Sensate® Somacoustics: A New Wave for Stress Management. Volume I

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Societal Stress

The human population has endured much stress since the turn of the century. Stress is both positive (eustress) and negative (distress). However, distress appears to represent the majority of human stress. In fact, prior to the Covid-19 pandemic, the majority of adults were reporting elevated amounts of distress (Clay, 2011; Ray, 2019). For example, close to 50% of American adults reported a moderate to high level of stress (Clay, 2011). Leading causes of distress were related to finances, job security, and economic concerns (Clay, 2011; Ray, 2019). Distress levels have only increased due to the unpredictability of COVID-19 and its future implications. The leading causes of distress are the same as they were in prior years. However, additional stressors have increased for parents and caregivers. Parents report more stress than non-parents (*Stress in America™ 2020: Stress in the Time of COVID-19, Volume One*, 2020). Leading parental stressors extend to their children's daily lives. Over 70% of parents report a significant amount of stress managing their children's online learning and nearly 75% of parents report disrupted routines or adjustment to new routines as stressful. In addition, there are concerns with the physical and mental health implications from COVID-19 (*Stress in America™ 2020: Stress in the Time of COVID-19, Volume One*, 2020).

Continued distress negatively affects mental and physical health. The central nervous system responds to physical and psychological stressors through the autonomic nervous system (ANS). The ANS is divided into the sympathetic and parasympathetic system. Both systems work to stimulate and relax key physiological systems when stressed. There are three stages of stress response within the body; Alarm, Resistance, & Exhaustive (Selye, 1950). The initial stressor leads to the alarm phase which is the body's "flight or fight" response. The sympathetic nervous system is activated by the release of key hormones such as cortisol and adrenaline which in-turn increases heart rate, blood pressure, and respiration rate (Godoy et al., 2018; Gordan et al., 2015). The alarm phase is intended to be short-lived by providing energy needed to respond to the stressor. The second phase of stress is the resistance, and this is when the body attempts to repair itself by activating the parasympathetic nervous system (Selye, 1950).

This is when the body attempts to self-regulate by reducing stress hormones and allowing the body and mind to return to baseline or homeostasis with heart and respiration rate, and blood pressure. However, if the stressor is not removed then the body will stay in the alert stage never allowing the body to recover during the resistance stage. Individuals are unable to return to homeostasis due to prolonged stress and can develop irritability, sleeplessness, headaches, suppressed immune function, and hypertension (Godoy et al., 2018; Won & Kim, 2016). The final phase of stress is the exhaustion stage. This is a period of time when the body has depleted its mental, emotional and physical resources to recover from stress (Selye, 1950). This is the stage when an individual is no longer able to cope and symptoms of individuals in this stage include burnout, fatigue, anxiety, feeling of hopelessness, and depression (Won & Kim, 2016).

Unfortunately, many individuals appear to be stuck in the second and third stages of stress response based on Selye's theory. According to the (2011) Stress in America report, nearly 50% of adults indicate stress fatigue and lack of interest/motivation in doing things. Moreover, approximately 45% of respondents indicate heightened anxiety and feelings of sadness/depression (Clay, 2011). These have worsened since the pandemic. Approximately 50% of adults demonstrate traits of anxiety and close to 60% exhibiting depression (Shah et al., 2020). According to the America's State of Mind report, there was a 20 % increase in anti-anxiety, anti-depressant, and anti-insomnia medications during the initial phase of the pandemic. The largest increase was in anti-anxiety medications at 34% compared to early February 2019 to mid-March 2019. Equally alarming is that nearly 80% of anti-anxiety, anti-depressant, and anti-insomnia medications were new prescriptions (*America's State of Mind Report*, 2020). Unfortunately, these medications do not help with positive behavior change. One year into the pandemic suggests adults have either gained or lost an undesired amount of weight as a result of negative eating behaviors, increased consumption of alcohol to assist with coping, and are not getting adequate sleep due to insomnia (*Stress in America™ One Year Later, A New Wave of Pandemic Health Concerns*, 2021). Individuals need positive coping mechanisms to assist with anxiety, insomnia, and other stress related symptoms.

There are several self-help methods for positive stress management including physical exercise, setting a sleep schedule, deep breathing exercises, eating healthy, and reducing alcohol intake. However, applying these skills requires motivation, self-determination, and self-discipline. With increased anxiety, fatigue from the lack of sleep, and depressive tendencies the motivation to apply these self-help options can be inconsistent. One of the easiest methods for management of stress related symptoms is deep breathing exercises.

Deep breathing techniques are postulated to stimulate the vagus nerve (Gerritsen & Band, 2018) which is the tenth cranial nerve that represents the primary component of the parasympathetic nervous system influencing mood, heart and respiration rate (Breit et al., 2018). The vagus nerve is a mixed nerve composed of 20% "efferent" fibers (i.e., sending signals from the brain to the body) and 80% "afferent" fibers (i.e., carrying information from the body to the brain) (Howland, 2014). Theoretical mechanisms of how deep breathing stimulates the vagus nerve to improve parasympathetic function is complex and may be attributed to indirect and direct respiratory patterns such as a slower respiratory rate, the ratio between inhalation and exhalation, "OM" chanting, and/or diaphragmatic breathing, (i.e., *deep abdominal breathing*) Gerritsen & Band, 2018; Kalyani et al., 2011; Stancák et al., 1993; Stancák et al., 1991).

Vagus Nerve Stimulation

Vagus nerve stimulation (VNS) can be defined as a "technique or method" that creates an action potential on afferent nerve fibers leading to the vagus nerve. The earliest recorded example of vagus stimulation was with massage in the late 1800's. It was observed that compressing and massaging the cervical region of the carotid artery could suppress seizures (Lanska, 2002). In addition, we know massaging the carotid artery can lead to decreased heart rate and blood pressure. The carotid sinus baroreceptors located in the artery are innervated by the carotid sinus nerve branch leading to the vagus nerve.

VNS is not new and research on the efficacy of stimulating the vagus nerve with electrical currents is well documented and understood in the medical community (Howland, 2014). Electrical stimulation (eVNS) can be achieved by a surgically implanted device that emits an electrical current to the right or left cervical vagus nerve. A transducer emits a volt to the nerve and the membrane potential of the nerve cell becomes more positive than when at rest (Purves et al., 2001a). This creates an action potential sending the signal to the brain. The voltage will not influence the intensity of the action potential. Instead, the voltage or intensity of the electrical current will increase the frequency of the action potential (Purves et al., 2001a). In addition, electrical currents may be applied transcutaneously to specific nerve endings such as through the auricular branch of the vagus nerve (Howland, 2014). Prior research has suggested electrical stimulation of the vagus nerve may be efficacious for reducing anxiety and improving depression (Aaronson et al., 2017; Breit et al., 2018; George et al., 2008; Noble et al., 2017; Rong et al., 2016; Rush et al., 2005).

Another possible mechanism is through mechanical wave (i.e., acoustic wave or soundwave) vibrations (aVNS). Mechanical waves need a medium to travel such as air or liquid compared to electrical waves. Soundwaves include audible (20hz-20Khz) and subaudible (0-20hz and >20Khz) vibrations. Ultrasound (>20Khz) vibrations have been commonly used in medical diagnostics and physical therapy (Carovac et al., 2011; Miller et al., 2012). In addition, infrasound vibrations influence the human body. There is debate on the negative effects of environmental infrasound from wind turbines on human health (Knopper et al., 2014). However, there is research supporting improved cell metabolism from infrasound and the effect from infrasound depends on the applied frequency, duration of exposure, and amplitude (Vahl et al., 2021). Nonetheless, soundwaves are pressure waves that create a physiological response, and it is believed this can occur in the central nervous system as well.

The body's mechanoreceptors can respond to a broad frequency of sound vibrations (Persinger, 2013). One of the most sensitive mechanoreceptors to sound vibrations are pacinian corpuscles. These are located throughout the body including below the skin, joint spaces, thoracic cavity and its organs (Iheanacho & Vellipuram, 2021; Purves et al., 2001b).When vibratory pressure is detected a compression force is transmitted to the central nerve fiber via fluid in the corpuscle. This deformation opens certain sodium channels in the nerve fiber and a receptor potential is generated. It's this action potential that sends the signal along the sensory nerve and is carried to the brain (Figure 1) (Purves et al., 2001b; Sigurdardóttir et al., 2019).

The possible mechanisms for the actional potential and transmitting the signal to the brain is likely the result of acoustic resonance (fluid, organs, and cavity) within the body (Persinger, 2013). It is theorized that the amplified sound wave is directly influencing the sub-branches of the vagus nerve. Soundwaves travel faster and further through water compared to air. The human body is composed mostly of water and the speed of sound is similar in many of the body's soft tissues (1500-1600 meters/sec) (Lloyd, ; Shin et al., 2010). The amplified sound waves from the abdominal cavity likely creates the action potential to stimulate the vagus nerve. Initial research using High Amplitude Low Frequency–Music Impulse Stimulation (HALF‑MIS) targeting the abdominal part of the vagal nerve and/or its afferent branches suggest a positive response (Sigurdardóttir et al., 2019).

Researchers conducted a pilot study utilizing eight, HALF-MIS sessions for 20 minutes per time in-combination with pharmacotherapy for depression over a period of 3-4 weeks. Results demonstrated a significant improvement in depressive ratings when comparing HALF‑MIS as an add‑on treatment to standard pharmacotherapy options (Sigurdardóttir et al., 2019). However, a 2021 study attempted to assess the vagus nerve response in chronic pain patients over a three week period and the researchers question the ability to stimulate the vagus nerve with this technology (Eshuis et al., 2021). Eshuis and colleagues applied various frequency therapeutic sessions of MAHL-MIS therapy (20-100 Hz) with music or higher frequency (200-300 Hz) with music through randomized means in 60 patients. There were eight treatment sessions that were 24 minutes in duration per session. Researchers utilized self-reported questionnaires (Numeric Pain Rating Scale (NSR), health related quality of life (EQ05D-3L) Pain Disability Index (PDI)) prior to and following the last session. However, no biometric data was obtained for parasympathetic response.

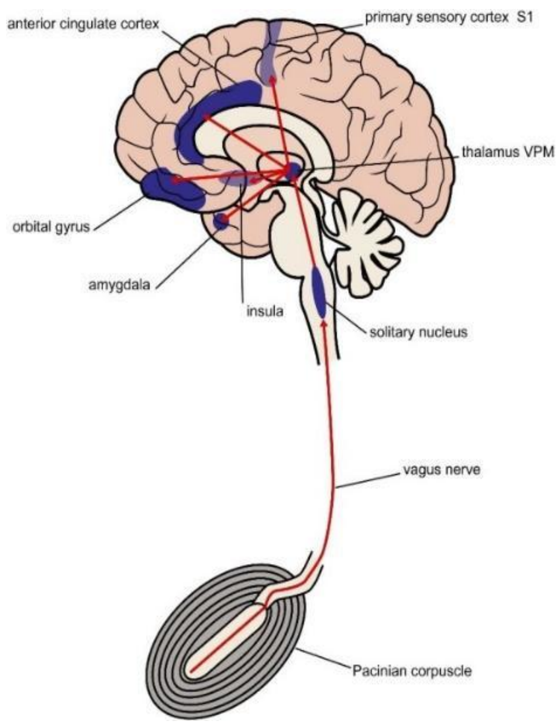

Figure 1. Pacinian corpuscles transfer afferent action potentials through the vagus nerve to the brainstem and subsequent areas of the brain implicated for mood (Sigurdardóttir et al., 2019).

Results suggest in both treatment groups that the average NRS score per patient after treatment was significantly lower than the average NRS per patient before treatment. There was no difference between groups and there was no difference over time with EQ-5D-3L and PDI. Researchers suggest various reasons for improvement in pain immediately following each treatment; rest, placebo, music, gate control theory, and VNS (Eshuis et al., 2021). However, the researchers reported how VNS on nociception is conflicting and is dependent upon the individual. Moreover, the researchers failed to monitor a proxy of vagal activity and the sample size was smaller than anticipated due to the COVID-19 pandemic (Eshuis et al., 2021). Therefore, results from this study should be cautioned given these limitations yet does offer a possible immediate benefit following treatment.

Vibroacoustic stimulation was originally suggested by Olav Skille as a mechanism for whole body vibration (WBV) and early reports suggest vibroacoustic stimulation may improve stress induced depression, anxiety, tension, and fatigue (Skille, 1989). These findings along with results from Sigurdardóttir et al., (2019) may support the use of aVNS as a feasible, effective, modality for individuals being treated for stress related symptoms.

Neurological effects from VNS

The U.S. Food and Drug Administration approved VNS as an adjunctive long-term treatment for chronic recurrent depression in patients over the age of 18 years (Carreno & Frazer, 2017). The vagus nerve efferent component originates in the brainstem. Whereas the initial termination point of its afferent fibers is primarily the nucleus solitarius, located in the medulla (Figure 1). As mentioned earlier, 80% of the vagus nerve is afferent meaning information is sent from the body to the brain. eVNS through functional magnetic resonance demonstrates changes in various regions of the brain and brainstem (Carreno & Frazer, 2017). More specifically, 4-weeks of VNS was found to alter the resting state functionality between the right amygdala and left dorsolateral prefrontal cortex and enhancement of the left insula which propagate improvement in depressive symptoms (Fang et al., 2017; Liu et al., 2016).

VNS is also believed to enhance the neurotransmission of the non androgenic and serotonergic systems that are associated with anxiety and depression. In fact, several eVNS studies have demonstrated improved dopamine, norepinephrine, and serotonin response within the brain (Carreno & Frazer, 2017). Albeit there are no studies on the use of aVNS and its effect on neurochemicals there are several studies on whole-body vibrations (WBV). Results from low-amplitude WBV suggest increased dopamine in the striatum and dopaminergic neurons in the brain (Zhao et al., 2014). In addition, whole body vibration between 20-30 hz significantly increase brain secretion levels, increases proteins for required neural plasticity (Ariizumi & Okada, 1983; Boerema et al., 2018), and reduces anxiety-related behavior (Oroszi et al., 2021). However, the latter may be related more to the effects from physical exercise given WBV is defined as passive physical exercise (Boerema et al., 2018).

The use of VNS and WBV do have limitations as the long-term therapeutic effects are not the result of acute use. Similar to antidepressants the benefits will be overtime as it may take between 1 to 12 months to see improvements based on depression and/or anxiety severity (Carreno & Frazer, 2017). However, as noted by Eshuis et al., (2021), there were immediate benefits following a MAHL-MIS therapy session such as relaxation and decreased pain perception. Therefore, benefits might be acute and/or long-term dependent upon the individuals severity and duration of stress related symptoms.

Sensate® Device

Sensate® (Sensate, Inc/BioSelf Technology Ltd of London, UK), is a non-electrical, vibrotactile device designed for stress management (Figure 2). Sensate® is one component of a complex, cross-modal (acoustic and aural) sensory experience (i.e., *Sensate® Somacoustics*) that supports relaxation and positive affect. The device utilizes low-frequency technology (<50 hz) to improve the parasympathetic nervous system's (PNS) response to chronic stress. There are two theoretical concepts of the Sensate® device: Bone Conduction and Thoracic Resonance.

Bone conduction is commonly used for patients with hearing abnormalities. Bone conduction hearing is placement of a vibrating transducer in contact with skin of the head (Lenhardt et al., 2007). Soundwaves in the human move much faster through bone when compared to soft tissue. For example, soundwaves can travel up to 2814 m/sec in the human skull and up to 3515 meters/sec in cortical regions of the bone (Lloyd, 2022).

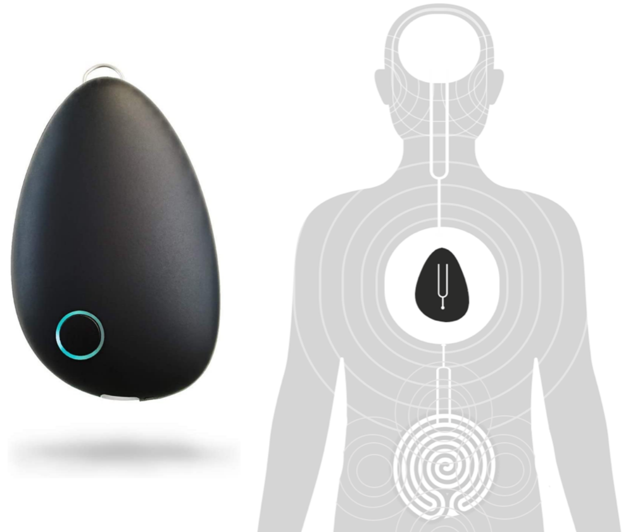

Figure 2. Sensate® device applies infrasonic sound technology for improved parasympathetic response to stress.

Cortical regions of the bone are mostly located in the outer layer of the long bones forming the shaft. A study by Lenhardt et al. 2007 demonstrated that placement of a transducer on various regions of the body could result in Ultrasonic detection (25 kHz and 62.5 kHz). However, further placement of the transducer from the ear must have greater energy as it takes approximately 5 db more energy to detect ultrasound at distant regions from head except for the neck and thorax (Lenhardt, 2007). Researchers were surprised with the sensitivity of the sternum as the placement of the vibrating transducer, at the sternum, is similar to the mastoid bone in sensitivity. Curved bones (e.g., rib bones) produce greater electrical energy according to Lendardt, (2007). Therefore, accordingly the sternum can easily be displaced due to greater bone movement which leads to greater amplification. In addition, additional energy may be the result of resonant properties within the thorax (Lenhardt, 2007).

Thoracic amplification can be supported by the results from Lenhardt, (2007) and research on chest percussion (Peng et al., 2014). Percussion is a common component of clinical chest physical examinations where the objective is to assess if an area is air, fluid, or solid-filled (Peng et al., 2014). Peng et al., (2014) evaluated the percussion of high and low frequency (50-200 hz) sound waves when placed on the chest using computed tomography. Their research supports that low frequency sound waves (60 Hz) travel a longer distance around the internal organs and the structural changes of the internal organs have a small effect on the transmission of low frequency waves (Figure 3).

The location of the afferent nerve branches that innervate to the vagus nerve are located throughout the thoracic cavity. The cross section of the CT image supports possible afferent aVNS with lower frequency soundwaves given the proximity of the transducer, resonant properties of the sternum/ribs (Lenhardt, 2007; Lloyd, 2022), and resonance of the thoracic cavity (Peng et al., 2021; Peng et al., 2014). As a result, the Sensate® device may be a novel aVNS modality that improves PNS function. An improved PNS response, from Sensate®, may result in lower levels of anxiety, insomnia, and other stress related symptoms leading to improved well-being.

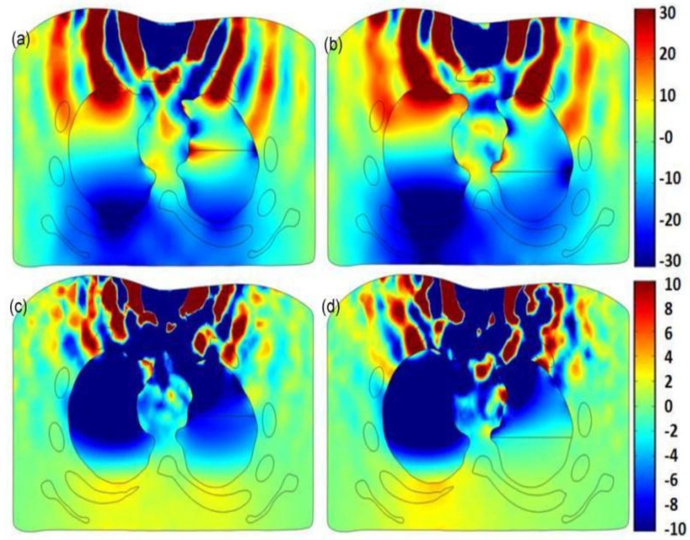

Figure 3. Simulation of 60 hz (A & B) and 120 Hz (C&D) excitation frequency cross section of the toros presenting displacement in the anterior to posterior direction. The color bar shows displacement in [um](Pen et al., 2014).

Biographical Note

Dr. Scott McDoniel has over 15 years of clinical research experience in health and wellness and has over 20 years of clinical experience in integrated healthcare.

Stefan Chmelik, M.Sc., inventor and founder of Sensate®, provided technical and clinical information on the Sensate® device. Stefan has over 30 years of clinical experience and is a noted pioneer with technology-assisted relaxation.

Conflict Statement

Dr. Scott McDoniel is an independent research consultant for BioSelf Technology, Ltd. Dr. McDoniel has no ownership of patents, stock, or equities to Sensate®.

For more information about Sensate® visit www.getsensate.com

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