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HRV: THE MANUFACTURERS AND VENDORS SPEAK

The Portable StressEraser Heart Rate Variability Biofeedback Device: Background and Research

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Heart rate variability biofeedback is a burgeoning clinical intervention for a variety of disorders. This paper describes a handheld heart rate variability biofeedback device called the StressEraser. The role of home training devices, the device algorithm and biofeedback method, and current research findings are highlighted. Additional attention is paid to the importance of user preferences and compliance with home practice when choosing appropriate interventions.

Introduction

There is now ample evidence that heart rate variability is a diagnostic marker of health and adaptability (cf. Lehrer, 2007). Correspondingly, there is a rapidly growing literature on the efficacy of heart rate variability/respiratory sinus arrhythmia (HRV/RSA) biofeedback for a variety of conditions. Respiratory sinus arrhythmia is the natural fluctuation of heart rate that is influenced by breathing and the impulses from the baroreceptors (Lehrer, 2007). Rather than summarize the empirical literature on HRV/RSA presented in this special issue, this article will summarize the background and current research on the StressEraser, a portable RSA biofeedback device.

Progress in HRV Instrumentation

Akin to the evolution of most technologies, the pioneers in the HRV/RSA field (e.g., Alexander Smetankin, Evgeny Vaschillo, Paul Lehrer, Richard Gevirtz, and Stephen Porges) laid the groundwork, and technology companies built on this foundation by bringing new solutions to diagnosticians, treatment providers, and consumers by implementing new algorithms within portable devices. As with most forms of biofeedback, HRV/RSA biofeedback is typically performed in clinical settings and clients are taught to generalize the method out of session. Home trainers, such as the StressEraser, provide the opportunity for biofeedback to expand beyond the clinic, enabling patients to better practice the techniques they learned in session. These home trainers also extend the scope of biofeedback technology to a base of clinicians and patients who are unaware of or naive to the advances in the field.

These advances are in some ways a double-edged sword for biofeedback providers. On the one hand, there is concern that home trainers may reduce patient contact because some of the services typically performed in the clinic are now available directly to the client. On the other hand, we have observed that people outside the field have a new awareness of the value of physiological feedback. There is hope that this expanded awareness can increase the scope and practice of psychophysiological assessment and treatment.

The StressEraser Home Trainer

The StressEraser is registered with the Food and Drug Administration (FDA) as a Class II (510[k] premarket notification–exempt) medical device, with an indication for relaxation, relaxation training, and stress reduction. It measures the real-time interbeat-interval (IBI) of the heart using finger photoplethysmography. The IBI data are transformed and displayed as an RSA wave on an LCD screen, allowing users to see the real-time fluctuations of their pulse rates. Using the RSA wave, users are guided to find their optimal slow respiration rates and to maintain a cognitive focus so that real-time heart rates and respirations covary in a perfect phase relationship (Figure 1). To achieve this, users inhale until the heart rate peaks and exhale until it begins to rise again. When done correctly, this creates a resonance between respiratory and baroreflex rhythms, the two primary sources of cardiac stimulation (Vaschillo, Vaschillo, & Lehrer, 2004). The breathing rate at which this occurs is called the resonant frequency (Lehrer, 2007). Resonant frequency differs from individual to individual but is usually somewhere between 4.5 and 7 breaths per minute. Breathing at this frequency produces large increases in HRV and baroreflex gain (Lehrer et al., 2003) and promotes respiratory efficiency (Giardino, Chan, & Borson, 2004).

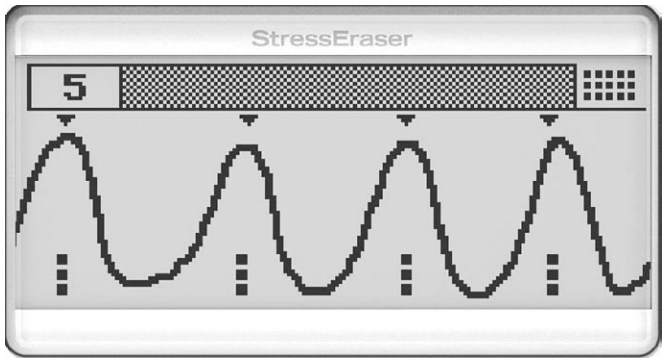

Figure 1. Optimal respiratory sinus arrhythmia pattern.

To assist users in slowing their breathing and maximizing the variations in heart rate, the StressEraser device uses a patent-pending algorithm that offers two types of feedback.

The device rewards users with points based on the wavelength for each RSA cycle. If the wavelength meets a certain threshold, users are given 1 point marked by three vertical squares. Two vertical squares receive .5 point and one vertical square receives no credit (see Figure 2 for the various symbols). The goal is to accumulate continuous points during the session (minimum suggested sessions are 5 minutes, with a goal of 20 minutes a day). To assist users in obtaining points, the device anticipates the peak of the RSA wave based on its slope and marks the peak with a triangle. The peak of the wave indicates the moment that a burst of vagal activity is about to begin during heart rate deceleration, indicating the parasympathetic response. Users are instructed to begin their exhale and to shift their thoughts to a calming focus phrase (Benson, 1975) when the triangle appears. They are instructed to extend their exhale for as long as possible until the wave begins to rise again. The large circle in the middle of Figure 2 is indicative of an exhale that is extended for too long, causing the wave to rise and fall without obtaining sufficient variability. There is no cue for the inhale. Ultimately, the goal is to create the smooth wave pattern as shown in Figure 1.

Because each individual RSA wave is analyzed by the device, it can detect breaks or "disruptions" in the wave even when there is sufficient RSA amplitude (see circle in upper right corner of Figure 2). Breaks in the wave usually are caused by strained breathing or excessive limbic activity, both of which increase sympathetic activity at an inappropriate time in the wave cycle. Mashin and Mashina (2000) found that cortico-limbic brain structures regulate cardiac rhythm during psychological relaxation. Therefore, if someone is breathing correctly but is worrying, for example, the device will not give credit because it registers disruptions as individual waves. Therefore, users must maintain a neutral/calm affective state during the sessions. In contrast, frequency measurements (e.g., spectral analysis) will not detect these periodic disruptions in the RSA wave because they provide a summary score over a fixed period of time.

Hence, the StressEraser provides a specific form of HRV biofeedback. Because the StressEraser uses a different algorithm than standard HRV biofeedback, it is possible that results from HRV studies cannot be generalized to the efficacy of the StressEraser and vice versa. Because of the intrawave measurement system on the device, users may receive periodic positive feedback when not doing proper RSA breathing, particularly those with high HRV. Studies are under way to determine the overlap between traditional HRV biofeedback measurements and the StressEraser. At minimum, a recent tech report by Porges, Heilman, and Handelman (2007), comparing the signals from the StressEraser with those of the Biopac MP35 (Biopac Systems, Goleta, CA), validated the application of the StressEraser as an indicator of respiratory HRV.

Users are encouraged to focus on efficiency once they become adept at using the device. To analyze efficiency objectively, users may access the history of each session by reviewing the time of use and points achieved. This feature may be particularly helpful for clinicians to assess progress and adherence, and it is also a key benefit for clinical studies. The emergence of PDAs and other portable compliance tools, such as electronic medication compliance aids, highlight the importance of objective methods for therapeutic monitoring outside the clinical setting to increase adherence to prescribed therapies and subsequent therapeutic outcomes (McKenney, Munroe, & Wright, 1992). Objective monitoring is also important, because there is clear evidence that people massively overreport out-of-session relaxation activities (cf. Kazantzis, Deane, & Ronan, 2004; Lehrer & Woolfolk, 2007).

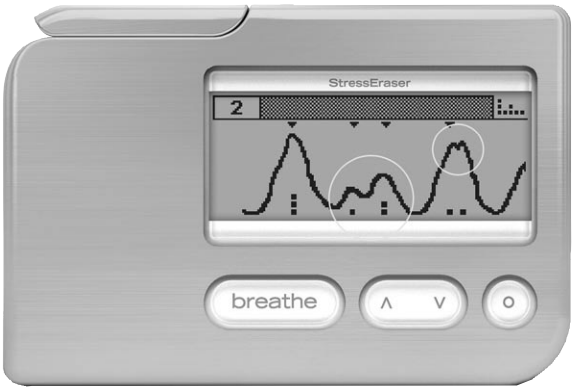

Figure 2. Respiratory sinus arrhythmia wave disruptions.

Research Using the StressEraser

There are numerous randomized clinical trials being performed with the StressEraser to assess the impact of the device as a stand-alone or adjunctive intervention for primary insomnia, generalized anxiety disorder, posttraumatic stress disorder, depression, cardiac rehabilitation, performance anxiety, and general stress levels. Most of these trials include both subjective (e.g., self-report) and objective (e.g., HRV and/or electroencephalogram) psychophysiological parameters. The control groups include alternate relaxation treatments, passive concentrative biofeedback, medications, treatment as usual, and/or historical controls. There are also several single-group studies completed or in progress using a dose-response model. In addition, some trials are assessing subjective user preferences. It is important to note that we are not able to present results on any disease states, because these indications are outside of the FDA indications of stress reduction, relaxation, and relaxation training. This section will focus primarily on general constructs associated with stress, such as stress-related symptoms of anxiety. The studies cited below were recently completed and are currently being prepared or have been submitted for publication.

Patient Preferences for Specific Treatments

Patient preferences and perceived helpfulness often are neglected components of the treatment process, yet these factors should be considered when providing interventions to people seeking help (Jonas, Linde, & Walach, 1999). In a recent hardware validation test with 23 persons reporting being stressed, 87.5% of users reported that the device was at least moderately helpful in relieving stress-related complaints, and 68.2% reported that they prefer the device to other relaxation/mediation techniques they had tried in the past. Moreover, users found the StressEraser significantly more helpful than other relaxation techniques they have tried. User-perceived helpfulness was highly correlated with the ability to use the device as directed.

In a pilot study, the StressEraser was used as an adjunct to cognitive behavioral therapy with 20 patients suffering from a variety of disorders. User-perceived helpfulness was assessed at the end of the study for those who engaged in other relaxation practices regularly. The samples for these comparisons varied on whether or not someone actually engaged in the other activities. In terms of comparisons, 73.3% (n = 11/15) reported finding the device more helpful than unassisted breathing exercises, 77.8% (n = 7/9) more helpful than meditation and 75% (n = 3/4) more helpful than yoga; only 27.3% (n = 3/11) of those who exercised regularly found the StressEraser more helpful (Reiner, in press). Logically, there was also a significant association between end-of-study user-perceived helpfulness and preference for the device with actual compliance. End-of-study user comments tended to suggest that the preference was primarily due to having a tangible tool for relaxation and the objective feedback on "whether they were doing it correctly." An interesting trend in this study was that more men than women appear to prefer the device over other relaxation techniques. This finding is in line with anecdotal evidence received from clinicians who report that men prefer the feedback and tangible nature of the device (and biofeedback in general) over unstructured relaxation paradigms.

Reducing Anxiety After Exposure to a Stressor

A recent randomized trial examined the short-term effects of the device compared with concentrative biofeedback, an alternative intervention, on state anxiety after exposure to a cognitive stressor in novice users (15-minute training) reporting moderate-to-severe levels of stress (Sherlin, 2007). The concentrative group used a StressEraser with a "smoothed" wave to display heart rate over 10-second intervals rather than in real time. Participants were instructed to watch the wave and let go of stressful thoughts to help their mind sync with their blood circulation. Results revealed that participants in both the StressEraser group and the concentrative biofeedback group significantly reduced their State Trait Anxiety Inventory-State scale (STAI-S) scores, $t(19) = 5.36$, $p < .0001$ and $t(21) = 3.97$, $p < .001$, respectively, but that participants in the StressEraser group had significantly reduced STAI-S scores compared to the concentrative biofeedback group, $F(1, 41) = 6.29$, $p < .05$. There was a significant dose response accounting for 26.2% of the variance. The more points users achieved with the device, the more likely they were to report improvement (see Figure 3).

Overall, results support the effectiveness of the device as a means to significantly reduce stress-related symptoms of state anxiety in novice users as compared with passive concentrative biofeedback. The dose-response relationship validates the scoring algorithm. An interesting finding in this study is that the concentrative intervention also significantly reduced state anxiety. Although the StressEraser was significantly superior, some of the efficacy of biofeedback appears to be a result of concentrative focus without active manipulation, and this highlights the powerful effect of using tangible tools to induce feelings of calmness. The psychophysiological results from the study are currently being analyzed.

The longer-term effects on the stress-related symptoms of anxiety have been assessed in several single-group studies. The clinical pilot study described above found that over the

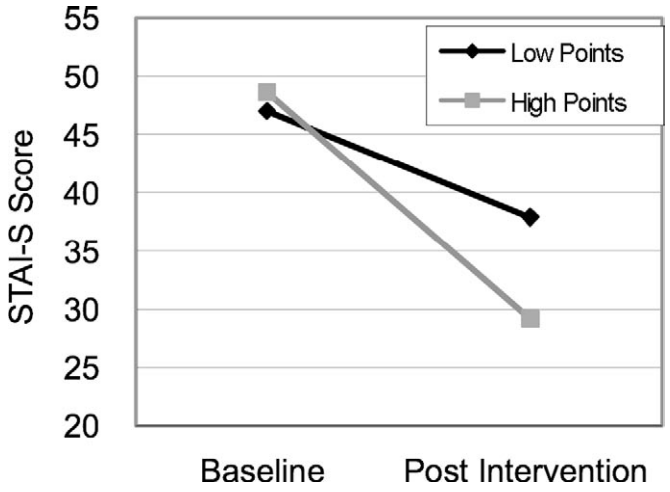

Figure 3. State anxiety dose response.

3-week period, there was a significant reduction in the STAI-Trait (STAI-T). There was also a significant dose response in that the more compliant a subject, the more likely they were to reduce their STAI-T scores. This study also revealed a significant reduction in trait anger as well as a significant dose response in this domain. The short and long-term results on the STAI were replicated during the StressEraser validation testing, though there was only a trend for the dose response. Overall, the effects of the device appear to be stable over time, but data from randomized clinical trials are still needed to determine long-term efficacy.

Use of the StressEraser in Performance Enhancement

It is logical that reduction in stress-related symptoms of anxiety may have utility in performance-enhancement settings (Davis, Sime, & Robertson, 2007). In a study of a National Collegiate Athletic Association Division I shooting team, Hayden and colleagues (2008) found that the device significantly reduced performance anxiety in the StressEraser group as compared with the waitlist control. The study had a small sample size (N = 12). An interesting finding in this study is that the change in performance anxiety was accounted for primarily by dramatic reductions in a few participants. This suggests that in performance domains, RSA biofeedback may be an "all or nothing" intervention.

Studies of Posttraumatic Stress Disorder

With any intervention, it is important to understand the mechanisms of change to truly understand why it may be effective. One longer-term study has recently been completed assessing the change in HRV. Zucker (2007) compared the effects of the StressEraser with progressive muscle relaxation (PMR) in persons with posttraumatic stress disorder. After the 4-week intervention, resting HRV (standard deviation of the normalized interbeat interval [SDNN]) significantly improved in the StressEraser group compared with the PMR group. The SDNN is a general index of HRV. Though these findings need to be replicated (currently being tested in a new trial), the increase in HRV may account for some of the stress-related symptom reductions in other studies. Because stressors reduce HRV (Berntson & Cacioppo, 2004; Delaney & Brodie, 2000) and people with lower HRV have been shown to be more reactive to stressors and have more psychological distress (cf. Lehrer, 2007), it is possible that increases in HRV reduce reactivity to stressors by increasing the flexibility of the autonomic nervous system.

Adverse Effects of HRV Training with the StressEraser

In our studies we keep close track of side-effect profiles. Although side effects were always mild and short-term (duration less than 15 minutes), they did exist for a subset of persons. Across studies, between 15% and 55% of users reported feeling drowsy, particularly after long sessions, and 2%–10% of persons reported anxiety when learning to use the device. Interesting to note, 10% of people in both the active and concentrative biofeedback groups in the acute state anxiety study reported a short-term (10- to 15-minute duration) increase in anxiety, suggesting that simply receiving feedback on one's physiology can provoke anxiety for some. The increased anxiety is particularly relevant for users who have difficulty learning to use the device and suggests that some users would clearly benefit from extended training (the training period in our clinical studies generally ranges from 15–30 minutes). This was evident in the acute study where all participants were given the same dose of treatment (15 minutes), but there was significant variability in efficiency.

Conclusions

When combined with the general HRV/RSA biofeedback literature, the results from the studies using the StressEraser, albeit limited in size and still being completed, reveal that HRV/RSA biofeedback is a promising intervention for those with stress-related problems, particularly those problems associated with low HRV. Ryan and Gevirtz (2004) reported that biofeedback may be particularly useful in primary care settings. The added benefits of portability and brief training time make the device particularly attractive in settings where time constraints limit patient contact and a home trainer can be a useful adjunct to office-based interventions. As the general public becomes aware of the powerful benefits and safety of mind-body and complementary and alternative medicine interventions, HRV biofeedback will play a primary

role. HRV biofeedback is the essence of mind-body medicine and should be a regular fixture in the clinician's tool box. No intervention is a panacea, and different problems require there be a multitude of techniques from which to choose. HRV biofeedback is one such tool that can help meet the needs of a heterogeneous client population with a variety of treatment needs and preferences.

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