Introduction

There has been considerable controversy regarding the efficacy and accuracy of any of the ElectroDermal screening devices for either the analysis of medical conditions or any disorder of the biological system. In fact, the objective opponents of the EDS devices have criticized any outcomes based upon this technique because the readings are often restricted to and determined by the interview and training of the examiner and are thus limited to an anecdotal setting. The technician has been considered the most important factor in the use of each of these devices in clinical practice. The history of the ElectroDermal-screening device is replete with both success and failures, but there have been very few scientifically validated studies.

The basic concept for all of the ElectroDermal screening devices, was the invention of Dr. Reinhardt Voll[1], who in the 1940s, discovered that the electrical resistance of the human body is not homogenous and that meridians existed over the body which may be demonstrated as electrical fields. Furthermore, he showed that the skin is a semi-insulator to the outside environment. By the 1950s Voll had learned that the body had at least 1000 points on the skin which followed the 12 lines of the classical Chinese meridians. Each of these points, Voll[2] called a Measurement Point (MP). Working with an engineer, Fritz Werner, Voll created an instrument to measure the skin resistance at each of the acupuncture points, patterned after a technique called Galvanic Skin Resistance (GSR). This was named Point Testing. In 1953, Voll had established the procedure that became known as Electro-Acupuncture according to Voll (EAVJ. This included two parts:

1. The first part was point testing in which a conductance measurement was taken in selected acupuncture points.
2. The second part was the establishment of a balance of the points and conductance by the use of feedback medicine. This became known as Medicine Testing.

During the 1950s, many investigators[3] including Nakatani studied the electrical conductance of the skin. They evaluated the elasticity, resistance, permeability, and chemistry among many other properties of the skin and found that there was a much lower skin resistance (higher conductance) at specific points on the skin. Normally, the skin has a resistance of 2-4 million Ohms but over the specific conductance points, the resistance of only 100,000 Ohms is found in normal healthy persons. These points corresponded to classical acupuncture points.

Later, these acupuncture points were investigated and were considered to be "information access windows" and the assumption was made that the health status of an organ will affect the concentrations of the ions at the measurement points along the meridian (measurement points). It was considered that inflammation of an organ may cause increase ion concentration and the increase of ions enhances the flow of electrons causing resistance to decrease while the conductance may increase. On the other hand, a degeneration of an organ may cause decease in ion concentration that hinders the flow of electrons, so as the resistance increases conductance decreases.

During the procedure of ElectroDermal analysis the body becomes an integral part of a closed circuit. The conductance circuit touches two areas on the body being tested. In the first point of contact, the ground electrode is held in the palm of the opposite hand to be tested. In the second place the test probe touches the specific acupuncture or conductance points on skin. After completing this closed circuit, a known amount of electric current is emitted from the instrument through the probe. The instrument then measures the conductance from baseline to peak and return to baseline through the conductance point that is being tested by the probe. This represents a dynamic conductance value.
Study Design

This study of ElectroDermal Analysis was designed as blinded to the EDA technician in which 100 patients were evaluated by the EDA technique without the aid of either a medical history or a physical examination or diagnosis and the same patient/subject was immediately evaluated by a separate rater, a medical doctor (MD) who had the benefit of a complete history and physical examination and complete laboratory test results. Following the data pooling an additional biostatistician evaluated and correlated the results. The construction of the study was to measure the capability of the EDA system for the purpose of evaluating the functional disorders of various systems of the human body and to evaluate the EDA without interview technique. This study was conducted after filing and with the approval of a United States Food and Drug Administration-approved Investigational Review Board.

Method of Study

In the first phase, each of the patients was randomly assigned to the study after appropriate approval was granted under the Good Practice Act. A complete medical and surgical history and examination was obtained at the time of the study and all of the necessary supporting laboratory data was provided to support the medical diagnosis. Each patient was evaluated, without any interview, by the EDA technician and then by the medical doctor. A diagnosis was made on the basis of the neurological examination, presence of antibodies, previous teased single fiber Sural nerve and muscle biopsies and detailed biochemical laboratory data. The laboratory, biopsy data, and neurological evaluation for each patient was compared to the medical diagnosis and the EDA graphic recording. Control patients without Chronic Inflammatory Demyelinating Polyneuropathy were also tested by the same EDA technician. Complete Human Leukocyte Antigen (HLA) typing was performed on over 100 patients with symptomatic Chronic Inflammatory Demyelinating Peripheral neuropathy Associated with Silicone Breast Implants[4] and it was found that the consistent pattern of genetic preponderance was DR13 in 30%, DR15 in 44%, DR51 in 32%, DR52 in 60%, DR53 in 46% and DQ1-DQ2 each in 34% of the patients. Moreover, combinations of DR13, DR15 with DR51, DR52 and DR53 appeared to be present in the most severely afflicted patients.

Equipment and Use

ElectroDermal Screening (EDS) and Analysis (EDA) consists of obtaining conductance measurements at different (acupuncture) locations on the skin, storing these baseline measurements and displaying these readings on a monitor. The normal flow of electrical energy is briefly inhibited by a micro current and the conductance was again measured. Three recordings are made at each acupuncture point; baseline, peak recovery and a second baseline. These recordings have been named the base and the balance tests. While the subject is the ground for a closed system, the instrument functions as a micro-Ohm meter. The technique is non-invasive and has no-risk to the subject. The instrument is calibrated to read the resistance on a scale of 0 (lowest conductance) to 100 (highest conductance). The higher conductance has been associated with inflammation while the lower conductance is associated with degeneration. Each of these acupuncture points become part of one or more channels or meridians and generally follow the Chinese Meridian lines. It is customary, therefore, to measure the conductance over many acupuncture points in one meridian. Thus, one point served to be a control for another point. Ordinarily, the normal individual will register about 50 plus or minus 5-10 on this scale for each point. In general, it is thought that the point of higher conductance represents an imbalance with higher energy while a lower conductance represent an imbalance with lower energy. However, this does not imply that a EDS disturbance (higher or lower conductance) corresponds to pathological changes in an organ that is named as a specific acupuncture point or meridian.

Analysis of Data
The patient population ranged in age from 25 to 62 with a mean of 47.5. There were 130 females in the study as compared to 0 males. The diagnostic categories included:

- 1. Chronic Inflammatory Demyelinating Polyneuropathy - 100 patients
- Each of these symptomatic patients were associated with a autoimmune etiology and had significant weakness and muscle bulk loss, distal sensory abnormalities as well as a variety of ELISA abnormalities and conclusive nerve -muscle biopsy that confirmed the diagnosis.
- Each of the patients/means of the data was statistically analyzed for rise/fall and peak in each of 54 acupuncture points. Furthermore, each patient was screened for history of medical illness, clinical features of disease and each had a complete laboratory evaluation which included a automated chemistry profile, glucose and complete blood count with sedimentation rate.
- 3. Statistical Analysis

Deviations of more than 1 standard deviation from the mean for each acupuncture (testing point) were calculated and the statistical mean was plotted for each patient/subject and group. Statistical difference of the means was then developed and calculated using the ANOVA method.

Results

The acupuncture points/meridians used for this study were lymph, palatine tonsil, lung, peripheral and central nervous systems, circulation, allergy, endocrine system (thyroid, pituitary, adrenal), heart, stomach, small and large intestines, pancreas, liver and gallbladder, kidney, carbohydrate metabolism, joint degeneration, connective tissue, skin, spleen, urinary bladder, uterus and fatty degeneration.

The mean data points with 1 SD variance for the 100 patients with peripheral neuropathy were consistently found in allergy (each patient has diffuse autoimmune disease with multiple allergies), circulation (profound vascular arteritis was demonstrated on biopsy), endocrine abnormalities included 47% incidence of measurable symptomatic thyroiditis and multiple estrogen/progesterone abnormalities, subtle hepatic (liver abnormalities with gall bladder obstructive disease, and significant lymphatic disturbances with silicone deposits found in multiple nodes and spleen).

Utilizing this technique, the statistical variation for each mean acupuncture point was calculated for the purpose of defining the appropriate diagnosis/ drug/remedy for therapy for the peripheral neuropathy. It was noted that the variance of the means in the peripheral neuropathy group demonstrates significantly less variation than the control (non-neuropathy) patients.

The EDA disturbances consistently found in the peripheral neuropathy patients but not in the controls:

- A. Allergy meridian - Higher conductance (overactive imbalance) – Inflammation
- B. Circulation meridian - Lower conductance (under active imbalance) – Degeneration
- C. Endocrine meridian - Lower conductance (under active imbalance) – Degeneration
- D. Liver meridian - Higher conductance (overactive imbalance) - Inflammation
- E. Lymphatic meridian - Higher conductance (overactive imbalance) – Inflammation
- F. Parenchymal and Lipoid degeneration meridian - Lower conductance (under-active imbalance) - Degeneration

Discussion

About 500 BC, Thales of Miler wrote a treatise on he static charge which was attached to amber and the use of electric shocks was further employed for the treatment of headaches. Two thousand years later, Volta invented
the electric condenser and the battery while Galvani experimented with the electrical properties of muscle and coined the phrase "animal electricity". Electronics first became a science when Ohm developed the mathematical equation that described the relationship between voltage, current and resistance[5]. This became known as Ohm’s Law. Which stated:

Voltage (V) is equal to Current (I) times Resistance (R); and therefore conductance is I/R.

Thus the age of electronics was born. It is believed that ions in the body are the source of flow by electrons and ions give the body the property of a semiconductor. It is these ions that regulate the flow of electrons and are found in base salts, enzymes, amino acids, hormones and all phosphate compounds[6].

As early as 1907 electrical techniques have been developed for the evaluation of skin conductance and in fact these were used for the purpose of measuring neurogenic lesions and to differentiate these from psychiatric disturbances. The use of ElectroDermal analysis is a form of acupuncture in which each acupuncture point may be analyzed as to it's own galvanic resistance and flow of micro-current is presumed.[7] It is apparent that comparative studies of the instrumentation of many devices that are available rarely use all of the ElectroDermal information that is presented for analysis. Furthermore, it has been shown that there are connections between the organ representation areas of the meridian and the release of both neurotransmitters and hormones. These meridians have further been shown to have organ representation in the brain. The mechanisms of the transmission of the electromagnetic potentials appear to be explicable in terms of the Aharonov-Bohm effect in Field Theory and Quantum Mechanics[8]. Furthermore, it has been suggested that each of the acupuncture points has a direct relationship to the specific anatomical structure or physiological function in the body, although they may not reflect the severity of pathological alteration of that organ or system.[9]

Reinhardt Voll5, in 1955, built the first instrument and originated the nomenclature, which has been in existence for most of the present day analytic equipment. Normal refers to an arbitrary value of 50, which is the resistance value of 0.0001 Ohms. The existence of values over 65 indicated, to Voll, an active irritation or "Itis" and the readings of below 50 indicated a degenerative phenomenon or "Osis". Moreover, it was noted that the indicator may rise and then fall to a lower value and this was called the "Indicator Drop". The term "Balancing" was coined by early practitioners when the drug tested balanced the meridian energy. The current concept of Meridians represent the lines of energy that pass through organ systems but do not necessarily represent a functional or pathological disturbance in those organ systems. Reinhardt Voll further described ElectroAcupuncture (EAV) measurement of eye structures, ear, nose and throat and in a series of lectures demonstrated that each acupuncture point bears a direct relationship to a specific anatomical structure or physiological function in the body. Measurement, utilizing the EAV device, allowed for a quantification of this electrical activity of each of these points, which infers the functional status of the disease process or structure in question. Furthermore, he demonstrated that medicine, if correctly chosen, could change the reading values to a more normal level. This discovery, suggested that not only could the correct medicine for each patient be selected, but at the most effective strength or potency. Voll discovered that the resistance of the body is not homogenous, all meridians show electrical fields, meridians were a product of the body's energy and the skin is a semi-insulator to the external environment.

Madill[10], in 1979, explicated the role of EAV as a tool for preventive therapy, while Fuller Royal[11] reviewed the importance of energy medicine to an understanding of homeopathy and acupuncture. In a series of studies, Tsuei and Lam studied the bioelectric activity, using EAV in 483 healthy subjects (348 males and 135 females).[12] They found differences between males and females, among different age groups and among different testers. In another study, Tsuei and Lam[13], demonstrated differences between patients with diabetes mellitus and normal controls. They showed that there were statistically significant changes in diabetic patients in pancreas and endocrine organ meridian/acupuncture points. Healthy subjects have been tested and there appear little differences in their age and gender differences for the acupuncture point studies. Moreover, disease states such as Diabetes Mellitus have shown differences in the electromagnetic energy from normal states and
these may be balanced with the introduction of properly used insulin, chlorpromamide and homeopathic remedies and nosodes.

In addition, Tsuei and Lam[14],[15] studied 300 patients with multiple allergies and concluded that EAV is a sensitive test and correlated significantly with the food challenge test in those patients. Furthermore, confirmatory studies in patients with an allergic response using the ElectroDermal-screening device provided a 70-75% correlation with the clinical history and physical examination and to that of allergen challenge test. This study was repeated in a double blind fashion and the correlation was 73%. There have been a number of individual case study anecdotal reports touting the use of the ElectroDermal Screening device for the measurement and treatment of any number of medical ills, but, unfortunately, they lack statistical verification, reproducibility and, therefore, are deficient in the reliability that is to be expected in modern medical studies.

**Peripheral Neuropathy: Human Leukocyte Antigen (HLA) Genetic Studies**

It has been reported, by several authors,[16],[17],[18] that the Human Leukocyte Antigen (HLA) DR 53 has been consistently found in patients with fibromyalgia associated with silicone breast implants. The HLA DR antigens are individual loci on lymphocytes and are useful in designating individual proclivity to specific medical conditions. Furthermore, DQ2, in those studies, appeared to be significantly increased in patients with silicone prostheses and with clinical evidence of disease. DQ2 is associated with DR7 and at the same time in linkage disequilibrium with DR 3 and DR 52, but the authors could not find an increased frequency of either B8, DR 3 or DR 52 in those patients with fibromyalgia. The presence of DR 53 gene was associated with auto-antibodies to B cells in symptomatic patients but was not associated with either the DQ 1 or DQ2 genes. One of these studies, that of Young, et al.,[19] reported that HLA DR53 gene was present in 68% of asymptomatic and symptomatic patients. However, the asymptomatic patients also had an increased frequency of DR1 and DR2 genes, and the DQ genes possibly represented protector genes. They concluded that symptomatic patients with breast implants share important DR53 positivity that differentiates them from asymptomatic patients. These authors concluded that a genetic characteristic that predisposes an individual to mount an immune mediated response as a consequence of silicone breast implantation as well as the composition and location of the implant prostheses may play a role in the body's response to silicone exposure. However, other investigators have found the presence of DQ1 gene present in 75% of symptomatic patients as well as the decreased frequency of the DR3 and DQ2 genes.[20]

The current study of over 100 patients with Chronic Inflammatory Demyelinating Neuropathy associated with Silicone Breast Implant Adjuvant Disease demonstrates an equal preponderance of HLA of DR13, DR15, DR51, DR52 and DR53 genes of 30%, 44%, 32%, 62% and 46% respectively. This study supports the thesis that HLA typing is clearly related to autoimmune sensitivity to silicone breast implants in those patients with Chronic Inflammatory Demyelinating Peripheral Neuropathy. Furthermore, the presence of more than one combination of DR gene 13+15+51, etc., appears associated with the more severe and progressive illness.

**The Future of ElectroDermal Analysis**

The major problem of ElectroDermal Screening is reproducibility. This appears related to the placement of the electrodes and the training/qualifications of the technician. Another major problem with the instrumentation is that it is configured to perform the measurement of amplitude of the conductance from a baseline and the declination of the peak in relationship to return to the base line using three points of reference. Most biological systems are not linear and that the inclination slope and the declination slope are as, if not more, important factors in determining the presence of a disturbance in the energy flow in anyone point in time. The EDA data obtained from a large group of patients, as this study demonstrates, may be analyzed as a statistical database for the purposes of developing more reliable scientific criteria for diagnosis and/or therapy.
Summary

This is a study of the correlation of ElectroDermal Analysis with both the clinical and laboratory diagnosis in 100 patients have been compared to 30 normal age adjusted control subjects. The correlation between the EDA measured abnormalities, using standard deviation (SDI) criteria and patients with Chronic Inflammatory Demyelinating Polyneuropathy disease state was statistically significant at 99.5% with a P< 0.005. Thus EDA has proven itself, when utilized by a skilled technician; to be a valuable tool for the analysis and definition of Chronic Inflammatory Demyelinating Polyneuropathy.


