BODY CORE TEMPERATURE AND THE LIFE VESSEL™ STUDY

Tosha Vann
Valerie Donaldson

The Life Vessel™, a novel relaxation device, was first described in a paper by Barry McNew and Valerie Donaldson that was presented at the Science of Whole Person Healing 2003, First Interdisciplinary International Conference, Bethesda, Maryland.

Introduction

As scientists we attempt to acquire knowledge about the world around us through investigation using a well specified scientific method. When choosing what is to be investigated there are many considerations to be made; these choices are often based on personal, educational, or professional reasons. In 2000 my mother was diagnosed with a kidney disease and after 3 years of traditional treatment without success, she began seeking alternative methods of treatment. She discovered The Life Vessel™, an enclosed chamber that uses frequency, vibration, light waves, and sound waves as a form of therapy. My mother received treatment from Dr. Valerie Donaldson, MD, at her clinic, Therapeutic Alternatives (now known as IAM Center of Pittsburgh—(Individualized Advanced Medical Center of Pittsburgh) for about 9 months and her kidney function began to improve. My mother's treatment involved more than just The Life Vessel™, there were dietary adjustments and various herbal supplements that went along with her treatment plan; however The Life Vessel™ is what people visit Dr. Donaldson's clinic for. As an aspiring scientist I was intrigued and inspired. I wanted to investigate how, why, and if The Life Vessel™ worked. In order to investigate this intriguing aspect of my personal environment I chose to make it a part of my educational experience and began to lay out a scientific experiment to study the effects of The Life Vessel™.

The theory behind how The Life Vessel™ works is based on a kind of medicine called Energy Medicine, which while controversial in its relationship to western medicine and science, has very ancient and enduring roots. Energy Medicine is based on the idea that the biological energy fields (created by the flow of ions within an organism) found within and around the human body can be altered by disease and disorder and that those same energy fields can in turn be used to treat disease and disorder (Oschman 2000: pg 1). This form of medicine can be dated as far back as 2750 BC when the use of electric eels as medical treatment was recorded (Oschman 2000: pg 5). Various forms of energy medicine in use today include the use of magnets, electrotherapy, acupuncture and therapeutic touch all of which have a very long history in human societies.

Formerly the existence of biological energy fields had been met with skepticism by the scientific and medical communities, but with advances in technology the existence of these biological energy fields has been confirmed. We now know that the human body is capable of generating electrical and magnetic fields due to the ions moving within our bodies. The electrocardiogram is one of the most readily recognizable tools that is used to measure the electrical activity of the heart. So while the existence of biological energy fields is no longer a debate their role as a therapeutic tool is gaining public interest and is still under some question in medical and scientific communities. Pulsed electromagnetic field (PEMF) therapy is a small pulse generating device that can be prescribed by a physician to assist in a slow healing fracture; this therapy works by creating a magnetic field that effectively induces the flow to current in surrounding tissue (Oschman, 2000: pg-75-74). In a double blind study looking at the effects of PEMF therapy on patients with cervical osteoarthritis, they found that the patients receiving the treatment did show a more significant improvement in their condition than those patients not receiving the treatment (Sutbeyaz et al, 2006).

A link must be established between the diseased state and a disruption in the biological energy fields, in order for a therapy to rely on the manipulation of biological energy fields as a way of treating a disease. Binggeli et al (1994) were able to demonstrate that tumor cells maintain lower membrane potentials than normal cells, demonstrating a link between biological energy fields and their implication in pathology. A theoretical basis for the use of energy medicine would be to suggest that while the causality of the altered energy field is not clear it might be possible to improve the disease state by returning the energy field to its normal state through these therapeutic manipulations.

"Alternative" therapies that attempt to generate physiological effects via noninvasive procedures rely on ideas surrounding the fact that cells throughout an organism are interconnected through cytoskeletal elements and their extra cellular matrix, allowing a stimuli encountered on the surface of an organism to have effect on all of the cells within that organism (Oschman, 2000).

Tensegrity is an architectural concept that describes a system including elements of tension and compression (Oschman 2000: pg 63). Ingber (2003) presents a model of signal transduction in cells based on the idea that cells and tissues within an organism use tensegrity and mechanoregulation in their system of information processing. This idea of the role of tensegrity in cellular signaling provides a model as to how individual components of an organism are able to function together as a whole within an integrated system lending insight into how therapies such as therapeutic touch can have an affect on an organism. Tensegrity's application in energy medicine offers a model as to how stimuli on the surface of an organism can have far reaching effects within that organism, and these effects can be direct, or via physiological routes already set in place by the organism such as neural responses and autocrine signaling.

The Life Vessel™ is patented as a relaxation device and FDA cleared for pain and stress management. The Life Vessel™ employs the entrainment of light and sound and a resonate frequency, as a means of restoring "balance and harmony" to the body. The Life Vessel™ is an enclosed chamber in which the patient lays flat while being non-invasively encompassed by sound in the form of music supplied by CD's, and light. Entrainment is a process by which two oscillating systems become synchronous. The Life Vessel™ acts on this principle of entrainment through which a resonant frequency coupled with frequency, vibration, light waves and sound waves entrains the cells and tissues of the patient. In this process the resonance is thought to have some altering affects on the patient, bringing the cells/tissues of the patient into synchronistic cellular coherency and allowing the functions of the Autonomic Nervous System (ANS), to become balanced, allowing healing to take place. This achievement in the Life Vessel allows the human body to go to a level below the level of known consciousness at a conscious state. At this level of consciousness, the body starts the healing process due to rebalancing the ANS naturally, detoxing naturally and creating a de-gravitational effect to the body allowing for synchronized cellular coherency. The ANS is the "unconscious" part of the nervous system, controlling heart rate, respiratory rate, and physiological processes such as digestion. The goal of balance of the ANS and hence balance in the physiological processes of the entire body is thought to be attained through the interaction of The Life Vessel™ on the Autonomic Nervous System (ANS) of the individual being treated. As the ANS of the body is balanced, stress on the body is effectively reduced. Stress is known to be the biggest initiator and promoter of disease and dysfunction in the body. As stress is reduced throughout the body's physiological mechanisms, it deters dysfunction and allows the body to balance and heal itself.

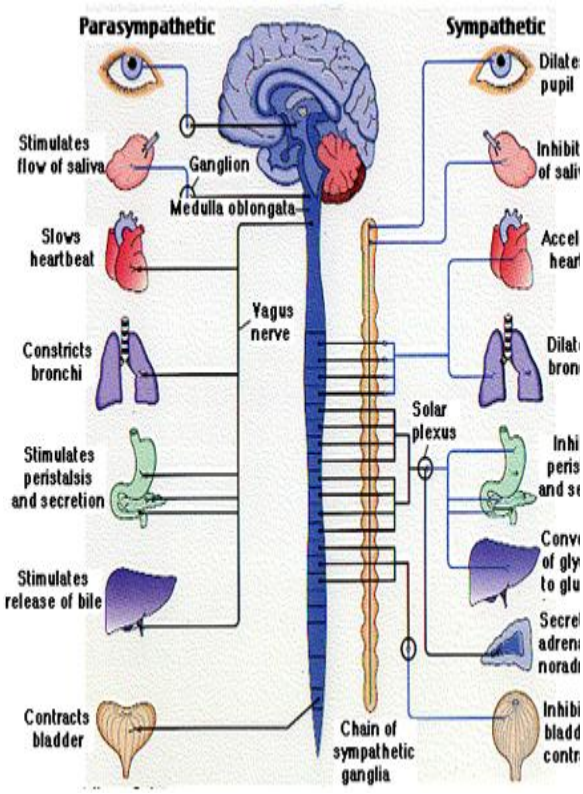


Figure 1- functioning of the Autonomic Nervous System (Biology Pages, 2003)

The ANS is made up of two branches, the sympathetic and parasympathetic (see figure 1). The two branches of the ANS are antagonistic, producing opposing effects on the same organs. The pathology of some diseases such as rheumatoid arthritis characterized by increased sympathetic control which represents an imbalance in the ANS, (Evrengul et al, 2004). An increase in sympathetic control has also been implicated in coronary artery disease (Sztajzel, 2004). An accepted noninvasive tool for measuring the function of the ANS is the Heart Rate Variability (HRV) test (Sztajzel, 2004). The contractile and electrical functioning of the myocardium is in large part regulated by the activity of the autonomic nervous system through the relationship between sympathetic and parasympathetic outflow (Sztajzel, 2004). Parasympathetic stimulation causes hyper-polarization and decreased heart rate, while sympathetic activity increases the rate of depolarization (Sztajzel, 2004). HRV is a noninvasive tool that measures sympathetic and parasympathetic activity on the sinus node of the heart (see figure 2) (Sztajzel, 2004). In a normally functioning heart, a balanced autonomic

nervous system is represented through continual variations in the heart rate, while reduced heart rate variability represents an imbalance present within the autonomic nervous system (Sztajzel, 2004). IAM Center of Pittsburgh uses ANSAR's (Philidelphia, PA) autonomic monitoring technology as a tool in determining the light and sound settings for individual patients in The Life Vessel™. ANSAR's autonomic monitoring technology was selected as it is the only commercially available, FDA certified, non-invasive, quantitative, independent and simultaneous measure of the two branches of the parasympathetic and sympathetic nervous system.

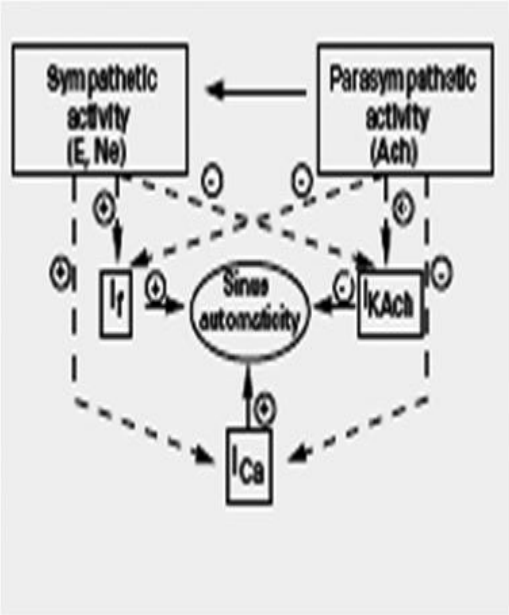


Figure 2 – functioning of the HRV on the sinus node of the heart (Sztajzel, 2004)

In the present study we will investigate whether or not we can demonstrate that the use of light and sound in the form of The Life Vessel™ is able to exert a measurable effect on the human body. The variable that will be investigated in this experiment is core body temperature. There are different ways in which the core body temperature of an individual can be regulated and affected. The human body follows a circadian rhythm in which core body temperature drops during evening hours (see figure 3). However in the presence of changing environmental conditions we are able to maintain our core body temperature within a specified range through physiological regulation. In the present study we are expecting to see a drop in core body temperature following the session in The Life Vessel™. This hypothesis is based on general observations made by Dr. Donaldson and her staff at *Therapeutic Alternatives/IAM Center of Pittsburgh.*

Figure 3- Cycles of the human core body temperature (Wikipedia, 2006)

Method

Experimental and control groups

Two populations will be investigated, an experimental group receiving The Life Vessel™ session at Therapeutic Alternatives/IAM Center of Pittsburgh and a control group not receiving the session. This project is approved by the Institutional Review Board for Human Subjects in Research at Cleveland State University. Participation in this project is voluntary; subjects for the experimental group are new or returning patients of Dr. Donaldson and were recruited at Therapeutic Alternatives/IAM Center of Pittsburgh. Subjects recruited for the control group were matched to the experimental subjects by age and gender. Signed consent was obtained from each subject, and each subject was given a Patient Instruction sheet (appendix A) with instructions regarding their participation. Participants were male or female between the ages of 18 and 65. The female subject must not be pregnant or lactating. All of the measurement taking was done by Dr. Donaldson and staff at Therapeutic Alternatives/IAM Center of Pittsburgh for the experimental group and by Tosha Vann in Cleveland, Ohio for the control group.

Autonomic Nervous System Monitoring/ ANS Test

The autonomic nervous system test is not a part of The Life Vessel™ session but is used as a diagnostic tool immediately prior to the session in The Life Vessel™. Thus, only participants in the experimental group received the ANS test. The ANS test is used to measure the function and

balance of the autonomic nervous system. The patient is seated in a chair and hooked up to the ANSAR monitor, which takes blood pressure readings 6 times during the test, and also measures heart rate, and breathing rate continually throughout the test. Patients are instructed to place their feet flat on the ground and their hands on their lap; they are to be still and quiet but not to enter into a meditative state. There are six phases to the test. The first phase lasts for 5 minutes during which there are no instructions given and a baseline is recorded. The second phase is designed to measure the parasympathetic response during which the patient is guided through 1 minute of deep breathing. After the deep breathing exercise the patient enters the third phase of the test in which they are given 1 minute to recover and return to normal breathing. During the fourth phase the patient is guided through one and a half minutes of Valsalva. Valsalva is an exercise in which the patient is instructed to take a quick deep breath and hold it, the first one is held for 15 seconds, they are then given 15 seconds to recover, returning to normal breathing, and then they are led through 4 back to back valsalvas holding for 10 seconds. The Valsalva is designed to place stress on the sympathetic nervous system. In the fifth phase the patient is given 2 minutes to recover and return to normal breathing. In the sixth and final phase of the test the patient is instructed to stand for 5 minutes with their arms resting on a chair placed in front of them and not resting at their sides. The action of standing during this stage of the ANS measurement is designed to see a response during a time period at which the body is neither at rest or stressed. At the end of the test a report is generated which displays a graphical representation of the functioning of the sympathetic and the parasympathetic nervous system as compared to the initial baseline taken during the first five minutes of the test.

Temperature taking

The patient was instructed to open their mouth and the oral thermometer was placed in the right pocket of the oral cavity. Once their lips were closed they were told not to bite the probe, talk, or breathe through their mouth. The thermometer was held in place until it beeps and the temperature measurement has stabilized. The temperature was logged into the data book.

The Life Vessel™ session

The patient's temperature was recorded within two minutes before entering The Life Vessel™. Upon entering The Life Vessel™ the patient was instructed to lay flat on their back and to be still. They were given the option of having a blanket. The lights and music were then turned on and the doors of The Life Vessel™ were closed. The subject was then left alone for the one hour duration of their session. Once the session was over the subject was led out of The Life Vessel™ and allowed to sit and rest. Their temperature was then recorded 15 minutes after exiting. The pre temperature was then subtracted from the post temperature and logged into the data table.

Control treatment

The subject's temperature was taken and they were then instructed to lie flat, on a bed or on the ground, for one hour. At the completion of the hour they were then instructed to sit up and their temperature was taken a second time after 15 minutes. The pre temperature was then subtracted from the post temperature and logged into the data table.

Analysis

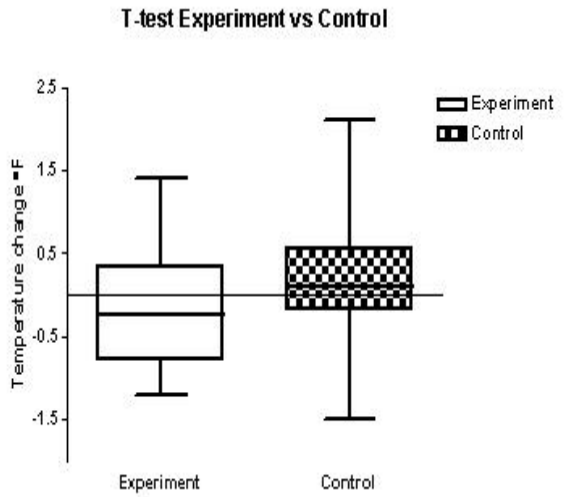
There were 40 experimental and 40 control subjects analyzed. The final temperature was subtracted from the initial temperature for both the experimental and the control group; a negative number indicates a drop in temperature while a positive number indicates a rise in temperature (See appendix B for table of raw data). The gathered data passed the Kolmogorov-Smirnov test for normality (see appendix C for histograms).

Results

The data were analyzed using a paired t-test. [analyzed using Graph Pad Prism Statistical Program (Palo Alto, CA)]. The t-test was used with a confidence of $p < 0.05$and the two populations were shown to have a significant difference, $p = 0.0186$ (Table 1). Graph 1 offers a representation of where the individual measurements of the two populations fall, with the experimental group showing more of a drop in temperature than the control group.

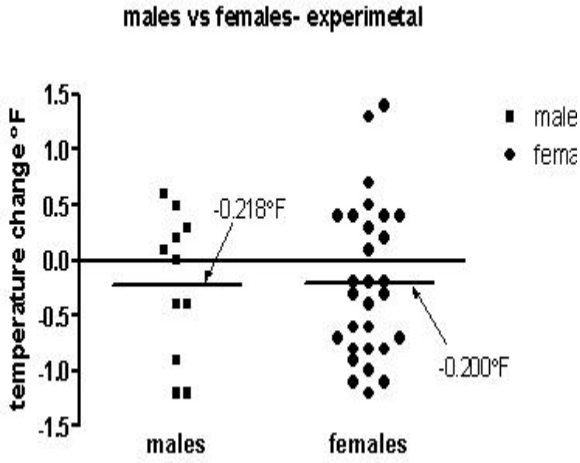
	Mean	Std dev	St.error	
Exp	-0.205	0.6793	0.1074	
Cont	0.185	0.6927	0.1095	
p value	t value	df	n	mean diff.
0.0186	2.5	39	40	-0.39

Table 1- Numerical results for the experimental and control groups and the statistical tests

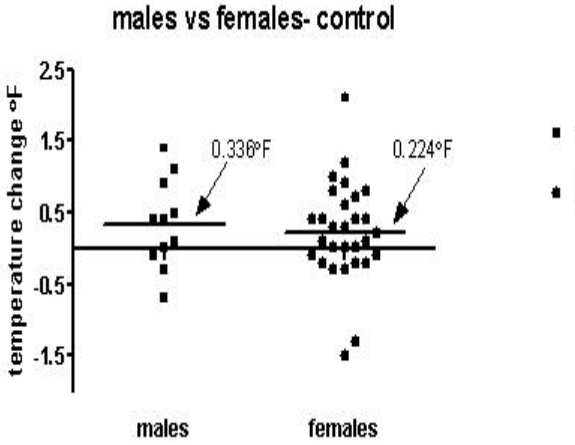


Graph 1- graphical representation of the temperature changes of the two populations

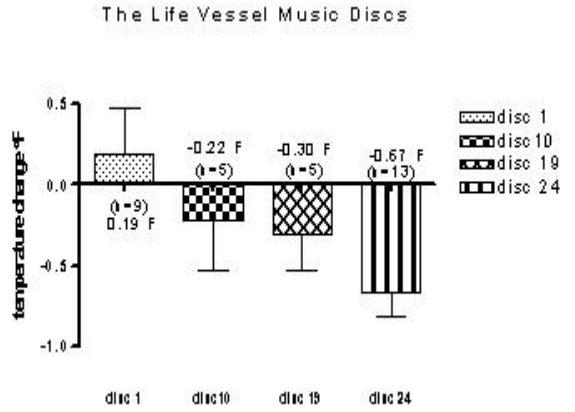
The data were also analyzed comparing the male and female populations for both the experimental and control groups and there was no significant difference found between males and females in either population, p = 0.941 and p = 0.642 respectively. (see graphs 2 and 3)



Graph 2- Comparison of males versus females in the experimental group.



Graph 3- Comparison of males versus females in the control group.



Graph 4– Graphical representation comparing the average temperature changes with the standard deviation bar associated with the different discs.

In a post analysis comparison of music we were able to record the number of the music disc that was used with each subject in the experimental group (see appendix C). The data referring to disc number were then compared using a one-way ANOVA. Data were compiled for 4 of the discs that were used by more than three subjects to see if there are any correlations between subject response and the disc used in their session. It was shown (table 2) that there was a significant difference in response for different discs p = 0.0428. Graph 2 offers a visual representation of the average change in temperature for the subjects according to which disc was used in their treatment. Patients using disc 24 showed on average more of a drop in temperature of -0.6692°C, while those using disc 19 had an average drop of -0.3 °C, those using disc 10 showed an average drop of -0.22°C, and those using disc one showed an average increase of 0.1889°C.

Disc #	1	10	19	24
mean	0.1889	-0.22	-0.3	-0.6692
Std Dev	0.8448	0.6834	0.5	0.5282
n	9	5	5	13
p value	0.0428			

Table 2 – Temperature change comparison of disc numbers used in the treatment of the experimental group.

Discussion

Based on statistically calculated data, there was a significant difference found between the experimental and control groups. The paired t-test, with a confidence level of p=0.05, found a significant difference between the means of the two populations with the experimental group showing more of a drop in temperature than the control group. This difference suggests that The Life Vessel™, utilizing sound waves, light waves, vibration and frequency in a resonant environment, does have a physiological impact on the human body. The hypothesis was confirmed as the data comparison of the different music discs used in treatment of the experimental group showed a measured decrease in core body temperature that was not observed in the control group.

It is important to point out, there were many variables that were not able to be effectively addressed in this study such as ambient temperature, a similarly devised enclosed environment, time of day, accuracy of measurement, and differences in treatment received by the subjects in the experimental group.

Ambient temperature is known to have an effect on core body temperature and in this design was accounted for grossly but was not accurately controlled or measured. It can be assumed that the ambient temperature for the experimental group should have been somewhat consistent because those measurements were made at the same location every time with no change in the thermostat temperature. However, the location at which the control measurements were made varied and therefore thermostatic temperature could have been different. A record of ambient temperature for both the pre and post measurements would be useful because it would allow us to rule out environmental factors as a source of the observed change in core body temperature.

Time of day was another factor that was not recorded in the data collection however it can be generally stated that all of the measurements were made during the day between the hours of 9:00 am and 6:00 pm (approximately). According to figure 3, showing the circadian rhythm of human core body temperature, during those hours of activity the general trend is towards an increase and/or stability of core body temperature. The times during which the measurements were taken would have normally corresponded to an increase in core body temperature as opposed to a drop, allowing one to draw the conclusion that even though time of day was not factored directly into the measurements, time of day would not have played a role in the measured decrease in temperature, and instead serve to add some strength to the measured results.

Oral temperatures are a relatively easy measurement to take; however there are many factors that can affect the reading such as eating, drinking and breathing. Patients were instructed on the taking of an oral temperature (appendix A), so it can be assumed that the oral temperatures were taken correctly; but the variability in oral temperatures does remain a potential source of error in the current study. Rectal temperatures are generally assumed to be a more consistent way of measuring core body temperature, and would have offered a more reliable measurement of core body temperature, but were not a practical possibility in this study. We assume that because all corresponding pre and post temperatures were made with the same instrument and patients were given clear written instructions that the potential for error in the taking of an oral temperature was minimized as best possible.

The Life Vessel™ is adjusted for specific patient needs; the music and lights are not chosen randomly. The details regarding the types of light and music used is proprietary information that was not available for inclusion in this study, that information could have possibly provided more insight into both experimental design and data analysis, allowing for more literature research regarding the properties of light and music of certain wavelength and frequency. With more information regarding the specific light and music in use it could have been possible to better predict, explain, and group the observed results. It might be even more informative to have generated a placebo in which the control subjects entered an enclosed chamber in which bogus light and sound was used.

While participation in this project was voluntary the experimental subjects were seeking treatment. This was not a behavioral study but it seems likely that behavior would be a factor in the outcomes for both the experimental and control group. The experimental group was aware that they were receiving a treatment and came seeking it, and the control group knew that they were not receiving any sort of treatment. It would have been useful to control for the behavioral

aspects of this study by doing a double blind experiment in which neither the subjects nor those administering knew whether the treatment was experimental or control. Also some sort of qualitative survey could have been useful in analyzing the attitude of subjects towards the treatment, both before and after the treatment was administered. This would allow some sort of measurement as to whether or not the patients themselves were able to distinguish an effect of the treatment.

The ideas presented by Ingber (2003) on tensegrity of the cell, that there are mathematical formulas that predict cell behavior, allow a construct in which to envision how a non-invasive therapeutic tool such as light or sound could induce change at a cellular level, and this change at a cellular level, which in turn could render some physiological change, via the regulatory networks that the body already has in place. So while this experiment does not point to any specific mechanisms through which The Life Vessel™ is causing a physiological change in individuals it does raise some interesting question as to how these non-invasive tools could have complicated interactions with the human body.

Vibroacoustic therapy is a form of music therapy in which a music chair, with 4 built in speakers are strategically placed supplying low frequency vibrations and music (Kvam, 1997). Vibroacoustic therapy acts on principles similar to those of The Life Vessel™. There are studies that have shown an improvement in patients reporting of symptoms when receiving Vibroacoustic therapy, in which low frequency acoustic vibrations and music are used as treatment (Kvam, 1997). There are also reports on the use of light therapy in treating seasonal affective disorder (Boenink et al, 1997). Also Sakakibara et al (2000) were able to demonstrate that bright light has an effect on the ANS. Although there are reported effects of light and sound on individuals, it is not clear exactly how light and sound actually work to have an effect. This present study did show that something different was occurring within the experimental group; however the experimental design did not allow a clear analysis as to what caused the difference between the two groups. It is not clear whether or not The Life Vessel™ acted alone in bringing about this difference or whether the other factors affecting core body temperature played a role in the measured observation. The strongest evidence supporting the idea that The Life Vessel™ is playing a role in the measured observations is the fact that there was an observed difference within the experimental group using different music discs in the session. That data suggests that there are differential properties of The Life Vessel™ warranting further investigation into exactly how The Life Vessel™ works.

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Appendix A:

Patient Instruction

Your temperature will be taken orally 2 times during your participation in this project. It is asked that you do not have anything to drink or eat, do not smoke, or have any chewing gum at least 15 minutes prior to your temperature being taken.

Your participation is greatly appreciated,

Dr. Donaldson and staff

Appendix B:

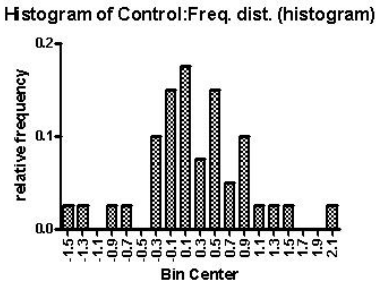
Body Temp Experimental Group

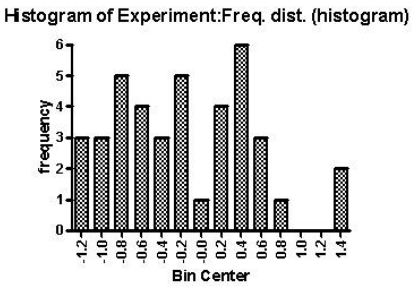
ID #	age	pre vessel	15 min post	gender	disc #	post-pre
100	52	96.9	96.9	m	19	0
101	52	97.7	96.5	m	24	-1.2
102	52	96.6	96.7	m	10	0.1
103	53	98	97.6	m	24	-0.4
104	66	98.4	97.6	f	7	-0.8
105	55	98.1	97.8	f	1	-0.3
106	51	97.6	96.7	m	24	-0.9
107	51	97.5	97.7	m	10	0.2
108	48	98.4	97.7	f	24	-0.7
109	48	97.7	98	f	1	0.3
110	56	97.7	98.1	f	7	0.4
111	55	97.6	97.4	f	19	-0.2
112	55	97.4	97.6	f	19	0.2
113	55	96.7	96.8	f	9	0.1
114	62	98.4	97.8	f	1	-0.6
115	62	98	97.7	f	5	-0.3
116	62	97.7	97.5	f	24	-0.2
117	62	98.6	97.6	f	10	-1
118	63	97.3	97.8	f	1	0.5
119	19	97.3	96.1	m	24	-1.2
120	55	96.6	96.4	f	1	-0.2
121	54	97.2	97.8	m	1	0.6
122	55	98.7	97.6	f	24	-1.1
123	25	97.4	96.6	f	1	-0.8
124	43	98.6	97.9	f	24	-0.7
125	54	96	96.5	m	10	0.5
126	55	98.5	97.4	f	19	-1.1
127	55	95.8	94.9	f	10	-0.9
128	53	97.3	96.9	m	24	-0.4
129	55	95.4	96.1	f	24	0.7
130	53	95.8	95.2	f	24	-0.6
131	52	97.4	97.8	f	23	0.4
132	62	96.2	97.5	f	1	1.3
133	46	96.5	96.9	f	23	0.4
134	53	97.8	97	f	24	-0.8
135	40	95.3	95.7	f	7	0.4
136	55	97.7	96.5	f	24	-1.2
137	25	96.3	97.7	f	1	1.4
138	63	96.9	96.5	f	19	-0.4
139	65	96.6	96.9	m	23	0.3

Body Temp Control Group

ID #	age	pre	15 min post	gender	post-pre
200	52	95.1	96.5	m	1.4
201	52	96	96.4	m	0.4
202	52	97.6	98.1	m	0.5
203	53	96.8	97.9	m	1.1
204	66	97.6	97.9	f	0.3
205	55	97.6	96.1	f	-1.5
206	51	98.6	98.6	m	0
207	51	98.8	98.5	m	-0.3
208	48	97.9	98	f	0.1
209	48	97.1	97.9	f	0.8
210	56	97.6	97.4	f	-0.2
211	55	98.1	98.7	f	0.6
212	55	98	97.9	f	-0.1
213	55	98.4	98.1	f	-0.3
214	62	97.6	98	f	0.4
215	62	98.4	98.6	f	0.2
216	62	97.8	98.2	f	0.4
217	62	98.1	97.9	f	-0.2
218	63	97.6	98.5	f	0.9
219	19	98.7	98	m	-0.7
220	55	97.8	97.7	f	-0.1
221	54	96.5	97.4	m	0.9
222	55	96.1	97.3	f	1.2
223	25	96.4	97.1	f	0.7
224	43	95.5	95.5	f	0
225	54	97.8	97.9	m	0.1
226	55	96.3	96.7	f	0.4
227	55	95.6	97.7	f	2.1
228	53	98	97.6	m	-0.4
229	55	96.5	97.5	f	1
230	53	96.2	94.9	f	-1.3
231	52	96.7	96.5	f	-0.2
232	62	97.1	97.9	f	0.8
233	46	96.8	96.8	f	0
234	53	97.4	97.5	f	0.1
235	40	98.3	98.7	f	0.4
236	55	97.7	98	f	98
237	25	98.5	98.2	f	-0.3
238	63	98	98	f	0
239	65	97	96.9	m	-0.1

Appendix C:





Tosha Vann
Dr. Valerie Donaldson, MD
IAM Center of Pittsburgh
www.iamcenterofpittsburgh.com
Email:valdonaldson@gmail.com