Heart Rate Variability Enhancement Through Nanotechnology: A Double-Blind Randomized-Control Pilot Study

Thomas H. Budzynski, PhD
Helen K. Budzynski, PhD
Karl Maret, MD
Hsin-Yi (Jean) Tang, PhD

ABSTRACT. *Background*. The objective of this study was to test whether a proprietary nanotechnology skin patch produced for the purpose of increasing energy was also capable of modulating certain of the resonant frequencies of the body, promoting greater autonomic nervous system balance as reflected in heart rate variability (HRV).

Method. The study is a treatment-control design with researchers blinded to the assignment of subjects to either placebo or energy patch groups. The HRV measures were obtained prior to and 15 min after the patches had been applied. The HRV was measured with a BioCom HRV system. The measurements were obtained in a treatment room with participants resting in a lounge chair. Participants were solicited from volunteers who lived in the Poulsbo area.

Results. Analysis of the two groups indicated that when the experimental group HRV data were examined for pre–post differences, the low frequency/high frequency (LF/HF) ratio decreased significantly ($p < .01$, one-tailed t test), the very low frequency (VLF) decreased significantly ($p < .05$), the LF decreased ($p = .011$), LF norm decreased ($p < .05$), and HF norm increased ($p < .05$). It should be noted that the normalized LF and HF parameters represent relative values of each power component in proportion to total power minus the VLF component. This emphasizes the controlled and balanced behavior of the two branches of the autonomic nervous system. It tends to minimize the effect of change in total power on the values of LF and HF components (Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology, 1996). The control group, however, showed no significant pre-post changes in these parameters. Comparisons *between* energy and placebo patch groups reached statistical significance ($p < .05$) only in the VLF parameter.

Conclusion. These results suggest that LifeWave Energy Patches appear to act on the autonomic cardiovascular factors influencing heart rate variability in the hypothesized direction. This technology can be used to augment neurotherapy especially in cases characterized by chronic stress or fatigue factors.

Thomas H. Budzynski is Affiliate Professor, University of Washington, Seattle, Washington.
Helen K. Budzynski is Professor Emeritus, University of Washington, Seattle, Washington.
Karl Maret is President, Dove Health Alliance, Aptos, California.
Hsin-Yi (Jean) Tang is Assistant Professor, Seattle University, Seattle, Washington.
Address correspondence to: Thomas H. Budzynski, PhD, Box 357263, Seattle, WA 98195 (E-mail: tbudzyn@cs.com).

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INTRODUCTION

LifeWave Patches

The purpose of this study is to examine the effect of LifeWave patent-pending nontransdermal patches on heart rate variability in humans (Schmidt, 2006). LifeWave patches are a proprietary nanotechnology developed to enhance athletic performance by modulating the physiological functioning of muscle cells. It is claimed that this is achieved through an increased rate of fatty acid beta-oxidation, thereby enhancing muscular stamina and strength. This study was undertaken to see whether use of these skin patches has an effect on the cardiovascular system and autonomic nervous system, measurable by heart rate variability (HRV).

The manufacturer of this technology claims that LifeWave patches "contain orthomolecular compounds in water-based solutions designed to passively interact with the human thermomagnetic field with the purpose of creating a system of frequency modulation, much in the same way a radio wave is modulated to communicate audio information" (Schmidt, 2006). The inventor, David Schmidt, claims to have achieved this effect by treating L-amino acids and D-sugars in a proprietary manner and then packaging these solutions in nontransdermal polyethylene films to be worn in a specific arrangement on the human body. According to independent testing, no organic molecules of the proprietary formula of stereoisomers (isomeric molecules whose atomic connectivity is the same but whose atomic arrangement is different) are capable of migrating transdermally to the participants (Brown, 2006).

According to Haltiwanger (2007), who is now employed by the manufacturer, the patches increase the products of metabolism, namely, adenosine triphosphate, calcium, and acetylcholine release. The organic materials in the LifeWave sports patches are said to be specifically selected to match resonant and sympathetic frequencies of biological components involved in mitochondrial energy production. This is a new mechanism of action wherein specific stereoisomers dissolved in water exhibit liquid crystal properties. When they crystallize out of solution, they form nanoscale-sized crystals that act as semiconducting biomolecular antennas capable of interacting with the oscillating bioelectromagnetic field of the body (Nazeran, Chatlapalli, & Krishnam, 2005).

A large percentage of users of LifeWave patches typically remark on the subjective sense of increased energy, strength, and endurance, which can appear even at the first use of the patches. Some users notice that the patches seem to allay the effects of daily stressors. Increases in sports performance have been shown in studies carried out at several universities.

It is hypothesized in this study that these patches are capable of promoting a generalized balance of other organ systems of the body, specifically the cardiovascular and autonomic nervous system, measurable through changes in HRV. In 2005, Nazeran et al. reported effects on HRV of those patches in 2 individuals from a sample of 10 healthy volunteers, showing data obtained during six different rest and exercise conditions with and without energy patches. They found that compared to the placebo patch period, the low frequency/high frequency (LF/HF) ratio declined considerably after exercise and rest during the energy patch period. This would indicate that the energy patches offered a better balancing of HF parasympathetic activity and LF sympathetic activity (Nazeran et al., 2005). The Nazeran study, like this study, was supported by funds from LifeWave, Inc.

Electrical and Magnetic Activities of the Human Body

Bioelectric signals are generated in every cell, tissue, and organ of the human body.

Each cell has a potential difference across its cell membrane that is maintained by differences in concentration of ions on opposite sides of the membrane. Cells also have ion channels in their biological membranes, and tiny electric currents passing through single ionic channels have been able to be demonstrated through specific patch clamp methods. This patch clamp technique is a procedure in electrophysiology that allows the study of individual ion channels in cells. This has allowed bioelectromagnetism to be extended to molecular biology.

Biomagnetic signals were not detected until recently because of their extremely low amplitude. The first pure biomagnetic signal, the magnetocardiogram, was only detected in 1963 by Baule and McFee (1963). An inductive detector coil used to pick up the magnetic heart field needs a compensating identical coil with opposite series winding placed alongside to cancel common magnetic fields from external sources. A remarkable increase in magnetic sensitivity of biomagnetic measurements was obtained with the introduction of the Superconducting Quantum Interference Device (SQUID), working with a very low temperature generated by liquid helium (Cohen, 1972; Zimmerman, Thiene, & Hardings, 1970). SQUIDs have been used to measure magnetic fields of organs such as hearts and brains. Wikswo, Barach, and Freeman (1980) were the first to measure the extremely small magnetic field of a frog nerve bundle. The aforementioned studies demonstrate the difficulties associated with the measurement of extremely small biomagnetic fields in living tissue.

The body is sensitive to externally applied electromagnetic stimuli such as microcurrent electrical signals and low-intensity magnetic fields. The authors, as well as other researchers, have also manipulated electromagnetic stimuli such as light and sound to alter brain waves thereby influencing brain performance (Budzynski & Budzynski, 2000; Budzynski, Jordy, Budzynski, Tang, & Claypoole, 1999; Siever, 2002). Microcurrent and cranial electrotherapy stimulation have been used for control of pain, anxiety, depression, and insomnia (Kirsch, 2001). Microcurrent therapy has also been used effectively for reducing signs and symptoms of muscle damage (Lambert, Marcus, Burgess, & Noakes, 2002).

If the technology devised by Schmidt is capable of modulating the natural bioelectromagnetic field of the body, it may potentially be useful in the future health care approaches, specifically, a possible nondrug approach to alleviate the symptoms of stress and to increase athletic performance. The question is how can activation of other biological functioning, such as autonomic nervous system activity, be understood as a consequence of LifeWave's technology through externally applied patches?

According to a 2004 U.S. patent application (US2004/0057983 A1) filed by the inventor of the LifeWave technology, it is claimed that when optically active substances, such as levo-rotary molecules (e.g., the amino acid L-glutamine) and dextro-rotary molecules (e.g., sugar or D-glutamic acid) are worn in patches on the human body, they are capable of exerting a beneficial effect on the supposed thermomagnetic energy of the human body. The thermomagnetic effect, as it is normally understood, was discovered in 1820 by the Estonian German medical doctor and physicist Thomas Johann Seebeck. He found that certain dissimilar metals when joined in a closed loop and having one junction heated induced a magnetic field in the nonheated junction. Whether very small thermomagnetic effects are capable of being produced in living systems through small temperature differentials in different tissues is as yet unproven. Schmidt claimed in his patent application that hypothetical thermomagnetic fields from the human body can interact with stereoisomers present in the patches and induce beneficial resonance feedback effects. This mechanism of action has not been scientifically proven to date.

The Body's Biofield Regulatory Systems

There are other explanations of how LifeWave patches may affect the body.

Dr. James Oschman, a biophysicist, draws from Szent-Gyorgyi's (1968) suggestion that the proteins in the body are semiconductors. He quoted Szent-Gyorgyi in stating, "Molecules do not have to touch each other to interact. Energy can flow through the electromagnetic field.... The electromagnetic field, along with water, forms the matrix of life. Water can form structures that transmit energy" (Oschman, 2000, p. 60). Each component of the organism, even the smallest cell, is immersed in and generates a constant stream of vibratory information. Through energy therapies it is said that one can restore and balance the vibratory circuitry (Oschman, 2000).

All living systems can sense minute changes in their electromagnetic environment and have many biosensors that are near to being quantum sensitive (Smith, 1986). Human beings have demonstrated electromagnetic sensitivity to a wide range of both static and dynamic fields. This includes the earth's geomagnetic field and a wide variety of man-made electromagnetic radiation. Smith and Best (1989) demonstrated that sensitive individuals can respond adversely to very low level electromagnetic fields. In addition, there are many types of cellular resonances including low-frequency surface tension wave resonances and higher frequency membrane and microtubule resonances. Control systems in the body exist in complex feedback networks capable of being influenced by external and internal bioelectromagnetic fields. These enzymatic control systems are embedded in the complex regulatory control systems that operate in the connected tissue matrix. This has been described in detail by Pischinger and Heine (1991). They named these regulatory pathways in the connective tissue matrix the "ground regulation system." This regulatory system is capable of affecting other organ systems in the body such as the autonomic nervous system and cardiovascular system. These complex regulatory pathways might be another explanation for the reported effects of LifeWave patches.

Rhythm and Variability Within Body Systems

If we accept that there is a range of regulatory frequencies operative in various tissues or organs, then the question is how to understand the way vibrational activity operates in these systems. In fact, high variability of oscillations and the integrated physiologic activities of an organ, system, or complex of systems in the body is associated with healthy functioning. Variability represents the capacity for systems to alter in adaptation to environmental living conditions. Giardino, Lehrer, and Feldman (2000) referred to these moment-to-moment actions of living systems as oscillations. These oscillations within cells, body systems, or multiple interacting systems are self-regulating and responsive to demands whether for chemicals, energy, nutrients, or the dynamics of changing body functions. Whereas oscillations are rapid changes in body functioning, circadian rhythms are longer in time periodicities allowing for body rest and repair. These oscillations and rhythms operate within observed ranges. Outside of these ranges bodily systems can produce negative reactions with other interacting systems. Disease susceptibility, and ultimately dysfunctional disease states, show evidence that these oscillations and rhythms become less flexible and less variable. The goal for healthy functioning is to achieve flexibility and balance of functioning of interacting systems to restore and maintain adaptability.

HRV

An example of this concept of flexibility in health functioning can be demonstrated in a review of the cardiovascular system wherein the heart rate, circulatory pressure and flow, and peripheral resistance make constant adaptations in response to environmental challenges. One can trace the pathology of hypertension to obtain an insight on how, when exceeding and heightening the midpoint of the normal oscillations of the cardiovascular and neurochemical systems over an extended period, the integration is impaired. In the cardiovascular system, as in almost all other bodily systems, the autonomic system plays a major role in self-regulation. The two divisions of the autonomic nervous system, the sympathetic and parasympathetic, maintain the needed rate of blood flow through the variability in heart rate control. Thus flexibility in systems as measured by variability provides a concept for healthy functioning.

Over the last decade or so, a cardiovascular phenomenon called HRV has generated a great deal of research because of its strong identification with cardiovascular fitness. The parameter HRV is derived from the electrocardiograph signal. It reflects the fact that the heart rhythm is adjusted in the sinoatrial node by the sympathetic and parasympathetic nerves of the autonomic nervous system. In a healthy individual the heart rate speeds up when the person exhales and it slows during inhalation. If viewed on a computer screen, the cardiotach signal (which is a transformation of beat-to-beat interval time into a DC level) of a healthy, relaxed individual appears to be sinusoidal (rhythmically cyclical) and synchronized with the respiratory cycle. It is called the respiratory sinus arrhythmia.Young, healthy hearts may show as much as a 30 beat-per-minute peak-to-peak difference. Less healthy hearts will show lesser degrees of this sinusoidal waveform. The HRV thus can be seen as an indicator of overall health (Cowan, 1995; Odemuyiwa, 1995).

Measurement of Heart Rate Variability

The BioCom is a biofeedback system designed to quantify and feed back cardiovascular parameter information. The program performs a spectral analysis of frequencies derived from electrocardiograph tracings, providing measures of very low frequency (VLF), 0.0033 to 0.04 Hz; LF, 0.04 to 0.15 Hz; HF, 0.15 to 0.4 Hz; and total power, 0.0 to 0.4 Hz. The VLF is primarily an index of sympathetic activity, whereas the HF is representative of parasympathetic influence. The LF range is more complex, as it can reflect a mixture of sympathetic and parasympathetic activity (McCraty, Atkinson, & Tomasino, 2001). An ideal spectral value is 0.1 Hz, indicating a balance of the sympathetic and parasympathetic nervous systems as seen in healthy individuals when they are engaged in steady diaphragmatic breathing of approximately six beats per minute.

Biological factors such as age, gender, and ethnicity are known to affect HRV, as do a variety of health problems and medications. In general, as people age, HRV decreases after the 4th or 5th decade. Women tend to have lower LF values than men, although this difference disappears after midlife. Trained athletes have higher HRV than sedentary individuals. Another study showed that exercise training increased HRV in healthy older adults. Even patients with coronary artery disease with just 2 months of exercise training increased their HRV (Goldsmith, Bigger, Steinman, & Fleiss, 1992; Iellamo, Legramante, Massaro, Raimondi, & Galante, 2000).

A variety of analyses have been applied to the R–R interval (the interval between R waves in the QRS complex) to derive parameters that have correlated with a number of variables. There are two types of HRV measurement: time domain analysis and frequency domain analysis (power spectral analysis). Time domain focuses on the measurement of time intervals between R–R intervals, whereas frequency domain analysis separates the parasympathetic and sympathetic components of autonomic control. Frequency domain analysis involves two basic parameters of measurement: HF (0.15–0.40 Hz) and LF (0.04–0.15 Hz). In general HF values are related to vagal tone (parasympathetic). LF values are associated primarily with sympathetic neural activity. The ratio of LF/HF is a sensitive indicator of balance in the cardiovascular system.

In this study, the frequency domain parameters of HRV were dependent variables utilized to test the outcome of LifeWave energy patches on HRV cardiovascular functioning.

Pilot Data. Hypotheses for this study were derived from the results obtained from anecdotal clinical sessions wherein clients were tested with a baseline period and then again approximately 15 to 30 min after wearing the LifeWave energy patches. It was also observed that when clients thought about disturbing events, the VLF (sympathetic tone) increased in the HRV spectral display. The VLF decreased when relaxing scenes were imaged. At the same time, the HF (high-frequency parasympathetic tone) increased. When the LifeWave patches were applied, the VLF decreased as well, indicating to the investigators that some changes were being made in the LF/HF ratio. From these pilot data the following hypotheses were derived:

As a result of wearing the real patches:

1. LF/HF ratio will decrease, indicating better balance of stimuli to the heart.
2. VLF will decrease, indicating decreased input of sympathetic stimuli to the heart.
3. LF norm will decrease, using normalized figures to take into the account the total power that differed widely among individuals.
4. HF norm will increase, also normalized for the same reason as just stated.

It is expected that the control (placebo) group will show significantly less change in the hypothesized direction.

METHOD

Participants

Interested adults were sought from sign-up sheets at local health clubs and community centers. Forty adult participants were chosen and divided randomly into two groups of 20 participants each. The participant consent form was read and signed by each individual. Participants who were undergoing treatment for health problems of a serious nature were excluded as were any participants using beta blocker medications. The E group (who received the real LifeWave patches) had an average age of 49 and consisted of 9 women and 11 men. The C group (who were given the placebo patches) had an average age of 48 and consisted of 16 women and 4 men. Participants had the right to terminate their participation at any point in the procedure upon request.

Design

The study used double-blind and randomized control design. There were 5 min of HRV measured before the LifeWave energy or placebo patch application. Both experimental and control group had the left and right energy or placebo patches applied over the lung meridian (just below the location where the collarbone and the shoulder bone meet). Left and right patches refer to the fact that they contain proprietary formulas of biomolecular stereoisomers, which when dissolved in water exhibit liquid crystal properties. The white patches contain L-stereoisomers and the tan patches contain D-stereoisomers. The white patches have been found to be most effective when placed on the skin over acupuncture points that are electrically positive, whereas the tan patches are most effective when placed over negative acupuncture points. The experimenter was blinded as to whether he was giving out a placebo or real patch pair. After 15 min, the participants had their HRVs measured once more. Following this procedure each participant received 15 LifeWave energy patch pairs as a gift for their participation.

Procedure

BioCom, a biofeedback system designed to quantify and feed back cardiovascular parameter information, was used. The program performs a spectral analysis of frequencies derived from electrocardiograph tracings. An ideal spectral value is dominant at 0.1 Hz, indicating a balance of the sympathetic and parasympathetic nervous systems, as seen in healthy individuals when they are engaged in steady diaphragmatic breathing of approximately six beats per minute.

FIGURE 1. Mean and standard error (SE) low frequency (LF)/high frequency (HF) post-pre differences.

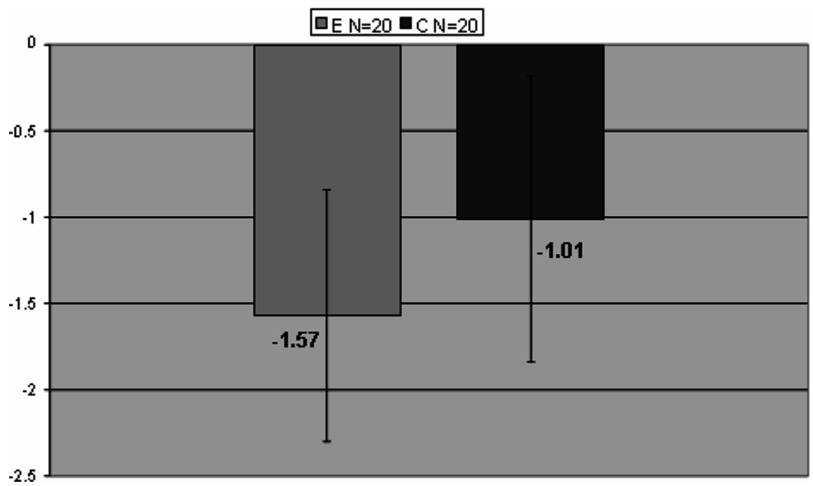
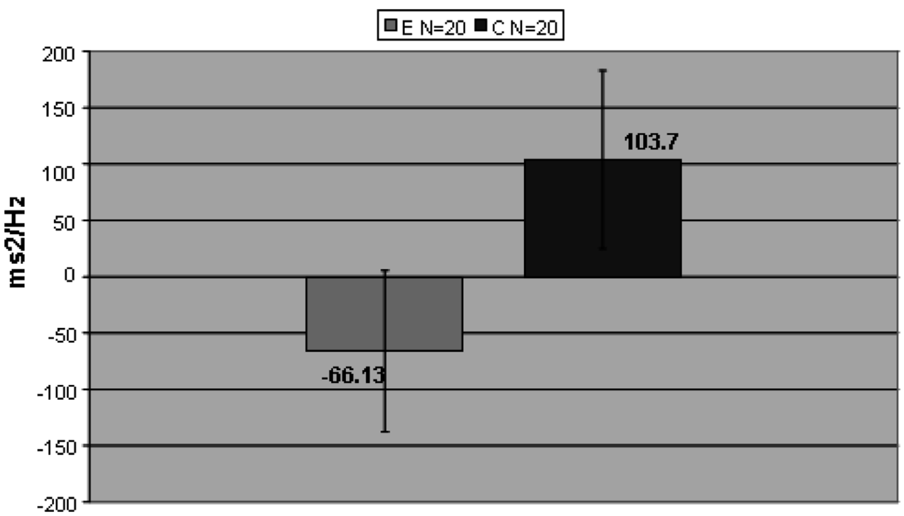


FIGURE 2. Mean and standard error very low frequency (VLF) post-pre differences.



Data Analysis

To see if patches appeared to produce a change in HRV parameters, the analysis included several paired sample *t* tests to determine pre–post differences for HRV parameters in each group. These pre-post differences for all parameters were then compared between the two groups. In addition, group means with standard errors and medians of each parameter were graphed (Figures 1–4).

Pre–post differences and between group differences were tested with *t* tests. Means and standard errors for each group are shown in Figures 1 to 4. Table 1 gives statistical results including median values for each group.

RESULTS

Post–pre results for all four frequency variables (LF/HF, VLF, LF norm, and HF

FIGURE 3. Low frequency (LF) norm mean and standard error post-pre differences.

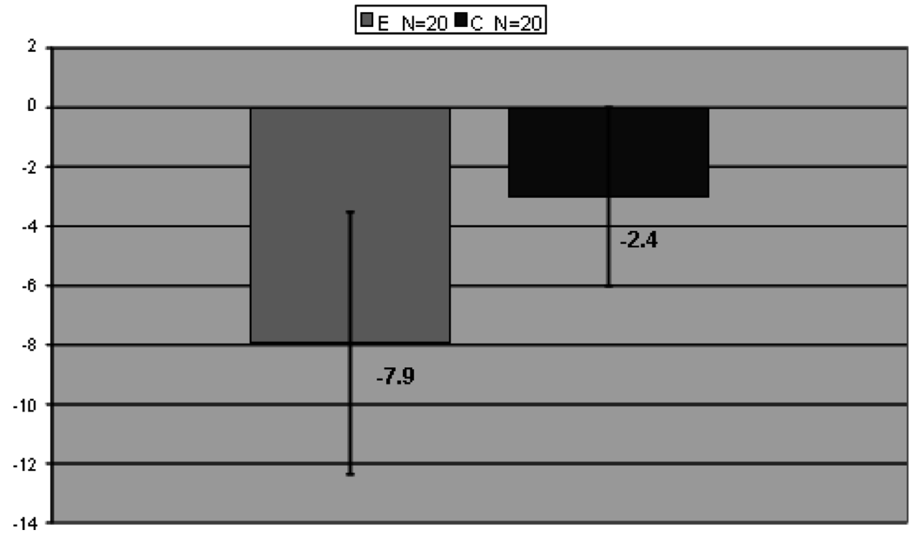
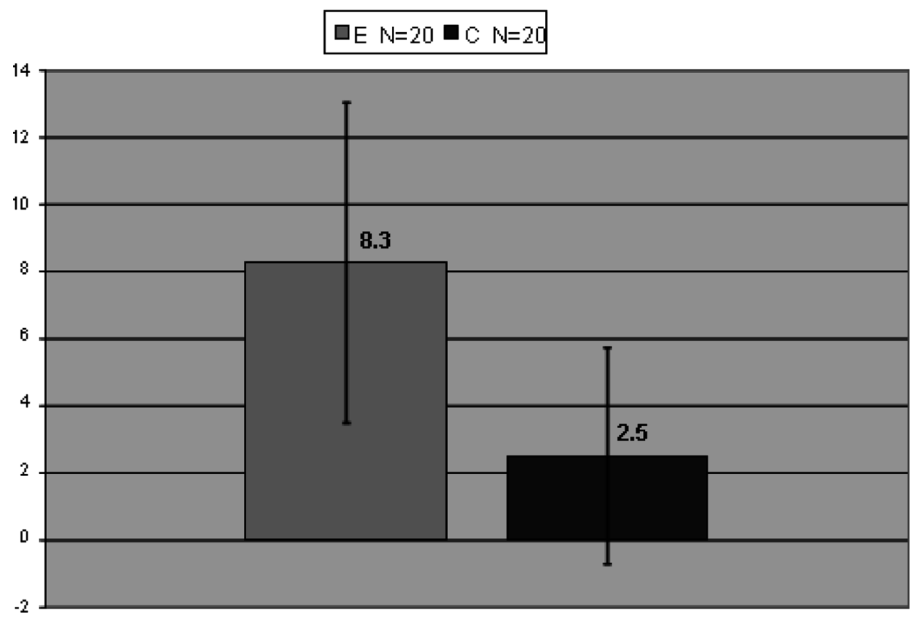


FIGURE 4. High frequency (HF) norm mean and standard error post-pre differences.



norm) were significant ($p < .05$) for the experimental group (see Table 1). However, post–pre data for the control group did not meet significance in any variable.

Comparisons of post–pre differences between groups showed significance only in the VLF parameter, that is, the VLF in the experimental group decreased significantly ($p < .05$) when compared to the control group. LF/HF, VLF, LF norm, and HF norm means and standard errors are shown in Figures 1 to 4.

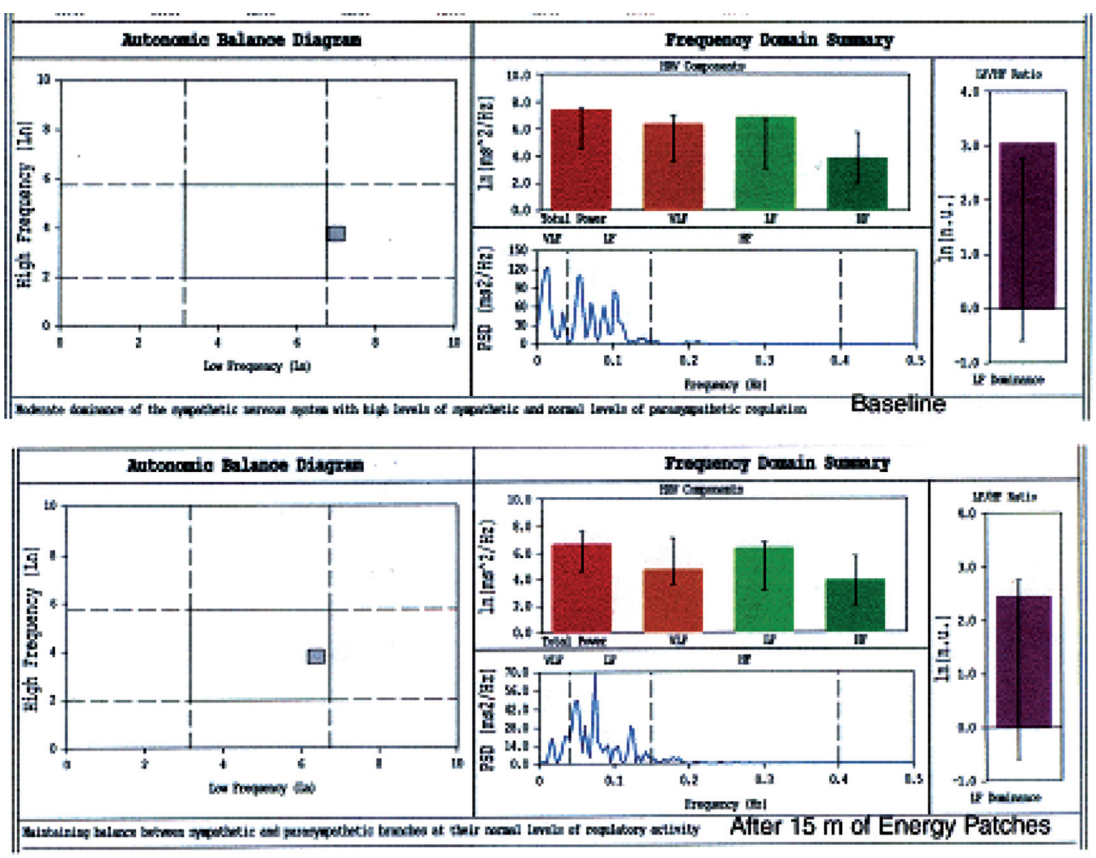
Figure 5 is a reproduction of the major part of the data sheet as generated by the BioCom program. A pre- and postsession are shown. Ideally, the small square should be located inside the center square. In this sample (drawn from a participant in the

TABLE 1. Summary of mean and median change in heart rate variability parameters.

	Experimental Group			Control Group		
	Pre	Post	*M* Change	Pre	Post	*M* Change
LF/HF						
M (*SE*)	4.8	3.2	−1.57 (0.73)	4.2	3.2	−1.01 (0.83)
Mdn	1.8	1.2	0.4	1.5	1.6	0.1
M (*SE*)	286	219.9	−66.00 (71.5)	287.7	391.5	+103.7 (79)
Mdn	235	127.1	−107.9	101	177.2	+76.2
LF norm						
M (*SE*)	61.2	53.3	−7.90 (4.4)	65.4	63	−2.4 (3)
Mdn	63.4	54.8	−8.6	61.5	64.2	2.7
HF norm						
M (*SE*)	38.8	47	+8.30 (4.8)	34.6	37.1	+2.5 (3.2)
Mdn	36.2	45.2	+9	38.5	35.9	−2.6

Note. LF/HF = low frequency/high frequency; VLF = very low frequency.

FIGURE 5. Partial BioCom data sheet.



experimental group) the square moves from a baseline outside the square to inside after the experimental patch period. The power spectral density units are msec squared/Hz. Note the computer-generated summary statement under each figure, that is, the *baseline* statement indicates sympathetic dominance, whereas the postexperimental period generates a computer software statement, "Maintaining balance between sympathetic and parasympathetic branches…." Note also the spike in the VLF portion (extreme left) of the power spectral density diagram at baseline and the fact that it is gone in the experimental period (after 15 min of wearing the LifeWave patches) in the bottom graph.

DISCUSSION

Lifewave Energy patches can result in a decrease of sympathetic drive to the heart. This may explain anecdotal reports from therapy clients that they feel less stressed when wearing them. Even though the between-group statistics did not prove to be significant in three of four of the variables, means and in particular medians showed definite trends in the hypothesized directions. The energy patches are now used in our clinic to help identify a sudden increase or decrease in anxiety or stress. For example, the VLF spike often appears during therapy sessions when a client experiences stress or anxiety. It tends to diminish or disappear when they relax.

Lifewave patches may serve to augment other therapy protocols including neurotherapy. It is suggested that future studies of this technology include other physiological measures in addition to HRV.

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