AN INTERNATIONAL CLINICAL STUDY of THE SONIC DISRUPTION OF SYMPATHETIC AROUSAL PRINCIPLE as DESIGNED in the BAUD DEVICE

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ABSTRACT

The purpose of this study was to determine whether the sonic disruptor sympathetic principle as embedded in the technology of the Bioaccoustical Utilization Device (BAUD) could be effective in alleviating symptoms related to emotional issues, impulsive behavioral issues, and/or chronic pain. Eighty-six patients treated by 19 therapists in the US, Switzerland, Portugal, and Denmark underwent treatment with the BAUD for one or more sessions. A Likert rating of symptomatology was recorded before and after treatment for all patients, and 3 wks after treatment in a subset of patients. Analysis of immediate post-treatment data using McNemar's test demonstrated clinically and statistically significant improvement in all three symptom groupings. Data recorded 3 wks post-treatment demonstrated stability of post-treatment results in most patients in the emotional issues and chronic pain categories (insufficient 3 wk post-treatment data were available in the impulsive behavioral issues category for analysis). These data suggest that the BAUD technology holds promise for alleviating from a variety of internationally trained therapists.

INTRODUCTION

The Sonic Sympathetic Disruptor principle has been discussed recently as part of the new realm of brain plasticity advances. (Doidge, 2007;Lawlis, 2009). Briefly it states that the brain arousal system has many personal qualities, but with sonic stimulation, can be modified (Lutz, 2004). The stimulation of the firing of the target pathway or circuit makes it susceptible to modification, and holds great promise for PTSD treatment, according to LeDoux's theory(LeDoux, 2001). However, these research efforts have been with the use of drugs (propanolol) to reduce traumatic imprinted memory. Neuronal connections can be monitored by these sonic disruptions theoretically by changes in E.E.G. shifts in electromagnetic measurements (Labbe; 2007; Maxfield, 1994). In a more demonstrable format, it has been known for centuries that music selections can modify sympathetic arousal, although there is a strong selectivity of soothing music (Bittman, et al.; 2005). The BAUD was engineered to have a more objective sonic application, using only frequency selection and a specific methodology.

The Bio-Acoustical Utilization Device (BAUD) is a FDA class 2 accessory medical device designed to enhance brain plasticity in biofeedback programs. The device creates independent square sound waves from 39 to 362 Hz that are heard separately in the left and right ears. The resulting interference between the two sonic waveforms creates a third sonic waveform. The underlying acoustical physics entrain the general EEG ranges by creating a third tone from the interference ratios between the two frequencies. It is thus purported to influence brain functioning at the unconscious level and perceived emotional functioning at the conscious level (Lawlis, 2009).

Despite case reports of its effectiveness in treating chronic pain and smoking cessation, as well as emotional disorders such as phobias, depression, anxiety, hoarding and psychosis in public forums, little research has been conducted with the device (Lawlis, 2004). One study, presented at the 2007 International Society for Neurotherapy Research conference, was

conducted with Attention Deficit and Hyperactivity Disorder (ADHD) patients. It is clear that additional studies are needed to more quantitatively define the benefits for patients with other disorders. Therefore, the present study compiled reports documenting treatment results for emotional issues, impulsive behavioral issues, and chronic pain for eight-six patients across four nations. It was hypothesized that treatment with the BAUD device using the principle for sonic disruption sympathetic would provide measurable symptom relief in one or more categories.

METHODS

Subjects. Reports were received on 86 patients treated by 19 therapists in the United States (38 patients), Switzerland (23 patients), Portugal (24 patients), and Denmark (1 patient). Patients were treated with the same protocol (see below) for one of three disorders: emotional issues (n = 50), impulsive behavioral issues (n = 19), or chronic pain (n = 17). The emotional issues were primarily anxiety and phobic problems with depressive syndromes. The impulsive behavioral issues involved behaviors (e.g., smoking, eating excessively, gambling) that were attempts to deal with emotional issues through lifestyle and behavioral compensation. The chronic pain issues dealt directly with long term pain, in particular back pain, headache and idiopathic pain.

BAUD device. The BAUD consists of a handheld sound-emitting appliance utilized by the patient in conjunction with a set of headphones. The BAUD has independent volume controls for the left and right ears. The device also has a tone (frequency) knob to adjust the sound frequency It also has a "disrupter" adjustment which functions as follows: the tone generated in the left ear is that presented to the right ear plus an offset based on the position of the disrupter knob. When the disrupter adjustment is set at the lowest level (0 Hz), the frequencies heard in each ear will be identical. At the other extreme, when the disrupter adjustment is at the highest level, the tone heard in the left ear will be that of the right ear plus 20 Hz

Treatment Protocol.

The patient places the headphones on and adjusts each of the volume knobs so that a moderately loud, yet comfortable level of sound is achieved. The wave form designed for the BAUD is a square wave intended to have a greater impact on brain function from its more abrasive response than the sine-wave characteristic of soothing sonic stimulators. The patient then imagines the stressful situation in as great a detail as possible, focusing on the emotion associated with the stress (e.g.,fear, dread, anger, etc). The patient rates the emotional or sympathetic state on a scale of 1-10 (1 being no emotion and 10 being very intense)(see Figure 1). Holding the image and emotion in mind, the patient adjusts the frequency to a point where the emotional feeling are stronger or intensified (greater than the scaled rating (1-10). This peak can also be measured by a GSR meter, heart rate variability or differential pulse meter. Most times, the higher sympathetic activity can be easily observed in sweating, breath rate and color of the skin. This frequency level is labeled the sympathetic arousal point.

(Insert Figure 1 here)

The next step is to neutralize or lessen the feelings by adjusting the disrupter frequency. At a certain point in the disruptor adjustment, the third frequency produces a distinct lessening of the problem's sensation level – whether emotional, impulse or pain. This third frequency is noticeable to the patient as disrupting the emotional arousal and creating a sense of calm or lessening of the emotional arousal. Another rating is requested between 1 and 10 to determine effectiveness impact. Most of the time, the image dissolves from the person's attention due to lack of emotional strength and is testimony to the rate of dissolution of the sympathetic arousal. The majority of the time the patient is puzzled with the dissolution.

The final steps have been added to t he protocol since these data were collected, but now considered part of the process of stabilizing the new pattern of firing. Using the Fifth Principle of Brain Plasticity (Lawlis, 2009) the subject is requested to hold the original imagery situation in mind while doing relaxation breathing. This method is basic to all desensitization programs and needs no validity proof that relaxation aids in disassociation to stressful stimuli; however, the method used alone usually takes more than a few moments. This timing of this phase is usually based on the patient's decision of when they want to move the last step.

The last step to be taken and considered to be vital is to shift the frame to a humorous perception and to laugh aloud. The research on humor and emotional shifts has clear implications to creating similar responses for releasing negative emotional association in rational behavioral techniques. However, the patients often note a surprising awareness that they can laugh at the stressful situations and their relief responses are often noticeable and can be joyous.

Statistical Analyses. Descriptive data (means and standard deviations) were calculated for pre- and post scores for each of the three symptom groups. However, the data were analyzed using the McNemar's test (1956, Siegel) because of the level of measurement. Significance was accepted when 3 criteria were satisfied: (1) p-value < .01, 2) there was at least a 2 point difference between the pre- and post-scores, and 3) the pre-post difference in scores crossed the mid-point of the rating scale (i.e., 5-6).

NOTE: The assumption in using this test is the need to determine clinical effectiveness. A t-test would only demonstrate changes, but in order for the clinical differences to be highlighted, the impact was defined as a post test be less than the mid-point than the pre-test, which would be above the mid-point since we defined the mid-points as being "manageable."

RESULTS

Descriptive data. Pre-post scores for the three symptom groups are shown in Table 1. All three categories demonstrated significant improvements ($p<0.0001$), while also demonstrating a greater than 2 point improvement in Likert ratings that crossed the midpoint of the scale. The emotional category met the criterion in 47 of 50 trials, the impulsive behavioral category met the criterion in 16 of 19 trials, and the pain category met the criterion in 16 of 17 trials.

Follow up data were recorded three months after treatment in a subset of patients. These data analyses are shown in Table 1.

DISCUSSION

These data suggest that the technology embedded in the BAUD was effective in alleviating symptoms for patients with emotional, impulsive behavioral, and chronic pain problems with some supporting analyses for enduring results. What is also striking is that improvements were recorded cross-culturally, and often after only short treatment periods.

It is hypothesized that brain plasticity is being affected by BAUD treatments perhaps in the way neural regulation is obtained in neurotherapy. However, psychological pathways are not thought as being so fluid as to permit such significant changes in a short period of time. The changes demonstrated are also greater than one would expect from simple attitudinal shift, or from improvement in the underlying problem (e.g., pain).

It is possible that the application of the BAUD is modifying stress responses and/or reducing sympathetic activation. In other work done with patients in the US, EEG data demonstrate that the amplitude of High Beta Wave activity was reduced. In addition, heart rate variability (HRV) responses in patients before and after BAUD sessions show changes

suggestive of greater parasympathetic control. It is noteworthy that these two technologies provide supportive and complementary data to the data outlined in this report.

In summary, the principle of sonic disruption of sympathetic arousal does have impact as defined and designed in the BAUD device. There were consistently reactions across therapists and cultures to promote alleviate symptoms in emotional and impulsive behavioral areas, and in chronic pain. Further study is needed to verify these results, identify other conditions that might benefit from BAUD treatment, and determine the long-term stability of treatment changes. Nevertheless, these data together with preliminary data showing shifts in brain wave patterns and neuronal control, offer promise for a viable new mode of treatment for a variety of psychological problem, such as cravings and phobias.

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Table 1. Likert ratings before and after treatment with the BAUD.

Symptom group	Pre-treatment Means (S.D.)	Post-Treatment Means (S.D.)	3 wks Follow-up Means (S.D.)
Emotional	7.5 (1.46)	3.6 (1.98)	2.44 (1.04)**
n	50	50	25
Range	6 -10	0 – 7	0 - 5
Criteria met for successful trials: 47/50*			
Impulsive Behavioral	7.7 (1.66)	2.9 (2.13)	3.20 (1.6)**
n	19	19	5
Range	8 -10	0 – 8	2 - 6
Criteria met for successful trials: 16/19*			
Chronic Pain	7.2 (1.64)	2.2 (1.33)	1.33 (2.06)**
n	17	17	9
Range	4 -10	0 – 7	0 - 3
Criteria met for successful trials: 16/17"			

*McNemar, $p \leq 0.0001$,

** McNemar, n.s., criteria not met since all remained less than midline,

T-tests Post - F/W Emotional = 1.01 n.s.

Post –F/W Impulsive = not appropriate for low n,

Post – FW Pain = 1.2 n.s.

Figure 1

Rating Scale of Emotional Stress Association