging process.

Review
In conclusion I would like to say that over 6 months and 11 sessions that the patient had we reached our goal! the patient was able to return back to the things he loved most. His sense of humor was back and he was able to play golf again with his brother. It was amazing to see the patient start as an individual sent home by his doctor to be a vegetable, into a strong willed, funny, and loving husband and brother. the patient was truly blessed to have come in contact with biofeedback and to receive the results he did.

The patient is currently living out his retirement as he should, playing golf, laughing lots and loving life even more. His self confidence has returned and his gambling has stopped.
Varhope charging the batteries
Varhope
charging the batteries

Chart

December 5, 2005

Chart

December 16, 2005

Chart

January 3, 2006

Chart

January 10, 2006
Discussion

The SCIO measures global electrical measures of the body. When there are abnormal measures of the electro-physiological factors, the device allows a feedback loop between the Central Nervous System (CNS) of the patient and the device. We have seen hundreds of clients in our Clinic, this report shows 3 cases intimately. But in the other cases there is almost always some improvement in the VARHOPE indices are even one therapy. Of our clients visits, some 50 plus % show very low electro-physiological factors, some all below 30% normal. The cybernetic electro-physiological feedback loop is used to help the client reduce stress and thus improve the electro-physiological factors. There was improvement in over 95% of the electro-physiological measures at the end of the session (post test) versus the pre test. The average improvement in electro-physiological VARHOPE factors is 5% per session. These clients report stress reduction and improved well being as well.

Norms of patient voltage, amperage, resistance, capacitance, inductance, reactance, impedance, and proton electron balance, have all been established.

When we intake air and breathe we oxidate. This produces a shift up and down of our amperage. Oxidation is measured as the average shift in amperage over a measured set of time. Hydration is the shift of voltage over a set of time.

Proton pressure versus electron pressure is the measure of which is more plentiful in the body. Excess protons means an acid condition, excess electrons means alkalinity. By measuring the electrical imbalance from the various electrodes of the SCIO we can measure the proton versus electron pressure. A balance form is reported at 70 where there are equal numbers of electrons and protons. Below 70 is excess protons, above excess electrons. A variation of the ph scale.

The SCIO software will allow the Central Nervous System (CNS) of the patient to guide to stabilize electrical and vibrational divergence in your body. This is the cybernetic loop or biofeedback component of the system.

• Important Note (This study had the following contributors:
  • Institution : International Medical University NE
  • Ethics Committee Int IRB : Ethics International
  • Medical staff has supervised the overall study
  • Peer review committee for the International Journal of the Medical Science of Homeopathy has reviewed and accepted this study for publication.
  • The purpose of this study was to assay the safety and efficacy of a visit to a trained SCIO therapist, exacting statistics are not assayed beyond the simple questions of reported success.
  • Thus this study points to further scientific studies of more refined statistics.)
Clinical Study No. 3. - VARHOPE Changes in a SCIO Session

Correction of aberrant body electric profiles such as voltage, amperage, resistance, impedance, proton + electron pressure,

Part of the Following:
Large Scale Study of the Safety and Efficacy of the SCIO Device

Chief Editor:
Prof N. Vilmos

Edited and Validated By:
Mezei Iosif, Sarca Ovidiu
Somlea Livia

Consultant:
International Ethics, Lebedei 58,
Oradea, Romania

Developed By:
The Centro Ricerche of Prof. William Nelson University of Venice + Padova, Italy

This study was performed in the field by practicing Biofeedback technicians. Data was collected and the study supervised by the Ethics International Institutional Review Board of Romania. The Data analysis and study presentation is done by The Centro Ricerche, University of Venice + Padova, Italy


(This article is translated into English and Hungarian from the original Romanian)

Abstract
This study demonstrates the safety and effective qualities of the SCIO device used in a large scale study. A large scale study of over 97,000 patients with over 320,000 patient visits reported their diseases. The SCIO measures global electrical measures of the body. When there are abnormal measures of the electro-physiological factors, the device allows a feedback loop between the Central Nervous System (CNS) of the patient and the device. Of the patient visits listed some 50 plus % showed very low electro-physiological factors, below 30% normal. The cybernetic electro-physiological feedback loop was then used to help the patient reduce stress and thus improve the electro-physiological factors. There was improvement in over 95% of the electro-physiological measures at the end of the session (post test) versus the pre test. The average improvement in electro-physiological VARHOPE factors is 5%. These patients reported stress reduction and improved well being as well.

Introduction

Overview
This large scale research was designed to produce a extensive study of people with a wide variety of diseases to see who gets or feels better while using the SCIO for stress reduction and patient monitoring. The SCIO is a biofeedback Universal Electro-Physiological Medical apparatus. The device is registered in Europe, America, Canada, S Africa, Australia, S. America, Mexico and elsewhere. The traditional software is fully registered. Some additional functions where determined by the manufacturer to be worthy of evaluation. Thus a study was necessary to determine safety and efficacy. (As a result of these studies these additional functions are now registered within the EC)

An European ethics committee was officially registered and governmental permission attained to do the insignificant risk study. Qualified registered and or licensed Biofeedback therapists where enlisted to perform the study. Therapists were enrolled from all over the world including N. America, Europe, Africa, Australia, Asia, and S. America. They were trained in the aspects of the study and how to attain informed consent and transmit the results to the ethics committee or IRB (Institutional Review Board).

2,569 therapists enlisted in the study. There were 98,760 patients. 69% had more than one visit. 43% had over two visits. There were over 320,000 patient visits recorded. The therapists were trained and supervised by medical staff. They were to perform the SCIO therapy and analysis. They were to report any medical suspected or confirmed diagnosis. Therapists personnel are not to diagnose outside of the realm of their scope of practice. Then the therapist is to inquire on any reported changes during the meeting and on follow-ups any measured variations. It must be pointed out that the Therapists were free to do any additional therapies they wish such as homeopathy, nutrition, exercise, etc. Therapists were told to not recommend synthetic drugs. Thus the evaluation was not reduced to just the device but to the total effect of seeing a SCIO therapist.

• Part 1. The emphasis was on substantiating safety followed by efficacy of the SCIO.
• Part 2. Proving the efficacy of the SCIO on normalizing the electro-physiological factors

Methods and Materials:

SCIO Device:
The SCIO is an evoked potential Universal Electro-Physiological Medical device that measures how a person reacts to items. It is designed to measure electro-physiological factors. Biofeedback is used for stress reduction and muscular re-education.

The SCIO measure global electrical measures of the body. Norms of measurement can only be assayed on an individual piece of equipment. The nature of the electrodes, the size or surface area of measurement, age and personal demographics, the reading mechanism etc. The SCIO has been registered in many countries and has been legally sold for over two decades. After thousands of patients tested with this device in the late 1980s, norms of the electrical parameters have been set. Norms of patient voltage, amperage, resistance, capacitance, inductance, reactance, impedance, and proton electron balance, have all been established.

When we intake air and breathe we oxidate. This produces a shift up and down of our amperage.
Oxidation is measured as the average shift in amperage ove a measured set of time. Hydration is the shift of voltage over a set of time.

Proton pressure versus electron pressure is the measure of which is more plentiful in the body. Excess protons means an acid condition, excess electrons means alkalinity. By measuring the electrical imbalance from the various electrodes of the SCIO we can measure the proton versus electron pressure. A balance form is reported at 70 where there are equal numbers of electrons and protons. Below 70 is excess protons, above excess electrons. A variation of the pH scale.

The SCIO software will allow the Central Nervous System (CNS) of the patient to guide to stabilize electrical and vibrational divergence in your body. This is the cybernetic loop or biofeedback component of the system. For complete functional details and pictures, see appendix.

### Basic Software Design:

The SCIO software is designed for electrophysiological connection to the patient to allow electrophysiological and rectification of subtle aberrance of the body electric. The feedback loop is established by measuring the electrophysiological factors, feeding them back to the CNS and re-measuring the changes, feeding them back to the CNS, and on and on till a satisfied result is attained for the day.

### VARHOPE Scores

As previously described, there are norms set for the Body electrophysiological measures. Since these measure are relative to age, sex, and other demographics, a percentage of the norm is used on the report. There is a degree of inaccuracy as well. norms are reported loosely as above 80%.

In this series of tests when the percentages of the global VARHOPE are all below 30%, the device patient records were used to report the post test or after therapy results.

### SOC Index (Library Function stressor questionnaire):

The SCIO interview opens with a behavioral medicine interview. This is called the SOC Index. Named after the work of Samuel Hahneman the father of homeopathy, he said that the body heals itself with its innate knowledge. But the patient can suppress or obstruct the healing process with some behavior. Hahneman said that the worst way to interfere with the healing process was allopathy or synthetic drugs. Theses upset the natural healing process by unnatural intervention and regulation disturbance. Other ways to Suppress or Obstruct the Cure are smoking, mercury amalgams, stress, lack of water, exercise and many others. This behavioral survey then gives an index of SOC.

The scores relate to the risk of Suppression and Obstruction to the natural Cure. The higher the scores the more the Suppression and or Obstruction. The scores of 100 or lower are ideal. A copy of the SOC index questions appear in the appendix.

### Study Technicians:

The study technicians were educated and supervised by medical officers. The study technicians were to execute the SCIO therapy and analysis. All were trained to the standards of the International Medical University of Natural Education. Therapists from all over the world including N. America, Europe, Africa, Australia, Asia, S. America and elsewhere were enlisted to perform the study according to the 1951 Helsinki study ethics regulations, since modified several times.

They were to chronicle any medical suspected or confirmed diagnosis. Therapists personnel are not to diagnose outside of the realm of their scope of practice. Then the study technician is to inquire on any disclosed observations during the test and on follow-ups report any measured changes.

To test the device as subspace against the placebo effect, two of the 2,500+ therapists were given placebo SCIO devices that were totally outwardly the same but were not functional. These two blind therapists were then assigned 35 patients each (only 63 showed). This was to assess the double blind factor of the placebo effect as compared to the device. Thus the studied groups were

A. Placebo group, and B SCIO group.

Cross placebo group manipulation was used to further evaluate the effect.

### Important Questions:

These are the key questions of the study

1. Define Diseases or Patient Concerns
2. Percentage of Improvement in Symptoms
3. Percentage of Improvement in Feeling Better
4. Percentage of Improvement Measured
5. Percentage of Improvement in Stress Reduction
6. Percentage of Improvement in SOC Behavior
7. What Measured+How (relevant measures to the patient’s health situation)
8. If Patient worsened please describe in detail involving SOC_

After the patient visit is was complete the data was e-mailed to the Ethics Committee or IRB for storage and then analysis. This maneuver minimized the risk of data loss or tampering. Case studies were reported separately in the disease analysis.

### Results:

Before we review the direct disease improvement profiles, we need to review the overall results. The first most basic of question in the results is the basic feedback of the generic patient conditions.

#### Percentage of Improvement in Symptoms

1. Percentage of Improvement in Symptoms
2. Percentage of Improvement in Feeling Better
3. Percentage of Improvement Measured
4. Percentage of Improvement in Stress Reduction
5. Percentage of Improvement in SOC Behavior

The SOC index gives us great insight to this study. Each disease has a different cut off were the ability of the SCIO to help was compromised. As a general index scores of 200+ where much less successful.

The electrophysiological aberrant group total number of patients was 55,921
SCIO Harness Patients, 55,921 Patients

OVERALL ASSESSMENT

A. Placebo Group- 63 cases with a Dbl Blind System and no Treatment
There were no cases of patients who reported a negative Improvement.

There were
• 19 cases reporting no improvement of Symptoms, 30% of group
• 12 cases reporting no improvement in feeling better, 19% of group
• 13 cases reporting no improvement in stress reduction 20% of group
• 12%—Percentage of Improvement in Symptoms
• 15%—Percentage of Improvement in Feeling Better
• 2%—Percentage of Improvement Measured
• 12%—Percentage of Improvement in Stress Reduction
• 3%—Percentage of Improvement in SOC Behavior

B. SCIO Treatment 163,870 patient visits
There were 658 cases of patients who reported a negative Improvement.

There were
• 512 cases reporting no improvement of Symptoms, .003% of group
• 759 cases reporting no improvement in feeling better, .004% of group
• 460 cases reporting no improvement in stress reduction .002% of group
• 65%—Percentage of Improvement in Symptoms
• 56%—Percentage of Improvement in Feeling Better
• 24%—Percentage of Improvement Measured
• 53%—Percentage of Improvement in Stress Reduction
• 20%—Percentage of Improvement in SOC Behavior

There was a overall 43% average improvement in the VARHOPE score from the therapy on each visit. There was an additional improvement on persuing visits.

Pre and Post SCIO Therapy Electro-Physiological percentages

<table>
<thead>
<tr>
<th>SCIO Treatment 163,870 patient visits</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>25</td>
<td>33</td>
</tr>
<tr>
<td>Amperage</td>
<td>21</td>
<td>27</td>
</tr>
<tr>
<td>Resistance</td>
<td>10</td>
<td>15</td>
</tr>
</tbody>
</table>

SCIO Treatment 100,834 patient visits

Below

Proton vs Electron 50 57

SCIO Treatment 63,036 patient visits

above

Proton vs Electron 79 77

Discussion

The results show significant improvement in symptoms and feeling better. The Collective results show a dramatic benefit to the SCIO therapist visit.

The Electro-physiological factors were slightly improved during the SCIO therapy. This is reported by most of our therapists. The Cybernetic Feedback loop of the SCIO to the CNS seems to be helpful in stabilizing the VARHOPE.

There is much more to the body electric than resistance. It is impossible to measure a frequency with a resistance device such as the Listen, Voll, Vega or other simple resistance devices. This makes for a very complicated fractal system that can be difficult to analyse. With a computer a vast amount of electrical data can be collected and analysed. This can then allow for the beginning of a true energetic medicine. Below is a abreviated list of electrical variables and thier corresponing components that our SCIO can analyse in the short space of minutes in a clinical setting. The time of ionic exchange is approximately one hundredths of a sec. Thus it would be impossible for a person who wants to test a patient with a manual device.

*articles in Promorpheus

As we pointed out in the Promorpheus, electricity as an electrical entity travels in the direction of, for example, your right thumb. Then for conduction of the electron, there is a magnetic field produced at 90°, and a static field will be produced at another 90°. This electromagnetic and electrostatic combination and its effect on conductance and from conductance is the basis for understanding electrical phenomena.

The factors of the electrotlyte in the body greatly effect the electrical nature of the body. The amount of minerals, liquids, oxygen, amino acids, fatty acids and others effect the nature of the electrolyte. So our total energetic medicine (beyond simple resistance variables) can offer us great insights into many facotrs of health. Since so much of energetic medicine is fixed in one channel resistance point probetechniques it is time for a quantum leap in the technology. In this article we will outline some basic aspects of energetic medicine for electroencephalographs electrocardiology and energetic medicine.

This article will outline the electron and its action. The photon link is outlined in the Promorpheus.

French physicist Coulomb laid out a law, which states: "The force of attraction or repulsion between two charged bodies is directly proportional to the product of the charges and inversely
Thus the force can be allowed in the following equation

\[ F \approx \frac{Q_1 \times Q_2}{D^2} \]

The inverse square law is a dictum of four-dimensional physics. Our ten-dimensional model questions its pervasiveness.

Here \( Q \) represents the force of the charges, \( D \) is the distance, and \( F \) is the force in dynes. A coulomb of charge, \( C \), is nearly \( 3 \times 10^9 \) esu. The strength of an electrical field will have the equation

\[ E \approx \frac{9 \times 10^9 \times q}{R^2} \]

This is called the electrical potential. The potential at a point is equal to the work needed to bring one coulomb charge to the point from an infinite distance away. Biology will need to monitor this effect very closely.

An electric potential is thus work per unit of charge. Kinetic energy, which is equivalent to work, is measured in a relationship of force to distance. A gram that is moved at one centimeter per second of velocity is an erg. A kilogram that is moved at one meter per second is known as a joule. When we have a joule per coulomb, this is known as a volt. One volt equals one joule divided by one coulomb. The volt is often a measure of potential energy. It is the difference between two points, between positive and negative charge; thus a six-volt battery with a potential difference of 6 joules or coulombs that can flow from one terminal to the other. Potential difference, thus, is an integral measurement of profound importance in biology and medicine.

If the surface of an item has a charge that is stored as potential energy, the ratio of charge to potential is called the capacitance of the body. The basic unit of capacitance is known as the farad, which is one coulomb per volt. If one coulomb of charge added to a body gives it potential of one volt, it has the capacitance of one farad. In a capacitor current is proportional to the rate of change of voltage.

Thus capacitance can be measured as a fluctuation in voltage (\( \Delta V \)) over a qualitative time.

\[ \text{1 Farad} = \frac{1\text{ Coulomb}}{1\text{ Volt}} \]

BOLD \( \frac{\text{dV}}{\text{dT}} = \text{Amps} \)

The farad is a very large unit, measuring a lot of potential. Often in electronics we use micro-farads, or even pico-farads; a micro-farad being 10-6 farads and a pico-farad being 10-12 farads. By having two sheets of a high conductor, such as metal, with an insulating material between them, we can produce a condenser or capacitor. In biology cellular forces will invoke pico-farads. Organismic forces must relate to and control micro-farads.

The capacitance of the capacitor is the amount of the electrical charge on its plate divided by the potential difference between its plates. This depends on several factors, such as the area of the plates. If the plates are made larger, greater charge can be put on them. The thickness of the insulating layer is important. The closer the plates are to one another, the greater the amount of charge that is held. It is the strength of the electric fields of the electric plates as they are brought closer together. In biology organs, cells, organ systems, and organisms must store charge to deal with metabolism and growth.

The material between the plates will have an influence on the capacitor. These insulators, or non-
The strength of the magnetic field created by a current is directly proportional to the strength of the electric current flowing through a wire. This relationship is expressed by the right-hand rule. Now let us look at some of the basic components and relationships of magnetic fields.

Precise systemic measurement of magnetic fields is invaluable for easy bio-force analysis. For biology, Ohm’s law offers an ability to calculate variables more accurately. Ohm’s law, when involved in quantic systems, is not an electrical system we must know the amperage, the voltage, and the resistance in order to be able to calculate variables more accurately. Ohm’s law, when involved in quantic systems, is not precise, but still shows the tendencies of electromotive force. For biology, Ohm’s law offers an invaluable systemic measuring system for easy bio-force analysis.

When we move one coulomb of charge per second, this is known as an ampere. An amp is movement or quantity of charge. Movement of charge, amps, is the most important criterion of Ohm’s law. It correlates to life force and indolamine production.

\[ 1 \text{ Amp} = 1 \text{ Coulomb per second} \]
\[ \text{Volts} = \text{Inductance} \times (d\text{Amps}) \text{ over } (d\text{Time}) \]
\[ \text{Amps} = \text{Capacitance} \times (d\text{Volts}) \text{ over } (d\text{Time}) \]

Dr. Ohm, a German physicist, found that electric current in a conductor is directly proportional to the potential difference between its ends. Thus he generated Ohm’s law, finding that the resistance of one ohm is generated in a conductor if the potential difference of one volt between its ends will cause a current of one ampere to flow through it. Thus we have generated and found Ohm’s law, which is

\[ \text{Ampere} = \text{Volts} \div \text{Ohms} \]
\[ \text{Ohm’s law is not strictly adhered to in electrolytes, discharge of gasses, and semiconductors; nor is it followed perfectly applicable to biology, for there are many different factors that can affect it. Changing potentials over time causes an instability in Ohm’s law for biology. But in knowing an electrical system we must know the amperage, the voltage, and the resistance in order to be able to calculate variables more accurately. Ohm’s law, when involved in quantic systems, is not precise, but still shows the tendencies of electromotive force. For biology, Ohm’s law offers an invaluable systemic measuring system for easy bio-force analysis.} \]

Now let us look at some of the basic components and relationships of magnetic fields.

When strongly polarized molecules align, they induce stronger and stronger magnetic poles. An electric current flowing through a wire will also generate a magnetic field of 90 (right-hand rule). The strength of the magnetic field created by a current is directly proportional to the strength of the current and inversely proportional to the distance from the wire. The formula for this will show that

\[ \text{Magnetic Fields} \propto \frac{(\text{Amp})}{(2\pi d)} \]

Thus a magnetic field strength can be measured in units of amperes per meter. Inductance is the factor measured for biological significance. Magnetic and paramagnetic forces can have strong implications in the long- and short-range forces of biology (see PROMORPHEUS).

A magnet near a stationary electric charge will not have an effect on it. If there is movement, then they have a natural influence on each other. Biology will need to be dynamic, and move constantly to use magnetic properties. The force of this influence is at right angles to both the velocity of the charge and the direction of the field. Stagnation is a magnet’s enemy.

The magnitude of this force is

\[ \text{Force} = \text{Charge in Coulombs} \times \text{Velocity in meters per second} \]
\[ \text{and Magnetic Force of Amperes per meter} \times \text{x the Permeability Factor through which the Magnetic Field permeates.} \]

This permeability factor times the magnetic factor, which is amperes per meter, is known as the magnetic flux density, or the magnetic induction, and is expressed in Webers per square meter. In an inductor the voltage is proportional to the rate of change in the current.

\[ \text{Inductance} \times \text{TIMES} \times (d\text{Amps}) \text{ over } (d\text{Time}) \times = \text{Volts} \]

These permeability factors are rated between that of the material and that of permeability of a vacuum. Materials that are high-ratio (that increase the flux density) are called ferro-magnetic; such as iron, cobalt, and nickel. Substances that are close to the ratio of 1, or other substances (which are very near to the relationship of the vacuum) are para-magnetic, and will contribute weakly, such as aluminum. There are substances like bismuth that are actually detrimental to the magnetic field. These are called diamagnetic, and their ratio is actually less than 1. Items which are non-magnetic will have no influence, and thus have a ratio of 1. Bismuth will have a place in biology, and is used in several homeopathics for energetic stability. Magnetic induction can be measured by changes in amperage over a qualitative analysis, such as the QXCI* machine test. This might be used to infer magnetic interaction, and thus, involvement of geopathic stress.

Thus we have outlined the concept of magnetic, static, and conductive forces, which are used to our understanding of the electrical nature of our homeopathic pharmaceuticals. By measuring the inductance, the dielectric constant and the conductance relationship, we can find an electrical profile for these various substances. This makes up an electrical fingerprint that allows us to calculate and plot its electrical nature. The trivector analysis is born. The long-range implications on energetic medicine are profound.

By charting the resistance, inductance, and dielectric constant of various homeopathic items we can get a trivector analysis of their electromagnetic fields. This trivector analysis gives us three vectors, which we will be able to apply to a three-dimensional space. Thus a variety of homeopathics have been analyzed for their trivector analysis. The dimension of time gives us a
four-dimensional relation that with some superb mathematics we can extrapolate the six virtual
dimensions using a trinary logic system.**

Here we can see some of the effects that sarcodes, nosodes, allersodes and classic herbals have
in their relationship to each other. This trivector analysis gives us a quality control factor for the
electric field of a homeopathic item. In analyzing patients we can analyze serum in blood or
personal field in a similar fashion. We can measure body pH from urine, blood, breath, etc., as well
as redox capacity and body fluid resistance. Skin resistance readings can be taken at several
points and easily averaged. Body voltage can be easily measured by dissimilar metals creating potential
across the electrolyte capacity of the body, just as in a battery. Most proficient instruments choose
to use silver and zinc (zinc because of its equi-potential for giving or receiving electrons, silver
because of its great medicine history). Amperage is a correlate of voltage and resistance by placing
similar metals in contact with the body (two silver probes contacting the frontal eminences). We
can get an amperage reading. For our device Carbon electrodes were chosen for their ability to
accept and donate electrons. Capacitance is measured by changes in voltage during a scheduled
interview. Inductance can be calculated through changes in amperage over the same interview.
Resonant frequencies of the body can be calculated from the equation

\[ \text{Resonance} \sim \text{Freq.} \sim 10^6 / \sqrt{1 - (\text{CAP}^2 + \text{IND}^2)} \]

From these readings we can now calculate a true metabolism chart to define a patient's overall
health and energetic well-being. .

The preliminary work has shown that where patients have valleys, or dips, in their fields,
homeopathic peaks will be helpful. Work on this is just starting; more work, funding and time
will be needed before we can find out if this is a viable technique for quality control and/or for
homeopathic utilization. Now, with the help of the computer, matching remedies is high-tech and
easy.

Another factor that we can use with this trivector analysis is that once we know the first three
vectors, and the vector of time, we might be able to extrapolate the other six virtual dimensions.
If we know the four factors of conductance, capacitance, inductance and time, we might be able
to extrapolate other dimensional effects from this four-dimensional type of field.

Biology needs to not only look into quantum physics but also needs to embrace an energetic
philosophy as well. This seems complicated at first, but is easy with today’s tools. Applying our
right-hand rule and Ohm’s Law to energetic medicine represents a dramatic quantum leap in
energetic medicine which is significant to the field.

---

** Bibliography **

** Books **

** Articles and studies **
- Full Spectrum Micronutrient Treatment of Bacteria (Homeopathic Treatment of Bacterial
- Homeopathic Stimulation of White Blood Cell Motility as Analyzed under the Microscope (A
- International Medical Journal of the Science of Homeopathy. IMUNE PRESS
There is other forces such as the large atom force that when the extreme energy in a sun forces protons to overcome their need to repel and forces them together. Thus all atoms past hydrogen are made in the stars. Gravity is the force that when matter is made all matter is drawn together. This is a weak force, as Newton once said — it takes a group of matter the size of the earth to make a liter of water weigh a kilo.

There is another weak force that is undeniable, the power of the mind. We know from Quantum theory that twin photons can be separated to any distance and when we tell one photon something the other twin knows it instantly. At the birth of the universe there was a big bang where all of the matter of the universe came through a singularity in ten to the minus 43 of a sec. Thus at one point in our past history all things were conjoined and as such there is an ability of a quantic system to influence another.

The observer effect of physics, the need for a double blind in medicine, and other evidence in the Proof movie. REF. There is not a law of Attraction as some have said but there is an effect of Attraction. There is a power of the mind (a known Quantic engine) to influence another Quantic system. Science has for a long time laughed at this and has purposefully avoided the proof of this true effect. And now science has become a search for funding not a search for truth. And since humiliation might interfere with funding most scientist still ignore the evidence. This is the height of ignorance to ignore.

So with some simple science taught in our schools let us analyze the development of biology. First our fifth grade science tells us we are mostly electro-magnetic-static and Quantic fields. Non-living things mostly obey the laws of thermodynamics. The laws of thermodynamics teach us that energy can not be created or destroyed, and that heat must flow from a hot body to a cold body.

**Basic Science**

In 5th grade we are all taught a basic scientific fact, we are made of atoms. All things are made of atoms. Atoms are made of electrons, protons, neutrons, and other much less numerous subatomic particles. The electrons and protons make up by far most of things and thus most of our bodies. The electrons and protons are electrically charged. The electrons are so highly charged that they never touch but instead repel when they approach another. The electrons, protons, and neutrons are very small and they are held apart from each other by fields. If we condense the solid matter of the electrons, protons and neutrons together the human body would be so small it would take a microscope to see it. If the proton is the size of a golf ball, the electron is smaller than the size of the point of a pin and it is over a mile away. Between the electron and proton thus is electro-magnetic-static fields, held by Quantic forces. So our bodies are more than 99.99999999999999999999999 fields empty of matter. These Quantic electro-magnetic-static fields are what we are. This is 5th grade science, maybe not the science taught in Seattle.

No one has yet to see the true nature of our existence. No one can see the electrons, protons, or the fields they make. So we are only able to see a macro form of it. Our brains are trapped inside our skull and thus we cannot directly perceive anything. We are thus stuck with an indirect perception. A perception that comes thru the brain and is effected by our brain state. We project our own feelings, memories, psychic mental states onto our perceptions. It is difficult not to. So as humans developed we have made many assumptions of how the universe works, what is the nature of our bodies and lives, and our belief in a power greater than our own. And with a sense of history and knowing that we must project, and twist ideas, we should always be humble and recognize that we can never know. We are stuck making good guesses, better and better guesses, but always guesses. This book is about making a better guess. (REF Perception book 1 + 2)

In 9th grade we are taught about light. Light is made of photons. Photons are electro-magnetic radiation, particles in wave formations that can transfer energy. Quantum Electro-Dynamics QED tells us of how when an electron absorbs a photon the electron goes to a higher quantum energy state. When the electron releases a photon it goes to a lower state. QED tells us of virtual photons and just how all electron, proton, neutron movement is connected to the photon.

Voltammetry is the science of understanding how a substance’s electro-magnetic field reacts with it’s environment. A hormone has electrons and protons and how they are placed in a 3 dimensional space will determine how it exchanges electron-magnetic action and this is measured by measuring the 3 dimensional effect of it voltammetric field. The amount of charged particles is the amperage, the pressure or potential of the charged particles is the volts. Basic 7th grade physics. Every compound having it’s own individual and distinct voltammetric signature field. REF Voltammetry.
The Human Body Electric

There are over one hundred trillion cells in the human body and all are sending signals to the brain via enervation and photon exchange. Making some ten to the 16 bits of data per second. Or less. 1,000,000,000,000,000 bits of data. The word area of the brain has developed as a small part of the human brain. About the size of a golf ball this small Broca area for words. Words coming in and words going out. The rest of the Brain is for life, metabolism and reproduction. Life is an unconscious process. Life is non-verbal. We do not have to think words to live. Words are for helping us function in social ways.

We have a reticular formation in the base of our brains that act as a filter to screen out unneeded data from our word area. The word area has the ability to assay about one million 1,000,000 bits of data at a time. More and the word area goes into overload. Below one thousand sensory bits and the system goes into sensory deprivation mode. It invents sensory data.

This means that ten to the sixteenth bits of data minus the ten to the 6 bits of data for the word area and the word area of the brain gets one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of the data sent to the brain. The unconscious non-verbal body electric gets all of this data and much more.

The hot coffee must succumb to the colder room and the two gradually equate their temperature. Biological systems outwardly seem to disobey these laws by maintaining a temperature difference and not succumbing to the room temperature unless the die. Then as the Washington Post editor says, after death they lose their battle with room temperature. Biology is using a slightly different system of laws with a more quantic system than thermodynamic. REF PROMORPHEUS.

A living thing must be able to metabolize and reproduce in some fashion to be considered alive. Metabolism is taking in nutrients, taking the energy from them, and excreting the remainder as excretions of waste products. Reproduction is assembling new tissue for repair and also to propagate the species. The energy is Quantic electro-magnetic-static in nature as is everything. The basic energy of the electromagnetic radiation that is Visible light or Infraredheat. Plants take in low energy ionic bound minerals and use the energy of visible light to make high energy covalent bound plant compounds which are then food for the animals. This is the process of photosynthesis as shown in the Calvin Cycle.

Animals take in the high energy compounds with electrons in high energy states. This energy is then gleaned in the cells via the Krebs Cycle to make ATP (Adenosine Tri-Phosphate) for energy. ATP is the key energy of most life.

The single cell systems such as bacteria set up a boundary layer such as a cell membrane to separate the thermodynamic world from the quantic interior. Entropy and thermodynamics dictate process in the non-living exterior versus the Quantic organism organized non random entropy interior. Metabolism and reproduction guided by a organized accounting of energy intake and outgo. Geared for metabolism and reproduction. Quantic Electromagnetic fields in cyclical organized fashion that is mostly dependent on the Quantic actions of DNA. DNA can only be described in the Quantic electromagnetic actions of the fields of it voltammetric structure.

Single celled organisms develop or evolve if you will allow us to say into multi celled organisms. This needs more complex DNA structures and the number of chromosomes needed grows. DNA acts as the chief accountant as it sends off RNA and messenger RNA to accomplish the goals of life. Life develops with tremendous diversification over 100,000,000 organisms have evolved with various and diverse functions. But all are Quantic electromagnetic exchange devices taking in energy, excreting waste products, and trying to reproduce. Everything having it’s own set of field intricacies, and a single reactive ever changing overall field signature. The Quantic Electro-magnetic-static field of an organism is reacting towards nutrition and away from toxins. To maximize metabolism. It reacts to mating signals and reproductive gesticulations to maximize reproduction.

Everything is a wash of field interactions and electromagnetic radiation photons. The cells of biology use this electromagnetic radiation for communication. Information for reproduction or Mitogenic radiation is in the visible, metabolism radiation is in the Infrared. Biology does not just send heat out as a waste product it is a communication network for cellular info exchange.

The multi-celled organisms diversify and all have an innate non-verbal Quantic electro-magnetic drive for survival. Biology operates thru field interactions. The height of DNA diversification is presently the development of a word are of the brain. And are where we think in words. This allows for explicit communication and exchange of thoughts, feelings, desire, fears, etc.
individual style of electron and proton interaction. This is how every substance reacts to another, the outer electrons never touch but the field interaction as determined by voltammetry is a definition of how they work.

Every atom or molecule can be balanced, positive charge, negative charge, or combination of both. This depends on the amount of protons and electrons. This is Basic grade school science.

The charged particles that travel make a current flow. The amount of charged particles in the amperage, the pressure or potential of the flow is the voltage, the resistance to the flow is the resistance. All organisms use this electrical flow of charged particles for each and every biological process.

The electron is the smallest charged particle to move, and most of electricity is of the traveling electron. But protons and ions range from the small to very large.

The outer electrons of a plant are taken to higher energy states thru the QED phenomena known as photosynthesis. These electrons are most often stored in carbohydrates and natural sugars. The body uses them for energy, making ATP from the electrons.

Energy transfer in the body takes place in many voltammetric ways. Water has free protons and free electrons and thus it is essential for life. Water does not conduct electricity, unless there are some mineral salts or electrolytes in the water. But as in the salt water the body has lots of water and electrolytes. Thus the body electric can thrive.

Fish like the shark swim and thus live in an electrolyte conductive medium. They develop electrical sensing systems, and can detect foods by their voltammetric signatures. In other land creatures like humans this electro sense is transferred to the skin and nose. But still voltammetric sensing of items are the basis for life.

We have the sense of sight for photon sensing, hearing for sound vibration detection, feeling for movement, pressure, heat, cold, balance, and the alkaline acid balance of chemicals. Smell and taste are voltammetric shape receptors sensors. (REF 2004 Nobel prize + electro sense). The largest gene family of our DNA is dedicated to the smell, over 3% in humans, 7% in some animals.

All of our senses are electrical in action and transfer mechanism. Some of our sensory system is directed to our verbal or conscious mind and most to our non-verbal unconscious.

In the human body there is massive transfer of electrical signals. The flow of food entering the colon during digestion is based on static electrical attraction. Water facilitates the entire body electric. The body heat is photonic and also contributes to information transfer. If we look at the body human with today's modern science of QED and electronic physics, a whole new science develops a world different than the synthetic drug and surgery medicine we have today. Today's so called modern medicine is based on a 200 year old reductionism 17th century Newtonian antiquated physics. A true new modern medicine of the body electric opens the door to a more affordable, sophisticated, safer, and more efficient modern medicine. (REF Body Electric, Science over Convention)

There is resistance to the flow of electricity. Louis Ampere discovered amperage, Volta discovered Volts, and Dr. Ohm put a law together to describe the relationship in terms of resistance. resistance is in Ohms and Ohms law states that voltage equals amperage times resistance. This is the first week of electronics class usually taught in 9th grade physics.

The spiritual cultures of the world know this and all exercises in spiritual development revolve around diminishing the words in the brain and coming aware more of the unconscious process. Mantras, meditation, stillness, yoga, kundalini, and many others all say we must control and diminish to effects of the verbal word mind to get in touch with our body energetic. The true self.

Much of the mistake of modern science and modern societies is to over value the words and the verbal process. Our society is presently over valuing the paper pushers and letting their need for words be more important than people. We need paper pushers and we need to have quality systems but there should be a requirement to try to minimize the over wordy and clarifying the process of our society for everyone to understand not just the small minded paper pushers. This is especially true for biology and medicine.

The very process of life in an innate unconscious non-verbal Quantic electromagnet field interaction. Words have little to do with it. But so-called modern medicine has overvalued the words. They wait for the patient to verbally notice something is wrong, go to the doctor office and announce what is wrong, answer the doctors' verbal questions, and receive verbal instruction. And yet this verbal exercise of medicine is only aware of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of one percent of the data. The body electric knows much more.

Patients words are influenced by their mood state. Patient’s all lie, at least that is what Dr. House tells us on TV. Patients sometimes say things they think the doctor wants to hear, they coverup things they don’t want the doctor to know and very often they are completely out of touch with their own feelings and symptoms. Once I asked a patient if they had regular bowel movements. She said of course once a week like clockwork. Words are often the only intervention given to a doctor. In ancient China the doctor was sometimes unable to see the patient if he was of royalty. So the Chinese doctors had to develop new skills. Words have been a hallmark of medicine but it is also one of the greatest limitations. You can be really sick and have no symptoms or any verbal awareness of your sickness. Many people have tended to not only over value words, but some assume falsely there is only words.

Now as we learned in 5th grade everything is made mostly of electrons and protons. Photons are involved in all exchange of energy states. Now in some materials the electrons are tightly bound and are unwilling to allow electron exchange. In concrete the atoms are bound tightly and the electrons are not very conductive. In a metal like copper the electrons are quite willing to allow electro energy exchange and transport of electrons. So copper is a good conductor.

The organization of atoms and electrons determines the nature of the substance. Atoms seek to have a balanced outer level of electrons as per quantum law. This is the nature of atoms and it is calculated in the Mendeleev table of elements. Atoms seek to find the balance of the noble elements.

This is the lesson from 10th grade chemistry. It is a simple lesson that tells us just how all atoms combine to make molecules. This lesson is based in Quantum theory. Those to say that quantum theory is not relevant to biology are expressing a rather concerning ignorance.

Molecules can be very very complex. But all of them are made of electrons, protons, neutrons etc held by Quantic forces. These molecules all have a structure of their outer electrons that can be assayed by the voltammetric signature. Voltammetry is the science of electrodes checking the
The body has a reactive trivector set of fields. An item not living has a stable unchanging field. So to measure the substances fields, and then the person’s reaction to those fields. A truly modern medicine is achieved, based on what we know of the body electric and basic high school physics.

**The Factors of Electro-potential**

What Are the Elements in the Human Body? Most of the human body is made up of water, H2O, with cells consisting of 65-90% water by weight. Therefore, it isn’t surprising that most of a human body’s mass is oxygen. Carbon, the basic unit for organic molecules, comes in second. 99% of the mass of the human body is made up of just six elements: oxygen, carbon, hydrogen, nitrogen, calcium, and phosphorus. All other elements can be toxic or inert.

1. Oxygen (65%) the heavy component of water
2. Carbon (18%) the structure of all organic compounds and the key of fatty acids
3. Hydrogen (10%) water and free protons
4. Nitrogen (3%) air and amino acids
5. Calcium (1.5%) bone, nerve and all membranes
6. Phosphorus (1.0%) bone, nerve and all membranes
7. Potassium (0.35%) intracellular
8. Sulfur (0.25%) amino acids, good bacteria growth
9. Sodium (0.15%) extracellular
10. Magnesium (0.05%) regulatory for health
11. Copper, Zinc, Selenium, Molybdenum, Fluorine, Chlorine, Iodine, Manganese, Cobalt, Iron (0.70%)
12. Lithium, Strontium, Aluminum, Silicon, Lead, Vanadium, Arsenic, Bromine (trace amounts)

Life must keep Potassium inside the cell and Sodium outside of the cell. The natural thermodynamic balance is for them to gravitate to be equal. So potassium has a natural pull to go out and sodium to go into a cell. Because the concentration gradient for potassium is directed out of the cell, while the concentration gradient for sodium is directed into the cell, there is a need for a sodium pump to stabilize the life of the cell. This takes the energy of ATP to operate the sodium pump. The sodium-potassium pump transports 2 potassium ions inside and 3 sodium ions outside at the cost of 1 ATP molecule. There should be twice as much potassium as sodium in the healthy human body.

Membrane potentials are defined relative to the exterior of the cell; thus, a potential of –70 mV implies that the interior of the cell is negative charge relative to the exterior. Life is electrical.

As we have said there should be twice as much potassium as sodium in the healthy human body. But people like salt and producers put more salt into foods to sell and satisfy customers. Potassium

The right hand rule describes the fields around a flowing current. And it says that as a current flows like your outstretched right thumb, a magnetic field is made at 90 degrees like your outstretched forefinger, and a static field is made at 90 degrees like your outstretched middle finger. Thus the fields of electricity are described. This is the second week of electronics class usually taught in 10th grade physics.

So all electrical action or flow of electricity generates a three dimensional field, at least. So we called the process of measuring this field the trivector. This is a type of 3-dimensional voltammetry.

Voltammetry is the science of understanding how a substance’s electro-magnetic field reacts with it’s environment. A hormone has electrons and protons and how they are placed in a 3 dimensional space will determine how it exchanges electron-magnetic action and this is measured by measuring the 3 dimensional effect of it voltammetric field. The amount of charged particles is the amperage, the pressure or potential of the charged particles is the volts. Basic 7th grade physics. Every compound having it’s own individual and distinct voltammetric signature field. REF Voltammetry

Volts times amps is a power index or what is known as Watts. Once we measure simple variables we can easily calculate a great variety of electrical forces. We can thus calculate volts, amps, ohms, reactance, susceptance, watts, capacitance, inductance, impedance, and other virtual mathematical calculations.

Knowing that reductionism has filed as a way to analyze the human body we can make more global measures of these energies of a human, compare them to norms, and then using safe micro-current stimulation change them.

We can detect and affect the body electric is safe and effective ways. The SCIO system is designed and registered to do just this. To detect and affect, EEG, ECG, EMG, GSR, electro-osmosis, trauma tissue, wounds, pain, charge stability, acid alkaline balance, voltammetric reactance of substances, oxygenation, hydration, redox potentials, electro-acupuncture, bio-resonance, super-learning, and other bio-electric functions. All from simple basic science taught in our schools today. REF clinical evaluation

Only with the 40 years of experience to sharpen and perfect the precision of the art. The first studies of Dr. Nelson on the body electric were done in Youngstown, Ohio. This ever dedicated scientist has artfully perfected this art of energetic medicine. All designed as a truly modern medicine to safely assay and treat the people.

The human body is a complicated intricate electrical assembly. It has a reactive set of fields that are driven towards life giving things like oxygen food etc. It is electrically repelled from toxins. This electrical field is processing the qualities of life such as metabolism and reproduction. Thus a vast ever changing system of electrical fields that are intricately interactive with the environment.

The human system is not a linear predictable or reduction type of system. Its vast complicated and elaborate functioning makes it a fractal complexity. As such it responds better to ever changing fractal stimulation not linear reductionist simple stimulation.

So developing an electrical treatment needed some advances in technology. First a cybernetic loop of measuring, calculation, stimulation, measuring, calculation, stimulation, measuring, calculation, stimulation, and so on. All at biological speeds. Then a reactive system that reacts to...
Varhope charging the batteries

It is a scientific fact that when a low level voltage and micro-current pulses are applied to the body, pain, energy activity, and healing are increased. The SCIO will let the patient’s body electric autophocalize a harmonic pulse to maximize this effect. This current applied to the cranium has been shown to help autism, attention deficit and hyperactive children. It has been shown helpful for anxiety, addictions, emotional disturbances, and insomnia.

There is published research on these therapies. The new world of energetic medicine can help you.

Life is Electric in all Aspects

Fatty Acids on the membrane act as extension cords to transport free electrons when needed. Calcium and Fatty Acids sit on the membrane. There is about a 50 to 100mv Charge across the membrane avg 70mv.

K+ concentration gradient (created by ATPase)

electrical gradient (created by opening K+ channel)

Na+

K+

Calcium and Fatty Acids sit on the Membrane

Negative Charge Inside

Positive Charge Outside

Na+

K+
occurs mostly in fruit and vegetables. Potassium makes foods turn Orange. So oranges, pumpkin, paprika, squash etc have the most. Most people get too much sodium and too little potassium. This puts pressure on the potassium-sodium pump. This wastes ATP needed for other cellular functions and stress the body electric. The excess sodium makes the body go acid with excess positive charge. This drives the charge stability of the body to the acid state and is reflected in the measurements made from the SCIO. There are many other factors that can upset this electrical balance.

The electro-potential of the cell membrane must be kept inside some strict limits to assure proper electrical activity for life. The cell is an electrical dynamo needing energy for activity. This energy comes from hot electrons (high quantum state energy of electrons in food). The food has gotten it’s energy from the sun’s visible light photons energizing the electrons to higher quantum states. The quantum energy is broken down in Krebs cycle to make ATP. Photons of heat are released. The cells will have electrical activity that is of a tight range and thus electro-medicine will need to decipher the code of the types of variations in the body electric that hallmark disease states. The cell must fight thermodynamics to live.

The factors of mineral balance especially sodium to potassium is largely a nutritional issue. To much sodium versus potassium is one of the greatest single health risks today. Oxygenation is also key. Smoking and lack of exercise is epidemic and killing millions. Over use and improper use of doctor prescribed medicines is also killing millions. Too much animal fat, trans-fatty acids, dextrose sugar, processed foods, food additives, environmental toxicity, mercury amalgams, and uncontrolled stress are life style factors that are killing millions of people. So the first place to start with health care is the behavior. Behavioral medicine is a ever growing issue of responsibility in health care. The SCIO devotes its first level of use and design to the education and possible correction of life style issues. It is important to point out the value and importance of correcting these issues for health.

Correlations between whole-body impedance measurements and various bio-conductor volumes, such as total body water and fat-free mass, are experimentally well established; we can measure many different factors of the body electric. First there is skin electro-potential.

Each of these small little batteries we call cells blend in harmony to make the multi-cellular organism we call the human. The hundred trillion cells in the human body act both in series and in parallel to make the electro-potentials of the human body. Most of these cells are surrounded by fluid (interstitial, lymph, blood etc.). Theses fluids are mostly water with lots of free protons, electrons and minerals which further enhance the electrical factors. The normal cell has a resting voltage potential across the membrane of 70milli-volts (-70mv). The brain cell will fire at peak electrical activity for life. The cell is an electrical dynamo needing energy for activity. This energy comes from hot electrons (high quantum state energy of electrons in food). The food has gotten it’s energy from the sun’s visible light photons energizing the electrons to higher quantum states. The quantum energy is broken down in Krebs cycle to make ATP. Photons of heat are released. The cells will have electrical activity that is of a tight range and thus electro-medicine will need to decipher the code of the types of variations in the body electric that hallmark disease states. The cell must fight thermodynamics to live.

The above diagram shows a key little known fact of biology. The factors of the wave formations of the system affects the polarity and the resting potential. The slight changes in these electrical profiles can be measured.

To measure skin resistance, we must apply a known voltammetric signal as an input and then see how much of it is resisted by the body, most applicably by the skin. The measure the galvanic skin resistance or impedance we need to be able to input a voltammetric signal into the electrode points. This is a variant signal in the SCIO of variant wave forms, and wave potentials. The measured output of resistance is usually non hertzian. Pulsations in resistance reactivity are fractal and non repeating.

The voltammetric signal of the SCIO is of a micro-current nature. The applied signal strength is derived from the base signal strength of the patient body natural. We are of the philosophy that signals exceeding twice the body norm will be considered invasive and the body will react adversely to such signals. We wish to just tickle the body with electro-stimulus near the natural. Thus the upper limits of the SCIO body stimulation output will be 5 volts, and 50 micro-amps. All of this is under the regulatory safety criteria specified.

Thus as seen in the EPFX FDA 1989 registration the SCIO is registered to measure volts and amps at 12 points of forehead, wrist and ankles. Input a voltammetric signal to these points, and then measure the reaction of resistance at these points. The SCIO then can acts as a frequency generator sending out voltammetric waveforms and a frequency counter measuring frequency response. From these simple criteria a host of electrophysiological data can spin out to assist the SCIO in correcting aberrant electrophysiological functioning. Electro-stimulation is helpful in osmotic stimulation, transcutaneous electro-nerval-stimulation for pain control and injury or wound healing, redox stimulation, and others. The SCIO uses a cybernetic loop of analysis to use this electro stimulation to adjust electro-physiology of the patient.

Smooth muscle intracellular pH: measurement, regulation, and function

Smooth muscle performs many functions that are essential for the normal working of the human body. Changes in pH are thought to affect many aspects of smooth muscle. Despite this, until recently little was known about either intracellular pH (pHi) values or pHi regulation in smooth muscle. Recent work measuring pHi with either microelectrodes or nuclear magnetic resonance spectroscopy is now providing some of this much needed information for smooth muscles. From these studies, it can be concluded tentatively that pHi is the same in different smooth muscles, approximately 7.06 (37 degrees C). This value is very close to those obtained in cardiac and skeletal muscle. It is clear that H+ is not in equilibrium across the smooth muscle membrane; i.e., pHi is regulated. Preliminary results in smooth muscle suggest that certain aspects of this regulation are different from that described for other muscle types. Changes in pHi have been found to produce marked effects on contraction in smooth muscle. Of particular interest is the fact that, unlike striated muscles, some smooth muscles can produce more force during an intracellular acidification.

**VARHOPE and Stress**

The above diagram shows a key little known fact of biology. The factors of the wave formations of people differ from person to person. The values shown are not perfect. The height of the curve is the voltage. The area under the curve is the Amperage. Proton pressure or the charge stability of the system affects the polarity and the resting potential. The slight changes in these electrical profiles can be measured.
The brain cell will fire with a process called action potential. An action potential is a very rapid change in membrane potential that occurs when a nerve cell membrane is stimulated. Specifically, the membrane potential goes from the resting potential (typically -70 mV) to some positive value (typically about +30 mV) in a very short period of time (just a few milliseconds).

What causes this change in potential to occur? The stimulus causes the sodium gates (or channels) to open and, because there’s more sodium on the outside than the inside of the membrane, sodium then diffuses rapidly into the nerve cell. All these positively-charged sodium ions rushing in causes the membrane potential to become positive (the inside of the membrane is now positive relative to the outside). The sodium channels open only briefly, and then close again. This difference makes a potential at the skin measured by the SCIO system, as with all biofeedback systems.

The SCIO measures electro-potential at the 12 harness points in the clear, then applies a voltammetric signal into any or all of the points, then measures the harness points with the applied signal. The amperage and voltage coming off of the non stimulated body's skin is of a range of zero to 5 milliamps and 1.5 volts. Zero is obvious as we all have seen the flat line in a movie telling us the person is dead. Normal people put off micro-amperage and milli-volts, the extreme can be seen at over a volt. The criteria of these potentials are derived from their location and oscillation.

If we measure on the scalp or the forehead as in the case of the SCIO, we can measure the transcutaneous correlate of the activity of brain cells firing in the brain below the point of measure. This is called EEG or electroencephalography. We can ascertain the Brain wave from the oscillation pattern. The pattern or rhythm of the brain wave is from 4 hertz as delta waves, 4-8 Hz for theta, 8 to 20 for alpha, and 20 to 100 for beta waves. If we measure the electro potential of the skin and filter out these waves we can get the EEG.

If we measure on the forehead, wrists and ankles as in the case of the SCIO, we can measure the transcutaneous correlate of the activity of muscle cells activity between the points of measure. This is called EMG or electromyography. We can ascertain the muscle activity from the oscillation pattern. The pattern or rhythm of the muscle waves is from 2 to 20 normally with variant spindles up to 1000 Hz. If we measure the electro potential of the skin and filter in these waves we can get the EMG.

If we measure on the wrists and left leg as in the case of the SCIO, we can measure the transcutaneous correlate of the activity of heart cells between the points of measure. This is called ECG or electrocardiography. We can ascertain the Heart wave from the oscillation pattern. The pattern or rhythm of the heart wave is from zero to 2 Hz. If we measure the electro potential of the skin and filter out these waves we can get the ECG. The heart signal is the largest in potential and smallest in time measured in biofeedback.

Formally, a measure of charge should be a multiple of the elementary charge $e$ (charge is quantized), but since it is an average, macroscopic quantity, many orders of magnitude larger than a single elementary charge, it can effectively take on any real value. Furthermore, in some contexts it is meaningful to speak of fractions of a charge; e.g. in the charging of a capacitor.

History

Coulomb's torsion balance

As reported by the Ancient Greek philosopher Thales of Miletus around 600 BC, charge (or electricity) could be accumulated by rubbing fur on various substances, such as amber. The Greeks noted that the charged amber buttons could attract light objects such as hair. They also noted that if they rubbed the amber for long enough, they could even get a spark to jump. This property derives from the triboelectric effect.

In 1600 the English scientist William Gilbert returned to the subject in De Magnete, and coined the New Latin word electricus from ηλεκτρον (elektron), the Greek word for "amber", which soon gave rise to the English words "electric" and "electricity." He was followed in 1660 by Otto von Guericke, who invented what was probably the first electrostatic generator. Other European pioneers were Robert Boyle, who in 1675 stated that electric attraction and repulsion can act across a vacuum; Stephen Gray, who in 1729 classified materials as conductors and insulators; and C. F. du Fay, who proposed in 1733 that electricity came in two varieties which cancelled each other, and expressed this in terms of a two-fluid theory. When glass was rubbed with silk,
Electric charge

Electric charge is a fundamental conserved property of some subatomic particles, which determines their electromagnetic interactions. Electrically charged matter is influenced by, and produces, electromagnetic fields. The interaction between charge and field is the source of one of the four fundamental forces, the electromagnetic force.

Electric charge is a characteristic of almost every subatomic particle found in the universe. It is quantized: when expressed in units of the so-called elementary charge $e$, it takes integer or fractional values. Electrons by convention have a charge of $-1$, while protons have the opposite charge of $+1$. Quarks have a fractional charge of $-1/3$ or $+2/3$. The antiparticle equivalents of these (positrons, antiprotons, and antiquarks, respectively) have the opposite charge. There are other charged particles. The discrete nature of electric charge was proposed by Michael Faraday in his electrolysis experiments, and then directly demonstrated by Robert Millikan in his oil-drop experiment.

In general, same-sign charged particles repel one another, while different-sign charged particles attract. This is expressed quantitatively in Coulomb's law, which states that the magnitude of the electrostatic repelling force between two particles is proportional to the product of their charges and the inverse square of the distance between them.

The electric charge of a macroscopic object is the sum of the electric charges of its constituent particles. Often, the net electric charge is zero, because it is favorable for the number of electrons in every atom to equal the number of protons (or, more generally, for the number of anions, or negatively charged atoms, in every molecule to equal the number of cations, or positively charged atoms). When the net electric charge is non-zero and motionless, one has the phenomenon known as static electricity. Even when the net charge is zero, it can be distributed non-uniformly (e.g., due to an external electric field, or due to molecular motion), in which case the material is said to be polarized. The charge due to the polarization is known as bound charge, while the excess charge brought from outside is called free charge. The motion of charged particles (e.g., of electrons in metals) in a particular direction is known as electric current.

Units

The SI unit of quantity of electric charge is the coulomb, which is equivalent to about $6.25 \times 10^{18}$ e ($e$ is the charge on a single electron or proton). Hence, the charge of an electron is approximately $-1.602 \times 10^{-19}$ C. The coulomb is defined as the quantity of charge that has passed through the cross-section of an electrical conductor carrying one ampere within one second. The symbol Q is often used to denote a quantity of electricity or charge. The quantity of electric charge can be directly measured with an electrometer, or indirectly measured with a ballistic galvanometer.

After finding the quantized character of charge, in 1891 Stoney proposed the unit 'electron' for this fundamental unit of electrical charge. This was before the discovery of the particle by J.J. Thomson in 1897. Today, the name "electron" for the unit of charge is no longer widely used.

Aside from the properties described in articles about electromagnetism, charge is a relativistic invariant. This means that any particle that has charge Q, no matter how fast it goes, always has charge Q. This property has been experimentally verified by showing that the charge of one helium nucleus (two protons and two neutrons bound together in a nucleus and moving around at high speeds) is the same as two deuterium nuclei (one proton and one neutron bound together, but moving much more slowly than they would if they were in a helium nucleus).

Conservation of electric charge

The total electric charge of an isolated system remains constant regardless of changes within the system itself. This law is inherent to all processes known to physics and can be derived in a local form from gauge invariance of the wave function. The conservation of charge results in the charge-current continuity equation. More generally, the net change in charge density $\rho$ within a volume of integration $V$ is equal to the area integral over the current density $J$ on the surface of the area $S$, which is in turn equal to the net current $I$:

$$\frac{\partial \rho}{\partial t} = \nabla \cdot \mathbf{J}$$

Thus, the conservation of electric charge, as expressed by the continuity equation, gives the result:

$$\mathbf{J} = \sigma \mathbf{E} + \mathbf{d}$$

The charge transferred between times $t_0$ and $t$ is obtained by integrating both sides:

$$\int_{t_0}^{t} \mathbf{J}\, dt = \int_{t_0}^{t} (\sigma \mathbf{E} + \mathbf{d})\, dt$$

Where $\mathbf{I}$ is the net outward current through a closed surface and $\mathbf{Q}$ is the electric charge contained within the volume defined by the surface.

Active transport across the membrane

Different types of transport across a cell membrane. Diffusion and osmosis are passive modes of transport, requiring no energy, moving from areas of high concentration to areas of low concentration.
Passive Transport across the membrane

A molecule or ion that crosses the membrane by moving down a concentration or electrochemical gradient and without expenditure of metabolic energy is said to be transported passively. Another name for this process is diffusion. All molecules and ions are in constant motion and it is the energy of motion - kinetic energy - that drives passive transport. Transport of uncharged species across a membrane is dictated by differences in concentration of that species across the membrane - that is, by the prevailing concentration gradient. For ions and charged molecules, the electrical potential across the membrane also becomes critically important. Together, gradients in concentration and electric potential across the cell membrane constitute the electrochemical gradient that governs passive transport mechanisms.

Three distinctive types of passive transport are recognized in biological systems:

- Transport by simple diffusion
- Facilitated diffusion: carrier proteins and ion channels
- Osmosis and hydrostatic pressure

Membrane potential (or transmembrane potential) is the voltage difference (or electrical potential difference) between the interior and exterior of a cell. Because the fluid inside and outside a cell is highly conductive, while a cell's plasma membrane is highly resistive, the voltage change in moving from a point outside to a point inside occurs largely within the narrow width of the membrane itself. Therefore, it is common to speak of the membrane potential as the voltage across the membrane.

The plasma membrane surrounds the cell to provide a stable environment for biological processes. The membrane potential arises from the action of ion channels, ion pumps, and ion transporters embedded in the membrane which maintain different ion concentrations inside and outside the cell. The term "membrane potential" is sometimes used interchangeably with cell potential but is applicable to any lipid bilayer or membrane.

Three special cases of physiological membrane potential with underlying mechanisms and the concept of equilibrium or reversal potential, which constitute the subject of electrophysiology and cellular biophysics, are addressed in this article. The former are resting membrane potential, action potential, and graded (postsynaptic) membrane potentials. The membrane potential of most not-excitable cells is kept at relatively stable value of resting potential. In contrast, electrically excitable cells like neurons and myocytes can "fire" action potentials. Neurons are specialized to use changes in membrane potential for fast communication, with other neurons, muscles, and secretory cells. When cell membrane depolarizes from resting potential and produces action potential, it travels down the axon to the synapses: the magnitude of the axonal membrane potential varies dynamically along its length. On reaching a (chemical) synapse, a neurotransmitter is released causing a localized change in potential in the postsynaptic membrane of the target neuron by opening ion channels in its membrane. Importantly, every occasion of action potential firing results from spatial and temporal summation of often a very large number of minuscule graded postsynaptic responses of both positive (membrane depolarization) and negative (membrane hyperpolarization) polarities. Ultimately, such important aspects as value of resting potential, maximum amplitude and after-hyperpolarization phase of action potential can be easily understood utilizing the concept of equilibrium potential. In the case of the resting membrane potential across an animal cell's plasma membrane, potassium (and sodium) gradients are established by the Na+/K+-ATPase (sodium-potassium pump) which transports 2 potassium ions inside and 3 sodium ions outside at the cost of 1 ATP molecule. In other cases, for example, a membrane potential may be established by acidification of the inside of a membranous compartment (such as the proton pump that generates membrane potential across synaptic vesicle membranes).

Reversal potential

An equilibrium or reversal potential of an ion is the value of transmembrane voltage at which...
the electric force generated by diffusional movement of the ion down its concentration gradient becomes equal to the molecular force of that diffusion. This means that the transmembrane voltage exactly matches (resists) the force of diffusion of the ion (or vice versa), such that the net current of the ion across the membrane is zero and unchanging. The equilibrium potential of a particular ion is designated by the notation \( E_{\text{ion}} \). The equilibrium potential for any ion can be calculated using the Nernst equation. For example, reversal potential for potassium ions will be as follows:

\[
E = E^0 + \frac{RT}{zF} \ln \frac{[K^+]}{[K^+]_{\text{in}}}
\]

The Nernst Equation and Resting Potential

At resting potential the sodium-potassium pumps move approximately the same electrical charge inside as outside the cell. However, potassium channels are also present allowing free flow of only potassium ions. The higher concentration of potassium inside the cell drives potassium ions to the outside. After a small number of potassium ions leave the cell the outside of the cell becomes positively charged compared to the inside, developing an electrical field. This electrical field balances the force on the ions from the concentration gradient and is known as the resting potential.

The Nernst equation for the potassium equilibrium potential over the cell membrane is

\[
E_K = -RT \ln \frac{[K^+]_{\text{out}}}{[K^+]_{\text{in}}}
\]

where

- \( E_K \) is the electric potential across the membrane due to the potassium concentration gradient
- \( R \) is the universal gas constant (8.314472 \( \text{J} \cdot \text{K}^{-1} \cdot \text{mol}^{-1} \))
- \( T \) is the absolute temperature (Kelvin = 273.15 + °C = 298.15) at 25°C
- \([K^+]_{\text{out}}\) is the potassium concentration outside the membrane
- \([K^+]_{\text{in}}\) is the potassium concentration inside the membrane
- \( zF \) is the number of electric charges carried by a mole of K+
- \( z \) is the number of electrons (one for K+)
- \( F \) is the Faraday constant, equal to 9.6485309×10^4 \( \text{C} \cdot \text{mol}^{-1} \)

Putting values in the equation gives this result. Try changing the values in the text fields and clicking the update button to compute a new value for \( E_K \) (values in formula will be updated).

The 10^3 term converts from Volts to milliVolts. The computed number is a little higher than the quantity measured in experiments (~70 mV) but all the factors in this complex physical process have been accounted for.

Apparently, even if two different ions have the same charge (i.e. K+ and Na+), they can still have very different equilibrium potentials, provided their outside and/or inside concentrations differ. Take, for example, the equilibrium potentials of potassium and sodium in neurons. The potassium equilibrium potential \( E_K \) is -84 mV with 5 mM potassium outside and 140 mM inside. The sodium equilibrium potential, on the other hand, \( E_{Na} \) is approximately +40 mV with approximately 12 mM sodium inside and 140 mM outside.

Resting potential and action potential are often referred as “potassium” and “sodium” potentials, respectively. This stems from the origin of the resting potential (proximity to the \( E_K \)), and the origin (activation of sodium channels) and the peak amplitude of the action potential (proximity to the \( E_{Na} \)).

Relatively static membrane potential of quiescent cells is called resting membrane potential (or resting voltage), as opposed to the dynamic electrochemical phenomena called action potential and graded membrane potential. Apart from the latter two, which occur in excitable cells (neurons, muscles, and some secretory cells in glands), membrane voltage in the non-excitable cells can also undergo changes in response to environmental or intracellular stimuli. For example, depolarization of the plasma membrane appears to be an important step in programmed cell death.
In principle, there is no difference between resting membrane potential and dynamic voltage changes like action potential from biophysical point of view: all these phenomena are caused by specific changes in membrane permeabilities for potassium, sodium, calcium, and chloride, which in turn result from concerted changes in functional activity of various ion channels, ion pumps, exchangers, and transporters. Conventionally, resting membrane potential can be defined as a relatively stable, ground, value of transmembrane voltage in animal and plant cells.

Generation of resting membrane potential is explicitly explained by Goldman equation. It is essentially the Nernst equation, in that it is based on the charges of the ions in question, as well as the difference between their inside and outside concentrations. However, it also takes into consideration the relative permeability of the plasma membrane to each ion in question.

For the three monovalent ions most important to action potentials: potassium (K⁺), sodium (Na⁺), and chloride (Cl⁻). Being an anion, the chloride terms are treated differently than the cation terms; the inside concentration is in the numerator, and the outside concentration is in the denominator, which is reversed from the cation terms. Pi stands for the permeability of the ion type i. If calcium ions are also considered, which are critically important for action potentials in muscles, the formula for the equilibrium potential becomes more complicated. The resting plasma membrane of the most animal cells is much more permeable to K⁺, which results in the resting potential to be close to the potassium equilibrium potential.

The resting potential of a cell can be most thoroughly understood by thinking of it in terms of equilibrium potentials. In the example diagram here, the model cell was given only one prominent ion (potassium). In this case, the resting potential of this cell would be the same as the equilibrium potential for potassium.

However, a real cell is more complicated, having permeabilities to many ions, each of which contributes to the resting potential. To understand better, consider a cell with only two permeant ions, potassium and sodium. Consider a case where these two ions have equal concentration gradients directed in opposite directions, and that the membrane permeabilities to both ions are equal. K⁺ leaving the cell will tend to drag the membrane potential toward EK. Na⁺ entering the cell will tend to drag the membrane potential toward the reversal potential for sodium ENa. Since the permeabilities to both ions were set to be equal, the membrane potential will, at the end of the Na⁺/K⁺ tug-of-war, end up halfway between ENa and EK. As ENa and EK were equal but of opposite signs, halfway in between is zero, meaning that the membrane will rest at 0 mV.

Note that even though the membrane potential at 0 mV is stable, it is not an equilibrium condition because neither of the contributing ions are in equilibrium. Ions diffuse down their electrochemical gradients through ion channels, but the membrane potential is upheld by continual Na⁺ influx and K⁺ efflux via ion pumps. Such situation with similar permeabilities for counter-acting ions, like potassium and sodium in animal cells, can be extremely costly for the cell if these permeabilities are relatively large, as it takes a lot of ATP energy to pump the ions back. Because no real cell can afford such equal and large ionic permeabilities at rest, resting potential of animal cells is determined by predominant high permeability to potassium and adjusted to the required value by modulating sodium and chloride permeabilities and gradients.

In a healthy animal cell Na⁺ permeability is about 5% of the K permeability or even less, whereas the respective reversal potentials are +60 mV for sodium and -80 mV for potassium. Thus the membrane potential will not be right at EK, but rather depolarized from EK by an amount of approximately 5% of the 140 mV difference between EK and ENa. Thus, the cell’s resting potential will be about -73 mV.

In a more formal expression, the membrane potential is the weighted average of each contributing ion’s equilibrium potential (Goldman equation). The size of each weight is the relative permeability of each ion. In the normal case, where three ions contribute to the membrane potential:

The GHK voltage equation for positive ionic species and negative:

$$E_m = \frac{RT}{F} \ln \left( \frac{\sum_i N P_{M_i} [M_i]^\text{out} + \sum_j M P_{A_j} [A_j]^\text{in}}{\sum_i N P_{M_i} [M_i]^\text{in} + \sum_j M P_{A_j} [A_j]^\text{out}} \right)$$

This results is the following if we consider a membrane separating two -solutions:

$$E_{i,K}, E_{i,Na}, E_{i,Cl} = \frac{RT}{F} \ln \left( \frac{P_{Na^+} [Na^+]^\text{out} + P_{K^+} [K^+]^\text{out} + P_{Cl^-} [Cl^-]^\text{out}}{P_{Na^+} [Na^+]^\text{in} + P_{K^+} [K^+]^\text{in} + P_{Cl^-} [Cl^-]^\text{in}} \right)$$

It is "Nernst-like" but has a term for each permeant ion. The Nernst equation can be considered a special case of the Goldman equation for only one ion:

$$E_{iNa} = \frac{RT}{F} \ln \left( \frac{P_{Na^+} [Na^+]^\text{in}}{P_{Na^+} [Na^+]^\text{out}} \right) = \frac{RT}{F} \ln \left( \frac{[Na^+]^\text{in}}{[Na^+]^\text{out}} \right)$$

- $E_m$ is The membrane potential
- $P_i$ is the permeability for that ion
- $[ion]^\text{in}$ is the extracellular concentration of that ion
- $[ion]^\text{in}$ is the intracellular concentration of that ion
- $R$ is The ideal gas constant
- $T$ is The temperature in kelvins
- $F$ is Faraday’s constant

The first term, before the parenthesis, can be reduced to 61.5 log for calculations at human body temperature (37°C)

$$E_X = 61.5 \text{ mV} \log \left( \frac{[X^+]^\text{out}}{[X^+]^\text{in}} \right) = -61.5 \text{ mV} \log \left( \frac{[X^-]^\text{out}}{[X^-]^\text{in}} \right)$$

Note that the ionic charge determines the sign of the membrane potential contribution.

The usefulness of the GHK equation to electrophysiologists is that it allows one to calculate the predicted membrane potential for any set of specified permeabilities. For example, if one wanted to calculate the resting potential of a cell, they would use the values of ion permeability that are present at rest (e.g. ). If one wanted to calculate the peak voltage of an action potential, one
Varhope charging the batteries

would simply substitute the permeabilities that are present at that time (e.g.):

- $E_m$ is the membrane potential, measured in volts
- $E_x$ is the equilibrium potential for ion $X$, also in volts
- $P_x$ is the relative permeability of ion $X$ in arbitrary units (e.g. siemens for electrical conductance)
- $P_{tot}$ is the total permeability of all permeant ions, in this case $P_{tot} = P_{K^+} + P_{Na^+} + P_{Cl^-}$

It is important to understand that ionic and water permeability of a pure lipid bilayer is very small, and it is similarly negligible for ions of comparable size, such as Na+ and K+. The cell membranes, however, contain a large number of ion channels, water channels (aquaporins), and various ionic pumps, exchangers, and transporters, which can selectively increase permeability of the membrane for different ions. The relatively high membrane permeability for potassium ions at resting potential results from inward-rectifier potassium ion channels which are open at negative voltages, and so called leak potassium conductances such as two-barrel open rectifier $K^+$ channel (ORK+) which is locked in the open state irrespective of voltage. These potassium channels should not be confused with voltage-activated $K^+$ channels responsible for membrane repolarization during action potential.

Values of resting membrane potential in the most of the mature (differentiated) animal cells usually vary between $E_K$ and around -40 mV. Resting voltage in the excitable cells capable of producing action potentials is usually balanced around -60 mV because more depolarized voltage would lead to spontaneous activation of voltage-activated sodium channels and generate action potential. Immature or not-differentiated cells demonstrate highly variable values of resting voltage usually significantly more positive than that in the differentiated cells. In such cells, the resting potential value correlates well with the degree of differentiation: undifferentiated cells can demonstrate resting potential value as low as 0 mV.

Maintenance of resting potential can be very costly for a cell, especially when the cell function requires a rather depolarized value of membrane voltage. For example, resting potential in day light-adapted blowfly (Calliphora vicina) photoreceptors can be as high as -30 mV. In insect photoreceptors depolarization is provided by light-activated TRP channels which cause fluctuations in membrane voltage in response to changing ambient light intensity. These changes in voltage then propagate as graded membrane responses to the synapses with a second-order neuron. At -30 mV, blowfly photoreceptor input resistance and membrane time constant can be as low as 10 MΩ and 1.5 ms, respectively, and the corner frequency of the voltage response power spectrum as high as 120 Hz. Such remarkably high corner frequency allows Calliphora vicina to produce the fastest functional responses ever recorded from an ocular photoreceptor. This excellent visual ability, however, is very expensive metabolically, because such a low membrane resistance results from numerous open voltage-activated potassium and light-activated TRP channels, which, in turn, requires high level of Na+/K+-ATPase activity to maintain the proper ionic gradients. As a result, blowfly retina is one of the most, if not the most, energy demanding tissues in the fly both under dark- and light-adapted conditions. Maintenance of resting potential in such cells may cost more than 20% of overall cellular ATP. On the other hand, high resting potential in the not-differentiated cells can be rather a great metabolic advantage, and not a burden for non-active cells such as stem cells. This apparent paradox is easily resolved by careful examination of the origin of that resting potential. Low-differentiated cells are characterized by extremely high input resistance.

---

**Indices and Equations**

Varhope charging the batteries

$E_m$ membrane potential

$E_x$ equilibrium potential for ion $X$

$P_x$ relative permeability of ion $X$

$P_{tot}$ total permeability of all permeant ions

---

**Figure Caption**

Varhope charging the batteries

141
which implies that leak and inward rectifier potassium channels, which are responsible for high potassium permeability at rest, as well as other leak conductances (chloride and sodium, for example), are not expressed at this stage of cell life. As an apparent result, potassium permeability becomes similar to that for sodium ions, which places resting potential in-between the reversal potentials for sodium and potassium as discussed above. And because all ionic permeabilities in such cells are virtually the basic ionic leaks of a lipid bi-layer, very little metabolic cost may be associated with maintenance of resting potential in such cells.

Neurons communicate with other neurons, muscles, and organs via action potentials (APs), brief transient waveforms quickly “moving” along neuronal axons. The typical duration of an action potential recorded with a pointed electrode is about 1 ms, which includes fast depolarization from the resting potential by means of opening of voltage-activated sodium channels, followed by slower repolarization of the membrane as a result of opening of voltage-activated potassium channels. After-hyperpolarization or “undershoot” is the final phase of an action potential which results from the activity of Na+/K+-ATPase (two K+ ions in, three Na+ ions out per cycle of pumping results in the net one positive charge leaving the cell, i.e. one negative charge entering the cell), opening of calcium- and sodium-activated potassium channels, and deactivating delayed-rectifier potassium channels.

Action potential is initiated when membrane is depolarized above action potential activation threshold, which is approximately 20 mV above the resting potential level in neurons (-60 mV). In neurons in vivo, initial depolarization is caused by spatio-temporal summation of graded excitatory postsynaptic potentials (EPSPs), which is the “natural” mechanism of action potential initiation in neuronal networks. For example, it may require hundreds and thousands of EPSPs simultaneously or almost simultaneously converging on the neuron to evoke an action potential because a typical amplitude of an EPSP is 0.1 mV and the excitatory graded potentials are offset by their inhibitory counterparts, inhibitory postsynaptic potentials (IPSPs). Alternatively, action potentials can be initiated by external injection of a brief depolarizing current pulse in vitro and in vivo, during physiological experiments and in certain medical devices (see cardiac pacemaker). Sodium and potassium channels are key components of AP generation and propagation. Voltage-activated sodium channels, which are predominantly closed at resting voltage levels, react to a depolarizing perturbation by further opening, first gradually and linearly, but then, beyond a certain threshold, in a robust avalanche-like manner. The principal mechanism of AP generation was discovered by Hodgkin & Huxley  and discussed in detail elsewhere (see Action Potential).

Inactivation of sodium channels is responsible for the so called "absolute refractory period" after action potential. During that period of an order of few milliseconds duration no consecutive AP can be evoked by no matter how large depolarization. During the relative refractory period, a
sufficient number of sodium channels (but not all) have recovered that an action potential can be provoked, but only with a stimulus much stronger than usual. These refractory periods ensure that the action potential travels in only one direction along the axon. Action potentials usually originate at the axon hillock, where voltage-activated sodium channel density is the highest and their activation voltage threshold is the lowest, but they can be initiated in any part of neuron including dendrites and soma, if density of sodium channels allows it.

Action potentials, originating from dendrites and soma have different shapes (broader in dendrites), and the critical amplitude of depolarizing perturbation (AP threshold level) changes as: dendrites > soma > axon hillock. APs usually propagate from axon hillock toward axonal synapses, but can also propagate back to soma and dendrites, although the biological significance and network calculation benefits of this phenomenon are not yet established.

Graded membrane potential calculation benefits of this phenomenon are not yet established.

Graded membrane potential

Figure 3. Graph displaying an EPSP, an IPSP, and the summation of an EPSP and an IPSP. When the two are summed together the potential is still below the action potential threshold.

A graded membrane potential is a gradient of transmembrane potential difference along a length of cell membrane. Graded potentials are particularly important in neurons that lack action potentials, such as some types of retinal neurons. Graded potentials that depolarize the membrane, increasing the membrane potential above the resting potential, are important as “triggering potentials” that can spread along the surface of neuronal cells to axon initial segments (the first part of the axon as it leaves the cell body) and trigger action potentials. Graded potentials that hyperpolarize the membrane potential to values more negative than the resting potential can inhibit the generation of action potentials.

Graded potentials can arise at either portions of cells that function as sensory receptors or at synapses that are activated by neurotransmitters. These two types of graded potentials are called receptor potentials or synaptic potentials. Graded potentials are distinct from action potentials in that graded potentials spread electric potential changes along cell membranes without activating the kind of constant magnitude propagating signal that is characteristic of the action potential. Graded potentials are highest at a source and decay with increasing distance from the source.

All other values of membrane potential

From the viewpoint of biophysics, there is nothing particularly special about the resting membrane potential. It is merely the membrane potential that results from the membrane permeabilities that predominate when the cell is resting. The above equation of weighted averages always applies, but the following approach may be easier to visualize. At any given moment, there are two factors for an ion that determine how much influence that ion will have over the membrane potential of a cell.

1. That ion’s driving force and,
2. That ion’s permeability

Intuitively, this is easy to understand. If the driving force is high, then the ion is being “pushed” across the membrane hard (more correctly stated: it is diffusing in one direction faster than the other). If the permeability is high, it will be easier for the ion to diffuse across the membrane. But what are ‘driving force’ and ‘permeability’?

- **Driving force**: the driving force is the net electrical force available to move that ion across the membrane. It is calculated as the difference between the voltage that the ion "wants" to be at (its equilibrium potential) and the actual membrane potential (Em). So formally, the driving force for an ion = Em - Eion

- **For example, at our earlier calculated resting potential** of −73 mV, the driving force on potassium is 7 mV ((−73 mV) − (−80 mV) = 7 mV. The driving force on sodium would be (−73 mV) − (60 mV) = −133 mV.

- **Permeability**: is simply a measure of how easily an ion can cross the membrane. It is normally measured as the (electrical) conductance and the unit, siemens, corresponds to 1 C·s·V⁻¹, that is one charge per second per volt of potential.

So in a resting membrane, while the driving force for potassium is low, its permeability is very high. Sodium has a huge driving force, but almost no resting permeability. In this case, the math tells us that potassium carries about 20 times more current than sodium, and thus has 20 times more influence over Em than does sodium.

However, consider another case—the peak of the action potential. Here permeability to Na is high and K permeability is relatively low. Thus the membrane moves to near ENa and far from EK.

The more ions are permeant, the more complicated it becomes to predict the membrane potential. However, this can be done using the Goldman-Hodgkin-Katz equation or the weighted means equation. By simply plugging in the concentration gradients and the permeabilities of the ions at any instant in time, one can determine the membrane potential at that moment. What the GHK equations says, basically, is that at any time, the value of the membrane potential will be a weighted average of the equilibrium potentials of all permeant ions. The “weighting” is the ions relative permeability across the membrane.

**Effects and implications**

While cells expend energy to transport ions and establish a transmembrane potential, they use this potential in turn to transport other ions and metabolites such as sugar. The transmembrane potential of the mitochondria drives the production of ATP, which is the common currency
of biological energy. Cells may draw on the energy they store in the resting potential to drive action potentials or other forms of excitation. These changes in the membrane potential enable communication with other cells (as with action potentials) or initiate changes inside the cell, which happens in an egg when it is fertilized by a sperm.

In neuronal cells, an action potential begins with a rush of sodium ions into the cell through sodium channels, resulting in depolarization, while recovery involves an outward rush of potassium through potassium channels. Both these fluxes occur by passive diffusion.

Again, because of the high relative permeability for potassium, the resulting membrane potential movement is not balanced by built-up of negative charges on the inner surface of the membrane. Ions flow from cytosole into the extracellular space carrying out positive charges, until their concentration gradient of potassium ions must first be set up. This work is done by the ion pumps/transporters and/or exchangers and generally is powered by ATP.

In the case of the resting membrane potential across an animal cell’s plasma membrane, potassium (and sodium) gradients are established by the Na+/K+-ATPase (sodium-potassium pump) which transports 2 potassium ions inside and 3 sodium ions outside at the cost of 1 ATP molecule. In other cases, for example, a membrane potential may be established by acidification of the inside of a membranous compartment (such as the proton pump that generates membrane potential across synaptic vesicle membranes).

Electroneutrality

In most quantitative treatments of membrane potential, such as the derivation of Goldman equation, electroneutrality is assumed; that is, that there is no measurable charge excess in any side of the membrane. So, although there is an electric potential across the membrane due to charge separation, there is no actual measurable difference in the global concentration of positive and negative ions across the membrane (as it is estimated below), that is, there is no actual measurable charge excess in either side. That occurs because the effect of charge on electrochemical potential is hugely greater than the effect of concentration so an undetectable change in concentration creates a great change on electric potential.

Generation of the resting potential

Cell membranes are typically permeable to only a subset of ionic species. These species usually include potassium ions, chloride ions, bicarbonate ions, and others. To simplify the description of the ionic basis of the resting membrane potential, it is most useful to consider only one ionic species at first, and consider the others later. Since trans-plasma-membrane potentials are almost always determined primarily by potassium permeability, that is where to start.

A diagram showing the progression in the development of a membrane potential from a concentration gradient (for potassium). Green arrows indicate net movement of K+ down a concentration gradient. Red arrows indicate net movement of K+ due to the membrane potential.

The diagram is misleading in that while the concentration of potassium ions outside of the cell increases, only a small amount of K+ needs to cross the membrane in order to produce a membrane potential with a magnitude large enough to counter the tendency the potassium ions to move down the concentration gradient.

- Panel 1 of the diagram shows a digramatic representation of a simple cell where a concentration gradient has already been established. This panel is drawn as if the membrane has no
permeability to any ion. There is no membrane potential, because despite there being a concentration gradient for potassium, there is no net charge imbalance across the membrane. If the membrane were to become permeable to a type of ion that is more concentrated on one side of the membrane, then that ion would contribute to membrane voltage because the permeant ions would move across the membrane with net movement of that ion type down the concentration gradient. There would be net movement from the side of the membrane with a higher concentration of the ion to the side with lower concentration. Such a movement of one ion across the membrane would result in a net imbalance of charge across the membrane and a membrane potential. This is a common mechanism by which many cells establish a membrane potential.

- In panel 2 of the diagram, the cell membrane has been made permeable to potassium ions, but not the anions (An-) inside the cell. These anions are mostly contributed by protein. There is energy stored in the potassium ion concentration gradient that can be converted into an electrical gradient when potassium (K) ions move out of the cell. Note that K ions can move across the membrane in both directions but by the purely statistical process that arises from the higher concentration of K inside the cell, there will be more K ions moving out of the cell. Because there is a higher concentration of K ions inside the cells, their random molecular motion is more likely to encounter the permeability pore (ion channel) than is the case for the K ions that are outside and at a lower concentration. An internal K+ is simply "more likely" to leave the cell than an extracellular K+ to enter it. It is a matter of simple diffusion doing work by dissipating the concentration gradient. As potassium leaves the cell, it is leaving behind the anions. Therefore a charge separation is developing as K+ leaves the cell. This charge separation creates a trans-membrane voltage. This trans-membrane voltage is the membrane potential. As potassium continues to leave the cell, separating more charges, the membrane potential will continue to grow. The length of the arrows (green indicating concentration gradient, red indicating voltage), represents the magnitude of potassium ion movement due to each form of energy. The direction of the arrow indicates the direction in which that particular force is applied. Thus, the building membrane voltage is an increasing force that acts counter to the tendency for net movement of potassium ions down the potassium concentration gradient.

- In Panel 3, the membrane voltage has grown to the extent that its "strength" now matches the concentration gradient's. Since these forces (which are applied to K+ ions) are now the same strength and oriented in opposite directions, the system is now in equilibrium. Put another way, the tendency of potassium to leave the cell by running down its concentration gradient is now matched by the tendency of the membrane voltage to pull potassium ions back into the cell. K+ continues to move across the membrane, but the rate at which it enters and leaves the cell are the same, thus, there is no net potassium current. Because the K+ is at equilibrium, membrane potential is stable, or "resting".

The resting voltage is the result of several ion-translocating enzymes (uniporters, cotransporters, and pumps) in the plasma membrane, steadily operating in parallel, whereby each ion-translocator has its characteristic electromotive force (= reversal potential = "equilibrium voltage"), depending on the particular substrate concentrations inside and outside (internal ATP included in case of some pumps). H+ exporting ATPase render the membrane voltage in plants and fungi much more negative than in the more extensively investigated animal cells, where the resting voltage is mainly determined by selective ion channels.

In most neurons the resting potential has a value of approximately -70 mV. The resting potential is mostly determined by the concentrations of the ions in the fluids on both sides of the cell membrane and the ion transport proteins that are in the cell membrane. How the concentrations of ions and the membrane transport proteins influence the value of the resting potential is outlined below.

The resting potential of a cell can be most thoroughly understood by thinking of it in terms of equilibrium potentials. In the example diagram here, the model cell was given only one permeant ion (potassium). In this case, the resting potential of this cell would be the same as the equilibrium potential for potassium.

However, a real cell is more complicated, having permeabilities to many ions, each of which contributes to the resting potential. To understand better, consider a cell with only two permeant ions, potassium and sodium. Consider a case where these two ions have equal concentration gradients directed in opposite directions, and that the membrane permeabilities to both ions are equal. K+ leaving the cell will tend to drag the membrane potential toward EK. Na+ entering the cell will tend to drag the membrane potential toward the reversal potential for sodium ENa. Since the permeabilities to both ions were set to be equal, the membrane potential will, at the end of the Na+/K+ tug-of-war, end up halfway between ENa and EK. As ENa and EK were equal but of opposite signs, halfway in between is zero, meaning that the membrane will rest at 0 mV.

Note that even though the membrane potential at 0 mV is stable, it is not an equilibrium condition because neither of the contributing ions are in equilibrium. Ions diffuse down their electrochemical gradients through ion channels, but the membrane potential is upheld by continual K+ influx and Na+ efflux via ion transporters. Such situation with similar permeabilities for counter-acting ions, like potassium and sodium in animal cells, can be extremely costly for the cell if these permeabilities are relatively large, as it takes a lot of ATP energy to pump the ions back. Because no real cell can afford such equal and large ionic permeabilities at rest, resting potential of animal cells is determined by predominant high permeability to potassium and adjusted to the required value by modulating sodium and chloride permeabilities and gradients.

In a healthy animal cell Na+ permeability is about 5% of the K permeability or even less, whereas the respective reversal potentials are +60 mV for sodium (ENa)and -80 mV for potassium (EK). Thus the membrane potential will not be right at EK, but rather depolarized from EK by an amount of approximately 5% of the 140 mV difference between EK and ENa. Thus, the cell’s resting potential will be about ~73 mV.

In a more formal notation, the membrane potential is the weighted average of each contributing ion’s equilibrium potential (Goldman equation). The size of each weight is the relative permeability of each ion. In the normal case, where three ions contribute to the membrane potential:

$$E_m = \frac{P_{K^+}}{P_{tot}}E_{K^+} + \frac{P_{Na^+}}{P_{tot}}E_{Na^+} + \frac{P_{Cl^-}}{P_{tot}}E_{Cl^-}$$

where

- $E_m$ is the membrane potential, measured in volts
- $E_i$ is the equilibrium potential for ion $X$, also in volts
Potassium equilibrium potentials of around -80 millivolts (inside negative) are common. Differences are observed in different species, different tissues within the same animal, and the same tissues under different environmental conditions. Applying the Nernst Equation above, one may account for these differences by changes in relative K+ concentration or differences in temperature.

For common usage the Nernst equation is often given in a simplified form by assuming typical human body temperature (37 C), reducing the constants and switching to Log base 10. (The units used for concentration are unimportant as they will cancel out into a ratio). For Potassium at normal body temperature one may calculate the equilibrium potential in millivolts as:

\[ E_{eq,K} = \frac{R T}{z F} \log \frac{[K^+]_o}{[K^+]_i} \]

Likewise the equilibrium potential for sodium (Na+) at normal human body temperature is calculated using the same simplified constant. You can calculate E assuming the an outside concentration,\([K^+]_o\), of 100mM and an inside concentration, \([K^+]_i\), of 10mM. For chloride ions (Cl-) the sign of the constant must be reversed -61.54 mV.

The resting membrane potential is not an equilibrium potential as it relies on the constant expenditure of energy (for ionic pumps as mentioned above) for its maintenance. It is a dynamic diffusion potential that takes mechanism into account—wholly unlike the equilibrium potential, which is true no matter the nature of the system under consideration. The resting membrane potential is dominated by the ionic species in the system that has the greatest conductance across the membrane. For most cells this is potassium. As potassium is also the ion with the most negative equilibrium potential, usually the resting potential can be no more negative than the potassium equilibrium potential. The resting potential can be calculated with the Goldman-Hodgkin-Katz voltage equation using the concentrations of ions as for the equilibrium potential while also including the relative permeabilities, or conductances, of each ionic species. Under normal conditions, it is safe to assume that only potassium, sodium (Na+) and chloride (Cl-) ions play large roles for the resting potential:

\[ E_m = \frac{R T}{F} \ln \left( \frac{P_{Na^+}[Na^+]_o + P_{K^+}[K^+]_o + P_{Cl^-}[Cl^-]_o}{P_{Na^+}[Na^+]_i + P_{K^+}[K^+]_i + P_{Cl^-}[Cl^-]_i} \right) \]

This equation resembles the Nernst equation, but has a term for each permeant ion. Also, z has been inserted into the equation, causing the intracellular and extracellular concentrations of Cl- to be reversed relative to K+ and Na+, as chloride’s negative charge is handled by inverting the fraction inside the logarithmic term. *Em is the membrane potential, measured in volts *R, T, and F are as above *PX are the relative permeability of ion X in arbitrary units (e.g. siemens for electrical conductance) *\([X]_Y\) is the concentration of ion X in compartment Y as above. Another way to view...
the membrane potential is using the Millman equation:

\[ E_m = \frac{P_{K^+}E_{eq,K^+} + P_{Na^+}E_{eq,Na^+} + P_{Cl^-}E_{eq,Cl^-}}{P_{K^+} + P_{Na^+} + P_{Cl^-}} \]

or reformulated

\[ E_m = \frac{P_{K^+}}{P_{tot}}E_{eq,K^+} + \frac{P_{Na^+}}{P_{tot}}E_{eq,Na^+} + \frac{P_{Cl^-}}{P_{tot}}E_{eq,Cl^-} \]

where \( P_{tot} \) is the combined permeability of all ionic species, again in arbitrary units. The latter equation portrays the resting membrane potential as a weighted average of the reversal potentials of the system, where the weights are the relative permeabilities across the membranes (\( P_{K^+}/P_{tot} \)). During the action potential, these weights change. If the permeabilities of \( Na^+ \) and \( Cl^- \) are zero, the membrane potential reduces to the Nernst potential for \( K^+ \) (as \( P_{K^+} = P_{tot} \)). Normally, under resting conditions \( P_{Na^+} \) and \( P_{Cl^-} \) are not zero, but they are much smaller than \( P_{K^+} \), which renders \( E_m \) close to \( E_{eq,K^+} \). Medical conditions such as hyperkalemia in which blood serum potassium (which governs \( [K^+]_o \)) is changed are very dangerous since they offset \( E_{eq,K^+} \), thus affecting \( E_m \). This may cause arrhythmias and cardiac arrest. The use of a bolus injection of potassium chloride in executions by lethal injection stops the heart by shifting the resting potential to a more positive value, which depolarizes and contracts the cardiac cells permanently, not allowing the heart to repolarize and thus enter diastole to be refilled with blood.

Measuring resting potentials

In some cells, the membrane potential is always changing (such as cardiac pacemaker cells). For such cells there is never any “rest” and the “resting potential” is a theoretical concept. Other cells with little in the way of membrane transport functions that change with time have a resting membrane potential that can be measured by inserting an electrode into the cell. Transmembrane potentials can also be measured optically with dyes that change their optical properties according to the membrane potential.

Summary of resting potential values in different types of cells

The resting membrane potential in different cell types are approximately:

- Skeletal muscle cells: −95 mV
- Smooth muscle cells: −50 mV

References

1. An example of an electrophysiological experiment to demonstrate the importance of \( K^+ \) for the resting potential. The dependence of the resting potential on the extracellular concentration of \( K^+ \) is shown in Figure 2.6 of Neuroscience, 2nd edition, by Dale Purves, George J. Augustine, David Fitzpatrick, Lawrence C. Katz, Anthony-Samuel LaManntia, James O. McNamara, S. Mark Williams, Sunderland (MA): Sinauer Associates, Inc.; 2001.
2. An illustrated example of measuring membrane potentials with electrodes is in Figure 2.1 of Neuroscience by Dale Purves, et al. (see reference #1, above).
3. Kimball’s Biology Pages - Muscles
Electromyography

(EMG) is a technique for evaluating and recording the activation signal of muscles. EMG is performed using an instrument called an electromyograph, to produce a record called an electromyogram. An electromyograph detects the electrical potential generated by muscle cells when these cells are both mechanically active and at rest. The signals can be analyzed in order to detect medical abnormalities or analyze the biomechanics of human or animal movement.

Nerve signals from the Central Nervous System CNS are sent to the medial parts of a muscle for activation of a muscle or the insertion points at the ends of a muscle to deactivate the muscle. The action of the muscle is the activation of small magnetic cells that draw over each other to make contraction. The process is a bio-electromagnetic process involving variant oscillations and non-linear dynamics.

Electrical characteristics

The electrical source is the muscle membrane potential of about -90mV. Measured EMG potentials range between less than 50 μV and up to 20 to 30 mV, depending on the muscle under observation.

Typical repetition rate of muscle unit firing is about 7–20 Hz, depending on the size of the muscle (eye muscles versus seat (gluteal) muscles), previous axonal damage and other factors. Damage to motor units can be expected at ranges between 450 and 780 mV.

The muscle frequencies used for contraction and relaxation of a muscle are complex and non-linear in analysis. There some frequencies that can act as tetanic freeze stimulation. High band waves as high as 10K can be also detected and corrected. The regulatory process of normal muscle activity is a complex and fractal environment. Irregular stimulation and regulatory frequencies can be detected.

Muscles respond to electrical stimulation. Micro-current stimulation can be used to help to normalize muscle activity by stabilizing the regulatory processes of the body. The body works at micro-current levels and the SCIO system can help regulate these processes thru a cybernetic loop of micro-current stimulation and detection. Muscle regulation activity is effected by pH thus charge stability, oxygenation (redox potential), nutrition, training and a host of other variables. These lifestyle factors must be addressed to fully correct muscle dysfunction.

History

The first documented experiments dealing with EMG started with Francesco Redi’s works in 1666. Redi discovered a highly specialized muscle of the electric ray fish (Electric Eel) generated electricity. By 1773, Walsh had been able to demonstrate that the Eel fish’s muscle tissue could generate a spark of electricity. In 1792, a publication entitled “De Viribus Electricitatis in Motu Musculari Commentarius” appeared, written by Luigi Galvani, in which the author demonstrated that electricity could initiate muscle contractions. Six decades later, in 1849, Dubois-Raymond discovered that it was also possible to record electrical activity during a voluntary muscle contraction. The first actual recording of this activity was made by Marey in 1890, who also introduced the term electromyography. In 1922, Gasser and Erlanger used an oscilloscope to show the electrical signals from muscles. Because of the stochastic nature of the myoelectric...
Signal, only rough information could be obtained from its observation. The capability of detecting electromyographic signals improved steadily from the 1930s through the 1950s, and researchers began to use improved electrodes more widely for the study of muscles. Clinical use of surface EMG (sEMG) for the treatment of more specific disorders began in the 1960s. Hardyck and his researchers were the first (1966) practitioners to use sEMG. In the early 1980s, Cram and Steger introduced a clinical method for scanning a variety of muscles using an EMG sensing device. It is not until the middle of the 1980s that integration techniques in electrodes had sufficiently advanced to allow batch production of the required small and lightweight instrumentation and amplifiers. At present, a number of suitable amplifiers are commercially available. In the early 1980s, cables that produce artifacts in the desired microvolt range became available. During the past 15 years, research has resulted in a better understanding of the properties of surface EMG recording. In recent years, surface electromyography is increasingly used for recording from superficial muscles in clinical protocols, where intramuscular electrodes are used for deep muscle only.

There are many applications for the use of EMG. EMG is used clinically for the diagnosis of neurological and neuromuscular problems. It is used diagnostically by gait laboratories and by clinicians trained in the use of biofeedback or ergonomic assessment. EMG is also used in many types of research laboratories, including those involved in biomechanics, motor control, neuromuscular physiology, movement disorders, postural control, and physical therapy.

In 1985 Dr. Nelson (now known as Desire' Dubounet) developed a cybernetic biofeedback system now known as the SCIO that can produce a natural level stimulation and measure the response. A cybernetic self focusing device that can be used for stabilizing muscle regulation. This technological advancement is safe and effective used around the world.

Using known technologies well established as safe and effective in the literature, Nelson was able to combine EMG, SSR, EEG, ECG, with micro-current technologies such as MENS, CES, trauma healing, and others to make a more advanced technology. After over two decades registered in the market place and no reports of significant risk, hundreds of studies have been published on its success. In fact the SCIO is perhaps the most researched biofeedback device in history.

**EMG Procedure**

There are two kinds of EMG in widespread use: surface EMG and needle (intramuscular) EMG. To perform intramuscular EMG, a needle electrode is inserted through the skin into the muscle tissue. A trained professional (most often a physiatrist, neurologist, physical therapist, or chiropractor) observes the electrical activity while inserting the electrode. The insertional activity provides valuable information about the state of the muscle and its innervating nerve. Normal muscles at rest make certain, normal electrical sounds when the needle is inserted into them. Then the electrical activity when the muscle is at rest is studied. Abnormal spontaneous activity might indicate some nerve and/or muscle damage. Then the patient is asked to contract the muscle smoothly. The shape, size and frequency of the resulting motor unit potentials is judged. Then the electrode is retracted a few millimeters, and again the activity is analyzed until at least 10-20 units have been collected. Each electrode track gives only a very local picture of the activity of the whole muscle. Because skeletal muscles differ in the inner structure, the electrode has to be placed at various locations to obtain an accurate study.

Intramuscular EMG may be considered too invasive or unnecessary in some cases. Instead, a surface electrode may be used to monitor the general picture of muscle activation, as opposed to the activity of only a few fibres as observed using a needle. This technique is used in a number of settings; for example, in the physiotherapy clinic, muscle activation is monitored using surface EMG and patients have an auditory or visual stimulus to help them know when they are activating the muscle (biofeedback).

A motor unit is defined as one motor neuron and all of the muscle fibers it innervates. When a motor unit fires, the impulse (called an action potential) is carried down the motor neuron to the muscle. The area where the nerve contacts the muscle is called the neuromuscular junction, or the motor end plate. After the action potential is transmitted across the neuromuscular junction, an action potential is elicited in all of the innervated muscle fibers of that particular motor unit. The sum of all this electrical activity is known as a motor unit action potential (MUAP). This electrophysiologic activity from multiple motor units is the signal typically evaluated during an EMG. The composition of the motor unit, the number of muscle fibres per motor unit, the metabolic type of muscle fibres and many other factors affect the shape of the motor unit potentials in the myogram.

Nerve conduction testing is also often done at the same time as an EMG in order to diagnose neurological diseases. Some patients can find the procedure somewhat painful, whereas others experience only a small amount of discomfort when the needle is inserted. The muscle or muscles being tested may be slightly sore for a day or two after the procedure.

**Normal results**

Muscle tissue at rest is normally electrically inactive. After the electrical activity caused by the irritation of needle insertion subsides, the electromyograph should detect no abnormal spontaneous activity (i.e., a muscle at rest should be electrically silent, with the exception of the area of the neuromuscular junction, which is, under normal circumstances, very spontaneously active). When the muscle is voluntarily contracted, action potentials begin to appear. As the strength of the muscle contraction is increased, more and more muscle fibers produce action potentials. When the muscle is fully contracted, there should appear a disorderly group of action potentials of varying rates and amplitudes (a complete recruitment and interference pattern).

**Electromyogram (EMG) and nerve conduction studies**

<table>
<thead>
<tr>
<th>Normal</th>
<th>The EMG recording shows no electrical activity when the muscle is at rest. There is a smooth, wavy line on the recording with each muscle contraction.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>The nerve conduction studies show that the nerves transmit electrical impulses to the muscles or along the sensory nerves at normal speeds (conduction velocities). Sensory nerves allow the brain to feel pain, touch, temperature, and vibration. Different nerves have different normal conduction velocities. Nerve conduction velocities generally get slower as a person gets older.</td>
</tr>
</tbody>
</table>
Electrical activity in a muscle at rest shows that there may be a problem with the nerve supply to the muscle. Abnormal wave lines when a muscle contracts may mean a muscle or nerve disorder, such as amyotrophic lateral sclerosis (ALS), post-polio syndrome, inflammation, or other muscle problems.

In nerve conduction studies, the speed of nerve impulses (conduction velocity) may be slower than what is normal for that nerve. Slower conduction velocities may be caused by injury to a nerve (such as carpal tunnel syndrome) or group of nerves (such as Guillain-Barré syndrome or post-polio syndrome). Nerve conduction velocities generally get slower as a person gets older.

**Abnormal results**

EMG is used to diagnose two general categories of disease: neuropathies and myopathies.

Neuropathic disease has the following defining EMG characteristics:

- An action potential volt-ammetric amplitude that is twice normal due to the increased number of fibres per motor unit because of reinnervation of denervated fibres.
- An action potential volt-ammetric amplitude that is reduced from normal due to the decreased number of fibres per motor unit because of reinnervation of denervated fibres.
- An increase in duration or frequency of the action potential
- A decrease in the number of motor units in the muscle (as found using motor unit number estimation techniques)

Myopathic disease has these defining EMG characteristics:

- A decrease in duration of the action potential (wave form aberration)
- A reduction in the area (amperage) to amplitude (voltage) ratio of the volt-ammetric action potential
- A decrease in the number of motor units in the muscle (in extremely severe cases only)

Because of the individuality of each patient and disease, some of these characteristics may not appear in every case.

Abnormal results may be caused by the following medical conditions (please note this is nowhere near an exhaustive list of conditions that can result in abnormal EMG studies):

- Alcoholic neuropathy
- Amyotrophic lateral sclerosis
- Axillary nerve dysfunction
- Becker’s muscular dystrophy
- Brachial plexopathy
- Carpal tunnel syndrome
- Centronuclear myopathy
- Cervical spondylosis
- Charcot-Marie-Tooth disease
- Chronic Immune Demyelinating Poly(radiculo)neuropathy (CIDP)
- Common peroneal nerve dysfunction
- Denervation (reduced nervous stimulation)
- Dermatomyositis
- Distal median nerve dysfunction
- Duchenne muscular dystrophy
- Facioscapulohumeral muscular dystrophy (Landouzy-Dejerine)
- Familial periodic paralysis
- Femoral nerve dysfunction
- Fields condition
- Friedreich’s ataxia
- Guillain-Barre
- Lambert-Eaton Syndrome
- Mononeuritis multiplex
- Mononeuropathy
- Motor neurone disease
- Multiple system atrophy
- Myasthenia gravis
- Myopathy (muscle degeneration, which may be caused by a number of disorders, including muscular dystrophy)
- Myotubular myopathy
- Neuromyotonia
- Peripheral neuropathy
- Poliomyelitis
- Polymyositis
- Radial nerve dysfunction
- Sciatic nerve dysfunction
- Sensorimotor polyneuropathy
EMG signals are essentially made up of superimposed motor unit action potentials (MUAPs) from several motor units. For a thorough analysis, the measured EMG signals can be decomposed into their constituent MUAPs. MUAPs from different motor units tend to have different characteristic shapes, while MUAPs recorded by the same electrode from the same motor unit are typically similar. Notably MUAP size and shape depend on where the electrode is located with respect to the fibers and so can appear to be different if the electrode moves position. EMG decomposition is non-trivial, although many methods have been proposed.

Applications of EMG

EMG signals are used in many clinical and biomedical applications. EMG is used as a diagnostics tool for identifying neuromuscular diseases, assessing low-back pain, kinesiology, and disorders of motor control. EMG signals are also used as a control signal for prosthetic devices such as prosthetic hands, arms, and lower limbs.

EMG can be used to sense isometric muscular activity where no movement is produced. This enables definition of a class of subtle motionless gestures to control interfaces without being noticed and without disrupting the surrounding environment. These signals can be used to control a prosthetic or as a control signal for an electronic device such as a mobile phone or PDA.

EMG signals have been targeted as control for flight systems. The Human Senses Group at the NASA Ames Research Center at Moffett Field, CA seeks to advance man-machine interfaces by directly connecting a person to a computer. In this project, an EMG signal is used to substitute for mechanical joysticks and keyboards. EMG has also been used in research towards a "wearable cockpit," which employs EMG-based gestures to manipulate switches and control sticks necessary for flight in conjunction with a goggle-based display.

Unvoiced speech recognition recognizes speech by observing the EMG activity of muscles associated with speech. It is targeted for use in noisy environments, and may be helpful for people without vocal cords and people with aphasia.

Key Studies References

A new method for objective quantification of localized muscle fatigue is described. The method is based on power spectrum analysis of myoelectric signals obtained from the fatigued muscle. It permits real-time investigations and yields statistically based criteria for the occurrence of fatigue. The findings are interpreted in terms of muscle action potential conduction velocity changes and rate of the fatigue development. (This points to a larger broader band of frequencies for EMG than previously supposed)

T. Sadoyama, T. Masuda and H. Miyano

Human Factors Engineering Division, Industrial Products Research Institute, 1-1-4, Yatabe-machi, Higashi, Tsukubagun, 305 Ibaraki, Japan

Accepted: 1 March 1983

Summary

A surface electrode array has been used to investigate the relationship between muscle fibre conduction velocity and the frequency spectrum during sustained isometric contractions of the biceps brachii. Measurement of muscle fibre conduction velocity was made directly, using the zero-crossing time delay method with two pairs of bipolar electrodes. It was found that the average conduction velocity during an intense (12 kg) sustained contraction decreased by about 20% at the end of the contracting period. Except for peak frequency, changes in the spectral parameters decreased in a similar manner. These results indicate that, during fatiguing contraction, spectral modifications are partly due to reduction in the action potential conduction velocity along the muscle fibers.

Keywords

Surface EMG - Conduction velocity - Spectral analysis - Electrode array - Sustained contraction

Influence of lactate accumulation of EMG frequency spectrum during repeated concentric contractions

ABSTRACT

One hundred and twenty consecutive maximal leg extensions at a constant angular velocity of 1.5 radians/s were performed by nine physical education students. Integrated electromyographic (IEMG) activity and power spectrum density function (PSDF) of the EMG were recorded from m. vastus lateralis, m. vastus medialis and m. rectus femoris using bipolar surface electrodes. Muscle biopsies were obtained from m. vastus lateralis before and after exercise. Tissue samples were analyzed for muscle fiber type distribution and lactate and glycogen concentration. Muscle force and IEMG decreased in parallel over the exercise period. Thus, the IEMG/force ratio was unchanged. Mean power frequency (MPF) of PSDF of the three muscles decreased by 10% (p<0.001) during the initial 25 contractions with no further decline during the latter part of exercise. The relative contribution of the highest bandwidth (130–1000 Hz) of the PSDF decreased (p<0.001) between the first and final contractions. Muscle glycogen concentration decreased from 85 ± 23 to 68 ± 22 mmol ± kg-1 w. w. during the exercise. Muscle and blood lactate concentration averaged 12.1 ± 8.8 mmol ± kg-1 w. w. and 3.8 ± 0.8 mmol ± kg-1 respectively. The relative changes in MPF and in the highest bandwidth were correlated with muscle lactate concentration and fiber type distribution: in individuals with a high proportion of fast twitch muscle fibers and/or the greatest lactate accumulation, MPF and high frequency components of EMG PSDF decreased most markedly.

Reductions in muscle force and IEMG are suggested to be partly due to a decreased motor neuron firing rate. It is discussed whether lactate or associated metabolic changes are influencing the motor unit action potential through feedback processes.
The surface EMG was recorded from above the quadriceps muscle in 3 male subjects during bicycle ergometry at work loads between 20 and 100% of the VO2 max to measure the EMG amplitude (RMS) and frequency (assessed from the center frequency of the power spectra) during this type of work. During brief (3 min) bouts of work the RMS amplitude of the EMG was linearly related to the work load; the center frequency of the EMG power spectra was the same at all work loads examined. In contrast, during sustained bouts of work maintained for 80 min at 20 and 40% of the VO2 max, the RMS amplitude of the EMG remained constant while the center frequency initially increased for the 20 min of work and then progressively decreased as the work continued. When work loads of 60, 80, and 100% of the VO2 max were sustained to fatigue, the RMS amplitude continually increased while the EMG frequency decreased from the beginning to the end of the work periods.

The results of this study showed that the EMG is a complex waveform, being influenced not only by fatigue, but to even a larger extent in many cases, the temperature of the exercising muscles. Therefore, although muscular fatigue caused an increase in the RMS amplitude and decrease in the center frequency, the increase in muscle temperature associated with the work opposed these changes by causing a reduction in the RMS amplitude and an increase in the center frequency.

**Median frequency of the myoelectric signal**

Effects of muscle ischemia and cooling

Roberto Merletti, Mohamed A. Sabbahi and Carlo J. De Luca

- Neuro Muscular Research Laboratory, Department of Orthopaedic Surgery, Children’s Hospital, 300 Longwood Ave., 02115 Boston, MA, USA
- Liberty Mutual Research Center, Hopkinton, MA, USA

Accepted: 31 October 1983

**Summary**

A study was performed to investigate the changes that occur in the median frequency of the myoelectric signal during local ischemia or reduction of intramuscular temperature produced by surface cooling. Data was obtained from experiments which involved the first dorsal interosseous muscle of 10 female and 16 male subjects. These subjects were asked to perform isometric constant-force abduction contractions of the index finger at 20% and 80% of maximal voluntary contraction level. The initial median frequency (IMF) of the myoelectric signal during the first 0.5 s of contraction as force was raised from 25 to 100% of maximum. Only one of five subjects showed evidence of increasing synchronization of motor unit discharge during contraction. Therefore, although muscular fatigue caused an increase in the RMS amplitude and decrease in the center frequency, the increase in muscle temperature associated with the work opposed these changes by causing a reduction in the RMS amplitude and an increase in the center frequency.

The results of this study showed that the EMG is a complex waveform, being influenced not only by fatigue, but to even a larger extent in many cases, the temperature of the exercising muscles. Therefore, although muscular fatigue caused an increase in the RMS amplitude and decrease in the center frequency, the increase in muscle temperature associated with the work opposed these changes by causing a reduction in the RMS amplitude and an increase in the center frequency.
Electromyographic activity related to aerobic and anaerobic threshold in ergometer bicycling

JUKKA T. VIITASALO, PEKKA LUHTANEN, PAAVO RAHKILA, HEIKKI RUSKO

- Department of Biology of Physical Activity, University of Jyväskylä, and Research Unit for Sport and Physical Fitness, Jyväskylä, Finland
- Correspondence to 2Department of Biology of Physical Activity, University of Jyväskylä, SF-40100 Jyväskylä, Finland.

KEYWORDS
- EMG integral
- EMG mean power frequency
- anaerobic threshold
- ergometer bicycling.

ABSTRACT
Electromyographic activity (EMG) of the knee extensor musculature (m. vastus lateralis, m. vastus medialis, m. rectus femoris), triceps surae (m. gastrocnemius, m. soleus) and m. tibialis anterior was studied in ergometer bicycling at five different power outputs around aerobic (AerT) and anaerobic (AnT) thresholds. EMGs were sampled with surface electrodes for ten revolutions at the beginning, in the middle and at the end of each work load and integrated (IEMG) separately for each of the muscles and for the descending (work) and ascending (rest) phase of the revolution. The mean power frequency (MPF) of the power spectral density function for the descending periods was also calculated. The first work load was 50% of the maximal load, the second at the AerT, the third at the AnT, the fourth between the AnT and the maximal load and the fifth load was maximal. The AerT and AnT were determined using blood lactate, ventilation volume and oxygen consumption.

The time course of muscle fiber conduction velocity and surface myoelectric signal spectral (mean and median frequency of the power spectrum) and amplitude (average rectified and root-mean-square value) parameters was studied in 20 experiments on the tibialis anterior muscle of 10 healthy human subjects during sustained isometric voluntary or electrically elicited contractions. Voluntary contractions at 20% maximal voluntary contraction (MVC) and at 80% MVC with duration of 20 s were performed at the beginning of each experiment. Tetanic electrical stimulation was then applied to the main muscle motor point for 20 s with surface electrodes at five stimulation frequencies (20, 25, 30, 35, and 40 Hz). All subjects showed myoelectric manifestations of muscle fatigue consisting of negative trends of spectral variables and conduction velocity and positive trends of amplitude variables. The main findings of this work are 1) myoelectric signal variables obtained from electrically elicited contractions show fluctuations smaller than those observed in voluntary contractions, 2) spectral variables are more sensitive to fatigue than conduction velocity and the average rectified value is more sensitive to fatigue than the root-mean-square value, 3) conduction velocity is not the only physiological factor affecting spectral variables, and 4) contractions elicited at supramaximal stimulation and frequencies greater than 30 Hz demonstrate myoelectric manifestations of muscle fatigue greater than those observed at 80% MVC sustained for the same time.

EMG Notes
1. MeSH Electromyography
4. Park, DG.; Kim, HC. Muscleman: Wireless input device for a fighting action game based on the EMG signal and acceleration of the human forearm.

EMG References
- Basmaijian, JV.; de Luca, CJ. Muscles Alive - The Functions Revealed by Electromyography. The Williams & Wilkins Company; Baltimore, 1985.
Varhope charging the batteries


Nervous system

The human nervous system consists of billions of nerve cells (or neurons) plus supporting (neuroglial) cells. Neurons are able to respond to stimuli (such as touch, sound, light, and so on), conduct impulses, and communicate with each other (and with other types of cells like muscle cells).

The nucleus of a neuron is located in the cell body. Extending out from the cell body are processes called dendrites and axons. These processes vary in number & relative length but always serve to conduct impulses (with dendrites conducting impulses toward the cell body and axons conducting impulses away from the cell body).

Neurons can respond to stimuli and conduct impulses because a membrane potential is established across the cell membrane. In other words, there is an unequal distribution of ions (charged atoms) on the two sides of a nerve cell membrane. This can be illustrated with a voltmeter:

With one electrode placed inside a neuron and the other outside, the voltmeter is ‘measuring’ the difference in the distribution of ions on the inside versus the outside. And, in this example, the voltmeter reads -70 mV (mV = millivolts). In other words, the inside of the neuron is slightly negative relative to the outside. This difference is referred to as the Resting Membrane Potential. How is this potential established?
The membranes of all nerve cells have a potential difference across them, with the cell interior negative with respect to the exterior (a). In neurons, stimuli can alter this potential difference by opening sodium channels in the membrane. For example, neurotransmitters interact specifically with sodium channels (or gates). So sodium ions flow into the cell, reducing the voltage across the membrane.

Once the potential difference reaches a threshold voltage, the reduced voltage causes hundreds of sodium gates in that region of the membrane to open briefly. Sodium ions flood into the cell, completely depolarizing the membrane (b). This opens more voltage-gated ion channels in the adjacent membrane, and so a wave of depolarization courses along the cell — the action potential.

As the action potential nears its peak, the sodium gates close, and potassium gates open, allowing ions to flow out of the cell to restore the normal potential of the membrane (c) (Gutkin and Ermentrout 2006).

Establishment of the Resting Membrane Potential

Membranes are polarized or, in other words, exhibit a RESTING MEMBRANE POTENTIAL. This means that there is an unequal distribution of ions (atoms with a positive or negative charge) on the two sides of the nerve cell membrane. This POTENTIAL generally measures about 70 millivolts (with the INSIDE of the membrane negative with respect to the outside). So, the RESTING MEMBRANE POTENTIAL is expressed as -70 mV, and the minus means that the inside is negative relative to (or compared to) the outside. It is called a RESTING potential because it occurs when a membrane is not being stimulated or conducting impulses (in other words, it’s resting).

What factors contribute to this membrane potential?

Two ions are responsible: sodium (Na+) and potassium (K+). An unequal distribution of these two ions occurs on the two sides of a nerve cell membrane because carriers actively transport these two ions: sodium from the inside to the outside and potassium from the outside to the inside. AS A RESULT of this active transport mechanism (commonly referred to as the SODIUM - POTASSIUM PUMP), there is a higher concentration of sodium on the outside than the inside and a higher concentration of potassium on the inside than the outside.

The Sodium-Potassium Pump Used with permission of Gary Kaiser

Sodium-potassium pump

The nerve cell membrane also contains special passageways for these two ions that are commonly referred to as GATES or CHANNELS. Thus, there are SODIUM GATES and POTASSIUM GATES. These gates represent the only way that these ions can diffuse through a nerve cell membrane. IN A RESTING NERVE CELL MEMBRANE, all the sodium gates are closed and some of the potassium gates are open. AS A RESULT, sodium cannot diffuse through the membrane & largely remains outside the membrane. HOWEVER, some potassium ions are able to diffuse out.

OVERALL, therefore, there are lots of positively charged potassium ions just inside the membrane and lots of positively charged sodium ions PLUS some potassium ions on the outside. THIS MEANS THAT THERE ARE MORE POSITIVE CHARGES ON THE OUTSIDE THAN ON THE INSIDE. In other words, there is an unequal distribution of ions or a resting membrane potential. This potential will be maintained until the membrane is disturbed or stimulated. Then, if it’s a sufficiently strong stimulus, an action potential will occur.
Membrane potential

Voltage sensing in a potassium ion channel. a, The control of ion flow through voltage-gated channels is very sensitive to the voltage across the cell membrane. By comparison, an electronic device such as a transistor is much less sensitive to applied voltage. b, MacKinnon and colleagues (Zhou et al. 2001) have found that the voltage sensors in a bacterial potassium channel are charged ‘paddles’ that move through the fluid membrane interior. Four voltage sensors (two of which are shown here) are linked mechanically to the channel’s ‘gate’. Each voltage sensor has four tethered positive charges (amino acids); the high sensitivity of channel gating results from the transport of so many charges, 16 in all, most of the way across the membrane (From: Sigworth 2003).

In a cross section view of the voltage-dependent potassium channel, two of the four paddles move up and down, opening and closing the central pore through which potassium ions flow out of the cell, restoring the cell’s normal negative inside, positive outside polarity.

ACTION POTENTIAL

An action potential is a very rapid change in membrane potential that occurs when a nerve cell membrane is stimulated. Specifically, the membrane potential goes from the resting potential (typically -70 mV) to some positive value (typically about +30 mV) in a very short period of time (just a few milliseconds).

What causes this change in potential to occur? The stimulus causes the sodium gates (or channels) to open and, because there’s more sodium on the outside than the inside of the membrane, sodium then diffuses rapidly into the nerve cell. All these positively-charged sodiums rushing in causes the membrane potential to become positive (the inside of the membrane is now positive relative to the outside). The sodium channels open only briefly, then close again.
The potassium channels then open, and, because there is more potassium inside the membrane than outside, positively-charged potassium ions diffuse out. As these positive ions go out, the inside of the membrane once again becomes negative with respect to the outside (Animation: Voltage-gated channels).

Threshold stimulus & potential Action potentials occur only when the membrane in stimulated (depolarized) enough so that sodium channels open completely. The minimum stimulus needed to achieve an action potential is called the threshold stimulus. The threshold stimulus causes the membrane potential to become less negative (because a stimulus, no matter how small, causes a few sodium channels to open and allows some positively-charged sodium ions to diffuse in). If the membrane potential reaches the threshold potential (generally 5 - 15 mV less negative than the resting potential), the voltage-regulated sodium channels all open. Sodium ions rapidly diffuse inward, & depolarization occurs.

All-or-None Law - action potentials occur maximally or not at all. In other words, there’s no such thing as a partial or weak action potential. Either the threshold potential is reached and an action potential occurs, or it isn’t reached and no action potential occurs.

Refractory periods

**ABSOLUTE**
- During an action potential, a second stimulus will not produce a second action potential (no matter how strong that stimulus is)
- corresponds to the period when the sodium channels are open (typically just a millisecond or less)
Another action potential can be produced, but only if the stimulus is greater than the threshold stimulus.

- corresponds to the period when the potassium channels are open (several milliseconds)
- the nerve cell membrane becomes progressively more ‘sensitive’ (easier to stimulate) as the relative refractory period proceeds. So, it takes a very strong stimulus to cause an action potential at the beginning of the relative refractory period, but only a slightly above threshold stimulus to cause an action potential near the end of the relative refractory period.

The absolute refractory period places a limit on the rate at which a neuron can conduct impulses, and the relative refractory period permits variation in the rate at which a neuron conducts impulses. Such variation is important because it is one of the ways by which our nervous system recognizes differences in stimulus strength, e.g., dim light = retinal cells conduct fewer impulses per second vs. brighter light = retinal cells conduct more impulses per second.

**How does the relative refractory period permit variation in rate of impulse conduction?** Let’s assume that the relative refractory period of a neuron is 20 milliseconds long and, further, that the threshold stimulus for that neuron (as determined, for example, in a lab experiment with that neuron) is 0.5 volt. If that neuron is continuously stimulated at a level of 0.5 volt, then an action potential (and impulse) will be generated every 20 milliseconds (because once an action potential has been generated with a threshold stimulus [and ignoring the absolute refractory period], another action potential cannot occur until the relative refractory period is over). So, in this example, the rate of stimulation (and impulse conduction) would be 50 per second (1 sec = 1000 ms; 1000 ms divided by 20 ms = 50).

If we increase the stimulus (e.g., from 0.5 volt to 1 volt), what happens to the rate at which action potentials (and impulses) occur? Because 1 volt is an above-threshold stimulus, it means that, once an actional potential has been generated, another one will occur in less than 20 ms or, in other words, before the end of the relative refractory period. Thus, in our example, the increased stimulus will increase the rate of impulse conduction above 50 per second. Without more information, it’s not possible to calculate the exact rate. However, it’s sufficient that you understand that increasing stimulus strength will result in an increase in the rate of impulse conduction.

**Impulse conduction** - an impulse is simply the movement of action potentials along a nerve cell. Action potentials are localized (only affect a small area of nerve cell membrane). So, when one occurs, only a small area of membrane depolarizes (or ‘reverses’ potential). As a result, for a split second, areas of membrane adjacent to each other have opposite charges (the depolarized membrane is negative on the outside & positive on the inside, while the adjacent areas are still positive on the outside and negative on the inside). An electrical circuit (or ‘mini-circuit’) develops between these oppositely-charged areas (or, in other words, electrons flow between these areas). This ‘mini-circuit’ stimulates the adjacent area and, therefore, an action potential occurs. This process repeats itself and action potentials move down the nerve cell membrane. This ‘movement’ of action potentials is called an impulse.
Conduction Velocity

- impulses typically travel along neurons at a speed of anywhere from 1 to 120 meters per second; the speed of conduction can be influenced by:
  - the diameter of a fiber
  - the presence or absence of myelin
- Neurons with myelin (or myelinated neurons) conduct impulses much faster than those without myelin.

The myelin sheath (blue) surrounding axons (yellow) is produced by glial cells (Schwann cells in the PNS, oligodendrocytes in the CNS). These cells produce large membranous extensions that ensheathe the axons in successive layers that are then compacted by exclusion of cytoplasm (black) to form the myelin sheath. The thickness of the myelin sheath (the number of wraps around the axon) is proportional to the axon's diameter.

Myelination, the process by which glial cells ensheathe the axons of neurons in layers of myelin, ensures the rapid conduction of electrical impulses in the nervous system. The formation of myelin sheaths is one of the most spectacular examples of cell-cell interaction and coordination in nature. Myelin sheaths are formed by the vast membranous extensions of glial cells: Schwann cells in the peripheral nervous system (PNS) and oligodendrocytes in the central nervous system (CNS). The axon is wrapped many times (like a Swiss roll) by these sheetlike membrane extensions to form the final myelin sheath, or internode. Internodes can be as long as 1 mm and are separated from their neighbors by a short gap (the node of Ranvier) of 1 micrometer. The concentration of voltage-dependent sodium channels in the axon membrane at the node, and the high electrical resistance of the multilayered myelin sheath, ensure that action potentials jump from node to node (a process termed "saltatory conduction") (french-Constant 2004).

Schwann cells (or oligodendrocytes) are located at regular intervals along the process (axons and, for some neurons, dendrites) & so a section of a myelinated axon would look like this:

Between areas of myelin are non-myelinated areas called the nodes of Ranvier. Because fat (myelin) acts as an insulator, membrane coated with myelin will not conduct an impulse. So, in a myelinated neuron, action potentials only occur along the nodes and, therefore, impulses 'jump' over the areas of myelin - going from node to node in a process called saltatory conduction (with the word saltatory meaning 'jumping'):
Because the impulse ‘jumps’ over areas of myelin, an impulse travels much faster along a myelinated neuron than along a non-myelinated neuron.

**Types of Neurons** - the three main types of neurons are:

- **Multipolar neurons** are so-named because they have many (multi-) processes that extend from the cell body: lots of dendrites plus a single axon. Functionally, these neurons are either motor (conducting impulses that will cause activity such as the contraction of muscles) or association (conducting impulses and permitting ‘communication’ between neurons within the central nervous system).

- **Unipolar neurons** have but one process from the cell body. However, that single, very short, process splits into longer processes (a dendrite plus an axon). Unipolar neurons are sensory neurons - conducting impulses into the central nervous system.

- **Bipolar neurons** have two processes - one axon & one dendrite. These neurons are also sensory. For example, bipolar neurons can be found in the retina of the eye.

**Neuroglial, or glial, cells - general functions include:**
1. forming myelin sheaths
2. protecting neurons (via phagocytosis)
3. regulating the internal environment of neurons in the central nervous system

**Synapse** = point of impulse transmission between neurons; impulses are transmitted from pre-synaptic neurons to post-synaptic neurons
Synapses usually occur between the axon of a pre-synaptic neuron & a dendrite or cell body of
a post-synaptic neuron. At a synapse, the end of the axon is ‘swollen’ and referred to as an end
bulb or synaptic knob. Within the end bulb are found lots of synaptic vesicles (which contain
neurotransmitter chemicals) and mitochondria (which provide ATP to make more neurotransmitter).
Between the end bulb and the dendrite (or cell body) of the post-synaptic neuron, there is a gap
commonly referred to as the synaptic cleft. So, pre- and post-synaptic membranes do not actually
come in contact. That means that the impulse cannot be transmitted directly. Rather, the impulse
is transmitted by the release of chemicals called chemical transmitters (or neurotransmitters).

Micrograph of a synapse (Schikorski and Stevens 2001).

Structural features of a typical nerve cell (i.e., neuron) and synapse. This drawing shows the
major components of a typical neuron, including the cell body with the nucleus; the dendrites
that receive signals from other neurons; and the axon that relays nerve signals to other neurons at a specialized structure called a synapse. When the nerve signal reaches the synapse, it causes the release of chemical messengers (i.e., neurotransmitters) from storage vesicles. The neurotransmitters travel across a minute gap between the cells and then interact with protein molecules (i.e., receptors) located in the membrane surrounding the signal-receiving neuron. This interaction causes biochemical reactions that result in the generation, or prevention, of a new nerve signal, depending on the type of neuron, neurotransmitter, and receptor involved (Goodlett and Horn 2001).

**Synapse**

When an impulse arrives at the end bulb, the end bulb membrane becomes more permeable to calcium. Calcium diffuses into the end bulb & activates enzymes that cause the synaptic vesicles to move toward the synapic cleft. Some vesicles fuse with the membrane and release their neurotransmitter (a good example of exocytosis). The neurotransmitter molecules diffuse across the cleft and fit into receptor sites in the postsynaptic membrane. When these sites are filled, sodium channels open & permit an inward diffusion of sodium ions. This, of course, causes the membrane potential to become less negative (or, in other words, to approach the threshold potential). If enough neurotransmitter is released, and enough sodium channels are opened, then the membrane potential will reach threshold. If so, an action potential occurs and spreads along the membrane of the post-synaptic neuron (in other words, the impulse will be transmitted). Of course, if insufficient neurotransmitter is released, the impulse will not be transmitted.

**Impulse transmission** - The nerve impulse (action potential) travels down the presynaptic axon towards the synapse, where it activates voltage-gated calcium channels leading to calcium influx, which triggers the simultaneous release of neurotransmitter molecules from many synaptic vesicles by fusing the membranes of the vesicles to that of the nerve terminal. The neurotransmitter molecules diffuse across the synaptic cleft, bind briefly to receptors on the postsynaptic neuron to activate them, causing physiological responses that may be excitatory or inhibitory depending on the receptor. The neurotransmitter molecules are then either quickly pumped back into the presynaptic nerve terminal via transporters, are destroyed by enzymes near the receptors (e.g. breakdown of acetylcholine by cholinesterase), or diffuse into the surrounding area.
This describes what happens when an ‘excitatory’ neurotransmitter is released at a synapse. However, not all neurotransmitters are ‘excitatory.’

**Types of neurotransmitters:**

1. **Excitatory** - neurotransmitters that make membrane potential less negative (via increased permeability of the membrane to sodium) & therefore, tend to ‘excite’ or stimulate the postsynaptic membrane

2. **Inhibitory** - neurotransmitters that make membrane potential more negative (via increased permeability of the membrane to potassium) & therefore, tend to ‘inhibit’ (or make less likely) the transmission of an impulse. One example of an inhibitory neurotransmitter is gamma aminobutyric acid (GABA; shown below). Medically, GABA has been used to treat both epilepsy and hypertension. Another example of an inhibitory neurotransmitter is beta-endorphin, which results in decreased pain perception by the CNS.

**Summation:**

1. **Temporal summation** - transmission of an impulse by rapid stimulation of one or more presynaptic neurons

2. **Spatial summation** - transmission of an impulse by simultaneous or nearly simultaneous stimulation of two or more pre-synaptic neurons
Literature cited


References


5. Purves et al., p. 34; Bullock, Orkand, and Grinnell, p. 134; Schmidt-Nielsen, pp. 478–480. 6.


15. Purves et al., p. 56. 16.


Further reading


• National Medical Series for Independent Study. Physiology. Lippincott Williams & Wilkins.
Long-term high frequency transcutaneous electrical nerve stimulation (hi-TNS) in chronic pain. Clinical response and effects on CSF-endorphins, monoamine metabolites, substance P-like immunoreactivity (SPLI) and pain measures.

Almay BG, Johansson F, von Knorring L, Sakurada T, Terenius L.

Eighteen patients with chronic pain syndromes of organic origin were treated by means of high frequency transcutaneous nerve stimulation (hi-TNS). The CSF levels of receptorassayable Fraction I and II endorphins, substance P-like immunoreactivity (SPLI), and the monoamine metabolites 5-HIAA, HVA and MOPEG were measured before and after one week of daily treatment. Furthermore, the effects on experimental pain measures were determined. The therapeutic effect was evaluated after 30 days and 3 months of treatment. Patients with low initial concentrations of endorphins in CSF, lower than those observed in healthy volunteers, tended to have the best response to hi-TNS. There were significant increases in Fraction I endorphins and SPLI in CSF, most pronounced in the patients who responded. There were no significant changes in 5-HIAA, HVA or MOPEG in CSF. However, in early responders, the serotonin metabolite 5-HIAA tended to decrease as contrasted to an increase in non-responders. The difference between the groups was statistically significant. Confirming our earlier studies, the therapy induced changes in pain measures showed a significant, positive correlation with increasing Fraction I endorphins in CSF. Our results suggest that hi-TNS induces central changes in the endorphinergetic, serotonergic and possibly substance-P-ergic systems.

Caroline S. Pace and John T. Tarvin

- Department of Physiology and Biophysics and Diabetes Research and Training Hospital, University of Alabama in Birmingham, 35294 Birmingham, Alabama
- Present address: Department of Physics, University of Mississippi, 38677 Oxford, Miss.

Received: 4 June 1982 Revised: 23 September 1982

Summary

Regulation of intracellular pH is an essential function and may be especially significant in the B-cell in which the influence of glucose on electrical activity is modulated by alterations in pH. Two possible regulatory processes have been examined: Na/H and HCO3/Cl exchange, by using inhibitors, an ionophore, and changes of ionic concentrations. In the presence of 11.1MM glucose we found that DIDS, an inhibitor of anion exchange, elicited a dose-response increase in the relative duration of the active phase with an ED50 of 99 M. Probenecid (0.5MM), an inhibitor of anion fluxes, also augmented the electrical activity (EA) due to glucose. Withdrawal of HCO 3 – elicited constant spike activity followed by a resumption of burst activity with a greater duration of the active phase compared to control.

These data are consistent with predicted cellular acidification. However, reduction of Cl o – by isethionate substitution produced no marked effect on EA. In contrast, Cl o – substitution for Cl– resulted in variable effects characterized by constant spike activity or a decrease in the duration of the active and silent phases along with silent hyperpolarization. Tributyltin, a Cl/OH, ionophore enhanced EA at 0.25 M with 120MM Cl o – , but reduced EA with 10MM Cl– as would be predicted with either cellular acidification or alkalinization, respectively. Amiloride at 100 M elicited constant spike activity perhaps due to inhibition of Na/H exchange. Reduction of Na o + from 142.8 to 40.8MM had a similar effect and enhanced the influence of amiloride. It appears therefore that interference with putative pH regulatory mechanisms in the B-cell are consistent with the hypothesis that cell pH is involved in regulation of EA.

Keywords DIDS - probenecid - amiloride - isethionate - tributyltin - mouse islet

Annual Review of Neuroscience

Vol. 7: 257-278 (Volume publication date March 1984)
(doi:10.1146/annurev.ne.07.030184.001353)

Effects of Intracellular H+ on the Electrical Properties of Excitable Cells

W Moody, Jr


Electrical Impedance Plethysmography

A Physical and Physiologic Approach to Peripheral Vascular Study

JAN NYBOER S.C.D., M.D.1; Marian M. Kreider M.D.1; Leonard Hannapel M.D.1

From the Department of Physiological Sciences, Dartmouth Medical School, Hanover, New Hampshire and Veterans Administration Hospital, White River Junction, Vermont.

The quantity of blood measured by electrical impedance plethysmography is defined by its resistive effect in parallel to the resistance of other tissue of the segment. By substitution of this parallel resistive value, together with data relative to the resistivity of blood and the length of the segment in the formula for the volume of an electrical conductor, we are able to derive the volume of the pulse in cubic centimeters. It follows that the volume displaced from the venous reservoir and the rate of refilling of the venous reservoir of an extremity may also be determined quantitatively.

Brain electrical correlates of psychological measures: Strategies and problems

<table>
<thead>
<tr>
<th>Journal</th>
<th>Brain Topography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publisher</td>
<td>Springer New York</td>
</tr>
<tr>
<td>ISSN</td>
<td>0896-0267 (Print) 1573-6792 (Online)</td>
</tr>
<tr>
<td>Issue</td>
<td>Volume 5, Number 4 / June, 1993</td>
</tr>
<tr>
<td>DOI</td>
<td>10.1007/BF01128698</td>
</tr>
<tr>
<td>Pages</td>
<td>399-412</td>
</tr>
<tr>
<td>Subject Collection</td>
<td>Biomedical and Life Sciences</td>
</tr>
<tr>
<td>SpringerLink Date</td>
<td>Tuesday, February 08, 2005</td>
</tr>
</tbody>
</table>
psychological variables gathered at a different time. For a population of 202 healthy adults using univariate and multivariate correlation techniques in a split half replication design, we confirm prior findings that subjects with better psychological scores show shorter evoked potential (EP) latency, suggesting that speed of processing is an important factor in cognitive performance. By canonical correlation we demonstrate a consistent, replicable relationship between electrophysiologic and behavioral data. We suggest that reliance upon univariate correlation may have fueled early controversies about relationships between electrophysiology and IQ. In addition we correlate psychological factors with the entire qEEG data set (both EP and spectral analyzed EEG) and demonstrate the use a multidimensional image graphics techniques to assist in visual assessment of the resulting correlation matrices.

Keywords: Evoked potentials - EEG spectral analysis - Behavior - Factor analysis - Canonical correlation - Split half replication - Correlational SPM

This work was supported in part by NIA program project PO1AG049853 to M. Albert and the Mental Retardation Program Project P30HD18655 to J.J. Volpe and the Children’s Hospital of Philadelphia.


ORIGINAL RESEARCH COMMUNICATIONS

Whole-body impedance—what does it measure?

KR Foster and HC Lukaski

• Department of Bioengineering, University of Pennsylvania, Philadelphia 19104-6392, USA

Although the bioelectrical impedance technique is widely used in human nutrition and clinical research, an integrated summary of the biophysical and bioelectrical bases of this approach is lacking. We summarize the pertinent electrical phenomena relevant to the application of the impedance technique in vivo and discuss the relations between electrical measurements and biological conductor volumes. Key terms in the derivation of bioelectrical impedance analysis are described and the relation between the electrical properties of tissues and tissue structure is discussed. The relation between the impedance of an object and its geometry, scale, and intrinsic electrical properties is also discussed. Correlations between whole-body impedance measurements and various bioconductor volumes, such as total body water and fat-free mass, are experimentally well established; however, the reason for the success of the impedance technique is much less clear. The bioengineering basis for the technique is critically presented and considerations are proposed that might help to clarify the method and potentially improve its sensitivity.

<table>
<thead>
<tr>
<th>Journal</th>
<th>Psychiatric Quarterly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Publisher</td>
<td>Springer Netherlands</td>
</tr>
<tr>
<td>ISSN</td>
<td>0033-2720 (Print) 1573-6709 (Online)</td>
</tr>
<tr>
<td>Issue</td>
<td>Volume 7, Number 1 / March, 1933</td>
</tr>
<tr>
<td>DOI</td>
<td>10.1007/BF01572720</td>
</tr>
<tr>
<td>Pages</td>
<td>107-114</td>
</tr>
<tr>
<td>Subject Collection</td>
<td>Medicine</td>
</tr>
<tr>
<td>SpringerLink Date</td>
<td>Tuesday, May 10, 2005</td>
</tr>
</tbody>
</table>

Corney Landis and T. W. Forbes

• Department of Psychology, New York State Psychiatric Institute and Hospital, New York, N. Y.

Summary

We have shown that it is reasonable to expect from the nerve sectioning studies on resistance of the skin and on the galvanic reflex, that a valid, standard technique can be worked out to give an index of sympathetic nerve reactivity, but that a systematic study of techniques and of the relationship between measures is a necessary first step toward such a measure if it is to be valid. Our experimental results indicate that curves for basic resistance vary with location of skin area and with technique used. Measurements with an ordinary standard Wheatstone bridge and a source of 1 1/2 volts gave no indication of a relationship to the functions under nervous control. Richter’s technique was apparently more sensitive in that it shows a greater range of variation, though we are not yet satisfied as to the exact nature of the electrical phenomena which the technique measures. We plan to make a more extensive study with simultaneous measurements and use still other techniques.

In closing we wish to stress two points which we have raised in this paper. First, that resistance and galvanic reflex curves from differing techniques cannot be assumed to be comparable until shown to be so; and second, previous experimental and clinical studies, indicate that valid measures of electrical skin phenomena when developed should provide valuable indices of neurological and physiological functions.
Large Scale Study of the Safety and Efficacy of the SCIO Device

Chief Editor:
Prof William Nelson M.D. IMUNE
The Centro Ricerche, University of Venice + Padova, Italy

Edited and Validated By IMUNE Medical Staff:
Mezei Iosif MD, Romania
Sarca Ovidiu MD, Romania
Igor Cetojevic MD, Cyprus
Matthias Heiliger M.D. Germany/Switzerland
Klara Hilf M.D. Hungary
Anna Maria Cako M.D. Hungary
Debbie Drake M.D. Canada
Bacean Aurel MD Romania

Consultant:
International Ethics, Lebedei 58,
Oradea, Romania
John Kelsey Phd, ND N.Z. Eng,
Gage Tarrant LBT, C.H.T, USA, Somleia Livia Romania
Richard Atkinson MCSP, Physical Therapist, West Yorkshire England

This study was performed in the field by practicing Biofeedback technicians. Data was collected and the study supervised by the Ethics International Institutional Review Board of Romania. The Data analysis and study presentation is done By the The Centro Ricerche, University of Venice + Padova, Italy

Abstract
A global and momentous research project was developed for the last two years. The SCIO device is a Universal ElectroPhysiological Medical device used for stress reduction and patient treatment. Over 2,200 qualified biofeedback therapists joined our Ethics Committee study to evaluate how stress reduction using the SCIO device could help a wide variety of diseases.

The device and thus the study has insignificant risk. There was a staff of medical doctors who designed and supervised the study.

Over 98,000 patients gave informed consent and participated in the study. The study would conclusively prove safety and efficacy of the SCIO Device. With over 60% of these patients having multiple visits. There were over 275,000 patient visits. With a total record of the SCIO patient information, therapy parameters and reactivity data. No names of patients were recorded for confidentiality.

Two of the 2,256 therapists were given blank devices that were completely visually the same but were none functional. These two blind therapists were then given patients to be in the placebo group. This was to evaluate the double blind component of the placebo effect as compared to the device. Thus the studied groups were a placebo group, and a treatment group. To measure the effect more clearly some of the treatment SCIO group were then moved into the placebo group, some of the placebo group were moved into the treatment SCIO group. The results confirm the safety and efficacy of the SCIO in stress reduction versus placebo testing.

This is just the first study in a long task of analysis in truly break down the data totally. This study verifies the safety and efficacy of the SCIO device. There were small effects seen in the placebo group and statistical effects in the treatment group.

Introduction
This research is to study millions of people with a wide variety of diseases to see who gets or feels better while using the SCIO for stress reduction and patient monitoring. The SCIO is a evoked potential Universal ElectroPhysiological Medical apparatus that gauges how a individual reacts to miscellaneous homeopathic substances. The device is registered in Europe, America, Canada, S Africa, S. America, Mexico and elsewhere. The traditional software is fully registered. Some additional functions where determined by the manufacturer to be worthy of evaluation. Thus a study was necessary to determine safety and efficacy.

An ethics committee was formed and governmental permission attained to do the insignificant risk study. Qualified registered and or licensed Biofeedback therapists where enlisted to perform the study. Therapists were enrolled from all over the world including N. America, Europe, Africa, Asia, and S. America. They were trained in the aspects of the study and how to attain informed consent and transmit the results to the ethics committee or IRB (Institutional Review Board).

2,256 therapists enlisted in the study. There were 95,832 patients. 69% had more than one visit. 43% had over two visits. There were over 320,000 patient visits recorded. The therapists were trained and supervised by medical staff. They were to perform the SCIO therapy and analysis. They were to report any medical suspected or confirmed diagnosis. Unlicenced personnel are not to diagnose. Then the therapist is to inquire on any reported changes during the meeting and on follow-ups any measured variations.

Methods and Materials

SCIO Device
The SCIO is a Universal Electro-Physiological Medical biofeedback device that measures how a person reacts to items. It is designed to measure reactions for allergy, homeopathy, nutrition, sarcodes, nosodes, vitamins, minerals, enzymes and many more items. Biofeedback is used for pre-diagnostic work and or therapy.

The SCIO software will allow the unconscious of the patient to guide to repair electrical and vibrational aberrations in your body. For complete functional details and pictures, see appendix.

SOC Index
The SCIO interview opens with a behavioral medicine interview. This is called the SOC Index. Named after the work of Samuel Hahneman the father of homeopathy, he said that the body heals itself with it’s innate knowledge. But the patient can suppress or obstruct the healing process with some behavior. Hahneman said that the worst way to interfere with the healing natural process was allopathy or synthetic drugs. Theses upset the natural healing process by unnatural intervention and regulation disturbance. Other ways to Suppress or Obstruct the Cure are smoking, mercury amalgams, stress, lack of water, exercise and many others. This behavioral survey then gives an index of SOC.

The scores relate to the risk of Suppression and Obstruction to the natural Cure. The higher the scores the more the Suppression and or Obstruction. The scores of 100 or lower are ideal. A copy of the SOC index questions appear in the appendix.

Study Technicians
The study technicians were educated and supervised by medical officers and medical doctors. All of the work was supervised by licensed health care professionals. The study technicians were to execute the SCIO therapy and analysis. All were trained to the standards of the International Medical University of Natural Education. Therapists from all over the world including N. America, Europe, Africa, Asia, and S. America and elsewhere were enlisted to perform the study according to the 1951 Helsinki study ethics regulations since updated.

They were to chronicle any medical suspected or confirmed diagnosis. Unlicenced personnel are not to diagnose. Then the study technician is to inquire on any disclosed observations during the test and on follow-ups report any measured changes.

To test the device against the placebo effect, two of the 2,256 therapists were given placebo SCIO devices that were totally outwardly the same but were not functional. These two blind therapists were then assigned 35 patients each (only 63 showed). This was to assess the double blind factor
of the placebo effect as compared to the device. Thus the studied groups were
A. placebo group, and B. Treatment Group.

**Important Questions:** these are the key questions of the study

1. Define Diseases or Patient Concerns
2. Percentage of Improvement in Symptoms
3. Percentage of Improvement in Feeling Better
4. Percentage of Improvement Measured
5. Percentage of Improvement in Stress Reduction
6. Percentage of Improvement in SOC Behavior
7. What Measured+How
8. If Patient worsened please describe in detail involving SOC.

After the patient visit is complete the data was e-mailed to the Ethics Committee or IRB for storage and then analysis. This maneuver minimized the risk of data loss or tampering. Case studies were reported separately in the disease analysis.

**Part 1. Results**

Before we review the direct disease improvement profiles, we need to review the overall results. The first most basic of question in the results is the basic feedback of the generic patient conditions. With over 96,000 patients and 256,800 patient visits we have direct evidence of the safety and efficacy.

1. Percentage of Improvement in Symptoms
2. Percentage of Improvement in Feeling Better
3. Percentage of Improvement Measured
4. Percentage of Improvement in Stress Reduction
5. Percentage of Improvement in SOC Behavior

The SOC index gives us great insight to this study. Each disease has a different cut off where the ability of the SCIO to help was compromised. As a general index scores of 200+ where much less successful.

**OVERALL ASSESSMENT**

**A. Placebo Group- 63 cases with a Dbl Blind System and no Treatment**

There were no cases of patients who reported a negative Improvement.

There were

- 19 cases reporting no improvement of Symptoms, 30% of group
- 12 cases reporting no improvement in feeling better, 19% of group
- 13 cases reporting no improvement in stress reduction 20% of group
- 12%— Percentage of Improvement in Symptoms
- 15%— Percentage of Improvement in Feeling Better
- 2%—. Percentage of Improvement Measured
- 12%-- Percentage of Improvement in Stress Reduction
- 3%----- Percentage of Improvement in SOC Behavior

**B. SCIO Treatment 321,315 patient visits**

There were 65 cases of patients who reported a negative Improvement.

There were

- 532 cases reporting no improvement of Symptoms, .003% of group
- 759 cases reporting no improvement in feeling better, .004% of group
- 460 cases reporting no improvement in stress reduction .002% of group
- 65%— Percentage of Improvement in Symptoms
- 56%— Percentage of Improvement in Feeling Better
- 24%—. Percentage of Improvement Measured
- 53%-- Percentage of Improvement in Stress Reduction
- 20%---- Percentage of Improvement in SOC Behavior

**GROUPS B—SOC Index 150 or below = B, above = C**

**B. SCIO Treatment 150,832 patient visits SOC Index below 150**

There were 45 cases of patients who reported a negative Improvement.

There were

- 137 cases reporting no improvement of Symptoms, .001% of group
- 230 cases reporting no improvement in feeling better, .002% of group
- 143 cases reporting no improvement in stress reduction .001% of group
- 67%— Percentage of Improvement in Symptoms
- 54%— Percentage of Improvement in Feeling Better
- 28%—. Percentage of Improvement Measured
- 57%-- Percentage of Improvement in Stress Reduction
- 29%---- Percentage of Improvement in SOC Behavior

**B. SCIO Treatment 170,483 patient visits, SOC Index above or at 150**

There were 45 cases of patients who reported a negative Improvement.

There were
• 213 cases reporting no improvement of Symptoms, .001% of group
• 529 cases reporting no improvement in feeling better, .003% of group
• 317 cases reporting no improvement in stress reduction .002% of group
• 64% --- Percentage of Improvement in Symptoms
• 56% --- Percentage of Improvement in Feeling Better
• 22% --- Percentage of Improvement Measured
• 52% -- Percentage of Improvement in Stress Reduction
• 17% ---- Percentage of Improvement in SOC Behavior

C. Placebo Group To SCIO Test Group Rotation- 60 cases moved from placebo to SCIO Harness Treatment

There were no cases of patients who reported a negative Improvement. There were
• 11 cases reporting no improvement of Symptoms, 19% of group
• 11 cases reporting no improvement in feeling better, 19% of group
• 10 cases reporting no improvement in stress reduction 18% of group
• 46% --- Percentage of Improvement in Symptoms
• 41% --- Percentage of Improvement in Feeling Better
• 22%---. Percentage of Improvement Measured
• 51%-- Percentage of Improvement in Stress Reduction
• 33%-- Percentage of Improvement in SOC Behavior

D. SCIO group to Placebo Group- 43 cases from SCIO group moved to Dbl Blind System and no Treatment

There were no cases of patients who reported a negative Improvement. There were
• 21 cases reporting no improvement of Symptoms, 51% of group
• 24 cases reporting no improvement in feeling better, 58% of group
• 19 cases reporting no improvement in stress reduction 33% of group
• 10% --- Percentage of Improvement in Symptoms
• 9%--- Percentage of Improvement in Feeling Better
• 2%---. Percentage of Improvement Measured
• 11%-- Percentage of Improvement in Stress Reduction
• 5%----- Percentage of Improvement in SOC Behavior

Discussion

There are several quite apparent results from our study. First the safety of the device is firmly established as a minimal risk. There is an insignificant report of small negative results and no reports of any significant problems.

There is a significant statistical evidence to show the efficacy of the device in reducing stress. Comparisons with the placebo group show a dramatic increase in reported stress reduction.

Next there is a significant difference in the SOC Index. Patients below SOC Index 150 had significantly better results in all conditions. This points to value of behavioral medicine interview and the need to reduce suppression and obstruction of cure ability.

The major findings are the significant positive effect on healing the SOC Index and the harness have. Users should note this result.

The significant measured criteria of the diseases will take volumes in reporting. There are case studies and measured criteria that will be presented. This will be in a continuation of this study in part 2 of the data analysis of this large scale study.

Appendix

Informed Consent:
The SCIO Biofeedback Medical device is registered in the Europe, S Africa, Mexico, Australia etc. It is a Biofeedback device that measures how a person reacts to items. It is designed to measure reactions for allergy, homeopathy, nutrition, sarcoed, nosodes, vitamins, minerals, enzymes and many more items. Biofeedback is useful for pre-diagnostic or therapy. These functions are registered in all of the above regions. Maitreya manufactures the hardware.

At QX Ltd., we have written a software that uses the SCIO data This software offers no risk and is completely safe. We recognize that this new type of system needs to be tested experimentally. The USA allows us to develop an Institutional Review Board and operate an Investigational Device Exemption for this software as long as all proper FDA policies are adhered to. To use this software in the USA we need to get informed consent from the patients or persons who are tested. Non-Significant Risk informed consent must be signed, implied, or understood.

The registered SCIO software and hardware uses a micro current medically safe pulse applied to the wrists, ankles and forehead. We safely measure some of the electrical aspects of the body. A variant micro current is then adapted to the patient to feedback the signal. The SCIO software will use the same medically safe standards to develop a wider range of variable wave forms to the body. The patient will choose and direct the therapy by their unconscious electrical reactions. This will help the therapist and the patient choose items that might be helpful. These choices are voluntary suggestions. The patient can greatly benefit from help with these choices. No items of significant risk are possible. These items are not part of the study and purchase of them is the patient’s responsibility.

There is insignificant risk and the only discomfort is sitting still for the 30 or 40 min evaluation. The patient name will be held confidential in the study. Participation is always purely voluntary. There is no penalty for withdraws. The other facts of the case are e-mailed to QX Ltd IRB. But
Appendix SCIO device description

To Whom It May Concern:

Re: Proprietary Rights of Medical Device known as SCIO

Ownership of all software rights to inventor William Nelson, all rights assigned to QX Ltd

Basic SCIO System Description

The SCIO system is a Universal Electro-Physiological Patient Interface. It can measure changes of electrical nature such as electro-potential, micro-amperage, voltage, galvanic skin resistance. This allows inference of oscillations, frequency, capacitance, electrostatic potential, inductance, electromagnetic potential, suscepectance, reactance, micro-wattage, resonant frequency, oxidation potential, hydration potential, and proton versus electron pressure.

The basic science was generated by Prof. William Nelson. His book the PROMORPHEUS was registered in it’s first form by the Library of Congress USA in 1982. Thus book introduces the concepts of the SCIO.

The basic technology was developed in 1985 and was registered as the EPFX in America in 1989. The EPFX stands for the acronym Electro-Physiological Feedback Xrroid. A Xrroid is the rapid testing of homeopathic medicines by an electrical reactivity device. The reactions are of a ionic nature as they reflect electro-potential changes. The speed of ionic exchange in the human body is approximately one hundredth of a second. So a computer device was needed for such testing. Analysis of the trivector field of a homeopathic is developed in this work and patented in Ireland in 1995. All substances have a particular volt-ometric or polography field. By description of the right hand rule all electrical activity takes place in three dimensions, Conductivity, Static, and Magnetic. An advanced three dimensional field analysis device known as the QQC was made and patented by William Nelson.

Since the measure of galvanic skin resistance requires a applied current, the applied current could be of the trivector analysis variety. The applied current could also be used for electro-therapy. Aberrant electrical patterns of the patient could be corrected by application of electrodynamic theory. When electricity flows thru healthy tissue it has a known result. When it flows thru injured or diseased tissue it has a different result. Application of electrodynamic theory produces the ability of the SCIO device to treat and correct injured or diseased tissue. This process is known as rectification.

These trivector signatures could be computerized and duplicated by the computer. A quantic coherence test kit was coupled to the system to improve data. The SCIO was then able to measure before and after electro potential changes to determine reactivity and susceptance. Providing a reactivity profile. When this is done at biological speeds of about one hundredth of a second it is called the Xrroid.

Thus the SCIO system could measure the basic elements of the body electric. Aberrant reactivity patterns could also be corrected using the principles of bioresonance in a process also known as rectification of electrical patterns.

The Electro-Physiological-Feedback-Xrroid / SCIO is also a biofeedback system. The definition of biofeedback is measuring a physiological response and feeding it back to the patient. Most of the

confidentiality is always guaranteed.

The results of the studies are to be published on the International Journal of the Medical Science of Homeopathy. These results are available in 2008 on the internet or through your therapist.

Over 35 studies on the device have already been published.

Since there are over 20,000 SCIO machines around the world, and all have access to the SCIO software, assuming 10 patient visits a week there might be over 400,000 data streams per month. We fully expect over a million bits of data in the first year alone. We will analyze all types of diseases - all types of clients - in one of the world’s largest studies of its kind. We welcome your participation.

The clinical therapist is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the therapist to personally conduct the consent interview. The therapist remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

The Centro Ricerche of Prof. William Nelson University of Venice + Padova, Italy Is the headquarters for the study IRB. There are researchers in over 25 different countries.

I am informed of the experiment on the SCIO software. I willingly give my consent to participate in the study. I give my consent for any children under my supervision or custody. I am to be guaranteed confidentiality of the data. I will be allowed to see the results of the publication in roughly one year. I recognize that there is no firm diagnosis resulting from the software. We are diagnosing and treating only Stress via Biofeedback.

I give my full and informed consent to partake in this research.

SIGNATURE_________________________________________

DATE______________________________________________

THERAPIST OR WITNESS________________________________

In short
1. This research is to study millions of people with a wide variety of diseases to see who gets or feels better while using the SCIO for stress reduction and patient monitoring.
2. the SCIO software will allow the unconscious of the patient to guide to repair electrical and vibrational aberrations in your body.
3. The device and the study is always voluntary, confidential and safe.
4. There are a wide amount of benefits already displayed by the thousands of users and millions of patients. A millions of people have already been helped.
5. Results of the study and answers to your questions are available.
devices feedback the information primarily to the conscious and thus then to the unconscious of the patient. The EPFX-SCIO system differs in that it feeds back the information or signal to the unconscious primarily and conscious secondarily. The unconscious should be directing these autonomic processes. So our device focuses on repairing the unconscious link directly.

Feedback of electro physiological processes are given as relaxation signals to the patient. The EPFX system measures a combination of the following physiological functions, voltage potential, current potential, skin resistance, Electro Physiological Reactance, Electro Physiological Susceptance, skin temperature and Frequency. These are the raw readings made at the extremities and the head harness. (see Diagram). The EPFX system applies a variant set of signals and then measures changes in the readings. The changes determine resonance, reactivity and coherency.

The QQC is a trademarked and proprietary process that does an analysis of the Polographic or voltametric three dimensional electrical pattern of a substance. This produces a substance electronic signature field. The Fields of these substances are sent into the patient via the harness. These variant patterns are of 0 Hz to mega Hz and of variant wave forms.

The total current is never over 5 milliamps. This represents a safe system rated as insignificant risk. All medical safety tests and quality control processes are applied.

The patient is evaluated before and after stimulation to measure any evoked potential changes that show patient reactivity. The type intensity and style of reactivity evoked potential offers insight into the patient health. Types of item reacting can be a link to therapy or deeper diagnosis.

The variant wave forms are trivector (voltammetric signatures of the Acupuncture points, nosodes, sarcodes, allersodes, etc.) This allows Electro-Physiological-Reactivity measurements (EPR).

The evoked potential differences (EPR) are used to show a provocative allergy component. Provocative allergy tests show how a patient reacts electro physiologically to an item. Changes in histamine and other allergic reactions are preceded by electrical reactivity.

The EPFX measures the Electrophysiologic Reactivity intensity of the patient to thousands of QOC trivector patterns. These are patterns of reactions to Sarcodes, Nosodes, Allersodes, Isodes, Nutritional, Acupuncture points, Herbal, Imponderable and Classic Homeopathics. The reaction patterns or profiles can relate disturbances of the patient. Therapies can then be arranged to develop harmonic reactions, desensitizations, biological resonance or rectification processes. Biofeedback is the operation that allows for the cybernetic loop of systemic feedback. The loop of measured reaction and bio-varied resonance response allow for a true feedback for self corrective Electrophysiological therapy. Hence it is called the Electro Physiological Feedback Xroid or as known in Europe SCIO.

Bibliography

Books

Articles and studies
Varhope charging the batteries

EPFX / SCIO - USE AND CLAIMS FOR THE DEVICE

EPFX / SCIO use and claim: Professional Biofeedback for Stress Detection and Stress Reduction.

We need to make very clear the use and thus claims for the EPFX Electro_Physiological_Feedback_Xrroid. The device has been legally FDA registered and marketed in America for twenty years.

The device is designed to measure and mend the body electric stress through a cybernetic biofeedback loop. It is designed and registered to send in a volt_ammetric electrical signal into the body, and then measure the reactivity or response to this signal. We measure the Volts, Amps, Oscillations of Volts and Amps, the Skin Resistance to the input signal, the Skin Temperature, and then calculate some virtual mathematical responses from the readings. All of this must happen at absolutely safe levels and adhere to stringent regulatory laws of the World government agencies. First do no harm is the primary law of medicine, It is our Prime Directive.

In other words we stimulate the body with a small safe electrical measure of the body electric, calculate the reaction, stimulate again, re_measure, calculate, re_stimulate, and on and on in a cybernetic biofeedback loop. A loop designed to give awareness feedback on stressors, and to reduce stress. Thus the simple use statement and claims are the device is designed for biofeedback stress detection and stress reduction. There are those who do not agree of the power of stress reduction, but their views do not change the claims for the EPFX. There is a vast amount of research showing the positive effects of stress reduction. Psycho-Somatic medicine has been proven for many decades. The Psycho-Neuro-Immuno link of the body is well documented. There is now the science of Psycho-Neuro-Immuno-Soma PNIS science, where the mind effects the neurology, the immunity, the body, and they all interact on each other.

The volt_ammetric signals are the volt_ammetric electro_chemical trivector signals calculated from the QQC device a registered medical device in Europe. The signals test homeopathic reactions to nosodes, sarcoodes, allersodes, isodes, classical homeopathics, imponderables, hormones, enzymes, herbas, vitamins and other supplements. The skin resistance and electrical reactions to these compounds gave us a Electro_Physiological_Reactivity (EPR) pattern. These reactions are not assuredly reliable, so please do not over react, but check any problem with more standard diagnostic means or refer to medical doctors who can.

Many many medical studies have shown that the EPFX / SCIO is helpful in treating a host of different diseases. The International Journal of the Medical Science of Homeopathy ISSN 14170876 has published over 100 such studies. The studies have proven the EPFX / SCIO therapy safe free from any significant risk. The studies have shown an Universal effectiveness, but the effect is from the original claim: Stress Detection (awareness) and Stress Reduction. Thus the EPFX device is designed for use on patients with some stress.

But even though the results are highly significant there is not enough evidence or need to readjust the original use and claims. Stress Detection and Stress Reduction are much more than enough. Even though Europe has allowed registration of many more claims, humbly we still maintain the simple, universal, unquestionable, and modest use and claim:
Stress Detection and Stress Reduction. Please do the same, offer no more claims than this.

In the medicine of Hans Selye, it is seen that stressors are the paramount problem in health care. All diseases start with a stressor and thus Stress Detection and Stress Reduction are truly early intervention health care.

With the Selye stress pathway of disease, we can see a universal, safe, and very effective way of helping people. By combining the Selye Stress systrm and the energetic medicine of the body electric we have for over twenty years developed a safe effective and legal system of biofeedback stress reduction medicine. The EPFX / SCIO device is sold only to professionals and under the order of a licensed health care professional. The SCIO bioresonance - biofeedback therapists are rigorously trained to:

1. Use safe forms of Stress Detection and Stress Reduction
2. Do a behavioral assay of how the patient may be suppressing and or obstructing their own natural innate curative process.
3. To refer to the patient's medical doctors, work with the system of medicine not to interfere with any doctors program.
4. Try to increase patient awareness, education, and enthusiasm.
5. This education is exactly supervised by the International Medical University of Natural Education. IMUNE

EPFX / SCIO use and claim: Professional Biofeedback for Stress Detection and Stress Reduction.

Stress Selye and the FLOW OF DISEASE

Disease starts when a stressor or blockage of flow causes a disruption in the flow. The ease is now dis-ease. Hans Selye outlined a medical system were disease comes into the body as some sort of stressor. This produces an ALARM reaction phase as that the body is trying to deal with the incoming stress. Thus the symptom is the ALARM reaction. If we fight the symptom not the cause we can interfere with healing. So when our child is exposed to a stress (like a bacteria from another child) a symptom presents, such as a sore throat. The symptom is sign of a disease in flow. The immune system needs help when it is burdened by stress. There is a proved Psycho-Immuno-Neuro link of the body that responds to any stress reduction.

As the stress continues the body acclimates and goes into the ADAPTATION phase. Here the symptom goes away from familiarization. But the disease progresses deeper. We now come to an ultra important conclusion that must change medicine forever. BEING SYMPTOM FREE IS NOT A SIGN OF HEALTH. In fact you can be symptom free and quite sick. Allopathy is for crisis intervention only.

If the stressor continues the body now progresses from the ADAPTATION phase to the EXHAUSTION phase. Here organs weaken. The first form is the FUNCTIONAL phase where organs dysfunction. They make less or excess hormones, enzymes, or others.

After a while they slip into the ORGANIC phase, where here the organs or organ will shrink (atrophy) or grow (hypertrophy).

There now is a physical disease. If the stressor continues the last phase results which is DEATH. Cellular death, organ death, organ system death, organism death. The next diagram relates the flow of disease.

HEALTH

STRESSOR (TOXIN ETC)-------->------------------->
• ADAPTATION
• EXHAUSTION
• FUNCTIONAL
• ORGANIC
• DEATH

The causes of disease or possible stressors are:
LACK OF AWARENESS TOXICITY
STRESS TRAUMA INJURY
HEREDITY PATHOGENS
ALLERGY PERVERSE ENERGY
MENTAL FACTORS DEFICIENCY OR EXCESS OF NUTRIENTS

When these enter the body they disrupt the ease of flow. This produces the Alarm symptom. Then the body adapts, symptoms go away, but if the cause continues the disease continues. Degeneration awaits.

BEING SYMPTOM FREE IS NOT A SIGN OF HEALTH.

The ability to restore or heal the body is based on how much life force the body has. This has an electrical component. The life force can be suppressed or obstructed by lifestyle or stress. This is the SOC index in the SCIO software.

With the advent of fractal and chaos theory we have seen the end of reductionism as a basis for medicine. The Selye system of medicine is all based on removing the stressors and thus their mutual interactions. Stress reduction combined with a behavioral component now form a basis for a new addition to the medical community. The reductionistic diagnosis is left to others and with stress reduction and behavioral advise a complementary system of medical intervention can be very helpful.

In Nelson Natural Medicine the flow of treatment is as follows:

1. Reduce or remove the cause of disease reduce the SOC index get the patient to take responsibility for their disease and their bodies, minds and spirits.
2. Try to naturally encourage repair the damaged organs resulting from the disease, via behavioral education and stress reduction.
3. Unblock the blockages to flow of energy in the body. Chiropractic, Acupuncture, Bioresonance, Biofeedback and other medical arts are dedicated to unblocking unbalances of flow.

4. Reduce the symptoms with natural methods and naturopathy, and never Interfere with the other doctors advise. Synthetic medicines are to be used when all natural methods fail.

5. Deal with the constitutional or metabolic typing, make up, or tendencies of the patient

**EPFX WELLNESS BIOFEEDBACK CONSULTATION WAIVER - EPFX / SCIO use and claim: Professional Biofeedback for Stress Detection and Stress Reduction.**

1. I fully understand that the attending therapists are not allopathic doctors (M.D.'s) and do not pretend to be, but are wellness consultants and are biofeedback specialists.

2. I fully understand the difference between the practice of allopathic medicine, nutritional wellness consulting, and Biofeedback.

3. I fully understand that the services provided by the attending therapists are not allopathic, but are behavioral, educational or biofeedback in nature.

4. I fully understand that the attending therapists perform their services within the parameters of a natural health care and wellness system using biofeedback and stress reduction.

5. I fully understand that the attending therapists do not offer allopathic drugs, surgery or chemical stimulants or radiation therapy. I understand that illness is not being diagnosed nor treated and that my wellness and stress are being measured.

6. I have solicited the attending, biofeedback therapists services in good faith, exercising my free will and following the dictates of my own conscience which allows me to select what I understand is most beneficial to my health.

7. I agree to consult my family medical doctor for a consultation of any risk or contraindications from biofeedback. If a medical doctor is not available, a referral for such services can be arranged.

8. I presently seek counsel, advice, opinions, biofeedback or points of view and/or programs within the scope of the attending therapists wellness and stress reduction practice. I am aware and, release the biofeedback technician to do biofeedback tests and treatments.

9. Please no taping or recording of any interview without permission, we welcome taping but only with the permission of the therapist.

**Signature of client or guardian**

__________________________________________________ date_______________

**Your Family or personal Doctor:**

________________________________________

**DISCLAIMER**

**Electro Physiological Feedback Xrroid System EPFX**

This system is to be used as a Biofeedback multimedia system. It is designed for stress detection and stress reduction. The device does not diagnose any disease other than stress. Stress can come from many sources, this system uses many multimedia treatments to treat stress. This device also measures patients Electrophysiological reactivity, which is another representation of stress. Only a licensed practitioner can diagnose a patient. The sensitivity is set so fine so as to pick up the earliest sign of stress and distress. Thus the results might be below the client recognition. The readings should be evaluated by trained staff. use additional tests or referrals for further clarity. No claims other that Biofeedback Stress detection and treatment are made of the system or results.

**Bibliography**

**Books**


**Articles and studies**


CPT CODES FOR THE SCIO

These are excerpts from a recent CPT code manual showing the possible insurance billing payments made by biofeedback and energetic medicine. If you use a superbill and are an approved supplier of services then a biofeedback therapist could get payment.

Pain rehabilitation service

97032 - APPLICATION OF A MODALITY TO ONE OR MORE AREAS; ELECTRICAL STIMULATION
(MANUAL), EACH 15 MINUTES

97112 - THERAPEUTIC PROCEDURE, ONE OR MORE AREAS, EACH 15 MINUTES; NEUROMUSCULAR
REEDUCATION OF MOVEMENT, BALANCE, COORDINATION, KINESTHETIC SENSE, POSTURE, AND/
OR PROPRIOCEPTION FOR SITTING AND/OR STANDING ACTIVITIES

This list is not an all inclusive list. Other rehabilitation modalities may be used in addition to those described in this policy.

90804
INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENTED, BEHAVIOR MODIFYING AND/OR SUPPORTIVE,
IN AN OFFICE OR OUTPATIENT FACILITY, APPROXIMATELY 20 TO 30 MINUTES FACE-TO-FACE WITH
THE PATIENT;

90805
INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENTED, BEHAVIOR MODIFYING AND/OR SUPPORTIVE,
IN AN OFFICE OR OUTPATIENT FACILITY, APPROXIMATELY 20 TO 30 MINUTES FACE-TO-FACE WITH
THE PATIENT; WITH MEDICAL EVALUATION AND MANAGEMENT SERVICES

90806
INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENTED, BEHAVIOR MODIFYING AND/OR SUPPORTIVE,
IN AN OFFICE OR OUTPATIENT FACILITY, APPROXIMATELY 45 TO 50 MINUTES FACE-TO-FACE WITH
THE PATIENT;

90807
INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENTED, BEHAVIOR MODIFYING AND/OR SUPPORTIVE,
IN AN OFFICE OR OUTPATIENT FACILITY, APPROXIMATELY 45 TO 50 MINUTES FACE-TO-FACE WITH
THE PATIENT; WITH MEDICAL EVALUATION AND MANAGEMENT SERVICES

90808
INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENTED, BEHAVIOR MODIFYING AND/OR SUPPORTIVE,
IN AN OFFICE OR OUTPATIENT FACILITY, APPROXIMATELY 75 TO 80 MINUTES FACE-TO-FACE WITH
THE PATIENT;

90809
INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENTED, BEHAVIOR MODIFYING AND/OR SUPPORTIVE,
IN AN OFFICE OR OUTPATIENT FACILITY, APPROXIMATELY 75 TO 80 MINUTES FACE-TO-FACE WITH
THE PATIENT; WITH MEDICAL EVALUATION AND MANAGEMENT SERVICES

LMRP Description Chronic pain is difficult and frustrating to manage, and patients who experience it are often viewed as being undesirable to treat. Patients with chronic pain are often characterized by low levels of activities of daily living (ADLs), a high demand for medication accompanied by physical and psychological dependency, high verbalization of pain, and the inability to work. In many cases, patients with chronic pain are so entrenched in pain behavior that a behavior modification approach is essential.

Pain rehabilitation programs are an innovative approach to the treatment of intractable pain. The goal of such programs is to give patients the tools to manage and control their pain, and thereby, improve their ability to function independently. Indications and Limitations of Coverage and/or Medical Necessity Patient Medical Necessity Criteria

Services furnished under outpatient hospital pain rehabilitation programs are considered medically necessary and appropriate if:

1. The patient’s pain is attributable to a physical cause;
2. The usual methods of treatment have not been successful in alleviating pain; and
3. A significant loss of ability by the patient to function independently has resulted from pain.

In addition, the following criteria must also be met:

1. The patient must be under the care of a physician;
2. The patient must have an evaluation which must include an evaluation of the physiological, psychological, and social aspects of pain;
3. The patient must have an individualized treatment plan which is specific to their needs and functional limitations;
4. The patient must exhibit limited functional status in relation to performance of ADLs;
5. The patient must have the cognitive ability to understand and carry out instructions and must be compliant and cooperative; and
6. The patient must demonstrate a high level of motivation to participate in their plan of care. The level of patient participation is usually measured by the team members and documented in the progress notes.

Clinical Guidelines

To enter the program, the patient must undergo an extensive evaluation. A problem-solving group attempts to identify the medical, behavioral, vocational, financial, social, and other significant problems of the patient. Coverage of services furnished under outpatient hospital pain rehabilitation programs, including services furnished in group settings under individualized plans of treatment, is available if the patient meets the criteria listed in this policy.

A pain rehabilitation program is one that employs a coordinated multidisciplinary team to deliver, in a controlled environment, a concentrated program which is designed to modify pain behavior through the treatment of physiological, psychological, and social aspects of pain. Such programs generally include diagnostic testing, skilled nursing, psychotherapy, structured progressive withdrawal from pain medication, physical therapy and occupational therapy to restore physical
fitness (mobility and endurance) to a maximal level within the constraints of a physical disability, and the use of mechanical devices and/or activities to relieve pain or modify a patient’s reaction to it (e.g., nerve stimulator, hydrotherapy, massage, ice, systemic muscle relaxation training, and diversional activities). The activities of this program are under general supervision and, as needed, direct supervision of a physician.

The multidisciplinary pain approach begins with a complete clinical evaluation. Comprehensive medical and psychosocial evaluations with particular emphasis on functional capabilities and behavioral responses to pain are essential. Previous medical records should be obtained to avoid repeating appropriately performed studies and unsuccessful treatment approaches.

The multidisciplinary team functions at several levels within the treatment process. They attempt to identify and resolve documentable organic problems when present and to improve the patient’s ability to cope with pain. In addition, considerable effort is devoted to improving the patient’s functional outcome, as measured by increased activity time, improved activities of daily living, increased distance walked, and increased tolerance for specific homemaking or vocational activities.

Pain rehabilitation services must be rendered under a written plan of care/treatment. The plan must:

1. Be consistent with the nature and severity of the individual’s symptoms and diagnosis and tailored to meet their specific needs;
2. Be reasonable in terms of the modality, amount, frequency, and duration of the treatment;
3. Include services which are generally accepted by the professional community as safe and effective treatment for the purpose used;
4. Be developed upon admission and establish specific individualized objectives, measurable, functional goals and how the goals will be met; and
5. Be signed by a physician.

Each pain rehabilitation session should be documented and it should reflect the treatment provided and the patient’s response toward their goals.

Diagnostic tests may be an appropriate part of pain rehabilitation programs. Such tests would be covered on an individual basis only when the diagnostic test can be reasonably related to the patient’s illness, complaint, symptom, or injury, and when they do not represent an unnecessary duplication of tests previously performed. The average program will usually last 4 weeks on an inpatient or outpatient basis or a combination thereof.

Reasons for Denials. A pain rehabilitation service will be denied for the following circumstances:

1. When the services do not meet all the criteria listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.
2. When a patient has a severe psychiatric disturbance which would not allow them to comprehend and retain new learning.
3. When the documentation indicates that the patient is not demonstrating progress toward achieving stated goals within a reasonable period of time. The time frame is included on the plan of care.

4. When the patient has attained his/her pain rehabilitation goals and does not require the skills of a qualified clinician.
5. When the documentation indicates a duplication of services (e.g., an overlap of physical and occupational therapies).
6. Some pain rehabilitation programs may utilize services and devices which are excluded from coverage, (e.g., acupuncture, vocational counseling). Some of the services that may be utilized have limited coverage criteria, (e.g., biofeedback, dorsal column stimulator, family counseling services). See Coverage Issues Manual (CIM) for coverage criteria.
7. Pain rehabilitation will be considered noncovered when chronic pain has resulted from a mental condition, rather than from any physical cause.
8. Chemical dependency should not be the primary diagnosis. The chemical dependency must be secondary to the pain syndrome.

Documentation Requirements The following documentation must be maintained in the patient’s medical record:

1. A physician order or referral for the Pain Rehabilitation services written by the treating physician (who evaluated the patient and determined that a medical need and rehabilitation potential exists).
2. A copy of the evaluation/assessment performed by the treating physician which establishes that the patient has a medical need for Pain Rehabilitation services and rehabilitation potential.
3. An evaluation/assessment of the patient performed by a physician and/or qualified staff members upon admission to the Pain Rehabilitation program to ensure the patient meets medical necessity criteria for the program.
4. An individual treatment plan which contains an individualized problem list, the specific procedure or activity to be done and the responsible discipline, the frequency and duration of the service(s), individual treatment goals (which are objective, measurable, and functional) and a discharge plan. The treatment plan(s) must be dated and signed by the physician.
5. Daily documentation (progress notes) which reflect the individualized activity, instruction given, the patient’s response to the skilled service, and the patient’s progress toward stated goals. The daily note must be signed by the qualified team member who rendered the service.
6. Monthly documentation notes which reflect the individual patient’s goals and progress.
7. Discharge summary to indicate the changes since the start of care, goals accomplished, the reason why goals were not achieved (if applicable), and the discharge plan.
8. Each progress note must be legible, dated, signed, and the credentials of the qualified person rendering the service must be present. In addition, if the HCPCS code billed is based on time, then the time spent by the provider in a face to face encounter with the patient should be documented.
CPT Codes

HCFA (Health Care Financing Administration) rules in favor of Medicare Coverage of urinary incontinence. The memorandum serves four purposes: 1) outlines the description and treatment of urinary incontinence 2) reviews Medicare's coverage history with respect to biofeedback for the treatment of urinary incontinence 3) analyzes the relevant scientific data related to biofeedback for stress, urge, and post-prostatectomy urinary incontinence, and 4) delineates the reason for a) supporting a positive national coverage decision for patients with stress and/or urge incontinence who have already undergone and failed a trial of pelvic muscle exercises and b) continues contractor discretion for the use of biofeedback as an initial treatment modality for urinary incontinence.

Thought Technology would like to thank the Continence Coalition for fighting for this and congratulations on your achievements on behalf of the industry as a whole.

9081X
Approximately 45-50 minutes.

90875
Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient) e.g. insight oriented, behavior modifying or supportive psychotherapy) approximately 20-30 minutes.

90876
Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient) (e.g. insight oriented, behavior modifying or supportive psychotherapy) approximately 45-50 minutes.

90901
Biofeedback training by any modality.

90911
Biofeedback training, anorectal including EMG and/or manometry.

95999
Unlisted neurological or neuromuscular diagnostic procedure.

96150
The initial assessment of the patient to determine the biological, psychological, and social factors affecting the patient's physical health and any treatment problems.

96151
A re-assessment of the patient to evaluate the patient's condition and determine the need for further treatment. A re-assessment may be performed by a clinician other than the one who conducted the patient's initial assessment.

96152
The intervention service provided to an individual to modify the psychological, behavioral, cognitive, and social factors affecting the patient's physical health and well being. Examples
include increasing the patient’s awareness about his or her disease and using cognitive and behavioral approaches to initiate physician prescribed diet and exercise regimens.

96153

The intervention service provided to a group. An example is a smoking cessation program that includes educational information, cognitive-behavioral treatment and social support. Group sessions typically last for 90 minutes and involve 8 to 10 patients.

96154

The intervention service provided to a family with the patient present. For example, a psychologist could use relaxation techniques with both a diabetic child and his or her parents to reduce the child’s fear of receiving injections and the parents’ tension when administering the injections.

96155

The intervention service provided to a family without the patient present. An example would be working with parents and siblings to shape the diabetic child’s behavior, such as praising successful diabetes management behaviors and ignoring disruptive tactics.

97112

Neuromuscular Re-education (procedure).

97535

Self care / home management

97750

EMG Scanning complete muscle testing for physical therapists.

99090

Analysis of information data stored in computers.

G0195

Two relate to swallowing evaluation. G0195 for the clinical evaluation of swallowing function and G0196 for an evaluation.

G0196

Subject

Coverage Decision Memorandum for Electrodiagnostic Sensory Nerve Conduction Threshold

Date: February 14, 2002

This decision memorandum addresses a request for a national coverage determination received from Neurotron. The service for which coverage is requested is electrodiagnostic sensory nerve conduction threshold (sNCT) to be used to diagnose sensory neuropathies, such as diabetic sensory neuropathies, uremic sensory neuropathies, and carpal tunnel syndrome. The memorandum serves four purposes: (1) gives a general overview of select measures to assess sensory nerve function; (2) reviews the history of Medicare’s coverage policies regarding sensory nerve conduction threshold; (3) analyzes relevant scientific and clinical literature on the use of sensory nerve conduction threshold and its impact as a diagnostic device on patient management for patients with sensory neuropathies; and (4) delineates the reasoning for our intention to issue a noncoverage determination.

Clinical Background

The nervous system is composed of the brain, spinal cord, and peripheral nerves. One of the main functions of the nervous system is to collect sensory information. This information is then processed and interpreted in order to initiate appropriate responses throughout the body. A neuron is the basic structural unit of the nervous system. It is composed of a cell body and two types of processes, dendrites and axons. Neurons collect incoming (afferent) information through dendrites whereas axons conduct outgoing (efferent) signals away from the cell body. Nerve fibers are composed of bundles of axons held together by connective tissue.

Sensory nerves, which carry impulses from sensory receptors to the brain, are composed of one or more of the following three fibers: (1) small unmyelinated (C fibers) fibers conduct temperature and slow pain; (2) small myelinated (A delta fibers) fibers conduct pressure, temperature, and fast pain; and (3) large myelinated (A beta fibers) fibers conduct cutaneous touch and pressure.

Evaluating the function of sensory nerves may be of clinical importance for individuals who suffer from metabolic, hereditary, or acquired disorders, as well as those who have experienced a traumatic injury. There are several methods of evaluating sensory nerve function. Such tests include: (1) nerve conduction studies (NCS); (2) sensory nerve biopsy; and (3) sensory nerve conduction threshold (sNCT). Of these, NCS is the most commonly used and widely-accepted diagnostic test.

NCS is used to measure action potentials resulting from peripheral nerve stimulation. It can help determine the diagnosis, severity, location, and distribution of a neuropathy and can assess the integrity of the axon and the myelin sheath (the insulation surrounding the axon). NCS can also detect dysfunction of both sensory and motor nerves. Typically, a nerve is stimulated with an electric shock at one location and a response is recorded at another location. Measurements include latency of response, conduction velocity, and amplitude of response. Of note, NCS primarily measures fast fibers. The test may cause mild discomfort from the shocks administered.

NCS is often performed in conjunction with electromyography (EMG). EMG is the study and recording or intrinsic electrical properties of skeletal muscles. It provides information on neuromuscular function and especially in detection of denervation of axonal neuropathy. EMG can help differentiate muscle wasting of neuropathic versus myopathic origin. It also aids in the differentiation of entrapment neuropathies versus proximal radicular compression. EMG involves the insertion of a needle directly into a muscle to record electrical activity. The procedure can be painful.

Sensory nerve biopsy provides information about the extent of both axonal degeneration and segmental demyelination. Biopsies are performed on a cutaneous nerve, typically the sural nerve. sNCT is non-invasive and typically conducted by technicians under the supervision of a physician. The test is performed by applying disposable surface electrodes on the skin of the patient. Three mild electrical stimuli are applied to a peripheral nerve. Measures are obtained using a portable, 6-V battery powered, microprocessor controlled, constant alternating current sinusoid waveform.
studies at intensities ranging from 0.01 mAmpere to 9.99 mAmpere at frequencies of 5 Hz, 250 Hz, and 2,000 Hz. The manufacturer asserts that abnormally high sNCT measures reportedly indicate a significant loss of nerve conduction, while abnormally low sNCT indicates a hyperesthetic state that corresponds with inflamed, irritated, or regenerating nerves. Typically, the procedure takes less than 30 minutes to complete.

Currently, there is only one sNCT device on the market, the Current Perception Threshold (CPT) by Neurotron. The CPT uses the minimal amount of painless transcutaneous electrical stimulus required to reproducibly evoke a sensation.

**FDA Status**

Neurotron received FDA 510(k) clearance in 1986 to market the electrodiagnostic sensory Nerve Conduction Threshold (sNCT)/CPT Neurometer for the evaluation of sensory nerve diseases and injuries. The predicate device was a vibratory end-organ tester.

**History of Medicare’s Coverage Policy on Sensory Nerve Conduction Threshold**

Currently, Medicare does not have a national coverage determination with regard to the use of sNCT devices in the evaluation of sensory neuropathies. Because some Medicare contractors have implemented local medical review policies describing this service as noncovered, Neurotron has requested a national coverage decision relating to the use of sNCT devices.

The benefit category appropriate for the sNCT/CPT Neurometer is set forth in section 1861(s)(3) of the Social Security Act (i.e., sNCT is a diagnostic test).

**Timeline of Activities**

- **June 22, 2001** - Neurotron requests a national coverage determination.
- **July 12, 2001** - Neurotron meets with medical officer and policy analysts in the Centers for Medicare and Medicaid Services (CMS, formerly known as the Health Care Financing Administration).
- **November 16, 2001** - Neurotron meets with CMS review team.

**General Principles for the Evaluation of Diagnostic Tests**

When CMS reviews a diagnostic test for a national coverage decision, among other things, it evaluates the clinical effectiveness of the test for the Medicare population. CMS considers the usefulness and effectiveness of the test on patient management. 42 C.F.R. §§ 410.32. An important consideration in this review is an assessment of the accuracy and technical characteristics of the test as compared to other diagnostic modalities. The optimal comparison is between the test under review and the gold standard, if one exists. Measures used to determine accuracy include sensitivity (probability of a positive test result in a patient with a disease) and specificity (the probability of a negative test result in a patient who does not have the disease). An increase in sensitivity does not necessarily mean that a test is more accurate. Specificity must be evaluated when determining if one test is more accurate than the other, because a highly specific test minimizes the number of false positive. In addition, increasing sensitivity or specificity is often accomplished at the expense of the other. However, even though a diagnostic test may be very accurate, if the information provided by the test does not alter management of the condition, CMS may determine that the test is not used in the medical management for the specific condition.

**Summary of Evidence**

In determining the articles that would be eligible for review, we used the following inclusion and exclusion criteria:

- **Inclusion Criteria**
  - Articles must be published in English language
  - Studies must have been conducted on human subjects
  - Studies must have enrolled at least 10 patients
- **Exclusion Criteria**
  - Editorials
  - Abstracts
  - Review Articles
  - Published Letters/Comments

Using various combinations of the following search terms: “sensory nerve conduction” “neurometer” “current perception threshold,” a total of ten studies were obtained. In addition, several articles were submitted for consideration by the manufacturer. The following represents a brief summary of the relevant studies.

Rendell (1989) compared NCS, CPT and vibration threshold (VT) as correlates of clinical severity of diabetic sensory neuropathy. Seventy-one subjects with an average age of 52, who had a history of diabetes were recruited and subjected to sensory and motor NCS as well as CPT at 5, 250, and 2000 Hz of the upper and lower extremities. In addition, 28 of the 71 subjects had repeated evaluations at 2, 6, 10, and 12 months after the initial procedure. Each patient received a symptomatic score for the upper extremity and one for the lower extremity. The symptomatic score was obtained by asking the patient to describe his or her symptoms, which was then converted to a final grade by the examiner. Each patient also received a physical score that consisted of a neurological examination with an increased emphasis on the sensory portion of the examination. The sensory modalities assessed included light touch, pain, and thermal sensation. The symptomatic and physical scores were derived from the Neurological Symptom Score and the Neurological Disability Score proposed by Dyck for evaluating peripheral neuropathy. Spearman correlation coefficients between NCS, CPT and vibration threshold were calculated. Correlation coefficients of NCS with clinical scores were significant in most instances. The authors noted that coefficients of CPT with clinical scores appeared to be higher than for NCS in several instances. The authors also created a classification scheme for severity of symptoms. They reported that CPT was better at discriminating between severity classes than NCS. Data on clinical utility were not provided.

Wesely (1988) examined peripheral nerve integrity in 23 dialysis patients using CPT and NCS. The median and peroneal nerves were selected and the tests were performed bilaterally. CPT
was performed concurrently with dialysis. CPT and NCS measures were compared to previously established normative values. Grading the severity of the neuropathies was accomplished by using a concurrent test grade change, a divergent test grade change, a convergent test grade change, and a no test grade change. These measures were compared to those taken a year later. The authors reported that CPT and NCS were highly correlated but that CPT was more sensitive. Details of clinical diagnosis, clinical examinations, and testing conditions were not provided. There was also no discussion of clinical utility.

Menkes (2000) evaluated CPT as an adjunctive test for detection of acquired demyelinating polyneuropathies. The authors used normative data previously established for absolute CPT, side-to-side CPT ratios, and intrasite CPT ratios between different frequencies in order to determine if CPT testing can be used to diagnose demyelinating polyneuropathies. Ten patients with demyelinating polyneuropathies and 10 patients with axonal polyneuropathies were recruited. Diagnosis of demyelinating polyneuropathy was based on the presence of two of the three following criteria: (1) clinical profile; (2) cerebrospinal fluid profile; and (3) NCS profile. Additional inclusion criteria for axonal polyneuropathy were based on NCS and EMG profiles. Ages ranged from 41-78 years. The technologist using the CPT was blinded to the study hypothesis and the patients’ diagnoses. C2 spinal nerve distribution, lateral antebraclial cutaneous nerve distribution, and sural nerve distribution were examined. The authors reported that CPT detected demyelinating polyneuropathies with 50% sensitivity and 100% specificity. They also stated that the diagnostic sensitivity was similar to those of other published diagnostic criteria. The diagnostic sensitivity of CPT testing for axonal polyneuropathies was reported as 70%. The authors concluded that CPT should be considered an adjunctive test to NCS and EMG in the diagnosis of demyelinating polyneuropathies. However, all patients in the study were diagnosed without using CPT. Also, the authors assert that CPT has similar sensitivity to other electrodiagnostic tests.

Katims (1989) studied 29 dialysis patients and compared the screening and evaluation of carpal tunnel syndrome by CPT to NCS. Patients completed a questionnaire to identify symptoms of carpal tunnel syndrome (CTS). CPT was performed on the median, ulnar, and peroneal nerves during hemodialysis. CPT measurements were graded into classes of severity. CTS was diagnosed using CPT by determining the difference between the CPT grades from median and ulnar nerves in the same hand. NCS was only performed on the ulnar nerve if CTS was suspected. The authors reported that the “overall severity of the neuropathy detected by both tests from the median and ulnar nerves in the same hand. NCS was only performed on the ulnar nerve if CTS was suspected. The authors reported that the “overall severity of the neuropathy detected by both tests from the median and ulnar nerves was highly correlated, r = 0.79 (p < 0.001). CPT yielded greater overall levels of detection severity for neuropathy (92%) than did NCS (79%) for the medial and peroneal nerves combined.” The authors conclude that the study supports previous findings that “CPT is sensitive for quantitatively evaluating the integrity of sensory afferents and is significantly correlated with [NCS] findings.” In addition, CPT is diagnostic for CTS.

Katims (1986) performed CPT on 44 normal subjects and 33 diabetic patients. A limited neurological examination was also performed to determine the presence of peripheral neuropathy. Although not stated, it may be inferred that all the diabetic patients had evidence of neuropathy on clinical examination. The authors reported a sensitivity of 94% for detecting neuropathy in the diabetic patients when the detected abnormal measurements from the 5 Hz and 2000 Hz frequencies for the three body locations tested (face, index finger, great toe) were combined. Although CPT typically includes the use of 250 Hz stimuli, the article did not state whether or not such stimuli were used, and, if so, what results were obtained. CPT in the normal subjects without clinical evidence of neuropathy varied significantly with age as well as the frequency and location of the stimulation. Because all patients presumably had signs of neuropathy on physical exam, but not all patients were diagnosed as having neuropathy based on CPT measurements, it is unclear from this study if CPT is more sensitive than a physical exam in detecting diabetic sensory peripheral neuropathy.

Masson (1989) performed a retrospective study that analyzed the use of CPT for the assessment of peripheral neuropathy in patients with type I or type II diabetes and then compared it to more traditional methods of quantifying nerve function. The authors recruited 31 healthy control subjects and 90 diabetic patients with type I or type II diabetes mellitus, with and without neuropathy to participate in the study. The participants were divided into 4 groups. The control group was group 1, while groups 2, 3, and 4 were composed of diabetics without neuropathy, diabetics with neuropathy, and diabetics with neuropathic ulcers, respectively. The study did not report how the presence or absence of neuropathy was determined. A cohort of 68 patients also had conventional assessment of peripheral nerve function, using a biothesiometer for the measurement of vibration perception threshold, a thermooesthesiometer for the measurement of warm thermal discrimination threshold, and peroneal motor conduction velocities. Ages ranged from 19-82 years. CPT measurements were significantly different between the neuropathy group versus the control group; the neuropathic ulcer group was also statistically different than the control group as well as the diabetics without neuropathy group. The authors reported statistically significant Spearman correlation coefficients (0.34 to 0.46) between 5 Hz and 250 Hz and thermal threshold, and between 2000 Hz and vibration perception threshold (0.42 to 0.69) and peroneal motor conduction velocity (-0.66). Sensory nerve conduction measurements were not reported. The authors state that these correlations suggest that CPT can provide information about the functional integrity of different fiber types. However, the authors point out that CPT may not directly stimulate nerve fibers but, instead, produce different sensations due to differential responses of cutaneous mechanoreceptors.

Ro (1999) performed CPT on patients with Fabry’s disease. These individuals are afflicted with an X-linked disorder caused by a deficiency of the lysosomal enzyme alpha-galactosidase A. The accumulation of glycolipids in dorsal root ganglia is responsible for the episodic burning pain and constant acroparesthesias experienced by these patients. Nerve biopsy specimens taken from these patients usually show loss of small myelinated and unmyelinated fibers. The study was designed to assess subjective complaints of pain and paresthesias as well as to compare the values of CPT and correlate NCS in detecting the sensory neuropathy. Sixteen patients from the same family (8 hemizygous men and 8 heterozygous women) were recruited for the study. Fifty healthy subjects were used as controls. All patients reported symptoms of neuropathic pain. They received a symptomatic score based on their self-rated symptoms. CPT was performed in the median and peroneal nerve distributions for all three stimuli (6 measurements). The locations for conducting NCS were not reported. All 16 patients had normal NCS. Abnormal findings using CPT were reported for 5 Hz (6 of 16, 37.5%), 250 Hz (8 of 16, 50%), but not 2000 Hz (0 of 16, 0%). The authors reported that the results showed CPT testing at low frequencies were significantly more sensitive than at a higher frequency and more sensitive than NCS in detecting sensory neuropathies in patients with Fabry’s disease, p < 0.001. There was no correlation between CPT testing and clinical symptom scores, duration of disease, creatinine clearance values or alpha-galactosidase A activities in either hemizygous or heterozygous patients.
Cheng (1999) studied 558 non-insulin dependent diabetics for the purpose of identifying risk factors for diabetic peripheral sensory neuropathy in type 2 diabetes. Patients were administered the following tests: monofilament testing, graduated tuning fork, and CPT. Those patients who had two or more abnormal quantitative sensory testings were defined as having diabetic sensory neuropathy. Of the 558 patients, 62 were classified as having neuropathy. Symptoms and findings on physical examination consistent with neuropathy were not reported. NCS was not performed.

Lerner (2000) evaluated the reliability and reproducibility of sNCT in establishing normative values for evaluation at the mental foramen area. The authors examined 34 healthy subjects who were tested twice over several days with sNCT. On the left side, the test showed no difference between the first and second test (p > 0.05). On the right side, there was a statistical difference between the first and second test for all three frequencies, but the confidence interval was very narrow and the differences were not clinically significant. The study also found significant differences between the left and right sides. The authors concluded that sNCT is a reliable method to quantify sensory nerve function in the mental foramen area in healthy subjects.

Rendell (1989) attempted to determine how useful CPT might be for assessing diabetic sensory neuropathy. The purpose of the study was to determine if CPT could map the extent of sensory neuropathy. Forty-four non-diabetic volunteers and 59 diabetic patients were subjected to a detailed clinical neurological examination consisting of questions regarding symptoms and a physical examination. An assessment of light touch, pain, vibratory, and thermal sensation was performed on each individual’s hand, wrist, elbow, foot, ankle, and knee. The results of these tests yielded a symptom score and a physical score. An examiner blinded to the results obtained from the clinical neurological examinations performed CPT evaluations on all subjects at sites identical to those used for light touch, pinprick, and thermal physical testing. CPT correlations with the physical score gave r values of 0.55 for 5 Hz, 0.60 for 250 Hz, and 0.62 for 2000 Hz. CPT correlations with the symptom score were not as strong. Correlation coefficients were 0.45 for 5 Hz, 0.46 for 250 Hz, and 0.51 for 2000 Hz. The symptom and physical scores, however, were not independently validated. Patients with diabetic neuropathy showed higher CPT values than non-diabetic volunteers and diabetics without neuropathy as revealed by physical examination. CPT measures were normal in diabetic patients without clinical evidence of neuropathy. The authors conclude that CPT “appears to be a useful technique for assessment of diabetic sensory neuropathy.”

Technology Assessments

In 1999, the American Association of Electrodiagnostic Medicine (AAEM) published a technology review of the Neurometer Current Perception Threshold. The opinions stated in the assessment, however, may reflect those of the author and not necessarily of the Association.

The summary of the literature was presented in the form of a table containing specific issues followed by various recommendations. Most of the published articles were studies correlating the performance of the CPT to results obtained from standard nerve conduction studies within populations of affected individuals with known diseases. According to the technology assessment the fundamental problem is the absence of an appropriate standard against which to measure CPT. Another problem with the technique is that it elicits multiple measures, and any abnormality detected is considered significant. Also, there is a tendency in the literature to arbitrarily assign various degrees of deviation from a normal population as grades of severity, with little additional information given. The technology assessment also concluded that “CPT provides only one set of values for each site studied, unlike nerve conduction studies which provide more information. Therefore, the location and type of peripheral nerve pathology is less clear with CPT testing.”

The report made the following recommendations:

“Determination of current perception threshold has the potential for evaluation of patients with peripheral nervous system diseases resulting in altered cutaneous sensation. This type of testing could potentially complement perception needle EMG and nerve conduction studies, to assist with evaluating treatment response or disease progression after a diagnosis is made. However, conflicting information and methodological problems exist regarding the utility of the Neurometer CPT for the diagnostic evaluation of specific disease conditions. Future research is needed to establish statistically expressed normal values and to demonstrate the sensitivity and specificity of the Neurometer CPT.”

Position Statements

We have not identified any position statements by medical professional societies on sNCT. In addition, we have not found any professional guidelines relating to the use of this technology. However, the American Association of Clinical Endocrinologists wrote to CMS on November 26, 2001 in support of Medicare coverage of sNCT. The Association believes that it is reasonable to perform sNCT in some diabetic patients, because it may detect neuropathy earlier than NCS (e.g., identified hyperesthesia) and could be used for monitoring improvement or worsening of diabetic polyneuropathy. The Texas Worker’s Compensation Commission also wrote to CMS on September 12, 2001 decision:

“The Spine Treatment Guideline Revision Workgroup review of CPT, a type of sensory conductive test, indicated that there was supporting literature for its effectiveness in some medical conditions but that there was little evidence to warrant its use for musculoskeletal conditions. However, staff’s review of the literature supplied by commenters supported the efficacy for CPT testing for peripheral neuropathy that is not clinically detectable through sensory nerve conduction velocity (NCV) studies. Staff’s review of the literature also supported the efficacy of CPT testing for the evaluation of radiculopathies and as an appropriate diagnostic tool for the quantitative measure of the functional integrity of sensory nerve fibers…”

We also contacted experts in the field of neuropathies. The experts were uniformly unaware of a use for sNCT that would alter patient management.

CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act, §§ 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, in general, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” §§ 1862(a)(1)(A).

CMS has issued regulations pertaining to the coverage of diagnostic tests under the part B program. Those rules provide that, except for a few exceptions, diagnostic tests must be ordered by the
physician who treats the beneficiary for a specific medical problem and the physician must use the results in the management of the beneficiary's specific medical problem. 42 C.F.R. §§ 410.32. In general, tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary. See also 42 C.F.R. §§ 411.15(k)(1).

As described below in this decision memorandum, we have fully examined the medical and scientific evidence submitted with the request for a national coverage decision, as well as the additional information obtained as a result of our own investigation. We have determined that the available evidence is not adequate to reliably conclude that sNCT is reasonable and necessary for the diagnosis of sensory neuropathies because it is not clinically effective. Therefore, we intend to issue a national noncoverage decision.

There is no gold standard for the evaluation of sensory nerve function. The most commonly used electrodiagnostic test is NCS. The principal limitation of NCS is that it measures velocity and amplitude only in the largest diameter and fastest conducting nerve fibers. It provides no information on the integrity of small- and medium-sized fibers. In addition, there is a wide range of normal values. A patient may have a drop in conduction velocity yet still fall within the normal range. Therefore, some patients with dysfunction of sensory nerves may not be detected using NCS.

sNCT reportedly assesses large, medium, and small fibers and does not cause the discomfort that may be experienced with NCS. Of note, sNCT bypasses some of the sensory receptors (e.g., Meissner's corpuscles, Pacinian corpuscles) and the sensations perceived by the subject are not those of normal sensation (e.g., heat, cold, touch, pain). The principal limitations of sNCT are the following: (1) it can only be performed on patients with normal attention and other cognitive abilities, as well as intact central nervous system sensory processing, because test results are based on the patient's ability to detect and report his or her perception of the administered stimuli; and (2) unlike NCS, sNCT does not assess the function of motor nerves. sNCT also measures responses to three different stimulus intensities. The greater number of measurements obtained with sNCT than with NCS may increase the likelihood of reporting an abnormal value. This is particularly problematic when the study population is determined to have a neuropathy using another testing modality, such as a physical examination. This may lead to the reporting of a higher sensitivity, but a lower specificity due to a higher number of false positives.

In our review of the literature we did not find any studies on the effect of sNCT on patient management. Only four studies compared sNCT to NCS. Each study had serious methodological flaws and specificity often was not or could not be determined. In general, the studies evaluated a small number of subjects and none masked the individuals performing the electrodiagnostic studies. Only the Rendell study reported detailed inclusion and exclusion criteria. Therefore, these studies may have produced biased results.

Rendell (1989) calculated Spearman correlation coefficients for NCS and sNCT with a symptomatic score and a physical score in patients with diabetes. Both scores as well as the classification of severity of neuropathy were not independently validated. A direct comparison between NCS and sNCT was not performed nor was a correction for multiple statistical analyses conducted. Therefore, the study is not adequate to demonstrate the relative accuracy of NCS and sNCT in assessing diabetic sensory polyneuropathy. Moreover, the diagnosis of neuropathy was based on history and physical examination, raising into question whether sNCT is more accurate in diagnosing diabetic polyneuropathy than a history and physical examination.

Weseley (1988) performed NCS and sNCT in dialysis patients and then graded measurements based on a classification system that was not independently validated. sNCT and NCS were not performed at the same time and greater abnormal findings on sNCT may have resulted from performing the test concurrently with dialysis. Physiological and physical changes during dialysis may affect a patient's ability to accurately detect test stimuli as well as nerve function. Also, sensitivity was based on the relative ability of each test to report an abnormal result consistent with a neuropathy in each patient. However, the use of an independent indicator of neuropathy was not reported. Instead, patients were assumed to have a neuropathy based on test measurements. Therefore, it is unclear if any of the patients had a neuropathy. Specificity was not reported. Finally, the authors did not perform a statistical comparison between NCS and sNCT. Therefore, the study is not adequate to demonstrate the relative accuracy of NCS and sNCT in assessing uremic neuropathy.

Katims (1989) performed NCS and sNCT in dialysis patients to assess these tests as screening measures for carpal tunnel syndrome (CTS) in uremic patients. The grading system and CTS questionnaire used in the study were not independently validated. Twelve subjects reported symptoms of CTS. NCS identified CTS in three of these subjects. sNCT identified CTS in five of these patients, but also identified CTS in two patients without symptoms of CTS. NCS did not identify any patients as having CTS who did not have symptoms. If the questionnaire used was an independent measure of CTS, sNCT may have a high false positive rate. This is consistent with the above observation that multiple measurements would result in a higher sensitivity but a lower specificity than NCS. Furthermore, although the authors reported that sNCT had a greater sensitivity than NCS for the median and peroneal nerves combined, which was not the main objective of the study, the comparison was not based on an independent measure of a neuropathy and a statistical comparison of sNCT and NCV was not performed. Therefore, the study is not adequate to demonstrate the relative accuracy of NCS and sNCT in assessing uremic neuropathy.

The study by Ro (1999) on patients with Fabry's disease suggests that sNCT may be more sensitive than NCS in detecting neuropathy in patients with Fabry's disease. This is of questionable clinical utility in the Medicare population since the symptoms of Fabry's disease often begin in childhood and are typically diagnosed by early adulthood. The study also suggests that sNCT may distinguish between sensory fiber types and may be more sensitive than NCS in detecting sensory neuropathies that affect only small myelinated and unmyelinated fibers. However, the patient population tested in this study was small (only 16 patients) and the symptoms scores were not independently validated.

In summary, the available scientific evidence is not adequate to demonstrate the accuracy of sNCT or the accuracy of sNCT as compared to NCS. Unlike NCS, sNCT does not assess the integrity of motor nerves, which is important in evaluating some patient populations, such as diabetics. In addition, it is not evident that sNCT offers any diagnostic advantages over a history and physical examination in detecting the presence of a neuropathy. There are also no clinical studies that we identified that demonstrate that the use of sNCT leads to changes in patient management in a particular Medicare subpopulation. As stated in 42 C.F.R. §§ 410.32, a diagnostic test is not reasonable and necessary unless its results are used by the treating physician (who also orders the test) in the management of the beneficiary's specific medical problem. In our discussions with
experts, we were also unable to identify a subpopulation in whom the results of sNCT would alter medical care. Although the Association of Clinical Endocrinologists believe that sNCT is useful to detect sensory neuropathies in some diabetic patients, we were unable to establish the specific changes in patient management that would occur with its use. Moreover, the potentially lower specificity of sNCT as compared to NCS may lead to the administration of unnecessary and possibly harmful treatments. Therefore, CMS concludes that the use of sNCT in the diagnosis of sensory neuropathies is not reasonable and necessary. However, we believe that sNCT merits further study and we encourage investigators to conduct well-designed clinical trials to demonstrate the clinical effectiveness of the test.

**Decision**

CMS concludes that the scientific and medical literature do not demonstrate that the use of sNCT to diagnose sensory neuropathies in Medicare beneficiaries is reasonable and necessary. Therefore, we intend to issue a national noncoverage decision.

1. All three tests are not necessarily equivalent in the type of information they give, and therefore are not presumed to necessarily be substitutive.

2. The terms Current Perception Threshold (CPT) and sensory nerve conduction threshold (sNCT) are used interchangeably in this memorandum.

3. Specificity is used to rule in disease, whereas high sensitivity rules out disease.


15. The manufacturers took issue with many aspects of this report and wrote a detailed response, with the matter currently in litigation.

**Clinical Background**

The normal wound healing process involves inflammatory, proliferative, and remodeling phases. When the healing process fails to progress properly and the wound persists for longer than one month, it may be described as a chronic wound. The types of chronic wounds most frequently addressed in studies of electrical stimulation for wound healing are: (1) pressure ulcers; (2) venous ulcers; (3) arterial ulcers; and (4) diabetic ulcers.

Pressure ulcers, also known, as decubitus ulcers, bedsores or pressure sores, are areas of localized skin/tissue damage caused by unrelieved pressure. This pressure squeezes the skin's blood vessels causing hypoxia. If the pressure is prolonged it results in tissue necrosis. Pressure ulcers are most common over bony prominences, such as the sacrum, heels, hips and elbows. Pressure ulcers are generally classified by stage. (See Table 1) Stage I pressure ulcers present as non-blanching
erythema with intact skin. Stage II ulcers involve a partial thickness loss involving the epidermis or dermis. Stage III ulcers are full thickness and extend down to, but not through, the underlying fascia. Stage IV ulcers involve tissue below the fascia, exposing muscle and even bone.

**Stage I**
Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area of the body may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue or purple hues.

**Stage II**
Partial thickness skin loss involving epidermis, dermis or both. The ulcer is superficial and presents clinically as an abrasion, blister or shallow crater.

**Stage III**
Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.

**Stage IV**
Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (e.g. tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

Prevention of pressure ulcers involves frequent repositioning of the patient, keeping the skin dry and, in some cases, using various support surfaces that keep a person’s weight evenly distributed. Once these wounds develop standard wound care includes frequent turning to relieve pressure, proper nutrition and good hygiene are standard therapies. The underlying immobility and difficulty relieving surface pressure points often makes treating these wounds a challenge.

Venous ulcers usually occur in the lower extremities. They result from venous obstruction or valvular incompetence. The subsequent venous hypertension then affects the vascular supply to surrounding tissue, resulting in tissue hypoxia and ulcer formation. Because the underlying pathophysiology is venous insufficiency, the treatment of venous ulcers should ultimately be directed on two fronts - correction of the underlying venous incompetence and wound care. Moist dressings combined with compressive stockings are usually effective in treating these ulcers, although the time to heal may be prolonged in some patients.

Diabetic ulcers are thought to develop from a combination of both small and large vessel disease, which affects tissue perfusion, and peripheral neuropathy, which leads to a loss of protective sensation. Injuries in these patients are often slow to heal, and might go unnoticed. Foot ulcers are a major health problem for diabetics. It is estimated that up to 15% of diabetics will develop a foot ulcer at some time in their life, and approximately 70% of such patients develop recurrent ulcers. Diabetic foot ulcers precede approximately 85% of lower limb amputations. Educating diabetics about routine foot care and self-examination can help to prevent foot ulcers. Moist dressings, debridement and off-loading are the mainstays of treatment.

Arterial ulcers result from inadequate blood flow to the site of a lesion to which blood flow is compromised. The ulcer may be very deep and usually appears black, necrotic, and has no granulation tissue. The surrounding tissue typically shows signs of arterial insufficiency, such as loss of nail growth or atrophic skin. These ulcers usually form between the toes, or on the ankle where the bone protrudes, or on the back of the foot. These ulcers may be very painful and are usually associated with diseases such as arteriosclerosis, systemic lupus erythematosus, or thromboangiitis obliterans. Treatment of the vascular impairment is an important component of good wound care.

Conventional or standard therapy for chronic wounds involves local wound care as well as systemic measures. Standard care considerations to promote wound healing include, debridement or removal of necrotic tissue, wound cleansing, and dressings that promote a moist wound environment. Systemic treatments include the use of antibiotics to control infection and optimizing nutritional supplementation. There are other conventional therapeutic modalities that may apply to certain subgroups of patients depending on their type of wound. Specific conventional therapies for venous ulcers include the use of compression devices aimed at decreasing venous stasis. Patients that have pressure ulcers require frequent repositioning to redistribute the pressure that is causing the ulcers. Off-loading of pressure and good glucose control for diabetic foot ulcers and establish adequate circulation for arterial ulcers.

Some clinicians have attempted to supplement conventional wound care therapies with courses of local electrical stimulation. The clinicians that administer electrical stimulation are predominantly physical therapists.

Not long after the discovery of electricity, clinicians tried to derive healing benefits from the application of electrical energy to the human body. Since the 1950’s, investigators have used electrical stimulation as a treatment modality for the healing of chronic wounds. The physiologic principles underlying this approach include the hypotheses that electrical stimulation can: (1) increase ATP concentrations in tissues; (2) increase DNA synthesis; (3) attract epithelial cells and fibroblasts to wound sites; (4) accelerate the recovery of damaged neural tissue; (5) reduce edema; (6) increase blood flow; and (7) inhibit pathogenesis.

Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. The types of electrical stimulation and devices can be categorized into 4 groups based on the type of current: low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternating current (AC) and transcutaneous electrical nerve stimulation (TENS). Electromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields rather than direct electrical current.

**Food and Drug Administration (FDA) Approval/Clearance**

FDA has granted premarket approvals for electrical stimulators as Class III devices for the indications of bone stimulation and deep brain stimulation. FDA has also cleared electrical stimulators as Class II devices when indicated for muscle stimulation. The FDA has not cleared or approved the use of electrical stimulation for the treatment of wounds. The FDA has concluded that the use of these devices for the treatment of wounds is significantly different than the use of these devices for the indications currently covered under a 510(k) clearance. They are considered Class III devices which require the manufacturer to go through the Premarket Approval (PMA) process. Therefore,
the manufacturers would have to show there is reasonable assurance of safety and effectiveness for the treatment of wounds before the FDA could issue an approval for these devices. As of this time, the law prohibits manufacturers to market the use of electrical stimulators for wound healing. Lack of approval for this particular indication, however, does not preclude physicians and other health care providers from providing this therapy, as an off-label use.

**History of Medicare Coverage**

Medicare coverage for electrical stimulation for wound healing has been historically left to carrier discretion. In 1981, however, CMS issued a national noncoverage determination, which barred coverage of a certain type of electrical stimulation (low intensity direct current, Medicare Medicaid Guide Sep. 20, 1981) for the treatment of pressure sores. Carriers had the discretion to cover other forms of electrical stimulation. In August 1995, CMS ordered a technology assessment of electrical stimulation for wound healing. Emergency Care Research Institute (ECRI), a technology assessment firm, was awarded the contract. This report was completed in February 1996.

CMS sent the ECRI report as well as information provided by the American Physical Therapy Association (APTA) to its technology advisory committee (TAC) in November 1996. The TAC, a committee of physicians employed by the government and CMS Contractor Medical Directors, assessed the quality of the clinical studies, and determined that electrical stimulation was not markedly superior or inferior to conventional or alternative therapies for chronic wound healing.

**According to the TAC analysis:**

“Wound healing is a complex process dependent on, and affected by factors such as volume, location, contamination, foreign bodies, infection, blood supply, edema, drainage, pressure, immobility, repeated trauma, drugs, irritants, topical applications, radiation, age, nutritional status, and coexisting diseases or conditions. Common therapeutic interventions include debridement, irrigation, soaks, topical agents, enzymes, dressings, pressure relief, and antibiotics. Electrical Stimulation (ES) is not commonly included in the standard line of defense for wound healing. The University Hospital Consortium (UHC) considers it an unproven adjunctive therapy for wound healing.”

Similar to the ECRI report, the TAC made the following separate conclusions based on the type of ES being use:

- There is no evidence that Direct Current (DC) improved wound healing.
- Studies did show that Pulsed Current (PC) improves healing rate of stage II-IV pressure ulcers. However, several confounding factors, number of patients, heterogeneity of patients, and no control over concomitant therapy compromised the studies used to reach this conclusion.
- A study did show that Alternating Current (AC) improved the healing rate of pressure ulcers. However, that study had a major flaw, in that the AC group consisted of primarily patients with Stage II ulcers, while the control group consisted of sicker patients with Stage IV ulcers.
- Improvement rate of Pulsed ElectroMagnetic Induction (PEMI) was so small that it was not considered clinically useful.
- Pulsed ElectroMagnetic Energy (PEE) did show improvement in the healing rate for Stage II ulcers when compared to conventional therapy. However, there was no standard of care provided in this study. Both the active and placebo group had 6 different types of dressing and topical agents.

Based on the TAC’s recommendation, in April 1997, CMS rescinded carrier discretion and issued a national noncoverage policy - CIM 35-98 — to be effective May 14, 1997. CMS essentially expanded upon the 1981 national noncoverage decision involving low intensity direct current for the treatment of pressure ulcers by noncovering all forms of electrical stimulation for the treatment of all types of chronic wounds.

In response to this decision, APTA requested a postponement of the effective date and presented additional data. This data was presented on June 17, 1997. After careful review, CMS notified APTA on July 7, 1997 that it planned to proceed with implementation of its noncoverage determination.

**Aitken v Shalala**

Six individual Medicare beneficiaries joined by the APTA brought suit in federal district court in Massachusetts to challenge CMS’s national noncoverage determination (Aitken v. Shalala, 986 F. Supp 57 (D. Mass., 1997)). The individual plaintiffs suffered from chronic wounds that had not healed with conventional therapies. Some of the plaintiffs alleged that each had experienced facilitated healing when they received adjunctive therapy using electrical stimulation, while other plaintiffs asserted that CMS’s decision prevented them from obtaining this adjunctive therapy, which might have helped their wounds to heal. The plaintiffs charged that the administrative record did not adequately support the national noncoverage decision.

The court found that “there needs to be at least a better explanation by HCFA of its coverage determination, and, perhaps, a revision of that determination.” 986 F. Supp at 62. The court noted that the administrative record contained a number of published papers concerning the value of electrical stimulation (ES), anecdotal support for the use of ES in clinical settings, publications by the Agency for Health Care Policy and Research (AHCPR), and a report from a health technology assessment consultant.

On the ECRI report, the court expressed concern that materials used in a staff presentation to a Technology Assessment Committee had not accurately portrayed some of ECRI’s findings. Specifically, the court noted that “ECRI’s conclusion that ES is about as effective as other therapies (‘not markedly superior or inferior’) does not support the conclusion that ES is not effective.” Id., at 63. Moreover, the court noted that the record contained anecdotal support from clinicians, and while the agency was not bound to accept this evidence, it was not “free to disregard it entirely, without explanation.” Id. In addition, the court specifically noted that AHCPR had issued a clinical practice guideline recommending electrical stimulation for certain ulcers that had proved unresponsive to conventional therapy. Id. at 64. The court noted that the “published studies tend to support the conclusion that ES is about as effective as ‘conventional therapy.’” Id. at 64. Finally, the court found that the record lacked adequate information to support the ES national noncoverage determination and questioned whether the record “supports the agency’s conclusion that ES should never be covered in any case.” Id. The court remanded the national coverage determination regarding reimbursement for ES to the Secretary for additional proceedings to “supplement the record with evidence adequate to support or modify its decision.” Id., at 65. Since the court decision, the Medicare carriers have made decisions about Medicare coverage for electrical stimulation of chronic wounds at a carrier-by-carrier level.

After the court’s decision, CMS reassessed its coverage policy on electrical stimulation of chronic wounds. Instead of attempting to buttress the administrative record with more documents to
support the remanded noncoverage policy, we performed a new, thorough, and extensive analysis. The following actions were the major steps in this coverage determination process:

On October 14, 1998 CMS received a memorandum from AHRQ’s Center for Practice and Technology Assessment. This memo noted that the overall conclusion of the initial ECRI report that “electrical stimulation is about as effective as other therapies (‘not markedly superior or inferior’)” appear to be accurate. Moreover, it suggested a tempered interpretation of the AHRQ Guidelines on Treatment of Pressure Ulcers. The guidelines state that “electrical stimulation could be considered as treatment for certain pressure ulcers unresponsive to conventional therapy.”

The recommendation to consider electrical stimulation treatment was made on the basis of level B evidence derived from five clinical trials involving 147 patients (not all receiving the treatment). “These studies were not adequately powered or persuasive because of other methodological faults.”

In an April 1, 1999 letter, APTA responded to the AHRQ letter. In this letter, APTA asked CMS to consider the broad national coverage policy the Association proposed in June 1997. The APTA had proposed a national coverage policy for pulsed current and pulsed electromagnetic induction for the following types of wounds shown non-responsive to conventional therapy: (1) Stage II - IV pressure ulcers, (2) partial and full thickness wounds secondary to venous insufficiency, arterial insufficiency, or diabetic neuropathy.

CMS performed its own systematic review of the literature to find articles published on this topic since the ECRI report. In addition, we reviewed several articles submitted by APTA for consideration. Given inconsistencies in the quality of the scientific literature and the results reported relating to the effectiveness of electrical stimulation, this issue was referred to the Medical and Surgical Procedures Panel of the Medicare Coverage Advisory Committee (MCAC).

**Benefit Category**

For an item or service to be covered by the Medicare program it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. Electrical stimulation is covered under the following statutorily defined benefit categories:

- §§1861(s)(1) Physician’s Services
- §§1861(s)(2)(A) Services and supplies furnished incident to a physician’s professional service;
- §§1861(p) Outpatient Physical Therapy Services

Electrical stimulation is considered a physician or physical therapy service under the Medicare program, and must be performed by a licensed health care professional.

**Summary of Evidence**

The number of published articles on electrical stimulation for the treatment of chronic wounds has increased considerably since the early 1990’s. There have also been hundreds of articles published on wound care in general. Of these, several are review articles and clinical practice guidelines. One of the most extensive, initial reports was produced by the Agency for Health Care Policy and Research (AHCPR), now known as the Agency for Healthcare Research and Quality (AHRQ) in 1994. Although this report focused largely on pressure ulcers, it advised clinicians to “consider a course of electrotherapy for Stage III and IV pressure ulcers that have proved unresponsive to
In 1996, CMS (then the Health Care Financing Administration) commissioned ECRI to conduct a technology assessment on electrical stimulation for the treatment of chronic wounds. ECRI searched 17 databases (some starting from 1969 to January, 1996) and identified 41 studies (18 randomized controlled trials, 22 case series and case reports, 1 comparative study) of electrical stimulation for the treatment of chronic wounds. ECRI’s definition of a chronic wound was a duration of 30 days or longer. They conducted several extensive analyses including a qualitative analysis of all studies, a quantitative analysis of normalized healing rates, a meta-analysis of normalized healing rates and a meta-analysis of proportion of lesions completely healed.

ECRI made the following qualitative conclusions: (1) “Although all ES (electrical stimulation) studies have at least 1 weakness, not all are potentially confounded.” (2) “ES controlled studies for venous ulcers are about equal to or slightly inferior in quality compared to other controlled studies for venous ulcers.” (3) “ES controlled studies for decubitus ulcers are about equal to or slightly superior in quality compared to other controlled studies for decubitus ulcers.” ECRI made the following quantitative conclusions: (1) “ES facilitates the healing rate of chronic ulcers.” (2) “ES facilitates the complete healing of chronic ulcers.” (3) “The relationship between outcomes and ES can be affected by wound size and type of stimulator.” (4) “Decubitus ulcers are more likely to heal completely in response to ES than venous ulcers.” ECRI’s general findings were: (1) “ES devices are safe when used appropriately” (2) Most types of ES are more effective than minimal treatment (e.g., saline-soaked gauze).” (3) “ES is not markedly superior to or inferior to conventional or alternative therapies. There is insufficient evidence to determine if clinically significant differences exist.” Conventional therapies were defined as “debridement, cleaning agents, topical agents, dressings, bandages, antibiotics (systemic or local), compression therapies, systemic medications, or nutritional supplements.” Alternative therapies were defined as “hyperbaric oxygen, growth factors, ultrasound, lasers, and ultraviolet light.” Although ECRI considered electrical stimulation and electromagnetic therapy collectively, these two treatment modalities are distinct in application and mechanism of action. For the remainder of this discussion, electrical stimulation and electromagnetic therapy will be considered separately. Electrical stimulation of chronic wounds is defined as the application of electrical current through electrodes placed directly on the skin in close proximity to a wound. Electromagnetic therapy of chronic wounds refers to treatment with electromagnetic fields.

**Evidence on Electrical Stimulation for the Treatment of Chronic Wounds**

Since the ECRI technology assessment was published in 1996, CMS performed an additional search of the literature to identify more current evidence on the effectiveness of electrical stimulation for the treatment of chronic pressure, venous, arterial and diabetic wounds. Medline from 1996 to April 2002 was searched iteratively using the following key words: electrical stimulation, electric stimulation or electrotherapy with wound(s) or ulcer(s). Searches were limited to human subjects and English language publications. Only studies that were not included in the ECRI technology assessment and assessed wound healing were reviewed. Four additional articles and a recent technology assessment were found and are summarized below.

In 1996, Baker and colleagues randomly assigned 80 patients (82.5%, age range of 17-76 years) with spinal cord injuries to one of three stimulation groups: group A received asymmetric, biphasic stimulation; group B received symmetric, biphasic stimulation; and group MC received microcurrent stimulation. The control group received the same stimulation procedures but no electrical current was applied. Patients were treated until their ulcers healed, the physician intervened, or the patient withdrew. Electrical stimulation was administered through surface, carbon-rubber electrodes. Three treatment sessions of 30-minute duration were provided daily. A total of 114 wounds were treated. The authors stated that the mean healing rates among the four groups were not significantly different. After combining the MC group with the control group (total of 39 wounds), the authors reported, “the combined control group was statistically slower to heal than the treatment group A.” One-way analysis of variance was used in the analysis of healing rates. Statistical significant was set at a p-value <0.05. Twenty-eight (25%) of the 114 wounds “wound.” Twenty-four (21%) of wounds had a “change of program.” The number of patients that withdrew from the study was not reported. Intent-on-treatment analysis was not used. The results of multivariate analyses to adjust for confounding variables were not presented.

In 1997, Baker and colleagues randomly assigned 80 patients (69% male, age range of 30-82 years) with spinal cord injuries to one of three stimulation groups: group A received asymmetric, biphasic stimulation; group B received symmetric, biphasic stimulation; and group MC received microcurrent stimulation. The control group received the same stimulation procedures but no electrical current was applied. Patients were treated until their ulcers healed, the physician intervened, or the patient withdrew. Electrical stimulation was administered through surface, carbon-rubber electrodes. Three treatment sessions of 30-minute duration were provided daily. A total of 114 wounds were treated. The authors stated that the mean healing rates among the four groups were not significantly different. After combining the MC group with the control group (total of 39 wounds), the authors reported, “the combined control group was statistically slower to heal than the treatment group A.” One-way analysis of variance was used in the analysis of healing rates. Statistical significant was set at a p-value <0.05. Twenty-eight (25%) of the 114 wounds “wound.” Twenty-four (21%) of wounds had a “change of program.” The number of patients that withdrew from the study was not reported. Intent-on-treatment analysis was not used. The results of multivariate analyses to adjust for confounding variables were not presented.

In a 1999 single arm pre-post study of patients with poor response to conventional therapy, Sumano and colleagues reported that 93% of patients experienced greater than 90% recovery of venous ulcers, 62% of patients experienced greater than 90% recovery of diabetic ulcers, and 92% of patients experienced greater than 90% recovery of surgical wounds and burns that had received conventional treatment with unsatisfactory results. Electrical stimulation was applied via electrodes clipped to stainless steel acupuncture filiform needles for 20 minutes. Treatment was applied daily or every other day depending on wound severity until no further progress could be observed (mean treatment = 24.5 days for the most severe wounds). The authors reported that 41 patients (93%) experienced excellent outcomes (>90% recovery); 3 patients (7%) had poor responses (60-90% recovery); and no patients had poor responses (less than 50% recovery).

In 1999, Gardner and colleagues published the results of a meta-analysis on the effect of electrical stimulation on chronic pressure ulcers.
stimulation on chronic wound healing. The authors analyzed 15 studies (9 randomized clinical trials (RCTs), 5 nonrandomized trials, 1 descriptive study), which included 24 electrical stimulation samples and 15 control samples. The type of wounds varied among studies as did the type of stimulation used. The mean percentage healing per week (PHW) was determined for each electrical stimulation (ES) and control (C) sample. The mean PHW was 22.22% (95% confidence interval =18.08-26.35%) for ES samples and 9.10% (95% confidence interval =3.82-14.38%) for control samples for all 15 studies. For blinded, placebo-controlled randomized clinical trials only, the mean PHW was 22.51% (95% confidence interval =15.44-29.58%) for ES samples and 9.01% (95% confidence interval =1.09-16.93%) for control samples. The 95% confidence intervals did not overlap when all 15 studies were analyzed. The 95% confidence intervals did overlap when the analysis included only blinded, placebo-controlled RCTs. The authors stated, “although electrical stimulation produces a substantial improvement in the healing of chronic wounds, further research is needed to identify which electrical stimulation devices are most effective and which wounds respond best to this treatment.”

In 2001, Cullum and colleagues published a technology assessment that was commissioned by the National Health Service Research and Development Health Technology Assessment Programme (NHS R&D HTA). The authors searched 19 databases for the period up to December 1999 and reviewed 16 randomized controlled trials, with the last study published in 1997. The authors reported the following: (1) For the treatment of chronic wounds, “the two small trials identified suggest a benefit associated with electrotherapy compared with sham electrotherapy or no electrotherapy to heal chronic wounds.” (2) For the treatment of venous leg ulcers, “no RCTs (randomized controlled trials) of the use of electrotherapy in treating venous leg ulcers were identified.” (3) For the treatment of ischemic ulcers, no recommendations for practice can be made.” (4) For the treatment of diabetic ulcers, “the one trial identified demonstrated no significant difference in ulcer healing between the intervention and control groups.” (4) For the treatment of pressure ulcers, “the three trials identified suggest a benefit associated with using electrotherapy to treat pressure sores.” The authors concluded: “Further research is required to clarify the relationship between the various physical therapies and chronic wound healing. The most promising physical therapies for further investigation are ultrasound for the treatment of venous leg ulcers and electrotherapy for the treatment of pressure sores.”

**Evidence on Electromagnetic Therapy for the Treatment of Chronic Wounds**

For electromagnetic therapy, ECRI stated the following: (1) “No evidence that PEMF (pulsed electromagnetic field) stimulation improves the healing rate of chronic decubitus or diabetic ulcers.” (2) No evidence that PEE (pulsed electromagnetic energy) stimulation improves the healing rate of chronic venous or diabetic ulcers.” (3) Insufficient data to determine whether PEE stimulation improves the normalized healing rates for stage III or IV decubitus ulcers.”

To identify additional evidence on the effectiveness of electromagnetic therapy for the treatment of chronic wounds since the ECRI report, CMS performed a separate search of the literature. Medline from 1996 to April 2002 was searched iteratively using the following key words: electromagnetic therapy and electromagnetic with wound(s) or ulcer(s). Searches were limited to human subjects and English language publications. Excluding articles reviewed by ECRI, we did not find any new primary research on the effectiveness of electromagnetic therapy on healing of chronic wounds or ulcers. There were 3 review articles that commented on electromagnetic therapy. They are summarized below.

In 1999, Houghton and Campbell authored a review of adjunctive therapies for the treatment of chronic wounds. They evaluated ultrasound, laser, ultraviolet light, superficial heating, pulsed electromagnetic fields and electrical stimulation; and concluded “electrical stimulation and ultrasound are the only therapeutic modalities that currently have sufficient clinical research evidence to support their use in the treatment of chronic wounds.”

In 2000, Sheffet and colleagues authored a review on electric and electromagnetic energy as adjuvant treatment for pressure ulcers. They reported that only moist wound dressings and adjunctive electrotherapy for unresponsive Stage III and IV pressure ulcers “receive high ratings for reported experimental evidence of validity.”

In 2001, HTA technology assessment reported the following: (1) “Only three small trials with a total of 92 patients were identified. These trials provided no evidence of a benefit of electromagnetic therapy for venous leg ulcers.” (2) Two small trials, with a total of 55 patients, were identified. These provide no clear evidence of a benefit of electromagnetic therapy for the treatment of pressure sores.”

**Medicare Coverage Advisory Committee**

On October 17th, 2000 the Medical Surgical Procedures Panel of the Medicare Coverage Advisory Committee (MCAC) met to discuss the topic of electrical stimulation for the treatment of wounds. This panel included nationally recognized experts in clinical and academic medicine, health services research, and ethics. In preparation for this meeting the panel was sent the following materials:

- Technology assessment prepared by ECRI in 1996 and the update to the technology assessment prepared by ECRI in 1997
- Literature review prepared by CMS since the ECRI report
- AHCPR Guidelines on Treatment of Pressure Ulcers
- Bibliography and copies of all articles

During the panel meeting, nine speakers from various organizations made presentations, representing a wide range of interests. These speakers included professional societies, such as the APTA, Association for the Advancement of Wound Care, and physicians. Dr. Rita Frantz, an expert on wound care suggested by the APTA, provided an overview of electrical stimulation for the treatment of wounds.

*As part of the meeting, the panel was asked to vote on a series of questions:*

1. Is the evidence adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy for chronic arterial ulcers?
2. Is the evidence adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy for chronic venous ulcers?
3. Is the evidence adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy for chronic arterial/diabetic ulcers?
In answering these questions, they were asked to consider the following points:

- Adequacy of study design — Is there evidence that the studies do not over or underestimate the effect of the intervention? For example, do patients who received the intervention differ systematically from those in the control group in ways that might affect outcomes? Do studies permit conclusions about the health outcome effects of the technology?
- Consistency of results — Are the results of the studies consistent or are they contradictory?
- Applicability to the Medicare population — Are the results of the studies applicable to the various Medicare populations?
- Expert testimony — Public comments, etc. should be considered with respect to the above considerations.

If the evidence is adequate to draw conclusions about the effectiveness of electrical stimulation as an adjunctive therapy, the panel was then asked what is the size of the overall health effect? If the evidence is found to be adequate the panel must then rate the effectiveness of the evidence.

**Actions of the Panel**

The panel decided to modify the first question to: “Is there adequate evidence to draw conclusions about the effectiveness of electrical stimulation, as an adjunctive therapy for chronic non-healing pressure, venous, and arterial ulcers? The panel decided not to distinguish between the types of wounds. Several panel members believed there was adequate evidence, at least in the aggregate, to draw a conclusion as to the effectiveness of electrical stimulation used for the treatment of chronic, non-healing pressure ulcers. In addition, some members of the panel stated that the evidence is clearly best for pressure sores and that aggregating the data enabled them to vote in the affirmative.

With regards to the second question, the panel concluded that the use of electrical stimulation for the treatment of chronic, non-healing wounds would be considered more effective, which means this intervention “improves health outcomes by a significant, albeit small, margin as compared with established medical items or services.”

**Issue of different types of devices**

At this meeting, CMS decided to defer to the panel’s discretion whether or not to answer the questions separately for each of the different types of electrical stimulation: direct current, pulsed direct current, alternating current or transcutaneous electrical nerve stimulation or pulsed electromagnetic field stimulation.

Dr. Frantz, PhD was recommended by the APTA to give an overview of the role of electrical stimulation in chronic wound healing. Dr. Frantz is a professor of nursing at the University of Iowa. Over the past 12-15 years she has studied the use of electrical stimulation to treat wounds of elderly patients primarily in nursing homes. She has received two NIH funded grants to study the effects of electrical stimulation, specifically TENS, on wound healing.

Dr. Frantz did address the issue of the different types of devices. Dr. Frantz stated that there are primarily four types of devices used to some extent in wound healing. Low intensity direct current, high voltage pulse current and two forms of alternating current — low voltage pulse micro-amperage current and TENS. According to Dr. Frantz, “you do see an occasional reference to the use of electromagnetic fields, it is different than electrical stimulation, which is using current. The research on electromagnetic field has been more limited particularly in humans.....studies done do not provide us with much information about what this electromagnetic field might do in a chronic wound.”

The panel decided not to vote on the various types of delivery systems for electrical stimulation. The panel appeared to believe that it could not get into great detail about the differences between the devices. However, the initial request for coverage filed by APTA proposed that CMS cover Pulsed Current (PC) and Pulsed (non-thermal) Electromagnetic Induction (PEMI) for the treatment of wounds. The panel ultimately concluded that they remained uncertain about whether there are differences in the technologies.

On February 21, 2001 the MCAC Executive Committee met and ratified the recommendations of the Medical/Surgical Procedures Panel. On May 1st, 2001 CMS received signed minutes from the February Executive Committee Meeting.

**CMS Analysis**

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. §§1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” §§ 1862(a)(1)(A).

**Our analysis focused on 4 questions:**

1. Is there evidence on the effectiveness of electrical stimulation on the healing of chronic wounds, such as chronic pressure, venous, arterial and diabetic wounds?
2. Is there evidence on the most effective type of device and form of electrical stimulation?
3. Is there evidence on the optimal duration of treatment with electrical stimulation?
4. Is there evidence on the effectiveness of electromagnetic therapy on healing of chronic wounds?

**Is there evidence on the effectiveness of electrical stimulation on the healing of chronic wounds?**

The evidence on the clinical effectiveness of electrical stimulation in the treatment of chronic wounds has grown substantially since the early 1990’s. Specifically, the studies have focused almost entirely on several types of chronic wounds: pressure ulcers, diabetic ulcers and ulcers due to venous or arterial insufficiency. Also, in their 1994 clinical practice guideline AHCPB, now known as AHRQ, recommended that electotherapy be considered for unresponsive Stage III and IV pressure ulcers (strength of evidence level B).

Since the CMS-commissioned ECRI Technology Assessment, several additional studies, including two randomized clinical trials, have reported a benefit in wound healing with electrical stimulation. In addition, the MCAC Medical Surgical Procedures Panel voted in favor of electrical stimulation for the treatment of chronic wounds in 2000. Lastly, the 2001 NHS technology assessment concluded that there was a benefit associated with electotherapy for chronic wounds. Although, the clinical
after a 30-day period of treatment, electrical stimulation is unlikely to provide benefit. Progressive healing is generally demonstrated by decrease in wound size in surface area or volume, decrease in amount of exudates, and decrease in amount of necrotic tissue.

Is there evidence on the effectiveness of electromagnetic therapy on healing of chronic wounds?

Unlike the situation with electrical stimulation, we did not identify any new studies on the effectiveness of electromagnetic therapy since the ECRI technology assessment. In 1996, ECRI reported that there was no evidence or insufficient data on the clinical effectiveness of electromagnetic therapy. Since then, two published reviews (Houghton and Campbell, Sheffet and colleagues) and the HTA technology assessment have reiterated and reinforced this position. There appears to be at least an informal consensus since all reports had similar conclusions. The paucity of new research and evidence also raises questions about the clinical utility of electromagnetic therapy for the treatment of chronic wounds. Based on these reports, the evidence is adequate to conclude that electromagnetic therapy is not clinically effective, and therefore, not reasonable and necessary, for the treatment of chronic wounds. Thus, Medicare will not cover any form of electromagnetic therapy for the treatment of chronic wounds. Further primary research is needed to fully evaluate this treatment modality.

Decision

Electrical stimulation is defined as the application of electrical current through electrodes applied directly to the skin in close proximity to the ulcer. Based on all of the evidence that we have reviewed in this matter, it is our intention to issue a positive coverage decision only on the use of electrical stimulation for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the treatment of wounds are noncovered. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. Electrical stimulation for the treatment of wounds will not be covered as an initial treatment modality. The use of electrical stimulation will be covered as adjunctive therapy only after there are no measurable signs of healing for at least 30-days of treatment with standard wound therapy and must be used in addition to standard wound care. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes: optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Specific wound care based on type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers and the use of a compression system for patients with venous ulcers. Wounds must be evaluated at least every 30 days during administration of electrical stimulation therapy. Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Medicare will not cover any form of electromagnetic therapy for the treatment of chronic wounds. Electrical stimulation should be discontinued when the wound demonstrates a 100% epithelialized wound bed. Electrical stimulation for wound healing is not covered in the home setting, as unsupervised use by patients in the home has not been found to be medically reasonable and necessary.
Analysis of variance (ANOVA) is a statistical procedure that is often used to compare means between groups. One way ANOVA is the simplest type and allows examination of one factor independent variables. (usually the treatment intervention), but does not permit consideration of other explanatory variables.

2. Ibid.
4. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Before such devices can be marketed, they must have an approved premarket approval application or be reclassified into Class I (general controls) or Class II (standards). Class III transitional devices and "new" devices (described in the paragraph above) are automatically classified into Class III by statute and require premarket approval by FDA before they may be commercially distributed.

5. In addition, lack of FDA approval or clearance for a specific non-labeled indication, when there are other labeled indications, is not an automatic disqualification for Medicare coverage.

6. AHCPR is now known as the Agency for Healthcare Research and Quality (AHRQ).


8. AHCPR defined "B" strength of evidence as: "Results of two or more controlled clinical trials on pressure ulcers in humans provide support, or when appropriate, results of two or more controlled trials in an animal model provide indirect support."

11. Analysis of variance (ANOVA) is a statistical procedure that is often used to compare means between groups. One way ANOVA is the simplest type and allows examination of one factor (usually the treatment intervention), but does not permit consideration of other explanatory variables.

19. The Health Technology Assessment conducted by the National Health Service was not sent to the panel, since it had not yet been published.
21. ECRI, 1996

11. ECRI, 1996.
12. Houghton and Campbell, 1999

Bibliography

- Feedar JA, Kloth LC, Gentzkow GD. Chronic dermal ulcer healing enhanced with monophasic pulsed electrical stimulation. Phys Ther 1991 Sep;71(9):639-49.


• Frantz, RA. Nursing intervention: healing pressure ulcers with TENS. Unpublished.


• Ovington LG. Dressings and ajunctive therapies: AHCPR guidelines revisited. Ostomy/Wound Management 1999;45[Suppl 1A]:94S-106S.


- Unger PG. A controlled study of the effect of high voltage pulsed current (HVPC) on wound healing. Unpublished.


- Zuder D, Stein A. Treatment of venous leg ulcers by low frequency pulsed electrical current (Dermapulse).abstract.
VIII. ANEXO

ANEXO - 1

ETIQUETAS DEL ‘SCIO’ (MEXICO)

ETIQUETA IDENTIFICATIVA

ESPECIFICACIONES TECNICAS

Etiqueta irá fijada en la parte inferior de la caja de interfase del ‘SCIO’.

Medidas: 100 mm alto x 120 mm ancho (Imagen a tamaño real).

Colores: a una (1) tinta. Negra.

Papel: Papel de etiqueta con pegamento en cara posterior de 110 gramos de color blanco.
Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirlo.

CERTIFICADOS VIGENTES

Certificado número 5-088-200-0105 de la Comunidad Europea clase 2A de acuerdo con el anexo II sección 3 de la directiva del consejo 93/42/EEC. Auditoría número 2002/43/62.


ETIQUETA DE SEGURIDAD Y GARANTÍA

Etiqueta irá fijada en cualquiera de los dos costados del ‘SCIO’.

Medidas: 25 mm alto x 60 mm ancho (Imagen a tamaño real).

Colores: a tres (3) tintas. Amarilla, azul y negra.

Papel: Papel de etiqueta plástico con pegamento en cara posterior de 80 gramos de color blanco.
Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su difusión o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla.

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su difusión o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla.
Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla.

QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN
Tel./Fax +34 93 429 88 63
quantumuniverse@biorresonancia.com

TRADUCCIÓN DEL CERTIFICADO DE GESTIÓN DEL SISTEMA –

PÁGINA 1

CERTIFICADO DE SISTEMA DE GESTIÓN DE CALIDAD

Número del certificado: 1-031-901-0312

El ORKI /Instituto de Ingeniería Médica y Hospitalaria/ en su calidad de ente certificador de sistemas de gestión de calidad, acreditado por el Cuerpo Nacional de Acreditación bajo el número NAT-4-0009/2001, certifica que

EL SISTEMA DE GESTIÓN DE CALIDAD DE LA PENTAVOX, S.R.L.
1043 Budapest, Calle Dugonics, 11

cumple con los requisitos de

MSZ EN ISO 9001:2001*

El alcance de la certificación:

Desarrollo y fabricación de aparatos electrónicos, cardiógrafo ambulante de sensor pasivo, sistema universal electrofisiológico


El plazo de vigencia del presente certificado: 30 de diciembre de 2006, desde que las verificaciones de Inspección de sistema, realizadas anualmente por el ente certificador dentro del plazo de vigencia, reporten de resultados satisfactorios.

Budapest, 30 de diciembre de 2003.

(Inicio)

Director General del ORKI

(Inicio)


Instituto de Ingeniería Médica y Hospitalaria
Tel: +36 1 356 1522
Institute for Medical and Hospital Engineering
Fac.: +36 1 357 7253
H-1125 Budapest, Calle Dózsaé, 3.

APOSTILLADO DEL CERTIFICADO DE GESTIÓN DEL SISTEMA

APOSTILLE

(Convención de la Síly, 23 octubre 1961)

1. Origen: MAGYAR KÖZTÁRSASÁG
REPUBLICA DE HONGRIA

2. a) Se firma por:

[CORDÓN DE FIRMAS"

2. b) Se firma en calidad de:

[CORDÓN DE FIRMAS"

3. Lugar:

Budapest

4. Fecha:

en revés, en lo que se refiere a: [ORDEN DE FECHAS"

5. Coherencia:

Attest

6. BUDAPEST

7. Autoridad:

A MAGYAR KÖZTÁRSASÁG Külügyminisztériuma
MINISTERIO DE AFUERAS
DE LA REPÚBLICA DE HONGRIA

8. Uso:

2003, 2, de septiembre, mes.

9. Firma / báculo signatura:

[ORDEN DE FECHAS"

4.580 Ft kincsebb illetékes bérlások
NA MÁSIC. APRIL 2003

A. Attest

László

[CORDÓN DE FIRMAS"

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla.

QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN
Tel./Fax +34 93 429 88 63
quantumuniverse@biorresonancia.com

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla.

QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN
Tel./Fax +34 93 429 88 63
quantumuniverse@biorresonancia.com
This communication is private, confidential and subject to the professional secret (Law 15/1999). It is forbidden its popularization or copy for any means or person different from the address. If you have received it by mistake, it is requested to warn to the originator and to destroy it. QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com

CERTIFICADO DE CONFORMIDAD - ORIGINAL

CERTIFICADO DE CONFORMIDAD - INGLES
Varhope charging the batteries

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla.

QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63
quantumuniverse@biorresonancia.com

This communication is private, confidential and subject to the professional secret (Law 15/1999). It is forbidden its popularization or copy for any means or person different from the address. If you have received it by mistake, it is requested to warn to the originator and to destroy it.

QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN Tel. / Fax +34 93 429 88 63
quantumuniverse@biorresonancia.com
ANEXO - 2

HOJA INFORMATIVA

¿Qué es la Biorresonancia-SCIO?

La Biorresonancia-SCIO es una máquina de electro-magnético y terapia.

El sistema SCIO mide los valores de: resistencia, amperaje, voltaje, capacidad, inductancia, oxigenación y pH del paciente. Este proceso se denomina “CALIBRACION”. Hecho esto el sistema realiza un “TESTAJE” de reactividad, el cual nos permite evaluar y valorar los datos obtenidos. Después del testado, quedan medidos 10.000 parámetros desde el punto de vista electromagnético, a nivel frecuencial, desde el que seleccionaremos las terapias más adecuadas.

Objetivo del estudio

Hacer una estadística de los resultados obtenidos de la calibración, testado y tratamiento con el sistema de Biorresonancia-SCIO en Fibromialgia (FM), con el fin de observar si hay una mejora en la sintomatología del paciente.

Metodología para el paciente

Después de ser valorado el paciente mediante unos cuestionarios, se le colocarán unos electrodos y se le hará la terapia que tendrá una duración entre 1 hora a una hora y media. La terapia se le repitará durante más o menos 5 sesiones. Después volverán los pacientes a rellenar los cuestionarios como unidad de medida, para valorar resultados.

- el tratamiento es relajante
- no es doloroso
- no tiene efectos secundarios
- y no es invasivo

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla.

QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA  Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com
Escala de alexitimia de Toronto

Señale el grado en que estas características se ajustan a su modo de ser habitual. Conteste lo más sinceramente posible, según los siguientes criterios:

A: Muy en desacuerdo
B: En desacuerdo
C: Ligeramente en desacuerdo
D: Ligeramente de acuerdo
E: De acuerdo
F: Muy de acuerdo

1. A menudo estoy confuso con las emociones que estoy sintiendo.
2. Me es difícil encontrar las palabras correctas para mis sentimientos.
3. Tengo sensaciones físicas que incluso ni los doctores entienden.
4. Soy capaz de expresar mis sentimientos fácilmente.
5. Prefiero analizar los problemas mejor que sólo describirlos.
6. Cuando estoy mal no sé si estoy triste, asustado o enfadado.
7. A menudo estoy confundido con las sensaciones de mi cuerpo.
8. Prefiero dejar que las cosas sucedan solas, mejor que preguntarme por qué suceden de ese modo.
9. Tengo sentimientos que casi no puedo identificar.
10. Estar en contacto con las emociones es esencial.
11. Me es difícil expresar lo que siento acerca de las personas.
12. La gente me dice que expreso más mis sentimientos.
13. No sé qué pasa dentro de mí.
15. Prefiero hablar con la gente de sus actividades diarias mejor que de sus sentimientos.
16. Prefiero ver espectáculos simples, pero entretenidos, que dramas psicológicos.
17. Me es difícil revelar mis sentimientos más profundos incluso a mis amigos más íntimos.
18. Puedo sentirme cercano a alguien, incluso en momentos de silencio.
20. Buscar significados ocultos a películas o juegos disminuye el placer de disfrutarlos.

PUNTUACION

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999) 137. Está prohibida su visión o copia por cualquier medio o persona distinta del destinatario. Si la ha recibido por error, se ruega avisar al remitente. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999) 138. Está prohibida su visión o copia por cualquier medio o persona distinta del destinatario. Si la ha recibido por error, se ruega avisar al remitente. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com
A: Muy en desacuerdo  B: En desacuerdo  C: Ligeramente en desacuerdo  
D: Ligeramente de acuerdo  E: De acuerdo  F: Muy de acuerdo

<table>
<thead>
<tr>
<th>Número</th>
<th>Enunciado</th>
<th>Puntuación</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A menudo estoy confuso con las emociones que estoy sintiendo.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>2.</td>
<td>Me es difícil encontrar las palabras correctas para mis sentimientos.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>3.</td>
<td>Tengo sensaciones físicas que incluso ni los doctores entienden.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>4.</td>
<td>Soy capaz de expresar mis sentimientos fácilmente</td>
<td>5 4 3 2 1 0</td>
</tr>
<tr>
<td>5.</td>
<td>Prefiero analizar los problemas mejor que sólo describirlos.</td>
<td>5 4 3 2 1 0</td>
</tr>
<tr>
<td>6.</td>
<td>Cuando estoy mal no sé si estoy triste, asustado o enfadado.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>7.</td>
<td>A menudo estoy confundido con las sensaciones de mi cuerpo.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>8.</td>
<td>Prefiero dejar que las cosas sucedan solas, mejor que preguntarme por qué suceden de ese modo.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>9.</td>
<td>Tengo sentimientos que casi no puede identificar</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>10.</td>
<td>Estar en contacto con las emociones es esencial.</td>
<td>5 4 3 2 1 0</td>
</tr>
<tr>
<td>11.</td>
<td>Me es difícil expresar lo que siento acerca de las personas.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>12.</td>
<td>La gente me dice que exprese más mis sentimientos</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>13.</td>
<td>No sé qué pasa dentro de mí.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>14.</td>
<td>A menudo no sé por qué estoy enfadado.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>15.</td>
<td>Prefiero hablar con la gente de sus actividades diarias mejor que de sus sentimientos.</td>
<td>0 1 2 3 4 5</td>
</tr>
<tr>
<td>16.</td>
<td>Prefiero ver espectáculos simples, pero entretenidos, que dramamas psicológicos.</td>
<td>0 1 2 3 4 5</td>
</tr>
</tbody>
</table>

17. Me es difícil revelar mis sentimientos más profundos incluso a mis amigos más íntimos. | 0 1 2 3 4 5

18. Puedo sentirme cercano a alguien, incluso en momentos de silencio. | 5 4 3 2 1 0

19. Encuentro útil examinar mis sentimientos para resolver problemas personales. | 5 4 3 2 1 0

20. Buscar significados ocultos a películas o juegos disminuye el placer de disfrutarlos. | 0 1 2 3 4 5
CUESTIONARIO DE BECK

INSTRUCCIONES: Rellene los datos anteriores. A continuación se expresan varias respuestas posibles a cada uno de los 21 apartados. Delante de cada frase marque con una cruz el círculo que mejor refleje su situación actual.

1. o Esta tristeza me produce verdaderos sufrimientos
   o No me encuentro triste
   o Ya no puedo soportar esta pena
   o Tengo siempre como una pena encima que no me la puedo quitar

2. o Me siento desanimado cuando pienso en el futuro
   o Creo que nunca me recuperaré de mis penas
   o No soy especialmente pesimista, ni creo que las cosas me vayan a ir mal.
   o No espero nada bueno de la vida
   o No espero nada. Esto no tiene remedio

3. o He fracasado totalmente como persona (padre, madre, marido, hijo, profesional, etc.
   o He tenido pocas cosas que valgan la pena
   o He tenido más fracasos que la mayoría de la gente

4. o Siento que he hecho pocas cosas que valgan la pena
   o No me considero fracasado
   o Veo mi vida llena de fracasos

5. o Ya nada me llena.
   o Me encuentro insatisfecho conmigo mismo.
   o Ya no me divierte lo que antes me divertía.
   o No estoy especialmente insatisfecho.
   o Estoy hartó de todo

6. o Siento que algo malo me puede suceder.
   o Siento que merezco ser castigado.
   o No pienso que esté siendo castigado.
   o Siento que me están castigando o me castigará.
   o Quiero que me castiguen

7. o Presiento que algo malo me puede suceder.
   o Siento que me acuso a mí mismo.
   o Me odio (me desprecio)
   o Estoy acusado de mí.
   o Estoy satisfecho de mí mismo.

8. o No creo ser peor que otros.
   o Me acuso a mí mismo de todo lo que va mal.
   o Me siento culpable de todo lo malo que ocurre.
   o Siento que tengo mucha y muy graves defectos.
   o Me critico mucho a causa de mis debilidades y errores.
9.  
- Tengo pensamientos de hacerme daño, pero no llegaría a hacerlo.
- Siento que estaría mejor muerto.
- Siento que mi familia estaría mejor si yo muriera.
- Tengo planes decididos de suicidarme.
- Me mataaría si pudiera.
- No tengo pensamientos de hacerme daño.

10.  
- No lloro más de lo habitual.
- Antes podía llorar, ahora no lloro ni aún queriéndolo.
- Ahora lloro continuamente. No puedo evitarlo.
- Ahora lloro más de lo normal.

11.  
- No estoy más irritable que normalmente.
- Me irrito con más facilidad que antes.
- Me siento irritado.
- Ya no me irrita ni lo que antes me irritaba.

12.  
- He perdido todo mi interés por los demás y no me importan en absoluto.
- Me intereso por la gente menos que antes.
- He perdido casi todo mi interés por los demás y apenas tengo sentimientos hacia ellos.

13.  
- Ahora estoy inseguro de mí mismo y procuro evitar el tomar decisiones.
- Tomo mis decisiones como siempre.
- Ya no puedo tomar decisiones en absoluto.
- Ya no puedo tomar decisiones sin ayuda.

14.  
- Estoy preocupado porque me veo más viejo y desmejorado.
- Tengo que esforzarme mucho para hacer cualquier cosa.
- No puedo trabajar en nada.
- Necesito un esfuerzo extra para empezar a hacer algo.
- No trabajo tan bien como lo hacía antes.

15.  
- Puedo trabajar tan bien como antes.
- Tengo que esforzarme mucho para hacer cualquier cosa.
- No puedo trabajar en nada.
- Necesito un esfuerzo extra para empezar a hacer algo.
- No trabajo tan bien como lo hacía antes.

16.  
- Duermo tan bien como antes.
- Me despierto más cansado por la mañana.
- Me despierto una o dos horas antes de lo normal y me resulta difícil volver a dormir.
- Tardo una o dos horas en dormirme por la noche.
- Me despierto sin motivos en mitad de la noche y tardó más de 5 horas.

17.  
- Me canso más fácilmente que antes.
- Cualquier cosa que hago me fatiga.
- No me canso más de lo normal.
- Me canso tanto que no puedo hacer nada.

18.  
- He perdido totalmente el apetito.
- Mi apetito no es tan bueno como antes.
- Mi apetito ahora es mucho menor.
- Tengo el mismo apetito de siempre.

19.  
- No he perdido peso últimamente.
20.  
- He perdido más de 2 Kg y ½.
- He perdido más de 5 Kg.
- He perdido más de 7 Kg y ½.
- Estoy tan preocupado por mi salud que me es difícil pensar en otras cosas.
- Estoy preocupado por dolores y trastornos.
- No me preocupa mi salud más de lo normal.
- Estoy constantemente pendiente de lo que me sucede y de cómo me encuentro.

21.  
- Estoy menos interesado por el sexo que antes.
- He perdido todo mi interés por el sexo.
- Apenas me siento atraído sexualmente.
- No he notado ningún cambio en mi atracción por el sexo.

### INVENTARIO DE DEPRESIÓN DE BECK (IDB)

<table>
<thead>
<tr>
<th>NÚMERO</th>
<th>ENTRADA</th>
<th>PUNTUACIÓN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Esta tristeza me produce verdaderos sufrimientos</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>No me encuentro triste</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Me siento algo triste y deprimido</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Ya no puedo soportar esta pena</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Tengo siempre como una pena encima que no me la puedo quitar</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Me siento desanimado cuando pienso en el futuro</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Creo que nunca me recuperaré de mis penas</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>No soy especialmente pesimista, ni creo que las cosas me vayan a ir mal</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No espero nada. Esto no tiene remedio</td>
<td>3</td>
</tr>
</tbody>
</table>

**CORRECCIÓN**

<table>
<thead>
<tr>
<th>APELLIDOS:</th>
<th>NOMBRE:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>EDAD:</th>
<th>FECHA:</th>
</tr>
</thead>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com
3
He fracasado totalmente como persona (padre, marido, madre, etc...)
He tenido más fracasos que la mayoría de la gente
Siento que he hecho pocas cosas que valgan la pena
No me considero fracasado
Veo mi vida llena de fracasos

4
Ya nada me llena
Me encuentro insatisfecho conmigo mismo
Ya no me divierte lo que antes me divertía
No estoy especialmente insatisfecho
Estoy harto de todo

5
A veces me siento despreciable y mala persona
Me siento bastante culpable
Me siento prácticamente todo el tiempo mala persona y despreciable
No me siento culpable

6
Presiento que algo malo me puede suceder.

7
Siento que me están castigando o me castigarán.
Quiero que me castiguen
Estoy descontento conmigo mismo
No me aprecio
Me odio (me desprecio)
Estoy asqueado de mí
Estoy satisfecho de mí mismo

8
No creo ser peor que otros
Me acuso a mí mismo de todo lo que me va mal
Me siento culpable de todo lo malo que ocurre
Siento que tengo muchos y muy graves defectos
Me critico mucho a causa de mis debilidades y errores

9
Tengo pensamientos de hacerme daño, pero no llegaría a hacerlo
Siento que estaría mejor muerto
Siento que mi familia estaría mejor si yo muriera
Tengo planes decididos de suicidarme
Me mataría si pudiera
No tengo pensamientos de hacerme daño

10
No pienso que esté siendo castigado.
No lloro más de lo habitual.
<table>
<thead>
<tr>
<th>Pregunta</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antes podía llorar, ahora no lloro ni aun queriéndolo</td>
<td>3</td>
</tr>
<tr>
<td>Ahora lloro continuamente. No puedo evitarlo</td>
<td>2</td>
</tr>
<tr>
<td>Ahora llora más de lo normal</td>
<td>1</td>
</tr>
<tr>
<td>No estoy más irritable que normalmente</td>
<td>0</td>
</tr>
<tr>
<td>Me irrito con más facilidad que antes</td>
<td>1</td>
</tr>
<tr>
<td>Me siento irritado todo el tiempo</td>
<td>2</td>
</tr>
<tr>
<td>Ya no me irrita ni lo que antes me irritaba</td>
<td>3</td>
</tr>
<tr>
<td>He perdido todo mi interés por los demás y no me importan en absoluto</td>
<td>3</td>
</tr>
<tr>
<td>Me intereso por la gente menos que antes</td>
<td>1</td>
</tr>
<tr>
<td>No he perdido mi interés por los demás</td>
<td>0</td>
</tr>
<tr>
<td>He perdido casi todo mi interés por los demás y apenas tengo sentimientos hacia ellos</td>
<td>2</td>
</tr>
<tr>
<td>Ahora estoy inseguro de mí mismo y procuro evitar el tomar decisiones</td>
<td>1</td>
</tr>
<tr>
<td>Tomo mis decisiones como siempre</td>
<td>0</td>
</tr>
<tr>
<td>Ya no puedo tomar decisiones en absoluto</td>
<td>3</td>
</tr>
<tr>
<td>Ya no puedo tomar decisiones sin ayuda</td>
<td>2</td>
</tr>
<tr>
<td>Estoy preocupado porque me veo más viejo y desmejorado</td>
<td>1</td>
</tr>
<tr>
<td>Me siento feo y repulsivo</td>
<td>3</td>
</tr>
<tr>
<td>No me siento con peor aspecto que antes</td>
<td>0</td>
</tr>
<tr>
<td>Siento que hay cambios en mi aspecto físico que me hacen parecer desagradable (o menos atractivo)</td>
<td>2</td>
</tr>
<tr>
<td>Puedo trabajar tan bien como antes</td>
<td>0</td>
</tr>
<tr>
<td>Tengo que esforzarme mucho para hacer cualquier cosa</td>
<td>2</td>
</tr>
<tr>
<td>No puedo trabajar en nada</td>
<td>3</td>
</tr>
<tr>
<td>Necesito un esfuerzo extra para empezar a hacer algo</td>
<td>1</td>
</tr>
<tr>
<td>No trabajo tan bien como lo hacía antes</td>
<td>1</td>
</tr>
<tr>
<td>Duermo tan bien como antes</td>
<td>0</td>
</tr>
<tr>
<td>Me despierto más cansado por la mañana</td>
<td>1</td>
</tr>
<tr>
<td>Me despierto una o dos horas antes de lo normal y me resulta difícil volver a dormir</td>
<td>2</td>
</tr>
<tr>
<td>Tardo una o dos horas en dormirme por la noche</td>
<td>2</td>
</tr>
<tr>
<td>Me despierto sin motivo en mitad de la noche y tardó en volver a dormirse</td>
<td>2</td>
</tr>
<tr>
<td>Dormirme</td>
<td>2</td>
</tr>
<tr>
<td>Me despierto temprano todos los días y no duermo más de cinco horas</td>
<td>3</td>
</tr>
<tr>
<td>Tardo más de dos horas en dormirme y no duermo más de cinco horas</td>
<td>3</td>
</tr>
<tr>
<td>No logro dormir más de tres o cuatro horas seguidas</td>
<td>3</td>
</tr>
<tr>
<td>Me canso más fácilmente que antes</td>
<td>1</td>
</tr>
<tr>
<td>Pregunta</td>
<td>Puntuación</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>Cualquier cosa que hago me fatiga</td>
<td>2</td>
</tr>
<tr>
<td>No me canso más de lo normal</td>
<td>0</td>
</tr>
<tr>
<td>Me canso tanto que no puedo hacer nada</td>
<td>3</td>
</tr>
<tr>
<td>He perdido totalmente el apetito</td>
<td>3</td>
</tr>
<tr>
<td>Mi apetito no es tan bueno como antes</td>
<td>1</td>
</tr>
<tr>
<td>Mi apetito es ahora mucho MENOR</td>
<td>2</td>
</tr>
<tr>
<td>Tengo el mismo apetito de siempre</td>
<td>0</td>
</tr>
<tr>
<td>He perdido 2’5 kilos</td>
<td>1</td>
</tr>
<tr>
<td>He perdido más de 5 kilos</td>
<td>2</td>
</tr>
<tr>
<td>He perdido más de 7’5 kilos</td>
<td>3</td>
</tr>
<tr>
<td>No me preocupa mi salud más de lo normal</td>
<td>0</td>
</tr>
<tr>
<td>Estoy preocupado por dolores y trastornos</td>
<td>1</td>
</tr>
<tr>
<td>Estoy constantemente pendiente de lo que sucede y de cómo me encuentro</td>
<td>2</td>
</tr>
<tr>
<td>He perdido todo mi interés por el sexo</td>
<td>3</td>
</tr>
</tbody>
</table>

**PUNTUACIÓN TOTAL (P.T.)**...
Institut de Reumatologia Barcelona

CUESTIONARIO DE ANSIEDAD ESTADO-RASGO (STAI)

Nombre y apellidos: .................................................................

Edad........................................... Sexo.................................. Fecha...................................

INSTRUCCIONES: A continuación, encontrará unas frases que se utilizan corrientemente para describirse uno a sí mismo. Lea cada frase y señale la puntuación de 0 a 3 que indique mejor CÓMO SE SIENTE USTED AHORA MISMO, en este momento. No hay respuestas buenas ni malas. No emplee demasiado tiempo en cada frase y conteste señalando la respuesta que mejor describa su situación presente.

1. Me siento calmado
2. Me siento seguro
3. Estoy tenso
4. Estoy contrariado
5. Me siento cómodo (estoy a gusto)
6. Me siento alterado
7. Estoy preocupado ahora por posibles desgracias futuras
8. Me siento descansado
9. Me siento angustiado
10. Me siento confortable
11. Tengo confianza en mí mismo
12. Me siento nervioso
13. Estoy desasosegado
14. Me siento muy “atado” (como oprimido)
15. Estoy relajado
16. Me siento satisfecho
17. Estoy preocupado
18. Me siento aturdido y sobreexcitado
19. Me siento alegre
20. En este momento me siento bien

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla.
Institut de Reumatologia Barcelona

CUESTIONARIO DE ANSIEDAD ESTADO-RASGO (STAI)

Nombre y apellidos ......................................................................................................................................................

Edad ......................................................................... Sexo ........................................................................ Fecha ........................................................................

INSTRUCCIONES: A continuación, encontrará unas frases que se utilizan corrientemente para describirse uno a sí mismo.
Lea cada frase y señale la puntuación de 0 a 3 que indique mejor CÓMO SE SIENTE USTED AHORA MISMO, en este momento. No hay respuestas buenas ni malas. No emplee demasiado tiempo en cada frase y conteste señalando la respuesta que mejor describa su situación presente.

<table>
<thead>
<tr>
<th>Frase</th>
<th>Nada</th>
<th>Algo</th>
<th>Bastante</th>
<th>Mucho</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Me siento calmado</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2. Me siento seguro</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3. Estoy tenso</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Estoy contrariado</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Me siento cómodo (estoy a gusto)</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

6. Me siento alterado

7. Estoy preocupado ahora por posibles desgracias futuras

8. Me siento descansado

9. Me siento angustiado

10. Me siento confortable

11. Tengo confianza en mí mismo

12. Me siento nervioso

13. Estoy desasosegado

14. Me siento muy “atado” (como oprimido)

15. Estoy relajado

16. Me siento satisfecho

17. Estoy preocupado

18. Me siento aturdido y sobreexcitado

19. Me siento alegre

20. En este momento me siento bien

Negativos ✖

positivos ☑
Institut de Reumatologia Barcelona

**ESCALA ANALÓGICA VISUAL DEL DOLOR (EVA)**

NOMBRE: ___________________________ FECHA: ________________

Por favor, en la siguiente línea marque usted el punto donde considera que se sitúa su dolor actual, teniendo en cuenta que el extremo izquierdo sería la ausencia total de dolor, y el extremo derecho un dolor insoportable.

0 1 2 3 4 5 6 7 8 9 10

**HAIQ**

Estamos interesados en saber cómo afecta su enfermedad a su capacidad para funcionar en la vida diaria. Por favor, añada cualquier comentario que le parezca interesante.

**Es usted capaz de ...**

<table>
<thead>
<tr>
<th></th>
<th>Sin dificultad</th>
<th>Con alguna dificultad</th>
<th>Con mucha dificultad</th>
<th>Incapaz de hacerlo</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ¿Vestirse solo incluyendo abrocharse los botones y atar las corbuses de los zapatos?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. ¿Enhebrarse la cabeza?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. ¿Levantarse de una silla sin brazos?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. ¿Acostarse y levantarse de la cama?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. ¿Cortar un filo de caramelo?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. ¿Abrir un cartón de leche nuevo?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. ¿Servirse la bebida?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. ¿Caminar fuera de casa por un terreno lano?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. ¿Subir 5 escalones?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. ¿Levarse y asegurar el cuerpo?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. ¿Sentarse y levantarse del sofá?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. ¿Ducharse?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. ¿Coger un paquete de azúcar de 1 kg. de una estantería colocada por encima de su cabeza?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. ¿Agacharse y recoger ropa del suelo?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. ¿Abrir la puerta de un coche?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. ¿Abrir tareas cerradas que ya antes habían sido abiertas?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. ¿Abrir y cerrar los grifos?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. ¿Hacer los recados y las compras?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. ¿Entrar y salir del coche?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. ¿Hacer tareas de casa como barrer o lavar los platos?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregunta</td>
<td>Sin dificultad</td>
<td>Con alguna dificultad</td>
<td>Con mucha dificultad</td>
<td>Incapaz de hacerlo</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------</td>
<td>----------------------</td>
<td>----------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>1. ¿Vestirse solo incluyendo abrocharse los botones y atarse los cordones de los zapatos?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. ¿Enjabonarse la cabeza?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. ¿Levantarse de una silla sin brazos?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. ¿Acocharse y levantarse de la cama?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. ¿Cortar un filete de carne?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. ¿Abrir un cartón de leche nuevo?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. ¿Servirse la bebida?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. ¿Caminar fuera de casa por un terreno llano?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. ¿Subir cinco escalones?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. ¿Lavarse y asearse todo el cuerpo?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11. ¿Sentarse y levantarse del retrete?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12. ¿Ducharse?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13. ¿Coger un paquete de azúcar de 1 kg de una estantería colocada por encima de su cabeza?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14. ¿Agacharse y recoger ropa del suelo?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15. ¿Abrir la puerta de un coche?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16. ¿Abrir tarros cerrados que ya antes habían sido abiertos?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17. ¿Abrir y cerrar los grifos?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18. ¿Hacer los recados y las compras?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19. ¿Entrar y salir del coche?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20. ¿Hacer tareas de casa como barrer o lavar los platos?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Puntuación total: [0-3]
1. Estudio A

1.1 Tablas y gráficos:

1.1.1 Alexitimia

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>Alexitimia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
</tr>
<tr>
<td>J1</td>
<td>60</td>
</tr>
<tr>
<td>J2</td>
<td>45</td>
</tr>
<tr>
<td>J3</td>
<td>40</td>
</tr>
<tr>
<td>J4</td>
<td>18</td>
</tr>
<tr>
<td>J5</td>
<td>53</td>
</tr>
<tr>
<td>J6</td>
<td>34</td>
</tr>
<tr>
<td>J7</td>
<td>73</td>
</tr>
</tbody>
</table>

### Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th>Rangos</th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEGATIVOS</td>
<td>6</td>
<td>4,50</td>
<td>27,00</td>
</tr>
<tr>
<td>POSITIVOS</td>
<td>1</td>
<td>1,00</td>
<td>1,00</td>
</tr>
<tr>
<td>EMPATES</td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### a. VAR00002 < VAR00001

#### b. VAR00002 > VAR00001

#### c. VAR00002 = VAR00001

### Estadísticos descriptivos

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>25</th>
<th>50 (Mediana)</th>
<th>75</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00001</td>
<td>7</td>
<td>46,1429</td>
<td>17,97617</td>
<td>18,00</td>
<td>73,00</td>
<td>34,0000</td>
<td>45,0000</td>
<td>60,0000</td>
</tr>
<tr>
<td>VAR00002</td>
<td>7</td>
<td>21,0000</td>
<td>14,62874</td>
<td>0,00</td>
<td>46,00</td>
<td>13,0000</td>
<td>18,0000</td>
<td>31,0000</td>
</tr>
</tbody>
</table>
1.1.2 BECK

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>BECK</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
<td>Después</td>
</tr>
<tr>
<td>J1</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>J2</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>J3</td>
<td>14</td>
<td>4</td>
</tr>
<tr>
<td>J4</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>J5</td>
<td>18</td>
<td>9</td>
</tr>
<tr>
<td>J6</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>J7</td>
<td>32</td>
<td>9</td>
</tr>
</tbody>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su ivulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com

---

**Estadísticos descriptivos**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>Percentiles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7</td>
<td>17,1429</td>
<td>7,33550</td>
<td>9,00</td>
<td>32,00</td>
<td>25, 50 (Mediana), 75</td>
</tr>
<tr>
<td>VAR00001</td>
<td>7</td>
<td>8,1429</td>
<td>4,29839</td>
<td>1,00</td>
<td>14,00</td>
<td>4,00 9,000 10,000</td>
</tr>
</tbody>
</table>

**Prueba de los rangos con signo de Wilcoxon**

<table>
<thead>
<tr>
<th></th>
<th>Rangos</th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00002</td>
<td>Rangos negativos</td>
<td>7</td>
<td>4,00</td>
<td>28,00</td>
</tr>
<tr>
<td>VAR00001</td>
<td>Rangos positivos</td>
<td>0</td>
<td>0,00</td>
<td>0,00</td>
</tr>
<tr>
<td></td>
<td>Empates</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>7</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

a. VAR00002 < VAR00001

b. VAR00002 > VAR00001

c. VAR00002 = VAR00001
1.1.4 HAQ

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>HAQ</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
<td>Después</td>
<td>Diferencia</td>
<td></td>
</tr>
<tr>
<td>J1</td>
<td>17</td>
<td>6</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>J2</td>
<td>25</td>
<td>16</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>J3</td>
<td>3</td>
<td>0</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>J4</td>
<td>14</td>
<td>7</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>J5</td>
<td>17</td>
<td>0</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>J6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>J7</td>
<td>29</td>
<td>8</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th>Rangos</th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00002 - VAR00001</td>
<td>6º</td>
<td>3,50</td>
<td>21,00</td>
</tr>
<tr>
<td>Rangos negativos</td>
<td>0º</td>
<td>.00</td>
<td>.00</td>
</tr>
<tr>
<td>Rangos positivos</td>
<td>1º</td>
<td>.00</td>
<td>.00</td>
</tr>
<tr>
<td>Empates</td>
<td>1º</td>
<td>.00</td>
<td>.00</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. VAR00002 < VAR00001
b. VAR00002 > VAR00001
c. VAR00002 = VAR00001

Estadísticos descriptivos

<table>
<thead>
<tr>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>Percentiles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25</td>
</tr>
<tr>
<td>VAR00001</td>
<td>7</td>
<td>15,0000</td>
<td>10,59874</td>
<td>.00</td>
<td>29,00</td>
</tr>
<tr>
<td>VAR00002</td>
<td>7</td>
<td>5,2857</td>
<td>5,90803</td>
<td>.00</td>
<td>16,00</td>
</tr>
</tbody>
</table>
## 1.1.5 STAI

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>STAI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
</tr>
<tr>
<td>J1</td>
<td>31</td>
</tr>
<tr>
<td>J2</td>
<td>23</td>
</tr>
<tr>
<td>J3</td>
<td>27</td>
</tr>
<tr>
<td>J4</td>
<td>44</td>
</tr>
<tr>
<td>J5</td>
<td>30</td>
</tr>
<tr>
<td>J6</td>
<td>31</td>
</tr>
<tr>
<td>J7</td>
<td>50</td>
</tr>
</tbody>
</table>

### Estadísticos descriptivos

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00001</td>
<td>7</td>
<td>33,7143</td>
<td>9,65599</td>
<td>23,00</td>
<td>50,00</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAR00002</td>
<td>7</td>
<td>16,1429</td>
<td>6,74360</td>
<td>4,00</td>
<td>25,00</td>
</tr>
</tbody>
</table>

#### Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00001</td>
<td>7</td>
<td>4,00</td>
<td>28,00</td>
</tr>
<tr>
<td>VAR00002</td>
<td>7</td>
<td>0,00</td>
<td>0,00</td>
</tr>
</tbody>
</table>

- a. VAR00002 < VAR00001
- b. VAR00002 > VAR00001
- c. VAR00002 = VAR00001
Varhope charging the batteries

1.1.6 EVA

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>EVA</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Antes</td>
<td>Después</td>
</tr>
<tr>
<td>J1</td>
<td>5</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>J2</td>
<td>7,5</td>
<td>7</td>
<td>0,5</td>
</tr>
<tr>
<td>J3</td>
<td>8</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>J4</td>
<td>7</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>J5</td>
<td>7</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>J6</td>
<td>8</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>J7</td>
<td>10</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com

Prueba de los rangos con signo de Wilcoxon

Rangos

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00001 - VAR00002</td>
<td>6º</td>
<td>3,50</td>
<td>21,00</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0º</td>
<td>.00</td>
</tr>
<tr>
<td></td>
<td>1º</td>
<td>.00</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. VAR00002 < VAR00001
b. VAR00002 > VAR00001
c. VAR00002 = VAR00001

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario.

Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com
2. Estudio B

1.1 Tablas y gráficos

1.1.1 ALEXITIMIA

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>Alexitimia</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
<td>Después</td>
<td>Diferencia</td>
<td></td>
</tr>
<tr>
<td>C1</td>
<td>62</td>
<td>35</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>C2</td>
<td>55</td>
<td>30</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>C3</td>
<td>52</td>
<td>35</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>C4</td>
<td>24</td>
<td>13</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>C5</td>
<td>19</td>
<td>14</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>N1</td>
<td>38</td>
<td>36</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>N2</td>
<td>23</td>
<td>25</td>
<td>-2</td>
<td></td>
</tr>
<tr>
<td>N3</td>
<td>42</td>
<td>45</td>
<td>-3</td>
<td></td>
</tr>
<tr>
<td>N4</td>
<td>44</td>
<td>54</td>
<td>-10</td>
<td></td>
</tr>
<tr>
<td>N5</td>
<td>54</td>
<td>58</td>
<td>-4</td>
<td></td>
</tr>
</tbody>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgaición o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com

Estadísticos descriptivos

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>25</th>
<th>50 (Mediana)</th>
<th>75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado antes</td>
<td>5</td>
<td>42,400</td>
<td>19,50128</td>
<td>19,00</td>
<td>62,00</td>
<td>21,5000</td>
<td>52,0000</td>
<td>58,5000</td>
</tr>
<tr>
<td>No_conectado antes</td>
<td>5</td>
<td>40,2000</td>
<td>11,27830</td>
<td>23,00</td>
<td>54,00</td>
<td>30,5000</td>
<td>42,0000</td>
<td>49,0000</td>
</tr>
<tr>
<td>Conectado después</td>
<td>5</td>
<td>25,4000</td>
<td>11,05893</td>
<td>13,00</td>
<td>35,00</td>
<td>13,5000</td>
<td>30,0000</td>
<td>35,0000</td>
</tr>
<tr>
<td>No_conectado después</td>
<td>5</td>
<td>43,6000</td>
<td>13,42758</td>
<td>25,00</td>
<td>58,00</td>
<td>30,5000</td>
<td>45,0000</td>
<td>56,0000</td>
</tr>
</tbody>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgaición o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com

Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado después</td>
<td>5</td>
<td>3,00</td>
<td>15,00</td>
</tr>
<tr>
<td>Conectado antes</td>
<td>0</td>
<td>0,00</td>
<td>0,00</td>
</tr>
</tbody>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgaición o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirla. QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com
<table>
<thead>
<tr>
<th></th>
<th>Empates</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No_conectado_después - No_conectado_antes</td>
<td>0°</td>
<td>5</td>
</tr>
<tr>
<td>Rangos negativos</td>
<td>1°</td>
<td>1,50</td>
</tr>
<tr>
<td>Rangos positivos</td>
<td>4°</td>
<td>3,38</td>
</tr>
<tr>
<td>Empates</td>
<td>0°</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

1.1.2 BECK

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>BECK</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
<td>Después</td>
<td>Diferencia</td>
</tr>
<tr>
<td>T1</td>
<td>26</td>
<td>10</td>
<td>16</td>
</tr>
<tr>
<td>T2</td>
<td>20</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>T3</td>
<td>19</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>T4</td>
<td>17</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>T5</td>
<td>18</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>P1</td>
<td>19</td>
<td>19</td>
<td>0</td>
</tr>
<tr>
<td>P2</td>
<td>20</td>
<td>22</td>
<td>-2</td>
</tr>
<tr>
<td>P3</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>P4</td>
<td>24</td>
<td>21</td>
<td>3</td>
</tr>
<tr>
<td>P5</td>
<td>24</td>
<td>28</td>
<td>-4</td>
</tr>
</tbody>
</table>

- a. Conectado_después < Conectado_antes
- b. Conectado_después > Conectado_antes
- c. Conectado_después = Conectado_antes
- d. No_conectado_después < No_conectado_antes
- e. No_conectado_después > No_conectado_antes
- f. No_conectado_después = No_conectado_antes
### Estadísticos descriptivos

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>25</th>
<th>50 (Mediana)</th>
<th>75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado antes</td>
<td>5</td>
<td>20,0000</td>
<td>3,53553</td>
<td>17,00</td>
<td>26,00</td>
<td>17,5000</td>
<td>19,0000</td>
<td>23,0000</td>
</tr>
<tr>
<td>No_conectado antes</td>
<td>5</td>
<td>18,2000</td>
<td>8,25833</td>
<td>4,00</td>
<td>24,00</td>
<td>11,5000</td>
<td>20,0000</td>
<td>24,0000</td>
</tr>
<tr>
<td>Conectado después</td>
<td>5</td>
<td>8,2000</td>
<td>4,20714</td>
<td>1,00</td>
<td>12,00</td>
<td>5,0000</td>
<td>9,0000</td>
<td>11,0000</td>
</tr>
<tr>
<td>No_conectado después</td>
<td>5</td>
<td>18,8000</td>
<td>8,92749</td>
<td>4,00</td>
<td>28,00</td>
<td>11,5000</td>
<td>21,0000</td>
<td>25,0000</td>
</tr>
</tbody>
</table>

**Percentiles**

<table>
<thead>
<tr>
<th></th>
<th>25</th>
<th>50</th>
<th>75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado antes</td>
<td>17,5000</td>
<td>19,0000</td>
<td>23,0000</td>
</tr>
<tr>
<td>No_conectado antes</td>
<td>24,0000</td>
<td>24,0000</td>
<td>24,0000</td>
</tr>
<tr>
<td>Conectado después</td>
<td>5,0000</td>
<td>9,0000</td>
<td>11,0000</td>
</tr>
<tr>
<td>No_conectado después</td>
<td>21,0000</td>
<td>25,0000</td>
<td>25,0000</td>
</tr>
</tbody>
</table>

### Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th></th>
<th>Rangos negativos</th>
<th>Rangos positivos</th>
<th>Empates</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado después - Conectado antes</td>
<td>5°</td>
<td>0°</td>
<td>0°</td>
<td>5</td>
</tr>
<tr>
<td>Conectado después - No_conectado antes</td>
<td>4°</td>
<td>2,00</td>
<td>2,00</td>
<td>5</td>
</tr>
</tbody>
</table>

- **No_conectado antes**
- **Rangos positivos**
  - 2°: 2,00
  - 4°: 4,00
- **Empates**
  - 2°: 
- **Total**: 5
### 1.1.3 HAQ

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>HAQ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
</tr>
<tr>
<td>T1</td>
<td>28</td>
</tr>
<tr>
<td>T2</td>
<td>26</td>
</tr>
<tr>
<td>T3</td>
<td>11</td>
</tr>
<tr>
<td>T4</td>
<td>10</td>
</tr>
<tr>
<td>T5</td>
<td>3</td>
</tr>
</tbody>
</table>

| P1        | 13      | 15      | -2         |
| P2        | 17      | 27      | -10        |
| P3        | 3       | 3       | 0          |
| P4        | 20      | 25      | -5         |
| P5        | 31      | 35      | -4         |

#### Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>Percentiles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado_antes</td>
<td>5</td>
<td>15,6000</td>
<td>10,87658</td>
<td>3,00</td>
<td>28,00</td>
<td>6,5000, 11,0000, 27,0000</td>
</tr>
<tr>
<td>No_conectado_antes</td>
<td>5</td>
<td>16,8000</td>
<td>10,20784</td>
<td>3,00</td>
<td>31,00</td>
<td>8,0000, 17,0000, 25,5000</td>
</tr>
<tr>
<td>Conectado_después</td>
<td>5</td>
<td>2,6000</td>
<td>3,28834</td>
<td>0,00</td>
<td>8,00</td>
<td>0,0000, 2,0000, 5,5000</td>
</tr>
<tr>
<td>No_conectado_después</td>
<td>5</td>
<td>21,0000</td>
<td>12,32883</td>
<td>3,00</td>
<td>35,00</td>
<td>9,0000, 25,0000, 31,0000</td>
</tr>
</tbody>
</table>

### Estadísticos descriptivos

#### HAQ Conectados

#### HAQ No Conectados
<table>
<thead>
<tr>
<th>Conectado_después</th>
<th>Rangos negativos</th>
<th>5'</th>
<th>3,00</th>
<th>15,00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado_antes</td>
<td>Rangos positivos</td>
<td>0'</td>
<td>0,00</td>
<td>0,00</td>
</tr>
<tr>
<td></td>
<td>Empates</td>
<td>0'</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No_conectado_después</th>
<th>Rangos negativos</th>
<th>0'</th>
<th>0,00</th>
<th>0,00</th>
</tr>
</thead>
<tbody>
<tr>
<td>- No_conectado_antes</td>
<td>Rangos positivos</td>
<td>4'</td>
<td>2,50</td>
<td>10,00</td>
</tr>
<tr>
<td></td>
<td>Empates</td>
<td>1'</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Conectado_después < Conectado_antes  

b. Conectado_después > Conectado_antes  
c. Conectado_después = Conectado_antes  
d. No_conectado_después < No_conectado_antes  
e. No_conectado_después > No_conectado_antes  
f. No_conectado_después = No_conectado_antes  

### 1.1.4 STAI

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>STAI</th>
<th>Antes</th>
<th>Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### STAI Conectados

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### STAI No Conectados

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario.**

Si lo ha recibido por error, se ruega avisar al emisor y destruirlo.

QUANTUM UNIVERSE S.L. C/ Paseo Fabra y Puig, 326 Entloº2ª- 08031 BARCELONA - ESPAÑA  
Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com

This communication is private, confidential and subject to the professional secret (Law 15/1999). It is forbidden its popularization or copy for any means or person different from the address. If you have received it by mistake, it is requested to warn to the originator and to destroy it.

QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº2ª- 08031 BARCELONA - SPAIN  
Tel./Fax +34 93 429 88 63 quantumuniverse@biorresonancia.com
### Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th>Rangos</th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado_después - Conectado_antes</td>
<td>4^*</td>
<td>3,50</td>
<td>14,00</td>
</tr>
<tr>
<td>Rangos negativos</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rangos positivos</td>
<td>1^*</td>
<td>1,00</td>
<td>1,00</td>
</tr>
<tr>
<td>Empates</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No_conectado_después - No_conectado_antes</td>
<td>1^*</td>
<td>3,00</td>
<td>3,00</td>
</tr>
<tr>
<td>Rangos negativos</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rangos positivos</td>
<td>3^*</td>
<td>2,33</td>
<td>7,00</td>
</tr>
<tr>
<td>Empates</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Conectado_después < Conectado_antes
b. Conectado_después > Conectado_antes
c. Conectado_después = Conectado_antes
d. No_conectado_después < No_conectado_antes
e. No_conectado_después > No_conectado_antes
f. No_conectado_después = No_conectado_antes

### 2.1.6. EVA

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirlo. QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº 2ª - 08031 BARCELONA - ESPAÑA  Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com

---

### Estadísticos descriptivos

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>25</th>
<th>50 (Mediana)</th>
<th>75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado_antes</td>
<td>5</td>
<td>42,200</td>
<td>8,34865</td>
<td>34,00</td>
<td>55,00</td>
<td>35,0000</td>
<td>41,0000</td>
<td>50,0000</td>
</tr>
<tr>
<td>No_conectado_antes</td>
<td>5</td>
<td>33,600</td>
<td>18,06378</td>
<td>9,00</td>
<td>54,00</td>
<td>15,5000</td>
<td>38,0000</td>
<td>49,5000</td>
</tr>
<tr>
<td>Conectado_después</td>
<td>5</td>
<td>20,600</td>
<td>14,69013</td>
<td>10,00</td>
<td>46,00</td>
<td>10,5000</td>
<td>18,0000</td>
<td>32,0000</td>
</tr>
<tr>
<td>No_conectado_después</td>
<td>5</td>
<td>34,600</td>
<td>17,41551</td>
<td>9,00</td>
<td>55,00</td>
<td>18,0000</td>
<td>40,0000</td>
<td>48,5000</td>
</tr>
</tbody>
</table>

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirlo. QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº 2ª - 08031 BARCELONA - ESPAÑA  Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com

---

### Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th>Rangos</th>
<th>N</th>
<th>Rango promedio</th>
<th>Suma de rangos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conectado_después - Conectado_antes</td>
<td>4^*</td>
<td>3,50</td>
<td>14,00</td>
</tr>
<tr>
<td>Rangos negativos</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rangos positivos</td>
<td>1^*</td>
<td>1,00</td>
<td>1,00</td>
</tr>
<tr>
<td>Empates</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No_conectado_después - No_conectado_antes</td>
<td>1^*</td>
<td>3,00</td>
<td>3,00</td>
</tr>
<tr>
<td>Rangos negativos</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rangos positivos</td>
<td>3^*</td>
<td>2,33</td>
<td>7,00</td>
</tr>
<tr>
<td>Empates</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Conectado_después < Conectado_antes
b. Conectado_después > Conectado_antes
c. Conectado_después = Conectado_antes
d. No_conectado_después < No_conectado_antes
e. No_conectado_después > No_conectado_antes
f. No_conectado_después = No_conectado_antes

### 2.1.6. EVA

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruirlo. QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº 2ª - 08031 BARCELONA - ESPAÑA  Tel./Fax 93 429 88 63 quantumuniverse@biorresonancia.com
<table>
<thead>
<tr>
<th>Pacientes</th>
<th>EVA Conectado</th>
<th>EVA No Conectado</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
<td>Después</td>
</tr>
<tr>
<td>T1</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>T2</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>T3</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>T4</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>T5</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>P1</td>
<td>9</td>
<td>8,5</td>
</tr>
<tr>
<td>P2</td>
<td>8,5</td>
<td>8</td>
</tr>
<tr>
<td>P3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>P4</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>P5</td>
<td>9</td>
<td>9</td>
</tr>
</tbody>
</table>

**Estadísticos descriptivos**

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Media</th>
<th>Desviación típica</th>
<th>Mínimo</th>
<th>Máximo</th>
<th>Percentiles</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25 (Mediana)</td>
</tr>
<tr>
<td></td>
<td>50</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>8,000</td>
<td>7,00</td>
<td>9,00</td>
<td>7,500</td>
<td>8,000</td>
</tr>
<tr>
<td>----------------</td>
<td>---</td>
<td>-------</td>
<td>------</td>
<td>------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>No_conectado_antes</td>
<td>5</td>
<td>7,900</td>
<td>2,19089</td>
<td>4,00</td>
<td>9,00</td>
<td>6,2500</td>
</tr>
<tr>
<td>Conectado_después</td>
<td>5</td>
<td>5,800</td>
<td>2,38747</td>
<td>2,00</td>
<td>8,00</td>
<td>3,5000</td>
</tr>
<tr>
<td>No_conectado_después</td>
<td>5</td>
<td>7,5000</td>
<td>2,00000</td>
<td>4,00</td>
<td>9,00</td>
<td>6,0000</td>
</tr>
</tbody>
</table>

Prueba de los rangos con signo de Wilcoxon

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>No_conectado_después</td>
<td>Rangos negativos</td>
<td>3⁴</td>
</tr>
<tr>
<td>- No_conectado_antes</td>
<td>Rangos positivos</td>
<td>0⁰</td>
</tr>
<tr>
<td></td>
<td>Empates</td>
<td>2¹</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>5</td>
</tr>
</tbody>
</table>

a. Conectado_después < Conectado_antes
b. Conectado_después > Conectado_antes
c. Conectado_después = Conectado_antes
d. No_conectado_después < No_conectado_antes
e. No_conectado_después > No_conectado_antes
f. No_conectado_después = No_conectado_antes
### Índice

<table>
<thead>
<tr>
<th>Capítulo</th>
<th>Página</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. OBJETIVOS GENERALES</td>
<td>6</td>
</tr>
<tr>
<td>II. INTRODUCCIÓN</td>
<td>7</td>
</tr>
<tr>
<td>1. Fibromialgia</td>
<td>7</td>
</tr>
<tr>
<td>1.1. Definición de Fibromialgia</td>
<td>7</td>
</tr>
<tr>
<td>1.2. Aspectos históricos</td>
<td>10</td>
</tr>
<tr>
<td>1.3. Impacto de la Fibromialgia</td>
<td>11</td>
</tr>
<tr>
<td>1.3.1. Etiología de la Fibromialgia</td>
<td>11</td>
</tr>
<tr>
<td>1.3.2. Enfoque psicosocial de la Fibromialgia</td>
<td>12</td>
</tr>
<tr>
<td>1.3.3. Síntomas de la Fibromialgia</td>
<td>13</td>
</tr>
<tr>
<td>1.3.4. Efecto Placebo</td>
<td>16</td>
</tr>
<tr>
<td>1.4. Diagnóstico de la Fibromialgia</td>
<td>17</td>
</tr>
<tr>
<td>1.5. Tratamiento de Fibromialgia</td>
<td>18</td>
</tr>
<tr>
<td>1.6. Tratamiento actual de Fibromialgia con Biorresonancia-SCIO</td>
<td>20</td>
</tr>
<tr>
<td>2. Biorresonancia y Biofeedback</td>
<td>24</td>
</tr>
<tr>
<td>2.1. Teoría del Campo Unificado</td>
<td>25</td>
</tr>
<tr>
<td>2.2. Metodología de la Teoría del Campo Unificado</td>
<td>26</td>
</tr>
<tr>
<td>2.3. Todas las formas de Energía son la misma Energía</td>
<td>28</td>
</tr>
<tr>
<td>2.4. Energía – Espacio – Tiempo</td>
<td>30</td>
</tr>
<tr>
<td>2.5. Las oscilaciones</td>
<td>31</td>
</tr>
<tr>
<td>2.6. Teoría ondulatoria</td>
<td>34</td>
</tr>
<tr>
<td>2.7. Concepto de resonancia</td>
<td>35</td>
</tr>
<tr>
<td>2.8. El ser humano desde una perspectiva energética</td>
<td>37</td>
</tr>
<tr>
<td>2.8.1. Aplicaciones prácticas</td>
<td>40</td>
</tr>
<tr>
<td>2.9. Definición de Biorresonancia</td>
<td>41</td>
</tr>
<tr>
<td>2.10. Definición de Biofeedback</td>
<td>42</td>
</tr>
</tbody>
</table>
3. Sistema de Bioresonancia, Biofeedback-SCIO
   3.1. Aparato “epfx / SCIO” 43
   3.2. Sistema trivectorial de medición 44
   3.3. Principios científicos del sistema de Biofeedback-SCIO 46
   3.4. Especificaciones Técnicas 51
   3.5. Efecto “xrroid” 54
   3.6. Componentes del sistema de Bioresonancia-SCIO 56

3.1. Aparato “epfx / SCIO” 43
3.2. Sistema trivectorial de medición 44
3.3. Principios científicos del sistema de Biofeedback-SCIO 46
3.4. Especificaciones Técnicas 51
3.5. Efecto “xrroid” 54
3.6. Componentes del sistema de Bioresonancia-SCIO 56

2. Estudio B 79
   2.1 Tablas y gráficos 79

II. MATERIAL Y MÉTODOS 61
1. Aparatología 61
2. Testado de Pacientes 61

III. III. MATERIAL Y MÉTODOS 61
1. Aparatología 61
2. Testado de Pacientes 61
3. Estudio A 61
   3.1. Diseño General del Estudio 61
   3.2. Selección y tamaño de la muestra 62
   3.3. Desarrollo del estudio 62
3.4. Estudio B 64
   4.1 Diseño General del Estudio 64
   4.1.1. Primer grupo 64
   4.1.2. Segundo grupo 65
   4.2. Selección y tamaño de la muestra 65
   4.2.1. Primer grupo 65
   4.2.2. Segundo grupo 65
   4.3. Desarrollo del estudio 65

IV. RESULTADOS 68
1. Estudio A 68
   1.1 Tablas y Gráficos 68
   1.1.1. Alexitimia 68
   1.1.2. BECK 70
   1.1.3. HAQ 72
   1.1.4. STAI 74
   1.1.5. EVA 76

V. DISCUSION DEL ESTUDIO 95
VI. CONCLUSIONES 103
1. Generales 103
2. Estudio A 103
3. Estudio B 103

VII. BIBLIOGRAFÍA 105
VIII. ANEXO 109

I. OBJETIVO GENERALES
Efectuar la validación en la eficacia del sistema de Bioresonancia en Biofeedback-SCIO para restablecer a un paciente de Fibromialgia de forma holística englobando la incapacidad para sentir y expresar emociones, el estado depresivo, de ansiedad, la capacidad funcional, el dolor y su percepción.

Debido al carácter que le confiere a este trabajo, el estatus de tesina, comprendemos que no hemos efectuado una validación con un carga muestral suficientemente amplia, pero esperamos poderlo realizar para presentarlos con la evidencia muestral y estadística apropiada en la lectura de la tesis que esperamos sea el resultado final de esta tesina.

Pretendemos, del mismo modo:
1. Evaluar los diferentes síntomas de un Síndrome de Fibromialgia de modo individual.
2. Valorar dichos síntomas con un sistema de medición electromagnética tisular, SCIO.
3. Evaluar los resultados de dichos síntomas reflejados en el software del sistema después de testar al paciente.
4. Buscar las frecuencias más alteradas de cada paciente en cada testaje.
5. Efectuar el tratamiento adecuado, dado los resultados anteriores, escogiendo la terapia de Biofeedback y/o de Bioresonancia.
6. Comparar los resultados anteriores al estudio y posteriores al mismo.

II. INTRODUCCIÓN

1. FIBROMIALGÍA

1.1. Definición de Fibromialgia

Aunque cada vez se hacen más estudios y se publican más artículos sobre Fibromialgia (FM), la verdad es que en términos masivos es poco conocida tanto por profesionales médicos, fisioterapeutas, psicólogos y lo que es peor, por el paciente que la sufre.

Para un/a paciente de Fibromialgia el dolor físico crónico, el dolor psíquico y la fatiga indescriptible, son sus eternos compañeros. La mayoría de pacientes diagnosticados son mujeres en un porcentaje del 80 a 90%. En España la padecen entre el 2 al 4% de la población lo que supone que habrá entre 500.000 y 1.500.000 personas con Fibromialgia diagnosticadas.

Aunque no es una "enfermedad nueva", se empezó a utilizar el término de Fibromialgia introduciéndose dentro de la literatura médica en 1984 1 como "un trastorno de la regulación dolorosa de etiología desconocida, que cursa con dolor amplio, generalizado, de origen idiopático, a menudo asociado a trastornos de tipo psíquico y que no puede ser explicado por trastornos degenerativos o inflamatorios de origen musculo-esquelético".

El Síndrome de Fibromialgia es una de las causas más comunes de dolor crónico músculo esquelético y su reconocimiento en clínica no es fácil, ya que la mayoría de las veces antes de pensar en la Fibromialgia el médico tiene que descartar otras enfermedades que comparten características con ella: poli mialgia, poliomiositis, poli artritis reumatoide, hipotiroïdismo, hiperparatiroidismo, síndrome de la fatiga crónica, síndrome doloroso miofascial, polineuropatía diabética, osteomalacia...

Está considerada dentro de las enfermedades reumáticas. Los mecanismos fisiopatológicos de esta entidad aún no están claramente definidos y no existe hasta el momento actual una teoría que explique todos los aspectos patogénicos implicados. La Fibromialgia ha sido enfocada desde varios puntos de vista en diversos estudios científicos que van desde alteraciones genéticas,2 hasta alteraciones de neurotransmisores en el sistema nervioso central y autonómico3.

Desde 1992 que la Organización Mundial de la Salud (OMS)4 reconoció la Fibromialgia como un Síndrome con entidad propia, catalogada dentro de los reumatismos de las partes blandas y caracterizada por dolores difusos y puntos dolorosos diana, hasta nuestros días se han realizado múltiples estudios y ensayos científicos donde se ha demostrado que es algo más que reumatismo de partes blandas. En la actualidad se trata de una manera multidisciplinar.

Previo al reconocimiento de la OMS, un comité del American College of Rheumatology5 propuso como criterios de clasificación dolor crónico generalizado conti en más de tres meses de evolución y dolor exagerado a la palpación por lo menos en once de los dieciocho puntos simétricos. La presión digital se tiene que ejercer con una fuerza de unos cuatro kilos y la reacción debe de ser de dolor intenso no sólo de una mayor sensibilización. A estos puntos se les denominó “Tender Points” o “Puntos Sensibles”, (que no deben confundirse con “los Puntos Gatillo”) y son los siguientes:

...
Con todo ello llegamos a la conclusión que la FM tiene dos características principales:

1. Dolor crónico generalizado de forma continua que puede llegar a inmovilizar a los pacientes, sobre todo por las mañanas. En medicina hablamos de dolor crónico, cuando hace por lo menos seis meses que está presente.

2. Dolor producido por un estímulo que en principio no sería doloroso, y la “alodinia” que es esa sensación de dolor que se produce cuando se realiza un estímulo que normalmente no debería producir dolor.

3. Con todo ello, al principio los médicos no estaban seguros de qué se trataba. Al mismo tiempo en Europa, publicaciones médicas alemanas, francesas e inglesas describían que algunos pacientes que tenían esos mismos síntomas, sufrían además un dolor exagerado a la palpación de ciertas zonas. Se creía que era debido a una irritación de la columna. Con lo que se determinó que existía una forma de reumatismo muscular no deformante, en la cual el dolor se acompañaba de hiper sensibilidad al presionar ciertas zonas produciendo una irradiación del dolor.

4. En el siglo XX se empezó a utilizar el término “fibrositis” para definir la inflamación del tejido fibroso. Este término podía incluir todo lo que supusiera un dolor muscular fuera cual fuera la causa que lo produjera, pudiendo ser hechos aislados. En aquellos años se pensaba que la causa del dolor radicaba en una inflamación localizada dentro de los músculos y de los tejidos fibrosos. Con todo ello, los médicos ingleses, canadienses y americanos decidieron utilizar el nombre de “fibrosis” para designar los dolores en general.

5. Posteriormente tras biopsias de los tejidos musculares doloridos, se observó que éstas no tenían signos de inflamación en un grupo numeroso de pacientes que acudían a consulta por molestias y dolores musculares difusos. La opinión médica fue, que ya no había pruebas que justificaran sus síntomas, posiblemente fuera porque la enfermedad era imaginaria y algunos médicos llegaron a diagnosticar a sus pacientes de “reumatismo psicógeno”.

6. Pero la realidad es otra. Existen publicaciones médicas americanas del año 1800, donde se describen a un tipo de pacientes, generalmente mujeres, que reúnen ciertos síntomas como fatiga, la disminución del tono nervioso, la inapetencia y la alteración del estado general. A este tipo de disfunción se le denominó “neurastenia”.

7. Al mismo tiempo en Europa, publicaciones médicas alemanas, francesas e inglesas describen que algunos pacientes que tenían esos mismos síntomas, sufrían además un dolor exagerado a la palpación de ciertas zonas. Se creía que era debido a una irritación de la columna. Con lo que se determinó que existía una forma de reumatismo muscular no deformante, en la cual el dolor se acompañaba de hiper sensibilidad al presionar ciertas zonas produciendo una irradiación del dolor.

8. En el siglo XX se empezó a utilizar el término “fibrositis” para definir la inflamación del tejido fibroso. Este término podía incluir todo lo que supusiera un dolor muscular fuera cual fuera la causa que lo produjera, pudiendo ser hechos aislados. En aquellos años se pensaba que la causa del dolor radicaba en una inflamación localizada dentro de los músculos y de los tejidos fibrosos. Con todo ello, los médicos ingleses, canadienses y americanos decidieron utilizar el nombre de “fibrosis” para designar los dolores en general.

9. Posteriormente tras biopsias de los tejidos musculares doloridos, se observó que éstas no tenían signos de inflamación en un grupo numeroso de pacientes que acudían a consulta por molestias y dolores musculares difusos. La opinión médica fue, que ya no había pruebas que justificaran sus síntomas, posiblemente fuera porque la enfermedad era imaginaria y algunos médicos llegaron a diagnosticar a sus pacientes de “reumatismo psicógeno”.

Queremos decir con ello, que los enfermos de Fibromialgia son más sensibles al dolor que las personas sanas, en cualquier lugar que se les presione. Según Goldenberg, “corrobora la idea de que el principal factor del dolor es el sistema nervioso central, más que el sistema músculo esquelético... De este modo se entiende el motivo por el cual la mayoría de personas con Fibromialgia, padecen dolores intestinales, en la vesícula biliar y en la pelvis”.
Pero no fue hasta 1970 aproximadamente, que un grupo de investigadores en Toronto señaló una serie de puntos dolorosos específicos, además del cansancio y las alteraciones del sueño. En el año 1981 como reconocimiento a la ausencia de fenómenos inflamatorios, se cambió el nombre de fibrosis, inflamación del tejido fibroso, por Fibromialgia, dolor en los músculos y tejido fibroso, hasta que en 1987, después de numerosos estudios científicos, se reconoció la existencia de la Fibromialgia como una entidad clínica.

Finalmente en 1992 la Organización Mundial de la Salud (OMS) reconoció a la Fibromialgia como un Síndrome con entidad propia y desde entonces han aumentado los estudios que se realizan para determinar la causa y para paliar los síntomas que se vuelven muy difíciles de soportar para el paciente que sufre dicho Síndrome.

1.3 Impacto de la Fibromialgia

1.3.1 Etiología de la Fibromialgia

Según nuestra experiencia, siempre hay más de una causa en cualquier condición de mala salud. El problema estriba en encontrarlas.

Aunque todavía no se conocen los mecanismos ni las causas que provoca la Fibromialgia, sí que como resultado de múltiples estudios, empiezan a coincidir unos puntos comunes:

- El riesgo de desarrollar la enfermedad la familia directa del paciente es de 8,5 veces mayor que en otros grupos, así como que sus implicados tienen connotaciones similares, no solo en la salud física, sino también en la psicológica. Todo ello nos lleva a una posible base genética. Hay estudios que indican que algunos fenotipos genéticos son más frecuentes en los enfermos con Fibromialgia, como puede ser el caso del gen que regula la enzima catecol-o-metil-transferasa situado en el cromosoma 22 y ligado a la inactivación de la dopamina y las catecolaminas. Otros investigadores relacionan la Fibromialgia con el gen que altera la producción de serotonina como causante de la depresión.

- Algunos estudios nos muestran posibles alteraciones comunes en los pacientes con Fibromialgia como son algunas alteraciones del eje hipotalamo-hipofisoadrenal (HHA), lo cual justificaría las alteraciones endocrinas en un buen porcentaje de pacientes, pero en este caso estaríamos hablando de consecuencias e no de causa probable.

- Otra posible consecuencia es la alteración o desequilibrio del Sistema Nervioso Autónomo. Algunos estudios nos muestran posibles alteraciones en los pacientes con Fibromialgia como son algunas alteraciones del eje hipotalamo-hipofisoadrenal (HHA), lo cual justificaría las alteraciones endocrinas en un buen porcentaje de pacientes, pero en este caso estaríamos hablando de consecuencias e no de causa probable. Otros estudios relacionan la Fibromialgia con el gen que altera la producción de serotonina como causante de la depresión.

1.3.2 Enfoque psicosocial de la Fibromialgia

En resumen podemos decir que la Fibromialgia es un Síndrome (un conjunto de signos y síntomas) que ocasiona dolores generalizados en todos los músculos, tendones y ligamentos del cuerpo. Los que sufren esta patología se quejan de que “les duele todo desde dentro”. Sienten un fuerte dolor en músculos y articulaciones, acompañado de una sensación de quemazón y/o fatiga muscular, incluidos los músculos de los ojos. Siempre están agotados y cansados, y el dolor puede llegar a ser invalidante. Los enfermos de Fibromialgia tienen dificultad para conciliar el sueño, que es ligero y superficial y nunca lo bastante profundo para ser reparador.

Si la Fibromialgia se presenta como alteración única la llamaremos Fibromialgia primaria y si se presenta asociada a otras enfermedades o alteraciones, la llamaremos secundaria o concomitante.

Síntomas asociados a la Fibromialgia:

- **Fibromialgia primaria**
  - Dolor: Es un dolor difuso, mal delimitado, que afecta a un amplio porcentaje de músculos y articulaciones, que aparece sin causa aparente. El dolor puede ser constante o intermitente, y puede ser de intensidad leve a severa. Algunos médicos todavía hoy en día, no consideran que la Fibromialgia sea una enfermedad “seria”. Es más, con frecuencia los mismos familiares dudan de la veracidad de unas molestias que el enfermo refiere, puesto que el médico les informa que las pruebas analíticas y de imagen, son normales.
  - Hay diferentes opiniones de si es positivo decir al paciente que tiene Fibromialgia o no. En principio el paciente de Fibromialgia no tiene por qué ser hipochondriaco. Este aspecto lo tiene que valorar el clínico. La experiencia nos dice que por norma general, muchos pacientes con Fibromialgia tienen mucho ganado si reciben una explicación comprensible sobre la naturaleza de su proceso para así poder aceptar sus propias limitaciones y adaptarse a un nuevo estilo de vida. La búsqueda, el peregrinaje por los diferentes especialistas para saber qué tengo y qué me pasa ya lo ha resuelto y con ello, es cuestión de adaptarse y concienciarse a la nueva situación.

- **Fibromialgia secundaria o concomitante**
  - Síntomas asociados a la Fibromialgia:
    - **Dolor**: Es un dolor difuso, mal delimitado, que afecta a un amplio porcentaje de músculos y articulaciones, que aparece sin causa aparente. Algunos médicos todavía hoy en día, no consideran que la Fibromialgia sea una enfermedad “seria”. Es más, con frecuencia los mismos familiares dudan de la veracidad de unas molestias que el enfermo refiere, puesto que el médico les informa que las pruebas analíticas y de imagen, son normales.
    - Hay diferentes opiniones de si es positivo decir al paciente que tiene Fibromialgia o no. En principio el paciente de Fibromialgia no tiene por qué ser hipochondriaco. Este aspecto lo tiene que valorar el clínico. La experiencia nos dice que por norma general, muchos pacientes con Fibromialgia tienen mucho ganado si reciben una explicación comprensible sobre la naturaleza de su proceso para así poder aceptar sus propias limitaciones y adaptarse a un nuevo estilo de vida. La búsqueda, el peregrinaje por los diferentes especialistas para saber qué tengo y qué me pasa ya lo ha resuelto y con ello, es cuestión de adaptarse y concienciarse a la nueva situación.
con el grado de actividad, cambios de tiempo, sueño insuficiente o el estrés. El dolor crónico activa una serie de procesos en el que intervienen diversas zonas del cerebro los cuales alteran los niveles psico-emocionales e incluso la memoria y el aprendizaje.

- **Rigidez**: Se produce principalmente al levantarse por las mañanas o cuando hay cambios de tiempo bruscos, sobre todo de cara al invierno.

- **Acroparestiasis**: de forma difusa en extremidades, sobre todo en manos.

- **Fatiga**: Sienten que se les ha agotado la energía (“estoy como si me hubieran dado una paliza” “se me han agotado las pilas”). La fatiga puede ser física y mental o bien las dos al mismo tiempo.

- **Trastornos del sueño**: La mayoría de pacientes se quejan de levantarse más cansados de lo que se han acostado. El sueño no es reparador. Esta alteración ha sido bien registrada por estudios electroencefalográficos. Los pacientes de Fibromialgia llegan con más dificultad y duran menos el estadio IV de la fase no REM. En esta fase es donde podemos observar el cincuenta por ciento de ondas Delta y es la fase del sueño profundo reparador. En el caso de los enfermos de Fibromialgia decimos que, su sueño profundo se ve constantemente interrumpido por actividad cerebral de tipo ondas alfa, es decir, es como si se despertaran parcialmente, tuvieran pesadillas toda la noche incluso con sobrealtos-descortezantes, pues estas ondas son las que mantienen la situación de alerta del cerebro y no deberían estar presentes en esta fase profunda del sueño. Se han hecho estudios con personas sanas a las que se les ha interrumpido el sueño en momentos paralelos a los electroencefalogramas de las Fibromialgias, consiguiendo que al cabo de varios días las personas sanas sometidas al estudio desarrollaran síntomas de Fibromialgia. No se sabe si la presencia de estas ondas alfa está relacionada con la causa de la enfermedad o es consecuencia de la misma. Algunas personas con Fibromialgia tienen otros síntomas asociados a éste, tales como apnea nocturna, mioclonías del sueño y bruxismo.

- **Dolor de cabeza**: pueden sufrir de procesos migrañosos, tensionales, cefaleas y dolor posterior de ojos, con alteración de la visión.

- **Síndrome temporomandibular**: dolor exagerado en la zona de las cervicales, hombros, cabeza y mandíbula. Se cree que el problema es el tejido blando que envuelve a esta articulación, no a la articulación en sí.

- **Trastornos digestivos**: molestias en estómago a una exploración normal, intestino irritable con estadios menores de estreñimiento alternado con diarrea, dolor abdominal, gases y náuseas. Candidas intestinales, en quienes hay un 10% de fluctuaciones de las concentraciones de azúcar en sangre, 60% de sensibilidad por la paracetamol, 80% de menopausia menores de 40 años y 90% de menopausia mayores de 40 años, hecho que ha sido bien documentado por estudios electroencefalogramas de las Fibromialgias, consiguiendo que al cabo de varios días las personas sanas sometidas al estudio desarrollaran síntomas de Fibromialgia. No se sabe si la presencia de estas ondas alfa está relacionada con la causa de la enfermedad o es consecuencia de la misma. Algunas personas con Fibromialgia tienen otros síntomas asociados a éste, tales como apnea nocturna, mioclonías del sueño y bruxismo.

- **Vejiga irritable**: experimentan una necesidad de evacuar la vejiga sin poder aguantar, sin que tengan ningún tipo de infección. Tienen también la sensación de estar excitados sexualmente pero las relaciones son dolorosas y las tienen que interrumpir. Sensación de placer-dolor.

- **Dolores de pecho**: estos dolores que a veces se confunden con cardiopatías, se les llama costocordialgia el cual se sitúa en la unión de las costillas y el esternón.

- **Alteraciones cognitivas y de memoria**: Falta de concentración, lapsos de memoria, falta de coordinación al hablar o al escribir, torpes, aturdidos. Esto puede variar de un día para otro.

- **Desequilibrio**: algunos pacientes sobre todo al cambiar de postura, sienten mareos, desequilibrio y alteraciones de la coordinación motora.

- **Sensibilidad exagerada**: intolerancias alimentarias a alimentos que antes toleraba bien, alteración ante el ambiente, la luz, el ruido y a los olores. Cuando aumenta la humedad o el frío, los dolores son agudos o subagudos. Entendemos por dolor agudo al que dura menos de quince días y subagudo al que dura más de quince días y menos de seis meses.

- **Manos y pies fríos**: Frío irracional en las extremidades que pueden estar acompañadas por cambio de color en la piel de pies y manos debido a un trastorno de la circulación (posible Síndrome de Raynaud). Acroarritmias, hormigüeos, calambres musculares y hinchazón en las piernas.

- **Depresión o ansiedad**: en muchos pacientes estos síntomas son secundarios a la Fibromialgia por lo que significa socialmente o al estado de tensión y tristeza que produce estar siempre con dolor sin poder organizar nada con tu vida.

- **También puede haber**: menstruación dolorosa, síndrome de los ojos secos, boca seca, alteraciones de la visión como ya hemos dicho anteriormente, síntomas menopáusicos exacerbados, con sofoques intensos y desequilibrios hormonales (alteraciones del hipotálamo y/o del Sistema Nervioso Parasimpático).

### 1.3.4 Efecto placebo.

El efecto placebo es la mejora que obtienen algunas personas a la ingesta de cápsulas o inyectables de sustancias que no contienen principio activo alguno. A dichas sustancias las llamamos placebo.

Cuando una persona inicie una sustancia o es sometida a una terapia encubierta que le va a ir bien, lo normal es que en el treinta por ciento de los casos el placebo funcione con respecto a la disminución de los síntomas en mayor o menor grado.

Del mismo modo, cuando un paciente acude a un médico y tras hacerle una breve exposición percibe que el médico le está atendiendo mirándole a los ojos y entendiendo, cuando éste le explica el tratamiento que le va a pautar, las normas que tiene que seguir y le da seguridad en el diagnóstico y en el pronóstico, el paciente sale del despacho con el convencimiento que está mejor y que va a superar el trance por el que está pasando. Por el contrario, si el médico no le deja que le explique, no le pregunta, presupone qué es lo que tiene y aunque el facultativo haya llegado a la misma conclusión en el diagnóstico y tratamiento que el anterior médico, el paciente no percibe su seguridad, cuando salga del despacho, seguramente tirará las recetas, se...
sentirá mal pensando que no tiene quién le ayude y aunque haga el tratamiento, al no hacerlo convencido, no obtendrá el resultado que obtendrá el primer paciente. Según todo lo anterior, también el médico produce efecto placebo en el paciente.

Se ha comprobado que el hecho de explicar al paciente en qué punto de su enfermedad está y cómo se va a llevar dicho cuadro, mejora la sintomatología del mismo. Esto tiene mucha importancia en la Fibromialgia por todas las variables que el cuadro representa. Los beneficios del efecto placebo son variables en el tiempo ya que pueden durar un minuto o años. Hay que tener en cuenta que el efecto placebo funciona porque se activa la función de las endorfinas.

La buena relación médico-paciente en donde exista entendimiento y confianza mutua, es la mejor base para garantizar el máximo de mejoría.

1.4 Diagnóstico de la Fibromialgia

No es fácil diagnosticar la Fibromialgia con tantos diagnósticos diferenciales y tantas variables. Estamos de acuerdo con el Dr. Martínez-Lavín en que para entender enfermedades como la Fibromialgia, es fundamental adoptar un modelo médico integral u “holístico” que considere al ser humano como una unidad biopsicosocial.

La Fibromialgia es un cuadro que aún hoy en día, tiende a confundir al profesional de la medicina, ya que casi todos sus síntomas son comunes a otras patologías. Lo normal cuando una persona se siente enferma es que el primer síntoma que le hace frenar de su vida cotidiana, sea el dolor. De inmediato o tras recetarle en AP (Atención Primaria) un antiinflamatorio, es que lo deriven a traumatología donde le harán las pruebas pertinentes, las cuales saldrán normales. Mientras dure este proceso (el cual muchas veces es largo en el tiempo), el paciente se siente más sensible emocionalmente e irritable, síntomas que trascienden así mismo en su trabajo, en su vida social y sobre todo, en la familia. Al mismo tiempo tiene problemas digestivos y lo envían al digestólogo (pruebas), no duerme bien y todas las pruebas salen normales, se le deriva al neuropsiquiatra (medicación, pruebas)... y el proceso sin encontrar un diagnóstico aceptable hace que el paciente se sienta cada vez con más ansiedad e inseguridad a la vez que hundido ya que aunque tiene mucho dolor y malestar, nadie le cree. Y esto sin tener en cuenta que en las pruebas de TAC o RNM encuentren una protusión discal por ejemplo, y le operen creyendo que ésa era la causa.

Cuando estudiaba en la Facultad, el Prof. de Pediatría nos explicaba que para diagnosticar a un niño hay que escuchar a la madre y que en el ochenta por ciento de las veces, la madre nos daba el diagnóstico de su hijo o una “pista” acertada que ayudará en el diagnóstico. En el caso de la Fibromialgia, el diagnóstico vendrá en un ochenta por ciento del historial clínico. Tenemos que dedicarle tiempo a nuestro paciente e irlo guiando para que nos expliquen no solamente los sitios donde les duele sino también hacerles una batería de preguntas para extraer la información que consideremos más necesaria y válida para el tratamiento del paciente en cada etapa. De este modo el clínico obtendrá la información y el paciente la confianza de que le están haciendo un estudio completo.

1.5 Tratamientos de la Fibromialgia

Como en todos los casos donde no se sabe la causa, no existe un tratamiento único y eficaz.

Lo que sí tenemos que tener claro es que el paciente debe saber qué le pasa, qué tiene y que debe colaborar para que su calidad de vida sea lo mejor posible. Como dice el Dr. Martínez-Pintor, “Si el médico no es capaz de transmitir al paciente que para su curación tiene que utilizar el cien por ciento de sus energías, de su fuerza, de sus ganas de ponerse bien; si no es capaz de transmitirle eso, entonces estaremos haciendo una medicina sesgada, farmacológica, “pastillera”. Necesitamos la colaboración del paciente. Ningún paciente con una enfermedad dolorosa crónica se cura, y si ni siquiera mejora, si no pone todo su esfuerzo y toda su energía”.

El tratamiento está dirigido a cada paciente de modo personalizado y mirará de paliar la sintomatología que le invalida. No existe ningún medicamento específico para la Fibromialgia que haya estado aprobado por la Agencia Europea del Medicamento o la Food and Drug Administración estadounidense.

Por ello, para la Fibromialgia se utiliza un tipo de tratamiento que no es curativo sino que pretende ser preventivo de unos síntomas y patológico de otros.

1. Tratamiento Farmacológico

- **Antinflamatorios y analgésicos**: Hay estudios que afirman una moderada reducción del dolor de antiinflamatorios no esteroides (AINES) con Alprazolam. No existe evidencia de la eficacia en el tiempo por lo que se considera que sus efectos iniciales pueden estar sujetos al efecto placebo.

- **Relajantes musculares**: No existe evidencia de la eficacia en el tiempo por lo que se considera que sus efectos iniciales pueden estar sujetos a efecto placebo.

- **Antidepresivos tricíclicos**: que se combinan con inhibidores selectivos de la recaptación de serotonina.

El médico decidirá en cada caso cómo y cuándo combinar los medicamentos, así como cuándo irlos cambiando en periodos cíclicos, teniendo en cuenta la gravedad y la calidad de vida del paciente.

2. Tratamiento psicológico

El tratamiento no obstante debería ser multidisciplinar con la coordinación de un especialista en Fibromialgia.
Con respecto a los tratamientos psicológicos específicos, encontramos dos de significativos que consisten en la modificación de hábitos, creencias y estrategias de afrontamiento.

Estos son los siguientes:

1. **Cognitivo – Conductual:** los componentes que se han mostrado eficaces en la recuperación de otros tipos de dolor, como el lumbar, las cefaleas, el dolor de brazo y hombro y el dolor crónico. Con ella, los pacientes consiguen ganar control sobre el impacto del dolor y sobre el funcionamiento físico.  

2. **Educación, Información y Conciliación:** la educación, información y conciliación en el Síndrome de Fibromialgia forman parte de la condición control del paciente con su sintomatología. De esta manera combate con herramientas propias, momentos difíciles, durante la evolución individual de la enfermedad. Se acostumbra a completar con ejercicios cardiovasculares como andar, nadar, etc.

La combinación de ambas técnicas produce efectos sinérgicos al mejorar los efectos de los síntomas.  

---

### 1.6 Tratamiento actual de la Fibromialgia con Biorresonancia-SCIO

Este Estudio es el resultado de observaciones sobre fenómenos que acaecían en nuestros pacientes y que empezaron a llamar nuestra atención hace veinticinco años (1983). Puesto que en un grupo de cinco pacientes de más o menos la misma edad, el mismo sexo, diagnosticados por el mismo médico (mismos criterios), tomando la misma medicación, diagnosticados de artritis de rodilla, sin excepción de peso por encima de cinco kilos, más o menos de la misma clase socio-económica y en el centro de Fisioterapia se les aplicaba la misma terapéutica, a unos se les empezaron a llamar nuestra atención hace veinticinco años (1983). ¿Por qué en un grupo de cinco pacientes de más o menos la misma edad, el mismo sexo, diagnosticados por el mismo médico (mismos criterios), a unos se les empezaron a llamar nuestra atención hace veinticinco años (1983)?

Con respecto a los tratamientos psicológicos específicos, encontramos dos de significativos que consisten en la modificación de hábitos, creencias y estrategias de afrontamiento.

#### 1.6.1 Cognitivo – Conductual

Los componentes que se han mostrado eficaces en la recuperación de otros tipos de dolor, como el lumbar, las cefaleas, el dolor de brazo y hombro y el dolor crónico. Con ella, los pacientes consiguen ganar control sobre el impacto del dolor y sobre el funcionamiento físico.  

#### 1.6.2 Educación, Información y Conciliación

La educación, información y conciliación en el Síndrome de Fibromialgia forman parte de la condición control del paciente con su sintomatología. De esta manera combate con herramientas propias, momentos difíciles, durante la evolución individual de la enfermedad. Se acostumbra a completar con ejercicios cardiovasculares como andar, nadar, etc.

La combinación de ambas técnicas produce efectos sinérgicos al mejorar los efectos de los síntomas.
se basaron en todo lo sintomático y en los estudios que se habían hecho para saber qué hay alterado y cuáles son las consecuencias de la Fibromialgia. Por ejemplo valoramos y equilibraramos los parámetros que en el software se denominan como: reparación del sistema nervioso autónomo, EEG, ECG, Testosterona, Cortisol, Serotonina, Neurotransmisores, Emociones, reparación muscular, neurológica, reparación del tejido lesionado, reducción de estrés, balance hormonal, corrección del flujo de la energía espi nal, absorción de nutrientes (proteínas, carbohidratos, grasas, vitaminas, minerales...), enzimas implicadas en la nutrición, hormonas implicadas en la nutrición ...

Fue a partir de este momento que nos dimos cuenta que los pacientes no solamente mejoraban mucho más, aumentando su calidad de vida y poniendo una esperanza en el futuro, sino que además si se hacía un mantenimiento de una vez al mes (dependiendo de cada caso), podíamos ir reequilibrando aquellas frecuencias que se iban alterando incluso antes de que fueran sintomáticas.

Esto nos animó a realizar este estudio y observar con el máximo de rigor científico el resultado final de la Fibromialgia con Biorresonancia-SCIO.

2. BIORRESONANCIA

El contenido de un curso de biofísica impartido conjuntamente por la Universidad de Barcelona y la Universidad Politécnica de Catalunya trata los temas siguientes:

Figura 2. Programa de Biofísica impartido en la UB y la UPC

El abordaje de la Medicina desde el campo de la Biofísica exige superar toda una serie de limitaciones de la Física Oficial que investigadores como el Profesor Dr. Fidel Franco están desarrollando desde hace bastantes años mediante la Teoría del Campo Unificado. Por este motivo, introduciremos algunos de los conceptos desarrollados por este investigador para explicar los fundamentos teóricos y, posteriormente, explicar el funcionamiento del aparato SCIO utilizado como herramienta terapéutica en esta tesina.

La base teórica del concepto de Campo Unificado, es considerar que todas las formas de energía son la misma energía. Ésta es la premisa básica para comprender que todos los sistemas biológicos, son sensibles a la acción de cualquier energía exterior expresada por medio de un campo físico.

La forma más eficaz de intervenir en cualquier sistema físico, es a través de un fenómeno de resonancia, pues con energías muy débiles se consigue transmitir la máxima energía al interior del mismo. Este hecho se constata por la
2.1 Teoría del campo unificado

Para entender los efectos de resonancia y adaptarlos a la resonancia en organismos vivos, es decir, poder hablar de la llamada biorresonancia, primero tenemos que detenemos a describir unos parámetros de "unificación", pues nosotros formamos parte de la estructura de un Universo donde todo está interrelacionado.

La Teoría del Campo Unificado describe las propiedades físicas del campo que engloba todos y cada uno de los objetos y fenómenos que puedan tener lugar en la naturaleza.

2.2 Metodología de la teoría del campo unificado

1. La heterogeneidad de la materia, es decir, vamos a asumir de entrada un hecho que todos conocemos: la materia es completamente heterogénea, como las personas y los objetos son distintos entre sí. Los líquidos se disponen en capas distribuidas según su densidad, así como los gases. Lo mismo ocurre en el Universo, donde las Galaxias son muy distintas entre sí, como ha de ocurrir en distintas regiones de nuestra Galaxia e incluso de nuestro Sistema Solar. El vacío no existe pues todo lo inunda una radiación de fondo, que será diferente en cada zona, incluida nuestra Galaxia e incluso nuestro Sistema Solar.

2. Todo proceso en la Naturaleza es una transformación. Es decir, considerando cualquier proceso de la Naturaleza y un observador solidario con los objetos físicos que intervienen en el mismo, éste ha de observar cambios en parámetros físicos tales como la conductividad y la frecuencia de dichos cuerpos.

3. Nada puede ocurrir al azar: no es viable ni el azar ni el caos. Todo obedece a una Ley Física y por esta razón asumimos la validez de la Ciencia. En dicho marco el objetivo de la Ciencia es predecir cómo han de evolucionar los procesos.

4. La tendencia de los cuerpos en la Naturaleza no es hacia el desorden sino hacia el orden organizado. Ello se ha puesto de manifiesto en el estudio de un conjunto de rotores de motores muy débilmente acoplados que llegan a sincronizarse si se espera un tiempo suficientemente largo. Los planetas del Sistema Solar están sincronizados entre sí. Las manchas solares corresponden a agrupamiento de planetas a un lado de la eclíptica.

5. No existe el orden ni el desorden, pues ambas son categorías que implican unos prejuicios culturales respecto a las diferentes formas de comportamiento en la Naturaleza. Cualquier forma de comportamiento de la Naturaleza, aunque no sea comprendida no merece ningún tipo de descalificación. Todo lo contrario, cualquier descalificación acerca del comportamiento de la Naturaleza es una proyección de nuestra propia valoración acerca de sus Leyes y el papel que nosotros jugamos en ella.

6. No debemos confundir impredecibilidad con indeterminismo. Asumir la impredecibilidad es aceptar la ignorancia. Asumir el indeterminismo, es considerar que la Naturaleza carece de Leyes.

7. Todo proceso incluye el resultado. El resultado está ligado al proceso y no puede ser analizado al margen del proceso.

8. No debemos confundir determinismo con predestinación pues si el resultado está ligado al proceso, obviamente dicho resultado depende de cómo se lleva a cabo el proceso. Ejemplo: La genética del ser humano.

9. Si hablamos en términos temporales todo proceso de la Naturaleza ha de tener una duración finita, porque finita es la cantidad de energía que interviene en el mismo.

10. Si utilizamos una metodología de trabajo en que pretendemos llegar desde lo particular a lo general, recurriendo al método analítico, hemos de tener en cuenta que dicho método puede tener consecuencias perversas pues "al aislar los objetos del todo que los contiene" fácilmente caemos en el gravísimo error de olvidarnos de la unidad frente a la individualidad. Caso de utilizar el método analítico, que es uno de los métodos usuales en nuestra cultura, debemos trabajar por lograr la Unificación y desde la Unidad restringimos a lo particular una vez establecido un método de individualización o identificación de los objetos y procesos analizados.

11. Cualquier Teoría Física debe cumplir tres requisitos:

   Sencillez, para que todos la podamos entender y utilizar

   Eficacia, para que podamos extraer el máximo de resultados prácticos en todos los ámbitos de la vida

   Unificación, para que pueda abarcar en cada período cultural todos los conocimientos y preocupaciones de dicho período y para que pueda integrar en su seno a los seres vivos, incluido el ser humano. En la medida que incluya al ser humano debe dar respuestas a los problemas de la vida y contribuir a la evolución espiritual del mismo.
12. En el fondo, la Ciencia no hace otra cosa que aprender de la Naturaleza y, si actúa sin prejuicios, llegará a comprender que cualquier proceso se realiza con el mínimo de Energía, o sea, los tres requisitos anteriores: sencillez, eficacia y unificación.

2.3 Todas las formas de energía son la misma energía

El Campo Unificado es un campo central. Esto implica que el Universo tenga un comportamiento cíclico, con periodos de sístole y de diástole que se suceden alternativamente. Por tanto, cualquier campo que podamos describir está incluido en el Campo Unificado y tendrá las propiedades del mismo.

Así mismo todo campo tiene su origen en la energía y actúa sobre la energía, es decir, la energía es el parámetro fundamental de todos los procesos. En otras palabras, el patrón principal necesario para analizar su comportamiento y estructura es la energía cuya característica es la siguiente

“La energía es siempre la misma tan sólo tiene diferentes manifestaciones y aplicaciones”.

Prueba de ello es que la energía eléctrica es indistinguible a pesar de que se puede obtener por diferentes procesos:

- Origen solar (generador fotovoltaico)...............energía eléctrica
- Origen cósmico (generador cósmico)...............energía eléctrica
- Origen químico (baterías).........................energía eléctrica
- Origen nuclear (central nuclear)....................energía eléctrica
- Origen térmico (fuel-oil o carbón)..................energía eléctrica
- Origen gravitacional (central hidroeléctrica)....energía eléctrica

La energía eléctrica siempre ha sido energía eléctrica sin encontrar diferencia alguna independientemente del medio obtenido para su obtención.

Analicemos esta afirmación:

- Según la Ciencia clásica todos los campos de energía se descomponen en cuatro fuerzas: Gravitatoria, Electromagnética, Fuerte y Débil. Sin embargo, la Teoría del Campo Unificado considera que todos se reducen a un campo de fuerzas único.

A continuación hagamos un breve recordatorio de los llamados efectos giromagnéticos, para comprender mejor la relación entre los campos electromagnéticos y los campos gravitatorios:

1. Efecto Barnett: Un cuerpo que gira con velocidad angular uniforme adquiere una imanación
2. Efecto Einstein-de Haas: Un cuerpo, suspendido libremente, comienza a girar al ser imanado.
3. Efecto Stewart-Tolman: En el seno de un anillo en rotación no uniforme aparece una fuerza electromotriz, por lo que puede medirse una intensidad
4. Un cuerpo sometido a una fuerza exterior que le produce una aceleración, muestra la presencia de un campo eléctrico puesto que se mide una corriente.

Es decir, el campo magnético se puede comparar con una rotación (como la corriente que circula a través de los hilos de una bobina que crea campos magnéticos), y el campo eléctrico también se puede comparar con aceleraciones lineales.

En consecuencia, un cuerpo como un astro o planeta tiene un campo magnético asociado por el mero hecho de girar alrededor de su eje, si tiene carga eléctrica asimétrica, aunque la intensidad y dirección varíen según la composición del planeta.

En el campo biológico y en el rango de muy bajas frecuencias, se pueden analizar por separado los efectos del campo eléctrico y los efectos del campo magnético. Un ejemplo de los efectos de los campos magnéticos sobre los tejidos biológicos los podemos encontrar en grán número trabajos sobre magnetoterapia publicados en la revista internacional “Bioelectromagnetics”.

En el área de la biología y la medicina se trabaja con campos electromagnéticos y en muchos casos sólo magnéticos aprovechando dicho campo en distintos rangos de frecuencias dependiendo de la indicación terapéutica: bajas, altas o medios.

Los procesos de oxidación-reducción asociados a los campos eléctricos o magnéticos, tienen gran importancia a nivel terapéutico, pues ayudan a comprender los procesos de oxidación-reducción y gracias a la comprensión de los mismos se pueden desarrollar métodos que favorezcan los procesos de reducción en el organismo o contribuyan a frenar los procesos de oxidación en el mismo. Por ejemplo, los parámetros de oxidación-reducción de las enzimas y hormonas son de gran relevancia para la evolución de enfermedades degenerativas y/o crónicas. Por ello ocupan un lugar importante en la terapéutica de Biofeedback-SCIO con Biorresonancia.

2.4 Energía-Espacio-Tiempo
El concepto de espacio (distancia) es muy relativo y el tiempo en recorrer esa distancia también es relativo pues dependiendo de la potencia del vehículo (energía) que se utilice para hacer ese recorrido (espacio), podemos necesitar más o menos tiempo en recorrerlo.

Para cada observador el espacio y el tiempo son relativos ya que dependen de la energía que se implique en el proyecto. Por ello hablamos de sensación espacial y sensación temporal. En consecuencia seguimos insistiendo en que la energía es el parámetro fundamental de todos los procesos y, por tanto, el tiempo es una medida de la energía invertida en un proceso.

En la Teoría del Campo Unificado se dice que la energía, la cual en estado condensado llamamos materia, es el soporte del espacio-tiempo. Es decir, el Universo ha de contener energía en todos sus puntos.

Al fijarnos en el ser humano, observamos que el ser humano forma parte del Universo y, por tanto, toda su energía que hasta ahora era calificada como física, psíquica y emocional, en realidad son manifestaciones de procesos biológicos que se manifiestan tanto en el interior como en el exterior por medio de campos que interaccionan entre sí.

Esto explica que podamos intervenir en la materia o en cualquier ser vivo por diversos caminos: por ejemplo,

- a través de la energía de un producto donde su acción viene dada a través de la energía que participa en las reacciones químicas,
- por medio de la energía de campos de frecuencias muy elevadas como pueden ser los infrarrojos o la luz, o bien
- por medio de campos de frecuencias mucho más bajas.

2.5 Las oscilaciones

Según el Prof. Dr. F. Franco, todos los procesos de la Naturaleza son del tipo oscilante porque el Campo Unificado es un campo central, es decir, en cualquier sistema identificado, siempre podemos encontrar una referencia dentro del mismo sistema. En consecuencia las soluciones de las ecuaciones de todos los procesos pueden ser representadas por funciones oscilantes: Todo oscila en la Naturaleza y el equilibrio viene dado por la oscilación. Como las oscilaciones de la economía, estaciones, día y noche, meteorología, etc.

Todos los procesos físicos de la Tierra están ligados al sistema solar y sobre todo al sol que es la referencia en dicho sistema. Un ejemplo, lo tenemos en la heliotaraxia que estudia la relación entre las oscilaciones del sistema solar y los ciclos biológicos observados en la Tierra.
Evaluar las diferencias entre los pulsos en ambas muñecas de cualquier persona es un método que permite determinar los efectos equilibradores o desequilibradores de cualquier estimulo.

Ejemplo 4: A lo largo del año, el máximo de actividad del corazón se encuentra en verano y las doce del mediodía y el mínimo se encuentra en invierno y a las doce de la noche (sólidos).

Una célula visible en un microscopio oscila continuamente y emite señales imperceptibles por nosotros por ser muy débiles y quedar fuera del rango de audición de nuestros sentidos. Cada célula dependiendo de su función emite una onda correspondiente a una vibración diferente. El ser humano presenta una realidad vibracional rica y apasionante que va desde el ritmo de los órganos vitales, hasta las emociones, pasando por la respiración y la actividad mental: cada capa o rango de frecuencias está integrada en la unidad que realmente somos.

2.6 Teoría ondulatoria

Llamamos onda al método de transmisión de la energía emitida por cualquier sistema oscilante y a la transmitida a través de un medio.

En cualquier sistema de la Naturaleza incluidos los seres vivos siempre existe la oscilación: Cada órgano humano tiene su propia frecuencia. El estómago tiene su propia frecuencia y lo mismo ocurre con órganos, bacterias, hormonas, aminoácidos... emiten una radiación mesurable con aparataología de medición bioeléctrica.

Conclusión, todo es energía y toda energía se transmite por medio de ondas, ya sean de sonido (bajas frecuencias), luz (altas frecuencias), radiación ultravioleta, etc.

Si tenemos en cuenta que cada onda transporta una energía, y que cada ser humano es el resultado de todo el conjunto de energías que lo forman, podemos decir con toda propiedad que al igual que otro objeto de la Naturaleza, el ser humano es así mismo energía.

Figura 5. Amplitud de los pulsos derechos e izquierdos en pacientes sanos y enfermos.

Figura 6. Interrelación de los campos electromagnético de varias personas.

2.7 Concepto de resonancia

La resonancia se puede definir como un intercambio de energía entre osciladores sincronizados.

Puesto que todos los sistemas de la Naturaleza son oscilantes, en todos los sistemas físicos puede darse fenómenos de resonancia.
Para dos o más frecuencias, cualquier sistema físico permite la entrada de una gran cantidad de energía que oscila en dicha frecuencia. Se dice que el sistema tiene una elevada conductividad para esta frecuencia.

Aplicar energía sobre un sistema aprovechando un fenómeno de resonancia es la forma más eficiente de intervenir en dicho sistema pues gran parte de la energía aplicada es absorbida por el sistema. De esta manera con energías muy débiles se consigue transmitir la máxima energía a su interior y también a su vez pueden detectarse alteraciones inducidas por dicha energía. Si nos encontramos lejos de la resonancia, entonces la energía aplicada es reflejada o transmitida por el sistema mismo pero la energía apenas es absorbida.

Ejemplos de picos de resonancia en diferentes objetos físicos:

1.- Cuarzo (en ordenadas la transmisión del material):

Figura 8. Pico de resonancia en cuarzo.

El cuarzo tiene un pico de resonancia en frecuencias del infrarrojo correspondientes a ondas de una longitud que ronda las 10 μm (1100cm⁻¹), muy próxima a la radiación corporal de 37º C.

2.- Solución de hemoglobina al 22%:

Figura 9. Pico de resonancia en una disolución de hemoglobina.

Una disolución de hemoglobina al 22% tiene una conductividad que varía con la frecuencia tal como vemos en el gráfico. Puesto que la escala es logarítmica el máximo se encontraría por encima de los 10 kHz. Por ello no nos extrañe que se haya observado el máximo número de infartos cuando hay tempestades eléctricas con picos de 28 kHz.

3.- Metales en el rango de las frecuencias ópticas:

Los metales tienen picos de absorción en el rango del visible. Ejemplo de la figura son los picos de absorción del oro en el rango de de los 3-4 eV

4.- Cualquier sistema mecánico:

Por efectos del viento, los puentes presentan oscilaciones de cimbreo y de torsión que son máximas para unas determinadas velocidades del viento en que se originan vórtices cuya frecuencia de oscilación entra en resonancia con la estructura.
2.8 El ser humano desde una perspectiva energética

Según la Medicina Tradicional China (MTC), el ser humano es “un microuniverso dentro del macrouniverso”.

Si utilizamos el concepto de sistema dissipativo desarrollado por Ilya Prigogine en su Teoría de las Estructuras dissipativas, se puede analizar al ser humano como un sistema dissipativo unificado abierto en un régimen no lineal más o menos cíclico, formado por un gran número de subsistemas dissipativos unificados, abiertos, acoplados y en equilibrio dinámico, organizados en esferas funcionales, y que interactúan coordinadamente. Aunque cada uno de ellos tiene una frecuencia de resonancia propia, sin embargo se organizan en diferentes niveles energéticos y tienden a buscar una frecuencia propia de resonancia que da pie a procesos de sincronicidad.

Así mismo, el ser humano es una Unidad, afirma el Prof. Dr. F. Franco, pero si también podemos considerar que está formado por una serie de tejidos acoplados entre sí y, como cualquier sistema, debe presentar dos frecuencias propias de acoplamiento: una de ellas en el rango de muy bajas frecuencias y otra correspondiente a frecuencias en el rango del infrarrojo.

El grado de acoplamiento entre los tejidos puede ser evaluado por un parámetro “S” que asociamos al sistema inmunitario. Pues bien, con el modelo teórico del ser humano se deduce que el Sistema Inmunitario depende de dos parámetros: conductividad y susceptibilidad magnética de los tejidos. Eso quiere decir que es posible evaluar el efecto de los campos sobre el ser humano analizando de qué manera cambian las propiedades físicas de los tejidos sobre los cuales actúan.

Hemos de matizar que el concepto de Sistema Inmunitario que aquí utilizamos abarca tres niveles:

Nivel 1: Defensivo, pero sin abusar del mismo como hace la Medicina Alopática.

Nivel 2: Equilibrador energético. Asumido parcialmente por la Medicina Alopática, pero coincidiendo con la filosofía de las medicinas energéticas y medicina tradicional china.

Nivel 3: El Sistema Inmunitario dirige la conducta. Esta conclusión es comprensible si recordamos la interacción entre el Sistema Inmunológico y el Sistema Neurológico a través de los neuropéptidos e inmunopéptidos.

Llamaremos “la mente” a la coordinación o acoplamiento de todos los tejidos que componen al ser humano. Por tanto, el cuerpo es un terminal de la mente.
Anализировано как индивидуум, афirma el Prof. Dr. F. Franco, el ser humano forma parte del Campo Unificado y decimos que se relaciona con el mundo a través de un proceso que llamamos “percepción”, donde capta sólo aquellas frecuencias de energía con las que sintoniza. En otras palabras, el proceso de percepción tiene lugar a través de un fenómeno de resonancia.

Pues bien, dado que la conducta está ligada a la percepción y ésta a su vez depende del nivel de sintonía o resonancia con el mundo que le rodea, llegamos a la conclusión que el parámetro de equilibrio de un ser humano, se incrementa en la medida que aumenta su nivel de integración o acoplamiento al Universo. La integración del ser humano en el Universo, consiste en aceptar y asimilar las Leyes del Campo Unificado y darles contenido práctico en cada uno de las distintas facetas de la vida. Para ello es básico conocer las Leyes que rigen nuestro Universo.

2.8.1 Aplicaciones prácticas

Según el desarrollo expuesto anteriormente por el Dr. Franco, existen tres conclusiones a tener en cuenta para las aplicaciones prácticas.

1.- Una primera aplicación práctica de estos resultados es que podemos clasificar las enfermedades en “frías” y “calientes”, coincidiendo con el Sr. Lezaeta.

a) Las enfermedades calientes son las que se manifiestan por un acusado incremento en la emisión de radiación en el rango del infrarrojo, es decir, cursan mediante fiebre pues el organismo reacciona elevando la temperatura, (frecuencia de resonancia) como método de estabilización. Muchas de estas enfermedades son de tipo infeccioso. Son las que tienen una curación más fácil y donde han sido más eficaces las vacunas y los antibióticos.

b) Las enfermedades frías se desarrollan sin incrementos importantes de la temperatura, como ocurre con las enfermedades de tipo neurológico. Por ser enfermedades frías, donde la frecuencia de resonancia está en el rango de muy bajas frecuencias, los campos magnéticos de muy baja frecuencia resultan de gran eficacia en todos los casos: fibromialgia, esclerosis múltiple, Parkinson y enfermedades de la percepción.

2.- Cada una de estas frecuencias es la envolvente de todo un rango de frecuencias detectables mediante técnicas detalladas de biorresonancia, que pueden ser aplicables a tratamientos sintomáticos.

3.- El tratamiento terapéutico pasará por tres niveles

   a) tratamiento energético general sin concretar en cuál de las dos frecuencias nos estamos centrándolo.

   b) tratamiento energético de estabilización por medio de una o ambas frecuencias de resonancia

   c) tratamientos sintomáticos de problemas planteados.

2.9 Definición de biorresonancia

En Física se considera que el fenómeno se produce al coincidir la frecuencia propia de un sistema mecánico, eléctrico, etc., con la frecuencia de una excitación externa. Es decir, si una enfermedad se desarrolló en el estómago la emisión de radiación emitida por dicho órgano debe variar y, por tanto dicho desequilibrio es detectable por la radiación emitida por dicho órgano.

En nuestro caso las radiaciones emitidas por un órgano, son detectadas por un aparato de Biorresonancia de forma similar a la sintonización de las diferentes emisoras de un transistor o un aparato de televisión.

A continuación se lleva a cabo un proceso de recogida de datos, valoración y selección de la información recibida. En este proceso el mismo organismo se autoarrecalibra de forma continua, pero aplica filtros para el consciente. Por ejemplo: El ojo es una perfecta cámara visual. Si nuestro consciente viera todo lo que nuestro ojo capta, no podríamos absorber tanta información. Lo mismo sucede con el oído, el olfato, el sentido...

A nivel inconsciente tenemos toda la información de nuestro organismo tanto física, como psíquica y mental, pero también es filtrada por el consciente. Sin embargo, se puede producir un fenómeno de resonancia con la frecuencia de las señales recibidas y almacenadas por el aparato de Biorresonancia.

En la práctica la formación reticular filtra la mayor parte de esta información y solo permite a unas cien mil señales alcanzar nuestra mente consciente por lo que nuestra mente consciente no aprovecha toda la realidad percibida.

2.10 Definición de Biofeedback

Una vez recogida la información, existen sistemas que aprovechan los datos recogidos, para efectuar directamente tratamientos mediante señales electromagnéticas de distintos rangos de frecuencias. En la medida que el aparato de tratamiento incorpore algún sistema para captar la información y corregir u orientar el método de tratamiento, podremos calificar de dicha forma, como un sistema “biorresonante con sistema biofeedback incluido”.

Habitualmente los sistemas de este tipo están diseñados para tratamientos específicos, sin embargo el aparato Quantum-Scio, que trabaja en un rango muy amplio de frecuencias, incluye el sistema biofeedback para todos los casos.
tratamientos que es capaz de efectuar. Con ello se consigue realizar tratamientos energéticos muy completos y desde diferentes perspectivas.

3. SISTEMA DE BIORRESONANCIA, BIOFEEDBACK-SCIO EL APARATO EPFX/ SCIO

3.1. Aparato EPFX/SCIO

El “SCIO” del latín: Saber, es un sofisticado sistema auxiliar de pre-diagnóstico, con la mayoría de sus funciones de aplicación automática. Esta caja de Biorresonancia, fue creada y desarrollada por el Prof. William C. Nelson, uno de esos escasos investigadores independientes, oriundo de Ohio (Warren, 19 de junio de 1951).

Durante su investigación, se interesó por un número de sistemas bioeléctricos previamente desarrollados por otros investigadores: los sistemas “Vega”, “Volt” y “Mora”, y las unidades de estimulación eléctrica craneal “CES” (Cranial Electro Stimulation). Todas estas unidades aplicadas al pre-diagnóstico de problemas de salud, evalúan la respuesta eléctrica del cuerpo por las señales emitidas por el mismo o bien actúan sobre el organismo aplicando señales magnéticas con el objetivo de tratar dichas enfermedades. El problema es que no pueden realizar ambos procesos de forma simultánea.

También estudió los sistemas de pequeñas energías del cuerpo: los meridianos de acupuntura, la kinesiología aplicada o testado muscular, etc.

El desequilibrio de cualquiera de estos sistemas energéticos del organismo, es un indicador de que algo empieza a fallar en nuestro organismo. Sería el momento de prevenir una enfermedad. El Prof. W.C. Nelson, diseñó un sistema completo que testara y equilibrara los niveles energéticos del organismo. A este sistema se le denominó “Quantum Xrroid Consciousness Interface”: SCI

El sistema de Biofeedback, utiliza una conexión cibernética para testar y equilibrar automáticamente durante la operación del sistema. Es decir, el mismo aparato se calibra automáticamente de forma constante. El sistema hace correcciones eléctricas a velocidades de menos de una centésima de segundo.

El SCIO es una herramienta de trabajo. Para optimizar los resultados se necesita que el profesional tenga conocimientos médicos y terapéuticos, aparte de conocimientos de Física e informática.

Este aparato ha sido diseñado para su utilización como un dispositivo de Biofeedback. Es decir, la medición de una respuesta fisiológica y la retro alimentación de ésta al organismo. El sistema cataloga y tabula el complejo potencial de las reacciones electro-fisiológicas de la persona.

La exactitud médica del dispositivo es limitada (85% fiabilidad) y como tal, los resultados no pueden ser tratados como un elemento de diagnóstico completo.

- El profesional deberá interpretar estos datos correctamente y corroborar los resultados con otras pruebas médicas diagnósticas.
- Este dispositivo es seguro, y no supone ningún riesgo para el paciente.

3.2. Sistema trivectorial de medición

El sistema trivector, incorporado dentro del SCIO, evalúa, por medio de una interface el voltaje, amperaje, resistencia y frecuencias medias, las señales emitidas por el cuerpo, en el rango de frecuencias del sistema de medida utilizado. Con estos datos se calculan parámetros eléctricos clásicos como la inductancia, capacidad, conductividad y frecuencia de resonancia del sistema reactivo del cuerpo durante un intervalo de tiempo. Es decir, a partir de dichos resultados se pretende modelar y cuantificar el nivel de conexión corporal.

Adaptando el trabajo de Becker31, Priori31, Beardall y otros, el Prof. Nelson ha desarrollado un sistema informatizado capaz de:

- Desarrollar el campo asociado a la corriente continua portadora en una diminuta señal multifrecuencial, que contribuya a regenerar células del cuerpo humano.
- Convertir, mediante el uso de técnicas como la diferenciación y re-diferenciación, un conjunto masivo de señales, en señales multi-fractales.
- Análisis no lineales, que desarrollan multi-señales para tratar los tejidos más complejos.

Datos almacenados:

El ‘SCIO’ contiene muestras de homeopáticos almacenados en la memoria. Las frecuencias propias de los mismos están también almacenadas en el programa. El modelo de energía trivector de cada una de las muestras, está calibrado de tal forma que el modelo de la persona sea variable y reactivo. De manera que podemos medir la reacción de un organismo a miles de elementos. Estos elementos están catalogados bajo los siguientes grupos:

- **Sarcoes**: Tejido sano, usado para la reconstrucción y desintoxicación de tejidos.
- **Nososdes**: Tejido enfermo o infeccioso, usado para la construcción inmunológica.
- **Alersodes**: Para la desensibilización de alérgicas.
- **Isodex**: Toxinas no orgánicas como el DDT que en la forma diluida se usan para la desintoxicación.
- **Nutricionales**: Aminoácidos, minerales, vitaminas, enzimas, etc.

---

*Anexo 1: Registros del SCIO*
Principios científicos del sistema de Biofeedback-SCIO

Determinación de los parámetros eléctricos: El fundamento físico del sistema radica en las leyes de la electricidad y posteriormente, el manejo de las matemáticas aplicadas a los circuitos biológicos que son modelizados como sistemas eléctricos resonantes. Es decir, el fundamento teórico y base principal es el electromagnetismo aplicado a la caracterización física y posterior tratamiento de tejidos biológicos mediante fenómenos de resonancia tanto en la parte de detección como en los métodos de tratamiento.

Obviamente el ordenador recibe, almacena y maneja los datos, mientras que la caja del “interface” actúa como receptor-emisor que se encarga de detectar y/o emitir señales de diversas frecuencias generadas a base de circuitos oscilantes. O sea, en lo que se refiere a la fase de pre-diagnóstico se determinan los parámetros eléctricos de capacitancia, inductancia e impedancia de los tejidos a partir de los valores del voltaje, amperaje, resistencia, capacitancia e inductancia que son medidos y calculados a velocidades muy elevadas. A partir de dichos valores, se deducen las reacciones biológicas celulares, potenciales de membrana y otras señales emitidas por el ADN y ARN de las mitocondrias, mediante el trabajo de Nelson en el campo genético.

Análisis de Fourier: Una vez recogida la señal emitida por un tejido durante un proceso metabólico, el sistema realiza el análisis de Fourier o estudio del espectro de frecuencias que caracterizan a las señales emitidas. A partir de tales frecuencias se busca la conexión emocional y los efectos biológicos de la misma. Por ejemplo, el llamado síndrome general de reacción de adaptación, está basado en la Teoría del Dr. Hans Selye que establece una correspondencia entre una serie de efectos de estimulantes hormonales y la reacción de nuestros organismos a los mismos en cada momento de nuestra vida.

En suma, las herramientas físicas mencionadas como es la caracterización eléctrica de los tejidos en un amplio rango de frecuencias, junto con el análisis de Fourier de las señales emitidas, parten de una visión unificada del ser humano plasmado en los modelos de correspondencia entre emociones y desequilibrios físicos. Dichas herramientas nos permiten describir al ser humano de una forma muy amplia (emocional, sensible, estados de consciencia, etc), así como determinar la influencia de parámetros medioambientales y agentes contaminantes que puedan contribuir a su desequilibrio.

Algunas propiedades importantes de transformaciones de Fourier como son linealidad, simetría, teorema de convolución, etc, pueden ser consultados en textos de Cálculo de matemáticas avanzadas y son de uso habitual por parte de Físicos y algunos Ingenieros.

Otra explicación de las transformadas de Fourier: Dado que una onda estacionaria compleja puede descomponerse o expandirse como una suma de ondas sinusoidales simples, en determinados tipos de análisis puede resultar más interesante representar dichos armónicos en el dominio de la frecuencia que en el dominio del tiempo, o lo que es lo mismo, en su representación espectral. Aquí, cada línea es el espectro de cada uno de los componentes armónicos de onda compleja de referencia. Por consiguiente, el espectro de una onda compleja, estará compuesto de diversas líneas, cada una de las cuales representa una onda simple o componente armónico.

La expresión matemática que permite la conversión al dominio de la frecuencia de los valores de representación de la onda compleja en el dominio del tiempo, fue desarrollada por Fourier y se denomina transformada de Fourier:

La Transformada de Fourier proporciona el valor $V(\omega)$ de cada ordenada del espectro para cada frecuencia angular $\omega$ ($\omega = 2\pi f$) a lo largo del eje horizontal. De la misma manera, la expresión matemática de la antitransformación de Fourier permite llevar a cabo el proceso inverso. Dicha fórmula es conocida como la transformada inversa de Fourier.

**Ejemplo de aplicación al caso del sonido: Audio analógico, audio digital:** Las variaciones de presión generadas por las emisiones sonoras pueden ser procesadas y registradas en equipos y soportes de distintos tipos. Cuando las variaciones de energía mecánica o magnética son un reflejo fiel de las variaciones de presión sonora que fueron previamente traducidas a fluctuaciones de naturaleza eléctrica, nos encontramos ante un procesado analógico (similar) de la señal de audio. Sin embargo, si esas materializadas variaciones de corriente eléctrica, son transformadas mediante una codificación numérica binaria, nos encontraremos ante un procesado de tipo digital.

A primera vista, todo proceso de codificación digital implica una mínima degradación de la señal original. Si bien, es igualmente cierto que cualquier proceso de conversión digital convenientemente administrado (en sus fases de muestreo, retención, cuantificación, compresión/expansión, filtrado, modulación, etc.), no sufrirá en ningún caso los graves inconvenientes del efecto canal propios de la transferencia analógica (ruído, distorsiones lineales o no lineales, etc.). Por otra parte, todas las copias digitales de una señal de audio original (de primera o...
enésima generación), serán siempre prácticamente idénticas en calidad a la original, circunstancia que nunca se produce en el supuesto analógico.

Además de las citadas, existen otras muchas ventajas del procesado de audio digital respecto del analógico: funcionalidad y agilidad de los procedimientos de trabajo, almacenamiento, conservación y transmisión de la señal, etc.

En el proceso arriba descrito, las fases más críticas se asocian a las tareas de conversión del campo analógico al digital y viceversa. En síntesis, un convertidor A/D transforma la señal de entrada analógica (tensión o corriente), en una frecuencia o serie de impulsos, cuyo tiempo se mide para proporcionar una salida digital representativa y proporcional; también puede efectuarse una comparación de la señal de entrada, con una referencia variable utilizando un convertidor interno D/A, para obtener una salida digital.

La conversión A/D se hace en varias etapas:

- **filtrado**: limita la anchura de banda de la señal analógica.
- **muestreo**: convierte una señal de tiempo continuo en una señal de tiempo discreto.
- **discretización**: convierte una señal de valor continuo en una señal de valor discreto.
- **codificación**: define el código de la señal digital, según la aplicación que se ejecuta.

Los convertidores D/A producen el efecto inverso al convertidor A/D. Estos circuitos, han de ser capaces, (a partir de la lectura del correspondiente código digital), de generar una tensión o corriente continua en el tiempo y en el valor lo más similar posible a la señal analógica originalmente introducida en la fase inicial del proceso.

**Ejemplo de aplicación a los tejidos biológicos**: La hipótesis con la que trabajamos es que las células vivientes hacen también análisis de Fourier, o sea, determinan el espectro de señales enviadas por cualquier estímulo. Esta sería una parte de la matriz biológica y una función del ADN, cuya expresión biológica podemos expresar en forma ondulatoria y analizada usando las transformadas de Fourier. Por tanto, el sistema neurológico y el sistema circulatorio y todos los tejidos del cuerpo realizarán el análisis de Fourier de forma automática.

El cuerpo puede percibir y responder a cualquier señal que desee. Así puede atender una señal visual o de sonido y bloquear otras. La formación reticular en este caso, tiene que hacer un análisis de Fourier complicado. Los procesos biológicos estudiados mediante las transformaciones Fourier, contienen implicaciones profundas para la biología, por ejemplo: la pupila enfoca la luz externa y auxilia al humano para dibujar una imagen en la mácula de la retina del ojo. El análisis del proceso por esta vía, permite su comprensión y extraer conclusiones del mismo.

**Resonancia armónica**: En términos biológicos pueden detectarse muchas frecuencias de resonancia: virus, bacterias y hongos, como todos los seres vivos, tienen frecuencias resonantes. Por ejemplo, si un virus es excitado con energías cuya frecuencia está en resonancia con su propia frecuencia, podría afectar al organismo donde reside. En psicología un cierto manejo de neuronas podrían ser sensibles a una condición resonante si los ritmos presentasen la señal excitadora. Por ejemplo, las fobias pueden producir efectos resonantes dentro de los circuitos neurológicos, empujando al organismo a extremos y a menudo induciéndolo a un ataque de ansiedad o pánico. La obsesión, la desilusión, la preocupación, la tristeza y muchos otros problemas psicológicos, pueden ser estudiados como factores resonantes con los neurotransmisores del cerebro. En suma, todos nuestros tejidos poseen su propia frecuencia que se expresa en los estados de salud o de enfermedad.

**Holografía**: En Biología se considera que una sola célula contiene el código de todo el organismo. Por tanto se pueden manejar todos los datos recogidos para elaborar un campo holográfico de todo el organismo biológico.

La biología celular recurre a las transformaciones Fourier, para manejar la información que llega y descifrarla. Obviamente los organismos multicelulares, deben tener habilidades superiores para transformar la información que llega. Debemos comparar los modelos de desequilibrio versus los normales, para poder analizar los procesos biológicos celulares.

Por tanto:

1. Las transformaciones de Fourier nos ayudan a fijar las curvas o formas de onda en las técnicas que permitirán entender los impulsos eléctricos extraídos del organismo.
2. Se desarrolla un sistema capaz de aplicar los análisis matemáticos de Fourier para desarrollar las curvas que fijan y muestran la reactividad del cerebro a varias sustancias homeopáticas e ítems (Sus patrones trivectoriales contenidos en el software).
3. Para el entendimiento de los análisis Fourier, el sistema gráfica todas las variaciones en actividad. Esto indica las fases y frecuencias en distorsión.
4. Siguiendo las propiedades importantes de las transformaciones de Fourier tales como la linealidad, etc, se puede entender cómo un sistema utiliza estos análisis matemáticos Fourier para aislar las formas de onda y contextualizarlas dentro de un ámbito biológico.
5. La biología debe utilizar las transformadas de Fourier, aplicarlas a varias interacciones de formas de onda, para traducirlas en otras señales mediante la célula. Es aquí donde es introducido el concepto de la holografía y cómo esta huella holográfica nos puede ayudar a entender los sistemas biológicos y ampliar nuestro entendimiento de las miles de funciones del ADN.
Nos auxiliamos en el sonido y sus vibraciones, para reconocer las resonancias. Podemos encontrar modelos de interferencia de ciertas vibraciones que se utilizan para cancelar o compensar otros tipos de frecuencias aberrantes o distorsionadas y así eliminar microorganismos patógenos.

La manera en que las células de nuestro organismo pueden interactuar, es elevadísima así como su interacción con el entorno (Potencial evocado). Todo ello constituye las técnicas de medicina vibratoria utilizada en el ‘SCIO’. Se forma similar a la naturaleza, una caída de agua suave, un viento agradable, el aire no tóxico, la expresión del amor con la palabra o el saludo, son algunos factores resonantes de la verdadera medicina bio-energética.

3.4. Especificaciones Técnicas

Evaluación energética del organismo: Decimos que los parámetros electromagnéticos más sutiles son medidos por el ‘SCIO’. La medicina bioelectrónica tiene su base en los parámetros que el software llama medidas del voltaje, amperaje, y resistencia (Llamado ‘VARHOPE’ dentro del sistema). El sistema ‘SCIO’ utiliza múltiples canales (110), para medir variantes de estas señales electromagnéticas y el flujo en todo el cuerpo. El ordenador es el instrumento con el que captamos las frecuencias que nos envía la caja de bioresonancia SCIO, y dicha caja hace de amplificador para recibir y responder a la gama de potenciales electrofisiológicos y/o, emocionales o ambientales, sean estos físicos o químicos.

La evaluación de las funciones del cuerpo y afecciones, se evalúan energéticamente de acuerdo a diversas señales:

1. Atenuación por reducción de la amplitud de onda, frecuencias altas y bajas.
2. Medición del ángulo de fase para revisar variables independientes del organismo o fase de unión: inductiva y/o capacitiva.
3. Potencial de corriente que maneja normalmente el cuerpo humano
   a) Restauración en circuitos discriminantes.
   b) Nivel de conductividad – bajo, medio y alto.
   c) Voltaje – bajo, medio, alto y energía potencial normal.
   d) Resistencia – baja, media, alta e impedancia normal.
   e) Disipación de potencia constante en el test de la cifra del tiempo.
   f) Transferencia dinámica capacitiva de la energía en el organismo.
   g) Factor de amplificación, ganancia, estabilidad, grados de detección a varias frecuencias y amplitudes.
   h) Balance eléctrico – lados derecho e izquierdo y cuadrantes.
   i) Estabilización: frecuencia, voltaje, Ohms y temperatura.

De todas estas evaluaciones energéticas del cuerpo, siguen derivándose múltiples situaciones, las cuales son más ampliamente explicadas en la bibliografía de este documento.

3.5. El efecto “Xroid”

El proceso ‘Xroid’ es la capacidad de medir la reacción de un organismo a velocidades biológicas. Este proceso queda reflejado en el test efectuado a la Reactividad Electro Fisiológica (EPR, por sus siglas en inglés), de una persona a miles de substancias a velocidades biológicas. Las velocidades biológicas son definidas como, las que se acercan a la velocidad de intercambio iónico en la reacción eléctrica de una persona, a los estímulos de su ambiente inmediato.

4. Respuesta a la frecuencia – Longitud de onda y forma de onda
   a) Distorsión de frecuencias en el sistema nervioso.
   b) Rehabilitación de pulsos sincrónicos por reacciones de impulsos normales.
   c) Filtro para eliminar puntos de unidades armonícas y resonantes.
   d) Impedancia y resonancia y rangos de frecuencias de las mismas.
   e) Modulación porcentual de caída de voltaje, valor de voltaje, rms (medición de la raíz cuadrada de la potencia).
   f) Constante de tiempo de los nervios: pequeña, medio y grande.
   g) Anchura de pulso: corto, medio y ancho.
   h) Factor ‘Q’ (calidad) en condiciones resonantes.
   i) Curvas características con cambios de amplitud.
   j) Factor de estabilidad e impedancia en mediciones en acoplamiento.
   k) Factor de ruido y niveles del sistema auditivo y vocal, corazón, sistemas circulatorio y muscular.
   l) Oscilaciones de impulsos iniciales sostenidos.
   m) Características de pulso – Tiempo de elevación, tiempo de caída y forma de onda.
   n) Potenciales del cuerpo: Demodulación y amplificación del cuerpo.
   o) Retroalimentación en los sistemas nerviosos humanos (sistema nervioso central y periférico, sistema nervioso autónomo), y daño de nervios.
   p) Control del ritmo cardiaco con audio generador de ángulos de fase con variables duales.
   q) Potenciales electromagnéticos de niveles de energía del organismo.
   r) Potenciales electroestáticos de niveles de energía del organismo.
   s) Reacción de degeneración del organismo.
   t) Reacción de un sistema visual por respuesta de pulso.
   u) Reacción electromagnética por inducción.

Esta comunicación es privada, confidencial y está bajo la protección legal (Ley 15/1999). Está prohibida su traducción o copia por cualquier medio a personas distintas del destinatario. Si la ha recibido por error, se ruega avisar al remitente y destruir la QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - ESPAÑA Tel./Fax 93 429 88 63 cefiro@biorresonancia.com
Dicha velocidad tiene valores de aproximadamente 1/100 de segundo en una persona normal y mucho menores en un atleta de élite.

El 'Xroid' fue creado por el Prof. W.C. Nelson\textsuperscript{34} y fue utilizado por primera vez en 1985 en el dispositivo 'EPFX', que fue el primer modelo de Bioresonancia con estas características. Se registró en el 'FDA' de los Estados Unidos de América en 1989. El dispositivo se ha ido desarrollando tecnológicamente, hasta el modelo existente en la actualidad que es el 'SCIO'.

El hecho de testar a una persona a dichas velocidades, produce un cambio en el campo de la Reactividad Electro Fisiológica (EPR) del paciente, quien podrá experimentar estados de hiperreactividad después de las pruebas. Algunas personas relatan el sentido aumentado de gusto, olor, coordinación, flexibilidad y hasta hipersensibilidad. El tiempo de recuperación parece variar según la condición de la persona, pudiendo ser mínimo de veinticuatro horas.

Hora después de una prueba de 'Xroid' se presentan varias mejoras en la claridad del pensamiento, coordinación de ojos y manos, etc.

Las partes que conforman el 'Xroid' son:

- **Resonancia**: Si la persona presenta una reacción inicial y necesita el estímulo.
- **Coherencia**: Indica una atracción armónica hacia el estímulo en concreto.
- **Reactividad**: Indica una reacción inmediata de la persona.
- **Rectificada**: Indica que una perturbación energética ha sido reparada.
- **Alérgico**: Indica una reacción alérgica a un ítem.

El PROCESO 'Xroid'. En la pantalla de testaje a la que se accede al pulsar el botón 'Test' desde la pantalla del menú principal, se pulsará el botón 'Preparar Test' y el sistema se preparará para iniciar el testaje de la reactividad electrofisiológica de la persona a los más de 11.000 datos contenidos en el software. Un total de 110 medidas de variables y reactividad son realizadas sobre cada sustancia. Ya que la reacción es reactiva-iónica, la reacción de prueba ocurre en pequeños intervalos de tiempo.

Windows no funciona en tiempo real. Así que para medir la reactividad de la persona se han de interrumpir las funciones de 'Windows' de esa pantalla. La instrucción adecuada es enviada a la caja SCIO (caja de Bioresonancia), que iluminará sus luces rojas. Cuando se completa el test la pantalla vuelve a 'Windows', y entonces los cálculos son mostrados en la pantalla. Durante el testaje o escaneado biológico, es preferible que la persona no hable ni se mueva. El tiempo de testado variará de persona a persona y se sitúa entre 3 y 3 minutos 30 segundos. Si bien es cierto que es la caja de Bioresonancia SCIO la que se encarga de captar las frecuencias, y de enviar y recibir la información durante el test, recomendamos que no se haga nada más con el ordenador.

Durante el testado un panel nos dará información sobre los valores de voltaje, amperaje, resistencia, hidratación, oxidación y otros que el aparato denomina como presión protónica y presión electrónica de la persona. Estos cálculos reflejan los resultados durante la operación de calibración y los datos demográficos. Ahora se puede iniciar un análisis más concienzudo sobre el estado de la persona.

Los valores o reacciones más bajas aparecen en la parte superior de la matriz, las reacciones más altas en la parte inferior. Los valores más significativos son los altos que se verán resaltados en rojo. Cuando más elevado es el número, más fuerte es la reacción, valores por encima de 95 son significativos. Estos valores no son un absoluto sino la mejor estimación matemática posible. Los valores en rojo son el equivalente a tres ‘desviaciones estándar’ del valor medio, en púrpura a dos ‘desviaciones estándar’ del valor medio, del valor amarillo y los valores en azul (poca o ninguna reactividad), se listan por orden de reactividad.

### 3.6. Componentes del sistema de Bioresonancia-SCIO

La persona que ha de ser testada, escaneada y/o tratada, es conectada a la caja SCIO que es el sistema principal de este sistema, mediante cinco electrodos principales: uno en cada extremidad y una banda circular en la cabeza. La caja de interface se conecta al puerto USB de un ordenador previamente cargado con el programa “Clasp 32”, que es el software de control sencillo y de uso sencillo, para medianos a grandes sistemas de 10 Gigabytes. Este software dispone de 500 pantallas y 72 terapias diferentes. Los electrodos son diseñados para proporcionar una gran conductividad y sensibilidad que se sitúan en ambas muñecas y tobillos. Así mismo el frontal, también de policarbonato tiene ocho bandas que se sitúan en ambas muñecas y tobillos. El frente de la caja SCIO es el interfaz del sistema, mediante diferentes electrodos de confección con un tamaño de 10 Gigabytes. Este software dispone de 500 pantallas y 72 terapias diferentes. Los electrodos son diseñados para proporcionar una gran conductividad y sensibilidad que se sitúan en ambas muñecas y tobillos. Así mismo el frontal, también de policarbonato tiene ocho bandas que se sitúan en ambas muñecas y tobillos.
Estos electrodos van conectados mediante puertos serie, a la caja de Biorresonancia-Biofeedback /SCIO (interface), y ésta, mediante una conexión USB-USB, está conectada a un ordenador.

Características del ordenador:

- Intel Core Duo procesador.
- 1 Giga de memoria RAM para XP y de 3 Giga para Windows Vista.
- Pantalla resolución 1280 x 800 para 15’4” y 1440 x 900 para 17”.
- Tarjeta de Sonido y de Video ATI o NVIDIA de última generación
- Aconsejable: disco duro con partición de 160 Gigas con programa de poder salvar imágenes
- Máximo hardware y software instalado.

Posibilidades de conectar otros electrodos:

En la parte trasera de la caja de Biorresonancia-Biofeedback / SCIO, existe una conexión de salida para poder incorporar otros electrodos a la terapia. Los expondrémos de izquierda a derecha:

1. Tenemos el rodillo grande: Está preparado para focalizar la terapia en zonas amplias. Se puede dejar fija en un punto (por ejemplo en un punto gatillo, en un disco protusionado, en un hígado inflamado...), o se puede ir deslizando por una zona amplia que haya que tratar.
2. El rodillo pequeño: aunque tiene las mismas aplicaciones que el grande, se utiliza principalmente para pequeñas articulaciones y para estética facial.
3. El electrodo de punto tiene una gran utilidad en puntos de acupuntura, terapias dentales, de piel como verrugas, manchas...
4. El electrodo oculaire canaliza las terapias oculares de una manera concreta, eficaz y anatómica, pudiendo también aplicarse, por su forma anatómica, indirectamente, a la sinusitis, rinsitis, bolsas de ojos y líneas de expresión oculares.

Figura 14. Electrodos rígidos para reforzar la terapia. Son de plata para máxima conductividad y Portamango y cable de conexión

Figura 15. Electrodos flexibles para reforzar la terapia de diversas formas para adaptarse a la zona a tratar, con conexión directa a la caja SCIO

5. El portaelectrodo tiene un carácter universal para todos los electrodos, menos para los podales. Gracias a su conexión mango-electrodo por el sistema de rosca, obtenemos una perfecta canalización del flujo de frecuencias.
6. El cable va unido por un extremo al Portaelectrodo y por el otro a la caja Biorresonancia / SCIO mediante una conexión directa.

Figura 16. Plantillas pódalas conectadas a la parte posterior de la caja

7. Los electrodos pódales permiten una potenciación de la terapia, al testar y activar las 72.000 terminaciones nerviosas situadas en cada planta del pie.

En la imagen inferior podemos observar a una persona conectada. La misma, puede estar sentada en una silla con brazos cómodo (situación que prefieren los pacientes con problemas lumbares y con procesos ansioso-depresivos por la posición de “alerta”), un sillón con o sin reposapiés o bien en camilla en cualquiera de sus muchas posiciones. Lo más importante es que el paciente se sienta cómodo y esté relajado durante la sesión para entrar de una manera más fácil en resonancia con su información frecuencial. Los pacientes con problemas psico-emocionales, prefieren el sillón a la camilla. La posición de “estirado” les resulta angustiante, en silla están en posición de alerta, en cambio en sillón consiguen estar relajados y más tarde o más temprano, abren su interior, lo que en el caso de pacientes con dolor crónico y sobre todo en Fibromialgias es esencial ya que, como hemos dicho en la introducción, tienen una sensación continua de no ser entendidos en su dolencia y cansancio.

Dicha sensación en algunos casos es verdad y entonces el sufrimiento es más importante. En otras ocasiones tienen el sentimiento que su médico tampoco les cree y entonces se sienten impotentes. Durante la terapia, intentamos que él o la paciente estén relajados pero sabiendo que les comprendemos y que “firmamos” un pacto el primer día de visita en el cual formamos una complicidad con el paciente. El ir relajado a dormir siempre a la misma hora, cumplir con un horario de comidas, una dieta apropiada a su sistema digestivo (intestino irritable o bloqueo intestinal), cuándo comer y cómo, cuándo hacer ejercicio, cómo y cuánto, concienciarse de la necesidad de tener un tratamiento adecuado para darle una mayor calidad de vida.

Es preferible que la estancia esté con una temperatura agradable así como la luz que no sea excesivamente potente, para que de esta manera incida a la relajación. Cuando la persona está relajada, baja...
dos o tres grados su temperatura corporal, gracias a la relajación que siente. Si es necesario, taparla con una mantita que le resulte agradable.

Figura 17. Paciente conectado y el sistema trabajando un tratamiento espinal

La audición del paciente de una música subliminal de relajación acompañada o no de audiovisuales, puede ser otra manera de conseguir un agradable bienestar en nuestro paciente. Por norma general, en un 80% aproximadamente de los casos, el paciente se queda dormido. En estos casos la sesión es más rápida por la disminución de resistencia consciente. Si el paciente está pensando en cosas que le preocupan, está creando inconscientemente una resistencia a la estabilización de las frecuencias, por lo que se tardará más en conseguir nuestro objetivo.

III. MATERIAL Y MÉTODOS

1. Aparatología

Se ha utilizado un hardware de Biofeedback modelo “SCIO” y un software específico instalado en un ordenador (siempre el mismo)

2. Testado de Pacientes

Se han realizado dos estudios. Los llamaremos A y B. Dichos estudios han sido realizados desde principios de mayo a diciembre de 2008.

El paciente para ser testado ha tenido que estar sin aparatos de radio-frecuencia durante la sesión. Aparte de esto, también tenía que estar relajado y tranquilo para no bloquear ni que saliera un testado erróneo bien sea por un falso positivo como por un falso negativo. La actitud de los pacientes ha sido relajada y positiva.

El paciente tenía que tener en la sala de terapia, la temperatura ambiente agradable ya que durante la terapia acostumbra haber un descenso de la temperatura corporal. La luminosidad de la sala la adecuamos hasta conseguir un ambiente relajante. El paciente ha de estar en una posición cómoda y relajada durante el proceso de la terapia.

3. Estudio A

3.1. Diseño del estudio

Hemos seleccionado un grupo de siete personas afectadas y diagnosticadas de Fibromialgia por médicos del Instituto Universitario de Reumatología de Barcelona del Dr. Martínez-Pintor.

Las personas se presentaron para el estudio con curiosidad por algo nuevo y con mucho interés por saber los resultados finales. La colaboración fue buena y mostraron interés durante la evolución de la terapia.

3.2. Selección y tamaño de la muestra estudio

Las personas seleccionadas han de tener los siguientes criterios de inclusión:

- La misma asistencia sanitaria (del Instituto Universitario de Reumatología de Barcelona, el cual se rige en los parámetros, criterios y diagnóstico del ACR y llevarán al menos tres meses sin modificar los tratamientos.

- Edad entre 30 y 60 años

Para prevenir bajas durante el estudio, seleccionaremos cinco personas más en cada uno de los grupos 1 y 2 como reserva.

Primero se les explica la naturaleza del estudio y que no hay ningún efecto secundario a la realización de estos tratamientos. Se les facilita un pequeño impreso donde se expone lo que es la Biorresonancia-SCIO, los parámetros que se van a medir.

3.3. Desarrollo del estudio

El tamaño de la muestra ha sido de 7 pacientes: En la gráfica se les denomina “J”
Pacientes diagnosticados de Fibromialgia con control médico en los últimos tres meses y tratamiento con Bioresonancia-SCIO.

Se les practicaron 5 sesiones con el sistema de biofeedback con el sistema SCIO con una periodicidad semanal y una duración de una hora y media la primera sesión y una hora las siguientes.

Primero, se les informó de forma verbal y mediante explicación escrita, en qué consistía el estudio.

Antes de hacerles tratamiento, utilizaremos como unidad de medida el cuestionario validado de la escala de Alexitimia de Toronto, el de Beck, el HAQ, el STAI y el test de valoración EVA. Al terminar el estudio se les volverá a pasar los cuestionarios para su valoración.

Para la valoración del estudio hemos seleccionado cinco tests:


2. Beck: Beck Depression Inventory (DBI)38, utilizada para medir los niveles de depresión. Se consideran estados depresivos aquellas puntuaciones superiores a 9

3. HAQ: Health Assessment Questionary39, 40, cuestionario para valorar la capacidad funcional. En su corrección se consideran valores normales aquellos inferiores a 1.

4. STAI: State-Trait Anxiety Inventory40, 41; utilizado para medir los estados de ansiedad considerando patológico cuando supera los 12-15 puntos

5. EVA: La Escala Visual Analógica es un instrumento validado para la expresión del dolor por parte del paciente. Fue diseñada por Scout Huskinson42 en 1976. Consiste en una línea continua. El extremo de la izquierda está marcado con un 0 (o ausencia de dolor) y el extremo de la derecha con un 10 (máximo de dolor). En dicha línea el paciente refleja su dolor. En 1978, Downie43 la expresó en número del 0 al 10, siendo 0 la ausencia de dolor y 10 el máximo dolor. Sólo se considera que el paciente mejora cuando disminuye su dolor en dos dígitos después de un tratamiento. Se considera dolor severo a partir de 7.

4. Estudio B

4.1 Diseño General del Estudio

4.1.1 Primer grupo

Los pacientes seleccionados fueron conectados y tratados. A este grupo lo llamaremos grupo "C", por haber sido tratados.

4.1.2 Segundo grupo

Los pacientes seleccionados fueron conectados pero no tratados. A este grupo le llamaremos "N" por haber sido sometidos a un tratamiento placebo, y no haber sido tratados.

4.2 Selección y tamaño de la muestra

La selección de los pacientes se realizó por riguroso orden de aparición (estudio simple ciego), sumando a esto el desconocimiento del profesional a dicha orden de aparición.

El primer paciente fue seleccionado dentro del primer grupo, el siguiente en el segundo, y así sucesivamente.
4.2.1. **Primer grupo**

Se seleccionaron dentro de este grupo el primer, tercer, quinto, séptimo y noveno pacientes que asistieron a la consulta. En las gráficas pertenecerá al grupo “C”.

4.2.2. **Segundo grupo**

Se seleccionaron dentro de este grupo el segundo, cuarto, sexto, octavo y décimo pacientes en asistir a la consulta. En las gráficas pertenecerán al grupo “N”.

4.3. **Desarrollo del Estudio**

Pacientes diagnosticados de Fibromialgia con control médico en los últimos tres meses y tratamiento con Bioresonancia-SCIO.

Se les practicaron 5 sesiones con el sistema de Biofeedback con el sistema SCIO con una periodicidad semanal y una duración de una hora y media la primera sesión y una hora las siguientes.

Primero se les informó de forma verbal y mediante explicación escrita, en qué consistía el estudio. Antes de hacerles tratamiento, utilizaremos como unidad de medida el cuestionario validado de la escala de Alexitimia de Toronto, el de Beck, el HAQ, el STAI y el test de valoración EVA. Al terminar el estudio se les volverá a pasar los cuestionarios para su valoración.

Para la valoración del estudio hemos seleccionado cinco tests:


- **Beck**: Beck Depression Inventory (DBI), utilizada para medir los niveles de depresión. Se consideran estados depresivos aquellas puntuaciones superiores a 9.

- **HAQ**: Health Assessment Questionary (HAQ): cuestionario para valorar la capacidad funcional. En su corrección se consideran valores normales aquellos inferiores a 1.

- **STAI**: State-Trait Anxiety Inventory, utilizado para medir los estados de ansiedad considerando patológico cuando supera los 12-15 puntos.

- **EVA**: La Escala Visual Analógica es un instrumento validado para la expresión del dolor por parte del paciente. Fue diseñada por Scout Huskinson en 1976. Consiste en una línea continua. El extremo de la izquierda está marcado con un 0 (ausencia de dolor) y el extremo de la derecha con un 10 (máximo de dolor). En dicha línea el paciente refleja su dolor. En 1978, Downie expresó en número del 0 al 10, siendo 0 la ausencia de dolor y 10 el máximo dolor. Sólo se considera que el paciente mejora cuando disminuye su dolor en dos dígitos después de un tratamiento. Se considera dolor severo a partir de 7.
IV. RESULTADOS

1. Estudio A

1.1 Tablas y gráficos:

1.1.1 Alexitimia

A continuación exponemos los resultados obtenidos a la realización del test de Alexitimia, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 1, grafico 1, tabla 2). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilconxon. La prueba de Alexitimia se valora dentro de un rango comprendido entre 20 y 100, entendemos que una puntuación a partir de 61 entraríamos a hablar en parámetros de distorsión, es decir persona que tienen problemas a la hora de expresar sus sentimientos; de esta manera observamos que, la mayoría de los pacientes presentaron una notable mejoría, después de haber sido sometidos a las 5 sesiones de Biorresonancia-SCIO.

Tabla 1. Valoración del Test de Alexitimia efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones.

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>Alexitimia Antes</th>
<th>Alexitimia Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1</td>
<td>60</td>
<td>24</td>
<td>36</td>
</tr>
<tr>
<td>J2</td>
<td>45</td>
<td>46</td>
<td>-1</td>
</tr>
<tr>
<td>J3</td>
<td>40</td>
<td>13</td>
<td>27</td>
</tr>
<tr>
<td>J4</td>
<td>18</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>J5</td>
<td>53</td>
<td>31</td>
<td>22</td>
</tr>
<tr>
<td>J6</td>
<td>34</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>J7</td>
<td>73</td>
<td>0</td>
<td>73</td>
</tr>
</tbody>
</table>

Grafica 1. Visualización gráfica del Test de Alexitimia efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones.

Tabla 2. Valoración del estadístico de Wilconxon en el Test de Alexitimia efectuado a los pacientes del estudio.

| Estadísticos de contraste
<table>
<thead>
<tr>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
</tr>
<tr>
<td>Sig. asintót. (bilateral)</td>
</tr>
</tbody>
</table>

a. VAR00002 < VAR00001
b. VAR00002 > VAR00001
c. VAR00002 = VAR00001

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruir.

QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN Tel/Fax: +34 93 429 88 63 cefiro@biorresonancia.com

Esta comunicación es privada, confidencial y sujeta al secreto profesional (Ley 15/1999). Está prohibida su divulgación o copia por cualquier medio o persona distinta del destinatario. Si lo ha recibido por error, se ruega avisar al emisor y destruir.

QUANTUM UNIVERSE S.L. C/ Fabra y Puig, 326 Entloº2ª - 08031 BARCELONA - SPAIN Tel/Fax: +34 93 429 88 63 cefiro@biorresonancia.com
1.1.2 BECK

A continuación exponemos los resultados obtenidos a la realización del test de Beck, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 3, grafico 2, tabla 4).

La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilcoxon. BECK es una prueba utilizada para medir los niveles de depresión. Se consideran estados depresivos aquellas puntuaciones superiores a 9; observamos, que existe mejoría en los pacientes, después de haber sido sometidos a las 5 sesiones de Bioresonancia-SCIO.

Tabla 3. Valoración del Test de Beck efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>BECK Antes</th>
<th>BECK Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1</td>
<td>19</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>J2</td>
<td>13</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>J3</td>
<td>14</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>J4</td>
<td>15</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>J5</td>
<td>18</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>J6</td>
<td>9</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>J7</td>
<td>32</td>
<td>9</td>
<td>23</td>
</tr>
</tbody>
</table>

Tabla 4. Valoración del estadístico de Wilcoxon en el Test de Beck efectuado a los pacientes del estudio.

<table>
<thead>
<tr>
<th>Estadísticos de contraste</th>
<th>a. VAR00002 &lt; VAR00001</th>
<th>b. VAR00002 &gt; VAR00001</th>
<th>c. VAR00002 = VAR00001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
<td>-2.371</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sig. asintót.</td>
<td>,018</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a. Basado en los rangos positivos.
b. Prueba de los rangos con signo de Wilcoxon
1.1.3 HAQ

A continuación exponemos los resultados obtenidos a la realización del test de HAQ, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 5, gráfico 3, tabla 6). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilcoxon. El cuestionario de HAQ valora la capacidad funcional, consideran valores normales aquellos inferiores a 1; observamos, que existe mejora en los pacientes, después de haber sido sometido a las 5 sesiones de Biorresonancia-SCIO.

Tabla 5. Valoración del Test de HAQ efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones.

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>HAQ Antes</th>
<th>HAQ Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1</td>
<td>17</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>J2</td>
<td>25</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>J3</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>J4</td>
<td>14</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>J5</td>
<td>17</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>J6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>J7</td>
<td>29</td>
<td>8</td>
<td>21</td>
</tr>
</tbody>
</table>

Tabla 6. Valoración del estadístico de Wilcoxon en el Test de HAQ efectuado a los pacientes del estudio.

<table>
<thead>
<tr>
<th>Estadísticos de contraste</th>
<th>VAR00002</th>
<th>VAR00001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
<td>-2.201</td>
<td></td>
</tr>
<tr>
<td>Sig. asintót. (bilateral)</td>
<td>.028</td>
<td></td>
</tr>
</tbody>
</table>

Grafica 3. Visualización gráfica del Test de HAQ efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones.

b. Prueba de los rangos con signo de Wilcoxon.
1.1.4 STAI

A continuación exponemos los resultados obtenidos a la realización del test de STAI, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 7, grafico 4, tabla 8).

La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilcoxon. El STAI es utilizado para medir los estados de ansiedad, se considera patológico cuando supera los 12-15 puntos; observamos que, la mayoría de los pacientes presentaron una notable mejora; después de haber sido sometidos a las 5 sesiones de Bioresonancia-SCIO.

Tabla 7. Valoración del Test de STAI efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>STAI</th>
<th>Antes</th>
<th>Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1</td>
<td>31</td>
<td>13</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>J2</td>
<td>23</td>
<td>22</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>J3</td>
<td>27</td>
<td>15</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>J4</td>
<td>44</td>
<td>25</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>J5</td>
<td>30</td>
<td>17</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>J6</td>
<td>31</td>
<td>4</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>J7</td>
<td>50</td>
<td>17</td>
<td>33</td>
<td></td>
</tr>
</tbody>
</table>

Grafico 4. Visualización gráfica del Test de STAI efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones

Tabla 8. Valoración del estadístico de Wilcoxon en el Test de STAI efectuado a los pacientes del estudio.

<table>
<thead>
<tr>
<th>Estadísticos de contrastea</th>
<th>VAR00002 &lt; VAR00001</th>
<th>a. Basado en los rangos positivos.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
<td>-2.366</td>
<td>Sig. asint. bilateral: 0.018</td>
</tr>
<tr>
<td>b. Prueba de los rangos con signo de Wilcoxon</td>
<td>VAR00002 &gt; VAR00001</td>
<td>c. VAR00002 = VAR00001</td>
</tr>
</tbody>
</table>
1.1.5 EVA

A continuación exponemos los resultados obtenidos a la realización del test de EVA, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 9, gráfico 5, tabla 10). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilconxon. La Escala Visual Analógica (EVA) es un instrumento validado para la expresión del dolor por parte del paciente, considerando que el 0 es la ausencia de dolor y 10 el dolor máximo, observamos que, la mayoría de los pacientes presentaron una notable mejora; después de haber sido sometidos a las 5 sesiones de Biorresonancia-SCIO.

Tabla 9. Valoración del Test de EVA efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>EVA</th>
<th>Antes</th>
<th>Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1</td>
<td>5</td>
<td>5</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>J2</td>
<td>7,5</td>
<td>7</td>
<td></td>
<td>0,5</td>
</tr>
<tr>
<td>J3</td>
<td>8</td>
<td>6</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>J4</td>
<td>7</td>
<td>3</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>J5</td>
<td>7</td>
<td>5</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>J6</td>
<td>8</td>
<td>4</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>J7</td>
<td>10</td>
<td>7</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

Tabla 10. Valoración del estadístico de Wilconxon en el Test de STAI efectuado a los pacientes del estudio.

<table>
<thead>
<tr>
<th>Estadísticos de contraste b</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAR00002 &lt; VAR00001</td>
</tr>
<tr>
<td>Z</td>
</tr>
<tr>
<td>-2,214</td>
</tr>
<tr>
<td>Sig. asintót. (bilateral)</td>
</tr>
<tr>
<td>.027</td>
</tr>
</tbody>
</table>

a. Basado en los rangos positivos.

b. Prueba de los rangos con signo de Wilcoxon
Se ha realizado una homogeneidad de medias de datos independientes y hemos usado la prueba no-paramétrica de rangos de Wilcoxon debido, a que la diferencia de las medidas no sigue una distribución normal y el tamaño de la muestra es muy reducido.

Los resultados nos permiten rechazar la hipótesis nula de las pruebas aceptando la hipótesis alternativa unilaterial con un P-value inferior a 0.05. La hipótesis alternativa consiste en que el tratamiento de Biorresonancia da un valor central suficientemente alejado de la media, para considerar una clara mejora.

2. Estudio B

2.1 Tablas y gráficos

2.1.1 Alexitimia

En este segundo estudio, se hicieron dos grupos de cinco pacientes cada uno. Los dos grupos fueron conectados con electrodos. Un grupo fue tratado y el otro grupo fue placebo. Ningún paciente de este estudio sabía si estaba siendo tratado o no.

A continuación exponemos los resultados obtenidos a la realización del test de Alexitimia, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 11, gráfico 6, tabla 12). La prueba estadística utilizada es el test estadístico de Wilcoxon, debido que la prueba de datos dependientes de Mann-Whitney, no se puede realizar debido al reducido tamaño de la muestra.

Tabla. 11 Valoración del Test de Alexitimia efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones. (C= pacientes tratados, N= pacientes placebos).

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>Alexitimia</th>
<th>Antes</th>
<th>Después</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td></td>
<td>62</td>
<td>35</td>
<td>27</td>
</tr>
<tr>
<td>C2</td>
<td></td>
<td>55</td>
<td>30</td>
<td>25</td>
</tr>
<tr>
<td>C3</td>
<td></td>
<td>52</td>
<td>35</td>
<td>17</td>
</tr>
<tr>
<td>C4</td>
<td></td>
<td>24</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>C5</td>
<td></td>
<td>19</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>N1</td>
<td></td>
<td>38</td>
<td>36</td>
<td>2</td>
</tr>
<tr>
<td>N2</td>
<td></td>
<td>23</td>
<td>25</td>
<td>-2</td>
</tr>
<tr>
<td>N3</td>
<td></td>
<td>42</td>
<td>45</td>
<td>-3</td>
</tr>
<tr>
<td>N4</td>
<td></td>
<td>44</td>
<td>54</td>
<td>-10</td>
</tr>
<tr>
<td>N5</td>
<td></td>
<td>54</td>
<td>58</td>
<td>-4</td>
</tr>
</tbody>
</table>
En este segundo estudio, se hicieron dos grupos de cinco pacientes cada uno. Los dos grupos fueron conectados con electrodos. Un grupo fue tratado y el otro grupo fue placebo. Ningún paciente de este estudio sabía si estaba siendo tratado o no.

A continuación exponemos los resultados obtenidos a la realización del test de Beck, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 13, gráfico 7, tabla 14). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricas, utilizando el test estadístico de Wilcoxon, debido a que la prueba de homogeneidad de medias, de datos dependientes (Mann-Whitney), no se puede realizar debido al reducido tamaño de la muestra. De esta manera observamos que, la mayoría de los pacientes conectados, a diferencia de los no conectados; presentaron una notable mejora; después de haber sido sometidos a las 5 sesiones de Bioresonancia-SCIO.

Tabla 13 Valoración del Test de BECK efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones. (C= pacientes tratados, N= pacientes placebos)

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>BECK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
</tr>
<tr>
<td>C1</td>
<td>26</td>
</tr>
<tr>
<td>C2</td>
<td>20</td>
</tr>
<tr>
<td>C3</td>
<td>19</td>
</tr>
<tr>
<td>C4</td>
<td>17</td>
</tr>
</tbody>
</table>
C5 | 18 | 1 | 17
N1 | 19 | 19 | 0
N2 | 20 | 22 | -2
N3 | 4 | 4 | 0
N4 | 24 | 21 | 3
N5 | 24 | 28 | -4

Grafica 7. Visualización gráfica del Test de BECK efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones (C= pacientes tratados, N= pacientes placebos)

Tabla 14. Valoración del estadístico de Wilconxon en el Test de Beck efectuado a los pacientes del estudio conectados y no conectados, antes de iniciar la terapia y después de las 5 sesiones.

Advertencia

No hay casos válidos suficientes para realizar la prueba de Mann-Whitney para VAR00004 * VAR00005 (5,00, 5,00). No se calcularán los estadísticos.

Estadísticos de contraste

<table>
<thead>
<tr>
<th></th>
<th>Conectado_después - Conectado_antes</th>
<th>No_conectado_después - No_conectado_antes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
<td>-2,023&lt;sup&gt;a&lt;/sup&gt;</td>
<td>-1,535&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sig. asintót. (bilateral)</td>
<td>0,043</td>
<td>0,593</td>
</tr>
</tbody>
</table>

a. Basado en los rangos positivos.
b. Basado en los rangos negativos.
c. Prueba de los rangos con signo de Wilcoxon

d. Conectado_después < Conectado_antes
e. Conectado_después > Conectado_antes
f. Conectado_después = Conectado_antes
g. No_conectado_después < No_conectado_antes
h. No_conectado_después > No_conectado_antes
i. No_conectado_después = No_conectado_antes
2.1.3 HAQ

Al igual que en los apartados anteriores, en este segundo estudio, se hicieron dos grupos de cinco pacientes cada uno. Los dos grupos fueron conectados con electrodos. Un grupo fue tratado y el otro grupo fue placebo. Ningún paciente de este estudio sabía si estaba siendo tratado o no.

A continuación expomemos los resultados obtenidos a la realización del test de HAQ, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 15, grafico 8, tabla 16). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilconxon, debido a que la prueba de homogeneidad de medias, de datos dependientes (Mann-Whitney), no se puede realizar debido al reducido tamaño de la muestra. De esta manera observamos que, la mayoría de los pacientes conectados, a diferencia de los no conectados; presentaron una notable mejora, después de haber sido sometidos a las 5 sesiones de Biorresonancia-SCIO.

Tabla 15 Valoración del Test de HAQ efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones. (C= pacientes tratados, N= pacientes placebos)

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>HAQ</th>
<th>Diferencia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
<td>Después</td>
</tr>
<tr>
<td>C1</td>
<td>28</td>
<td>3</td>
</tr>
<tr>
<td>C2</td>
<td>26</td>
<td>8</td>
</tr>
<tr>
<td>C3</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>C4</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>C5</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>N1</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>N2</td>
<td>17</td>
<td>27</td>
</tr>
<tr>
<td>N3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>N4</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>N5</td>
<td>31</td>
<td>35</td>
</tr>
</tbody>
</table>

Tabla 16. Valoración del estadístico de Wilconxon en el Test de HAQ efectuado a los pacientes del estudio conectados y no conectados, antes de iniciar la terapia y después de las 5 sesiones.

3. Advertencia

No hay casos válidos suficientes para realizar la prueba de Mann-Whitney para VAR00004 * VAR00005 (5.00, 5.00). No se calcularán los estadísticos.
2.1.4 STAI

Al igual que en los apartados anteriores, en este segundo estudio, se hicieron dos grupos de cinco pacientes cada uno. Los dos grupos fueron conectados con electrodos. Un grupo fue tratado y el otro grupo fue placebo. Ningún paciente de este estudio sabía si estaba siendo tratado o no.

A continuación exponemos los resultados obtenidos a la realización del test de STAI, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 17, gráfico 9, tabla 18). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilcoxon, debido a que la prueba de homogeneidad de medias, de datos dependientes (Mann-Whitney), no se puede realizar debido a la reducida tamaño de la muestra. De esta manera observamos que, la mayoría de los pacientes conectados, a diferencia de los no conectados; presentaron una notable mejora, después de haber sido sometidos a las 5 sesiones de Bioresonancia-SCIO.

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>STAI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
</tr>
<tr>
<td>C1</td>
<td>55</td>
</tr>
<tr>
<td>C2</td>
<td>34</td>
</tr>
<tr>
<td>C3</td>
<td>41</td>
</tr>
<tr>
<td>C4</td>
<td>45</td>
</tr>
<tr>
<td>C5</td>
<td>36</td>
</tr>
<tr>
<td>N1</td>
<td>22</td>
</tr>
<tr>
<td>N2</td>
<td>38</td>
</tr>
<tr>
<td>N3</td>
<td>9</td>
</tr>
<tr>
<td>N4</td>
<td>45</td>
</tr>
<tr>
<td>N5</td>
<td>54</td>
</tr>
</tbody>
</table>

Tabla. 17 Valoración del Test de STAI efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones. (C= pacientes tratados, N= pacientes placebos).
Grafica 9. Visualización gráfica del Test de STAI efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones (C= pacientes tratados, N= pacientes placebo no tratados)

Tabla 18. Valoración del estadístico de Wilcoxon en el Test de STAI efectuado a los pacientes del estudio conectados y no conectados, antes de iniciar la terapia y después de las 5 sesiones.

Advertencia

No hay casos válidos suficientes para realizar la prueba de Mann-Whitney para VAR00004 * VAR00005 (5,00, 5,00). No se calcularán los estadísticos.

2.1.5 EVA

Al igual que en los apartados anteriores, en este segundo estudio, se hicieron dos grupos de cinco pacientes cada uno. Los dos grupos fueron conectados con electrodos. Un grupo fue tratado y el otro grupo fue placebo. Ningún paciente de este estudio sabía si estaba siendo tratado o no.

A continuación exponemos los resultados obtenidos a la realización del test de EVA, el cual fue contestado por cada paciente antes de iniciar la primera tanda de 5 sesiones y al finalizar la última sesión (ver tabla 19, grafico 10, tabla 20). La prueba estadística utilizada es una homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilcoxon, debido a que la prueba de homogeneidad de medias, de datos dependientes (Mann-Whitney), no se puede realizar debido al reducido tamaño de la muestra. De esta manera observamos que, la mayoría de los pacientes conectados, a diferencia de los no conectados; presentaron una notable mejora, después de haber sido sometidos a las 5 sesiones de Bioresonancia-SCIO.
Tabla 19 Valoración del Test de EVA efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones. (C= pacientes tratados, N= pacientes placebos)

<table>
<thead>
<tr>
<th>Pacientes</th>
<th>EVA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Antes</td>
</tr>
<tr>
<td>C1</td>
<td>9</td>
</tr>
<tr>
<td>C2</td>
<td>7</td>
</tr>
<tr>
<td>C3</td>
<td>8</td>
</tr>
<tr>
<td>C4</td>
<td>8</td>
</tr>
<tr>
<td>C5</td>
<td>8</td>
</tr>
<tr>
<td>N1</td>
<td>9</td>
</tr>
<tr>
<td>N2</td>
<td>8,5</td>
</tr>
<tr>
<td>N3</td>
<td>4</td>
</tr>
<tr>
<td>N4</td>
<td>9</td>
</tr>
<tr>
<td>N5</td>
<td>9</td>
</tr>
</tbody>
</table>

Grafica 10. Visualización gráfica del Test de EVA efectuado a los pacientes antes de iniciar las terapias y después de las 5 sesiones (C= pacientes tratados, N= pacientes placebos).

Tabla 20 Valoración del estadístico de Wilcoxon en el Test de EVA efectuado a los pacientes del estudio conectados y no conectados, antes de iniciar la terapia y después de las 5 sesiones.

Advertencia

No hay casos válidos suficientes para realizar la prueba de Mann-Whitney para VAR00004 * VAR00005 (5,00, 5,00). No se calcularán los estadísticos.

<table>
<thead>
<tr>
<th>Estadísticos de contraste¹</th>
<th>Conectado después - Conectado antes</th>
<th>No_conectado después - No_conectado antes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z</td>
<td>-1,841</td>
<td>-1,633</td>
</tr>
<tr>
<td>Sig. asintót.</td>
<td>,066</td>
<td>,102</td>
</tr>
</tbody>
</table>

¹ Basado en los rangos positivos.
² Prueba de los rangos con signo de Wilcoxon

a. Conectado después < Conectado antes
b. Conectado después > Conectado antes
c. Conectado después = Conectado antes
d. No_conectado después < No_conectado antes
e. No_conectado después > No_conectado antes
f. No_conectado después = No_conectado antes
En este estudio se ha intentado hacer una homogeneidad de medias de datos dependientes no-paramétricos, debido a que no cumplen los datos los criterios de normalidad y la muestra es muy pequeña. Debido a la limitada muestra el programa SPSS, advierte que no hay casos válidos suficientes para realizar la prueba de Mann-Whitney, por lo que hemos realizado una homogeneidad de medias de datos independientes no-paramétricos de Wilcoxon comparando los sujetos tratados antes y después contra los sujetos no tratados antes y después.

Podemos exponer a la vista de los resultados que podemos rechazar la hipótesis nula, es decir, que el paciente no ha notado mejora, con un riesgo alfa de 0.05 unilateral en todas las pruebas realizadas a individuos tratados con Biorresonancia. Del grupo placebo que no ha recibido tratamiento con Biorresonancia solo podríamos rechazar la nula y aceptar la alternativa en una prueba (STAI) y en las otras no podríamos rechazarla.

Debido a lo anteriormente mencionado podemos observar que en todas las pruebas de los pacientes que han sido tratados hemos tenido evidencia estadística suficiente para rechazar la hipótesis nula y afirmar que el paciente muestra mejora en las pruebas. Por el contrario, en los pacientes control no tratados en todos menos uno no podemos rechazar la hipótesis nula por la cual, evidentemente, no muestra mejora en las pruebas realizadas.

Estos resultados lejos de ser definitivos, requieren una ampliación del estudio con una mayor muestra, para poder aplicar las pruebas estadísticas correspondientes y tener una potencia estadística adecuada.

V. DISCUSIÓN DEL ESTUDIO

El síndrome de la Fibromialgia es un conjunto de síntomas de los cuales todavía no disponemos con certeza cuál es la causa que los produce. Por ello desde varias décadas se está haciendo diversos estudios de investigación en diversas especialidades dentro del campo de la sanidad, para poder paliar los síntomas y mejorar la calidad de vida de los pacientes que padecen este Síndrome.

La Fibromialgia, hay que tratarla desde un punto de vista pluridimensional, es decir, desde un punto de vista global. Por ello somos muchos y de muchas especialidades los profesionales que nos preocupan este síndrome. Especialidades como: fisioterapeutas, reumatólogos, psicólogos, terapeutas ocupacionales, asistentes sociales..., trabajamos día a día para controlar la Fibromialgia.

Por este motivo, hemos pensado que el sistema de Biorresonancia-SCIO, puede sernos muy útil para tratar dicha patología, ya que trabaja todas las áreas afecta por éste Síndrome.

Como ya hemos dicho anteriormente, estos pacientes son extremadamente sensibles; tienen los niveles de dolor y de susceptibilidad muy bajos. Esto provoca un aumento de la sintomatología cuando algún familiar, amigo o profesional pone en duda sus dolencias.

Por ello, a este tipo de pacientes hay que tratarlo de una manera diferente, ya que cada vez que se enfrentan a una situación conflictiva la sintomatología aumenta, y por lo tanto, el dolor, la ansiedad y la depresión.

Es muy importante que el paciente se sienta respaldado y comprendido por su familia, sobre todo marido o esposa e hijos; del mismo modo también es muy importante que sienta que su terapeuta le comprenda y tenga confianza en él, es decir, que el terapeuta le transmita al paciente que va hacer todo lo que sabe para ayudarle y que entiende su sufrimiento. Esto nos llevará a una mejor eficacia y rapidez de la terapia, consiguiendo por ello una mejoría de su sintomatología.

Se puede decir que los pacientes de Fibromialgia responden muy favorablemente a la terapia de Biorresonancia-SCIO, ya que a ellos no les provoca ningún tipo de dolor ni de molestias, sólo tienen que estar cómodos, relajarse y no pensar en nada que les ocasione negatividad, ya que el sentimiento de la misma crearía una Resistencia en el flujo de las ondas frecuenciales durante el tratamiento, y dificultaría la rectificación de las mismas.
Cuando se empezó a diseñar el estudio para esta tesis se pensó en seleccionar un grupo de 10 pacientes, hacerles terapia y observar los resultados. A cada paciente se le haría cinco sesiones, la primera de hora y media y las demás de una hora. Haciendo de esta manera un estudio de homogeneidad de media de datos independientes.

Para valorar dichos resultados se utilizarían los tests de Alexitimia, BECK, HAQ, STAI y EVA. Estos tests se realizaban antes de la primera sesión y al finalizar la última. Cuando llevábamos 7 pacientes de los 10 que marcaba el estudio, observábamos que la mejora que sentían los pacientes pudiera estar ligada a un factor psicosomático como podría ser la novedad de la prueba o bien la presencia optimista del terapeuta. Para descartar dichas dudas se diseñó un segundo estudio. Haciendo una prueba de homogeneidad de medias de datos independientes para comparar las dos poblaciones.

Este segundo estudio consistía en un simple ciego. Se seleccionaron 10 pacientes y decidimos que todos serían conectados al sistema de Biorresonancia-SCIO, pero sólo a 5 se le haría la terapia. Evidentemente a los otros 5 se simularía que se les estaba haciendo terapia.

El primer estudio que llamaremos “A”, se desarrolló desde mayo a julio, esto quiere decir, que climatológicamente hablando estamos viviendo una evolución de primavera a verano. Durante este período el paciente “tipo” de Fibromialgia siente remisión de los síntomas sobre todo referente a los entumecimientos y los dolores. A demás estas estaciones en las cuales predomina el sol, favorecen el estado anímico de todas las personas, máxime en los pacientes afectos de dicho Síndrome.

Al contrario, en el segundo estudio al cual llamaremos “B”, el proceso sucedió a la inversa, es decir, empezó en octubre y finalizó en diciembre. Esta época del año evoluciona con fríos, humedades y lluvia, y además, disminución de las horas solares. Además este otoño-invierno coincidió con unos cambios climáticos extremos, habiendo oscilado la temperatura 10ºC en un mismo día. Esto no ayuda a los pacientes pues provoca un aumento de la sintomatología músculo-esquelética, alteración del sueño y aumento en sus síntomas ansioso-depresivos principalmente.

Durante el segundo estudio observamos un cambio de actitud de los pacientes respecto al primer estudio. La duda que en los pacientes del segundo estudio existía de si iban a ser o no ellos los seleccionados para la terapia, creó cierta incertidumbre e inseguridad respecto al carácter aleatorio del estudio. El paciente estaba más preocupado de si estaban siendo tratados o no, que de relajarse y observar sus síntomas. Esto en un paciente con otra patología quizá no sería tan significativo, pero en el caso del Síndrome de Fibromialgia se agudiza más dada su susceptibilidad tan acusada.

A todos los pacientes se les informó que si ellos pertenecían al grupo de pacientes que aleatoriamente no se les hacia terapia, una vez finalizado el estudio, se les efectuarían 5 sesiones de terapia no valorables para el estudio de investigación.

Estas sesiones extras fuera del estudio se propusieron debido a que éticamente no nos parecía correcto dejar a 5 personas de dentro del estudio sin terapia ya que debían tener una compensación por su voluntariedad, y evitar posibles niveles de frustración que pudieran alterar el resultado del estudio.

Con respecto a los resultados en el estudio “A” observamos:

- Aunque existen diferencias según diversos autores en determinar a partir de qué valor en el test de Alexitimia se considera patológico/distorsionante o no, nos adheriremos al criterio del estudio “Validez Psicométrica de la Escala de Alexitimia de Toronto (TAS-20): un estudio Transcultural” en el que llegaron al acuerdo de que a partir de 61 se consideraba que la persona testada sufría problemas a la hora de expresar sus sentimientos.

  A pesar de todo, si observamos la Tabla 1, veremos que antes de hacer la terapia, los pacientes no tenían un grado de Alexitimia preocupante. Tan sólo uno de ellos. No obstante todos los valores bajaron ostensiblemente después de las cinco sesiones. Los pacientes estaban más predispuestos a la expresión emocional.

El hecho que los pacientes en el primer testaje de Alexitimia no tuvieran unos parámetros alterados, posiblemente nos puede hacer pensar que no tienen problemas a la hora de expresar sus sentimientos. Y sí es posible que el problema lo tengan con el receptor de la información sea éste profesional o familiar. Da la impresión que si no se expresan más es porque se protegen contra comentarios que saben les pueden hacer sufrir.

- Con respecto al Test de Beck, teniendo en cuenta que consideramos síntomas distorsionantes depresivos a todos aquellos pacientes que superen el 9 como resultado de la corrección de dicho Test, nos encontramos con que todos los pacientes empiezan por valores superiores a 9 y que después de las sesiones 2 de ellos están por debajo de 9 y el resto han bajado sus valores de 5 a 23 puntos, observándose un cambio en su actitud hacia el futuro y el presente.

- En cuanto al Test de HAQ el cual valora la capacidad funcional, consideramos los valores normales que están por debajo de 1. Después de las sesiones, 3 de los 7 pacientes están por debajo de 1 y los demás han mejorado ostensiblemente, obteniendo de esta manera un aumento de su capacidad funcional y por lo tanto de su calidad de vida.
- El Test de STAI el cual mide los estados de angustia y ansiedad, en los casos de Fibromialgia bastante frecuente y prácticamente siempre reconocida por el paciente y que no sabe justificar, no sabe porqué; los valores hasta donde podemos hablar de normalidad oscilan entre 12 a 15. En este estudio los descensos hacia la normalidad, menos en un caso donde el paciente tenía problemas familiares que le impidieron hacer un curso normal, han sido muy grandes, pudiendo encontrarnos descensos desde 12 a 33 puntos. Si tenemos en cuenta que la ansiedad produce dolor psíquico y éste, sufrimiento, podríamos decir que ha habido un claro descenso en los niveles de sufrimiento.

- Con respecto a la Escala Visual Analógica (EVA) sabemos que para que haya un cambio reconocido tiene que haber un descenso de 2 puntos con respecto a la primera medición. De los 7 pacientes, 5 de ellos bajaron de 2 a 4 puntos y en otros 2 no. De hecho uno de los 2 que no bajó era porque sus percepciones de dolor eran ya bajas, y la otra persona que sólo bajó 0.5 puntos, tenía como artrósis a parte de su Fibromialgia, la cual habría que haberla tratado con otro protocolo de terapia para bajar sus niveles de dolor. Lo curioso, es que todos los pacientes al finalizar la terapia comentaban que habían tenido un descenso considerable de dolor, incluso los 2 que no habían bajado.

Con respecto a los resultados del estudio “B”, recordemos que forma parte de un reducido número de muestra: 10 personas; de las cuales, aunque a todas les colocamos los electrodos, sólo a 5 se les hizo tratamiento y a las otras 5 no. Observamos que la reducida muestra del estudio no nos permite hacer una comparativa de los estadísticos dependientes, pero precisamente por eso, porque la muestra es pequeña podemos ver la relación del contraste a nivel gráficas de una manera clara.

No obstante, antes de observar las gráficas comparativas tenemos que tener en cuenta que este estudio se realizó de cara al invierno, de Octubre a Diciembre. Durante este tiempo es cuando la Fibromialgia tiende a hacer crisis en forma de brotes normalmente. Su “termorregulación” se altera con periodos de escalofríos internos intensos a la vez que sudoraciones, el sueño se vuelve alterado y con pesas dillas, tienen entumecimientos lo cual empeora su capacidad funcional y aumentan los dolores, y todo ello, juntamente o como consecuencia decaen en síntomas depresivos y/o ansiedad.

Pues bien, no obstante de este cuadro, los resultados fueron los siguientes:

- Con respecto a la Alexitimia, que como hemos dicho en el estudio anterior se considera dentro de la normalidad todos los resultados del Test inferiores a 61, observamos en la tabla 11 y el gráfico 6 unos resultados de contraste. Mientras los “no tratados” siguen igual e incluso empiezan, los “tratados” tienen una clara mejoría en todos los casos. No obstante al realizar la prueba de homogeneidad de medias, de datos dependientes de Mann-Whitney no se pudieron hacer los cálculos por muestra insuficiente, por lo tanto utilizamos la prueba estadística de homogeneidad de medias de datos independientes no-paramétricos, utilizando el test estadístico de Wilcoxon.

- En relación con el Test de Beck, recordemos que los límites de la normalidad están en el resultado de la prueba inferior a 9. Así podremos valorar que todos los pacientes excepto el “N3”, están muy por encima de dicho valor. Después de realizar el estudio, observamos una estabilización en los resultados de los “no conectados”, mientras en los “conectados” observamos una clara mejoría.

- Con respecto a la valoración de la capacidad funcional (HAQ), sabemos que la normalidad tiene que ser inferior a 1. Tal y como observamos en la tabla 15 y el gráfico 8, en los dos grupos queda reflejada una marcada discapacidad en la capacidad funcional antes de iniciar las sesiones. Al finalizar las mismas, podemos observar como hay un empeoramiento importante en los “no conectados”, justificado por ese empeoramiento climático que antes mencionábamos, mientras que los del grupo de “conectados” tienen una franca mejoría, algunos de ellos con un descenso de su valor en 25 puntos.

- En la valoración de la ansiedad mediante el Test STAI, observamos un cierto estancamiento en los “no conectados” y una clara mejoría en todos los casos de los “conectados” menos en uno, el “C3”, que estaba sometida a una alteración provocada por una desavenencia con una hija. Con lo cual entraría a formar parte de una ansiedad provocada por un factor externo. Los demás tienen los valores previos entre 16 el más bajo y 37 el más alto. En esta época climática son muy importantes estos resultados ya que si los niveles de ansiedad son bajos, observamos que el resto de sintomatología estará más controlada y al revés.

- Como resultado del estudio de los pacientes valorados con el Test de EVA, respecto al nivel de dolor que perciben, observamos que los valores de inicio son todos más altos que en el estudio “A”. Esto es debido al clima que además este año se ha presentado con fuertes variaciones en el termómetro, habiendo sufrido variaciones de incluso 10ºC en un mismo día. No obstante, si observamos la Tabla 19 y la Gráfica 10, vemos que mientras los “no conectados” se mantienen estables, los “conectados” mejoran incluso más significativamente en el campo del dolor que los del estudio “A”, excepto la persona de “C3” de la cual ya hemos expuesto su caso.
VI. CONCLUSIONES

1) GENERALES

Llegamos a la conclusión que el sistema de Bioresonancia-SCIO, puede ser un instrumento útil para la terapéutica de los pacientes afectos del Síndrome de Fibromialgia.

Dado que el Síndrome de la Fibromialgia repercute en varios niveles (nervioso, músculo-esquelético, digestivo, endocrino, etc.) en nuestro organismo y que el software incorporado EPIC/SCIO nos permite trazar a nivel de varias frecuencias, y por lo tanto, a varios niveles, puede ser un buen tratamiento, como se ha desarrollado a lo largo de todo el trabajo, para este Síndrome.

Hemos podido comprobar, que para el paciente es satisfactorio notar cómo todos sus síntomas van disminuyendo, ya que la Fibromialgia no solo causa dolor físico sino también psíquico y alteraciones psicológicas; ganando al mismo tiempo una seguridad en sí mismos que antes no tenía.

2) GRUPO A

La conclusión de este estudio es que podemos afirmar que las pruebas del tratamiento con Bioresonancia mejora la sintomatología de los pacientes con un cierto riesgo alfa de 0,05 al rechazar la hipótesis nula. Pero creemos la muestra era demasiado pequeña (siete individuos), que es aconsejable realizar el estudio con una mayor muestra para poder utilizar pruebas estadísticas de mayor potencia, y así darle mayor validez.

3) GRUPO B

Debido a lo anteriormente mencionado podemos observar que en todas las pruebas de los pacientes que han sido tratados hemos tenido evidencia estadística suficiente para rechazar la hipótesis nula y afirmar que el paciente muestra mejoría en las pruebas. Por el contrario, en los pacientes control no tratados en todos menos uno no podemos rechazar la hipótesis nula por la cual, evidentemente, no muestra mejoría en las pruebas realizadas.

Estos resultados lejos de ser definitivos, requieren una ampliación del estudio con una mayor muestra, para poder aplicar las pruebas estadísticas correspondientes y tener una potencia estadística adecuada.

VII. BIBLIOGRAFÍA

13 Crofford, L.J.; Demitrack, M.A. “Evidence that abnormalities of central neurohormonal systems are key to understanding fibromyalgia and chronic fatigue syndrome”. Rheum Dis Clinic North Am, 22;267 (1996).
Varhope
charging the batteries

The Long-term pathological Findings of the Camelford Toxicity Group

1990
Varhope
charging the batteries
Dear Reader,

In this study we compared 73 patient subjects pre and post measure of voltage, amperage, resistance, and Oxidation after receiving two EPFXX therapies over one week at our clinic in Budapest. The results show that the EPFXX can enhance these electrical variables in a short time.

Sincerely, Istvan Bandics MD

Abstract

In this study we took 73 patient/subjects from the medical clinic and tested their global Voltage, Amperage, Resistance, Hydration and Oxidation body electrical parameters in per and post fashion. Each subject was treated with the EPFXX device for one week after pre and before post testing. The patients had significant increases in their post electrical measures. These factors are called the VARHO.

Introduction

The body electric is well recognized aspect in medicine. The EPFXX devices address many factors of the body electric. Muscles are magnetic in action. Nerve impulses trigger magnets in muscle tissue to pull over each other. The power is an index of voltage and amperage which when multiplied against each other gives the power coefficient called watts.

The EPFXX device measures the body voltage, amperage, and skin resistance. Voltage and amperage are correlates of eeg emg and ecg amplitude and volume. Where skin resistance or impedance is directly measured as voltage loss thru skin tissue. The EPFXX then can further calculate estimates of oxidation and hydration by time comparisons of changing capacitance and inductance variables.

Then the EPFXX can input low current oscillations to harmonically tune to tissue electrical factors to help balance this Voltage, Amperage, Resistance, Hydration, Oxidation and ph. This is referred to as VARHOP repair and it is refurbished of the body electric factors. They also used the sport...
oxygen formula. This results in increased performance.

In this test 73 Hungarian medical patients between the ages of 25 – 50 were given two or three sessions on the EPFX over a week to balance their body electric VARHO profile. The body electric patterns of the VARHO were measured pre and post. None of these patients had extreme disease. They were ambulatory patients who presented with normal moderate complaints. The control was the subject’s base line body electric measures. A pre test of measure showed that patients have little changes in normal conditions.

Data Results

<table>
<thead>
<tr>
<th></th>
<th>Pre Measure Average</th>
<th>Post Measure Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>.78</td>
<td>1.02</td>
</tr>
<tr>
<td>Amperage</td>
<td>275 microamps</td>
<td>325 microamps</td>
</tr>
<tr>
<td>Resistance</td>
<td>75kohms</td>
<td>65kohms</td>
</tr>
<tr>
<td>Hydration</td>
<td>1.5</td>
<td>2.75</td>
</tr>
<tr>
<td>Oxygenation</td>
<td>.55</td>
<td>1.02</td>
</tr>
<tr>
<td>Electrical Reactivity</td>
<td>75 e.v.</td>
<td>110 e.v.</td>
</tr>
</tbody>
</table>

Summary

The body has an electro-potential across all of the cell membranes. When this is deadened the cell dies. There is a collective global electrical potential that is a reflection of the health of the body. In this study we show how the EPFX can increase the VARHO electrical factors in just a few treatments.

Professor Desiré Dubounet

and her friends have spent over 35 million dollars to bring the world a professional and thorough course on Wellness, Naturopathy and Neuro-Electro-Physiology of Biofeedback as Bioresonance.

She is such a humanitarian Angel, she lets you pay for the course videos, books and materials with Karma...

These are the TOP FIVE REASONS to get a Doctorate in Wellness PHD International Medical University degree at home.

1. Getting a degree means you will increase your earning potential. Studies have shown that at home study is just as good as attended classes.
2. Study and Complete Courses at Your Own Pace. Use this to maximize the learning.
3. Scheduling Convenience. Work when you are ready to work.
4. Teaching Faculty Who Actually Have Work Experience in Your Field of Study. Global faculty at IMUNE is with worldwide famous doctors.
5. Save Money on Travel, Parking, Childcare, and Books. You save money the world saves energy, this makes you and the world better.
6. Employer Support. Many employers offer tuition reimbursement for employees’ tuition associated with training in their fields. Employers also tend to encourage enrollment in online degree programs because they know employees will be able to go to school and still be able to be committed to their jobs. Don’t be afraid to ask your employer. Every company needs a wellness consultant.

Professor Desiré Dubounet the world’s most famous Naturopath and her friends have spent over 35 million dollars to bring the world a professional and thorough course on Wellness, Naturopathy and Neuro-Electro-Physiology of Biofeedback as Bioresonance. She is such a humanitarian Angel, she lets you pay for the course videos, books and materials with Karma go to www.imune.name for more information.
Investigator-sponsored Trials

Thousands of clinical trials are conducted each year around the world. They are sponsored or funded by a variety of organizations such as medical institutions, foundations, voluntary groups and pharmaceutical companies, in addition to federal agencies such as the National Institutes of Health and the Departments of Defense and Veterans Affairs. In addition, some clinical trials, sponsored by individual physicians, are called investigator-sponsored trials (ISTs).

ISTs are like other clinical trials, except that they are mostly single-center studies with an individual physician acting as both the lead investigator and the sponsor. As a result, ISTs tend to be minimally funded. However, if the drug or medical device under investigation in the trial is already available commercially (perhaps for another indication or population), the investigator will often try to engage the manufacturer to obtain some form of funding (e.g., donating the drug or medical device). Data generated through ISTs are often published and contribute significantly to academic research that in turn is referenced and utilized by other treating physicians and entities involved in the disease area or condition. Ownership of the products being investigated in the ISTs remains with the patent holder or manufacturer. Therefore, if the investigator is not the patent holder, he may neither submit the data from ISTs to a regulatory authority nor obtain approval to market the product. The investigator will need to work with the patent holder to obtain the rights to the product and it may be necessary to license the product to a manufacturer to secure the funding needed for the resources required for product approval. Data from ISTs are accepted by many regulatory authorities to support marketing applications or supplements as long as the trials were conducted in strict conformance Good Clinical Practice guidelines and the regulatory authority has access to uninterpreted data from the trial. ISTs are held to the same regulatory standards as all trials involving human subjects. Investigators who sponsor and/or participate in clinical trials have serious responsibilities because of the involvement of human subjects and their risks in participating. There are many regulations specifying the responsibilities of sponsors and investigators. Investigators who are both sponsors and investigators (investigator-sponsors) of clinical trials must shoulder both sets of responsibilities and become very familiar with all applicable laws and regulations surrounding the conduct of human studies to ensure compliance. In the US, the Code of Federal Regulations (21 CFR Part 312 Subpart D for drugs and biologics and Part 812 Subparts C and E for medical devices) describes these serious responsibilities for both the sponsor (21 CFR 312.50) and the investigator (21 CFR 312.60). Additional responsibilities and requirements are described throughout 21 CFR 312 and 812; those specifically relating to informed consent and IRB approval are described in 21 CFR Parts 50 (Protection of Human Subjects) and 56 (IRBs), respectively. The specific responsibilities for sponsors and investigators in drug and biologic clinical trials are similar but not identical to those for sponsors and investigators in trials for medical devices. Investigator-sponsors must determine whether an Investigational New Drug application (IND or Investigator IND) must be submitted to the US Food and Drug Administration (FDA) before beginning the trial. An IND is usually required if the study involves an unapproved product or an approved product for a new indication, or evaluation of an approved product in a new patient population. The IND must include all
the information specified in 21 CFR 312.23. To complete the IND, the investigator-sponsor usually seeks permission from the original product manufacturer to cross-reference the company’s IND or Investigational Device Exemption, or approved New Drug Application or Premarket Application to obtain the necessary information (e.g., data from animal studies and previous human studies and manufacturing information). By submitting an IND, the investigator assumes responsibility for providing all necessary information (such as the study protocol, adverse event information, annual reports, etc.) to FDA to maintain compliance with regulations. It remains the investigator’s responsibility to determine whether the study is exempt from the requirement to submit an IND. FDA generally does not accept INDs it considers exempt (see 21 CFR 312.2(b)(1) for criteria that exempt studies from IND regulations).

Table 1 lists some common reasons why investigators sponsor clinical trials in spite of the tremendous regulatory burden such studies entail. A key challenge investigator-sponsors face is the large amount of time they must dedicate to the study and how that impacts caring for patients in their medical practices. The investigator-sponsor must supervise the trial, interact with the IRB, develop budgets, deal with audits and inspections and travel as needed. Well-qualified, experienced, trained and efficient personnel (in particular the study coordinator, but also including the sub-investigators, research nurses and laboratory personnel) become essential to the investigator in managing the trial workload.

Investigator-sponsors who take the time at the beginning of the trial to train any noncertified personnel in the International Conference On Harmonization (ICH) guideline, Good Clinical Practice E6(R1) will generally save time on the back end and improve the quality of the study.

### Table 1. Advantages for Investigators In Sponsoring Clinical Studies

1. **Patient care:** Investigators can more rapidly offer their patients unapproved but promising products or treatments.

2. **Scientific collaboration:** ISTs allow Investigators to remain at the cutting edge of their therapeutic interests.

3. **Scientific contribution:** When Investigators publish the results of their studies, they enable manufacturers to become essential to the investigator in managing the trial workload.

4. **Professional recognition:** Publications provide the Investigator with professional recognition as an expert or thought leader in the field. There is value in publishing even those studies that did not meet their primary hypotheses.

5. **Funding:** As the Investigator becomes well-known in the field, he is able to secure funding more easily, thereby furthering future research.

### What’s in It for the Patient?

ISTs are a very good option for patients to obtain access to new and as yet unapproved research therapies. People often participate in ISTs because they have exhausted approved treatment options that either did not work for them or produced intolerable side effects. Carefully conducted ISTs are a relatively safe and quick way to get access to products that have the potential to treat the disease or condition that have the potential to improve patient health or quality of life. Further, since investigators are often specialists in the disease area being studied, some patients participate to gain access to expert medical care for their condition, thereby playing a more active role in their own healthcare. Still others participate in ISTs for the purely altruistic reason of wanting to contribute to the advancement of medical knowledge.

Not all patients who apply to participate in an IST will be accepted. Each patient must meet predetermined eligibility criteria, such as age, sex, type and stage of disease, previous treatment history and other medical conditions. These criteria help to reduce the amount of variation and "noise" in the study, without threatening the scientific integrity of the trial, by removing medical variations that might complicate data analyses and the ability to draw relevant and sound conclusions. Patients may also be excluded because the researcher has already enrolled the required number of participants needed to test the hypothesis stated in the study protocol.

Once subjects are selected to participate in the IST, the law requires the investigator to obtain informed consent. The investigator must provide patients with complete and accurate information about what will happen during the trial and disclose all known or suspected risks. Participants must sign a written informed consent form, which indicates they understand the trial is a research study, have been informed about the associated risks and are aware that their participation is voluntary and they can leave the clinical trial at any time. Additionally, the consent form should outline in detail the amount of time participants will have to devote to the trial and the types of activities; for example, they may need to visit the study site at specified intervals, be subjected to additional tests, get more treatments than are normally necessary, stay in the hospital and/or follow complex dosage requirements. Patients use the material in the informed consent document to decide whether or not to enter a clinical trial and to make an informed decision about the level of risk they are willing to accept before they enter the trial.

The investigator should clearly explain to participants (when applicable) that they may not receive the investigational drug and may instead receive a placebo. They should also be prepared mentally for partial or no effectiveness from the treatment. The investigators should encourage the participants to learn as much as possible about the clinical trial and the investigational treatment and to freely discuss their questions and concerns with members of the research team.

### Registration of Clinical Trials

Investigators and sponsors usually register their trials with databases such as http://clinicaltrials.gov/, an interactive online database managed by the National Library of Medicine. Clinicaltrials.gov facilitates the registration of trials in accordance with the International Committee of Medical Journal Editors (ICMJE) initiative requiring prior entry of clinical trials in a public registry as a condition for publication. Members of the public can find information about clinical trials by searching clinicaltrials.gov, as it lists both federally and privately supported clinical
research. The site, which is updated regularly, offers information on the objectives of each trial, eligibility criteria, locations and contact details to obtain more information.

Summary

For patients, ISTs are a viable option for obtaining access to unapproved treatments. For physicians acting as investigator-sponsors, ISTs offer key benefits such as professional recognition and the opportunity to continue participating and collaborating in cutting-edge scientific investigations (see Table 1). However, ISTs present challenges to both investigators and patients. To be successful, investigators and investigator-sponsors must be highly motivated leaders with the skills and drive to coordinate the activities of many people to ensure completion of all study activities. Success generally requires careful planning, evaluation and management of the multiple aspects of conducting a clinical trial in accordance with all applicable regulations and ensuring that the various pieces of the puzzle fall into place seamlessly.

While ISTs provide patients with accelerated access to new treatments, these treatments have not received thorough review by a regulatory agency such as FDA or the European Medicines Agency, and as such, risks and uncertainties are unavoidable. Volunteers need to ask relevant questions of the researchers, remain vigilant for changes in their health status (particularly adverse changes), report them immediately and, in general, be aware that they shoulder significant responsibility as participants in an IST.

References

- Good Clinical Practice: Consolidated Guideline E6(R1), ICH (June 1996).

Author

Naseem Kabir, M5, RAC, is director, regulatory affairs international, at Genzyme Corporation, based in Cambridge, MA. She has been in the pharmaceutical and medical device industries for 20 years and in regulatory affairs for the last 12 years. Kabir holds a master of science in zoology from the University of Chennai, India and is RAC-certified in both the US and EU. She is a member of the Board of Editors for RAPS’ Regulatory Focus magazine and can be reached at naseem.kabir@genzyme.com.