THE EFFECTS OF ELECTRICAL STIMULATION OF THE RING OF EARTH POINTS WITH THE SHELI TENS™ ON OSTEOPOROSIS

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The work reported in this dissertation is original and carried out by me solely, except for the acknowledged direction and assistance gratefully received from colleagues and mentors.

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Vera Marie Borgmeyer

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ABSTRACT

The purpose of this experimental study was to research the effects of electrical stimulation of the Ring of Earth acupuncture points with the SheLi TENS™ on osteoporosis. An AccuDEXA, a peripheral bone mass density test was the dependent and repeat measure in this experiment along with urine levels of a collagen cross-linked teleopeptide, a bone marker known as NTx. Serum levels of Calcitonin were also drawn on the experimental group. Calcitonin is a hormone produced by the thyroid gland and is a primary regulator of calcium in the bone. A protocol, approved by the Institutional Review Board was followed for each volunteer. Forty-five participants were selected, based on a Pre Bone Density, indicating a clinical level of osteopenia/osteoporosis and their willingness to carry out the protocol of stimulation of the acupressure points that comprise the Ring of Earth daily for six months as well as taking the necessary supplements for the modeling of new bone. Subjects were screened by the Nurse Researcher, according to the inclusion criteria and asked to sign an Informed Consent. They were then randomized into the experimental or the control group for the study. The control group took recommended supplements but received no electrical stimulation. The independent variable for this research was the Ring of Earth. The subjects in the experimental group were taught the Ring of Earth using the SheLi TENS.™ All participants brought to the initial screening visit, a recent AccuDEXA of their bone density. During the session, an intake history was done by the RN and each participant completed a Symptom Index©, a Pain Profile©, and were assessed as to risk factors of having bone fractures in the future. Vital signs, including Temperature, Pulse, Respirations and Blood Pressure were recorded. The same tests and procedures were repeated on all participants at the end of six months. At the end of the research, a mixed analysis of variance (ANOVA) using the SPSS for the scores on the Symptom Index©, Pain Profile©, standard deviation scores from the AccuDEXA and results from the cross-linked teleopeptides (NTx) was used for statistical analyses. The Ring of Earth intervention yielded a statistically significant reduction in symptoms with a $p = .020$ level. However, there were no statistically significant differences in lowering the bone density or the level of pain or normalizing urine cross-linked teleopeptides (NTx). A t-test was used for statistical analysis of the Calcitonin results. Using the stimulation of the Ring of Earth did not yield a statistical significant difference in increasing serum levels of Calcitonin in the experimental group. Additional interesting findings are presented. Implications and future research recommendations are included.

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CHAPTER 1: INTRODUCTION

Purpose of the Study

The purpose of this research was to document and measure the effects of electrical stimulation of the Ring of Earth acupressure points on osteoporosis. The specific effects measured were the level of change in bone mineral density (BMD), in total symptoms, level of pain, in Calcitonin, and in urine N-teleopeptides (NTX) before and after stimulation.

Background of Problem

Osteoporosis is a silent and debilitating disease that progresses over a lifetime. Some think that the increase in incidence of osteoporosis is due to stress and habits of life style. Osteoporosis causes thinning and porous bones with a loss of bone mass, demineralization and may precipitate a fracture. "The spine is the most common region for fracture with 33% of women 65 or older having sustained spinal vertebra fractures leading to a loss of height, kyphosis and chronic back pain."[1] Bone in the human being is a living tissue. It involves a complex balancing process of construction of new bone and reabsorption or bone removal carried out by cells called osteoclasts. It is documented that this process is influenced by many factors, including race, gender, genetics, diet, exercise, lifestyle, stress, vitamins, minerals and a host of other factors that will be covered in this dissertation.

This project grew out of a small pilot study completed early in 2002. In that study, six out of ten volunteers demonstrated a significant increase in serum Calcitonin levels after a single application of electrical stimulation with the LISS or SheLi TENS™ to thirteen specific acupressure points called the Ring of Earth.

Importance of the Study

The goal of this continued research was to identify a non-drug, energetic alternative for the treatment of osteoporosis for men and women. Activating the body to produce its own supply of Calcitonin appeared to be an ideal treatment.

Calcitonin is one of the major regulatory hormones of calcium metabolism and stimulates cartilage growth in the bones. It is produced by the thyroid gland and is responsible for maintaining the health and integrity of the human skeleton. If thyroid function were normal, one could hypothesize that stimulation of acupressure points proximal to the thyroid is a potentially viable method for increasing Calcitonin. It is also produced in many other tissues in the body. This effect would cause the body to lay down new bone and thereby increase bone density. When proven, this method would serve as a treatment for osteoporosis.

Scope of the Study

The treatment, proposed in this study necessitated approval from the Institutional Review Board (IRB) of Holos University Graduate Seminary. The Protocol, with a detailed consent form was approved on September 04, 2002. This process was necessary to ensure that the research was ethical and safe for all the participants.

The standard medical diagnostic measurement to assess bone health is bone density. In this experimental research, each subject's bone density was measured in three ways: (1) using an AccuDEXA; (2) urine collected and analyzed to assess N-teleopeptides (this is the most reliable bone marker for before and after intervention); and (3) serum Calcitonin levels. All of the above were measured before and after the intervention.

Intervention involved daily self-application of electrodes, delivering an electrical stimulation with the SheLi TENS™ to acupressure points in the vicinity of and/or associated with the thyroid. The intervention protocols called for a treatment period of six months. The population included healthy, ambulatory men and women aged 45 years or older with established osteoporosis. At the conclusion of the research, with all data collected, statistical analysis of the data (specifically a mixed analysis of variance (ANOVA) and a t-test) was performed to assess the subsequent results.

Organization

Chapter 2, the Review of Literature, will give a historical background of this innovative intervention out of the field of Energy Medicine. It will also present the rationale for the study. Chapter 3 will detail the designs and methods for the research study. Chapter 4 will outline the results and statistical findings. Chapter 5 will present a discussion of the results with implications for individuals with osteoporosis. It will also include limitations of the study as well as suggestions for possibilities and potentials for future research investigations.

Chapter 1 Endnotes:

[1] Brown, S. (1996). Better Bones, Better Body. New Canaan, CT: Keats Publishing Inc., p. 38.

CHAPTER 2: REVIEW OF LITERATURE

Overview

The human being is the focus of this study. Through time, with advances in knowledge and research, the concept of mankind has evolved from strictly a physical entity to a composite of body, mind and spirit. He/she is more than the physical. The human body is the vehicle that carries the non-physical, i.e., the mind and spirit. Both the mind (how we think) and the spirit (how we feel) impact the health and well being of the physical form embodying them. This is part of the essence of Energy Medicine.

This Review of Literature gives an overview of the science of Energy Medicine. The origins of this science can be traced in history, as far back as the Han dynasty in the practice of acupuncture and acupressure. The use of this ancient medical treatment for illness prevails to the present day. This Review also covers in detail, one disease called osteoporosis, including its pathology, ancillary factors, and the use of acupuncture as a form of 21st century medical treatment. This chapter will also discuss the pilot study that launched this investigation.

Historical View of Health and Healing

Western Medicine – Origins and Basic Concepts

The title of "Father of Medicine" is generally relegated to Hippocrates, who was born around 460 B.C. on the island of Cos. He wrote many essays, treatises and books on which many of the fundamental concepts modern medicine are founded, and was fascinated with the human anatomy and its response to surgery. To this day, the Hippocratic oath is recited by those entering the field of medicine as a pledge to maintain the highest standards of conduct and, above all, to do no harm. Hippocrates and the

Greeks debated and investigated how to chart and map the components of the body. They described and named muscles, sinews and dissected the same. Interestingly, they also believed in the power of breath, a concept that has survived into our modern times.

Eastern Medicine – Origins and Basic Concepts

In comparison, in the Han dynasty, from 25 - 220 B.C., the essential outlines of acupuncture were already in place.[1] Where was the truth or the essence of the human being? Was the truth of the body within this human structure, namely the various organs and body parts we call human as the Greeks maintained or without the body itself? The Chinese believed the life force of the human being was detected in the pulse. They also delved into the nuances, the subtleties, listening and skillfully touching the body. "The Greek and the Chinese doctors knew the body differently because they felt it differently."[2]

Modern Concepts

According to Dr. C. Norman Shealy in *The Illustrated Encyclopedia of Healing Remedies*, from those early times in Greece, only two schools of thought have prevailed in medicine: science and empirical knowledge.[3] The premise beneath each theory is a search for the truth about life. Those in the school of science primarily use the left-brain to learn and know, and to prove issues that deal with life and mystery through analytical methods. On the other hand, the empiricists base their pursuit of truth on and embrace nature, its laws, what one can know from sense experience, and belief in a life force emanating from the divine. Their orientation seems to stem more from the right brain, seeking connections, intuiting truth and looking to nature to reveal its essence. Western medicine falls into the category of science, whereas the Eastern medicine and similar

philosophies search for truth and healing in the natural, believing that the body and mind have ways to heal from within.[4]

Some of the old Greek concepts of the body have prevailed to this day. Foremost among them is the premise that the human body is a dynamic organism, composed of organs, muscles, glands, nerves and skeleton. In essence, the body is a biomechanical set of industrial processes, computers, wires, pulleys and levers. This view of the body coincides with the modern molecular-biology model, which dates back to Sir Isaac Newton and other scientists. The theory was based on physics and the important laws of the universe. The Greeks viewed the body as a biological machine. This mechanical approach to the body, is still commonly held by American physicians, and especially surgeons, engaged in conventional medicine today. In the molecular-biology model, the assumption is that if one knew all the pieces and parts of the machine, then one could fix it or build a new one (i.e. the whole must equal the sum of its parts). With current advances in stem cell research as a leading example, it is clear that this approach still resonates strongly with many 21st century western medical researchers. They prefer to cut genes from deoxyribonucleic acid (DNA) strands and insert them elsewhere.[5] Essentially, a defect in the body is detected in a gene and cut out to eliminate the illness.

Through all of history, humankind has searched for answers to life, to mystery and disease in its passion for knowledge. Rudolph Steiner attests, that as human beings, we have an insatiable need for knowledge.[6] This has been an endless pursuit for a way to preserve eternal youth. It dates back to Methuselah. This human being was said to have lived 969 years in the first age after creation.[7]

Energetic View of Health and Healing

Most energy healing practitioners believe that there is more to the human equation than parts, like organs, bones and perfectly functioning bio-molecules. To them, much of what can and does affect the human body is intangible, such as emotion, consciousness, subtle energy, the meridians and the life force of soul and spirit.

Dr. Richard Gerber, in *Vibrational Medicine for the 21st Century,* presented a new vibrational medical model of human functioning that provides a potential bridge for physicians and others to go beyond the Newtonian theory to explore the facets of the human mind and spirit in various states of health and illness. He emphasized that the "vibrational or energetic model of healing does not deny the validity of discoveries in molecular biology or bio-mechanical functions of the body's organism."[8] Instead, it is built on previous theories and used Einstein's equation of $E = mc^2$, which mathematically described how matter and energy were interrelated. Vibrational Medicine provided an expanded environment for explaining life.

Illustrating that not all Western medicine is lock-stepped in its Newtonian concepts, some Russian researchers sought "to create devices that influence cellular metabolism, by targeting the DNA through modulated radio and light frequencies."[9] By this method, they attempted to repair genetic materials by using vibration in the form of sound frequencies that essentially matched the resonant frequency of DNA. It is amazing that they have done it and have research in place to prove it scientifically.

Acupuncture and Acupressure

One of the life-energy systems that Western medicine sometimes recognizes is the acupuncture-meridian system. According to Gerber, this network "consists of a series of

conduits or channels for life energy that acupuncturists attempt to manipulate through the insertion of extremely fine needles into special points upon the skin."[10] Acupressure points are unique zones on the skin located along the specialized life energy pathways or circuits known as meridians. These meridians carry a type of life force energy called chi or Qi. According to Dr. Joe Helms, Qi is the Chinese character for energy and it is the circulation of Qi that is at the foundation of Chinese medical tradition. It is the flow of life and palpable energy of the human being giving warmth, stimulating the function and interactions of organs.[11] Acupressure points may also be stimulated electrically by means of a LISS or a SheLi TENS™. This whole acupuncture-meridian system originated with the ancient Chinese (for whom holism was a given) over 5000 years ago. Through study, they were the first to learn of, embrace the belief in, and create methods to explore the premise that the mind and the body worked as an organic whole.

Foundations of Chinese Medicine

To understand acupressure, one must first understand the philosophical concepts that gave rise to it. These are the concept of five elements and of the universal life energy, Qi.

What is the origin of chi? Actually, it has three main sources, namely genetics, nutrition, i.e. from the food we eat and then directly from the environment. The human body is a marvel in the many ways it uses the different forms of energy, e.g. in nutrition or the food and nutrients ingested, from DNA as well as the information processing from the internal as well as the external environment to maintain the general health of the organism. Food and the interplay of nutrients with water provide fuel, which through biochemical processes are converted into chemical energy. The marvelous

communication system in the body is primarily the central nervous system, which uses electrical energy to telegraph messages to the various organs and muscles of the body. This is a complex system, similar to the Morse code, using electrical signals and synapses innate to the human body, that relays information from the brain to the various parts and back again. In addition, our genes in the form of DNA contain an array of coded blueprints responsible for the construction of each human being as well as a reservoir for data storage and communication similar to the Internet service on a computer.[12] We are on the verge of a new type of medicine further exploring the vibrational frequency of cells of the body but also specifically the vibrational behavior of the DNA. It is all Qi.

Human beings are complex and have complex circuits of energy in and around their bodies. Gerber purports that these life-energy and Spiritual-energy systems are the multi-dimensions of the 21st century human being, and are the components of the field of Vibrational Medicine.[13] Conventional doctors and practitioners do not accept much of this potentially evolutionary change in the field of modern medicine. However, some do and in some circles Vibrational Medicine is also known as Energy Medicine.

The Concept of Energy and Energy Medicine

This introduces the concept of energy. Since the days of Isaac Newton in the 1600's, "energy is defined as the capacity to do work."[14] Matter, when influenced by gravitational force takes on energy. Sometimes, this was seen as a wave and some quantum physicists termed it "matter waves." Different laws govern this transfer of energy.

> "With Law # 1, the wave characteristics from substances, remain constant in proportion to their composition. Whereas, in Law #2, all substances are giving off waves of energy and these waves are characteristically similar to the elements they emanate from, and these

> waves are the attracting repelling force causing all elements to combine or repel the substance they emanate from. Finally, Law # 3 states that all elements either conduct, resist hold or transform energy." [15]

Thus, a wave or a particle can provide energy. The human body is a network of substances emanating waves, as well as a reservoir of elements conducting, sometimes resisting or holding and other times transforming energy into a new creation.

What is the field of Energy Medicine? Generally defined, it includes the many and varied traditional, complementary, alternative as well as mainstream healing practices that treat the body, mind and spirit of the individual. It includes all concepts of energy, e.g., light, touch, sound, material, the spiritual, by incorporating imaging, the electromagnetic, the vibrational and electrotherapy. "Energy Medicine is the art and science of fostering the physical, psychological and spiritual health and well being. It combines a rational knowledge and intuitive understanding of the energies in the body and the environment."[16] In this combination, we are embracing a holistic model for medicine and for life.

There are a number of pioneers in the field of Energy Medicine. Among them, since 1971, Dr. Shealy has been exploring ways of making spirituality an integral part of medical practice. He opened his first holistic clinic in La Crosse, Wisconsin, with spiritual care a part of the medical care offered to patients. Eventually, Dr. Shealy took it a step further and in 1978 with other colleagues, he founded the American Holistic Medical Association. Shortly thereafter, terms like Complementary, Quantum, Integrative and Alternative Medicine began to be used in the health care industry. Many of these concepts did not fit into the conventional and allopathic mode of medicine, which had prevailed for almost a century. Dr. Elmer Green further substantiated the term "Energy Medicine" by founding the International Society for the Study of Subtle

Energies and Energy Medicine in 1989.[17] The movement toward holism in healthcare, reached a national status in 1992, when Congress created a National Institute of Health Division of Alternative Medicine, more recently termed the Institute of Complementary and Alternative Medicine.[18]

Energy Medicine views the human body as made up of living tissue, meridians and genetic cells that generate energy and this in turn pulses electricity. The human body emanates waves of energy and because of this process; there is constant communication with its own genetic matrix, the environment as well as other higher dimensions. The inherent goal for the human being is to always seek balance or equilibrium.[19]

Recent work by Neurobiologist, Dr. Candace Pert demonstrated that neuro-peptides are the chemicals produced by emotions.[20] With this research, thoughts that trigger feelings or emotions produce neuro-peptides. Neuro-peptides are short chains of amino acids manufactured by the brain that transmit information to nerves, axons, and nerve synapses. Some are hormones.[21] Neuro-chemicals include neuro-peptides that affect moods; produce natural painkillers, natural tranquilizers, and can even affect the appetite. They allow information to pass from one circuit to another.[22] With this action, emotions become the matter or the substance of the body. In another words, the mind becomes the body. Cells are impacted not only by thoughts but also by external energy forces such as sound, weather, touch, color and the energy systems of other people as well as electromagnetic energy given off by airplanes, MRI, etc.

Dr. Caroline Myss, in her book *Anatomy of the Spirit* gives three principles in managing the energy of the human body. They are:

1. **Biography Becomes Biology.** The human body is essentially the history book carrying chapters from previous generations. The family tribe is condensed into the genetic codes and blue prints.
2. **Personal Power is necessary for health.** Our sense of power is a result of our beliefs and attitudes we carry.[23]
3. **"You alone can help yourself heal."**[24]

Edgar Cayce further confirmed that "attitude and emotions are the four square foundation of an individual's pyramid for soul growth."[25] Further, in his text, he explored attitudes and charkas as the relay points or contacts between our physical and spiritual bodies. Dr. Joseph Campbell, in the *Mythic Image,* gave us a depiction of the chakra system.[26] In the human body, there are at least seven energy centers or chakras, which are vertically aligned along the human spinal cord. Each chakra is also connected with life lessons one must master in order to gain self-knowledge and power in order to progress on the path of higher consciousness. According to Myss, each center contains a truth, which pulsates, "directing us to live according to the right use of its power."[27]

Essentially, one creates his or her own health as well as their own illness. Myss' third principle is about taking one's own power back and no longer believing or acting like a doctor or practitioner can fix or cure a malady. Physicians can and sometimes successfully eliminate symptoms, but healing happens as a person meets the challenge and recreates their life by activating their will and tapping the source within. Myss wrote another whole text on this subject entitled, *Why people don't heal and how they can.* To summarize her book, people don't heal because they are afraid; they don't want to forgive, or they don't want to take the journey of their lives.[28] In essence, they refuse to

take their own power, stay chronically ill, and eventually die. This is an ultimate example of the effects of one's negative attitudes and beliefs on health. The researcher will be aware of extremely negative individuals as subjects for this study and attempt to enroll subjects who take responsibility for their own health.

Torkom Saraydarian describes a block to the healing of oneself. He proposes that irritation is the destructive fire and is a block to healing. According to him, what happens in the human energy system is that a poison is produced as a result of irritation. This poison is called Imperil. According to his Guide, Master Morya, if one entertains irritation, then the effects of Imperil occur in all systems of the body plus the lower spiritual bodies.[29] So much of life has to do with our choices and decisions to be in harmony with our nature and structure as spiritual beings with a human body, versus opposing nature and the laws of nature.

In *Reconnecting with Nature,* Michael Cohen's underlying thesis is that so much of what is wrong with lack of health, psychological issues as well as political and societal ills stems from estrangement from our nature. And we learn this from each other. In this process of estrangement or denying nature, " we lose our natural integrity and its blessings."[30] As the spiritual beings that we are, it seems the body is the way to make our connection to the spirit world, the real source, which then brings one to their life purpose, self-realization, healing and wholeness.

A model of Energy Medicine for the 21st century promoted by Gerber is Vibrational Medicine. He bases it on "modern scientific insights into the energetic nature of the atoms and molecules making up our bodies, combined with the mystical observations of the body's unique life-energy systems that are critical but less well

understood aspects of human functioning."[31] Amazing research was done in the Ukraine in the 1970's, documenting that normal cells vibrate at a frequency between 52-78 billion cps or cycles per second, (Ukraine) known as Giga frequency. Each cell contains genes made up of DNA and Ribonucleic acid (RNA). With normal cells vibrating at a Giga frequency, the being is at full power with all circuits of the energy system emanating life or chi. Health and holism is at optimal level in the human being.

Authors such as Drs. Christine Page, Keith Hagenbach and Christiane Northrup emphasize that illness or a disease like osteoporosis is a manifestation of the body vibrating out of synch and that, at times, illness is a messenger or a wake-up call to go deeper and go inside.[32,33] Herein, lies the wisdom and the guidance for healing. Healing happens on the inside and from the inside out.

What is meant by illness as a messenger? Getting sick can serve many functions. According to Page, it can be many things, including a prime mover for transition, a voice, the soul's message noting avoidance, a provider of secondary gain, a means for punishing others, a teacher for the soul, a gift of growth and healing for others or a karmic healing. It can also be a defense mechanism triggering helplessness or an initiation to move to another dimension.[34] Yet, for the ordinary citizen and the medical doctors, the message may fall on deaf ears and closed minds and be relegated to a surgical procedure or extraction of a diseased part of the body without any heed to the energetics of the system. Many ordinary people obtain a drug from a doctor to remedy the ailment. Others may heed the message and seek out a holistic approach, using acupuncture or other natural ways to heal the root cause instead of simply treating the symptoms.

Principles of Acupuncture

Background

The acupuncture meridian system originated with the ancient Chinese. They postulated that a human being has many levels. They based their cosmology, (which forms the principle basis of acupuncture and the concept of chi) on the Five Basic Elements of Earth, Water, Fire, Air and Wood. This Five Element Theory taps into the truths held by the ancient traditions of China, India and Native American.[35] Their core premise was that the universe was made up of these basic elements, and that each human being is a microcosmic representation of this universe. For example, the element of Earth "is the nurturing mother and it is taken up in the digestion and assimilation of food. It provides substance and stability and that lends to steadiness and solidarity."[36] The earth gives human beings the solid ground of connection with the universe. Organs specifically connected to the element of earth are the bladder, spleen, stomach and intestines. According to Helms, the earth is also the source of the four other elements, i.e., Wood, Fire, Air and Water, and as such represents the center of balance among these five elements.[37] It is this element of Earth that provided the groundwork and served as an essential component of the research presented in this dissertation.

Introduction to the West

Since the early 1950's, the prevailing thought in the West was that if acupuncture worked at all, it worked as a placebo effect, mainly because the subject believed it could work. This, on an average was one third of the time. Part of the problem in accepting acupuncture was that there were no anatomical structures outlining the meridians, those live wires or energetic pathways under the skin. The acupressure points themselves were

"hundreds of little DC generators, like little dark stars sending their electricity along the meridians."[38] The Chinese discovered this internal network more than 5000 years ago, and have been exploring and exploiting it ever since, but without the scientific and engineering rigor demanded by the West.

Dr. Robert Becker discovered through his experiments with fractures and infections that "electricity was the most important growth stimulus to the human cells."[39] The bonus was that there were no side effects, and with this process he tapped into the body's ability to heal it-self. When an acupuncture patient received electrical stimulation, Dr. Becker demonstrated pictorially the electrical conductivity maps at the skin level.

Use of Acupuncture to Treat Osteoporosis

With this background of the evolving practice of medicine and the advent of Energy Medicine, the stage is set for an alternative approach to healing bones afflicted with osteoporosis. Dr. Shealy is an inventor, a scientist and a researcher in holistic medicine. He has intuited a combination of acupressure points and named them rings or circuits of energy pathways along the meridians using the five basic elements of Earth, Fire, Air, Water and Crystal. Over the last ten years, he has investigated these rings or circuits of chi and published research results demonstrating the effects of electrical stimulation upon neuro-chemicals and different hormones of the human body.[40] [41] [42]

Pilot Study

With each new step of discovery, a new question emerges. Recently, in a research endeavor, Dr. Shealy and I had subjects use a LISS unit or a SheLi TENS™ (two pieces of equipment that provide a form of trans-cutaneous electrical stimulation-

see description on the following page), on the Ring of Earth acupressure points (see Figure 2, page 20, and Figure 3, page 21) and then measured serum Beta-endorphins, which are our feel good hormones. There was minimal effect. However, later in a mini pilot study, ten individuals used the same units, five with the LISS and five with the SheLi TENS™ and the hormone Calcitonin was measured Pre and Post intervention. The six subjects, who had a measurable level of Calcitonin prior to the intervention, had a significant elevation, as high as 80% in their serum Calcitonin level. This result was measured after a single application of electrical stimulation to the thirteen acupressure points called the Ring of Earth.

LISS TENS

The LISS TENS unit was developed by Saul Liss and first used at the Shealy Institute in Springfield, MO by Dr. Norman Shealy in 1975. It emits one to four milliamps of current with 15,000 pulses per second modulated 15 times and 500 times per second. It has been used in well over 20,000 patients with no complications. This is depicted in Figure 1 (a), page 19. Instructions for the use of this device are found in APPENDIX A, page 88.

SheLi TENS

The SheLi TENS is a modification of the original old Electreat, which sparked the idea in the mid 1960's for the modern TENS. It is the first modern TENS that has the wide range of frequencies of its antique predecessor and it is the only TENS other than the LISS that we have found capable of activating acupuncture points neurochemically. This is depicted in Figure 1 (b), page 19. Instructions for the use of this device are found in APPENDIX A, page 88.

(a) (b)

Figure 1. TENS Devices.

Ring of Earth Points	
K1	In the depression at the junction of anterior and middle third of the sole in a depression between the 2nd and 3rd metatarso-phalangeal joint when the toes are plantar flexed.
B54	Exact midpoint of the popliteal transverse crease.
B60	Between the posterior border of the external malleolus and the medial aspect of tendo calcaneus, at the same level as the tip of the malleolus.
LI16	In the depression between the clavico-acromal extremity and the spine of the scapulae.
ST9	Posterior to the common carotid artery on the anterior border of the M. sternocleidomastoid, lateral to the thyroid cartilage.
SI17	Posterior to the angle of the jaw on the anterior border of M. sternocleidomastoid.
GV20	7 cun* above the posterior hairline, midway on a line connecting apex of both ears.
Notes: 1. *1cun=distance between the two creases marking the joints of the distal and middle phalanges of the middle finger.	

Table 1. "Ring of Earth" Acupressure Points.

K1 - In the depression at the junction of anterior and middle third of the sole in a depression between the 2nd and 3rd metatarso-phalangeal joint when the toes are plantar flexed.

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B60 - Between the posterior border of the external malleolus and the medial aspect of tendo calcaneus, at the same level as the tip of the malleolus.

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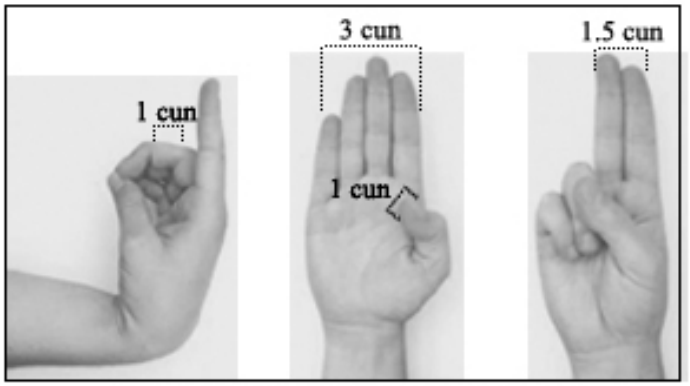
*1 cun = distance between the two creases marking the joints of the distal and middle phlanges of the middle finger.



The cun is a Chinese unit of measurement.

Figure 2. Ring of Earth – Details of Acupressure Points.

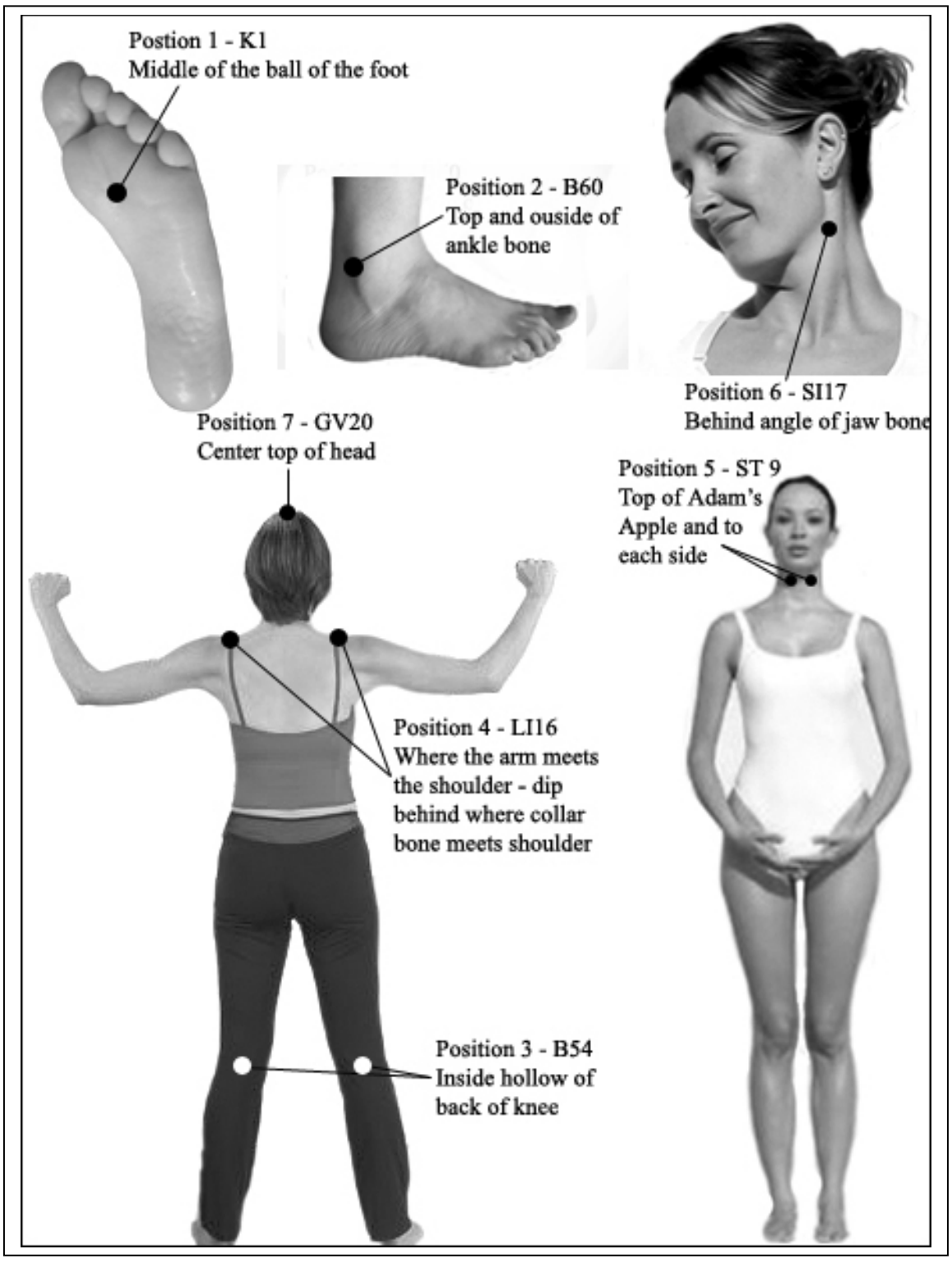


Figure 3. Ring of Earth Points - All Positions.

The Role of Calcitonin

The writer's forthcoming research question is what effect will stimulating the Ring of Earth with the SheLi TENS™ have upon a disease process, such as Osteoporosis, in which Calcitonin is the primary hormone. In order to answer this, we first need to understand what Calcitonin is and what are its functions in the human body.

Calcitonin is a 32 amino acid polypeptide hormone, originating primarily from the C-cells of the thyroid glands and other tissue sources in humans[43] and discovered by Dr. David Copp and his colleagues in 1961.[44] The other tissue sources of Calcitonin, according to Silverman, include the pituitary and neuro-endocrine cells.[45] According to Dr. Leonard Wisneski, Calcitonin is one of the major regulatory hormones of calcium metabolism and it is available for therapy as human Calcitonin, synthetic salmon Calcitonin, natural porcine Calcitonin and both natural and analog eel Calcitonin.[46] According to his data, salmon and eel Calcitonin are the most potent forms. In this study, we will deal primarily with the human Calcitonin produced within the human body.

One author described Calcitonin as "regulating the tone" of calcium in body fluids.[47] From its name, cal can be short for calcium and tonin, a likely term for tone. Calcitonin is secreted in response to high blood calcium levels. Essentially, according to Dr. Susan Brown, Calcitonin moves calcium from the blood back into the bones and it does this by "stimulating the kidneys to increase their absorption of calcium and phosphorus from the blood and then stimulates the bones to increase mineralization."[48] The parathyroid glands, which produce parathormone, take calcium from the bone and move it back into the blood. Calcitonin's main job is to preserve bone and part of its role, is to counterbalance the work of the parathyroid glands. Its direct osteoclastic action was

confirmed in the early 1980's.[49] In Shealy's Ring of Earth, the acupressure points, as seen on (page 19-20), are Kidney 1, Bladder 54, Bladder 60, Large Intestine 16 and Small Intestine 17. In addition, the acupressure points called Stomach 9, are lateral or to the topside of the thyroid gland. And as presented in this research, the subjects stimulated these pairs of points with a Giga frequency using the SheLi TENS™ three minutes daily. This was significant. The subjects applied electrical stimulation to these points in the form of high frequency radio waves in the giga-hertz range. This range was calculated between 52 and 78 billionth cycles per second and is the identical range of the vibrational frequency of normal cells. The performance of the SheLi TENS™ and its ability to put out a Giga frequency was confirmed by testing with an oscilloscope by the Principal Investigator before each unit was used in the research. The Ring of Earth points are right in synch with the functions of Calcitonin and the sites where Calcitonin is produced in the human body.

Related Hormone Physiology

Many systemic hormones interplay in the very complex and complicated process of bone making and bone remodeling. The process is ongoing and dynamic and involves untold cellular functions with some directed toward the resorption or removal of old bone and others involved with the creating of new bone. We have already seen some of the interplay between Calcitonin and the parathyroid glands. In addition, Brown outlines that thyroxin is also critical in the metabolic effects of Calcitonin from the thyroid, as is "insulin from the pancreas, growth hormone from the pituitary and Vitamin D as synthesized and activated by the kidney as well as glucocortical adrenal hormones and the sex hormones of estrogen and androgen."[50] The roles of each of these hormones are

multi-faceted. Wisneski further confirms the many extensive interactions in the effects of Calcitonin.[51] As an added note regarding the points of the Ring of Earth, another very significant point is GV or Governing Vessel 20. This point is located on the top of the head, up from both ears and back from the nose and right over the pineal gland, which ultimately influences the pituitary gland. It is often referred to as the Master Gland of the body. This point is electrically stimulated constantly while doing the six pairs of points that make up the Ring of Earth.

Of course, in addition to the interplay of various hormones with Calcitonin, magnesium is also critical. It is known to stimulate the thyroid's production of Calcitonin, the bone-preserving hormone. Sixty per cent of our total body magnesium is found in the bone. "Magnesium is a critical component of over 350 enzymes so that its deficiency may manifest in virtually any organ system."[52] It neutralizes toxins, acids and alkalinizes body fluids. Deficiency of this alkaline mineral may cause kidney disorders, headaches, nervousness, insomnia, tooth decay, osteoporosis, heart problems, hardening of the liver, stiffened joints, constipation, mental disturbances, gastric acidity, arthritis and neuritis.[53] Muscles, nerve centers, blood vessels, lung and the brain all require magnesium for proper functioning. In individuals with osteoporosis, most humans are more concerned with getting enough calcium, but rarely worry about enough magnesium.

Calcitonin as a Treatment

Shortly after discovering Calcitonin's ability to lower serum concentrations of Calcium, associated with inhibiting osteoclast activity, physicians became aware of its potential for treating osteoporosis.[54] By the mid 1970's, research moved from animal to human studies and the investigations were multiplied to produce and give Calcitonin for

osteoporosis. As a result, by the end of the decade, with industry-sponsored studies completed, application for an injectable Calcitonin by the name of Calcimar for treatment of postmenopausal osteoporosis was submitted to the FDA. Much debate followed. Calcimar was first disapproved; then it was approved in 1984, contingent on a four-year study.[55] This study proved to be a failure due to non-compliance with daily injections, etc. During this time, investigators did not have DEXA or the dual photon x-ray absorptiometry for measuring bone mineral density. Simple x-rays were used. However, 30% of the bone had to be affected before it would show up on the x-ray.

Other studies documenting the effects of injectable Calcitonin found that it increased lumbar spine bone mass in late postmenopausal women.[56] Side effects included nausea, vomiting, local reactions and flushing of face and hands. There was also the inconvenience of the injection. Clinically, the untoward effects were mild and related to the dosage of injection. Individuals, who are allergic to Calcitonin, usually have a severe anaphylactic reaction, which may result in death. Giving the injection is sometimes inconvenient, but the benefits of injectable Calcitonin usually outweigh the inconvenience.

There is one oral preparation of Calcitonin, called sCT available and has the potential to be a safe and long-term treatment for Osteoporosis.[57] A nasal spray of Salmon Calcitonin, called Miacalcin has been available since 1995 in the United States. At least eight published studies have reported its effectiveness in increasing bone mass density (BMD) especially in the spine and trabecular bone.[58] The recommended dose for Miacalcin is 200 I U, in alternating nostrils. The bioavailability of nasal Calcitonin is about 25% or less of the given dose, compared with an intra-muscular or subcutaneous

injection, which is 70% bio-available. The nasal spray Miacalcin continued to be studied. In fact, a large, double blind research project called the PROOF Study, over a five year period, researched the effects of different dosages of 100 IU, 200 IU and 400 IU of Miacalcin nasal spray used daily and its effects on the incidence of vertebral fractures. The data was disappointing, but the results did show that Miacalcin 400 IU was the only dose to significantly increase spinal bone density.[59] None of the dosages were reported to significantly decrease the risk of new fractures. However, in the study, there was a 59% discontinuation rate, which was higher than expected. Bone mineral density and fracture risk trends did not correlate in this study.[60]

During this same year, the 40th anniversary of the discovery of Calcitonin, Silverman suggested it was time for all interested parties to reassess the drug's role in the treatment of osteoporosis. In addition to the effects previously described, injectable Calcitonin also has a wide variety of laudable physiological effects. These include use as an analgesic, especially in Paget's disease and cancer of the bone. Six double-blind studies have confirmed the efficacy of this usage.[61]

What evidence exists that the human body's own Calcitonin can be affected by electrical stimulation of the Ring of Earth? Other uses are given in our article, documenting the initial pilot study completed by Dr. Shealy and myself.[62] Briefly, with this study, I recruited 10 people, six women and four men and did a fasting blood draw for Calcitonin. Then, I did one application of electrical stimulation, using the SheLi TENS™ to the Ring of Earth points for five minutes to each pair. Governing Vessel 20 was stimulated continuously during this time. I waited thirty minutes and then did a post

serum draw for Calcitonin. No further intervention was done. You can view the actual results from the article in Table 2 below.

In summary, it showed six individuals, who initially had a measurable level of Calcitonin, having a significant increase in their levels with a single application of electrical stimulation to the ROE. Interestingly, the other four were all postmenopausal women; none of them had a measurable level of Calcitonin as evidenced in the pre draw. Essentially, they stayed the same with still no measurable level after the intervention.

Calcitonin (pg/ml)					
Subject #	**Sex**	**Age**	**Before**	**After**	**Stimulator Used**
1	F	35	3	5.4	LISS
2 [1]	F	56	6.0	8.0	Shealy
3 [2]	F	42	<1	<1	LISS
4 [2]	F	42	<1	<1	LISS
5 [2]	F	72	<1	<1	Shealy
6 [2]	F	53	<1	<1	LISS
7	M	69	3.2	4.5	Shealy
8	M	62	2.7	4.1	Shealy
9	M	26	5.1	7.1	Shealy
10	M	45	8.1	12.1	Shealy

Notes:
1. This subject also used the LISS for stimulation and had her Calcitonin level increase from 6.6 to 7.1 pg/ml.
2. The four women with unmeasurable Calcitonin levels are all post-menopausal.
3. On those who had measurable Calcitonin, levels increased from 30-80%.

Table 2. Results from Pilot Study.

In research trials, for the treatment of post-menopausal osteoporosis, Miacalcin has been compared to a class of drugs called Bisphosphonates that include Fosamax and Actonel. "All three have been shown to increase bone mineral density (BMD) in the spine with Fosamax and Actonel producing a significant increase in hip bone density. However, Miacalcin demonstrated an ability to reduce vertebral fracture rates as well as being beneficial in reducing bone pain."[63]

According to authors Eric Colman, Randy Hedin, Joslyn Swann and David Orloff, an estimated 4 million prescriptions were written in 2001 for Mircalcin, in the U.S., which says it is a widely used drug by American physicians.[64] With its favorable minimal side effect profile and its demonstrated effect on BMD, it may be time to reassess and increase its use for the treatment of patients with osteoporosis.

Osteoporosis

Medical Description

According to Dr. John Lee, osteoporosis " … is a multi-factorial skeletal disorder of progressive bone mass loss, with demineralization and fracture proclivity, which accelerates with menopause."[65] It predominantly affects white post-menopausal women. Osteoporotic bones have lost Calcium and bone proteins, are porous and fragile and easily break or fracture. The bone loss that precedes a fracture is a silent process and may go undetected until the bone actually breaks. According to Dr. S. Brown, "the spine is the most common region of fracture, with one third of women 65 years or older having sustained spinal vertebra (back) fractures leading to loss of height, kyphosis (or humpback) and chronic pain."[66]

Another way of defining osteoporosis is an imbalance between bone formation and bone resorption or removal. It is as if the skeleton or bone structure of the human body starts to deteriorate so that bone resorption dominates and the formation of new bone cells called osteoblasts is interrupted. This results in weakened bone. The structure and foundation of the body starts to weaken from the inside out. Imbalance prevails!

Extent and Cost of the Condition

What is the extent of osteoporosis in the United States? The National Osteoporosis Foundation has published that there are 34 million Americans, who have osteoporosis or a low bone mass density (BMD). In this statistic, four out of five of those Americans are women. "The annual cost of osteoporosis treatment in the U.S. is estimated to be $14 billion per year. The high cost is related to fractures of the hip, spine and wrist."[67] Many times there are complications due to the surgical intervention and subsequent immobility necessary to allow the fracture to mend and heal. Individuals, who previously led independent lives, living alone, now require acute or supervised and assisted living situations. This is another factor in escalating costs related to osteoporosis.

Relevance of Estrogen

It is obvious, from the above statistic, that the population most affected by osteoporosis is women and more specifically older women after menopause. "Half of all postmenopausal women and 15% of white men older than 50 years will have an osteoporosis-related fracture in their lifetime, with 15% of those occurring in the hip."[68] Menopause can occur naturally or be surgically induced with removal of the ovaries and/or uterus. Because osteoporosis occurs more frequently in women after menopause, a number of authors propose that osteoporosis is therefore due to estrogen deficiency. It *is* a factor. On the other hand, other experts, specifically, Lee, Brown and Shealy propose that because levels of progesterone decline with menopause, it may also be necessary to supplement with a source of natural progesterone as well as natural estrogen.

Osteoporosis is certainly connected and impacted by a decline in both estrogen and progesterone.

Other factors

Osteoporosis is a multi-factorial disease. There is not just one deficiency. A lack of absorbable Calcium has been investigated extensively and a conclusion reached that a certain amount of calcium citrate plus vitamin D and other nutrients, especially absorbable Magnesium are essential for the body to make new bone. Exposure to natural light everyday is a factor in off setting Osteoporosis. The amount of gastric juices containing hydrochloric acid (HCl) produced in the stomach starts to decline as one ages and this affects absorption of calcium.

Dr. Steven Cummings, et al, at the University of California identified dozens of factors that critically affect bone loss among the elderly, and specifically among women.[69] In their research, they assessed bone mass and other potential risk factors in 9516 Caucasian women over 65 who had no previous hip fracture over a four-year period. In their follow-up, there were 192 women who had a first hip fracture. None of these fractures were due to a car accident. When a hip fracture occurred during the time of the study, the fractures were validated by x-ray. With their multivariate analysis, Cummings' team identified sixteen independent risk factors for a hip fracture besides bone mineral density. Individuals who have three or more of these risk factors have a sound prediction of a hip fracture in their lifetime. These risk factors include:

- Current use of anti-convulsant drugs.
- The inability to rise from a chair without using one's arms.
- A history of maternal hip fracture (especially if the mother fractured a hip before age 80.)
- Previous hyperthyroidism.
- Current use of long-acting tranquilizers and mood-altering drugs.

- A resting pulse of 80 beats or more per minute.
- Poor overall self-rated health.
- Tendency to stand on feet less than four hours a day.
- Advancing age.
- Any fracture since age 50.
- Weighing less than you did at age 25.
- Current caffeine intake.
- Poor distant depth perception.
- Low–frequency contrast sensitivity (impaired vision).
- Being taller at age 25.
- Lack of exercise, as in not walking for exercise.
- Low bone density.
  - A full 16 of these risk factors were independent of bone density, i.e. the existence of any of these risk factors in themselves, significantly increased a woman's risk of hip fracture, regardless of the woman's bone density.
  - Other less significant risk factors identified in this study included:
- Current smoking (versus never having smoked)
- Current thyroid medication.
- Having fallen in previous year versus no falls.
- Poor neuromuscular function as in gait speed and coordination.
- Low body weight.
- Poor functional-status score with low functioning in general.[70]

Clearly, osteoporosis is not simply a deficiency in Calcium or reduced estrogen and progesterone. Bone formation is a complex process and with the listing of the risk factors is impacted by genetics, any organ or endocrine dysfunction, daily exposure to sunlight, dietary and mal-absorption issues, physical exercise, and the intake of nutrients and/or drugs.

Osteoporosis and Men

While osteoporosis is more researched in women, it does occur in men, with the incidence of fracture usually occurring ten years later than it occurs in women.[71] Famous men in history afflicted with osteoporosis include Benjamin Franklin, Winston Churchill and Pope John Paul II. Also, men who choose to use alcohol, smoke, avoid exercise and

refrain from taking the essential nutrients for a balanced structural system increase their risks for osteoporosis.

In comparison, men do not live as long as women. While, they do not have the hormonal change of menopause, they do have testosterone levels diminishing as they age. "Research documents a correlation between bone fragility and age-related hypogonadism"[72] according to Kathleen Geier. The National Osteoporosis Foundation sponsored a Gallop poll in 1996, surveying 1000 men in the U.S., and found that most men think osteoporosis is a woman's disease and generally do not know how to prevent or treat it or that it is linked to heredity and other factors.

Screening for Osteoporosis

In the U.S., screening for osteoporosis during annual physical examination is becoming more common in the 21st century, especially for women. The measurement routinely recommended at age 50 and over is a bone mass density (BMD). It is virtually a painless procedure, but is a bit costly. Various ways to measure BMD are available, including measuring bone density by means of various types of bone scans and performing an actual biopsy. The scans are like advanced x-rays that detect small changes in the bone mass. Whereas in earlier times, 30% of bone mineral had to be gone before bone loss could be seen using a "standard" x-ray, new scans can discriminate small changes in bone density. They are safe, painless, non-invasive and reimbursed by Medicare every two years and with other insurance carriers covered at least partially. Cost of the DEXA bone scan is about $250.00.

There are peripheral machines that measure the bone density in the finger, wrist, heel and the shin. One of these is called the AccuDEXA and has been approved by the

FDA. The bone mineral density is expressed as a t-score and is compared to two standards or norms, known as "age matched" and "young normal." The "age-matched" reading, called the "Z score," compares BMD to someone in the tested person's age, sex and size category. The "young normal" reading, called a "T score," compares measured bone density to the optimal peak density of a healthy young adult of the same sex.[73] The cost of the AccuDEXA is about $25.00 (see APPENDIX E, page 111). Risk, while undergoing this scan, includes exposing the individual to a small amount of radiation. This is the same amount one's body absorbs when taking a cross-country airplane flight. Once an individual has this information, they can discuss with their health practitioner the implications of the results, in light of their medical history and an assessment of the former risk factors identified by Cummings.

Prevention and Treatment

Calcium Supplement

Osteoporosis is a preventable disease. Multiple studies are available documenting the effect of nutrients, trace minerals, exercise and diet. Various combinations of Calcium with or without fortification of vitamin D decreased spinal fractures in osteoporotic women with an average age of 63.[74] Calcium is a most important and vital alkaline mineral. It is a factor in blood clotting and is primary for the growth and contractions of muscle all throughout the human body. Calcium helps to regulate the heartbeat, helps to transmit nerve impulses, helps to lower blood pressure and is critical for preventing bone loss in osteoporosis. This mineral aids in maintaining the permeability of cell membranes, thereby facilitating the protein structuring of DNA and RNA, which keeps the neuromuscular system functioning normally and the skin being

healthy.[75] This mineral works in conjunctions with other minerals and vitamins to accomplish the above functions. Calcium as a mineral does not work alone. A further study at the University of California, San Francisco, found that post-menopausal women could increase BMD with ingestion of four nutrient supplements, namely, Calcium 1000mg, Zinc 15 mg, Manganese 5 mg and Copper 2.5 mg daily. With these four supplements and three of them trace minerals, women gained 1.48% of bone density. Women taking no supplements lost over 3% bone mass within the same two-year period.[76]

Bone making in the human body is a dynamic process and is always seeking balance. The type of calcium ingested is also critical, as all forms are not equally absorbed. For example, calcium linked to the citrate molecule is assimilated and more bio-available to the cells versus calcium carbonate. With this combination, "it also plays a protective role against the formation of kidney stones and does not appear to interfere with iron absorption."[77] Also, calcium supplements should always be balanced with Magnesium in a 2:1 ratio, with 2 parts Calcium to 1 part Magnesium. They work in tandem together in the many biochemical processes.

Other Measures

Another measure of prevention includes the daily diet, as the food and drink one chooses for nourishment. If one has any of the published risk factors, it is recommended that one adjust and include in the daily diet, whole (real) foods, such as vegetables, fresh fruit, beans, fish, seeds, grains and some meat. A wide variety of foods are recommended. Find ways to reduce anti-nutrients e.g. sugar, coffee, sodas, alcohol and the use of any drugs. What an impact it would be for the youth and children of our

nation, if soda pop machines were removed form schools, cafeterias and colleges and replaced with real fruit, water and vegetable juices. Actually, in recent news, access to soda machines is being limited to after school hours in parts of Greene County in Springfield, Missouri.

The other area of prevention is physical exercise. For example, walking three times a week can have measurable effects on the process of bone rebuilding. This is documented by Miriam Nelson et. al.,[78] in a one year walking program with postmenopausal women and measuring the effects on bone. With weight-bearing exercises, such as walking, dancing, jogging, climbing stairs as well as using measures to manage daily stress, one keeps the human energetic systems in equilibrium. These include external stresses in the form of environment, work, relationships as well as emotional, physical and spiritual factors that impact our daily living. Minimize, simplify and prioritize in order to walk in balance on the earth.

Many treatments prevail for those men and women unable to offset or prevent the process of osteoporosis. Most of these are used in conventional medicine and range from hormone replacement therapy (HRT), Calcitonin, and Parathyroid hormone to drugs such as Alendronate (Fosamax), Raloxifene (Evista), Forteo, Risedronate and Etidronate.

Juliet Compston and Nelson Watts published a table demonstrating the effects of combination therapy, primarily hormone therapy with a variety of the drugs aforementioned on bone mass density from multiple research trials (see Table 2, page 35).[79] Studies do indicate that using combination therapy for those who prefer drugs, results in greater bone mass density than mono-therapy and possibly increases effects on

bone turnover. However, none of these have sufficient power to establish whether combination therapy has greater anti-fracture efficacy.[80]

Effect of combination therapy, on bone mineral density in randomized studies[81]					
Study	**# Patients**	**Treatment**	**Duration**	**Spine**	**Femoral Neck**
Wimalawansa (1955)	58	HRT	4 years	6.8	4.0
		Etidronate		6.8	1.2
		HRT + Etidronate		10.9	7.3
		Calcium		-3.8	-5.0
		Control		-8.6	-7.8
Wimalawansa (1998)	72	HRT	4 year	7.0	4.8
		Etidronate		7.3	0.9
		HRT + Etidronate		10.4	7.0
		Calcium + vitamin D		-2.5	-4.4
Lindsay et al. (1999)	428	HRT + Alendronate	1 year	3.6	2.7
		HRT + placebo		1.0	0.5
Bone et al. (2000)	425	Alendronate	2 years	6.0	2.9
		CEE		6.0	2.6
		CEE + Alendronate		8.3	4.2
		Control		-0.6	-0.6
Harris et al. (1999)	261	HRT	1 year	4.6	1.8
		HRT + Risedronate		5.2	2.6
Johnell et al. (1999)	330	Alendronate	1 year	4.3	2.7
		Raloxifene		2.1	1.7
		Alendronate + Raloxifene		5.3	3.7
		Placebo		0.06	0.31
				NS	No data
Meschcia et al. (1993)	95	Eel Calcitonin	2 years	NS	No data
		HRT		4.2	
		Eel Calcitonin + HRT		9.2	
		Control		-7.2	
Watts et al. (1995	66	Oestrogen	2 years	NS	NS
		Oestrogen + methyltestosterone		3.4	NS
Cosman et al. (2001)	52	HRT	3 years	NS	NS
		HRT + PTH		13.4	4.4[1]

Notes: 1. Total hip. BMD, bone mineral density: HRT, hormone replacement therapy: CEE, conjugated equine oestrogens: PTH, parathyroid hormone. NS, no significant change (numerical value not provided)

Table 2. Effects of Combination Therapy on Osteoporosis.

The landmark Framingham Study did show that women receiving estrogen therapy such as Premarin had greater BMD, than those not receiving the same estrogen drugs after seven years of treatment.[82] However, more recently, the news from our

national media has disseminated the latest detrimental side effects of HRT as causing a significant increase in breast and uterine cancer.[83] [84]

Conclusions

In this new age of Energy Medicine, why not combine the best of our rational knowledge regarding an alternative method of treating and reversing osteoporosis and match that with heightened intuition, by using electrical stimulation of a circuit of acupuncture points to tap the healing energies of one's own body? This alternative method would propose increasing the body's level of Calcitonin by using the SheLi TENS™ for the electrical stimulation, which delivers between 52-78 billion cycles per second to the cells (Giga frequency) and thereby effecting a change in the bone mass density.

This investigation is a further development of the research previously mentioned done by Shealy and Borgmeyer and received IRB approval. A complete copy of the protocol is attached as Appendix D. In this research study, participants took all the nutrients necessary to build bone. An assessment of their diet, exercise habits, lifestyle, and symptoms as well as a current BMD was completed before beginning the protocol. A modified assessment of risk factors for the prediction of future bone fractures was also part of the initial interview. In the experimental group, a serum level of Calcitonin was drawn and a urine specimen obtained to measure N-teleopeptide (NTX), a bone marker, prior to beginning stimulation of the Ring of Earth. After the six-month intervention period, all of the above procedures were repeated in a post visit with the individual. My hope is for a decrease in their physical symptoms, improved pain control, bone mass density increased on their AccuDEXA, effecting a reversal of the osteoporotic processes,

urine NTX markers decreased and Caclitonin levels increased. It is the quest of this researcher to find an alternative method to increase Calcitonin in the body and at the same time, affect the bone diminishing effects of osteoporosis in all people, especially women.

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CHAPTER 3: RESEARCH METHODS

This chapter discusses the experimental methodology and procedures used in the research study. It captures the researcher's role in these activities, the protocol, and selection of subjects with demographics, data collection and transfer. Finally, the researcher gives statistical tests and measurements used to analyze all the data that was collected in the study.

Study Design

Protocol

An experimental design was constructed to implement the activities and procedures for this research on osteoporosis. It detailed the precise treatment process and the sequence of interventions. The purpose of this review process was to insure that the research was carried out in accordance with established ethical and moral practices. This protocol was submitted to the IRB of Holos University, and approved on September 2, 2002. The original protocol and update reports are included in APPENDIX D, page 95.

The independent variable, for this research was the use, by the intervention group of electrical stimulation with the SheLi TENS™ on the Ring of Earth acupressure points.

A control group was used to mitigate the effects of extraneous or "unplanned for" variables. Each subject was asked to pick a white piece of paper from a container as a method of randomization into two groups. The result was that each subject randomly fell into either the intervention group or the control group. All entries were typed with either "control group" or "SheLi TENS™."

Description of the Testing Environment

The testing environment for the experimental group was not a controlled variable, as subjects carried out the intervention in their own homes each day. The RN researcher suggested that when they got ready to do the Ring of Earth stimulation each day, that they would do it in a quiet relaxed atmosphere and to use a timer. The other caution given was not to do the intervention too late in the day, as it could interfere with their ability to have a good night sleep.

The Researcher's Role

The Researcher's role, in the beginning of the study was to establish the experimental protocols, recruit and screen all subjects initially by telephone and once eligible, carry out the screening visit to collect data for the research. The latter involved intake of their medical-surgical history, medications and nutritional supplements, witnessing consent forms, monitoring subjects completion of Pain Profile©, found in Appendix I, page 116, a Symptom Index© located in Appendix M, page 121 and a risk assessment for osteoporosis, found in Appendix H, page 114. Vital signs along with height and weight were recorded on each participant's research record. The RN researcher drew blood for Calcitonin and instructed subjects in giving urine specimens for the NTx bone marker.

The Researcher conducted the intermittent telephone calls and did the final follow-up visit on all participants who completed the research protocol. During the study, the Researcher also filed reports every three months to the PI and the IRB. These are found in APPENDIX D, page 95. It was also her responsibility to notify the PI of any untoward reactions reported by the participants in a timely fashion and carried out the

directives and orders of the PI. Essentially, the researcher carried out all activities pertinent to running this research project.

Finally, the researcher also shipped specimens to Penn State University according to their standard procedures once all data was collected. She also secured AccuDEXA reports from the local physician's office on a periodic basis. All records pertinent to each research subject were filed carefully, in alphabetical order for easy access, and at all times confidentiality of records were strictly maintained.

Test Subjects

Recruiting

The recruitment of volunteers to participate in the research was accomplished in various ways. Flyers were posted in various senior centers, Health Food stores, pharmacies and letters sent to several Unity churches. Advertisements were placed in a local newspaper for several months, and radio spots on National Public Radio and Dr. Shealy's local radio show also took place. All methods of recruitment clearly spelled out the specifications of the research as well as the requirements necessary to become a volunteer.

Inclusion Criteria

To be included in this study, subjects must have had or demonstrated the following:

- A recent Bone Density Test with a diagnosis of osteopenia or osteoporosis.
- Shown a willingness to participate in the study by signing a voluntary informed consent form (see APPENDIX B).
- Shown ability and stated willingness to follow the directions of the Principal Investigator (PI) and the research staff.
- Be in reasonable good health.

The subjects could also take natural progesterone cream during the experimental period, as long as they have been using it for at least three months.

Not included in the study were any volunteers with pacemakers or any implanted electrical device, those who had had a Thyroidectomy, those who were taking Calcitonin spray or injections, those taking Fosamax or any osteoporosis drug, steroids, Ipriflavone, Vitamin K, blood pressure or cardiovascular drugs (including channel blockers and synthetic hormones), and those who were smokers.

Initial Screening and Testing

Subjects accepted in the study were also informed that they could be dropped from the study at any time upon request or at the discretion of the PI (for example, if the PI became aware of adverse reactions occurring during the study).

Potential subjects were initially screened by telephone to determine eligibility for the study. If they were deemed appropriate, they were then scheduled for an AccuDEXA, a peripheral form of x-ray screening to ascertain bone density. This was conducted at a family practice office in Springfield, Missouri. The middle phalanx of the middle finger of the non-dominant hand was used for this procedure. Different personnel working in the family practice office took this x-ray. The researcher paid the cost of the Pre- and Post-intervention AccuDEXA tests. The routine cost for this procedure was $25.00, but the PI was able to negotiate a lower price with the doctor's office ($10 per AccuDEXA). A sample of this report is found in APPENDIX E, page 111.

The results for the AccuDEXA reported the bone density in two ways. The T score and the Z score were reported and compared to the standard deviation as defined by the World Health Organization. Each subject's report listed his or her bone mass density

values. For this research, the t-score was used for comparison with score relative to Young Healthy Normal individuals. A range of 1 – 2.5 standard deviations below the mean is an indication of osteopenia, while BMD values lower than 2.5 standard deviations below the mean are defined to have osteoporosis. This score, based on World Health Organization protocols, ensured that the results would meet standards for validity and reliability.

Once osteopenia/osteoporosis was confirmed, a more comprehensive intake was conducted with each subject. Individuals were advised that this could take up to 2.5 hours. During this appointment, the protocol was explained and intake of their medical-surgical and nutritional history was documented. Vital signs (temperature, pulse, respirations and blood pressure) as well as allergies, height and weight were recorded. Each eligible volunteer was asked to read and sign an Informed Consent form to participate in the research (see APPENDIX B, page 89). Inclusion requirements were carefully documented for each participant and made available for the Principal Investigator (PI) to review for accuracy.

Each participant then completed a Symptom Index© and a Pain Analog Scale©. The Symptom Index© was a list of 144 symptoms plus 6 if a man and plus 12 if a woman, adapted from the Cornell Medical Index by Dr. Shealy in 1999 and was used with his permission. Participants were advised to list symptoms current within the last ten days. An Ideal score was 0 symptoms. The PI also developed the Pain Profile© in 1986 and this was used in this research with his permission. The Pain Profile© was a rating scale that allowed the person to rate intensity or severity of pain on a scale from 0 to 100 with the latter score being excruciating and intolerable. The optimal goal was 0

for pain. Data from these two tests were compared to those completed during the post-intervention follow-up visit to determine the degree and scope of any potential reduction in pain and symptoms. Both of these tools have been widely used and published, and therefore provide a high degree of reliability and validity. A copy of these tools can be found in APPENDIX M, page 121 (Symptom Index) and APPENDIX I, page 116 (Pain Profile).

A tool, to identify risk factors for developing bone fractures in the future was given to each subject, as part of the initial assessment. This included the subject's schedule of exercise; nutritional habits, (e.g., consumption of dairy, alcohol, coffee, and sodas), as well as past and present fractures and family history of osteoporosis. For this appointment, subjects brought all medications and nutritional supplements they were currently taking and all information was carefully documented by the intake R.N. researcher. A list of nutritional supplements and dosages required for the making of new bone was discussed and given to the subject. Notations were made of nutrients that they were already taking. Once this data was gathered and documented, an explanation of experimental versus the control group was given. Subjects were randomly assigned to either the experimental group or the control group. Once those randomized into the control group had completed their six months participation, they were given an opportunity to crossover into the experimental group. Their demographics were compiled to allow comparison within and between the groups in terms of race, age and gender.

Test Subject Demographics

The participants for this research ranged in age from forty-two to eighty-eight years' young. Forty-four out of the forty-five participants or 97% were female. The researcher did not discriminate in seeking applicants, but throughout all the screenings only one male came forward who was eligible and agreed to participate. In further age and history analysis, 88% of the women were menopausal. All participants were Caucasian. Age and sex groupings for each of the groups are listed in Table 3, page 48.

Age Groups	**Intervention**	**Control**	**Total**
40-49	2	1	3
50-59	8	1	9
60-69	11	8	19
70-79	8	3	11
80-89	1	2	3
Totals:	**30**	**15**	**45**
Sex	**Intervention**	**Control**	**Total**
Female	29	15	44
Male	1	0	1
Totals:	**30**	**15**	**45**

Table 3. Test Subject Demographics.

Experimental Protocols – Intervention Subjects

In addition to the AccuDEXA for bone mineral density (BMD), a urine specimen was obtained on all subjects to ascertain NTx, a bone marker. All specimens were frozen and sent in batches to the Core Endocrine Laboratory at Penn State University for analysis. For volunteers randomized into the intervention group, blood was drawn, centrifuged and the serum frozen to determine Calcitonin levels before and after the intervention. The latter was also sent in batches to Penn State. Penn State Lab., assuring reliability and validity for reported Calcitonin and urine NTx levels, set the values for

normative ranges. A statement to this effect from Dr. Laurence Demers, Director of the Endocrine Laboratory of Penn State may be found in APPENDIX C (page 94).

Participants in the experimental group were shown the SheLi TENS™ with its two leads, sponges and 9-volt battery compartment. A demonstration of its use was given, including application of the leads to the acupressure points on the skin according to the diagram. In some cases, the participant asked that the points be dotted with a permanent marker on their skin. The researcher reminded them that the actual acupressure point was the size of a needle pinpoint. However, the sponge was 1.5 inches wide so they were sure to apply the electrical stimulation on or very proximal to the points. Once all points were demonstrated, the subject signed an agreement that they understood the use of the SheLi TENS™ on the Ring of Earth acupressure points and that they felt comfortable using the device as well as locating the above points on their skin. A picture of the human body with the Ring of Earth acupressure points marked was given to each participant. An equipment agreement was also signed, asking for a credit card number in lieu of a deposit of $250 for the unit in case of loss or permanent damage. Retail cost of the SheLi TENS™ is $650. At the conclusion of their participation in the research in osteoporosis, Dr. Shealy offered them a special price of $250 if they chose to purchase the unit. 40% of the women did purchase the SheLi TENS™ once they finished the research.

Diaries were given to the participants, to keep daily entries during their six months of participation. Instructions given were to check daily that they had used the SheLi TENS for three minutes on each pair of points for the ROE and that they had taken the designated vitamins and minerals for making new bone. On the form they had space

to note exercise, reactions and benefits. A sample of a diary page is cited in APPENDIX J, page 117. If they were in the control group, they marked their diaries in a similar way except for using the SheLi TENS™. Comprehensive contact information for the researcher RN was listed on a business card and also listed at the top of each diary page. Volunteers were encouraged to call with questions or to report untoward reactions. The Research Nurse also made regular contact with the participant by telephone or e-mail, checking on their status and compliance with the protocol.

Post-Testing Procedures

At the end of six months participation in the research, the subjects were notified to have a repeat AccuDEXA done. Once completed, a post evaluation visit was scheduled. All visits with participants were usually carried out at Dr. Shealy's research office. In this session, subjects filled out a Post Symptom Index, a Pain Profile and the diaries were reviewed and collected. Vital signs, height and weight were recorded as well as changes in medications and nutritional supplements. Health status for the previous six months was reviewed and changes documented. With each participant, a careful noting of changes that they noticed while doing the research were entered on their records. Finally, a post clean voided urine specimen for the NTx was requested and secured for all subjects, plus a veni-puncture done to obtain a Calcitonin serum level on the experimental group. All specimens were processed according to standard procedures published by the Core Endocrine Laboratory of Penn State University.

At the conclusion of collecting all data from the research subjects, all frozen urine and serum specimens were packaged with dry ice and sent by FedEx overnight to Penn State University. Once values were determined and reviewed by Dr. Demers, he returned

them to the research office. The data was then displayed according to Pre and Post levels. The information logged for each subject was given a study number and initials as the results were tabulated and displayed. All data was analyzed using the Statistical Package for the Social Sciences (SPSS) data analysis program. The data was analyzed by using a mixed analyses of variance (ANOVA), adjusting for the baseline level of observed differences and a **t test** for analyses of Calcitonin results.

Safety Issues

General safety was evaluated by monitoring the occurrence of any adverse effects experienced by the test subjects. Subjects were instructed to notify the Research Nurse as soon as possible should adverse or unusual symptoms occur. The Nurse, in turn, would report the situation to the PI. In the event of any reaction, the PI was to notify the IRB board, record the adverse reaction(s) in a complaint file, and, in the event of a major adverse reaction (e.g., death or immediate threat of death), notify the FDA within 24 hours. In the case of adverse effects, the PI, in accordance with good clinical practice, would carry out proper therapeutic measures and follow up.

CHAPTER 4: RESEARCH FINDINGS

Statement of Findings

The researcher carried out a quantitative research design for this study. The essential elements for this design included a control group, randomization of subjects and manipulation of one variable. The hypothesis of this experimental research was that stimulation of the Ring of Earth acupressure points with a SheLi TENS™ would raise serum Calcitonin levels and effect an increase in bone density. In this study design, the dependent variables were the Symptom Index, the Bone Mineral Density, as measured by the AccuDEXA, measurement of pain, as determined by ratings on the Pain Profile and finally use of N-teleoptides or NTx, a bone marker as measured in a urine specimen. These are dependent variables because they may and presumably are influenced by the independent variable. It was the intent of the researcher to structure the experiment with precision and controls in order to directly control for confounding factors. The independent variable for this research was stimulation of the Ring of Earth acupressure points with the SheLi TENS™ once daily for a period of six months.

One of the best statistical methods available to determine group differences and interactions of group differences is a mixed analysis of variance (ANOVA) and calculating the F ratio.[1] The ANOVA is efficient, comparing different group means and at the same time maintains one single overall significance level. In this design, the researcher used a combination of between-subjects i.e., the control and experimental group and within-subjects' design giving a pre-test and post-test. "The statistic, the F ratio is a variance ratio that examines the group means and provides a conservative measure of differences among the treatment conditions."[2] The F ratio was used

specifically, to separate the systematic differences (or experimental errors) by having a "built in" accounting for mathematical variations.

For each of the following calculations in the data displayed, the alpha level was set at a = 0.05, meaning that the research has 5 chances out of a total of 100 of making a type 1 error. Statistically speaking, the null hypothesis was that the researcher's data would show no difference at all between the means of each group. Certainly, the hypothesis would stand as proved, if the null hypothesis was disproved. How would this be reflected in the data?

The data collected and analyzed did reflect a difference between the pre-test and post-test levels for the experimental group and the control group in totals for the Symptom Index, AccuDEXA, Pain Analog and the bone marker Urine NTx. In the analysis of data for Calcitonin levels, within the experimental group, i.e., pre and post levels, there was a slight difference. Unfortunately, the difference was in the wrong direction ending with a lower level. However, in looking at both the experimental and control groups combined, there was a significant decrease in total symptoms, captured on the Symptom Index with a (p=.001). Furthermore, within the treatment group, there was a significant reduction in symptoms for that group with a (p=.020). In summary, for all the other variables, none of the data collected for this research in osteoporosis indicated a significant statistical difference between the experimental and control group at $p > 0.05$ level. The following pages display a summary of the statistical results of the research data as processed by SPSS. The differences, between the control and the experimental group are covered with each measured variable in the following pages. APPENDIX N, page 125 contains tables of the "raw" data obtained during the experimental research.

There was an interaction of groups (experimental versus control) by repeated measure (F (1,43) = .287, p = .595). Within the experimental group, there was a significant reduction in total symptoms for that group (p=.020). When looking at both the experimental and control groups combined, there was a significant change in symptoms with a (p=.001). See Figure 4 below for a graph of this data and Table 4 below for the actual statistics.

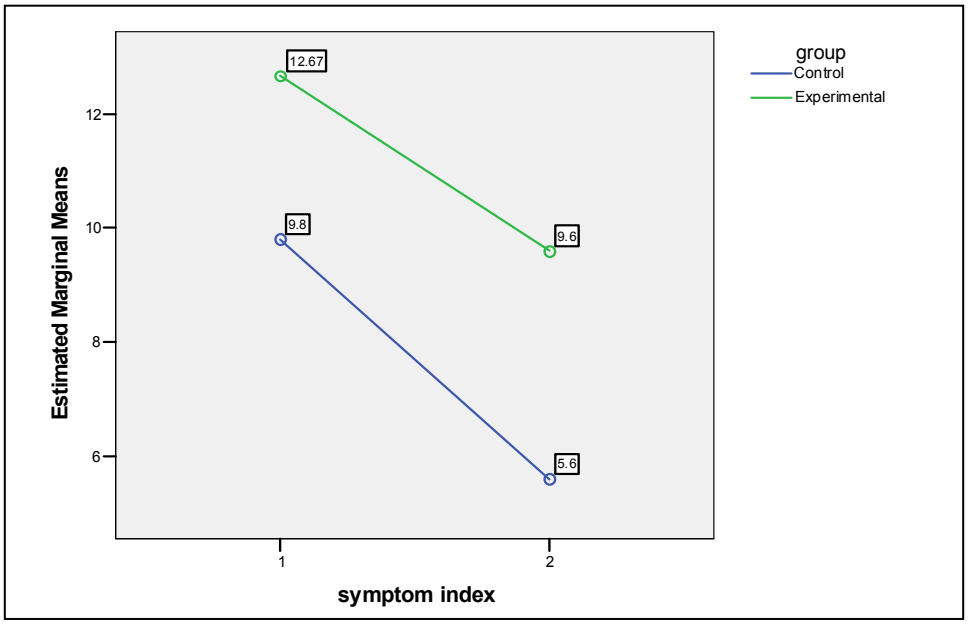


Figure 4. Symptom Index Data Statistics.

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F
symptom	Sphericity Assumed	264.022	1	264.022	11.812
	Greenhouse-Geisser	264.022	1.000	264.022	11.812
	Huynh-Feldt	264.022	1.000	264.022	11.812
	Lower-bound	264.022	1.000	264.022	11.812
symptom * group0control1exp	Sphericity Assumed	6.422	1	6.422	.287
	Greenhouse-Geisser	6.422	1.000	6.422	.287
	Huynh-Feldt	6.422	1.000	6.422	.287
	Lower-bound	6.422	1.000	6.422	.287

Table 4. Symptom Index Data Statistics.

With the Bone Density measurements, there was no significant interaction of groups (experimental versus control) by repeated measures (F (1,43) = 0.014, p = .905. Stated in another way, the experimental and control groups did not differ significantly in their standard deviations on their bone mineral density over six months of time. See Figure 5 below for a graph of this data and Table 5 below for the actual statistics.

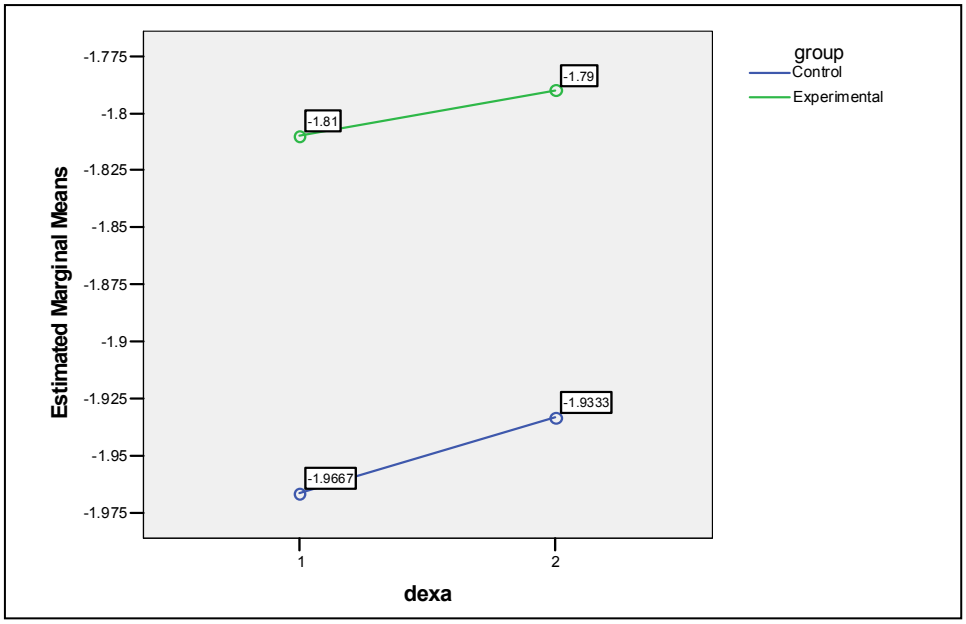


Figure 5. Dexa Data Statistics.

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
dexa	Sphericity Assumed	.014	1	.014	.232	.633
	Greenhouse-Geisser	.014	1.000	.014	.232	.633
	Huynh-Feldt	.014	1.000	.014	.232	.633
	Lower-bound	.014	1.000	.014	.232	.633
dexa * group0control1exp	Sphericity Assumed	.001	1	.001	.014	.905
	Greenhouse-Geisser	.001	1.000	.001	.014	.905
	Huynh-Feldt	.001	1.000	.001	.014	.905
	Lower-bound	.001	1.000	.001	.014	.905
Error(dexa)	Sphericity Assumed	2.641	43	.061		
	Greenhouse-Geisser	2.641	43.000	.061		
	Huynh-Feldt	2.641	43.000	.061		
	Lower-bound	2.641	43.000	.061		

Table 5. Dexa Data Statistics.

With the measurement of collagen cross-linked teleopeptides (NTx), there was no significant interaction of groups (experimental versus control) by repeated measures (F (1,41) = .083, p = .774). In another words, the experimental and control groups did not differ significantly from each other in urine values measuring the bone marker, N-teleopeptides over the time span of six months. See Figure 6 below for a graph of this data and Table 6 below for the actual statistics.

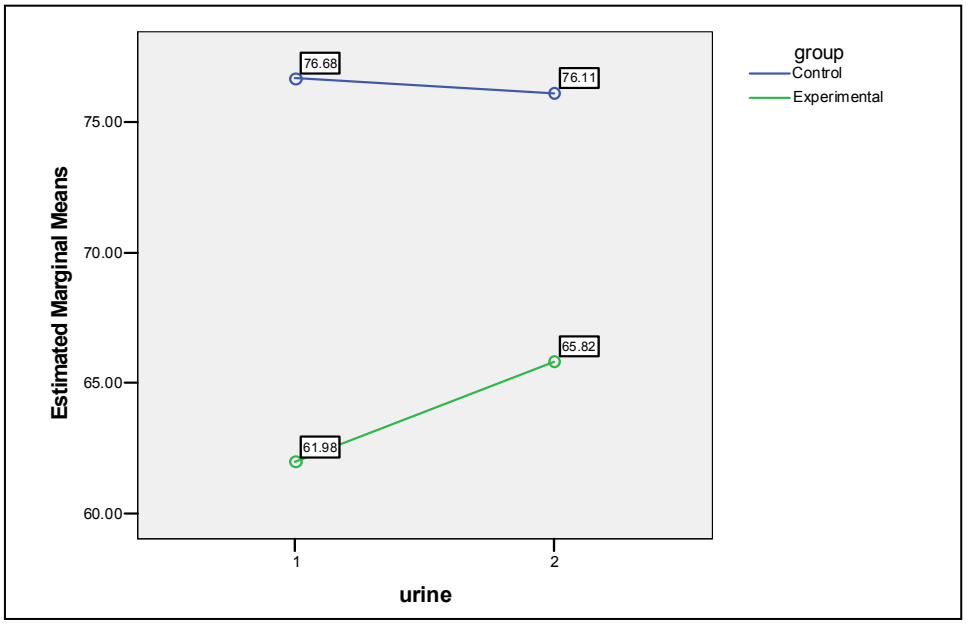


Figure 6. Urine Data Statistics.

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
urine	Sphericity Assumed	52.419	1	52.419	.046	.831
	Greenhouse-Geisser	52.419	1.000	52.419	.046	.831
	Huynh-Feldt	52.419	1.000	52.419	.046	.831
	Lower-bound	52.419	1.000	52.419	.046	.831
urine * group0control1exp	Sphericity Assumed	94.959	1	94.959	.083	.774
	Greenhouse-Geisser	94.959	1.000	94.959	.083	.774
	Huynh-Feldt	94.959	1.000	94.959	.083	.774
	Lower-bound	94.959	1.000	94.959	.083	.774
Error(urine)	Sphericity Assumed	46718.771	41	1139.482		
	Greenhouse-Geisser	46718.771	41.000	1139.482		
	Huynh-Feldt	46718.771	41.000	1139.482		
	Lower-bound	46718.771	41.000	1139.482		

Table 6. UrineData Statistics.

With the pain ratings recorded on the Pain Profile©, there was no significant interaction of groups (experimental versus control) by repeated measure (F (1,43) = 2.247, p = .141). Stated in a little different way, the experimental and control groups did not differ significantly from each other in their ratings of pain over the time span of six months. See Figure 7 below for a graph of this data and Table 7, page 58 for the actual statistics for this measure.

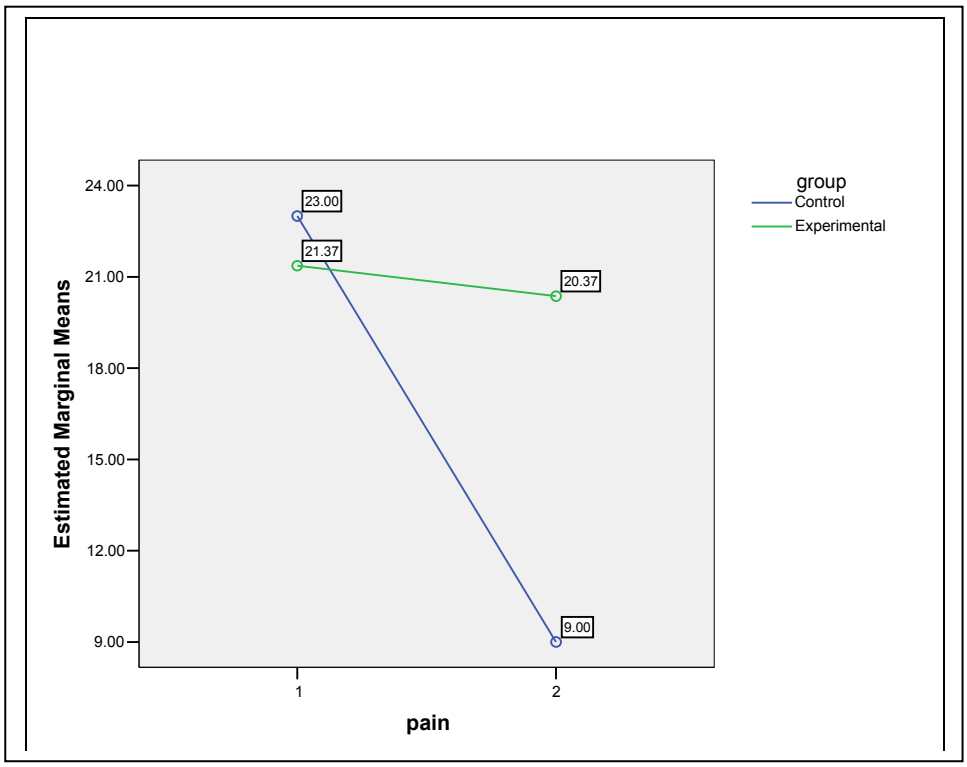


Figure 7. Pain Data Statistics.

Tests of Within-Subjects Effects

Measure: MEASURE_1

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
pain	Sphericity Assumed	1125.000	1	1125.000	2.991	.091
	Greenhouse-Geisser	1125.000	1.000	1125.000	2.991	.091
	Huynh-Feldt	1125.000	1.000	1125.000	2.991	.091
	Lower-bound	1125.000	1.000	1125.000	2.991	.091
pain * group0control1exp	Sphericity Assumed	845.000	1	845.000	2.247	.141
	Greenhouse-Geisser	845.000	1.000	845.000	2.247	.141
	Huynh-Feldt	845.000	1.000	845.000	2.247	.141
	Lower-bound	845.000	1.000	845.000	2.247	.141
Error(pain)	Sphericity Assumed	16173.000	43	376.116		
	Greenhouse-Geisser	16173.000	43.000	376.116		
	Huynh-Feldt	16173.000	43.000	376.116		
	Lower-bound	16173.000	43.000	376.116		

Table 7. Pain Data Statistics.

Figure 8 below gives a graphic view of the Calcitonin levels prior to starting the electrical stimulation with the SheLi TENS™ on the Ring of Earth. Please note the large portion of blue on the pie graphic giving a visual of the number of subjects with no measurable serum level of Calcitonin.

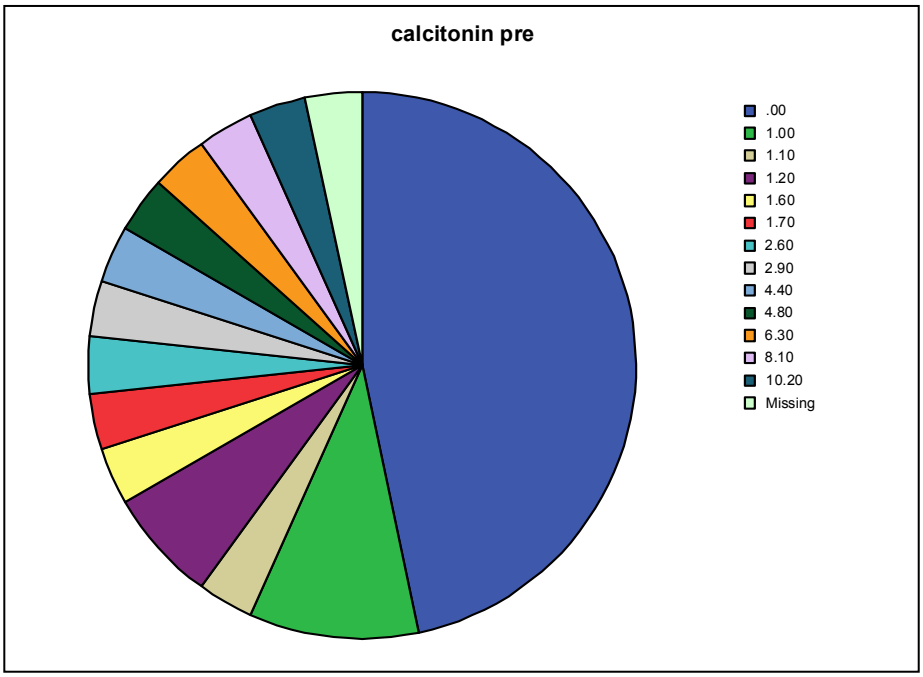


Figure 8. Calcitonin Data.

Paired Samples Statistics

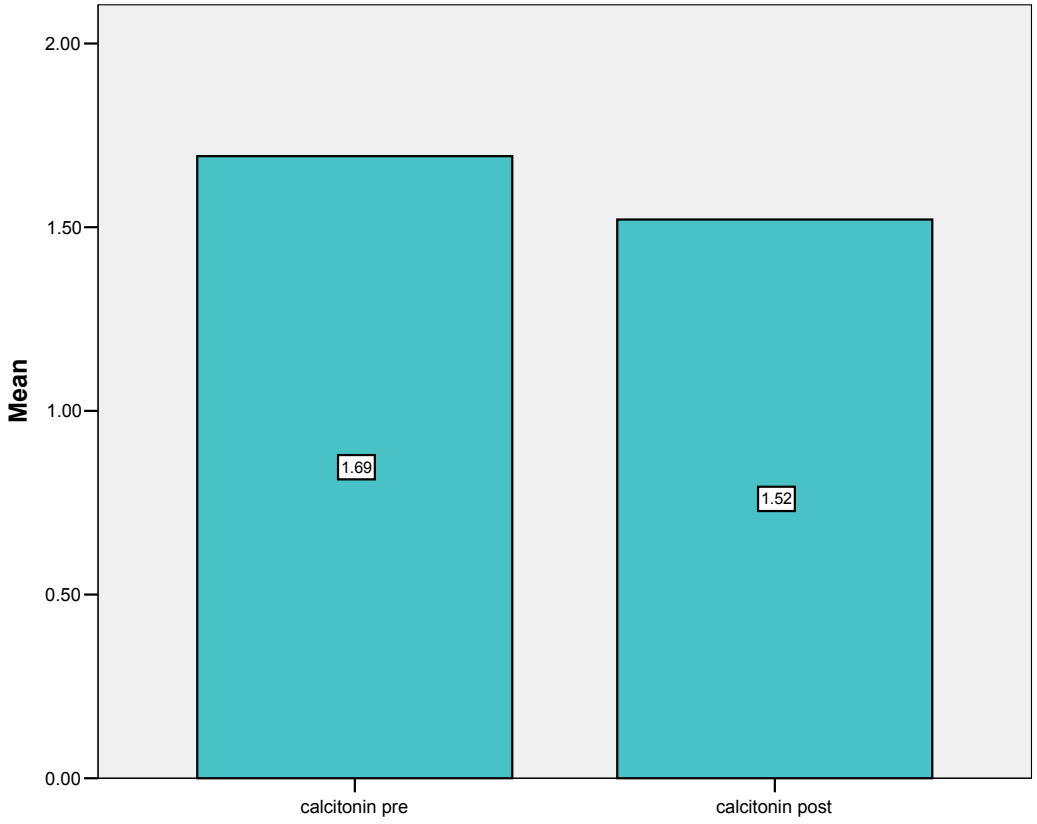
		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	calcitonin pre	1.6931	29	2.64790	.49170
	calcitonin post	1.5207	29	2.38288	.44249

(a)

Paired Samples Test

		Paired Differences					t	df	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	calcitonin pre - calcitonin post	.17241	1.29032	.23961	-.31840	.66323	.720	28	

(b)



(c)

Table 8. *Calcitonin Pre and Post Mean Scores*

The paired sample statistics used for the pre and post Calcitonin values for the experimental group revealed there was no significant difference in the pre and post levels for the group over a span of six months.

Anecdotal Results

After the experimental protocol was completed, the researcher received spontaneous feedback from a number of subjects pertaining to the effects they noticed while doing the experiment. These included:

- Many women reported they felt more energetic while using the SheLi TENS™ and taking the supplements.
- Individuals expressed amazement at how their AccuDEXA improved.
- Reported knees were far less painful and leg cramps disappeared.
- Several women said they felt so much better doing the Ring of Earth. They said it also helped greatly in dealing with daily stresses.
- Several ladies believed that the most important outcome in doing the research was stopping their daily intake of soda pops.
- Doing the Ring of Earth helped reduce illusions, fears and several women reported that the ROE helped control their allergies, decreasing the number of injections needed to control their symptoms.
- Another lady said, that while using the SheLi TENS™, she had less pain and achiness in her body.

Chapter 4 Endnotes:

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CHAPTER 5: CONCLUSIONS, DISCUSSIONS, AND SUGGESTIONS

Summary

In the original pilot study, the SheLi TENS™ was used on the Ring of Earth and only the Calcitonin level was measured in 10 subjects before and after the intervention. In this expanded research, other measurements were used to monitor effects on symptoms, measured by the Symptom Index©, on bone density as measured by the AccuDEXA, Calcitonin levels as well as a bone marker, called NTx or urine teleopeptides. Individuals gave ratings for their pain levels on the Pain Profile before and after the six-month interval. All measurements were taken on subjects in the control group and the experimental group, with one exception. Calcitonin levels were measured only in the experimental group. The period of participation for all subjects was six months. In this expanded model of this research in osteoporosis, there were improved health effects. Unfortunately, from a scientific point of view, the results were statistically significant only with the measure of the Symptom Index. None of the other measures resulted in statistically significant data. In the following sections, the researcher would like to discuss some of those findings.

Results

The results of this experimental research did not show significant statistical evidence that SheLi TENS™ electrical stimulation of the acupressure points known as the Ring of Earth raised Calcitonin serum levels or optimal urine teleopeptides (NTx) nor did it cause an increase in bone density in individuals with osteoporosis. With this experiment, there was no statistical correlation reached in the above measures, between

the experimental and control groups over the time period of six months. There was one exception, in using the measure of the Symptom Index. When looking within the experimental group, there was a significant reduction in symptoms for those using the SheLi TENS™ on the Ring of Earth at the (p=. 020) level.

Symptom Index

The Symptom Index© was developed as an adaptation of the Cornell Medical Index[1] as a list of symptoms related to every organ of the body. As a tool, it measures stress. Why is stress a consideration? According to Hans Selye, in his original and pioneering research on stress,[2] he identified many physical and chemical stressors as well as emotional and psychological ones. Part of Selye's theory included that all of us have one weak organ in our bodies and this organ breaks down as total stress increases and may eventually manifest in disease. Symptoms alone do not mean there is an illness. However, often symptoms are a precursor to developing an illness. Selye emphasized that prolonged and increased stress can cause disease, such as hypertension, diabetes, arthritis, allergies and myocarditis.[3] This is important groundwork, as we look a little closer at the raw data collected from the participants on the Symptom Index. © There was a reduction in the number of symptoms as seen in the following charts. Another way to state this observation is that an increased number of participants had fewer symptoms after the Ring of Earth intervention. This was done without medicine or a surgical intervention by simply using electrical stimulation on acupressure points for twenty minutes each day.

# of Symptoms Reported	Pre Ring of Earth	Post Ring of Earth
0-9 Symptoms	11	16
10-19 Symptoms	11	11
20-30 Symptoms	8	3

Table 9. *Raw Scores of Symptom Index Experimental Group*

This was also considered statistically significant, when both the treatment and control groups were combined. The statistical significance was at (p=.001) level. In order to further delineate some meaning to the above data, according to the originator of the Symptom Index, © Dr. Shealy[4] claims that 30 or more symptoms indicate a possible serious illness or mental disease. One out of the 45 subjects had a post score of 32. With 20 or more symptoms, this level of stress meant possible serious illness or mental disease. And in this area, in the final analysis, there were 10% of the total number of subjects or 3 people. Finally, in the less than 10 symptom category, 11 individuals or 36% started out with this total and at the end of the experiment, 16 or 53% individuals had less than 9 symptoms. This represented a 17% improvement with a decrease in physical symptoms in this sub-group. Again, this result did reach p = 0.001 level of significance, but it made a difference in subjects who participated in the research. With the control group, 9 individuals or 60% decreased their total number of symptoms to less than 5 symptoms.

AccuDEXA

In this measure of bone mineral density, 55% of the subjects in the experimental group had an increase in bone density using this peripheral measurement. This measure of change was not significant statistically. To the researcher, this reflected a trend and movement toward healthier bone. Of course, the ideal measurement to capture changes in the spine, femoral neck etc., would have been to have a full bone density on each subject. The cost was prohibitive for this doctoral research. Certainly the AccuDEXA,

which measures bone mineral density in the middle finger was an adequate measure but was not a comprehensive measure. For future research, this would have to be a primary consideration in adjusting the design of the research.

Of course, the design for this study also stipulated measurement of the bone mineral density right after six months intervention of using the SheLi TENS™ on the Ring of Earth. Would an assimilation of new bone take more time and in which bones does the body reflect this process the earliest? Perhaps, measuring the BMD at three months, 6 months or even up to one year after stopping the Ring of Earth would have captured maximal effect of the daily stimulation, which was done for six months. These are all questions generated by the data.

As a note of interest, in the control group, over half or 53% of the women improved their standard deviation in their bone density. There is a suggestion that individuals with normal body temperature may improve bone density with the use of Calcium, Magnesium, Vitamin D, Boron, Copper, Manganese and other supplementation.[5] [6] [7] Is there a placebo effect operative here? Yes, there could be a placebo effect. Or could this be an effect of individuals taking a specified menu or regimen of vitamins, minerals and especially an absorbable Magnesium and nutritional supplements that promote an increase in the bone remodeling process and subsequently are reflected in an increase in bone mineral density? Most previous research in Osteoporosis has not included an absorbable Magnesium as part of the menu of minerals to increase bone mineral density. Another possibility to explain the increase in bone density is that it could be an effect of the education and instruction given by the RN researcher.

Pain Profile

Pain is certainly a subjective symptom and it is recognized that tolerance for pain varies with each individual. In documenting the pre score for pain, the area was noted on the analog form so that the same area was again evaluated at he end of six months. In the experimental group, 40% had a reduction in their pain level. The rating of pain was reduced anywhere from 5 to 90%. This result was not a statistically significant level. Two individuals started with no pain and ended the research protocol with 0% pain. At the same time, 46% of the women in the control group documented a decrease in pain. This result approached the statistical significant level but it did not reach the 0.05 level. The range of pain reduction in the control group ranged from 10 to 70%. Three individuals or 20% of the group had a 0 level of pain at the beginning of the protocol and ended the project at the same 0 level with no pain. With the end totals pretty similar, more research is needed and this researcher would suggest a criteria for a future study in osteoporosis that the pain be bone pain and correlated with the diagnosis of osteoporosis.

With the results in both the control and experimental groups, was this the effect of the nutritional supplements, amount of daily exercise, a conscious decision to restore bone health, a systemic effect of the stimulation of the Ring of Earth with the SheLi TENS,™ a placebo effect or a combination of all of the above. Certainly, there was an effect produced that resulted in a reduction of pain in a number of participants. And the analysis of variance confirmed that it was not a statistical significant outcome due to the intervention. The change in each group was not significant. However, some individuals were able to significantly reduce pain in their lives and for each of them that represented

and tapped a power within them to create health in their bodies as a result of their participation in this osteoporosis protocol.

Bone Marker: Urine NTx

The collagen cross-linked urine teleopeptides or NTx was used as a scientific measurement of physiological changes showing a halt to bone breaking down and resulting in a decrease in bone mineral density. This diagnostic measure usually reflects concurrently what is actually happening in the bone. The results in this research were inconclusive and not statistically significant. In checking the raw data, I found 13 individuals out of 30 or 43% went to within normal limits as specified by Core Endocrine Lab. at Penn State. Again, while the literature confirms that this effect is usually more immediate, the researcher would question if an interim delay of two weeks, a month or six weeks after the Ring of Earth stimulation with the SheLi TENS™ was stopped, if this would have stabilized their urine NTx levels within the normal reference ranges for men and women.

Calcitonin Levels

The graph, illustrating the Calcitonin pre and post levels for the experimental group, clearly confirms that the results were far from being statistically significant for this research. Upon further reflection and some analysis of the hard data, some consideration of critical factors seems important for future research. In order for the thyroid to function optimally, it requires the mineral Iodine. The thyroid produces several bone regulating hormones, notably thyroxin and Calcitonin.[8] Thyroxin regulates the rate of metabolism in all cells in the body, including bone cells. However, production of too much or too little thyroxin has significant effects. Balance is critical. According

to Cummings,[9] too much thyroxin increases bone breakdown and too little causes a decrease in calcium absorption. This too causes bone loss. Calcitonin slows bone resorption and produces recalcification of osteopenic bone.[10] Calcitonin moves calcium from the blood into the bone [11] and therefore is a key factor in the laying down of new bone. Unfortunately, in this osteoporosis research, a significant number of subjects had <1 level of serum Calcitonin before beginning the protocol for the research. This meant they had no measurable Calcitonin in their blood due to insufficient production by the thyroid and other tissues. In the original pilot study, with only 10 subjects, there were 4 who had <1 Calcitonin level on the pre-draw and all four stayed at <1 in the post-draw for Calcitonin. Temperatures were not recorded for this pilot group. It would seem that the thyroid needs at least an elemental level of Calcitonin to trigger further production. The following pie graphs (Figure 9 and Figure 10, page 69) demonstrate this finding.

Compliance with Research Protocol

A valid question arising out of the results of this research is: What was the rate of compliance of subjects in the Experimental Group for six months? How many days did the participants actually do the Ring of Earth with the SheLi TENS? ™ I took time to tally the number of days each subject in the experimental group used the SheLi TENS™ on the Ring of Earth acupressure points. Once I added totals for each participant, I divided that # by 180 (# of days for 6 months) and then multiplied by 27 (# of participants with diaries) and found there was a rate of 88% for compliance in this study.

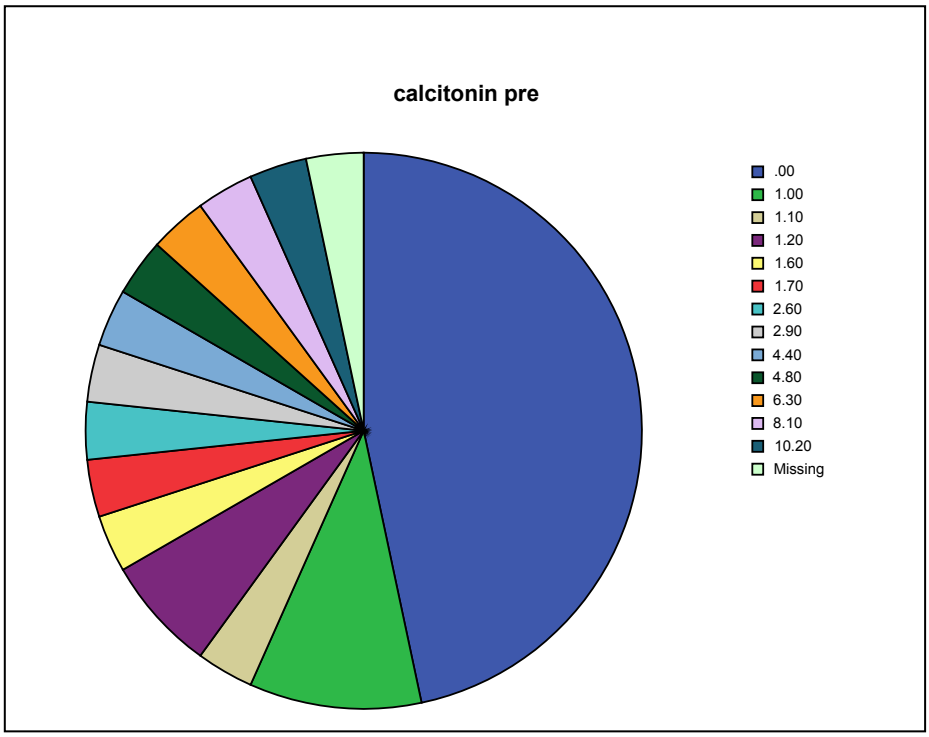

Figure 9. Pre-Intervention Calcitonin Levels..

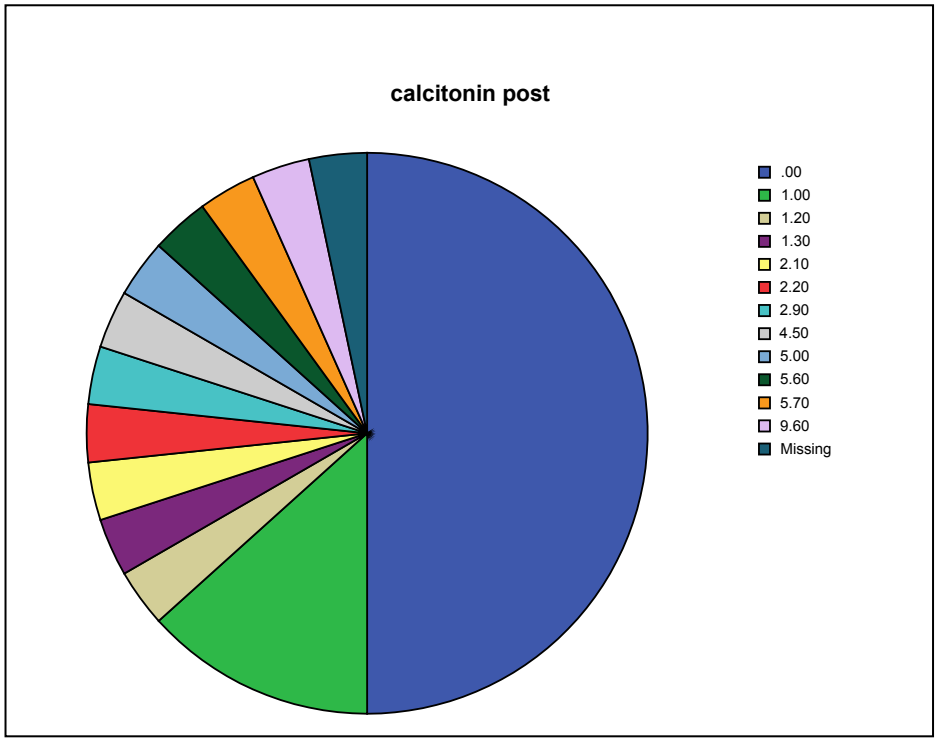

Figure 10. Post-Intervention Calcitonin Levels..

In the previous pie charts, mapping the raw scores of Calcitonin levels Pre and Post intervention display that close to 50% of the participants had <1.0 or no measurable Calcitonin in their blood. Furthermore, 45% in the Post group had less than 2.20 pg/ml of serum Calcitonin.

Body temperature is also a critical essential component for thyroid health. Temperatures below 98 degrees, symptoms such as cold hands and feet, inability to lose weight, fatigue, disturbance in sleep and dry skin are all indicators of a sluggish thyroid. Individuals enrolled in this research were checked for this set of symptoms. For low body temperature, they were strongly advised to go on a preparation developed by Biotics Research of Iodine 20 drops per day and recheck their temperatures in one month. They were asked to record this information on their diary. Questions or difficulties were to be called or e-mailed to the RN researcher for solutions or further recommendations. The physician PI requested further analysis of the laboratory results for Calcitonin. In looking at the raw data on Calcitonin levels, this researcher decided to do a further correlation of Calcitonin levels with body temperatures, registered before the participant began the osteoporosis protocol and at the conclusion of their participation in the research. Values are displayed in Table 10 (page 72).

With this informational data, one can see that 15 individuals out of 29 in the experimental group had no measurable Calcitonin level. Out of these, all but one had a body temperature of 98° or above. However, 19 subjects out of 29 or 66% had a body temperature below 98.6 prior to starting the research. At the conclusion of the research, at the end of six months, 21 out of 29 participants had a temperature below 98.6. This result is grossly significant since a body temperature below 98.6 suggests a sluggish

thyroid. Eight out of nine treated subjects, achieved increased Calcitonin levels at the conclusion of the study. Also, these same eight subjects began the study with a normal body temperature. One of these participants was on Synthroid for low thyroid. The ninth subject had a sub-normal temperature and she used the Iodine drops during the six months of research. The remaining six subjects' Calcitonin level either decreased or the change was minimal and insignificant. Of noted interest, one participant started the research with a body temperature of 95.6 and she had a positive level of Calcitonin in the serum. She had been on Armour Thyroid, a medication for years for hypothyroidism. With the use of an Iodine supplement, she did increase her temperature to 97.4. She was an example and proof that one can increase Calcitonin and one's temperature even though taking Armour thyroid daily. It is the conclusion of this researcher that low body temperatures and low Calcitonin serum levels are related. It therefore appears that individuals with normal body temperature have a probability of increasing their Calcitonin levels, with stimulation of the Ring of Earth by the SheLi TENS.™

Only one subject in the Control Group had a subnormal temperature, below 98.6 and she used the Iodine drops during the six months of research. At the end of the study, 13 out of the 15 subjects registered a temperature of 98° or above with the majority at 98.6. None of these were on any supplement of Iodine. There were 2 subjects, with temperatures of 96.0 and 95.4 respectively and the RN researcher suggested they start taking an Iodine preparation.

To the researcher, it appears that low body temperature, suggesting clinical hypothyroidism, may depress the level of Calcitonin and significantly inhibit a response to electrical stimulation of the Ring of Earth.

S#	Pre Cal.	Post cal.	Pre Temp	Post Temp	Iodine
CC	1	<1	98.6	98.4	None
DJ	<1	<1	99.4	99.0	None
TM	<1	<1	98.4	98.8	None
CS	1.2	<1	98.6	96.4	None
KU	<1	<1	98.6	98.8	None
PW	<1	<1	98.0	98.0	None
BH	1.1	<1	98.4	96.0	None
JI	2.6	<1	98.6	98.0	None
HW	<1	<1	98.4	98.4	None
DD	1.6	<1	98.0	99.2	None
CSc	<1	<1	98.0	98.4	Yes
*JP	<1	<1	98.6	98.0	None
ED	<1	<1	98.0	97.8	Yes
OO	<1	<1	97.6	98.6	None
TZ	2.9	<1	98.4	98.4	None
JM	<1	1	98.6	98.6	None
AT	<1	1	98.6	98.0	None
JG	4.4	4.5	98.8	98.6	None
SZ	4.8	5.7	98.0	97.8	None
PT	<1	2.2	97.8	98.0	Yes
PZ	<1	2.9	98.4	98.4	None
CP	<1	1.2	98.2	99.4	None
MG	1.7	2.1	98.0	98.4	None
MS	1	1.3	97.8	97.8	None
VB	8.1	5.6	97.2	98.2	Yes
JS	10.2	9.6	98.6	97.8	None
JJ	1	1	98.4	98.0	None
PR	6.3	<5	98.0	98.2	Yes
MP	1.2	1	95.6	97.4	Yes

Notes: 1. "Within Normal" limits for Calcitonin Levels:
Female < 14 pg/ml
Male < 19 pg/ml.
Only one male fell within these limits, and is indicated by an asterisk.

Table 10 Calcitonin Levels Correlated with Body Temperature.

Conclusions

While all the data collected in this interesting protocol did not reach the statistically significant level in any area, unraveling the data and looking at it from different angles certainly reveals that some of the participants had positive health changes some of the time. Certain individuals even experienced going to a normal bone density and many were grateful to know the nutrients and their dosages necessary to create better bones and thyroid health. Further research is suggested using the independent variable of stimulation of the Ring of Earth with the SheLi TENS.™ With a grant, a researcher could design the study using a full bone density, capturing small changes in the spine, femoral bones, the hip etc., as well as having in the admission criteria, that all participants have a positive level of serum Calcitonin before being approved for the research as well as a normal body temperature. Uniformity in supplements for building new bone could be dispensed for the entire project as well as regular clinic visits to monitor temperature, exercise regimen, the procedure of doing the Ring of Earth using the SheLi TENS™ and compliance with all the stipulations outlined in the protocol. Furthermore, if the subjects enrolled could be followed and monitored for Calcitonin levels and changes in bone mineral density for an interval of six months and a year after completing the intervention for the experimental study. This follow-up would insure maximum capture of the effect of electrical stimulation of the acupressure points of Ring of Earth in subjects with osteoporosis.

Suggestions for Follow-up Research

Certainly, I've suggested ways of further tailoring this research in the future throughout the previous section on conclusions. I recommend a further extension of this

research and as a pilot study to use the willing participants from the experimental group who had an increase in their Calcitonin levels and do a twelve month or eight-teen month follow-up for a second post-draw for serum Calcitonin and perhaps a full bone density. At that time, I would also check their body temperature. Any participant with a temperature below 98.6 would be placed on Iodoral, 1 capsule daily to enhance thyroid function. Consideration could also be given to having a second bone mineral density performed on the same group of participants.

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[3] Ibid.
[4] Private conversation held July 23, 2005 between C. Norman Shealy and Vera Borgmeyer.
[5] Riggs, R., Hodgson, S., O'Fallon, W. & others. (1990).
[6] Grover D. (2002).
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APPENDIX A
INSTRUCTIONS FOR USE OF THE TENS DEVICES

HOLOS INSTITUTES OF HEALTH INC. RESEARCH UNIT
1211 East Woodland
Springfield Missouri 65804
417-267-4678 or 887-2838

INSTRUCTIONS FOR THE USE OF LISS AND/OR SHELI TENS™

The LISS Stimulator is a form of TENS (Transcutaneous Electrical Nerve Stimulator) which has been approved by the FDA (Food and Drug Admin).

The LISS Stimulator utilizes water-moistened sponge electrodes or self-adhesive electrodes to conduct a maximum of 4 milliamp ere current, producing no or only a slight sensation on the skin. During use, most people using the LISS on the head will notice a slight flicker of lights when their eyes are closed. The stimulation is perfectly safe and will not cause any problems with your optic nerves or eyes. The electrodes are held in place on the temples or at the front of and the back of the head with a headband secured with Velcro or a baseball cap.
When used transcranially (over the temples), the LISS causes a rise in Serotonin, Endorphins and other NEUROCHEMICALS naturally produced by your body.
Treatment should be done no later than 1 pm unless otherwise ordered by a physician.
Treatment time should be 20-60 minutes.

1. You have two split sponges, wet thoroughly and insert them into the rubber cups so that the lip of the cup fits into the split in the sponge.
2. The unit will have a roller knob. When the red lights come on, this tells you the battery is working. Adjust the control to where you feel a sensation, then slowly adjust back to where you feel nothing or at least two amber lights are lit up.
3. In doing the Ring of Earth, you will place one sponge on the top of your head and 2 more sponges on the first pair of acupuncture points on the balls of your feet. Leave all in place as you treat the other points using the SheLi TENS™.

If the Amber Lights do not come on:

1. Make sure the sponges are wet enough.
2. Make sure the headband or cap is tight enough or the electrode snugs enough making a solid contact of the sponge or the electrode with the skin.
3. If it still doesn't work, call Vera at 267-4678 or Kim 887-2838.
4. The LISS is sold in U.S. but requires a Prescription. Except for Research.

12-5-2002

APPENDIX B
INFORMED CONSENT FORM

DOCTOR IN CHARGE OF STUDY: C. Norman Shealy, M.D., Ph.D.

NAME OF EQUIPMENT/ THERAPY

Osteoporosis is a multi-factorial bone disorder that manifests in serious loss of Bone mass, demineralization and a tendency for bone fracture, which heightens at Menopause. It predominantly affects Caucasian women and Dr. John Lee says the incidence, if one lives long enough is 100%. Osteoporotic bones have lost Calcium, are porous, fragile and can easily fracture. The bone loss that precedes a fracture is a silent process and may go undetected until the bone breaks. Medical costs for individuals with a fracture continue to escalate plus the inactivity necessary for the bone to mend further precipitates the disease process. The cause of the osteoporosis may still not be addressed. Calcium Citrate with Vitamin D and estrogen replacement are agents used to treat Osteoporosis. It takes a myriad of factors to maintain bone in the body. Calcitonin was discovered in 1961 and has been widely used clinically for the treatment of Osteoporosis, hypercalcemia, Paget's disease and the relief of bone pain. By 1992, worldwide sales of Calcitonin exceeded $900 million, of which 85% was for Osteoporosis. Research has demonstrated it has excellent analgesic effects and its impact on pain is fairly immediate.

In the body, Calcitonin is a hormone produced by the thyroid gland and is a primary regulator of Calcium in our bones. Since its discovery, it can be given by injections or intra-nasally. Calcitonin, as a drug is expensive and has potential serious side effects, since it is derived from salmon.

In a small study recently, we found increased Calcitonin blood levels after a single episode of electrical stimulation of the Ring of Earth (ROE), which consists of thirteen specific acupuncture points and should be of considerable interest to those seeking an alternative for the treatment of the disorder of Osteoporosis. A copy of the results is available.

In addition, we have treated at least several dozen patients with chronic pain with stimulation of the Ring of Earth, with significant and lasting benefits in pain management.

This research project will consist of an experimental study in which subjects with a diagnosis of Osteoporosis, verified by a Bone Mass Density test by their health practitioner agree to use the SheLi TENS™ on the Ring of Earth acupressure points daily for a period of six months. They will agree to take Calcium Citrate, Magnesium, Vitamins C, D and B6 as well as Boron, Folic Acid, Manganese and

Copper, which are the essentials for making new bone. A follow-up Bone Mass Density test will be done at the completion of six months in the Study.

PURPOSE:

This is a clinical investigational study, using electrical stimulation of the Ring of Earth acupuncture points daily with the SheLi TENS™. The purpose is to measure the changes in bone mass as determined by a Peripheral Bone Mass Density Test. Blood may also be drawn for Calcitonin levels and serum will be frozen until the end of the study. If, there are significant bone density improvements, blood will be drawn again to determine changes in Calcitonin levels.

INCLUSION CRITERIA:

1. Subjects must have a recent Bone Density Test with a diagnosis of osteopenia or Osteoporosis.
2. Subjects will show willingness to participate by signing voluntary informed consent form.
3. Subject will show ability and state willingness to follow the directions of the Principal Investigator (PI) and the research staff.
4. Subjects will be in reasonable good health.
5. Subjects taking Natural Progesterone cream as long as they have been using it for at least three months.

EXCLUSION CRITERIA:

1. Individuals with a Pacemaker or any implanted electrical device.
2. Thyroidectomy.
3. Subjects taking Calcitonin spray or injections.
4. Subjects taking Fosamax or any osteoporosis drug, Steroids, Ipriflavone, Vitamin K, any blood pressure or cardiovascular drugs including channel blockers and synthetic estrogenic hormones.
5. Smokers.

PROCEDURES:

1. The length of the study is 6 months for each patient.
2. You may experience a reversal of your osteoporotic process by an increase in your bone density. You will receive Yinergy Gel, which is an excellent Magnesium supplement to use daily as you do the Ring of Earth. You will agree to take the following nutritional supplements on your own: Calcium Citrate, Folic Acid, Boron, Manganese, Vitamins C, D and B6 and Copper. Amounts will be determined by your weight and given during the Initial Screening Visit.

3. Your first visit in the study will be a screening visit with the Research Coordinator, Vera Borgmeyer RN. At that time, vital signs will be recorded, as well as a brief health history. Each subject will complete a Symptom Index and a Pain Analog Scale. As part of the initial assessment, risk factors for fractures will be ascertained as well as their nutritional intake, habits of regular exercise, exposure to sunlight, alcohol and caffeine consumption, family history of osteoporosis, exposure to heavy metals, taking Calcium and other nutritional supplements and for how long as well as their willingness to take responsibility for their healing. Subjects will be taught how to do the Ring of Earth using the SheLi TENS™ and the nurse will do the first intervention while in the Holos Research Center. They will do the Ring of Earth daily for six months. Blood will also be drawn for a Calcitonin level and the Serum frozen for possible analysis.
   Participants will be asked to keep a daily diary.

POSSIBLE BENEFITS

The therapy outlined may increase the bone mass in your bones and actually begin to reverse the process of osteopenia silently taking place in your bones.

POTENTIAL RISKS

You may receive little or no benefit from the treatments.

There is the possibility of irritation or bruising at the puncture site for drawing blood.

ALTERNTIVE TREATMENTS:

You do not have to participate in this Research Study.

RIGHT TO LEAVE STUDY

1. As a volunteer, you will be starting the Study of your own free will, without any kind of pressure, and you may quit the Study any time you wish. You will not be penalized or lose any of the benefits or rights to which you may be entitled.
2. Any new information, which is developed during the course of the Study, will be made available to you and that information may influence your willingness to continue participation in the Study. Every effort will be made to advise you of any future information developed from this project.
3. If you fail to follow instructions, the PI may terminate your participation in this Study, or if your own doctor determines that you are not doing well or that your safety is in question.

CONFIDENTIALITY OF RECORDS

Your identity as a part of this Study will be kept confidential. Employees of the Food and Drug Administration, the sponsoring institution and members of the Institutional Review Board can look at, and copy your medical records as well as any information collected during this Study.

For your safety, your name, address and social security number will be filed at the Sponsor's office. Results of the Study may be reported in scientific presentations or publications, but you will not be identified.

Your identity will not be disclosed to anyone else, unless required by law.

There will be no charge for these treatments or for the Serum level of Calcitonin.

QUESTIONS

This form has told you what this Study is about. If you have any questions about the Study, or injuries as a result of the Study, Vera M. Borgmeyer, RN, the Study coordinator, or Dr. C. Norman Shealy, M.D. PhD will assist you. The 24-hour number to call is 417-267-4678.

SUBJECT STATEMENT

I am signing this consent freely and am not being forced. I understand that, by signing this form, I do not lose any rights to which I am entitled.

I hereby state that I have the legal capacity to enter into contract and that no guardian has been appointed for me.

I have read and consent and the Study information has been fully explained to me. Any questions that have occurred to me have been fully answered by the Study coordinator or the doctor in charge of the Study. I may request a signed copy of this form.

I agree to cooperate with all research personnel and to follow the procedures as outlined to me.

By signing this Consent Form, I am authorizing release of my medical records to the Food and Drug Administration, the Institutional Review Board and any third party required by law.

_____	_____
Subject's Signature	Date
_____	Or (if required)
Subject's Name (Printed)	
_____	_____
Signature of Legal Representative	Date
_____	_____
Legal Representative Name (Printed)	Relationship
_____	_____
Witness' Signature	Date
_____	
Witness' Name (Printed)	

8/22/02 vmb; Rev. 11/02

APPENDIX C
LETTER, MILTON S. HERSHEY MEDICAL CENTER

PENNSTATE Milton S. Hershey Medical Center

Dr. Laurence M. Demers, DABCC, FACB
Distinguished Professor, Pathology and Medicine
Director, Core Endocrine Laboratory
Penn State College of Medicine
Milton S. Hershey Medical Center
Division of Clinical Pathology, M.C. H158
P.O. Box 850
Hershey, PA 17033-0850

June 17, 2005

Vera Borgmeyer, RN, Registrar

Holos University

5607 S. 222nd Rd.

Fair Grove, MO 65648

DEAR MS BORGMEYER;

We recently performed blood and urine tests for Calcitonin and the collagen crosslink N-Teleopeptides in our Core Endocrine Laboratory (CEL) on samples submitted from your institution. The Core Endocrine Laboratory is an accredited hormone testing laboratory that supports testing for patient care and research for the Milton S. Hershey Medical Center, The Penn State College of Medicine and outside institutions such as pharmaceutical houses, Institutes and other Academic Health Centers. The laboratory is certified by CLIA and JCAHO and conforms to Good Laboratory Practice performing appropriate quality assurance to insure the most accurate and precise results. The CEL also participates in the College of American Pathologists Proficiency testing program to insure accurate and reliable test results.
All of our test methods have been validated in-house and meet appropriate standards set by JCAHO and CLIA for patient care testing.
If you have any further questions concerning the CEL, I can be reached at 717-531-8316.

Sincerely,

Dr. Laurence M. Demers
Director, Core Endocrine Laboratory
Distinguished Professor, Pathology and Medicine

APPENDIX D
EXPERIMENTAL PROTOCOLS AND REPORTS

The following are the initial and follow-on reports sent to the PI and IRB pertaining to the study. Reports were required every 3 months.

Initial Protocol

STUDY ID #: 413

DATE APPROVED BY THE IRB: **September 4, 2002**
DATE STUDY TO BEGIN: **November 2002**
Principal Investigators: **C. Norman Shealy, MD, PhD and Vera Borgmeyer, RN, MA**

PROTOCOL RESEARCING THE EFFECT OF STIMULATION OF THE RING OF EARTH WITH THE LISS AND SHELI TENS™ ON OSTEOPOROSIS

Location: Holos Research Unit, Springfield Missouri

1.0 STUDY CONDUCT

1.1 Background

Osteoporosis is a multi-factorial bone disorder that manifests in serious loss of bone mass, demineralization and a tendency for bone fracture, which heightens at menopause. It predominantly affects Caucasian women and Dr. John Lee says the incidence, if one lives long enough is 100%. Osteoporotic bones have lost Calcium, are porous and fragile and can easily fracture. The bone loss that precedes a fracture is a silent process and may go undetected until the bone breaks. Medical costs for individuals with a fracture continue to escalate plus the inactivity necessary for the bone to mend further precipitates the disease process. The cause of the disorder may still not be addressed. Calcium Citrate with Vitamin D and estrogen replacement are agents used to treat Osteoporosis. It takes a myriad of factors to maintain bone in the body. Calcitonin was discovered in 1961 and has been widely used clinically for the treatment of osteoporosis, hypercalcemia, Paget's disease and the relief of bone pain. By 1992, worldwide sales of Caclitonin exceeded $900 million, of which 85% was for osteoporosis. Research has demonstrated it has excellent analgesic effects and its impact on pain is fairly immediate.

Calcitonin is a hormone produced by the thyroid gland and is a primary regulator of Calcium in our bones. It is given by injections or intra-nasally. Calcitonin as a drug is expensive and has potential side effects since it is derived from salmon.

In a small study recently, we found increased Calcitonin blood levels after a single episode of electrical stimulation of the Ring of Earth (ROE), which consists of thirteen specific acupuncture points and should be of considerable interest to those seeking an alternative for the treatment of the disorder of Osteoporosis. A copy of the results is attached.

In addition, we have treated at least several dozen patients with chronic pain with stimulation of the Ring of Earth, with significant and lasting benefits in pain management.

This research project will consist of an experimental study in which subjects with a diagnosis of osteoporosis, verified by a Bone Mass Density Test (AccuDEXA) by their health practitioner agree to use the SheLi TENS™ on the Ring of Earth acupressure points daily for a period of six months. They will agree to take Calcium (citrate form), Magnesium, Vitamin C, D and B6 as well as Boron, Folic Acid, Manganese and Copper, which are the essentials for making new bone.

1.2 Objective

To evaluate and measure the changes in bone mass as determined by a peripheral bone density test. An assessment of each subjects' Risk Factors for Fractures will also be completed. Dr. Steven Cummings at the Univ. of California, San Francisco verified that low bone density in combination with a high number of risk factors is the best and most accurate predictor of osteoporotic fracture for the individual. A copy of this Index is in Appendix.

1.3 Study Design

Up to 65 individuals will complete a Symptom Index and a Risk Factor survey before and at the end of the Study. They will also complete a Pain Analog Scale during the Screening visit and at the end of the Study. A copy of both of these tools is attached. Each subject will have a baseline Bone Mass Density Test showing a clinically significant level of osteopenia or osteoporosis. Blood may be drawn on these subjects and kept until the end of the study. At the completion of the Study, another Bone Mass Density Test will be performed. If bone density reflects significant improvement, blood will be drawn again to determine changes in Calcitonin levels.

1.4 Subject Population

1.4.1 Inclusion Criteria

a. Subjects must have a recent Bone Density Test with a diagnosis of osteopenia or osteoporosis.

b. Subjects will show willingness to participate by signing a voluntary informed consent form.

c. Subject will show ability and stated willingness to follow the directions of the Principal Investigator (PI) and the research staff.

d. Subjects will be in reasonable good health.

e. Subjects taking Natural Progesterone cream as long as they have been using it for at least three months.

1.4.2 Exclusion Criteria

a. Individuals with Pacemaker or any implanted electrical device.

b. Thyroidectomy.

c. Subjects taking Calcitonin spray or injections.

d. Subjects taking Fosamax or any osteoporosis drug, steroids, Ipriflavone, Vitamin K, blood pressure or cardiovascular drugs including channel blockers and synthetic hormones

e. Smokers

1.4.3 Potential Risks

a. There is the possibility of irritation or bruising at the blood draw site.

1.4.4 Discontinuation Criteria

a. A subject may be dropped from the study at any time at their request or that of the PI of the project and reported to the IRB.

b. If the subject terminates her participation in the study prematurely, the drop date and reason will be recorded in her Report Form and reported to the IRB.

c. If adverse reactions occur during the study, the PI can determine whether the subject should discontinue participation in the research and report it to the IRB in writing.

1.5 Evaluations

1.5.1 Safety

Safety will be evaluated by monitoring the occurrence of any adverse effects. Adverse effects will be reported as follows:

a. The subject will be instructed to notify the Research Nurse as soon as possible should adverse or unusual symptoms occur. The Nurse in turn will report to the PI.

b. In the event of any reaction, the PI must notify the IRB chair within 24 hours and the full board within 72 hours. Any adverse reaction will be recorded in the complaint file and reported to the full IRB board. If there is a major adverse reaction (such as death or immediate threat of death), the FDA and the Chair of the IRB will be notified within the first 24 hours and then in writing.

c. In case of adverse effects, the PI in accordance with good clinical practice, will carry out proper therapeutic measures and follow-up.

1.5.2 Efficacy

Efficacy will be addressed by comparing differences on the Bone Mass Density Test after using the Ring of Earth.

1.5.3 Statistical Analyses

The data will be analyzed using a mixed analysis of covariance (ANOVA) adjusting for a baseline level of observed difference. For each subject, the mean difference will be calculated and considered the units of measure. Additional statistical methods will be used as appropriate.

1.6 Special Instructions

All subjects will be required to sign the Informed Consent Form. All subjects will be instructed in doing the Ring of Earth using the SheLi TENS™ and given a list of the nutritional supplements they are to take while participating in the Study.

Subjects will sign a Demonstration Sign-off sheet verifying that they have been instructed regarding the above procedures and feel they do understand them.

2.0 Management and Regulation

2.1 Monitoring

Monitoring responsibility performed by the sponsor's monitors includes but are not limited to:

2.1.1 Screening Visit

2.1.2 Bone Density Test.

Subjects will have a baseline Bone Density Test and bring that report with them on the first visit. They will complete a Symptom Index and a Pain Analog. As part of the initial assessment, risk factors for fractures will be ascertained as well as their nutritional intake, habits of regular exercise, exposure to sunlight, alcohol and caffeine consumption, family history of osteoporosis, exposure to heavy metals, taking Calcium and other nutritional supplements and for how long as well as their willingness to take responsibility for their healing. Blood may be drawn and stored for future Calcitonin testing.

Subjects in the experimental group will be taught how to do the Ring of Earth using the SheLi TENS.™ They will do the Ring of Earth daily for six months.

2.2 Monitoring Personnel

Vera M. Borgmeyer, RN; C. Norman Shealy, M.D., PhD,
or his designated appointee, M.D. or FNP.

2.3 Regulatory Considerations

None.

2.3.1 Protocol Agenda

The PI shall not implement a change in or otherwise deviate from the protocol if the change may increase the risk to study subjects or adversely affect the validity of the investigation or the rights of human subjects. Changes may be made to reduce the risk to subjects. However, the PI must notify the Chair of the IRB in writing prior to such changes and also the IRB Board.

2.3.2 Subject Report Form Completion and Submission

Reports of progress or lack of progress will be sent to the IRB every 3 months for one year from the start date, which is November 2002. Study will not last longer than one year unless protocol is resubmitted to the IRB.

Subject Report Forms will be completed at the end of one year. The PI shall maintain them with a final report to the IRB.

(Note: The Informed Consent Form was attached to the original, but is not included here. This form may be found in APPENDIX B.)

Report #1

STUDY ID #: 413

DATE APPROVED BY THE IRB: **September 4, 2002**
DATE STUDY TO BEGIN: **November 2002**
Principal Investigators: **C. Norman Shealy, MD, PhD and Vera Borgmeyer, RN, MA**

PROTOCOL RESEARCING THE EFFECT OF STIMULATION OF THE RING OF EARTH WITH THE LISS AND SHELI TENS™ ON OSTEOPOROSIS

I'm proposing the following changes to the Protocol ID #413. This is done with the approval of Dr. C Norman Shealy, Principal Investigator.

1) Instead of using the LISS and the SheLi TENS™ on the Ring of Earth, subjects will use only the SheLi TENS™ for electrical stimulation.
REASON: Initially, we thought using the SheLi TENS™ on Governing Vessel 20, the acupuncture point on the top of the head would be too strong a frequency and therefore not tolerated so we would use the LISS. However, once we received the SheLi TENS™ in November and tried them on ourselves, we found it was well tolerated. Using only the SheLi TENS™ provides a uniform frequency of Giga hertz and it makes the procedure much simpler for the subject doing the Ring of Earth intervention. So, instead of using 2 instruments with 3 leads each, now they use one instrument with 3 leads.

2) The population for the Study is reduced to 30 subjects in the experimental group and 30 subjects in the control group.
REASON: This number is adequate for a doctoral dissertation study. The other consideration is the increased expenses of the various laboratory and AccuDEXA measurements.

3) Dr. Shealy strongly suggested that I add to the Study Design, measurement of NTx i.e. cross-linked N-teleopeptide by obtaining a urine sample in the Screening Visit and at the end of the Study. Published clinical studies document and demonstrate that NTX provides the most responsive and specific indicator of the bone resorption process of all currently known markers.
REASON: Measuring NTx from a urine sample would be done by the Research Lab at Penn State University and based on the research that NTx is the most responsive and specific indicator for bone resorption, it conceivably could shorten the time necessary using the Ring of Earth daily from six months to three months.

Respectfully submitted,

Vera Borgmeyer, RN MA

#1 REPORT TO THE INSTITUTIONAL REVIEW BOARD

I apologize for being late in filing my first report. I completed revision of #413 Protocol and Informed Consent per recommendations from the IRB in their September, 2002 meeting. A copy is attached to this report.

The research study outlined in Protocol #413 began in December 2002. As of this date, seven individuals have been enrolled in the Study. The first 10 volunteers will be assigned to the experimental group per Dr. Shealy's instructions. There have been no untoward reactions or side effects reported by the subjects using the Sheli TENS™ on the Ring of Earth acupressure points.

Delayed enrolling in the project for the past two months has been due to my unavailability to screen with increased workload as Registrar. Active recruiting of subjects is now being done. We have had radio spots on KSMU, ads in the local newspaper and personal contacts.

Due to Dr. Shealy terminating the sale of Yinergy products, Yinergy Gel as the Magnesium Gel supplement can no longer be used. This will be substituted with a Magnesium supplement.

Report #2

 # 2 REPORT TO THE INSTITUTIONAL REVIEW BOARD RE PROTOCOL #413 ON THE USE OF THE SHELI TENS™ ON THE RING OF EARTH

As of this date, July 31, 2003, there are 22 subjects enrolled in my Research Study. Five individuals have completed the Protocol. I continue very actively to do screenings with eligible candidates. After Norm did radio spots and advertisements in our local paper, the News-Leader, I did 50-60 phone screenings to determine eligibility. Many did not qualify for the research due to being on osteoporosis and/or cardiovascular drugs. Recruitment has been slow during July. I did have one individual drop out prematurely. No untoward reaction reported due to the electrical stimulation. She said she had too much pain to do the intervention. She had a history of vertebralplasty. For the pain, she went to see her doctor who said she shouldn't be in Research and proceeded to put her on Fosamax.

Another participant refused to have blood drawn and urine collected. She was referred to me with the Bone Density done. She completed the protocol as a member of the Control Group.

I continue to brainstorm, look for willing candidates and recruits for my research. If you have suggestions, please let me know.

And so it is this July 31, 2003!!

Sincerely,

Vera M. Borgmeyer, RN, MA

Report #3

#3 REPORT TO THE IRB RE PROTOCOL #413 RESEARCHING THE EFFECTS OF STIMULATION OF THE RING OF EARTH WITH THE SHELI TENS™ ON OSTEOPOROSIS

Since my research study has been in progress for one year, I am resubmitting my protocol to the Expedited Institutional Review Board (IRB) for continued approval.

As of this date, nine women have completed the Protocol. Five out of the nine women decided to purchase the SheLi TENS™ unit. Dropouts totaled 3 during this first year of the Study. In summary: one individual had too much back pain to do the ROE daily; another woman I called to schedule final appointment said she "stopped doing the stimulation." She didn't bother to call me. She reported she didn't feel like doing it. My impression was she was very depressed and lacked the motivation to complete the Study. Finally, the third woman apparently completed most of the stipulations of being in the control group, except refused to give urine or allow me to collect blood and had no time to do the Final follow-up visit. No untoward reactions have been reported by the participants, due to electrical stimulation with the SheLi TENS™ to the Ring of Earth.

Presently, I have 15 participants in the active process of doing the research study. I have three additional volunteers who have had an initial phone screening with their initial AccuDEXA completed and are scheduled for a Screening Visit. I've had 12-15 individuals call re their interest but who did not qualify either because of being on drugs or the AccuDEXA scans proved they did not have osteoporosis.

There were several major changes that occurred during this first year of the Research. During the spring, due to Dr. Shealy terminating the sale of Yinergy products, Yinergy Gel as the Magnesium Gel supplement could no longer be used. I am now recommending Magnesium Taurate or the newly formulated Magnesium Gel. The other change this fall was losing our research office at 1211 East Woodland in Springfield, when the owner decided to rent the house. Screenings are now usually carried out at the Holos Research office in Fair Grove Missouri.

Recruitment continues to be a priority. Another press release was done in November and Norm wrote a series of letters to physicians in the local area. We plan to do spot announcements on KSMU radio during December. I also placed an ad in the Bolivar paper called The Herald-Free Press for the month of October. About two weeks ago, I spent a day personally canvassing health food stores, Senior Centers, Fitness Centers and Retirement Homes using flyers and personal exchanges to recruit subjects with osteoporosis. One encounter was interesting. I went to the Hammons Heart Institute and saw the Director, asking her to post my flyer in a public access area. She said she could not do that unless I was willing to submit my protocol to the IRB at St. John's Hospital. I assured her it had already been approved by an IRB and said "No Thank You" and dusted the dirt from my shoes.

For the December issue, I wrote an informative article for the Ozark Senior Living newspaper. I plan to submit an ad or article in the Women's Business magazine. Presently, I'm compiling a list of Retirement Residences and will explore whether I can do an educational session on Osteoporosis and at the end ask for volunteers for the research. The other population I plan to do a mailing is with Registered Nurses

and LPNs within a 30-50 mile radius. I requested a mailing list from the Missouri State Board of Nursing and I will extrapolate names according to zip codes. And so the recruiting efforts to discover sixty subjects for my research study goes on. With the Harmonic Concordance of this past month, I requested the assistance of four Higher Guides to gather willing subjects for Research Mission #413. And so it is on this gray winter November day in the year 2003.

Sincerely,

Vera M. Borgmeyer, RN, M.A.
November 25, 2003

Report #4

 # 4 REPORT TO THE IRB RE PROTOCOL #413 RESEARCHING THE EFFECTS OF STIMULATION OF THE RING OF EARTH WITH THE SHELI TENS™ ON OSTEOPOROSIS

I received approval for continuance of my Research Protocol on November 26, 2003. In December, my protocol had been in effect for one year and according to the Institutional Review Board rules, the protocol had to be resubmitted. The approval was given by the Expedited Review Board.

At present, I have the following statistics to report:

Subjects Enrolled:	**33**
# Completed Protocol:	**19**
Active Participants:	**14**
Dropouts:	**3**

I have 7 possible recruits, who are either going off of osteoporosis medications, getting their Pre-AccuDEXA scan or cogitating their entry into the Research. It is interesting to note also that at present, all my subjects are women. I have screened about 5 men but none of them qualified according to my entry criteria. In the statistics, I had 3 women drop out during the first year of my research. No untoward reactions have been reported by the participants due to using the electrical stimulation with the SheLi TENS™ on the Ring of Earth. I have had many favorable reports from the participants who have completed the study. Five women have purchased the SheLi TENS™ after completion of the research protocol.

Late in December 2003, Norm had me send off the lab work on the first 10 participants who had completed the osteoporosis research. Norm and I were pleased with the initial results. In general, 70% had a decrease in their urine NTx (Bone Marker) level that reflects an increase in bone density. With the AccuDEXA, 40% had a decrease in their t-score, which is what I was hoping; 40% had an increase in their t-score and 20% had no change. With the Calcitonin levels, 30% had an increase in Calcitonin level (Researcher's preferred direction); 30% had a decrease in their serum levels and 40% had no change. In the latter group, essentially they did not have enough to measure initially e.g. <1.0 pg/ml and after six months they stayed at that level. With our discussion of these results, we also came to a decision to modify Protocol #413 slightly with the following measures.

Calcitonin will be drawn Pre and Post **only** on the individuals randomized into the Experimental Group. Rationale for this change in the design of the research is that my hypothesis is that the stimulation of the Ring Of Earth affects the Calcitonin produced by the thyroid. The subjects in the Control Group are taking the nutritional supplements **only** and are not doing the stimulation with the SheLi TENS.™

As members of the control group finish the Protocol, that I offer them the opportunity to crossover into the Experimental Group.

With this report, I am submitting both of these changes to the Expedited IRB for their approval.

Recruitment continues to be my major priority. The march of my osteoporosis research continues. Some days I feel a bit weary because it is taking so long to recruit

sixty subjects. However, hope and determination prevail. It was such a good feeling to cross the halfway mile marker. Spot announcements on KSMU radio will be done from January 26 until April 21, 2004. I'm very grateful to Norm for making announcements on his one-hour radio show promoting health and wellness. Late in December, he started back with AM-KWTO and now does a one-hour show weekly, usually on Thursdays at 2 pm. He takes questions about health as listeners call in about issues and ways to treat imbalance with alternative measures. As a result, I've received an increased number of calls with inquiries for the project and continue my research process on my way to my dissertation.

Submitted on February 19, 2004 by

Vera M Borgmeyer

Report #5

 # 5 REPORT TO THE IRB RE PROTOCOL #413 RESEARCHING THE EFFECTS OF STIMULATION OF THE RING OF EARTH WITH THE SHELI TENS™ ON OSTEOPOROSIS

It is amazing that it is time for my 3-month report to the IRB concerning my Research! As of this date, I report the following statistics:

Total Subjects Enrolled: 39
Of Subjects Completed Protocol: 20 (Experimental = 15;Control = 5)
Active Participants: 19 (Experimental= 10; Control = 9)

Dropouts during this 3 months = 2 (total attrition # = 5)

It feels like I've had more screenings than the numbers reflect but those are the facts. I have 5-7 individuals "in process' either going off medications, getting their Pre-AccuDEXA or contemplating their decision to do the research. I've had inquires re my research from individuals in Chicago, Kansas, Santa Fe and the country of Mexico. Word is certainly in the airwaves. I've done many phone screenings and at least 7-9 did not qualify once they got their AccuDEXA Scan.

I'm reporting 2 dropouts. When I called one individual to schedule final follow-up visit, she reported that she stopped doing the Protocol and refused to do the final visit. The other lady developed critical symptoms with her asthma and said she was seriously ill for weeks and unable to do the stimulation or take the supplements. To my knowledge, there were no untoward reactions in either case due to the electrical stimulation with the SheLi TENS.™

I continue to follow-up on any referral I receive and I do regular check-ins with the individuals enrolled either by phone or e-mail to encourage all to cross the finish line and complete the protocol. Recruitment is my priority and my challenge. The spot announcements have ended on KSMU, however Dr. Shealy continues to advertise on his weekly "Wellness Program" on KWTO-AM each Thursday at 2 pm. Thanks so much Norm!

To end this report I'd like to share a healing vignette. Recently, on a Friday I was doing an osteoporosis screening session with an energetic woman in her 60's. As I was taking her health history, she shared she had a lump in her breast and was due for a biopsy the following Monday. I suggested when she got home that afternoon, to take a piece of flannel, saturate with castor oil, covering the area on the affected breast, wrapping with Saran inside her bra. "Oh," she said, "I'll wear it through the night also." She did so. When she went for her appointment the following Monday, the doctor found the lump so small that he cancelled her surgery. Could it be the castor oil effect? He decided to keep an eye on her and recheck her in a month and then again in 3 months. She was so excited in telling me the news! With this note of healing, I end my report!

Respectfully submitted,

Vera M Borgmeyer, HUGS student
May 21, 2004

Report #6

EFFECTS OF STIMULATION OF THE RING OF EARTH WITH THE SHELI TENS™ ON OSTEOPOROSIS

Time has passed so quickly this summer and I find it is time to file my 3-month report to the IRB concerning my Research! As of this date, I report the following statistics:

Total Subjects Enrolled: 49
Of Subjects Completed Protocol: 27 (Experimental 18; Control 9)
Active Participants: 22 (Experimental-16; Control-6)
Dropouts during this 3 months = 3 (total number = 8)

This summer I've had a steady pace of doing screenings for new subjects and follow-ups by phone or e-mail and the final follow-up on individuals who successfully complete the protocol. What a journey this has been and at the same time revealing with insights into human behavior.

Dr. C. Norman Shealy, my Principal Investigator for the Study consulted with me early on and strongly recommended that I adjust the Design of the Research Study in the following way: Set the original number for the Experimental Group in the Study at 32 (and for insurance you notice I have 34 enrolled with +2) and the Control Group to ½ the Experimental Group at 16. I concurred with his recommendation since this coincides with acceptable practice in scientific research. With this report, I am submitting my request for this slight change of design in my research for approval from the Expedited Institutional Review Board. With this approval, I will continue recruiting for at least two more subjects for the Control Group giving me a cushion of 1 in the event of dropout.

Above, I have indicated this last quarter that I had 3 dropouts. One individual after 2 weeks of doing the protocol suddenly decided to relocate. In July, I screened another senior lady, who was experiencing grief as a result of her spouse making his transition last February. I suggested a few measures for this process. The next morning she dropped off the equipment at Kim's office and announced she was moving to L.A. Another individual experienced serious health problems and discontinued the protocol on her own. Human behavior continues to reveal and unravel.

During this time and to my knowledge, there were no untoward reactions in any of my subjects using electrical stimulation with the SheLi TENS™ on the Ring of Earth.

This summer on July 29th and August 6th, we had a site visit by the FDA, investigating the Institutional Review Board (IRB). The material involved all protocols that had been submitted the last 3 years. My protocol was a primary focus as it was approved within that time frame. I understand after very careful scrutiny of my Protocol #413, it was found in excellent order. What an interesting process this is!!

Respectfully submitted,

Vera M Borgmeyer, HUGS ABD student
August 25, 2004

Report #7

#7 REPORT TO THE IRB RE PROTOCOL #413 RESEARCHING THE EFFECTS OF STIMULATION OF THE RING OF EARTH WITH THE SHELI TENS™ ON OSTEOPOROSIS

With this report, I'm asking for approval of continuance of my Research Protocol #413 from the Expedited Institutional Review Board! According to the Institutional Review Board rules, the protocol has to be resubmitted annually. I'm heading into my final stretch with my research so this should be my final request! To summarize the changes and adjustments in my Protocol for #413 they are:

Calcitonin will be drawn Pre and Post **only** on the individuals randomized into the Experimental Group.

As members of the control group finish the Protocol, I offer them the opportunity to crossover into the Experimental Group.

The Design of the Research Study was adjusted September 2004 in the following way: Set the original number for the Experimental Group at 32 and reduce the Control Group to 16.

TOTAL SUBJECTS ENROLLED: 49
#Of Subjects Finished: 34 (Experimental 20; Control 14)
Active Participants: 15 (Experimental 12; Control 3)
Dropouts during this 3 months: 3 (total number = 11)

On Tuesday, November 9, 2004 I sent a second batch of specimens to Penn State University for analysis of Serum Calcitonin levels and Urine NTx bone markers. It will be exciting to get these laboratory reports and do a further analysis of the results. I love data, so this will be like a holiday. My plan is to send the last batch sometime in February as my last subjects complete their protocol.

During these last three months and to my knowledge, there were no untoward reactions in any of my subjects using electrical stimulation with the SheLi TENS™ on the Ring of Earth. A number of my participants report an increased sense of well being as well as more energy and fewer bouts with even any minor illnesses while doing the osteoporosis protocol. May health and abundance prevail with all beings!!

Respectfully submitted,

Vera M Borgmeyer, HUGS ABD student
November 29, 2004

Report #8

#8 REPORT TO THE IRB RE PROTOCOL #413 RESEARCHING THE EFFECTS OF STIMUATION OF THE RING OF EARTH WITH THE SHELI TENS™ ON OSTEOPOROSIS

My quarterly report is being filed a little late due to complicating circumstances! I apologize. As of this date, I report the following statistics:

TOTAL SUBJECTS ENROLLED: 48
29 in the Experimental Group have completed Protocol
15 in the Control Group have completed the Protocol
ACTIVE participants: 2 (Experimental Group)
Dropouts during these 4 months: 3

Well, I've had to readjust dates for sending my last batch of specimens to Penn State University for analysis of Serum Calcitonin levels and Urine NTx bone markers. I will do this as soon as I can finish intake with my final participants, hopefully sometime in April.

During these last four months, I have had one untoward reaction reported by one of my subjects while using electrical stimulation with the SheLi TENS™ on the Ring of Earth. In December 2004, JP reported loss of vision! An eye specialist, who placed him on steroids to reduce swelling of the optic nerve, examined him. I immediately reported the incident to Dr. C. Norm Shealy, the Principal investigator who said to stop using stimulation to Governing Vessel 20 (on top of the head) suggesting slight adjustment of the acupressure points stimulated. I filed a report with Julie Penick, Acting Director of the IRB who in turn sent immediate notice of the incident to the Federal Drug Administration (FDA). I kept in close touch with JP and gave reports to Norm as I received them with careful documentation in his research chart. JP's vision starting improving by December 22, 2004 and he was more than all right with continuing the protocol. According to his eye doctor who diagnosed it as ischemic optic neuropathy, he will have a permanent defect in his left eye. He did have a normal MRI. JP continued to do the Ring of Earth and I did his final visit February 18, 2005 and Norm also saw him for consultation. After Norm's careful scrutiny of meds and treatment JP had been on, he felt this could have been an untoward effect of the medicine Lupron, an injection JP receives every 3 months. I checked with Julie to see if any further documentation was necessary for the FDA and she said no more was necessary.

Finally, I've had 3 research participants drop out of the Study. One was a farmer who opted to "take care" of other family rather than do self-care for osteoporosis! Another lady had completed the protocol as a "control" and wanted to do the crossover but developed inner ear problems after returning from Florida and the stimulation would cause dizziness even on the lowest setting. And the third participant even bought the unit on the initial screening but didn't follow through on the protocol! With Dr. Shealy's approval, the final number for the Experimental Group will be 30 and the Control Group 15 subjects. Human nature continues to be revealing! All in all I've had some great and conscientious research participants.

With the research component almost complete, my focus is on writing sections of my dissertation! And so it is.

Submitted by Vera M Borgmeyer RN ABD

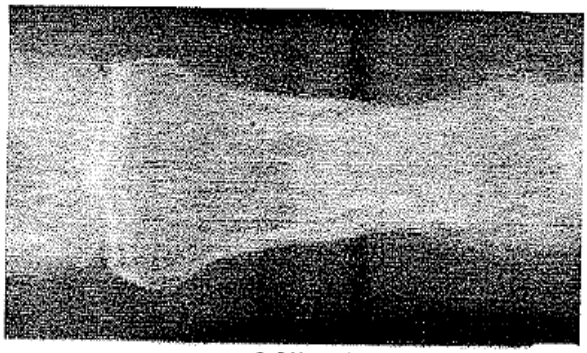
APPENDIX E
ACCUDEXA BONE DENSITY REPORT

accuDEXA BONE DENSITOMETRY REPORT

Date: *08/18/02 06:47 PM* Version 1.50 (01/09/01) NDB 1.1 Unit # 675T Sensor # 5509

Patient ID	77777
Gender	Female
Age	57 years
Ethnicity	Caucasian

Image not for diagnosis



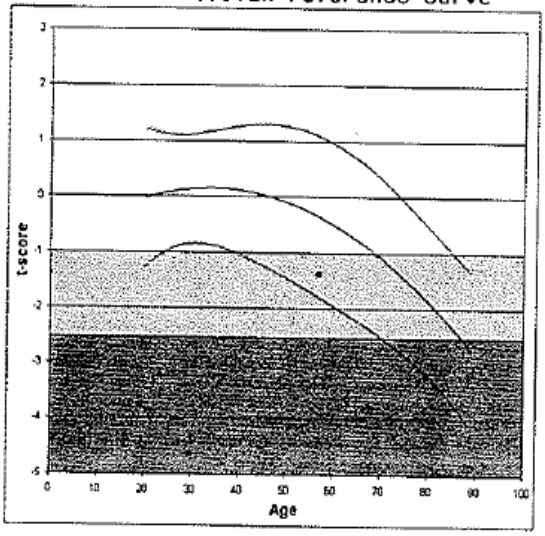
Calibration status: Passed

BMD Test Results

BMC	1.581 g
Area	3.597 cm²
BMD	0.440 g/cm²

z-score	-0.7	89%	Age-matched BMD
t-score	-1.4	86%	Relative to YHN
Analysis	Osteopenia		Based on WHO guidelines

Female Caucasian reference curve



Legend

t score	Analysis
t > 1	High BMD
1 ≥ t ≥ -1	Normal
-1 > t > -2.5	Osteopenia
t ≤ -2.5	Osteoporosis

SCHICK TECHNOLOGIES, INC.

Figure 11. Example of accuDEXA Bone Density Report.

APPENDIX F
DEMONSTRATION ROE FOR THE SHI-LI-TENS™ DEVICE

Holos Research Unit
5607 South 222nd Road
Fair Grove, Missouri 65648-8192

The Ring of Earth and the use of the SheLi TENS™ have been demonstrated to me. I feel comfortable using them for the Osteoporosis Research Study.

_____ _____

Subject Name Date

_____

Print Name

Demonstrated by: _____ _____

Date

September, 2002 vmb

APPENDIX G
EQUIPMENT AGREEMENT

HOLOS RESEARCH
5607 South 222nd Road
Fair Grove, MO 65619
417-267-4625

EQUIPMENT DISBURSEMENT AGREEMENT

Patient _____ Phone #_____

Address _____ DOB _____

_____

EQUIPMENT _____

Credit Card/Check #_____ Exp. Date _____/_____

C/C Holder Name _____

Date _____ Date Returned _____

AGREEMENT

The above-described equipment is being distributed to you for the purpose of the Research Study you are currently participating in. It is to be used as instructed within the Research protocol only. It is to be returned at the end of your participation in the Research Study in the same good working order as distributed. If you have any difficulty with equipment during the study, you must contact Holos Research at the above number as soon as possible.

To insure that the equipment is returned promptly at the end of your participation in the Research Study and in good working condition, a deposit of $250 or a credit card number is required. You will not be charged if equipment is returned upon completion of the Research Study and is in good working order.

Patient Signature _____ Date _____

Printed Name _____

Witness Signature _____ Date _____

Printed Name _____

APPENDIX H
OSTEOPOROSIS FRACTURE RISK ASSESSMENT

OSTEOPOROSIS FRACTURE RISK ASSESSMENT: Your Checklist

	Yes	No
I am 65 years of age or older.	____	____
I am Caucasian or Asian living in the U.S.	____	____
I am underweight or have lost weight since age 25.	____	____
I am physically inactive and rarely exercise.	____	____
I am weak; for example I cannot rise from a chair without using my arms.	____	____
I rank my overall health as poor.	____	____
I was taller than my peers at age 25.	____	____
I spend less than 30 minutes 3 times a week outdoors in the sunshine.	____	____
My resting pulse is 80 beats or more per minute.	____	____
I generally do not consume milk, yogurt or cheese every day.	____	____
I generally consume less than one serving / day of green leafy vegetables, (collards, Kale, broccoli, bok choy; dandelion greens, etc.	____	____
I eat meat, fish or other flesh foods more than once a day.	____	____
I regularly add salt to my food.	____	____
I use canned or packaged foods more than twice a day.	____	____
I use sugar or have sweetened foods more than twice a day.	____	____
I drink 2 or more cups of coffee, or 4 or more cups of tea or Chocolate daily.	____	____
I drink 2 or more colas or soft drinks daily.	____	____
I eat fast foods two or more times a week.	____	____
I presently smoke.	____	____
I used to smoke.	____	____
I have 2 or more alcoholic drinks per day.	____	____
I regularly use or have used steroids e.g. Prednisone over long periods of time.	____	____
I use anti-convulsant drugs such as Dilantin.	____	____
I use tranquilizers and mood-altering drugs.	____	____
I used Depo Provera for several years.	____	____
I use aluminum-containing antacids on a daily basis, e.g.Gelusil Rolaids, Mylanta, Maaolox	____	____
One of my parents fractured a hip.	____	____
I have documented low bone density (2.5 standard deviations below young normal values.)	____	____
I experienced a fracture after age 50.	____	____
In my vision, I have poor distance depth perception.	____	____
I have an overactive thyroid.	____	____
I am lactose intolerant or allergic to dairy products.	____	____

I have fallen in previous year.	____	____
There were times when my period stopped for many months (not including pregnancy, lactation or menopause.)	____	____
Menopause was naturally early (before age 43).	____	____
Menopause was surgically induced by ovary removal.	____	____
TOTAL	____	____

Each of these factors listed above may well be associated with the development of osteoporosis and an increased risk of osteoporotic fracture. The greater your numbers of yes answers, the more reason for you to begin a serious osteoporosis-prevention and bone-rebuilding program now. If you answered YES TO 4 or more of the bulleted items, or had a total of 10 or more yes answers overall, you are likely at high risk for an osteoporotic fracture at some point in the future.

(Adapted from: Brown, Susan. (1996). Better Bones, Better Body. Connecticut: Keats Publishing Inc.)

APPENDIX I
PAIN PROFILE

On the columns below, grade yourself (circle your choice):

Pain Intensity:	100 = intolerable, excruciating, horrible.																				
PAIN INTENSITY (SEVERITY)	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Physical Activity:	100% restricted = bed ridden. 75% restricted = up and about, but very little. 50% restricted = can't work, up and take care of myself, must rest frequently. 25% restricted = must rest every 4 to 6 hours, light work exhausts me, can't do fun activities. 0 = normal, I do any physical activity I choose.																				
DECREASE IN PHYSICAL ACTIVITY	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
PERCENT OF TIME PAIN FELT	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Effect on Mood:	0 = normal; 100 = totally withdrawn, panicked, overwhelmingly depressed.																				
EFFECT ON MOOD	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Drugs Consumed:	Doctor will do this. Mark all drugs you take on reverse side this page.																				
DRUGS CONSUMED	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Sexual Function:	0 = no activity; 100 = perfectly normal activity.																				
EFFECT ON SEXUAL ACTIVITY	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Overall Feeling of Well-being:	0 = terrible; 100 = best anybody could feel.																				
OVERALL WELL-BEING	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Overall Energy:	0 = can't get up or get going; 100 = most I've ever experienced.																				
OVERALL ENERGY	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100

NAME _____ DATE _____

APPENDIX J
SAMPLE DIARY NOTES FOR OSTEOPOROSIS RESEARCH

Holos Research Unit 5607 South 222nd Rd. Fair Grove MO. 65648
Principal Investigators: Dr. C. Norm Shealy and Vera Borgmeyer RN
Telephone: 417-267-4625 or 888-272-6109

CLIENT'S NAME: MVW

DATE:	DID RING OF EARTH		COMMENTS ON EFFECTS, PAIN, SUPPLEMENTS, ETC.
12-22-02	Yes	Walked	Took all rec. supplements! Continue on Iodine gtts. 20 daily.
12-23-02	"	"	"
12-24-02	"		" Christmas Eve preparations. I feel good!
12-25-02	"	"	" Happy Christmas Day with friends/family.
12-26-02	"	"	" No pain anywhere.
12-27-02	Yes	"	" Feel good!
12-28-02	"	Walked	"
12-29-02	Yes	No exercise.	" Did Ring of Earth late in day-didn't bother sleep.
12-30-02	"		Really felt electrical stimulation in the toes! Using affirmation.
			Took supplements.
12-31-02	Yes	Walked	Took all rec. supplements + started Eyebright for my eyes.
1-1-03		"	" " Did ROE late @ 6:30 pm.
1-2-03		"	" " Good day.
1-3-03		"	" "
1-4-03		"	" Poor night of sleep; ate late. Now taking Boron 5mg. Daily.
1-5-03		"	" " Studied today! Mentally attuned.
1-6-05		"	" "
1-7-03		"	" " Early morning temperature 97! Continue Iodine.
1-8-03		"	" "
1-9-03	No		I forgot and remembered too late! Took supplements.
1-10-03	Yes	Walked	Took all rec. supplements. Really felt electrical stim. in my feet.
1-11-03	"	"	" Had large intestine action with > bowel movements.
1-12-03	"	"	" Did morning meditation after bath.
1-13-03	"	"	" Really felt ROD in my feel & all over. Awesome!!
1-14-03	"	"	" Distracted times; Sleep really sound.
1-15-03	"	"	" Did ROE right before HS. Great night of sleep.
1-16-03	"	"	" I did ROE early on this snowy morning. >Feeling.
1-17-03	"	"	"
1-18-03	"		" Worked 3 hrs cleanup. Good energy.
1-19-03	"	"	" > sensation while doing ROE with SheLi TENS™.
1-20-03	"	"	"
1-21-03	"	"	" Felt a lot of sensation in abdomen. Took 2 Aleve.

APPENDIX K
SCREENING FORM

HOLOS INSTITUTES OF HEALTH RESEARCH UNIT

SCREENING VISIT FOR PROTOCOL #413 ON OSTEOPOROSIS

Visit Date: _____ Intake Person: _____

Patient Name: _____ Date of Birth: _____Age: _____
Address: _____
Home Telephone: _____; Work phone: _____
e-mail_____

NEXT OF KIN: _____
Their Tel. Or address_____

SEX: _____Female Race: (circle)
_____Male White Black Asian Indian Oriental Other
Employment: (Circle)
Paid Student Volunteer Homemaker Retired Other

VITAL SIGNS:
Oral Temp. ___ F; Pulse___ beats/min. Resp._____ Sitting B/P: _____
Height: _____ Weight: _____lbs. Eligible for Liq. Iodine: _____
ALLERGIES: _____
DIET (Current)_____
EXERCISE: _____

CURRENT MEDICATIONS: _____
_____
_____
NUTRITIONAL SUPPLEMENTS & DOSAGES: _____

SIGNIFICANT HEALTH CHALLENGES: (Diabetes; Hypertension; CHD)

EXCLUSION CRITERIA:

____Has pacemaker or any implanted device.
____Thyroidectomy
____Taking Calcitonin spray or injections.
____Taking Fosmax or any Osteoporosis drug, Miacalcin, Steroids, Ipriflavone, Vitamin K, any B/P or Cardiovascular drugs including channel blockers or Synthetic Estrogen hormones.
____Smokers.

INCLUSION CRITERIA:

___Subjects must have a Bone Density test with a diagnosis of osteoporosis.
___Subjects will be in reasonably good health.
___Subjects taking Natural Progesterone cream as long as they have been using it for at least three months.
___Subjects will show willingness to participate by signing Informed Consent Form.
___Subject will show ability and state willingness to follow the directions of the Principal Investigator and the research staff.

PERTINENT PHYSICAL FINDINGS: _____

_____

_____

_____

SYMPTOM: ____PAIN ANALOG: _____RISK FACTOR SURVEY: ___

CONSENT SIGNED: _____EQUIP. AGREEMENT_____DEMO.SIGNED_____

RING OF EARTH DEMONSTRATED & DONE_____BY WHOM: _____

SERUM DRAWN FOR CALCITONIN: _____FASTING: ___; NON: ____

Date & Time

URINE FOR NTX_____

_____ DATE: _____

RN Signature

November 2002

APPENDIX L
SUPPLEMENTS DETERMINED TO BE TAKEN FORM

SUPPLEMENTS DETERMINED BY C. Norm Shealy, M.D TO BE TAKEN DURING OSTEOPOROSIS RESEARCH

The following to be determined by your weight!

MULTIVITAMIN _____
Dr. Shealy's Essentials: 90-110 lbs-2 daily; 111 to 130 lbs 3 tabs daily & above 4! If one takes the Essentials + the Youth Formula + Calcium Citrate with Vit. D, then that is all that is necessary for the Research.

VITAMIN C _____
At least 2 Grams daily!

CALCIUM CITRATE W/ VITAMIN D_____
1200-1500 mg per day

VITAMIN B6 or COMPLEX_____
B6 at least 100 mg daily!

BORON_____
4mg daily!

FOLIC ACID (B-Vitamin)_____
800-mcg daily!

MAGNESIUM GEL Use 2 teaspoons twice a day on the skin
Or Magnesium Taurate 250-375 mg daily at night.

MANGANESE_____
5-7 mg daily

COPPER_____
1.5 to 3 mg daily

ZINC_____
12 to 15 mg daily

Thank you for your cooperation!
Vera Borgmeyer, RN Research Nurse 12-6-2002

APPENDIX M
SYMPTOM INDEX

Name: _____ Date: _____

When people are chronically ill, they often have other symptoms. Do you have any of the following? PLEASE CHECK ONLY THOSE THAT YOU HAVE NOW OR HAVE HAD WITH YOUR CURRENT ILLNESS.

_____ Depressed mood.
_____ Loss of interest or pleasure in things you used to enjoy.
_____ Significant weight change (loss or gain).
_____ Frequent eating between meals.
_____ Insomnia.
_____ Hypersomnia.
_____ Sleep walking.
_____ Agitation.
_____ Sluggishness, slow to function.
_____ Fatigue, low energy, feeling tired a lot of the time.
_____ Feelings of worthlessness or guilt.
_____ Difficulty concentrating, thinking, and remembering.
_____ Indecisiveness.
_____ Recurrent thoughts of death or suicide.
_____ Suicide attempts.
_____ Nervous exhaustion
_____ Worrying excessively or being anxious.
_____ Frequent crying.
_____ Being extremely shy or sensitive.
_____ Lumps or swelling in your neck.
_____ Blurring of vision.
_____ Seeing double.
_____ Seeing colored halos around lights.
_____ Pains or itching around the eyes.
_____ Excess blinking or watering of the eyes.
_____ Loss of vision.
_____ Difficulty hearing.
_____ Ear ache.
_____ Running ear.
_____ Buzzing or other noises in the ear.
_____ Motion sickness.
_____ Teeth or gum problems.
_____ Sore or sensitive tongue.
_____ Change in sense of taste.
_____ Nose stuffed up.

_____
_____ Runny nose.
_____ Sneezing spells.
_____ Frequent head colds.
_____ Bleeding from the nose.
_____ Sore throat even without a cold.
_____ Enlarged tonsils.
_____ Hoarse voice even without a cold.
_____ Difficulty or pain in swallowing.
_____ Wheezing or difficulty breathing.
_____ Coughing spells.
_____ Coughing up a lot of phlegm.
_____ Coughing up blood.
_____ Chest colds more than once a month.
_____ High blood pressure.
_____ Low blood pressure.
_____ Heart trouble.
_____ Thumping or racing heart.
_____ Pain or tightness in the chest.
_____ Shortness of breath.
_____ Heartburn.
_____ Feeling bloated.
_____ Excess belching.
_____ Discomfort in the pit of your stomach.
_____ Nausea.
_____ Vomiting blood.
_____ Peptic ulcer.
_____ Change in appetite.
_____ Digestive problems.
_____ Easy burning skin.
_____ Dizziness or light-headedness.
_____ Feeling faint or fainting.
_____ Numbness in any part of your body.
_____ Cold hands or feet even in hot weather.
_____ Paralysis.
_____ Blacking out.
_____ Fits, convulsions, or epilepsy.
_____ Change in your handwriting.
_____ Tendency to shake or tremble.
_____ Tendency to be too hot or too cold.
_____ Sweating more than usual.
_____ Hot flashes.
_____ Being short of breath with minimal effort.
_____ Failure to get adequate exercise.
_____ Being overweight.
_____ Being underweight.

_____
_____Having lost more than half your teeth.
_____Bleeding gums.
_____Badly coated tongue.
_____A lot of small accidents or injuries
_____Varicose veins.
_____Headaches.
_____Other aches or pains.
_____Feeling pessimistic or hopeless.
_____Have had any kind of surgery within the past year.
_____Being upset easily by criticism.
_____Having little annoyances get on your nerves and make you angry.
_____Getting angry easily.
_____Getting nervous around strangers.
_____Feeling lonely.
_____Having difficulty relaxing.
_____Being troubled by frightening dreams or thoughts.
_____Being disturbed by work or family problems.
_____Excess hunger.
_____Getting up frequently at night to urinate.
_____Urinating more than 5-6 times a day.
_____Unable to control your urine.
_____Burning or pains when you urinate.
_____Black, brown, or bloody urine.
_____Constant urge to urinate.
_____Constipation.
_____Diarrhea.
_____Black or bloody bowl movement.
_____Grey bowl movement.
_____Pain when you move your bowels.
_____Bleeding from your rectum.
_____Stomach pains which double you up.
_____Frequent stomach trouble.
_____Intestinal worms.
_____Hemorrhoids.
_____Yellow jaundice.
_____Biting your nails.
_____Stuttering or stammering.
_____Any kind of problem with your genital or sexual organs.
_____Sexual problems.
_____Hernia or rupture.
_____Kidney or bladder disease.
_____Stiff or painful muscles or joints.
_____Swelling joints.
_____Pain in your back or shoulders.
_____Painful feet.

_____
_____ Swelling in your armpits or groin.
_____ Trouble with swollen feet or ankles.
_____ Cramps in your legs at night or with walking.
_____ Itching or burning skin.
_____ Excess bleeding from a small cut.
_____ Wishing that you could get psychological or psychiatric help.
_____ Being tense or jittery.
_____ Being easily upset.
_____ Being in low spirits.
_____ Being in very low spirits.
_____ Believing that your life is out of your hands and controlled by external forces.
_____ Feeling that life is empty, filled with despair.
_____ Having no goals or aims at all.
_____ Having failed to make progress towards your life goals.
_____ Feeling that you are completely bound by factors outside yourself.
_____ Feeling sad, blue, or down in the dumps.
_____ Feeling slowed down or restless and unable to sit still.
_____ Being confined to bed by illness.

For men only:
_____ Having urine stream that is very weak or very slow.
_____ Having prostate trouble.
_____ Having unusual burning or discharge from your penis.
_____ Having swelling or lumps in your testicles.
_____ Having your testicles painful.
_____ Having trouble getting erections (getting hard).

For women only:
_____ Having trouble with your menstrual period.
_____ Bleeding between your periods.
_____ Having heavy bleeding with your periods.
_____ Getting bloated or irritable before your periods.
_____ Taking birth control pills (in the last year).
_____ Having lumps in your breasts.
_____ Having excess discharge from your vagina.
_____ Feeling weak or sick with your periods.
_____ Having to lie down when your period starts.
_____ Feeling tense and jumpy with your periods.
_____ Having constant hot flashes and sweats.
_____ Have had a hysterectomy or on hormonal replacement.

APPENDIX N
RAW DATA

The following tables (Table 11 through Table 16) contain the raw pre- and post-intervention test measurements.

Test Subject	Pre	Post	Control Subject	Pre	Post
CC	10	12	AE	16	7
VB	4	2	IJ	14	13
DJ	10	5	CK	1	1
JJ	11	2	LS	10	5
JM	5	12	HK	8	10
TM	3	3	OO	16	2
MS	29	14	SP	0	4
CS	23	20	Emc	0	0
AT	10	2	PO	17	14
KU	3	6	ED	16	10
PW	20	20	JH	7	4
JS	20	15	AS	8	10
JG	4	3	GH	4	2
BH	4	5	BA	10	1
SZ	6	9	NS	20	1
PR	21	10	N=15		
TT	15	9			
JI	13	18			
PZ	18	4			
HW	8	13			
DD	2	3			
CSc	29	12			
CP	12	4			
MP	27	32			
JP	14	14			
MG	15	15			
ED	10	3			
OO	2	2			
SC	28	11			
TZ	4	8			
N=30					

Note:
Best plan is that the number of symptoms decreases.

Table 11. Raw Data - Symptom Index.

Test Subject	Pre	Post	Control Subject	Pre	Post
CC	-2	-1.3	AE	-2.2	-1.9
VB	-1.4	-1.6	IJ	-1.5	-1.4
DJ	-1.2	-1	CK	-3.1	-3.3
JJ	-3.4	-3.2	LS	-1.8	-1.9
JM	-1.3	-1.3	HK	-1.2	-0.6
TM	-1.4	-1.4	OO	-2.9	-2.8
MS	-1.4	-1.7	SP	-1.7	-1.5
CS	-2.1	-2.7	Emc	-2.7	-2.6
AT	-1	-0.7	PO	-2.1	-1.8
KU	-2.9	-2.8	ED	-1.8	-1.8
PW	-1.7	-1.6	JH	-2.5	-2.5
JS	-2.8	-2.6	AS	-1	-1.7
JG	-1.4	-1.3	GH	-1	-0.9
BH	-1	-1.2	BA	-1.2	-1.5
SZ	1.4	0.2	NS	2.8	-2.8
PR	-2.9	-2.5			
PT	-1.3	-1.5			
JI	-1.4	-1.6			
PZ	-3	-3.3			
HW	-3.1	-2.9			
DD	-0.3	-0.3			
CS	-1.3	-1.2			
CP	-2.3	-2.2			
MP	-1.1	-0.6			
JP	Spine -2.5	-1.7			
MG	-2.4	-2.3			
ED	-1.8	-1.9			
OO	-2.8	-2.7			
SC	-0.5	no data			
TZ	-3.3	-3.5			

Note:

t > 1 => High BMD

t = +1 to –1 => Normal

t = -1 to –2.5 => Osteopenia

t >= 2.5 => Osteoporosis

Table 12. Raw Data - Dexa Scores.

Test Subject	Pre	Post	Control Subject	Pre	Post
CC	65%	40%	AE	35%	45%
VB	10%	15%	IJ	0%	15%
DJ	25%	15%	CK	0%	0%
JJ	20%	0%	LS	30%	15%
JM	0%	5%	HK	0%	5%
TM	0%	0%	OO	15%	0%
MS	30%	60%	SP	0%	0%
CS	40%	60%	Emc	0%	10%
AT	30%	1%	PO	25%	5%
KU	0%	25%	ED	45%	10%
PW	10%	25%	JH	70%	0%
JS	10%	15%	AS	40%	5%
JG	15%	25%	GH	0%	0%
BH	25%	20%	BA	25%	0%
SZ	0%	25%	NS	5%	0%
PR	25%	5%	N=15		
TT	10%	30%			
JI	15%	50%			
PZ	90%	0%			
HW	20%	10%			
DD	2%	5%			
CSc	4%	25%			
CP	20%	0%			
MP	15%	50%			
JP	70%	5%			
MG	60%	25%			
ED	10%	0%			
OO	0%	0%			
SC	35%	45%			
TZ	0%	45%			
N=30					

Table 13. Raw Data – Pain Level (%).

Test Subject	Pre	Post	Control Subject	Pre	Post
CC	15	22.6	AE	38.9	52.5
VB	81.6	66.7	IJ	63	70.2
DJ	79.9	77.3	CK	67	66.2
JJ	56.4	50.3	LS	32.7	75.9
JM	46.8	98.1	HK	96.3	73.1
TM	93.4	79.3	OO	75.3	72.3
MS	65.3	68.8	SP	42.1	71.5
CS	88.4	84	Emc	65.5	80.8
AT	71.2	77.2	PO	358.8	124.2
KU	55.8	132.8	ED	64.9	106.4
PW	52.9	53	JH	47.5	114.5
JS	40.2	73.4	AS	40.1	53.7
JG	70.2	44.6	GH	47.6	55.4
BH	23	44.5	BA	84.8	120.8
SZ	29.5	50.7	NS	25.7	4.2
PR	43.9	98.8	N=15		
TT	30.4	39.5			
JI	78.9	59.6			
PZ	108.6	93.5			
HW	37.9	71.3			
DD	35.7	66.2			
CSc	106.4	90.2			
CP	72.3	59.9			
MP	44.5	68.1			
JP[2]	15	22.6			
MG	81.6	66.7			
ED	79.9	77.3			
OO	56.4	50.3			
SC	46.8	98.1			
TZ	93.4	79.3			
N=30					

Notes:

1. Urine NTx Reference Range (nm BCE/mmol Creatine):
   Pre-menopausal: 20-60
   Post-menopausal: 25-65
   Male: 10-45
2. Only test subject JP was male.

Table 14. Raw Data – Urine N-teleopeptides (NTx) Bone Markers.

Test Subject	Pre	Post
CC	1	<1
VB	8.1	5.6
DJ	<1	<1
JJ	1	1
JM	<1	1
TM	<1	<1
MS	1	1.3
CS	1.2	<1
AT	<1	1
KU	<1	<1
PW	<1	<1
JS	10.2	9.6
JG	4.4	4.5
BH	1.1	<1
SZ	4.8	5.7
PR	6.3	<5[2]
TT	<1	2.2
JI	2.6	<1
PZ	<1	2.9
HW	<1	<1
DD	1.6	<1
CSc	<1	<1
CP	<1	1.2
MP	1.2	1
JP[3]	<1	<1
MG	1.7	2.1
ED	<1	<1
OO	<1	<1
SC	ND	ND
TZ	2.9	<1
N=30		

Control Subject	Pre	Post
AE	ND	ND
IJ	ND	ND
CK	ND	ND
LS	ND	ND
HK	ND	ND
OO	ND	ND
SP	ND	ND
Emc	ND	ND
PO	ND	ND
ED	ND	ND
JH	ND	ND
AS	ND	ND
GH	ND	ND
BA	ND	ND
NS	ND	ND
N=15		

Notes:

1. WNL Calcitonin:
   Female:< 14 pg/ml
   Male: < 19 pg/ml
2. Test subject PR post results were <5 for this test; results from a different lab were 13.0.
3. Only test subject JP was male.
4. "ND" = no data.

Table 15. Raw Data – Calcitonin Level.

Subject	Grp[1]	Symptom Index		Dexa		Pain		Urine NTx		Calcitonin	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
01 CC	1	10	12	-2	-1.3	65%	40%	56.8	60.4	1	<1
02 VB	1	4	2	-1.4	-1.6	10%	10%	112.2	51.2	8.1	5.6
03 DJ	1	10	5	-1.2	-1	10%	5%	36	30%	<1	<1
04 JJ	1	11	2	-3.4	-3.2	20%	0	101.9	34.3	1	1
05 JM	1	5	12	-1.3	-1.3	0%	5%	15	19.9	<1	1
06 TM	1	3	3	-1.4	-1.4	0%	0%	ND	ND	<1	<1
07 MS	1	29	14	-1.4	-1.7	30%	60%	81.6	66.7	1	1.3
08 CS	1	23	20	-2.1	-2.7	40%	60%	79.9	77.3	1.2	<1.0
09 AT	1	10	2	-1	-0.7	30%	1%	56.4	50.3	<1	1
10 KU	1	3	6	-2.9	-2.8	0%	25%	46.8	98.1	<1.0	<1.0
11 PW	1	20	20	-1.7	-1.6	10%	25%	93.4	79.3	<1.0	<1.0
12 JS	1	20	15	-2.8	-2.6	10%	15%	65.3	68.8	10.2	9.6
13 JG	1	4	3	-1.4	-1.3	15%	25%	88.4	84	4.4	4.5
14 BH	1	4	5	-1	-1.2	25%	20%	71.2	77.2	1.1	<1.0
15 SZ	1	6	9	1.4	0.2	0%	25%	55.8	132.8	4.8	5.7
16 PR	1	21	10	-2.9	-2.5	25%	5%	52.9	53	6.3	5
17 PT	1	15	9	-1.3	-1.5	10%	30%	40.2	73.4	<1.0	2.2
18 JI	1	13	18	-1.4	-1.6	15%	50%	70.2	44.6	2.6	<1.0
19 PZ	1	18	4	-3	-3.3	90%	0%	23	44.5	<1.0	2.9
20 HW	1	8	13	-3.1	-2.9	20%	10%	29.5	50.7	<1.0	<1.0
21 DD	1	2	3	-0.3	-0.3	2%	5%	43.9	98.8	1.6	<1.0
22 CSc	1	29	12	-1.3	-1.2	4%	25%	30.4	39.5	<1.0	<1.0
23 CP	1	12	4	-2.3	-2.2	20%	0%	78.9	59.6	<1.0	1.2
24 MP	1	27	32	-1.1	-0.6	15%	50%	108.6	93.5	1.2	1
25 JP[3]	1	14	14	-2.5	-1.7	70%	5%	37.9	71.3	<1	<1
26 MG	1	15	15	-2.4	-2.3	60%	25%	35.7	66.2	1.7	2.1
27 ED	1	10	3	-1.8	-1.9	10%	0%	106.4	90.2	<1	<1
28 OO	1	2	2	-2.8	-2.7	0%	0%	72.3	59.9	<1	<1
29 SC	1	28	11	-1.2		35%	45%	ND	ND	ND	ND
30 TZ	1	4	8	-3.3	-3.5	0%	45%	44.5	68.1	2.9	<1
31 AE	0	16	7	-2.2	-1.9	35%	45%	38.9	52.5	ND	ND
32 IJ	0	14	13	-1.5	-1.4	0%	15%	63	70.2	ND	ND
33 CK	0	1	1	-3.1	-3.3	0%	0%	67	66.2	ND	ND
34 LS	0	10	5	-1.8	-1.9	30%	15%	32.7	75.9	ND	ND
35 HK	0	8	10	-1.2	-0.6	0%	5%	96.3	73.1	ND	ND
36 OP	0	16	2	-2.9	-2.8	15%	0%	75.3	72.3	ND	ND
37 SP	0	0	4	-1.7	-1.5	0%	0%	42.1	71.5	ND	ND
38 Emc	0	0	0	-2.7	-2.6	0%	10%	65.5	80.8	ND	ND
39 PO	0	17	14	-2.1	-1.8	25%	5%	358.8	124.2	ND	ND
40 ED	0	16	10	-1.8	-1.8	45%	10%	64.9	106.4	ND	ND
41 JH	0	7	4	-2.5	-2.5	70%	0%	47.5	114.5	ND	ND

Subject	Grp[1]	Symptom Index		Dexa		Pain		Urine NTx		Calcitonin	
		Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
42 AS	0	8	10	-1	-1.7	40%	5%	40.1	53.7	ND	ND
43 GH	0	4	2	-1	-0.9	0%	0%	47.6	55.4	ND	ND
44 BA	0	10	1	-1.2	-1.5	25%	0%	84.8	120.8	ND	ND
45 NS	0	20	1	-2.8	-2.8	60%	25%	25.7	4.2	ND	ND

Notes:
1. Intervention Group = 1; Control Group = 0.
2. "ND" = no data.
3. Only test subject #25 (JP) was male.

Table 16. Raw Data - Summary.