

IMPLICATIONS OF HEART RATE RHYTHM ANALYSIS FOR THE
STUDY OF LIFEWAVE PATCHES

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The purpose of this study is to test how effectively the analysis of the electrocardiogram can be used to detect changes in the human body when the Lifewave X15 nanotechnology patch is applied. Lifewave has developed a series of products based on nanotechnology in which very small particles are assembled as receiver-transmitter units in a “soup” of amino acids and d-sugar molecules. Using the thermal energy generated by the body these tiny units are designed to frequency modulate the thermal carrier thus producing small bioelectromagnetic signals which are tuned to affect selected cellular structures in the body. The particular patch under investigation here is a proprietary type of Lifewave patch which has been labeled the X-15.

The X15 and to earlier Lifewave products of this nature, are designed to passively interact with the human thermomagnetic field. By forming nanotechnology-sized crystallized semiconductors in the patches, there is created a solution capable of field modulation of certain specific frequencies, chosen by the inventor (Schmidt, 2006; Haltiwanger, 2004, 2005) for activating selected bodily functions such as increasing the output of adenotriphosphate (ATP) for mitochondrial energy production or formulating glutathione for increased antioxidant activity. A later section describes the manufacturing process more minutely so that readers can become aware that with the use of these patches, no substance enters the body, and the patch is clearly bioelectromagnetic in nature.

As a measurement to test the autonomic nervous system effects on the heart, the heart rate rhythm with a power spectral density (PSD) analysis allows the delineation of the sympathetic and parasympathetic nervous systems effects. Since the heart rhythm is well

known to be an indicator of total body health, the spectral components of the ECG are useful for testing subtle effects of a treatment.

The Rhythmic Body

The body is a rhythmic, vibrating system, whose cellular units generate a wide range of electromagnetic frequencies. These bioelectric signals are generated in every cell and tissue in the body and can be actively traced and differentiated from one bodily system to another. Recently, a spate of research, begun in 1963 by Bongham Kim and confirmed by others (in Lee, et al, 2004 and Shin et al, 2005; quoted Fujiwara & Yu, 1967; Cho, et al, 2004; Lee, et al, 2004; as other studies), has been able demonstrate that with the use of a special dye, they could show the presence of a structural network of the bioelectromagnetic system. This structural system is possibly the transport for conduction of the bioelectromagnetic flow throughout the body (Wijk, et al, 2007).

Whatever way might be the means by which the vibrations transmit bioelectric frequencies so as to conduct energy flow, the cellular systems and organs of the body do respond to minute specific frequency bio-signal changes in their environment. These systems constitute a regulatory mechanism with complex feedback networks involving enzymatic, chemical, and bioelectromagnetic discharges. Pischinger and Heine (1991) named these regulatory pathways in the connective tissue matrix the “ground regulation system” which is as capable of regulation as are other structural pathways such as the autonomic nervous and cardiovascular systems.

Heart Rhythm and its Variability

The heart rate and its variability can be reduced to time and frequency domain parameters often serve as a window to the general health of the body (Grossman, 1992). These tracings are expressive of both dynamic and cumulative loads, in that they can show sensitivity not only to the momentary stimulus from efferent/afferent peripheral pathways, but can indicate the effect from central vagal activity upon the heart sinus nodes. Many recent endeavors in research have been focused on the use of cardiac responses to test how they are

influenced by mental states, physiologic stress, drugs and health status. Thus, under laboratory conditions such as when applying a mental stimulus, the analysis can depict changes in vagal (parasympathetic) tone apart from changes in sympathetic tone (Kawachi & Allostasis Study Group of John D. and Catherine T. MacArthur Research Network, 1997). Also, under laboratory conditions, stimuli from the periphery of the body can be inferred when neural impulses from the brain are controlled.

One would think that these influences observed in cardiac responses could be parceled out quite independently. Yet, both vagal and sympathetic cardiac nervous systems are not functionally independent due to the neuronal complexity of the two systems in co-location and extensive modulation during cardiac activity (Ji, Gupta & Weiss, 2010). Furthermore, since all possible parameters in the body are not under control even in a laboratory controlled environment, the more feasible approach has been to examine the more interactive measures of heart rate variability, autonomic balance and parasympathetic (vagal) tone for depiction of effects on heart rate rhythm. In the next section, we will explore the intricacies of the various heart rhythm variables in relation to each other during a 5 minute tracing of the heart rhythm activity, including heart rate variability and autonomic balance.

Heart Rhythm Analysis Components

When tracings are made of the heart rhythm for a 5 minute interval and then subjected to an analysis of time and frequency changes over that interval, a number of measures can be elicited. All of these measures are not useful. Porges and Byrne (1992) noted that a long history in study of the neural modulation of the heart has laid bare any hope that one could instantly measure the neural modulation between the heart and the brain. Since heart rate is neurally mediated, then it should follow that monitoring of the heart rhythm would immediately reflect mental status, stress, emotions, attention and other manifestations in the brain. Not so. Too many mediating feedback loops arbitrate the response, creating multiple phasic increases and changes in oscillatory amplitude.

Then, since heart rate is continuously non-constant, but varies widely in frequency and amplitude within an interval of time, considerable interest has been drawn to accounting for

the variable nature of the heart rhythm. The evidence shows that in testing variability over a lengthy illness, the heart rate variability decreases under conditions of stress, illness, and age and increases during healthy states. A high heart rate variation shows that the heart displays a greater amplitude and capacity to respond when the heart signals the need. Nonetheless, heart rate variability as an intermediate level measurement of change may be questionable as a variable of interest in this study. It may be too general a measure for use to study a defined stimulus. Heart rate variability is complex. Of the multiple statistically defined measures of heart rate variability, none have been universally accepted. It has been granted by many researchers, however, that a 5 minute interval is generally as accurate for most purposes as is the 24 hour measurement.

Finally, in utilizing the Fast-Fourier analysis of the heart rhythm, another possible choice of variables is the vagal tone, a measure of high frequency (HF) rhythm to capture the parasympathetic contribution to the heart beat. The low frequency heart rate (LF) spectral component is predominantly sympathetically mediated although not completely free of vagal influence. Despite this confluence, change in the Low frequency/high frequency (LF/HF) ratio ought to reveal systematic differences in a pre-post test format. All told, *autonomic balance* may well trump *heart rate variability* as being more forthright as a response to a study measuring the effect of a bioelectromagnetic stimulus.

The X-15 patch

Early in the Twentieth Century, Dr. Albert Abrams used calibrated instruments to measure radiations from numerous areas of the body. He concluded that the body was composed of electromagnetic energy, eliciting differing frequencies and amplitudes from various organs and tissues. Frequencies of from .01 to 999 Hz with varying intensities of 20 to 600 microamps have been documented, producing a vibrational character to tissues (Young, 2005). David Schmidt, designer of the LifeWave patches, capitalized on this advancing knowledge by using nanotechnological processes to formulate the exact amino acid and d-sugar molecular structure necessary to flag the specific frequencies that he desired. The LifeWave patch, by tapping specific frequencies, act as antennae for the thermomagnetic activity of the

body and then the nanotransmitters modulate this “carrier” to the specific frequency required to activate the target cell. These tiny modulated signals become the catalyst for the increased production of such substances as ATP or glutathione.

The X-15 patch is the latest in a series of nontransdermal patches designed by David Schmidt. Each patch type was formulated to affect certain specific frequencies of the body. The details of the function of the X-15 Patch remain undisclosed until the patent-pending period is over. This study has been conducted to explore its possible effects on the cardiovascular and autonomic nervous systems.

It should be noted that in each generation of Lifewave patches the impermeability (nontransdermal) properties have been retained. The patches were studied by outside agencies to ascertain that there was no passage of any substances from the patch into the body (Brown, 2004). This was further validated by the UCLA laboratory and the USADA for the Olympic Board (USADA & UCLA Laboratory, 2004).

The Study Design and Procedure

The design of this pilot study was a single-sample, pre-post experiment in which 20 subjects were tested using the following procedure: The Biocom Heart Rhythm Scanner (1998-2009 Biocom Technologies) was used to measure the heart rhythm before and after the application of the X15 patch.

- a. Subjects were seated in a lounge chair and offered a bottle of water for hydration. A consent form was reviewed with the researcher and signed. The subject then filled out a form for demographic and health status information.
- b. An ECG sensor was placed on the middle finger of each hand and subjects were warned to try to remain still and also not to talk. When the ECG signal had stabilized a Baroreceptor Sensitivity test was first taken for 1 minute. The screen showed a ball which rose and fell in a 6 cycle pattern for use in training subjects in regular slow breathing. This exercise taught the subjects an efficient breathing pattern in the hope that the breathing variable would be controlled somewhat across subjects. A second test, the Autonomic Balance Test, then was administered for 5 minutes.

- c. An X-15 patch was then given to the subject to apply just below the umbilicus or at the base of the sternum. After a period of 10 minutes, the above test routine was repeated.

Analysis and Results of Study

The BioCom system generates a number of heart rate parameters among which are an Autonomic Balance score and an Autonomic Tonus score. The Autonomic Balance is the ratio between levels of the sympathetic and parasympathetic activity. The Autonomic Tonus is a net level of the sympathetic and parasympathetic activity. A predominant parasympathetic nervous system functioning is a state of relaxation, whereas a predominant sympathetic nervous system functioning is typical for stress or anxiety. A balanced autonomic nervous system functioning is indicative of an idle calm state. This autonomic ratio is expressed by LF/HF or the low frequency divided by the high frequency component.

We had hypothesized that the X15 patch would bring the autonomic nervous system more in balance. It appears that this result did occur as shown in Figure 1. The mean pre-post values were significantly different at the $p < 0.05$ one-tail level.

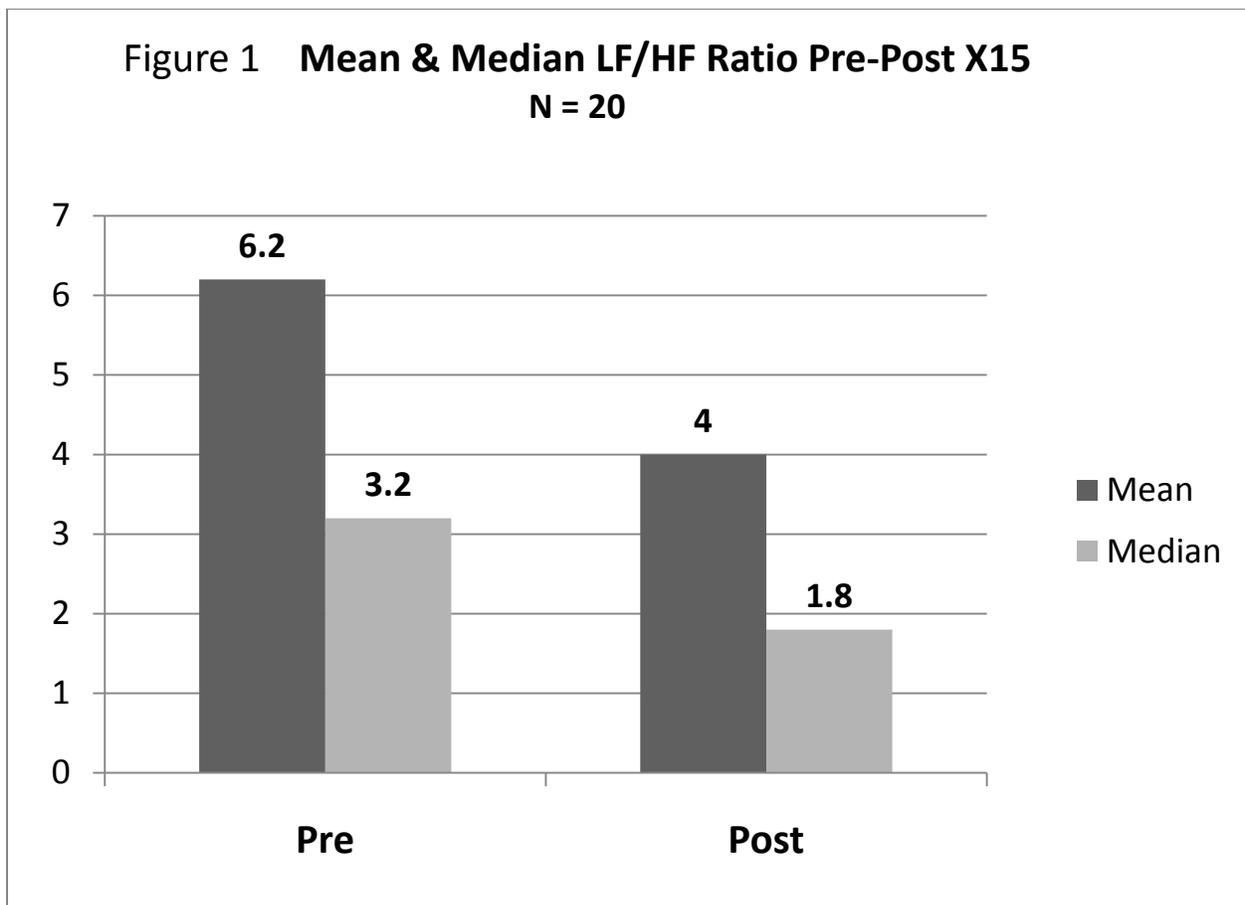
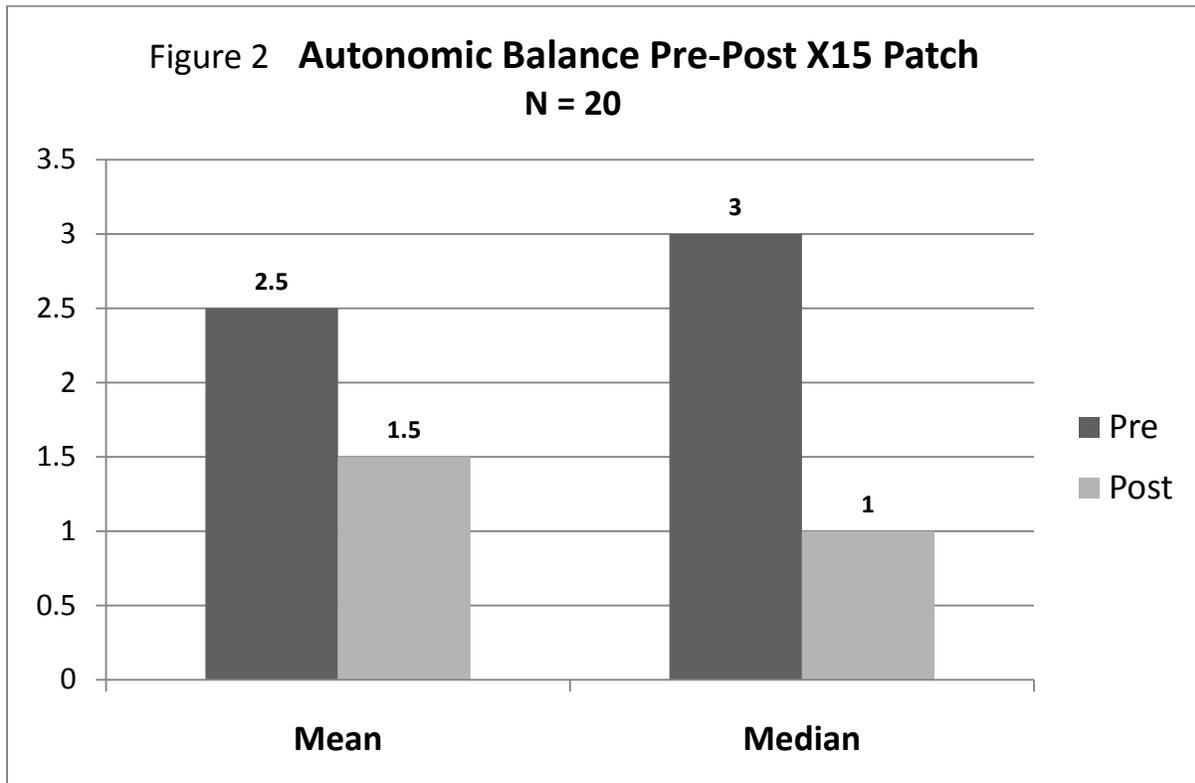


Figure 1 includes the median as well as the mean scores however, in both cases the LF/HF ratio has decreased in the post condition.

The Biocom system also calculates an Autonomic Balance score. It ranges from -10 points to +10 points. Negative points indicate parasympathetic predominance and positive points are indicative of sympathetic predominance. Biocom Technologies has conducted several studies in collaboration with East Carolina University (USA), City of Osaka University Medical School (Japan), and Nationale Institute of Biophysics (Russia). The purpose of these studies was to build a normative database for three HRV tests used in Biocom products. Over 630 subjects of both genders and ages ranging from 10 and 80 years old were tested. All subjects were screened by healthcare professionals to select those having no apparent health problems and not taking any medications. The study cohort included 266 males and 364 females. All test results were statistically analyzed and respective normative sets were built. The resulting normative database is a property of Biocom Technologies. In the present study each subject received an Autonomic Balance score based on their parasympathetic and sympathetic functioning.

Figure 2 shows the mean and medians for the pre-post Autonomic Balance using the X15 patch application. The pre-post mean data for the patch group are significantly different at the $p < 0.04$ level one-tail.

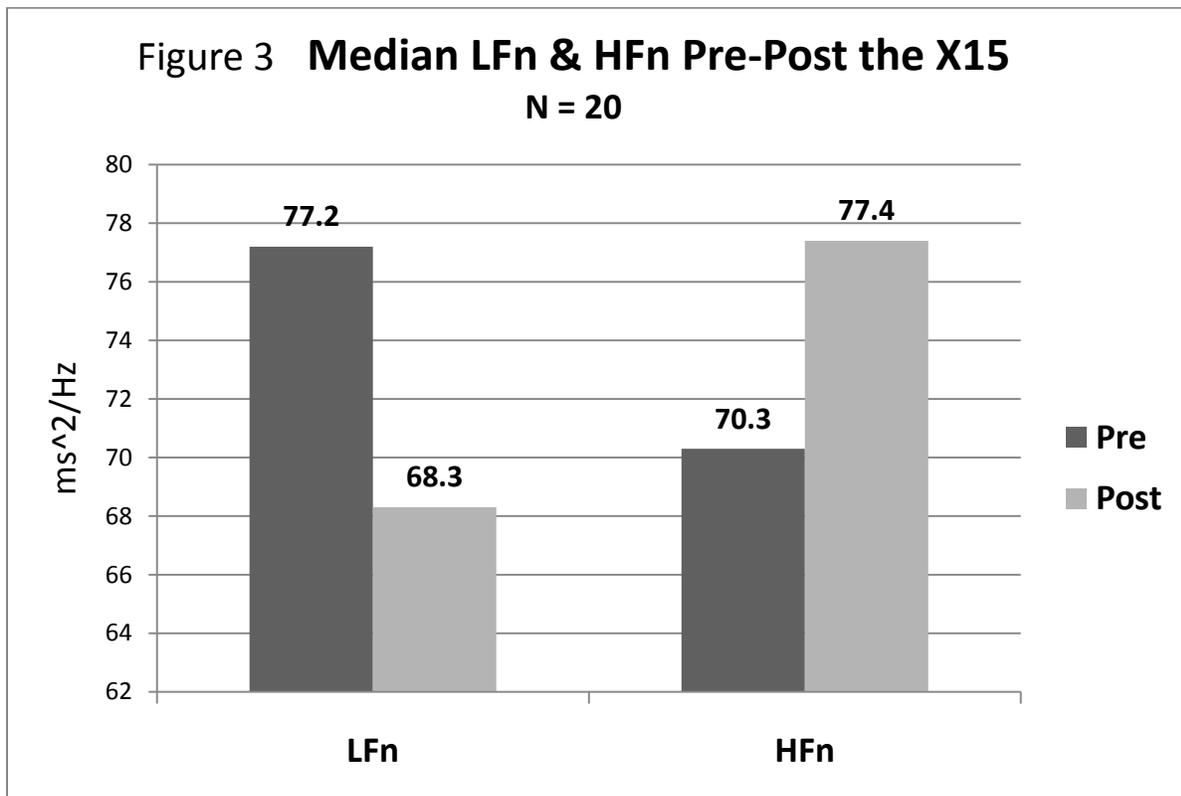


Like Figure 1, this separate method of calculating cardiac innervation balance shows the change towards balance as a result of the X15 influence.

Median LFn and HFn

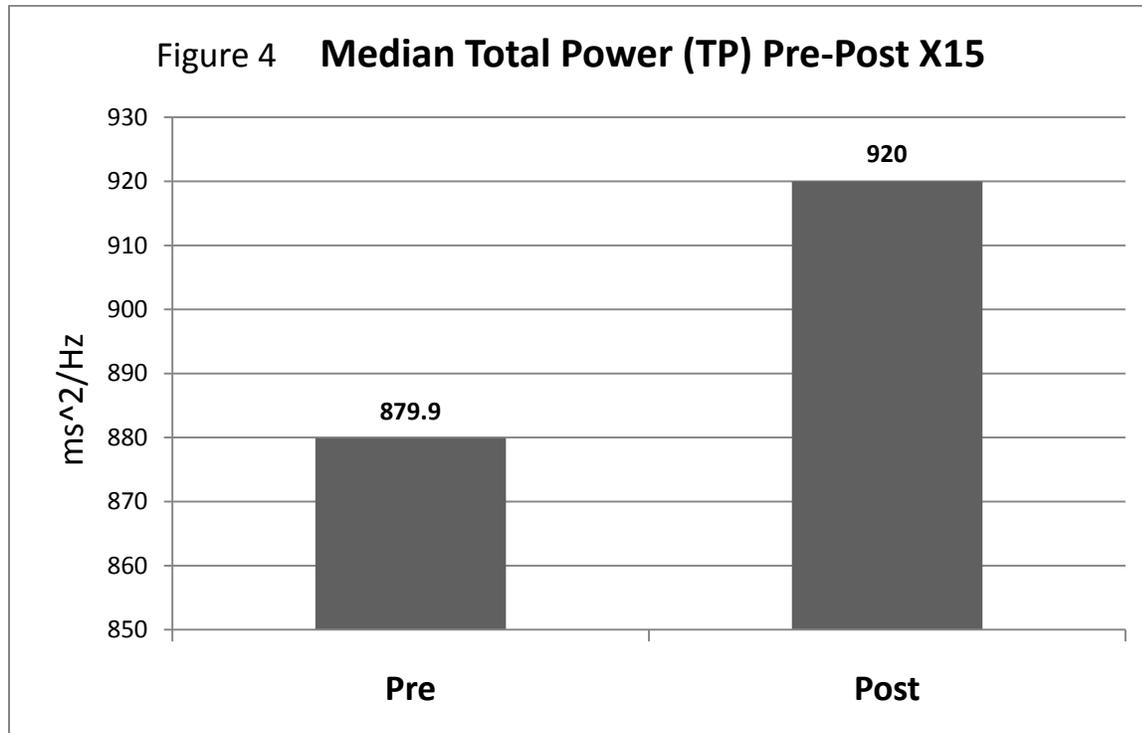
The LFn and HFn are the LF and HF values normalized by partialing out the effects of the VLF component which has an influence on both types. The normalized unit represents the relative value of each power component in proportion to the total power minus the VLF component. Perhaps more clearly than any other this Figure (3) illustrates the autonomic influence the X15 patch has on cardiovascular innervations.

Although the variance in scores was too large for statistical significance, it is instructive to note in Figure 3 that the medians of pre-post LFn and HFn exhibit the relative effects of the sympathetic and parasympathetic systems as they affect the heart. As shown, the LFn (SNS) decreases after the X15 is applied, while the HFn (PNS) increases as a result of the application of the X15.



Total Power is a power spectrum value of RR intervals calculated for a frequency range from 0.0033 Hz to 0.4 Hz. It is the *net effect* of the autonomic regulation on cardiovascular function. Figure 4 shows only

the median values because one subject's scores were very high thus skewing the mean. Apparently the X15 patch tended to *increase* Total Power.



Percentage of Subjects Changing Toward Balance

Conclusions based on the test result actual readings of all the HRV parameters are generated by comparing the subject's readings with normal ranges taken from a normative database built in a special study on a large number of clinically validated healthy individuals (Details available in Biocom Technologies Manual, p.15, 1998-2009).

When calculating individual results for the 20 subjects with the application of the X15 patch: 30% achieved balance (sympathetic score was equal to the parasympathetic); 55% changed toward balance; and 15% changed away from balance. When the two autonomic systems were broken out individually the activity of the SNS showed 20% changed toward balance while 55% changed away from balance and 25% remained the same. The activity of the PNS however, was found to produce a 55% change toward balance with 30% worsening and 15% remaining the same. Thus it would appear that most of the change in Autonomic Balance produced by the X15 patch was due to an *increase of parasympathetic activity*. This particular patch did not increase heart rate variability as we had thought it might, however, the hypothesis that it would produce a balancing of autonomic innervation to the heart was supported.

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