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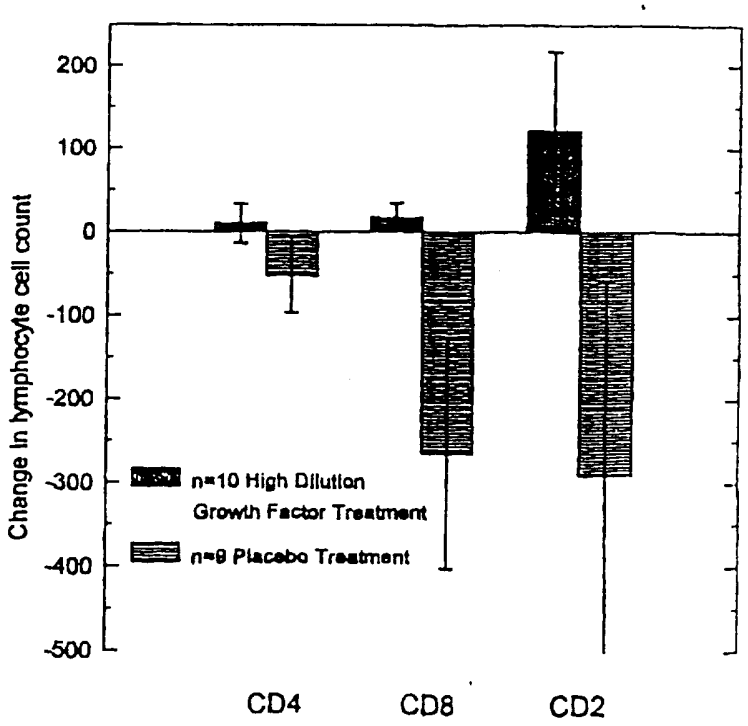
(54) Title: Therapeutic Homeopathic Dilutions Of Growth Factors And Methods Of Their Use

(57) Abstract:

The present invention comprises homeopathic dilutions of growth factors and methods for their use. Disorders which may be effectively treated with the compositions of the present invention include chronic viral disorders, such as HIV, AIDS, chronic fatigue syndrome and Epstein-Barr viral infections, cancer and diabetes. Homeopathic dilutions of growth factors are preferably administered orally. In alternative embodiment, patients are treated with radiofrequency signals corresponding to homeopathic dilutions of growth factors.



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THERAPEUTIC HOMEOPATHIC DILUTIONS OF GROWTH FACTORS AND METHODS OF THEIR USE

Field of the Invention

This invention relates to the treatment of disorders such as chronic viral infections, cancer and diabetes and more particularly to the use of homeopathic dilutions of growth factors to treat such disorders.

Background of the Invention

One aspect of this invention relates to the treatment of chronic viral infections by administration of homeopathic dilutions of growth factors. Chronic viral infections, such as herpes simplex virus, Epstein-Barr virus (ERV), human immunodeficiency virus (HIV), papilloma virus, chronic fatigue syndrome, Coxsackie B, hauta virus and hepatitis B virus, affect signal transduction mechanisms with deleterious effects within and between the host's immune and nervous systems. During chronic viral infection, host cell signal transduction and cell cycle regulation are altered, often causing cell injury and cell death.

Viruses lack the necessary biochemical machinery to manufacture proteins and must therefore insert their genetic material into a host cell genome in order to proliferate. Viruses consist of a protein coat and genetic material. RNA viruses additionally contain reverse transcriptase, an enzyme that translates the RNA into a DNA strand before insertion in the host cell genome.

During viral infection, the protein coat binds to the host cell's surface membrane enabling viral genetic information to subsequently enter the host cell. Entry occurs via various methods, one of which is attachment to specific membrane receptors, including growth factor

receptors. For example, the cell receptors for the Epstein Barr and herpes simplex type 1 viruses have been identified as the third component of the complement receptor and the fibroblast growth factor receptor, respectively. Insertion of viral genetic information into the host cell's genome subverts the cell's normal metabolic and genetic mechanisms in order to prioritize viral gene expression and replication.

Chronic, or long-term, viral infections occur when the virus overcomes or effectively disrupts the normal neuronal and immunological defense mechanisms of the host. Several viruses, such as herpes simplex virus, EBV, human herpes 6 virus (HH6V), hepatitis B and HIV cause latent (asymptomatic) infections in specific cell populations. Viral replication subsequently occurs in response to extracellular stimuli (Garcia-Blanco, M.A. and Cullen, B.R. 1991 Science 254:815-820). Infections persist as continuous viral replication occurs without substantial disruption of host cell function. Chronic viral infections terminate only when viral replication is disrupted.

Viral infection erodes feedback communication between the host's immune and nervous systems. For example, synthesis of adrenocorticotrophic hormone (ACTH) by lymphocytes after viral infection disrupts the normal feedback loop between pituitary/hypothalamus secretion of ACTH and the adrenal gland's synthesis of glucocorticoids in response to ACTH signals. Over-expression of ACTH causes increased expression of glucocorticoids which consequentially down-regulates the pituitary and suppresses the activities of T lymphocytes. This constant stress response often leads to extreme fatigue and exhaustion in patients with chronic viral infections. In an immune compromised patient, chronic infection leads to entry of virions into the bloodstream, the lymphatic

vessels and/or the nerve pathways resulting in infection of new and distant cell populations.

Long-term DNA viral infections correlate with chronic or cancerous illnesses. For example, hepatitis B viral infection was correlated with liver cirrhosis 44% of the time and primary hepatocellular carcinoma 58% of the time compared to 17% in a control group. EBV infection was correlated with Hodgkin's disease of the mixed cellularity type 60% of the time. Herpes type viral nucleic acid sequences from herpes simplex 1 and 2, cytomegalovirus and EBV was found in the cerebrospinal fluid of patients with acute encephalitis. In addition, EBV was found to induce receptors for human herpes 6 virus (HH6V). HH6V was, in turn, found to be a cofactor in causing chronic fatigue syndrome and AIDS. The ability of viruses to cause cancer is contained within specific sequences of the viral genome, known as oncogenes, that modulate gene transcription and regulation.

Gene transcription and regulation are modulated under normal conditions by growth factors. Growth factors are cell signalling polypeptides that bind to specific cell membrane receptors and initiate a cascade of intracellular events that affect cell proliferation and differentiation. As stated above, many growth factors bind to the same cell surface receptors as viruses and therefore activate the same metabolic pathways used by viral infected or transformed cells.

There are gene sequence homologies between growth factors, proto-oncogenes and viral oncogenes. Normal non-cancer cells contain proto-oncogenes that are homologous to the oncogene sequences found in some cancer causing viruses. Proto-oncogene as well as oncogene sequences have the power to regulate the cell cycle. Growth factors regulate the cell cycle by manipulating proto-oncogenes. Some proto-oncogene sequences are

homologous with growth factors or their receptors. For example, the B chain of platelet-derived growth factor (PDGF) is homologous to the proto-oncogene c-sis (Doolittle, R.F., et al. 1983 Science 221:275-77). The receptor for epidermal growth factor (EGF) is homologous to the proto-oncogene c-erbβ (Downward, et al. 1984 Nature 307:521-527).

Growth factors and viruses use the same transcription sites to regulate cell proliferation and/or viral replication, and are thus in a somewhat competitive state with one another. For example, TGFβ plays a critical role in the transmission of biological information by acting as an on/off switch that couples cell behavior to the external environment. Within the TGFβ promoter lies the proto-oncogene *c-fos* which codes for key transcription factors located at AP-1 transcription sites. Subversion of *c-fos* gene expression by HIV enhances HIV transcription and replication independent of control sites located at tat and $NF_t\beta$ (Roebuck, K.A. et al. 1993 J. Clin. Invest. 92:1336-1348). Viral transcription in the human T-cell leukemia virus type 1 (HTLV-1), a virus with many characteristics similar to HIV, is tightly regulated by a Tax transactivator site located at the *c-fos* AP-1 site within the TGFβ promoter (Kim et al. 1990 J. Exp. Med. 172:121-129). When the TGFβ promoter is activated so is HTLV-1 Tax. Chronic viral infection coincides with aberrant expression of growth factors throughout the body as viruses have evolved to successively overcome the regulatory actions of their competitors, growth factors.

Chronic viral infections can lead to up-regulation of growth factor expression. For example, HIV infection up-regulates expression of tumor necrosis factor alpha (TNFα) and transforming growth factor beta (TGFβ). Over-expression of either of these growth factors disrupts normal transcriptional control of gene expression, leading

to suppression of hematopoietic progenitor cells and increased HIV replication. TGFβ, secreted by HIV-infected lymphocytes, also promotes growth of Kaposi's sarcoma cells, fibroblasts and endothelial cells.

Specific hemopoietic growth factors have been used to treat diseases such as AIDS and cancer. Hemopoietic growth factors are logical therapeutic immunomodulators to use for treatment of chronic viral infections and other diseases for several reasons. First, endogenous growth factors such as granulocyte-macrophage colony stimulating factor (GM-CSF) and macrophage colony stimulating factor (M-CSF) stimulate proliferation of hemopoietic progenitor cells. Second, lymphocytes, macrophages and natural killer cells that normally produce these factors are quantitatively and qualitatively defective after infection by HIV, HH6V or EBV. Third, primates infused with GM-CSF showed low toxicity with some positive but inconsistent rises in platelet number.

However, clinical studies on AIDS patients using GM-CSF and M-CSF at pharmacological concentrations (ug/kg/day) have produced mixed results. For example, injections or intravenous administration of GM-CSF at concentrations of 0.5-0.8 ug/kg/day transiently increased leukocyte, neutrophil, eosinophil and monocyte counts in AIDS patients with no significant rise in platelet counts or change in reticulocyte and lymphocyte counts (Miles, S. 1992 AIDS Res. Hum. Retroviruses 8:1073-1080). Sub-cutaneous injections of 0.25-4.0 ug/kg/day improved leukocyte counts with no improvement in hemoglobin or platelet counts. However, the side effects included increased HIV replication, increased levels of P24 antigen, chills, nausea, myalgia and flu-like symptoms (Poli, G. et al. 1991 J. Exp. Med. 173:589-597; Scadden, D.T. 1990 Hematopoietic Growth Factors in Trans. Med., Wiley-Liss Inc., New York, pp. 163-176). GM-CSF also

occasionally caused thrombocytopenia. Granulocyte colony stimulating factor (G-CSF) has been effective in correcting neutropenia with some minor increases in lymphocyte counts. Additionally, hemoglobin and reticulocytes increased in numbers in patients given G-CSF alone or in combination with erythropoietin. However, resumption of treatment with AZT after use of these growth factors led to severe anemia. Pharmacological doses of growth factors often have harsh side effects.

Homeopathy is founded on the principles of pharmacology except with much higher dilutions (much lower concentrations). Homeopathic medicine dates back to the nineteenth century. One of the basic tenets of homeopathic medicine is that a cure for a disease can be evoked by using a high dilution medicine that resembles but is different from the cause of the disease. Homeopathy is widely accepted as a useful therapeutic throughout Europe, the British Commonwealth countries and India, and has been demonstrated to have characteristic and reproducible effects. A critical review of more than 100 controlled and/or clinical studies of homeopathy determined that patients received positive healing benefits from homeopathy beyond the placebo effect (Kleijnen, J. et al. 1991 Brit. Med. J. 302:316-323).

Many homeopathic medicines are used at concentrations of micrograms (10^{-6} M) and nanograms (10^{-12} M); however, other homeopathic dilutions exceed Avogadro's number (6.023×10^{-23}). When homeopathic compounds are diluted 1:10, with repeated succusions (similar to vortexing) and repetitively diluted by this procedure at least 24 times a potency is achieved (10^{-24}) that is so highly dilute that the probability of a single molecule of the original substance remaining in the volume used is less than 1×10^{-10}. Homeopathic practitioners believe that the potency of a compound increases with increasing

dilutions. The standard homeopathic dosage is 10-15 drops of a 10^{-12} molar, or 6C, solution administered two to three times per day. A 10^{-60} molar or 30C may be given only one time per day. A 10^{-400} molar or 200C may be given only one time per month or year. A 6C dilution approximates 1 ng/ml, which is used in cell culture but would be considered a lower than physiological dose when used orally.

Highly dilute homeopathic medicines have been effective in treating some viruses in vivo. Homeopathic dilutions of 1×10^{-200} to 1×10^{-1000} of typhoidinum, hydrophobinum, tuberculinum, nux vomica and malandrinum 100% inhibited pock-like lesions caused by a chicken embryo DNA virus on the chorio-allantoic membrane compared to controls (Singh, L.M. and Gupta, G. 1985 Brit. Homeopathy 74:168-174). Other homeopathic medicines, the same medicines at different homeopathic concentrations or control phosphate buffered solution (PBS), had lesser to no effect.

While the exact mechanism of action of homeopathic medicines is unknown, magnetic image resonance measurements on serial dilutions of substances indicate that the hydroxyl (OH) groups in the solvent of solutions continue to change as dilutions become successively higher (Sacks, A.D. 1983 J. Holistic Med. 5:175-176; Smith, R. and Boericke, G. 1968 J. Am. Inst. Homeopathy 61:197-212; Smith, R. and Boericke, G. 1966 J. Am. Inst. Homeopathy 59:263-279). It is clear that the specific effects of homeopathics are of a non-molecular origin, yet provide potent biological information that is clinically effective. It has been postulated that highly dilute compounds transfer biological activity to cells by electromagnetic fields (Benveniste, J. 1993 Frontier Perspectives 3:13-15).

Experiments in several laboratories have

provided evidence that a specific biological activity can be initiated and/or modulated by highly dilute substances that contain hardly a molecule. An argument against a molecular basis for the activity is that heating dilutions to 70° F for 30 minutes or exposure to magnetic field strengths of 50 Hz, 150 gauss, for 15 minutes totally suppresses these effects. Del Giudice et al. have hypothesized that interactions between the electric dipoles of water and the radiation fields of a charged molecule generate a permanent polarization of water which becomes coherent and has the ability to transmit specific information to cell receptors, somewhat like a laser (Del Giudice, E., Preparata, G., Vitiello, G. 1988, Phys. Rev. Lett. 61:1085-1088).

The cell surface membrane is the interface between electromagnetic waves and biological activity of cells. Cell membranes maintain a carefully controlled surface potential that is transiently altered by electromagnetic fields, viral attachment, and binding of neurotransmitters, hormones and growth factors to their receptors. Liboff suggests that specific ionic currents are induced by Faraday's Law which affects the cell surface receptors and ion channels. (A.R. Liboff 1985, J. Biol. Physics 13:99-102.) In specific regions of the cell, such as the location of ionic channels and cell receptors, there may be reduced wave scattering. Ionic species or charged side chains on cell receptors, will follow a resonating circular or helical well-defined orbit under the influence of electromagnetic signals. Liboff points out that channelized ions are constrained to move along helical paths. Similarly, receptor molecules are constrained within the lipid bilayer and will resonate with specific frequencies given proper periodic stimulus. Any movement or conformational changes of growth factor receptors will induce signal transduction processes. The

well-ordered water molecules that participate in intermolecular hydrogen bonding networks are present in the interface regions between growth factors and their receptors, however they are not significant for protein binding (Clackson, T. and Wells, J.A., 1995 Science 267:383-386). Ordered water molecules are observed in several other protein-protein interfaces and can be present in the bound and unbound states. For example, water molecules which fill gaps between imperfectly packed regions of human growth hormone receptors' extracellular domain in the ligand/receptor bound state are fully available for electromagnetic activation in the unbound state. The integration of these separate schools of thought suggests that high dilutions of substances create changes in electromagnetic forces inducing resonance in cell surface signal proteins thus transferring biological activity through cell receptors or ionic channels and initiating signal transduction processes.

Bioelectromagnetics underlies biochemical reactions. The science of bioelectromagnetics studies the interactions of electromagnetic fields in living systems (Rubik, R. and Flower, R.G. 1994 Electromagnetic applications in medicine, Expanding Medical Horizons: Report to NIH on the Status of Alternative Medicine, U.S. Govt. Printing office, Washington, D.C.; Tenforde, T.S. and Kaune, W.T. 1987 Health Physics 53:585-606). Electrical stimulation of cells temporally changes the cell's membrane potential and evokes consequential changes of RNA, DNA and protein synthesis (Bourguignon, G.J. and Bourguignon, L.Y. 1987 FASEB J. 1:398-402; Rodan, G.A. et al. 1978 Science 190:690-692). Several studies on the effects of administering electromagnetic signals have been published. For example, Thomas et al. demonstrated behavioral changes in rats following administration of a cyclotron electromagnetic field which resonates for the

signal for unhydrated lithium ions (Thomas J.R. et al. 1986 Bioelectromagnetics 7:349-357). Researchers also report inhibition of tumor growth after administration of human interferon alpha (IFN-α) plus DC current (Sersa, G. and Miklavcic, D. 1990 Molecular Biotherapy 2:165-168).

Few effective treatments are available for disorders such as chronic viral infections, cancer and diabetes. Insulin-dependant diabetes, while regulated by insulin still has many systematic complications. Despite more than ten years of aggressive research, both conventional and naturopathic, no definitive treatment exists for HIV infection or acquired immunodeficiency syndrome (AIDS). There thus continues to be a need in the art for effective treatments for chronic viral infections, cancer and diabetes.

Summary of the Invention

It is an object of the present invention to provide an effective treatment for disorders including chronic viral infections, cancer and diabetes which will slow the progression of disease and/or relieve disease symptoms. An additional objective is to provide such a treatment which does not lead to unwanted side effects. Another objective of the present invention is to provide such a treatment at a reasonable cost.

These and other objectives are achieved by administering homeopathic dilutions of growth factors, or electromagnetic signals, preferably radiofrequency signals, corresponding to homeopathic dilutions of growth factors, to patients.

Growth factors are cell signalling polypeptides which modulate cell proliferation and differentiation by binding to specific cell membrane receptors. Binding of growth factors to cell membrane receptors initiates a cascade of intracellular events that affect gene

transcription and expression within the cell. Growth factors range in size from 3,500 to 250,000 daltons and, unlike hormones, generally act on nearby cells via autocrine and paracrine mechanisms. However, they may also act as second messengers for hormone signals.

Proteins, such as growth factors, may evolve from a common ancestor to the point where they no longer share amino acid sequence similarity. However their relatedness may be evident from a structural comparison. Polypeptide growth factors, a diverse group of regulatory agents, have similar protomeric structures. McDonald and Hendrickson have classified growth factors into six superfamilies based on homology of characteristic three dimensional structures (1993 Cell 73:421-424). X-Ray crystallographic and NMR studies have shown that growth factors contain relatively few recurring structural folds despite their diversity. When structural folding is considered, several proteins previously regarded as hormones, such as insulin and growth hormone, are subsumed into the definition of growth factors. Cytokines and growth factors are very similar in both size and function. The term "growth factor" as used herein, therefore encompasses cytokines and some hormones as well as the traditional growth factors.

A specific growth factor may have many cell sources and can use different signal transduction pathways at different times and with different cells. Growth factors are involved in complex feedback loops between the immune, nervous and endocrine systems.

The homeopathic dilutions of growth factors of the present invention are preferably of a concentration of less than about 10^{-6} molar, and preferably between about 10^{-6} molar and about $10^{-100,000}$ molar. Some of the homeopathic dilutions may thus contain less than one molecule of growth factor. Homeopathic dilutions of growth factors

are preferably administered orally, including liquid or solid form, such as pellets or tablets, however they may also be injected at key acupuncture or skin conductance points.

Growth factors which may be utilized in the present invention include granulocyte macrophage-colony stimulating factor (GM-CSF), granulocyte-colony stimulating factor (G-CSF), macrophage-colony stimulating factor (M-CSF), tumor necrosis factor (TNFα), transforming growth factors (TGFs), epidermal growth factors (EGF), stem cell factor (SCF) platelet-derived growth factors (PDGF), nerve growth factor (NGF), fibroblast growth factors (FGF), insulin-like growth factor (IGF), growth hormone, interleukin-1, interleukin-2, keratinocyte growth factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, insulin, bombyxin, neu differentiation factor, v-Sis, glial growth factor/acetylcholine receptor-inducing activity and other proteins that belong to their structural superfamilies.

Chronic viral infections that may be treated using the homeopathic dilutions of growth factors of the present invention include HIV, EBV, herpes simplex, papilloma, cytomegalovirus, Coxsackie B, hauta virus, human herpes 6 virus and hepatitis B viral infections. Other disorders which may be effectively treated using the methods of the present invention include insulin-dependent and non-insulin dependent diabetes, and cancers such as leukemia and adenocarcinoma.

Description of the Figures

Figures 1A and B show electrical conductance points for the hand and foot as determined by Voll.

Figure 2 shows the different outputs measured by the LISTEN system.

Figures 3A and B show the absolute change and percentage change in lymphocyte counts in HIV-positive patients after one month of oral administration of homeopathic dilutions of growth factors compared to administration of placebo.

Figure 4 shows the percent changes in serum lipids in HIV-positive patients after one month of oral administration of homeopathic dilutions of growth factors.

Figure 5 shows the percentage change in serum calcium and phosphorus levels in HIV-positive patients following one month of oral administration of homeopathic dilutions of growth factors.

Figures 6A and B show electrical conductance values for HIV-positive patients prior to treatment with either homeopathic dilutions of growth factors or placebo. Figures 6C and D show the percentage change in electrical conductance following one month of treatment.

Figures 7A and B show the change in peripheral blood lymphocyte counts for two HIV-positive patients following treatment with homeopathic growth factor signals.

Figure 8 shows the change in peripheral blood lymphocyte counts over time for a control HIV-positive patient.

Figure 9 shows the change in total T lymphocyte cell, CD8 and CD4 counts for an HIV-positive patient prior to and following administration of radiofrequency signals corresponding to homeopathic dilutions of growth factors.

Figure 10 shows the mean values of electrical conductances for fifteen patients with chronic EBV infection before treatment.

Figure 11 shows the electrical conductances of eleven EBV patients after treatment with homeopathic growth factor signals and naturopathic supplements.

Figure 12 shows the electrical conductances for

two cancer patients prior to treatment with the LISTEN system.

Figure 13 shows the change in white blood cell count in a patient with chronic lymphocytic leukemia both before and during treatment with radiofrequency signals corresponding to homeopathic dilutions of growth factors and homeopathic liquid dilutions of growth factors.

Figure 14 shows the electrical conductances for two patients with insulin dependent diabetes prior to treatment with the LISTEN system.

Detailed Description

The homeopathic dilutions of the present invention typically comprise between 1 x 10^{-6} and 1 x $10^{-100,000}$ molar dilutions of growth factor in a pharmaceutically acceptable diluent. The preferred diluent is 100% grain alcohol. However, other diluents are known in the art and may be employed in the present invention to increase solubility and stability of lyophilized growth factors. A 20% glycerine base and water without alcohol were used in the clinical study described in Example 1. The homeopathic dilutions are preferably administered orally, but may also be injected into acupuncture or skin conductance points, or administered intravenously. In a preferred embodiment, homeopathic dilutions of growth factors are administered by means of liquids or tablets which retain the memory of the homeopathic dilution. The tablets are made from a suitable organic material, such as lactose (Botanical Labs., Bellingham, Washington) by methods well known in homeopathy (see, for example, the United States Homeopathic Pharmacopeia). Alternative methods of administration may also be used, such as topical application. Example 1 describes the preliminary results of a double-blind placebo controlled clinical study

evaluating the effects of administration of homeopathic dilutions of growth factors on lymphocyte counts in HIV patients.

Radiofrequency signals corresponding to homeopathic dilutions of growth factors may be administered as illustrated by Examples 2-8, in which Example 2 describes a one time evaluation of homeopathic growth factor signals on HIV positive patients; Example 3 demonstrates the effect of repeated administrations of homeopathic growth factor signals on two HIV-positive patients; Example 4 shows a four year longitudinal study of an HIV-positive patient treated with homeopathic growth factor signals; Example 5 describes the effects of administration of homeopathic growth factor signals to patients with Epstein-Barr viral infections (EBV); Example 6 describes the treatment of two cancer patients with signals corresponding to homeopathic growth factors; Example 7 demonstrates the effects of administration of homeopathic growth factor signals to a patient with chronic lymphocytic leukemia; and Example 8 demonstrates the effects of administration of homeopathic growth factor signals to two diabetic patients.

In Examples 2-8 patients were treated using the Life Information System TEN (LISTEN) (BioSource, Inc., Orem, UT) which determines skin resistance or electrical conductance. The basic tenet behind the LISTEN system is that the points on the body normally referred to as "acupuncture points" have an optimal electrical resistance (100,000 ohms) in healthy subjects which changes during illness. Each acupuncture point is associated with a specific meridian, or line of electrical conductance, which in turn is associated with a particular organ or system of the body (Voll, R. 1977 Topographic positions of the measurement points in electro-acupuncture. 1st English edition, H. Schuldt translator, Medizinish

Literarische Verlagsgesellschaft mbH, C. Beckers Buchdruckerei GmbH & Co. KG, M. Sc. Uelzen, Germany, vols 1-4 + supplement). Furthermore, Voll showed that the electrical activity at each of these points is related to the functional status of the specific organ or system (See, for example, Am. J. Acupuncture 8:97-104, 1980). Figures 1A and 1B illustrate hand and foot conductance points as defined by Voll. Points coded LY are related to lymph tissue, LU to lung tissue, LA to large intestine, NE to the nervous system, TR to neuroendocrine points, SP to spleen and PA to the pancreas.

By determining the electrical resistance at different points on a patient, it is possible to determine which organs are affected by a disease. For example, Bergsmann and Woolley-Hart demonstrated significant differences in electrical conductances between human patients with and without liver disease at acupuncture points corresponding to the liver (Am. J. Acupuncture 1:27-32, 1973). During the 1930-1940s Burr and associates at Yale published more than sixteen papers on bioelectric potential, or skin conductance, and its significance as an indicator of physiological states, such as cancer, in animal models (See, for example, Langman L. and Burr, H.S. (1949) Am. J. Obstet. Gyn. 57:274-281). In addition, a patient can be treated by providing a radiofrequency electrical signal which restores electrical conductance at specific points to normal levels.

The LISTEN system is a modified computer-based system which, in addition to determining electrical resistance at specific conductance points, can be used to administer radiofrequency signals corresponding to specific compounds, such as homeopathic dilutions of growth factors. These signals are generated by digital codes pre-programmed into the system by the manufacturer. The patient to be evaluated holds a source electrode, or

brass bar, covered with wet gauze in one hand. The practitioner holds a second brass electrode, or probe, like a pen and touches a specific conductance point in the other hand or in a foot with the probe while firmly supporting the finger or toe.

Conductance points are said to be approximately 3 mm in diameter and located in the epidermal layer of the skin, often at the neck of the bones. In order to obtain the most accurate and reproducible measurement, the probe is placed at a 45° angle to the bone. Three tests are conducted per point in order to determine the reliability of the measurement.

The LISTEN system determines three significant outputs: the rising slope; the maximal conductance; and the falling slope as shown in Figure 2. The maximum is defined as the electrical conductance (ohms) produced at a patient's skin point in response to a maximal 5 volt stimulus. An internal clock calculates the time in seconds for the ohm meter to reach maximal conductance, and then during a constant one second period records the maximum and minimum conductance. The rising slope equals the maximum conductance divided by the seconds of time to reach maximum. The falling slope equals the maximum minus the minimum divided by seconds of time (in this case 1 second). Optimal resistance at an acupuncture skin point is 100,000 ohms (Zong-xiang 1981 Am. J. Acupuncture 9:203-216), scaled on this Y-axis at a value of 50 arbitrary units. Conductances in the range of 48-54 units at all skin conductance points on the hands and feet are thus indicative of optimal human vitality or state of health. Calibration of the LISTEN device with a resistor occurs every six months so that 50 units = 100,000 ohms with 1% precision. Preliminary studies on 28 points in 15 'healthy' individuals determined that the mean maximum conductance was 50.3 ± 0.58 units (SEM) with a rise of

20.1 ± 0.57 units/sec.

The general protocol followed in Examples 2-8 is outlined below. Baseline conductance measurements were obtained on the right side plus one left side point for the spleen meridian in order to discover which points varied in their maximum and minimum from the optimal range of 48-54 and which points varied in rise from 14 ± 0.3 and fall from 1.25 ± 0.3. The areas in the body most out of balance were thus determined. The point with the highest abnormal reading or the highest point in the area with the greatest numbers of imbalanced energy was selected. The Specific Listings category of the LISTEN system was blind scanned in order to determine which growth factor was most likely to balance the specific point in terms of maximum-minimum readings and rise and fall readings. A radiofrequency signal corresponding to the selected growth factor was then administered to the patient for a period of one second to determine if it alone would balance the electrical conductance at the chosen point. All available growth factor signals were tested in this manner until it was determined which growth factor or combination of growth factors balanced all the points. If chronically low points could not be brought back into the normal range, a growth factor signal was selected which brought the conductance reading back close to normal. In the following examples, all points were brought back into the normal range.

Some patients in Table III were then challenged with radiofrequency signals corresponding to a variety of viruses. Each virus signal was tested for its ability to raise the patient's normal reading. Readings above 75 were considered to be a positive test. A signal corresponding to both the selected growth factor and the virus that stressed the normal point was subsequently administered to determine whether the selected growth

factor could balance the electrical conductance under stress conditions.

The LISTEN system may be employed to determine whether a therapeutic agent would be effective in returning one or more specific organs or tissues of the body to optimal vitality by administering a signal corresponding to the therapeutic agent to the skin conductance point related to that organ or tissue and determining whether the signal returns the conductance at that point to the optimal level. The LISTEN system can thus be used to screen multiple therapeutic agents for efficacy in treating a specific disorder.

Example 1

Twenty-two HIV-positive patients were enrolled in a double-blind placebo controlled study to evaluate the therapeutic efficacy of oral administration of homeopathic dilutions of growth factors in raising lymphocyte counts in HIV seropositive (HIV+) patients. In order to qualify for the study, patients had to be over 18 years of age, have CD4 counts in the range of 180-550 cells/mm^3, fall within CDC classifications A1, A2, B1, B2, B3 and C2, and not be receiving antiviral therapy, either during or three weeks prior to the commencement of the study. The patients were randomly assigned to either a placebo group or a treatment group, with 11 patients being enrolled in each group.

Homeopathic dilutions of insulin-like growth factor (IGF_1), transforming growth factor (TGFβ1), BB-platelet-derived growth factor (BB-PDGF) and granulocyte macrophage-colony stimulating factor (GM-CSF) were prepared as follows. IGF_1, TGFβ1, BB-PDGF (all from Genzyme, Boston, MA) and GM-CSF (tradename Leukine, Immunex Corp., Seattle, WA) were diluted to a 10^{-4} concentration, equivalent to a homeopathic potency of 3C.

Serial dilutions of 1:100 were made according to the protocol described in the United States Homeopathic Pharmacopeia to provide potencies of 30C (10^{-60}) for BB-PDGF and TGFβ1, 200C (10^{-400}) for GM-CSF, and 1M ($10^{-2,000}$) for IGF_1, BB-PDGF, and TGFβ1. Each dilution was prepared in a 20% glycerine base solution in water without alcohol.

Patients in the treatment group were orally administered 10 drops each of BB-PDGF (both 30C and 1M dilutions), TGFβ1 (both 30C and 1M dilutions), IGF_1 (1M dilution) and GM-CSF (200C dilution) three times per day. All growth factor dilutions were administered at the same time. The dilutions of each growth factor were contained in a separate bottle, thus four bottles of homeopathic dilutions of growth factors or four bottles of placebo were given to each participant. Patients in the control group were administered dilutions of 20% glycerine alone, which tasted and appeared to be the same substance but contained no growth factor dilutions.

Figures 3A and 3B show the changes in lymphocyte counts after one month of oral administration of homeopathic dilutions of growth factors compared to placebo treatment, with Figure 3A showing the absolute change in lymphocyte counts and Figure 3B showing the percentage change in lymphocyte counts. The data show that lymphocyte counts in patients receiving homeopathic dilutions of growth factors increased, while patients receiving placebo continued to lose lymphocyte counts. Specifically, CD4 cells increased 10 $\pm$ 23 cells/mm^3 for the treatment group compared with -52 $\pm$ 45 cells/mm^3 for the placebo group (5 $\pm$ 6.4% versus -14 $\pm$ 8.7%); CD8 cells increased 5 $\pm$ 5 cells/mm^3 in the treatment group compared with -264 $\pm$ 138 cells/mm^3 for the placebo group (5 $\pm$ 8.0% versus -8 $\pm$ 16.2%); and CD2 cells increased 122 $\pm$ 96 cells/mm^3 for the treatment group compared with -290 $\pm$ 231 cells/mm^3 for the placebo group (5 $\pm$ 5.8% versus

-8 ± 13.1%). CD4 cells are generally associated with helper T lymphocyte cells, CD8 cells are associated with suppressor T lymphocyte function and CD2 cells represent total T lymphocytes.

Figure 4 shows the changes in serum lipids after one month of treatment with homeopathic dilutions of growth factors compared to placebo. While high cholesterol levels (above 200 mg/dl) are associated with increased risk of heart disease, cholesterol levels below 160 mg/dl are associated with increased risk of mortality. Cholesterol levels depend upon high (HDL) and low (LDL) density lipoproteins. The precursors of adrenal steroids are cholesterols derived from LDLs. The higher the HDL levels, the less risk of coronary heart disease. Cholesterol levels increased in patients receiving homeopathic dilutions of growth factors by 5 ± 5% (152 ± 12 to 159 ± 13 mg/dl) versus -6 ± 3% (168 ± 16 to 162 ± 17 mg/dl) in the placebo group. HDL levels increased 10 ± 8% in the treatment group versus 6 ± 6% in the placebo group. LDL levels increased 10 ± 6% in the treatment group versus -6 ± 6% in the placebo group. Triglycerides participate in transferring energy from food into cells. High triglyceride levels in HIV-positive patients are an indicator of "wasting" and progression to AIDS. In the present study, triglyceride levels dropped in the treatment group by -6 ± 11% compared with an increase of 4 ± 6% in the placebo group.

Figure 5 shows the percentage change in serum calcium and phosphorus levels following one month of oral administration of homeopathic dilutions of growth factors compared to administration of placebo. Calcium levels increased by 1 ± 1% in the treatment group compared with -2 ± 1% in the placebo group, while phosphorus levels increased by 6 ± 4% in the treatment group compared with -11 ± 8% in the placebo group. Many researchers

hypothesize that low serum calcium levels reflect poor absorption of minerals and negatively affect signal transduction processes in cells via calcium and inositol polyphosphate second messengers.

Prior to commencement of treatment, the LISTEN system was employed to determine electrical conductance for each patient at 112 skin conductance points. Each conductance point correlates to specific organs and tissues of the body according to the Electroacupuncture According to Voll (EAV) system (see, for example, Am. J. Acupuncture 8:97-104, 1980). The optimal range for conductance (50.78 relative units ± 3.05 Std. Dev.) was identified from measurements on 34 non-viral infected "healthy" controls. In the HIV-positive patients, electrical conductances at 16 of the skin points were found to be outside the normal range, with 13 of the points being above optimal, 1 being below optimal, and 2 falling at the lowest end of optimal, as shown in Figure 6A and B. These points, which correlate with the lymphatic system, lungs, cell metabolism, spleen, nerves, the neuroendocrine organs (including thymus-thyroid) and the liver are known to be key areas directly disrupted by HIV invention.

Electrical conductances at these 16 points were determined again following one month of treatment with either homeopathic dilutions of growth factors or placebo. As shown in Figures 6C and D, most of the hyper-electrical conductance points decreased in patients administered homeopathic dilutions of growth factors compared to patients administered placebo. The spleen1 and spleen4 points also decreased, while conductance at the liver point increased after one month of treatment. Treatment with homeopathic dilutions of growth factor thus brought conductances into the normal range at 12 of the 16 key skin points. In contrast, electrical conductances of

patients on placebo increased at 8 of the 13 hyper-electrical conductance points and decreased at an additional 5 hyper-electrical conductance points.

Example 2

Using the protocol outlined above, eleven HIV positive patients with CD4 counts in the range 67-570 were evaluated with the LISTEN system to determine whether electrical conductances could be balanced with growth factor signals. Electrical conductance was measured at points known to be weak in HIV and AIDS patients, including points corresponding to the spleen (SPCL), spleen lymphocytes homing to the upper body (SP1L), spleen lymphocytes homing to the lower body and gastrointestinal tract (SP2L), spleen blood filtering function (SP3L), environmentally related allergies (AL1R), general allergies (ALCR), lymph tissue of lungs (LY4R), lymph nodes (LY1R), general lymph function (LYCR), lymph drainage of tonsils/throat (LY1aR) and connective tissue (FICR).

Signals corresponding to growth factors at potencies of 6C (1:100 diluted six times = 10^{-12}), 30C (1:100 diluted thirty times = 10^{-60}), 200C (1:100 diluted 200 times = 10^{-400}), 1000C (1:100 diluted 1000 times = 10^{-2000}), also termed "1M," were administered.

The results of the study are shown in Table I, wherein the number of patients who responded optimally (i.e., electrical conductance achieved optimal range) to signals corresponding to different potencies of growth factors is indicated.

TABLE I

	Appeared No. of People	6C	30C	200C	1000C
Nerve Growth Factor (NGF)	7/11	3	2	1	4
Insulin-like Growth Factor-1 (IGF_1)	10/11	6	4	6	7
Acidic Fibroblast Growth Factor (αFGF)	6/11	2	3	1	5
Basic Fibroblast Growth Factor (βFGF)	6/11	2	2	5	4
BB Platelet-derived Growth Factor (BB-PDGF)	9/11	3	5	1	5
AA Platelet-derived Growth Factor (AA-PDGF)	8/11	3	4	3	2
AB Platelet-derived Growth Factor (AB-PDGF)	7/11	3	5	3	4
Transforming Growth Factor alpha (TGFα)	5/11	2	2	4	3
Epidermal Growth Factor (EGF)	5/11	0	2	2	3
Stem Cell Factor (SCF)	5/11	3	1	3	2
Transforming Growth Factor-beta 1 (TGFβ1)	6/11	3	3	1	6
Transforming Growth Factor-beta 2 (TGFβ2)	4/11	1	2	2	1
Granulocyte-Macrophage Colony Stimulating Factor (GM-CSF)	7/11	2	0	4	3
Tumor Necrosis Factor alpha (TNFα)	7/11	4	2	4	4
Macrophage Colony Stimulating Factor (M-CSF)	7/11	2	2	2	4

In ten of the eleven patients, administration of insulin-like growth factor (IGF_1) signal brought the electrical conductance back into the normal range, with some patients responding to more than one dilution. BB Platelet-derived growth factor (BB-PDGF) and AA platelet-derived growth factor (AA-PDGF) were also highly effective in returning electrical conductance measurements to normal. Signals corresponding to higher dilutions of growth factors appeared to be more effective in restoring the electrical conductance to normal values.

In a separate study, an asymptomatic HIV-positive patient was given a simultaneous radiofrequency signal challenge of HIV using the LISTEN system while scanning dilutions specifically for βFGF to determine which dilutions between 6x and 6C might be useful. Signals corresponding to dilutions of 20x, 30x, 200x, 400x, 600x, 800x and 6C were found to bring the electrical conductances back into the optimal range.

Example 3

Two HIV-positive patients were treated with signals for homeopathic dilutions of growth factors using the LISTEN system several times per week for a period of

three months using the protocol outlined above.

Peripheral blood lymphocyte counts were obtained for both patients at, or shortly after, the commencement of treatment with homeopathic growth factor signals and again at the end of the study. Prior to the commencement of treatment, both patients had a CD4 count of less than 200. Patient 2 was treated with homeopathic growth factor signals alone, while patient 1 was treated with a combination of homeopathic growth factor signals and, in addition, was treated therapeutically with homeopathic medicines and/or some botanicals corresponding to the digital codes from the LISTEN. Neither patient was on anti-retroviral therapy.

Signals of homeopathic growth factors corresponding to a combination of dilutions were administered for one second to skin points associated with organs and tissues known to be weak in HIV and AIDS patients, as outlined in Example 2. Growth factors were selected based on their ability to effectively return conductance levels to normal. The number of times that signals corresponding to specific growth factors returned electrical conductance levels to optimal are shown in Table II.

TABLE II

GROWTH FACTORS	NUMBER OF APPEARANCES	
	Patient One	Patient Two
Nerve Growth Factor (NGF)	14	7
Insulin-like Growth Factor-1 (IGF_1)	4	8
Acidic Fibroblast Growth Factor (αFGF)	13	6
Basic Fibroblast Growth Factor (βFGF)	4	0
BB Platelet-derived Growth Factor (BB-PDGF)	1	8
AA Platelet-derived Growth Factor (AA-PDGF)	5	0
AB Platelet-derived Growth Factor (AB-PDGF)	0	0
Transforming Growth Factor alpha (TGFα)	10	0
Epidermal Growth Factor (EGF)	3	0
Stem Cell Factor (SCF)	5	0
Transforming Growth Factor-beta 1 (TGFβ1)	5	0
Transforming Growth Factor-beta 2 (TGFβ2)	0	2
Granulocyte/Macrophage-Colony		

Stimulating Factor (GM-CSF)	0	2
Tumor Necrosis Factor alpha (TNFα)	0	0
Macrophage-Colony Stimulating Factor (M-CSF)	0	0

Nerve growth factor (NGF), acidic fibroblast growth factor (αFGF) and transforming growth factor alpha (TGFα) were most effective in bringing the electrical conductance measurements back into the normal range.

Prior to being treated with homeopathic growth factor signals, patient 2 had been treated with a variety of different botanicals. For the four-month period immediately prior to the commencement of homeopathic growth factor treatment, patient 2 was treated with the botanical bitter melon (called momordica) which resulted in increases in CD8, CD3, CD2 and CD19 counts of more than 50 percent. Bitter melon (momordica) was then discontinued. As shown in Figure 7A, administration of signals corresponding to homeopathic growth factors resulted in a slight increase in patient 2's peripheral blood lymphocyte counts without any other medical treatment. The average loss of CD4 cells in HIV-positive patients is 20% of the cells per year.

For patient 1, administration of signals corresponding to homeopathic dilutions of growth factors increased the CD4 count by 76%, while the CD8, CD2 and CD3 counts increased by 38%, as shown in Figure 7B.

These results are in marked contrast to the typical course of progression for HIV and AIDS in which the lymphocyte count continues to drop as the disease progresses. Figure 8 shows the decrease in peripheral blood lymphocyte counts over time for a typical HIV-positive patient. This patient did not receive any homeopathic growth factor treatment, but did receive botanical supplements.

Example 4

Figure 9 shows the change in total T lymphocyte cell, CD8 and CD4 counts for an HIV-positive patient over a period of four years. This patient was infected with HIV in 1982. In September 1992 (month 21) the CD4 cell count plummeted to 106 cells/mm^3. The average annual decrease in CD4 cells in this range is reported to be 32 cells/mm^3 when taking anti-retroviral therapeutics (Dept. of Epidemiology, University of Washington). However, after three months of daily treatments with radiofrequency signals corresponding to homeopathic dilutions of growth factors, the CD4 cells increased by 138 cells/mm^3 and by month 33, in September 1993, the CD4 cell count was 225 cells/mm^3, 199 cells/mm^3 higher than the previous year. Each time the patient received the growth factor radiofrequency signals, lymphocyte counts increased. When the patient did not receive the growth factor signals, the CD4 lymphocyte counts dropped, despite the fact that the patient was continually receiving weekly acupuncture treatments.

For example, between months 30 and 33 (June 1993 and September 1993) the patient regularly balanced electrical conductance points (four office visits, no growth factor signals administered). The CD8 and total T lymphocyte cell counts increased 300-350 cells/mm^3, but the CD4 cells dropped 17 cells/mm^3. The CD4 cells continued to drop until growth factor signals were given regularly (months 38 to 42; February to June 1994). During this time the patient had seven office visits and during four of them (2 in March, 1 in April and 1 in May) was treated with growth factor signals for NGF, AB-PDGF, IGF_1, βFGF, and TGFα. During this five month period the patient's CD4 count rose 30 cells/mm^3, from 180 cells/mm^3 to 210 cells/mm^3. The CD8 and total T lymphocyte counts also rose 430-475 cells/mm^3. CD8 cell counts above 500 cells/mm^3

correlate with low viral replication and perhaps longer survival due to their secretion of growth factors yet to be characterized (1994 International Conference on AIDS).

There was only one time period (months 33-38; Sept. 1993 to February 1994) that a single growth factor signal, IGF_1, was given, and CD4, CD8 and total T lymphocyte cell counts dropped 45 cells, 475 cells and 700 cells, respectively. This may be due to only giving one growth factor signal, or more probably to the death of this patient's father, and extensive transcontinental travel and exhaustion during the terminal stages of the father's illness. Grief and loss are well known stress factors that depress immune function. This patient did not receive any conventional drug treatments.

Example 5

Electrical conductances of fifteen Epstein-Barr virus (EBV) patients were measured at acupuncture points for the immune system using the LISTEN system. The results are shown in Figure 10. Higher than normal conductances were found at points corresponding to: lymph drainage of tonsils/throat (LY1aR) lymph tissue of lungs (LY4R); connective tissue (FICR); spleen lymphocytes homing to the lower body and gastrointestinal tract (SP2L); and spleen B lymphocytes and blood purification duties of spleen (SP3L). These results coincide with the clinical symptoms of patients with chronic EBV infection.

Eleven of the fifteen patients were subsequently treated for 3-9 months with a combination of homeopathic growth factor signals and botanicals corresponding to the LISTEN digital codes. Each patient was treated once per month using the previously outlined protocol. As shown in Figure 11, significant improvement in electrical conductances occurred. Fewer clinical symptoms were also observed and reported by the patients. For example, the

patients had less upper respiratory distress, less sore throats, more energy, fewer complaints regarding tendonitis, and somewhat improved digestion. These are all typical complaints of EBV patients.

Five of these patients were tested for the ability of signals corresponding to different dilutions of growth factors to normalize electrical conductances during one appointment. The results are shown in Table III.

TABLE III

Patient	EBV Titers	Intake Titer Levels	Growth Factor	Dilution
#1	VCA IgG	892	AA PDGF	6C
#2	VCA IgG	640	AA PDGF	800x, 30C
	EA	80	BB PDGF	800x, 6C
	EBNA	pos	AB PDGF	800x
			TGFβ1	800x
			TGFβ2	800x
			TGFα	800x
			αFGF	6C
			IGF1	800x, 6C
				200C, 1000C
#3	VCA IgG	640	Stem Cell Factor	30C
	EA	80		
	EBNA	neg		
#4	VCA IgG	160	AA PDGF	6C
	EA	80		
	EBNA	pos		
#5	VCA IgG	1280	IGF1	6C, 12C, 1000C
	EA	neg	Insulin	30C
	EBNA	40	TGFβ1	600x, 6C, 1000C
			βFGF	6C, 1000C
			TGFα	30C, 1000C
			NGF	6C
			Growth Hormone	1000C

As outlined above, a dilution of 6C is equal to 1:100 diluted six times (10^{-12} M). A dilution of 800x is equal to 1:10 diluted 800 times.

Prior to treatment, each of the five patients was tested for the presence of the following EBV titers: viral capsid antigen (VCA), early antigen (EA), and Epstein-Barr nuclear antigen (EBNA), as shown in Table III. In non-EBV infected subjects these titers are either negative or close to zero. Patient 1 was symptomatic with sore throat, sinus drainage and swollen glands at time of electrical conductance testing. Patients 2 and 5 were similar in that both had gall bladder surgery, hysterectomies, fibromyalgia, and were over forty and over-weight. Patient 2 also had chronic HPV and HSV infection. Patient 5's fasting blood sugar readings were indicative of mature onset of non-insulin dependent diabetes. Patient 3 additionally diagnosed as having multiple sclerosis. Patient 4 was additionally diagnosed as having rheumatoid arthritis.

All available growth factor signals were tested for patients 1 and 3-5. Based on the earlier HIV data, potentially useful growth factors were tested on patent 2 to determine effective dilutions, as shown in Table III.

Patient 5 was balanced on each of seven individual appointments using only growth factors. The growth factors were able to bring the electrical conductances into the normal range of 45-55 at every acupuncture point (over 30 points), often without additional supplementation with naturopathic medicines.

As described earlier all five patients demonstrated improved clinical symptoms. The growth factors found to be effective in treating these EBV patients included PDGF, TGFβ, αFGF, IGF1, NGF, insulin, growth hormone, and stem cell factor.

Example 6

Two cancer patients were administered signals corresponding to homeopathic signals of growth factors

using the standard LISTEN protocol. Patient 1 had chronic myeloid leukemia (CML), which is a stem cell disease in which stem cells fail to respond to physiologic feedback signals that regulate growth and differentiation of hematopoietic precursors. This patient had just begun treatment with alpha-interferon several hours before testing with the LISTEN system. Patient 2 had an adenocarcinoma (renal cell carcinoma) removed from her left side approximately 18 months prior to this study, and had metastases to the lung, skull and possibly to the bones and liver at the commencement of this study.

As shown in Figure 12, these two patients had significantly different electrical conductances. Both patients' electrical conductances were normalized by administration of specific homeopathic growth factor signals and naturopathic supplements. For patient 1, signals corresponding to combined dilutions of IGF1 were found to bring the conductances back into the normal range. For patient 2, signals corresponding to 30x, 100C and 1000C dilutions of NGF, an 8x dilution of AA PDGF, and 6C and 30C dilutions of TGFβ1 were found to be effective. The naturopathic supplements alone did not balance the electrical conductances.

Patient 2, following treatment using the LISTEN system five times per week for one month, no longer tested positive for cancer, using the serum AMAS™ test (Anti-Malignin Antibody in Serum determined with TARGET™ Reagent; Oncolab, Inc., Boston, MA). In this test, the higher the component result number, the more indicative the result is of cancer. The AMAS™ normal range for S-TAG is 0-399; for F-TAG 0-299; and for net-TAG 0-99. The specific results of the AMAS™ test for this patient after one month of treatment were as follows: S-TAG 184 μg/ml (normal); F-TAG 79 μg/ml (normal); and net-TAG 105 μg/ml (borderline). AMAS™ test results continued to improve

with continued administration of radiofrequency signals corresponding to homeopathic dilutions of growth factors. Two months later, after continued treatment, the results of the AMAS™ test were as follows: S-TAG 152 μg/ml (17% decrease); F-TAG 70 μg/ml (11% decrease) and net-TAG 82 μg/ml (now in normal range with a 22% decrease). All component measurements indicated normal results had been achieved. The results of blood chemistry analyses for Patient 2 before treatment and after one month of treatment with signals corresponding to TGFβ1 are shown in Table IV.

TABLE IV

Blood Chemistry	Before Treatment	After Treatment
Chemistry		
Sodium	139 meg/l	143
Potassium	3.3 meg/l	4.8
Chloride	100 meg/l	108
CO_2	25 meg/l	23
Glucose	173 (high) mg/dl	149 (high but closer to normal)
Calcium	8.7 mg/dl	9.0
Bun	18.0 mg/dl	18.0
Creatinine	1.2 mg/dl	1.2
Bun/Creat.	15.0	15.1
Uric Acid	5.5 mg/dl	6.2 (high)
Cholesterol	301 (high) mg/dl	357 (high)
Triglycerides	523 (high)	305 (high but closer to normal)
Albumin	4.0 g/dl	4.1
Globulin	2.6 g/dl	2.5

Blood Chemistry	Before Treatment	After Treatment
A/G ratio	1.5	1.6
Total Bilirubin	0.6 mg/dl	0.4
Direct Bilirubin	0.4 mg/dl	0.0
Alkaline Phosphatase	62 u/l	108
LDH	136 u/l	150
AST (SGOT)	8 u/l	15
ALT (SGPT)	8 u/l	18
CBC		
WBC	7 x1000/ul	5.9
RBC	3.93 (Low) mil/ul	4.49 (resolved)
Hemoglobin	11.7 (Low) g/dl	13.6 (resolved)
Hematocrit	35.1 (Low) %	41.7 (resolved)
MCV	89.3 fl	92.9
MCH	29.8 pg	30.3
MCHC	33.3 %	32.6
Neutrophils	55.9%	62.9%
Lymphocytes	34.4%	32.7%
Monocytes	7.4% (monocytosis)	2.4% (resolved)
Eosinophils	1.4%	1.2%
Basophils	0.9%	0.8%
Platelet count	342,000/ul	348,000/ul

Prior to treatment, Patient 2 had anemia, as indicated by the hemoglobin, hematocrit and red blood cell count (RBC), and immune stress, indicated by slightly elevated monocyte counts. Following treatment with radiofrequency signals corresponding to TGFβ1 for a period of one month, the patient's anemia and monocytosis had resolved. The patient's liver enzyme values (SGOT and

SGPT) were also greatly improved, as was the alkaline phosphatase level.

Example 7

Figure 13 shows a change in white blood cell count in a patient with chronic lymphocytic leukemia both before and during treatment with radiofrequency signals corresponding to homeopathic dilutions of growth factors.

This patient was diagnosed with chronic lymphocytic leukemia in April 1992. From April 1993 to April 1994 (months -12 to 0 on the time scale) the white blood cell count doubled from 24,700 to 49,000 cells/mm3. In April 1994 (months 0 to 7) the patient began receiving radiofrequency signals corresponding to growth factors on a weekly basis. During this treatment period, the white blood cell count maintained a relatively low non-progressive state, as noted by the significantly different regression line during that time versus the general treatment period regression line. The patient initially progressed to higher counts of white blood cells when orally administered 10^{-12}M and 10^{-24}M dilutions of GM-CSF. The white blood cell counts were dramatically decreased by introducing homeopathic dilutions of 10^{-60}M and $10^{-2,000}$M BB-PDGF plus a homeopathic dilution of HH6V into the protocol.

Example 8

A study was performed using the LISTEN system on two patients with insulin-dependent diabetes. Both patients were between 11 and 12 years of age and were treated within one year of onset of disease. Patient 1 serum-tested positive for Coxsackie B3 virus, which has been implicated through epidemiological studies to be a causative factor in the onset of diabetes. Patient 2 was not tested for Coxsackie B virus. The highly abnormal

conductances of these patients shown in Figure 14 were brought into the normal range by the administration of signals corresponding to naturopathic supplements plus a 6C dilution of insulin. On one occasion, patient 1's conductance points were completely balanced with signals corresponding to combined dilutions of stem cell factor or vasopressin without the need for additional signals of naturopathic supplements. These corrections in electrical conductance correspond with greater control of blood glucose level.

In a separate treatment session, all available signals for homeopathic growth factors were scanned to determine which signal would bring patient 2's conductances back to the normal range. A signal corresponding to a 600x dilution of βFGF was found to be most effective.

Although the present invention has been described in terms of specific embodiments, changes and modifications can be carried out without departing from the scope of the invention which is intended to be limited only by the scope of the appended claims.

AP/P/96/00867

Claims

1. A composition comprising a homeopathic dilution of one or more purified growth factor.

2. A composition as recited in claim 1, wherein said one or more purified growth factor is selected from the group consisting of granulocyte macrophage-colony stimulating factor, granulocyte-colony stimulating factor, macrophage-colony stimulating factor, tumor necrosis factor, transforming growth factors, epidermal growth factors, stem cell factor, platelet-derived growth factors, nerve growth factors, fibroblast growth factors, insulin-like growth factor, growth hormone, interleukin-1, interleukin-2, keratinocyte growth factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, **bombyxin, neu differentiation** factor, v-Sis and glial growth factor/acetylcholine receptor-inducing activity.

3. A composition as recited in claim 1 wherein the concentration of said homeopathic dilution is less than about 10^{-6} molar.

4. A composition as recited in claim 3 wherein the concentration of said homeopathic dilution is between about 10^{-6} molar and about $10^{-100,000}$ molar.

5. A composition as recited in claim 1 wherein said homeopathic dilution of a purified growth factor is impregnated on a solid medium.

6. A composition as recited in claim 5 wherein said solid medium comprises a tablet.

7. A composition as recited in claim 1 wherein said homeopathic dilution of a purified growth factor is in a liquid form.

8. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes comprising administering a homeopathic dilution of one or more purified growth factors.

9. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 8 wherein said disorder is a chronic viral infection.

10. A method for treating a patient having a chronic viral infection as recited in claim 9, wherein said chronic viral infection is selected from the group consisting of HIV, Epstein-Barr virus, herpes simplex, papilloma, cytomegalovirus, hepatitis B, Coxsackie B, hauta virus, and human herpes 6 virus.

11. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 8, wherein said purified growth factor is selected from the group consisting of granulocyte macrophage-colony stimulating factor, granulocyte-colony stimulating factor, macrophage-colony stimulating factor, tumor necrosis factor, transforming growth factors, epidermal growth factors, stem cell factor, platelet-derived growth factors, nerve growth factors, fibroblast growth factors, insulin-like growth factor, growth hormone, interleukin-1, interleukin- 2, keratinocyte growth factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, **bombyxin, neu differentiation**

factor, v-Sis and glial growth factor/acetylcholine receptor-inducing activity.

12. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 8, wherein the concentration of said homeopathic dilution is less than about 10^{-6} molar.

13. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 12, wherein the concentration of said homeopathic dilution is between about 10^{-6} molar and about $10^{-100,000}$ molar.

14. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 8, wherein said homeopathic dilution is administered orally.

15. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 14, wherein said homeopathic dilution is administered in a solid form.

16. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 15, wherein said solid form comprises a tablet.

17. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim

14, wherein said homeopathic dilution is administered in a liquid form.

18. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 8, wherein said homeopathic dilution is administered by injection at a skin conductance point.

19. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 8, wherein said homeopathic dilution is administered intravenously.

20. A method for modifying blood lymphocyte counts in a patient comprising administering a homeopathic dilution of one or more growth factors.

21. A method for modifying blood lymphocyte counts as recited in claim 20, wherein said growth factor is selected from the group consisting of granulocyte macrophage-colony stimulating factor, granulocyte-colony stimulating factor, macrophage-colony stimulating factor, tumor necrosis factor, transforming growth factors, epidermal growth factors, stem cell factor, platelet-derived growth factors, nerve growth factors, fibroblast growth factors, insulin-like growth factor, growth hormone, interleukin-1, interleukin-2, keratinocyte growth factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, bombyxin, neu differentiation factor, v-Sis and glial growth factor/acetylcholine receptor-inducing activity.

22. A method for modifying calcium levels in a

patient comprising administering a homeopathic dilution one or more growth factors.

23. A method for modifying calcium levels as recited in claim 22, wherein said growth factor is selected from the group consisting of granulocyte macrophage-colony stimulating factor, granulocyte-colony stimulating factor, macrophage-colony stimulating factor tumor necrosis factor, transforming growth factors, epidermal growth factors, stem cell factor, platelet-derived growth factors, nerve growth factors, fibroblast growth factors, insulin-like growth factor, growth hormone, interleukin-1, interleukin-2, keratinocyte growt factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, **bombyxin, neu differentiation factor, v-Sis and** glial growth factor/acetylcholine receptor-inducing activity.

24. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes comprising administering a radio frequency signal corresponding to a homeopathic dilution of one or more growth factors.

25. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 24, wherein said disorder is a chronic viral infection.

26. A method for treating a patient having a chronic viral infection as recited in claim 25, wherein said chronic viral infection is selected from the group consisting of HIV, Epstein-Barr virus, herpes simplex, papilloma, cytomegalovirus, hepatitis B, Coxsackie B, hauta virus, and human herpes 6 virus.

27. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 24, wherein said growth factor is selected from the group consisting of granulocyte macrophage-colony stimulating factor, granulocyte-colony stimulating factor, macrophage-colony stimulating factor, tumor necrosis factor, transforming growth factors, epidermal growth factors, stem cell factor, platelet-derived growth factors, nerve growth factors, fibroblast growth factors, insulin-like growth factor, growth hormone, interleukin-1, interleukin-2, keratinocyte growth factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, **bombyxin, neu differentiation** factor, v-Sis and glial growth factor/acetylcholine receptor-inducing activity.

28. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 24, wherein said radio frequency signal corresponds to a homeopathic dilution of less than about 10^{-6} molar.

29. A method for treating a patient having a disorder selected from the group consisting of chronic viral infections, cancer and diabetes as recited in claim 28, wherein said radio frequency signal corresponds to a homeopathic dilution of between about 10^{-6} molar and about $10^{-100,000}$ molar.

30. A composition as recited in claim 2, wherein the growth factor is granulocyte macrophage-colony stimulating factor.

31. A composition as recited in claim 2,

wherein the growth factor is transforming growth factor-beta.

32. A composition as recited in claim 2, wherein the growth factor is platelet-derived growth factor.

33. A composition as recited in claim 2, wherein the growth factor is insulin-like growth factor.

34. A method as recited in claim 24, wherein the radio frequency signal is administered to the patient at one or more skin conductance points.

35. A method as recited in claim 24, additionally comprising obtaining a baseline conductance measurement at one or more skin conductance points in the patient to identify at least one abnormal conductance point prior to administering the radio frequency signal, and subsequently administering the radio frequency signal at the abnormal conductance point.

36. A method as recited in claim 24, additionally comprising administering multiple radio frequency signals corresponding to dilutions of a combination of growth factors to the patient.

37. A method as recited in claim 24, wherein the radio frequency signal is administered to the patient repeatedly.

38. A composition consisting essentially of a homeopathic dilution of one or more growth factors.

39. A composition as recited in claim 38, wherein the growth factor(s) is selected from the group consisting of granulocyte macrophage-colony stimulating factor, granulocyte-colony stimulating factor, macrophage-colony stimulating factor, tumor necrosis factor, transforming growth factors, epidermal growth factors, stem cell factor, platelet-derived growth factors, nerve growth factors, fibroblast growth factors, insulin-like growth factor, growth hormone, interleukin-1, interleukin-2, keratinocyte growth factor, ciliary neurotrophic growth factor, Schwann cell-derived growth factor, vaccinia virus growth factor, bombyxin, neu differentiation factor, v-Sis and glial growth factor/acetylcholine receptor-inducing activity.

FIGURE 1A

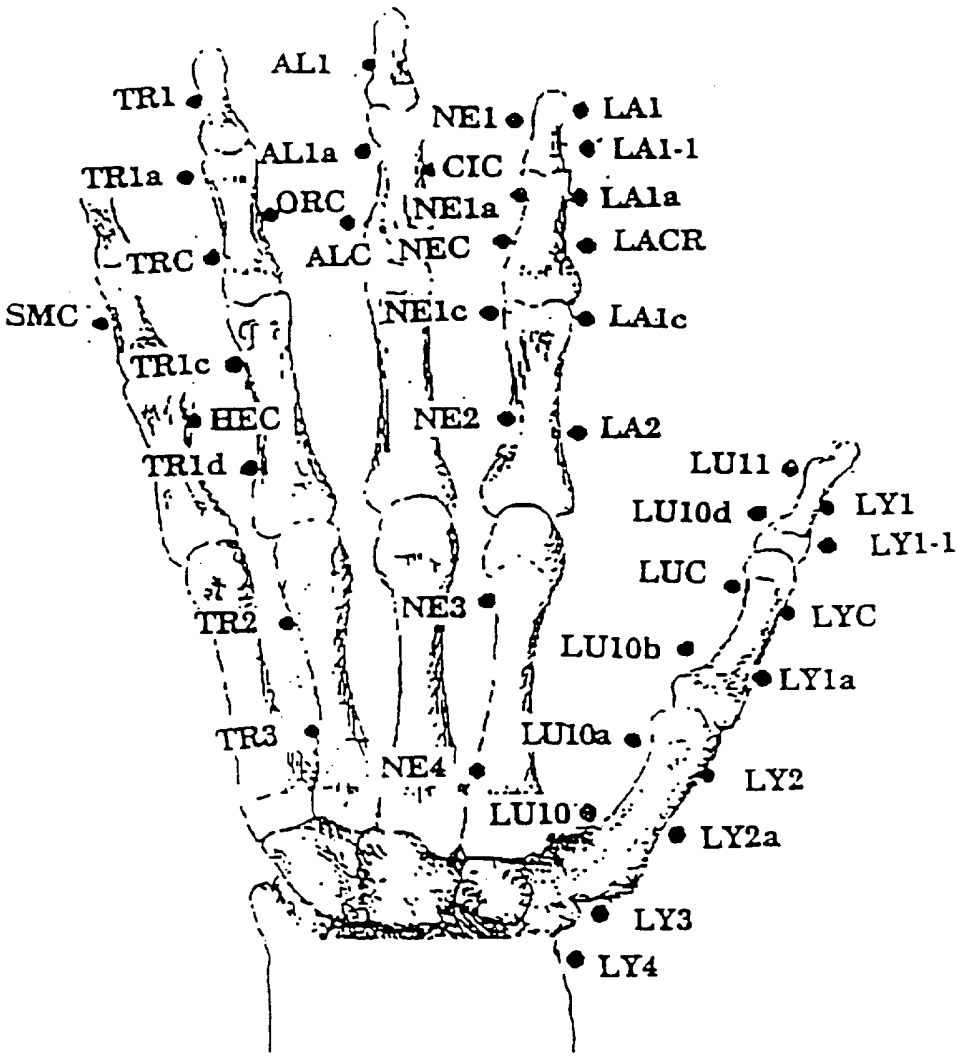

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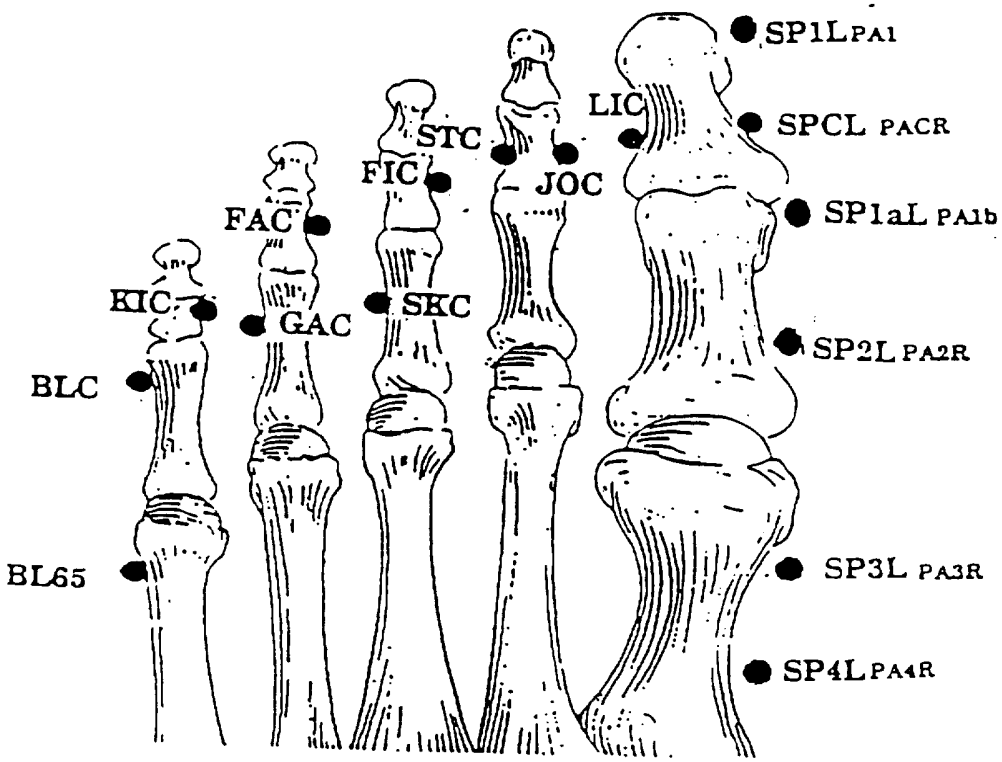
FIGURE 1B



AP/P/96/00867

FIGURE 2

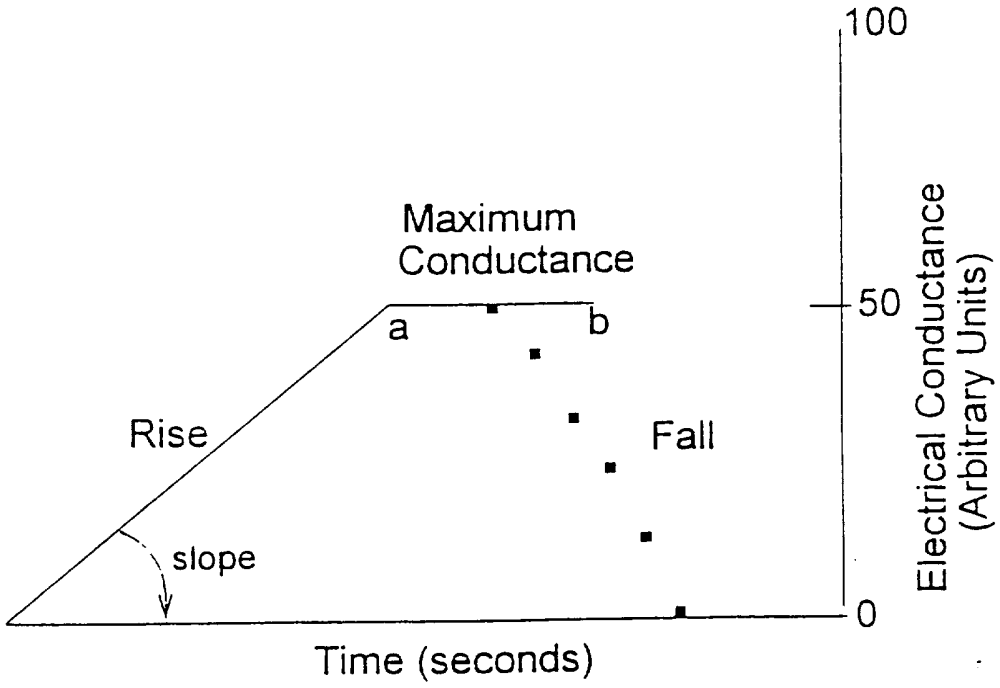


FIGURE 3A

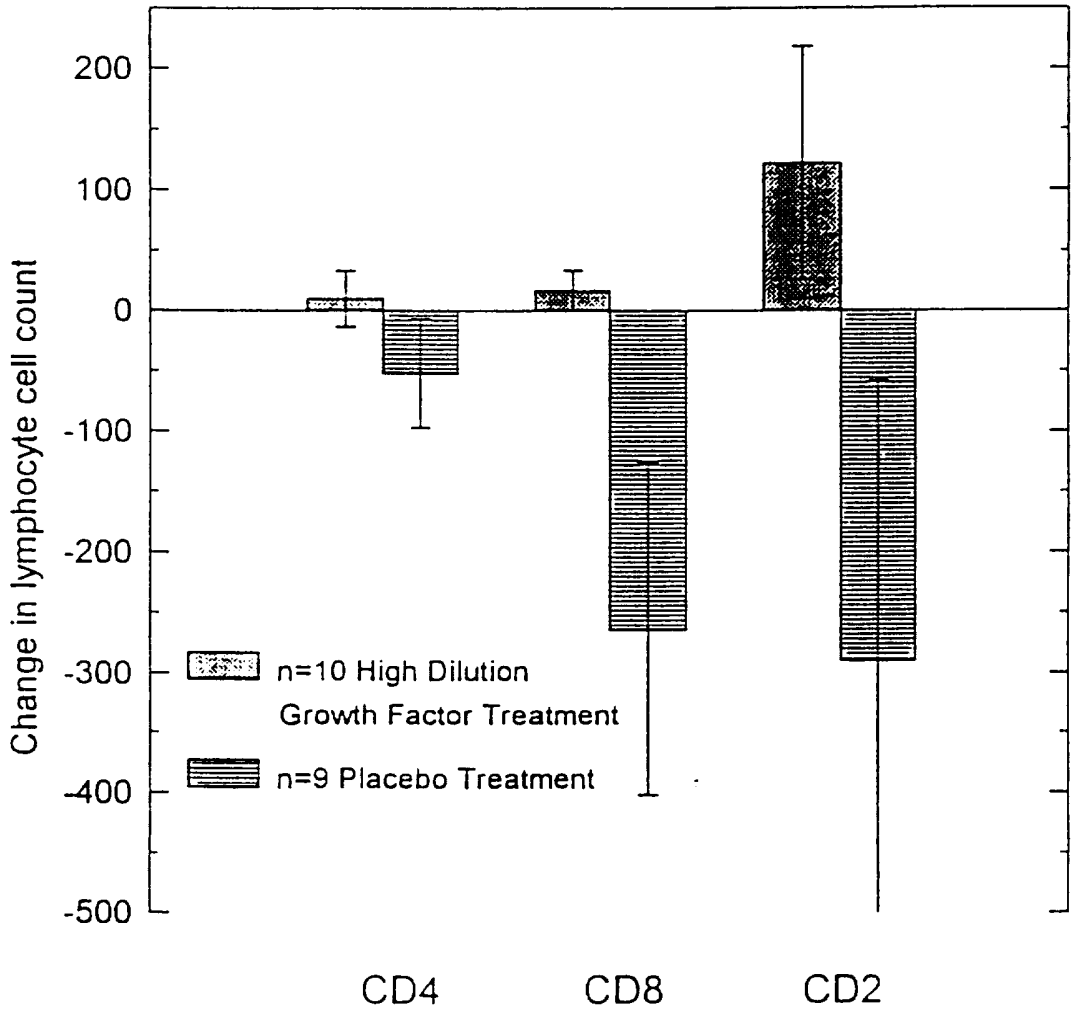


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FIGURE 3B

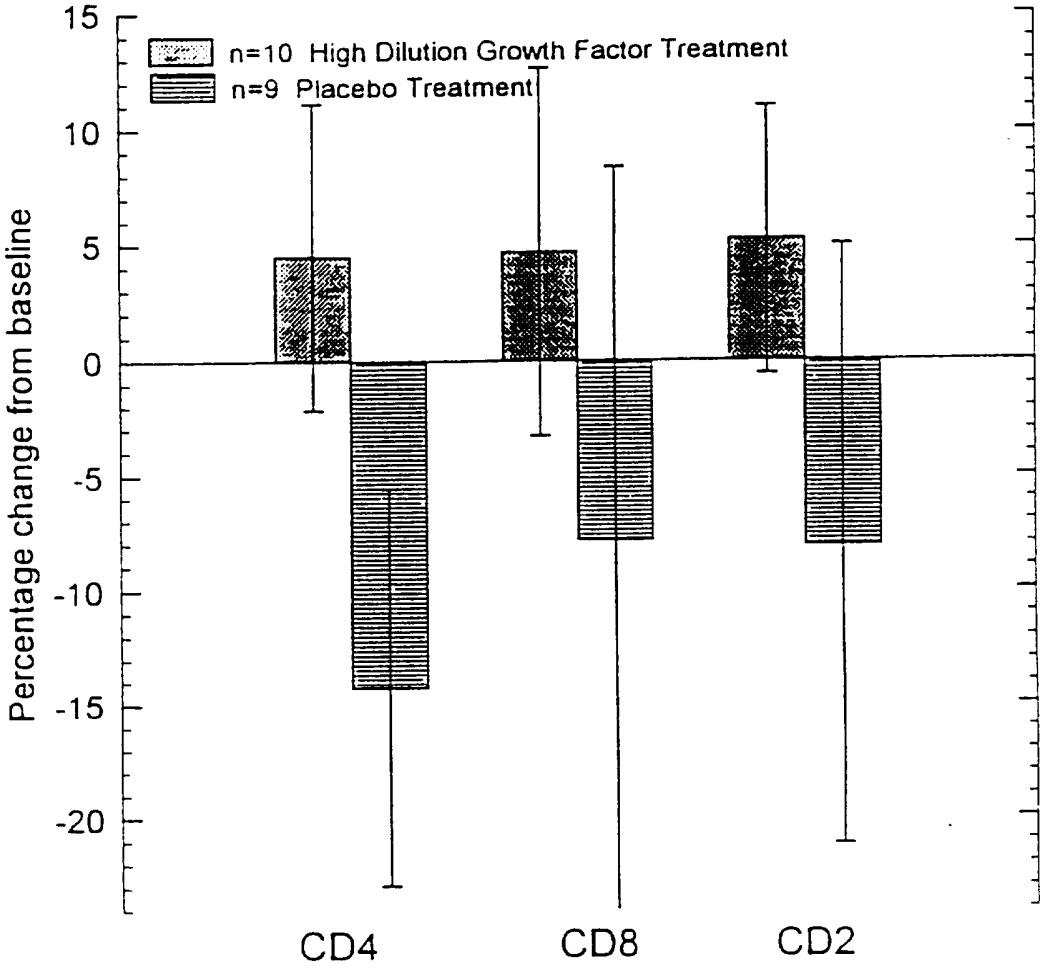
n=10 High Dilution Growth Factor Treatment
n=9 Placebo Treatment
Percentage change from baseline
15
10
5
0
-5
-10
-15
-20
CD4
CD8
CD2

FIGURE 4

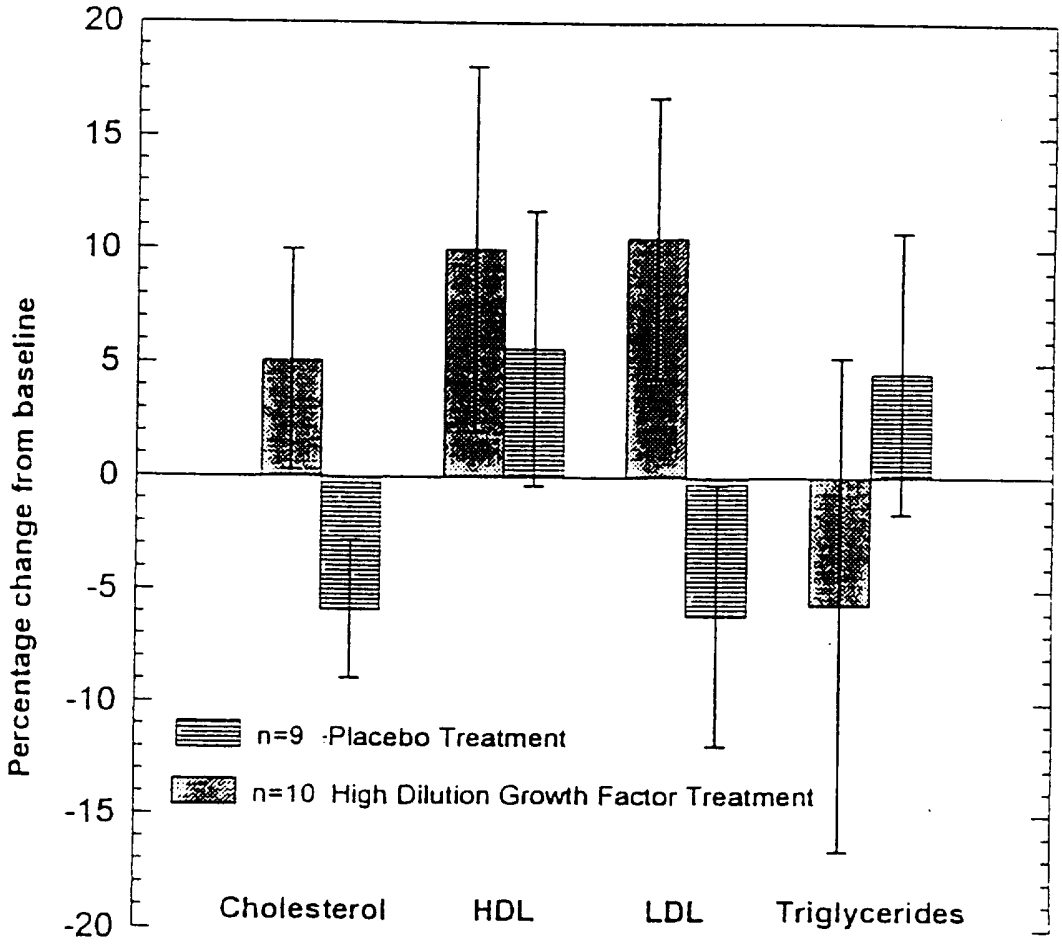

FIGURE 5

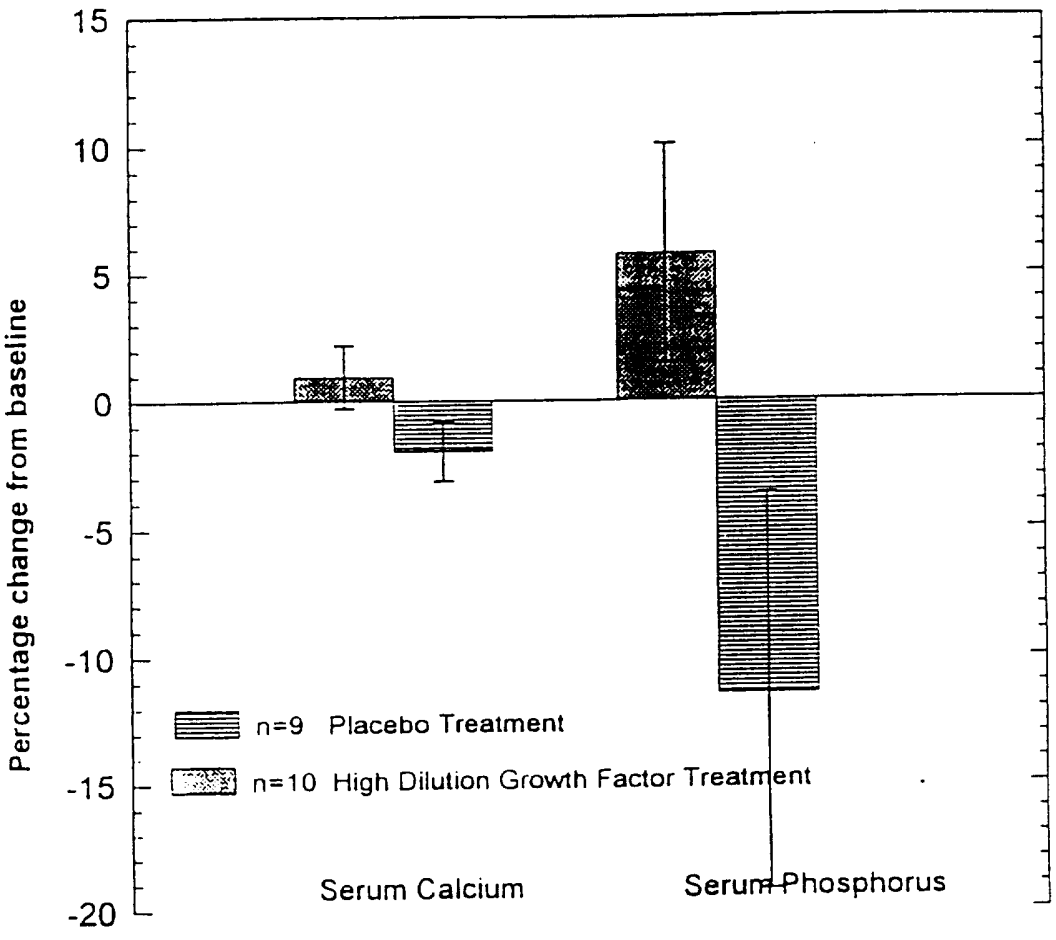
15
10
5
0
-5
-10
-15
-20
Percentage change from baseline
n=9 Placebo Treatment
n=10 High Dilution Growth Factor Treatment
Serum Calcium
Serum Phosphorus

FIGURE 6A

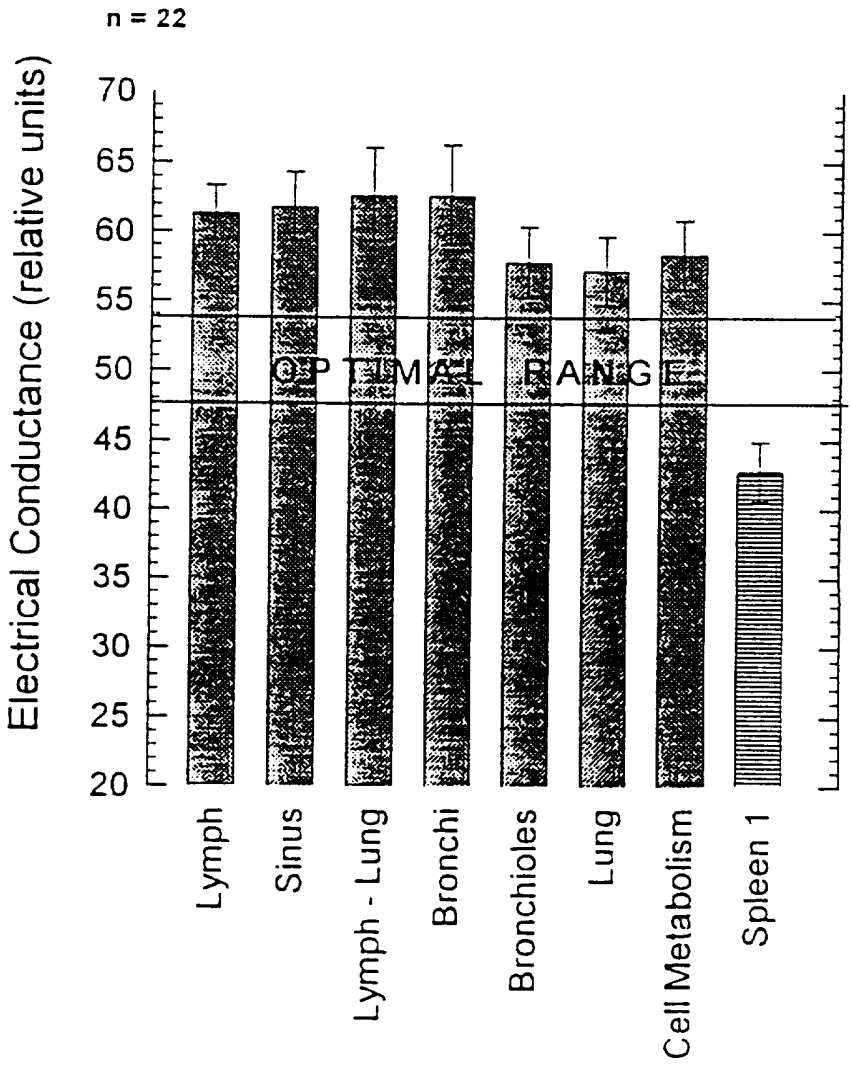

FIGURE 6B

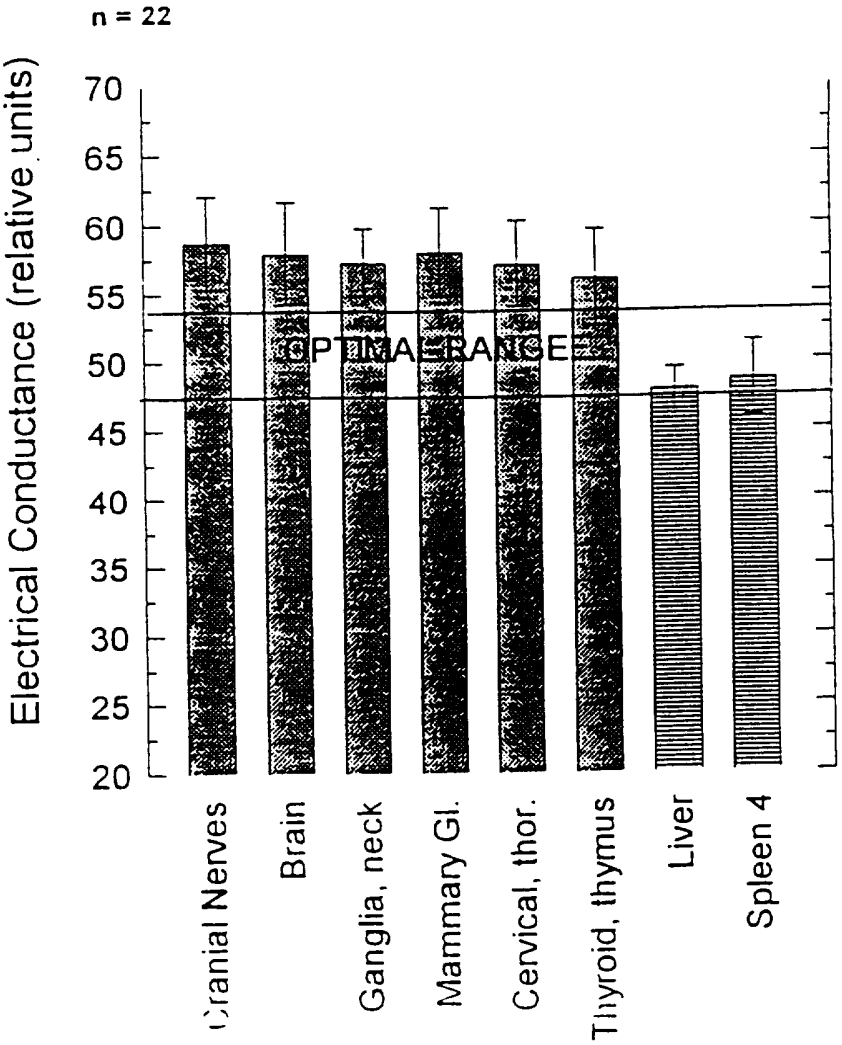

FIGURE 6C

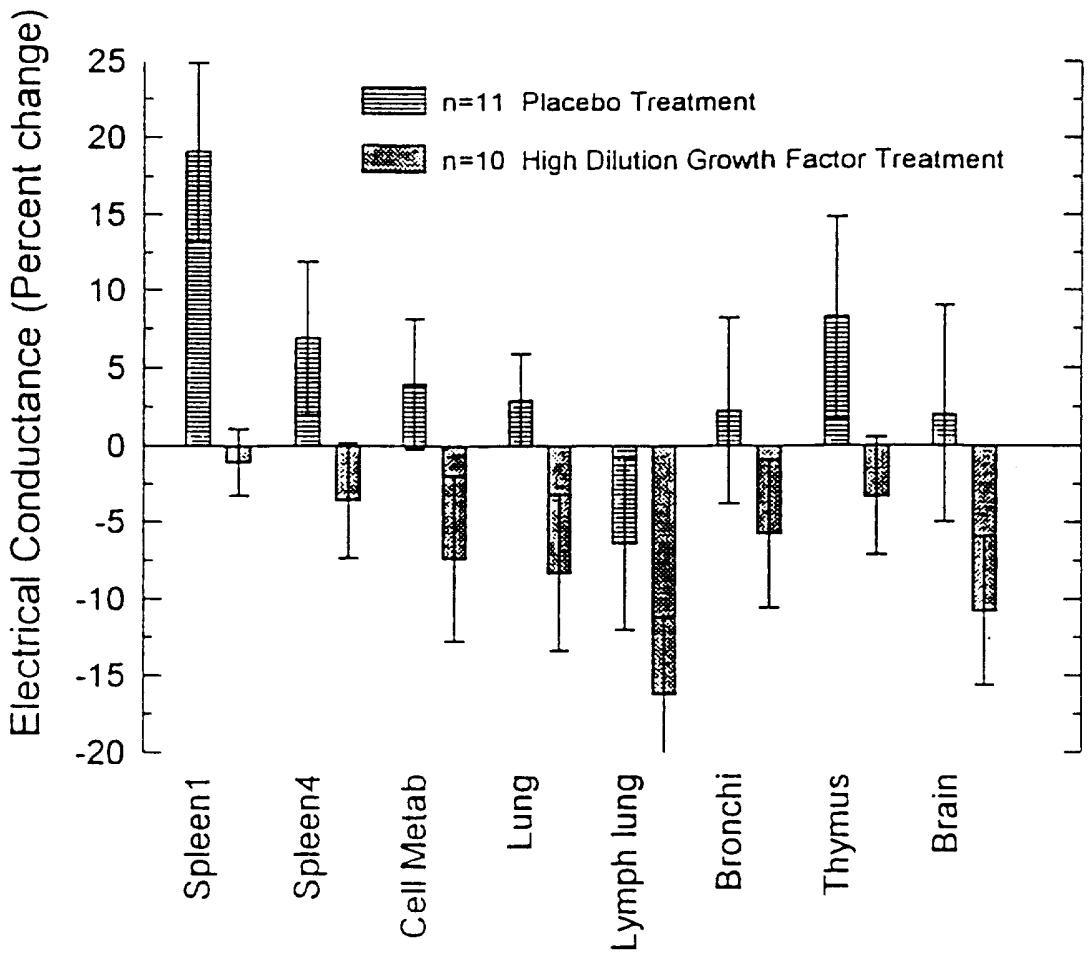

FIGURE 6D

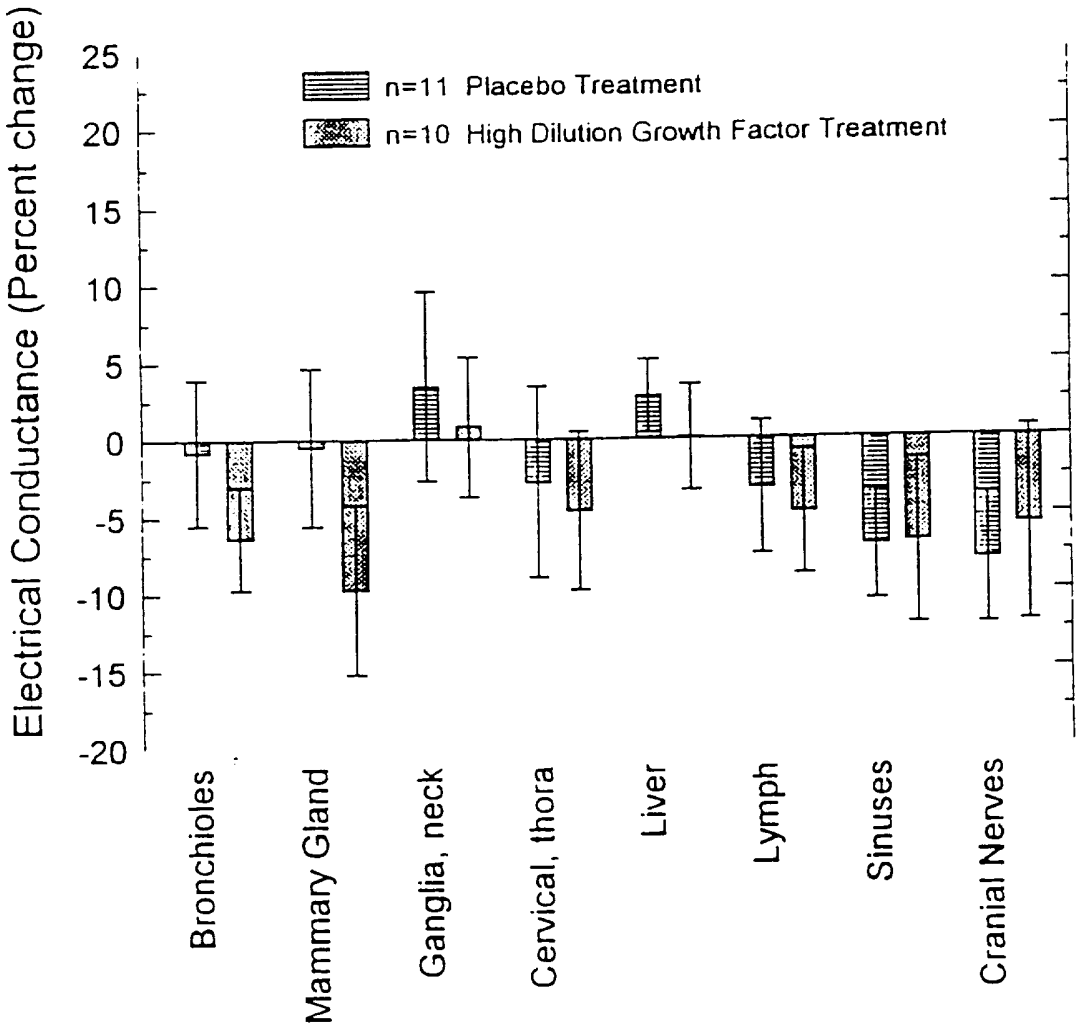

FIGURE 7A

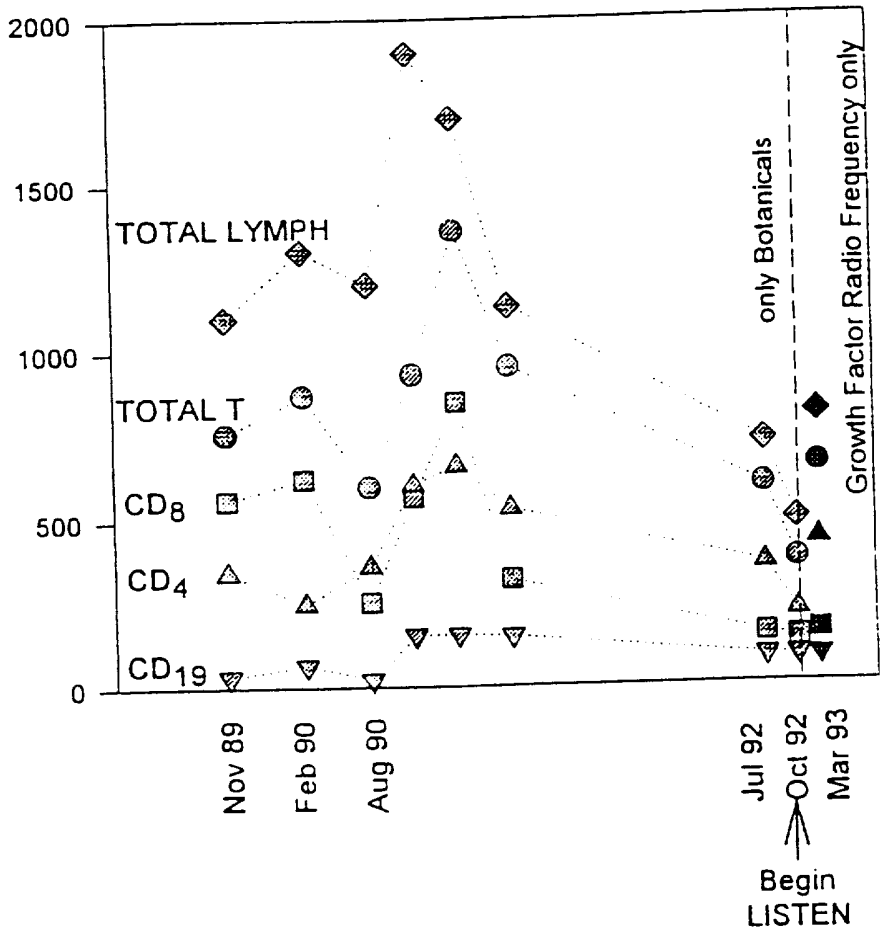

FIGURE 7B

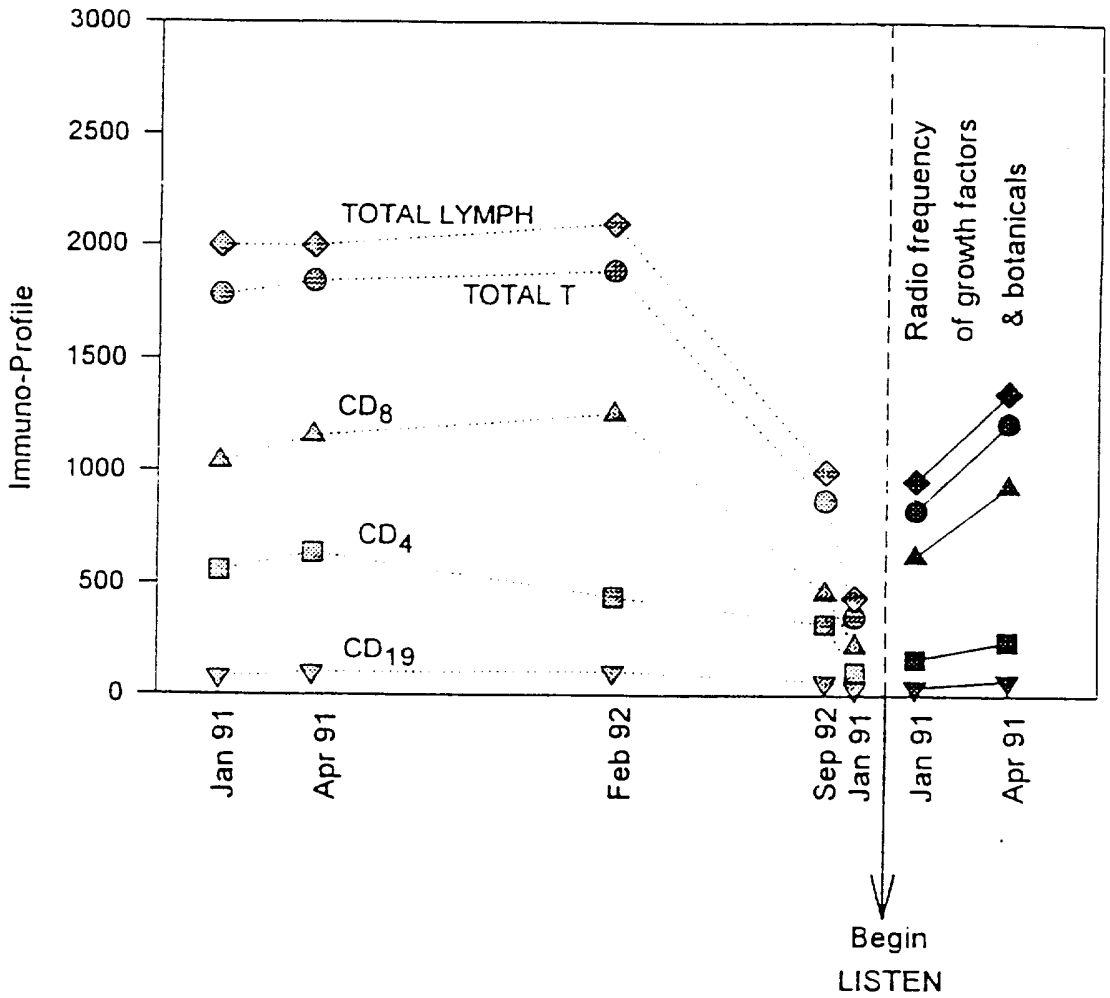
3000
2500
2000
1500
1000
500
0
Immuno-Profile
TOTAL LYMPH
TOTAL T
CD8
CD4
CD19
Jan 91
Apr 91
Feb 92
Sep 92
Jan 91
Jan 91
Apr 91
Radio frequency
of growth factors
& botanicals
Begin
LISTEN

FIGURE 8

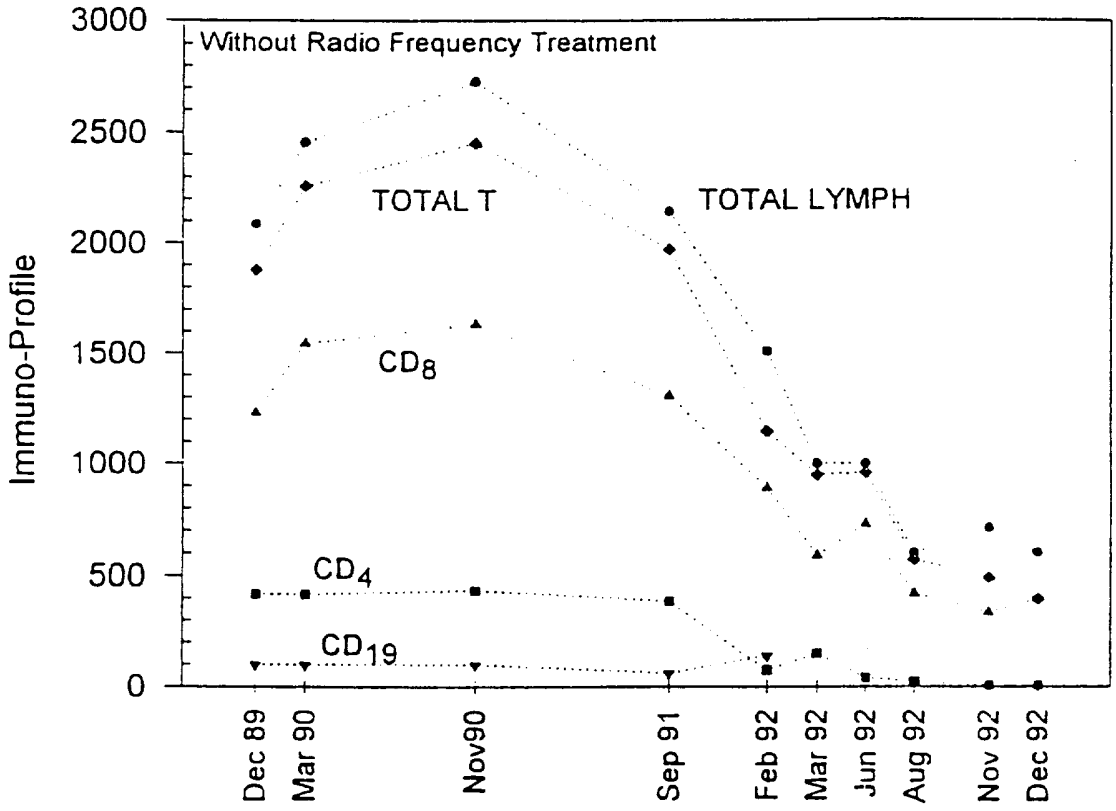

FIGURE 9

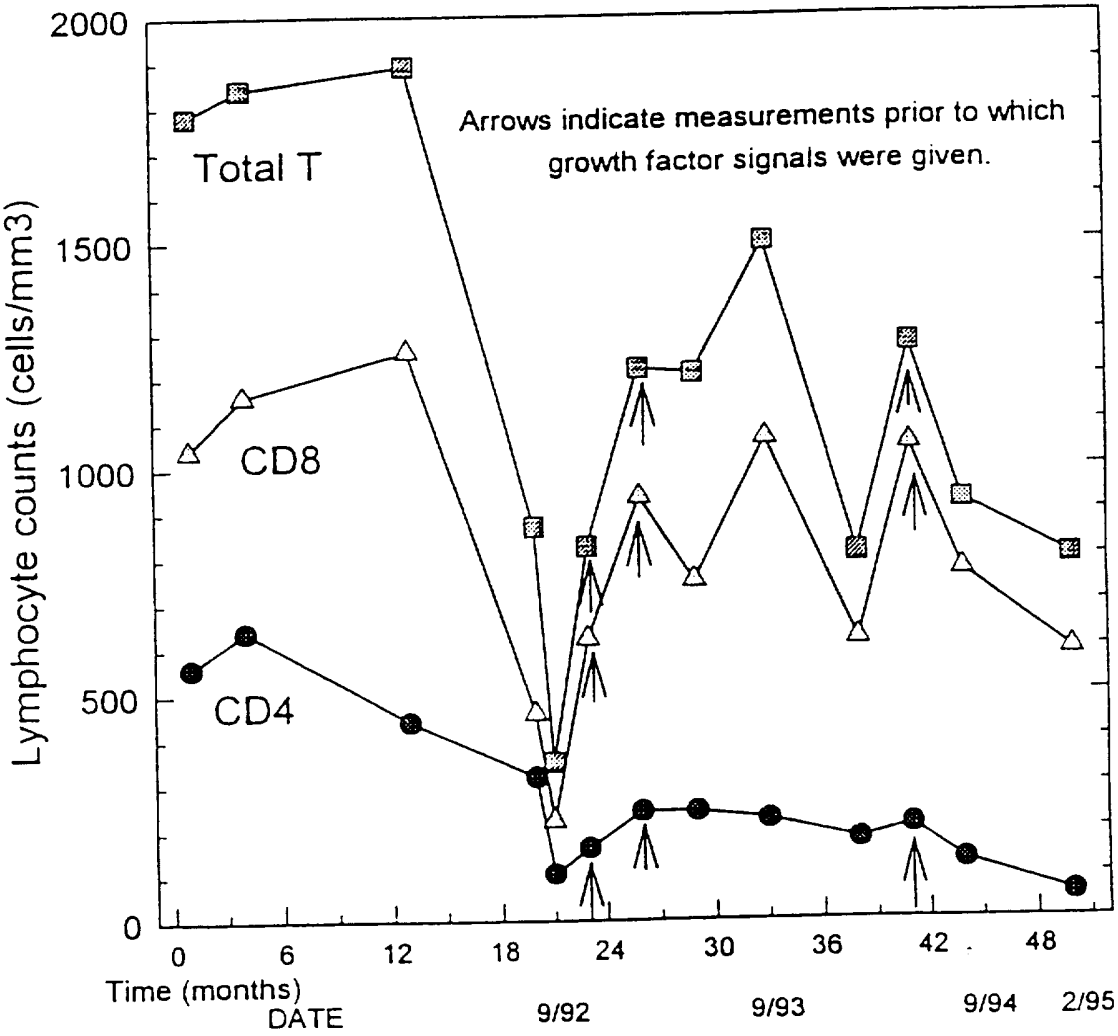

FIGURE 10

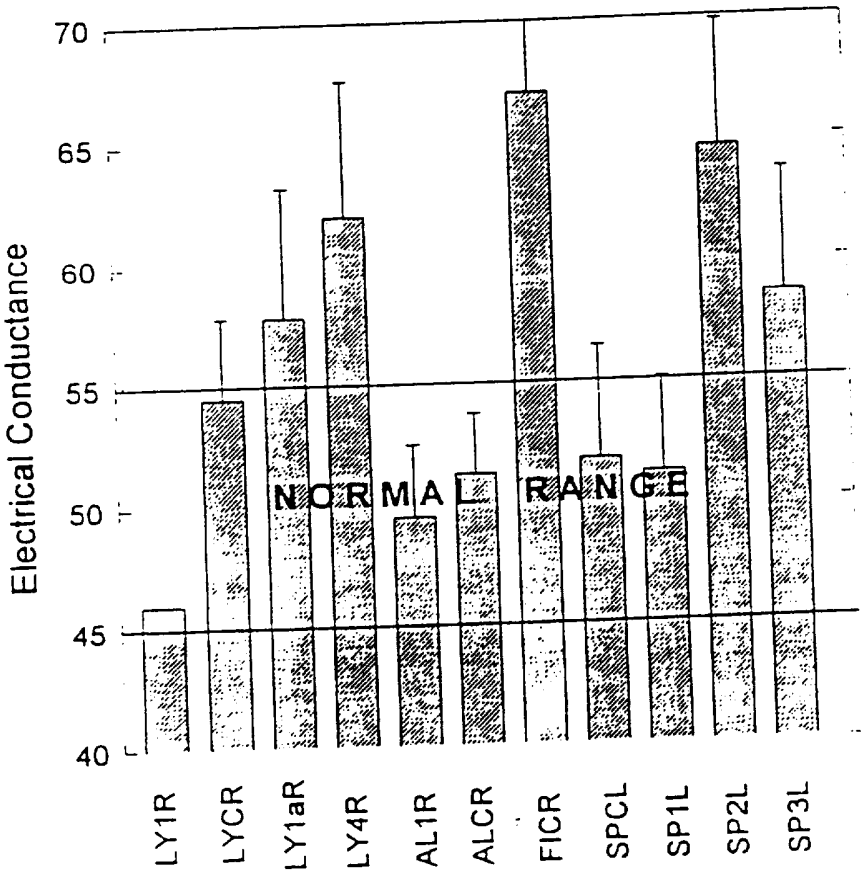

FIGURE 11

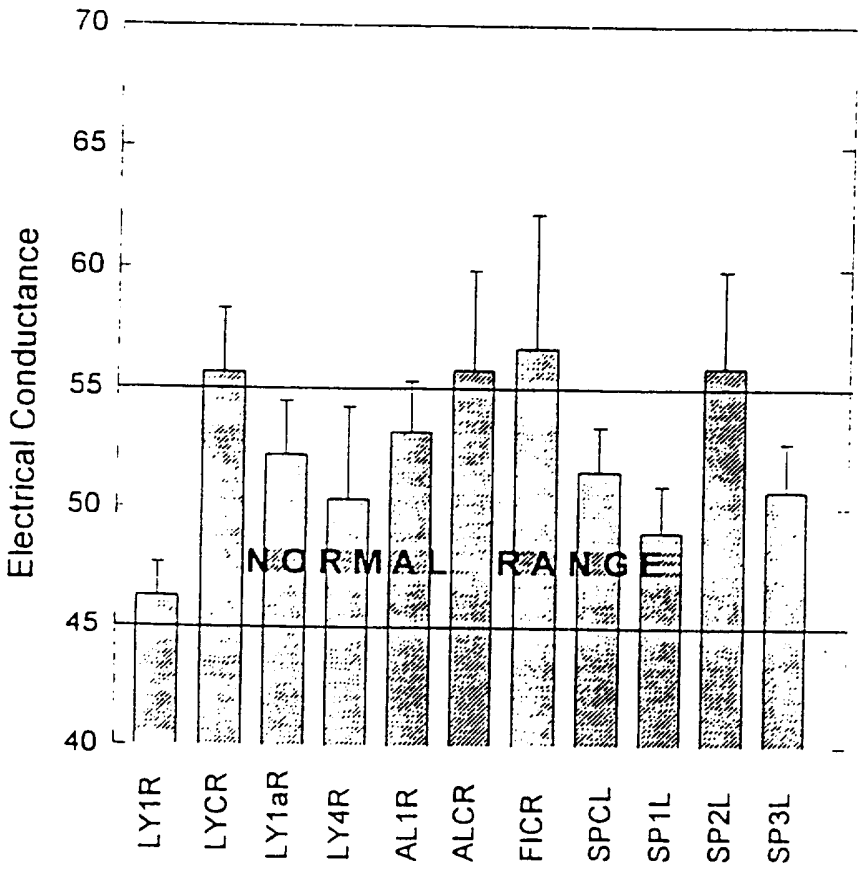

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FIGURE 12

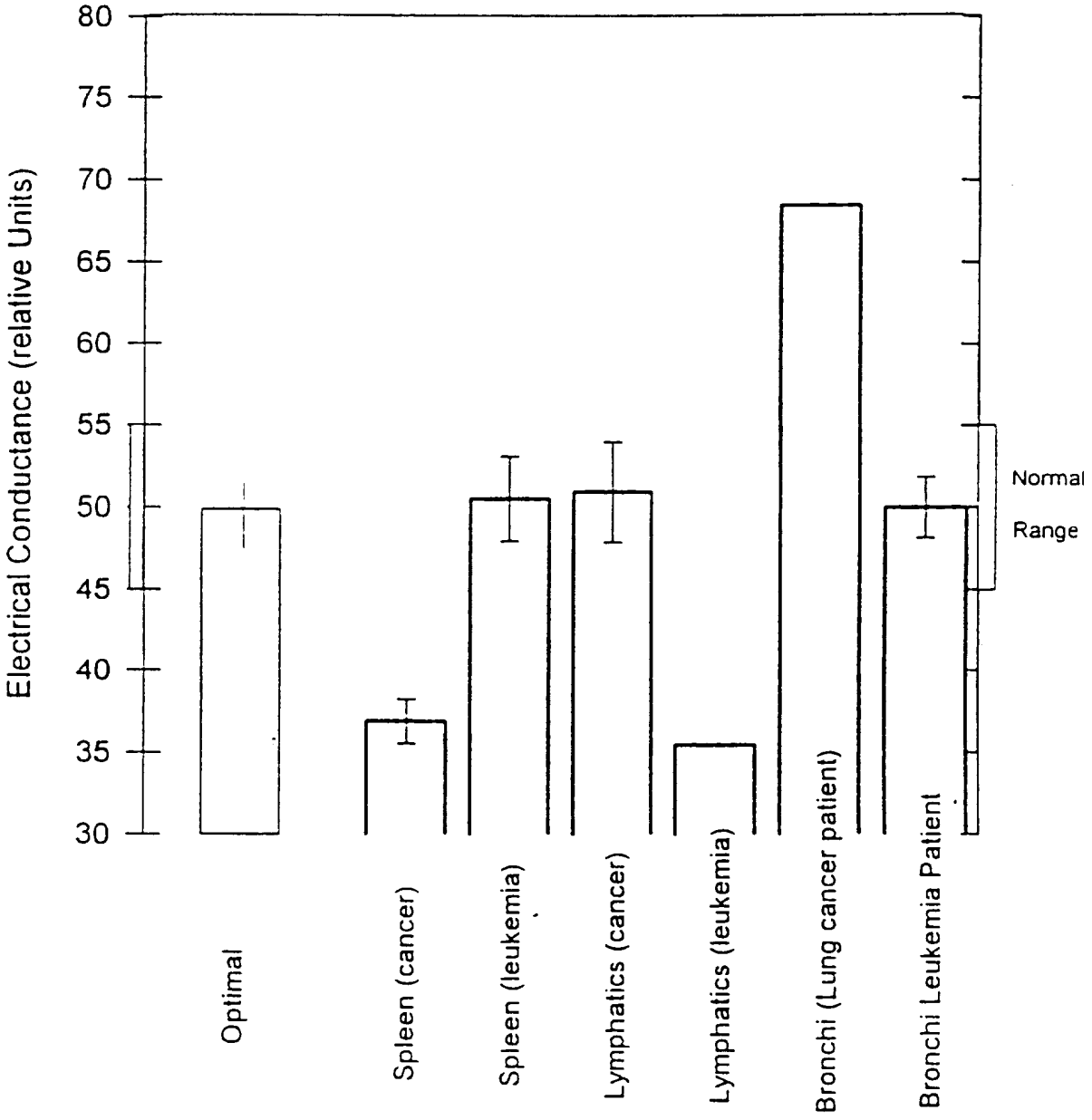

FIGURE 13

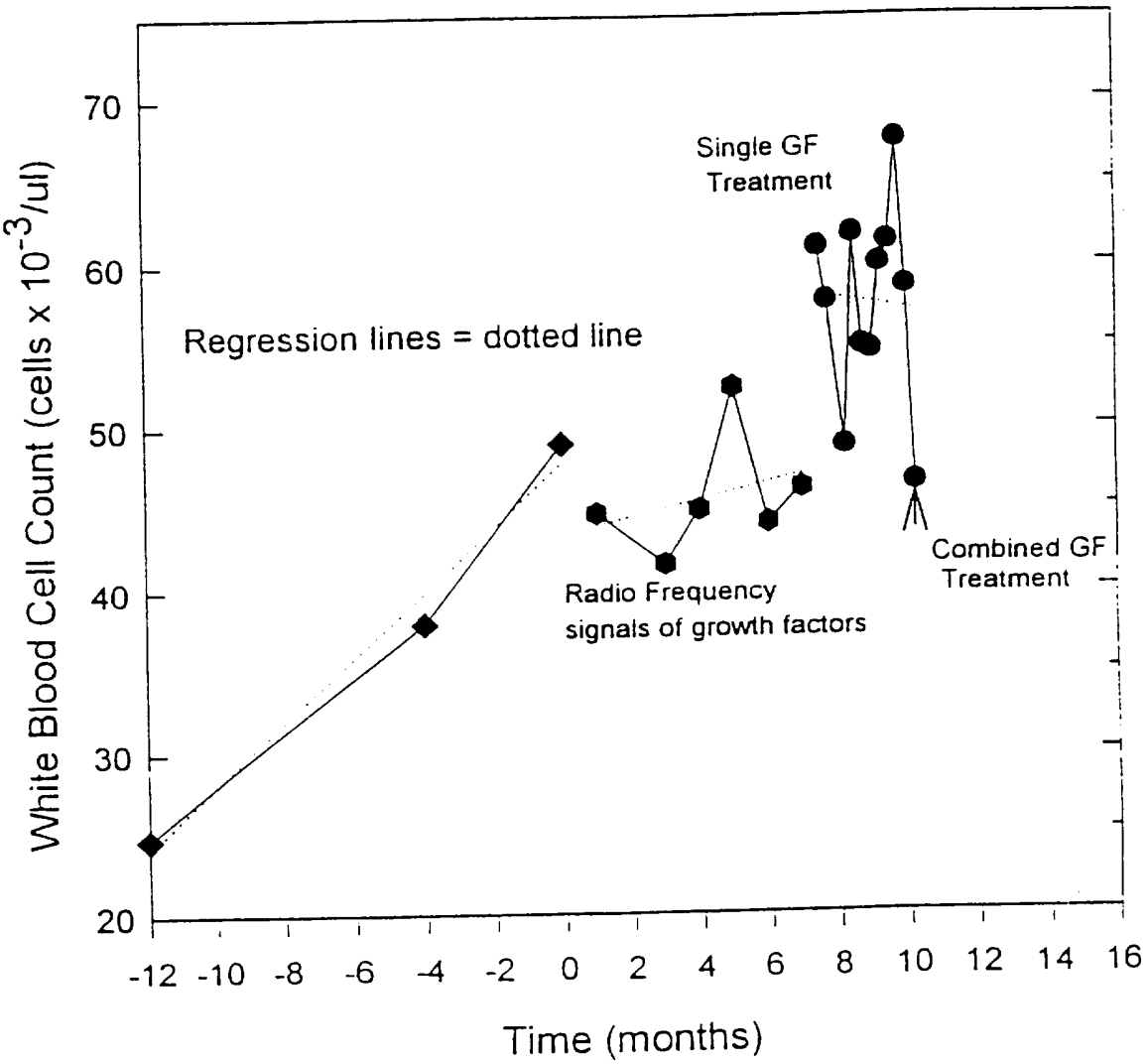
White Blood Cell Count (cells x 10^{-3}/ul)
70
60
50
40
30
20
-12 -10 -8 -6 -4 -2 0 2 4 6 8 10 12 14 16
Time (months)
Regression lines = dotted line
Single GF Treatment
Radio Frequency signals of growth factors
Combined GF Treatment

FIGURE 14