

Bio-Magnetic Research Institute

Randomized Double-Blind Crossover Study to determine the impact of “Pressure Point” eyewear

Hypothesis: “Pressure point” eyewear will reduce physiological stress, relieve eyestrain, improve mental focus, and visual clarity. In addition, the “Pressure Point” eyewear will reduce migraine headache inflammation/pain as evidenced by the reduction of the major migraine headache acupuncture points.

Subject Guidelines: Subjects were required to meet the following guidelines for consideration of inclusion in the study: were not pregnant, did not have any electrical implants (i.e. pacemakers), were 18 years of age or older.

In addition to meeting the subject guidelines, subjects were required to meet one or more of the following criteria for inclusion in the study.

- a. **Stress/anxiety inclusion:** Individuals were required to have a score of 15 or greater on the General Health Questionnaire (GHQ) using the *Likert* scoring scale. This score identifies them as currently being in distress.
- b. **Mental focus:** Individuals who acknowledged that they were having difficulty with mental focus were accepted for evaluation of mental focus improvement.
- c. **Visual clarity:** Individuals who acknowledged that they were having difficulty with blurry or fuzzy vision.
- d. **Eyestrain:** Individuals who acknowledged having “tired”, “red”, or “burning” eyes.
- e. **Migraine Headache:** Individuals must currently have, or have experienced within the past 48 hours a migraine headache.

Methods:

This study will be a randomized double blind crossover study using the following methods:

A. Stress:

- a. In addition to a General Health Questionnaire score of greater than fifteen (15), initial stress levels were evaluated using Nerve-Express. (*Nerve-Express is a simple non-invasive, fully automated computer-based system designed for quantitative assessment of the Autonomic Nervous System (ANS), both Sympathic and ParaSympathic systems respectively, based on Heart Rate Variability (HRV) analysis. The Nerve-Express system is used for objective evaluation and validation of various treatments, for research and documentation, and for evaluation of Autonomic Activity before and after a patient is affected by medication, exercise, physical treatment, stress, beta-blockers, or in our case, “Pressure-point” eyewear*)

Heart Rate Variability Background: The autonomic nervous system (ANS) governs 99.9% of all physiological functions, including the action of the heart, secretions of different glands, and the assimilation and utilization of nutrients, among many other vital activities. It is well known that mental and emotional states directly affect the ANS.

Analysis of heart rate variability serves as a dynamic window into the functioning of ANS. Measuring variability in heart rate reflects the synergistic action of the two branches of the ANS, the Sympathetic Nervous System (SNS) and the Parasympathetic Nervous System (PNS).

An optimal level of variability within an organism’s key regulatory systems is critical to the inherent flexibility and adaptability that characterize healthy functioning systems. In a healthy individual the heart rate represents the net effect of the PNS (“rest and digest”) response, which slows heart rate, and the SNS (“fight or flight”), which accelerates it.

Abnormalities of the ANS not only impair the quality of our life, but also threaten its very existence. Depletion of the body's energy system, leaves the body unable to properly absorb and utilize nutrients. Balancing and enhancing the energy system dramatically restores the ability of the body's organs to effectively perform their functions.

- b. An Initial baseline measurement was taken using Heart Rate Variability. Individuals waited a twenty-minute wash-out period. Participants then put on the first of two pair of glasses (#-01). The Heart Rate Variability test was then repeated. Another wash-out period of twenty minutes was followed with the participant putting on the 2nd pair (#-02) of glasses and a 3rd Heart Rate Variability test was performed.
- c. In addition to the Heart Rate Variability test, participants were tested for the Stress EAV protocol. This and all EAV protocol points were defined using the "*Acupuncture Comprehensive Index*" for the specific symptom being tested.
 1. EAV Stress Protocol:
 2. He6 (right)
 3. Ki6 (right and left)
 4. St36 (right and left)
 5. UB34 (right and left)
- d. A baseline EAV test was performed. Participants were then given the "Pressure Point" eyewear (#-1) and asked to sit for 5 (five) minutes. After 5 (five) minutes the EAV protocol was repeated. Participants were then given a washout period of 20 minutes. "Pressure Point" eyewear" (#-2) was then tested using the Stress EAV protocol.
- e. At the beginning of the EAV test, participants were asked to identify their level of stress based on a scale of 1-10. This was again repeated at the end of the testing.

B. Mental Focus

- a. Mental Focus EAV Protocol
 - i. Hypothalamus (right and left)
 - ii. Small Intestine 5 (right and left)
 - iii. Kidney 8 (right and left)
 - iv. Stomach 3 (right and left)
 - v. Large Intestine 11 (right and left)
- b. A baseline EAV test was performed. Participants were then given the "Pressure Point" eyewear (#-1) and asked to sit for 5 (five) minutes. After 5 (five) minutes the EAV protocol was repeated. Participants were then given a washout period of 20 minutes. "Pressure Point" eyewear (#-2) was then tested using the Mental Focus EAV protocol.

C. Anxiety

- a. Anxiety EAV Protocol
 - i. Conception Vessel 12
 - ii. Liver 3 (right)
- b. A baseline EAV test was performed. Participants were then given the "Pressure Point" eyewear" (#-1) and asked to sit for 5 (five) minutes. After 5 (five) minutes the EAV protocol was repeated. Participants were then given a washout period of 20 minutes. "Pressure Point" eyewear (#-2) was then tested using the Mental Focus EAV protocol.
- c. Participants were asked at the beginning and at the end of the test what their anxiety level was on a scale of 1-10.

D. Eye Disorders

- a. EAV Protocol
 - i. GB1 – (right and left) specific for eye strain
 - ii. LI13 – (right and left) specific for cloudiness
 - iii. CX1 – (specific for blurred vision)

- iv. GB 20 – (right and left) specific for dull vision
- v. CX6 – (right and left) specific for Glaucoma
- b. A baseline EAV test was performed. Participants were then given the “Pressure Point” eyewear” (#-1) and asked to sit for 5 (five) minutes. After 5 (five) minutes the EAV protocol was repeated. Participants were then given a washout period of 20 minutes. “Pressure Point” eyewear” (#-2) was then tested using the Mental Focus EAV protocol.
- c. Participants were asked at the beginning and at the end of the test to read a standard Eye Chart in an effort to help them identify any improvement in visual clarity. .

E. Migraine Headaches

- a. Migraine Headache EAV protocol
 - i. GV23-2
 - ii. GBI-1 (right and left)
 - iii. GV 16
- b. A baseline EAV test was performed. Participants were then given the “Pressure Point Eyewear” (#-1) and asked to sit for 5 (five) minutes. After 5 (five) minutes the EAV protocol was repeated. Participants were then given a washout period of 20 minutes. “Pressure Point” eyewear” (#-2) was then tested using the Migraine Headache EAV protocol.
- c. Individuals were asked at the beginning and again at the end of testing their level of pain on a scale of 1-10.

Randomization

The randomization process utilized the Excel spreadsheet formula listed below to generate a random number between 1 and 1,000,000 for each of the 30 members of Group A and Group B. The spreadsheet was then recalculated 10 times. The random number formulas were then converted to a fixed numerical value and listed in ascending order to assign a group number to each patient number.

- A. Group A received the Placebo product in the First Treatment Period and Active product in the Second Treatment Period. Group B received the Active product in the First Treatment Period and Placebo in the Second Treatment Period.
- B. Each unit of product was assigned a number consisting of the two digit Patient Number followed by a “1” or “2” to signify the Treatment Period (i.e. 01-1 = Patient 01 Treatment Period 1, 03-2 = Patient 03 Treatment Period 2).
- C. Investigators remained blinded to the Patient’s group number until the study data was gathered.

F. RANDOMIZATION TABLE

=RANDBETWEEN(1,1000000)

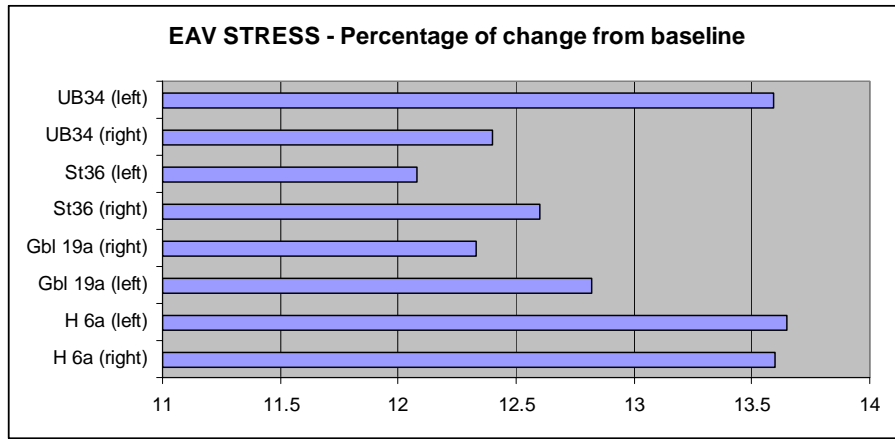
Group A Placebo/Active		Group B Active/Placebo	
Random #	Group	Random #	Group
40888	A	264406	B
361963	A	444665	B
523893	A	125979	B
701387	A	48867	B
215202	A	99057	B
331128	A	892057	B
211804	A	301057	B
856227	A	865298	B
932252	A	644095	B
760587	A	473723	B
731245	A	183002	B
204106	A	362792	B
122492	A	522061	B
797874	A	761258	B
934181	A	667707	B

Patient No.	Randomization	Group
01	40888	A
02	48867	B
03	99057	B
04	122492	A
05	125979	B
06	183002	B
07	204106	A
08	211804	A
09	215202	A
10	264406	B
11	301057	B
12	331128	A
13	361963	A
14	362792	B
15	444665	B
16	473723	B
17	522061	B
18	523893	A
19	644095	B
20	667707	B
21	701387	A
22	731245	A
23	760587	A
24	761258	B
25	797874	A
26	856227	A
27	865298	B
28	892057	B
29	932252	A
30	934181	A

RESULTS

A. STRESS

a. Percent of change of Active “Pressure Point” eyewear” from baseline:



The average percentage of change for the Active “Pressure Point” eyewear from baseline for all EAV stress points is 12.88%.

b. Heart Rate Variability Results

This chart represents the average change in heart rate variability using the active “Pressure Point” eyewear

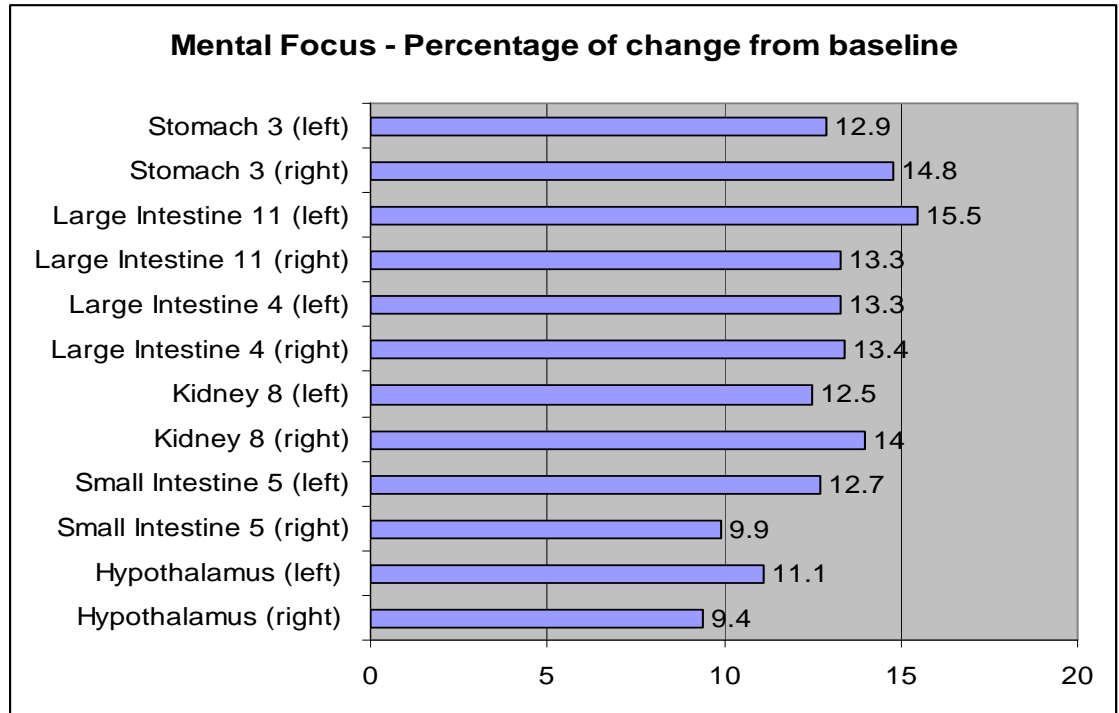
	Baseline	Active	Difference
Parasympathetic	-1.53	-1.37	-.016
Sympathetic	1.1	1.0	-0.1
Physical Fitness Level	9.8	9.2	-0.6
Tension Index – supine	181	156.6	-24.4VS
Tension Index – upright	377.1	308.5	-68.6VS

***VS=Very Significant**

The changes in the Parasympathetic and Sympathetic systems were minimal, however: the tension index (TI) which identifies the level of cardiac stress shows marked improvement.

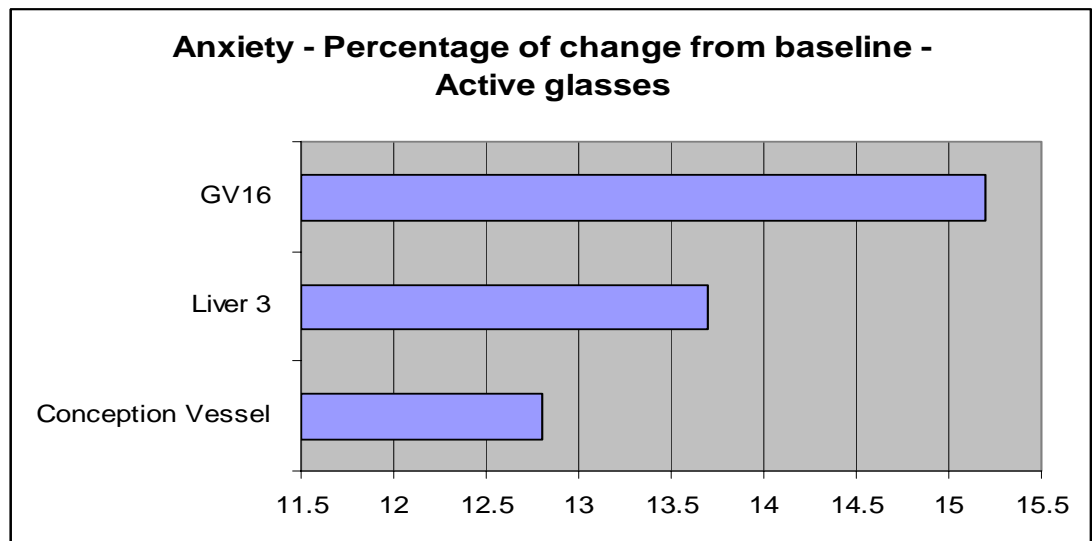
B. MENTAL FOCUS

Percentage of change of Active “Pressure Point” eyewear from baseline:



C. ANXIETY

Percentage of change of Active “Pressure Point” eyewear” from baseline



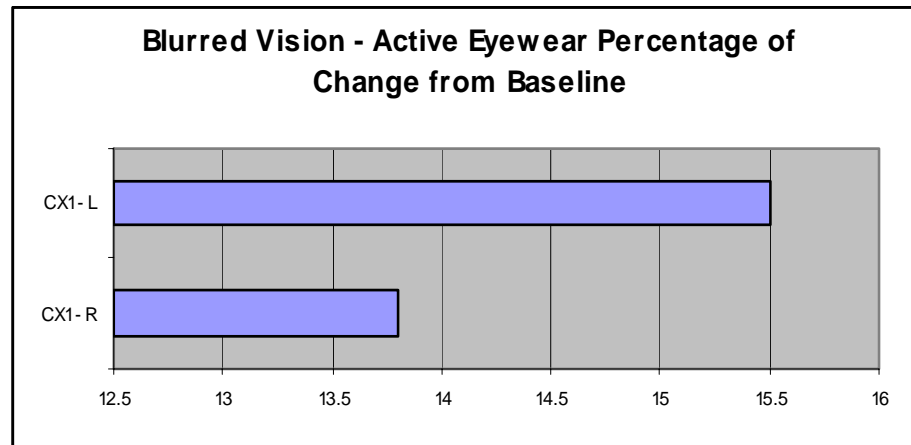
The average percentage of change for the Active “Pressure Point” eyewear

from baseline for all EAV anxiety points is 13.9%. 7% of the active “Pressure Point” eyewear users indicated that their level of anxiety improved over the course of the testing.

D. EYE DISORDERS

a. Blurred Vision

Percentage of change of Active “Pressure Point” eyewear” from baseline

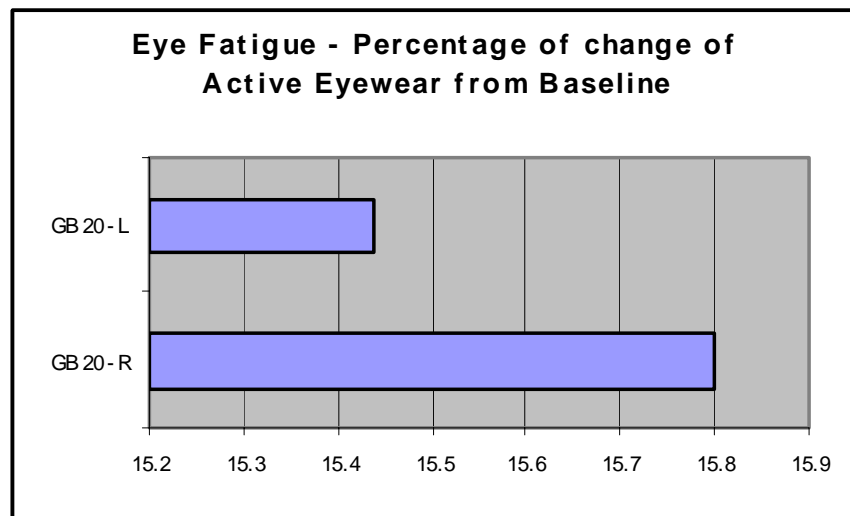


The average percentage of change for the Active “Pressure Point” eyewear from baseline for all EAV blurred vision points is 14.7%.

6% of the individuals using the active “Pressure Point” eyewear tested indicated that they saw an improvement in their blurred vision.

b. Eye Fatigue

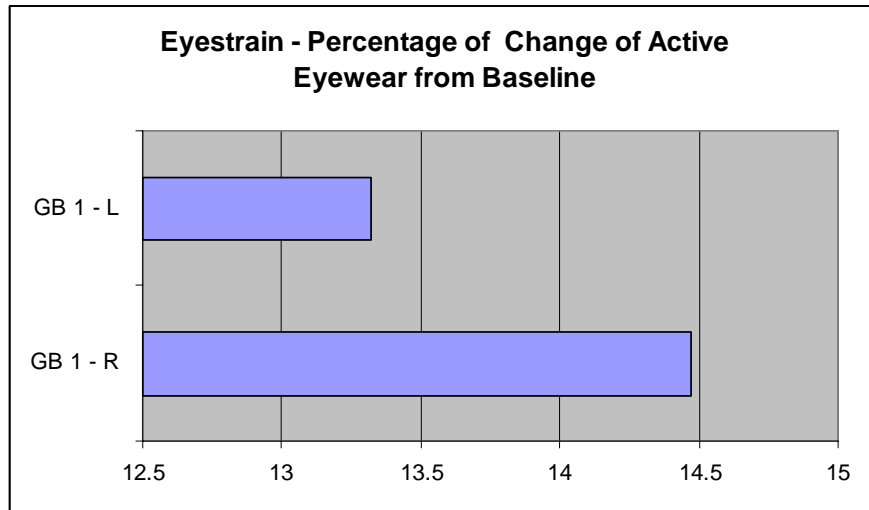
Percentage of change of active “Pressure Point” eyewear from baseline



The average percentage of change for the active “Pressure Point” eyewear” from baseline for all EAV eye fatigue points is 15.6%.

c. Eye Strain

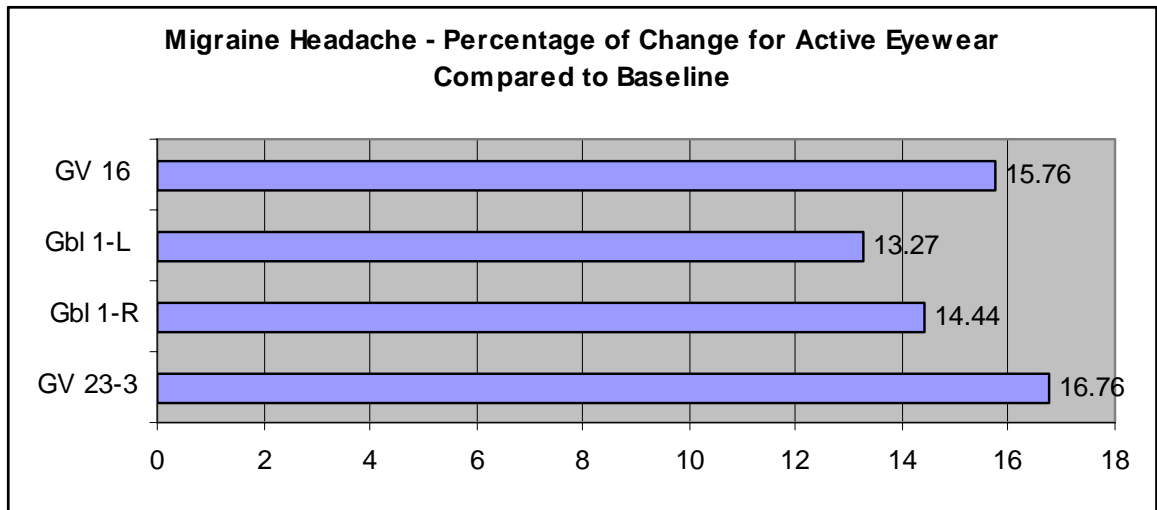
Percentage of change of Active “Pressure Point” eyewear from baseline



The average percentage of change for the active “Pressure Point” eyewear from baseline for all EAV eyestrain points is 13.9%.

E. Migraine

Percentage of change of active “Pressure Point” eyewear from baseline



The average percentage of change for the active “Pressure Point” eyewear from baseline for all EAV migraine points is 15.5%.

10% of the active “Pressure Point” eyewear users indicated an improvement from 10-30% over the course of the testing.

Conclusion:

This double blind crossover study clearly demonstrates the *immediate* improvement in EAV acupuncture feedback concluding that the “Pressure Point” eyewear will in fact reduce psychological stress, relieve eyestrain, improve mental focus and improve visual clarity. In addition, the eyewear makes a significant improvement in migraine pain/inflammation as evidenced both by changes in EAV as well as self-reported by clients. It appears that the source of the migraine is not significant.

Heart Rate Variability further validates the reduction of stress that participants experienced using the “Pressure Point” eyewear.

Note: 3 individuals felt discomfort while applying the “Pressure Point” eyewear. This was described as mild pain to “tingling”. None of the participants felt the need to remove the glasses.

Possible Theory

There are several theories as to why the Active “Pressure Point” eyewear improves i.e., reduces stress and anxiety, improves mental focus and visual clarity and reduces the pain of migraines as demonstrated by the change in the EAV and Heart Variability readings.

A. Acupuncture

Sixteenth century Chinese doctors believed that illness was due to an imbalance of energy in the body. In acupuncture, one of the body’s fourteen (14) major meridians, or energy-carrying channels, are stimulated to overcome illnesses and conditions which correct imbalances in the energy channels.

Acupuncture is also thought to decrease pain by increasing the release of chemicals called endorphins, which block pain. Many acu-points are near nerves. When stimulated, these nerves cause a dull ache or feeling of fullness in the muscle. The stimulated muscle sends a message to the central nervous system (the brain and spinal cord), causing the release of endorphins. Along with other neurotransmitters (body chemicals that modify nerve impulses) the message of pain is blocked and not transmitter to the brain.

B. Neurons are bio-electric signals which are responsible for communication throughout the nervous system. This nerve transmission consumes one-half of all the brain’s energy (nearly 10% of the whole body’s energy. The “Pressure Point” Eyewear when worn is approximately 1 thumb’s width below the hypothalamus points on either side of the head. This structure is a part of the Hypothalamus-pituitary-adrenal axis (HPAA). The HPAA is central to our entire endocrine system. The hypothalamus is the central regulator responsible for the shifting of homeostasis. The HPAA is the conduit for our emotions and psychological stress is primarily mediated through this axis. It has, like the whole neuroendocrine system, far-reaching interaction with the other hormonal systems as well as the rest of the autoregulations systems.

It is possible that the “Pressure Point” eyewear is stimulating the posterior hypothalamus by invoking resynchronization of the neocortical electrical activity.

- C. The “Pressure Point” eyewear may be modifying the signaling to assist in brain synchronization similar to sound therapy. Specific frequencies can create a rhythm which assists the right and left hemispheres of the brain to “synchronize” and enhance communication between both sides of the brain. In doing so, the brain “adapts” to the new complex mental stimulation, resulting in an increase in brain activity. We know that brain waves induced by “sound” therapy can produce a 15-50% increase in the production of several beneficial neurochemicals such as acetylcholine, serotonin, beta-endorphins and vasopressin which increases mental focus and memory, prevents depression, and boosts immune functions.

Serotonin – Studies show that there is a chemical hierarchy in humans associated with social “rank” that is linked with serotonin levels. Those in high office, higher positions on sports teams and those of higher rank in academic clubs have been found to have higher levels of serotonin than their lower ranking peers. Low levels of serotonin are associated with depression, violent behavior, and suicide.

Beta-Endorphins – These are the body’s natural pain killers. Normal levels of beta-endorphins enhance our overall sense of well being. High levels are associated with feelings of immense joy and euphoria. People with normal to high levels of beta-endorphins are less likely to drink alcohol while those with low levels are at a much higher genetic risk of becoming alcoholics.

Acetylcholine – Studies show that increasing acetylcholine levels improve performance in a variety of memory and intelligence tests and increase alertness. Low levels of the neurotransmitter are associated with Alzheimer’s disease.

Vasopressin – Normal levels of vasopressin aid, in part, to the formation of memories. It was approved by the FDA to regulate the bladder.

General Health Questionnaire

We want to know how your health has been in general over the last few weeks. Please read the questions below and each of the four possible answers. Circle the response that best applies to you. Thank you for answering all the questions.

Have you recently:

- I) Been able to concentrate on what you're doing?
 - 1) Better than usual
 - 2) Same as usual
 - 3) Less than usual
 - 4) Much less than usual
- II) Lost much sleep over worry?
 - 1) Not at all
 - 2) No more than usual
 - 3) Rather more than usual
 - 4) Much more than usual
- III) Felt that you are playing a useful part in things?
 - 1) More so than usual
 - 2) Same as usual
 - 3) Less so than usual
 - 4) Much less than usual
- IV) Felt capable of making decisions about things?
 - 1) More so than usual
 - 2) Same as usual
 - 3) Less than usual
 - 4) Much less than usual
- V) Felt constantly under strain?
 - 1) Not at all
 - 2) No more than usual
 - 3) Rather more than usual
 - 4) Much less than usual
- VI) Felt you couldn't overcome your difficulties?
 - 1) Not at all
 - 2) No more than usual
 - 3) Rather more than usual
 - 4) Much more than usual
- VII) Been able to enjoy your normal day to day activities?
 - 1) More so than usual
 - 2) Same as usual
 - 3) Less so than usual
 - 4) Much less than usual
- VIII) Been able to face up to your problems?
 - 1) More so than usual
 - 2) Same as usual
 - 3) Less than usual
 - 4) Much less than usual
- IX) Been feeling unhappy or depressed?
 - 1) Not at all
 - 2) No more than usual
 - 3) Rather more than usual
 - 4) Much more than usual
- X) Been losing confidence in yourself?
 - 1) Not at all
 - 2) No more than usual
 - 3) Rather more than usual
 - 4) Much more than usual

XI) Been thinking of yourself as a worthless person?

- 1) Not at all
- 2) No more than usual
- 3) Rather more than usual
- 4) Much more than usual

XII) Been feeling reasonable happy, all things considered?

- 1) More so than usual
- 2) Same as usual
- 3) Less so than usual
- 4) Much less than usual

Likert Scale 0,1,2,3 from top to bottom of each question was used.

Scores of 11-12 are typical

Scores greater than 15 are evidence of distress