Relaxis™ vibratory counterstimulation therapy (Sensory Medical, Inc., San Clemente, CA) is the only non-drug treatment cleared by the U.S. Food and Drug Administration (FDA), for the symptoms of restless legs syndrome (RLS).\(^1\) Furthermore, a recently published meta-analysis comparing Relaxis therapy with FDA-approved RLS drug therapy demonstrated no significant difference between the two.\(^2\) That is, Relaxis therapy and RLS drug therapy produce comparable levels of sleep improvement as reported by RLS patients. Relaxis therapy, of course, has none of the widespread side effects of drug treatment. The few adverse effects reported during Sensory Medical’s two clinical studies were mild to moderate and included temporary worsening of RLS symptoms, leg cramps, tingling, soreness, pain and motion sickness. All adverse effects resolved on their own (without medical intervention) after stopping device use.

I was the principle inventor of Relaxis therapy for the treatment of sleep disturbance associated with RLS. During my psychiatry residency at Stanford University, I had learned the principles of sleep medicine from Dr. William Dement, considered to be the father of sleep medicine. Later, I completed a residency in diagnostic radiology, including neuroradiology, followed by a two-year fellowship in cardiovascular and interventional radiology, both at Stanford.

From my medical training, I knew that FDA-approved RLS drugs interfere with either dopamine or GABA (gamma-aminobutyric acid) neurotransmitters within the brain. The widespread pharmacological influence of these drugs on brain function can cause a suite of undesirable side effects that may degrade RLS patients’ quality of life. For this reason, I sought a non-drug treatment for sleep loss associated with RLS.

I conceptualized RLS as purely a sensory disorder. RLS sensations arise within the brain but feel as though they originate in the legs. From this perspective, the dysphoric sensations that RLS patients think are coming from their legs are, in fact, dysphoric sensations within the brain that are projected by the brain to the legs. That is, RLS sensations seem to arise in the legs, though they do not.

I viewed dysphoric RLS symptoms as having characteristics similar to those of a hallucination, a dream or even the phantom limb syndrome. In these three conditions, individuals experience specific sensation when no external stimulus is present to explain the origin of the sensation experienced. For example, amputees who have the phantom limb syndrome experience the presence of a limb that is no longer present. Furthermore, some amputees may have RLS in the absent limb. These patients experience the dysphoric sensations of RLS in a limb that is no longer present.\(^3\)\(^4\) Similar to hallucinations, dreams and the phantom limb syndrome, RLS patients experience difficult to describe, irritating and uncomfortable sensations in their legs even though no irritating external stimulus or leg abnormality is present to explain such sensations.

The dysphoric sensations of RLS come on as an RLS “attack” – most often when a patient is drowsy and at rest or when a patient is asleep. During times of drowsiness or sleep, the brain blocks out many external stimuli. With the brain substantially “unplugged” from the external world, RLS attack sensations arise within the brain and are perceived as originating from the legs.

In an attempt to diminish the magnitude of dysphoric RLS sensations, RLS sufferers twist, bend, and flex their feet, legs and thighs. Such movements are voluntary, performed to decrease RLS dysphoria. However, these movements only postpone the inevitable; the need to stand and walk. Standing and walking generate “real” leg sensations (pressure on the soles of the feet, sensations from joints and muscles and feelings from the skin) that flood into the brain. With the influx of real leg sensations, dysphoric RLS leg sensations rapidly fade away. The process is similar to waking up from a scary dream. Upon waking, dream images and feelings quickly fade as sensory inputs from the outside world overwhelm frightening dream sensations.

For the RLS sufferer, the “phony” RLS sensations arising from within the brain are swamped by real leg sensations once the patient stands and walks about. Though these movements lead to a substantial degree of relief, they do so at the expense of sleep. An RLS patient who is standing or walking about is no longer in bed sleeping. Furthermore, after the RLS patient gets back in bed and drowsiness returns, a new round of RLS dysphoria may arise, repeating a cycle that will cause further sleep loss.

With this conceptual framework in mind, my Sensory Medical team and I reasoned that if we could develop a device to generate pleasant, “real” leg sensations applied while an RLS patient was still lying in bed, the dysphoria of RLS might be interrupted without the RLS patient having to get out of bed and walk around. This concept is based on the principle of counterstimulation.

Everyone has experienced the principle of counterstimulation. When an individual swings a hammer at a nail but misses the nail and mistakenly hits his or her thumb, the individual reflexively shakes his or her hand back and forth. Shaking generates skin, joint and muscle sensations that flood into the brain at the same time as the thumb pain. The pairing or
matching of nonpain sensations from the shaking hand with the pain sensations from the thumb diminishes the overall experience of thumb pain.

Shaking is a counterstimulus to thumb pain. Similarly, when RLS patients get out of bed, stand, and walk about to “break” an RLS attack, they are engaging in activities that are counterstimuli to their RLS symptoms.

Our team sought to develop a device that could supply counterstimulation in a way that eliminated the need for RLS patients to become fully awakened and get up from bed to relieve their symptoms. Once fully awakened it is difficult for RLS patients – or for anyone, for that matter – to return to sleep.

Our team tested many forms of counterstimulatory sensory input and determined that patient-controlled vibration was pleasant to the majority of RLS patients. Furthermore, vibration could be easily applied while an RLS patient was in bed. Other forms of sensory input were either not easy to use in bed or were found to be insufficient to overwhelm the sensory dysphoria of RLS.

Based on this early research, we developed the Relaxis device. It consists of six electric motors (which generate vibration) embedded in a cloth-covered foam pad, and a controller. The controller allows each patient to select his or her own comfortable level of vibration intensity.

Each patient generally chooses a pad placement that is based upon the spot where RLS dysphoria is the worst. For a week prior to using the pad as a treatment during RLS attacks, patients are instructed to place the pad under their legs and experiment with controller settings. The purpose of this phase of treatment is to allow patients to familiarize themselves with the pad and its controller and to learn which level of vibration intensity feels best. The controller remembers the last pad setting (vibration intensity) so that once a patient has established his or her optimal setting, the pad can be turned to the optimal setting with just the press of one button. At the end of a 30-minute treatment cycle, vibration gradually slows down, automatically, from treatment-level vibration to the off setting. Vibration is slowly decreased to the off position within the controller, so as not to awaken the patient with an abrupt change in vibration intensity.

Relaxis therapy is not for every one. For vibratory counterstimulation to be successful, the sensation of vibration must be pleasant to each RLS patient. Relaxis therapy is designed to relieve symptoms at the onset of an RLS attack using vibration to counter the unpleasant sensations associated with RLS. Based on our early experience with vibratory counterstimulation, we learned that about 10 percent of the RLS population feels that vibration is irritating and uncomfortable. For these patients, it is possible that RLS symptoms might temporarily worsen while using our device. The combination of irritating vibration plus RLS dysphoria could be worse than just RLS dysphoria by itself. For that reason, prior to prescribing the Relaxis system, RLS patients need to be screened to eliminate those who find the vibration unpleasant.

We theorize that the vibration delivered by the Relaxis pad is a counterstimulus to RLS dysphoria. Others may conceptualize the Relaxis effect in slightly different ways, such as (i) vibration “extinguishes” RLS dysphoria, (ii) vibration takes “attention” away from or “distracts” awareness from RLS dysphoria, (iii) vibration “conditions” a patient to focus on vibration and not on RLS dysphoria or (iv) vibration diminishes RLS dysphoria through “biofeedback.” Whatever one’s conceptual framework,
clinical trials have demonstrated that the Relaxis device significantly improves the subjective evaluation of sleep in patients with moderate to severe primary RLS.2, 6

To date, four peer-reviewed publications examining the benefit of the Relaxis system have been published. Part I of this series showed that Relaxis pads were significantly superior to sham pads at improving the quality of sleep.6 The statistical technique of meta-analysis was used in Part II to show that the degree of subjective sleep improvement from Relaxis therapy was not significantly different than treatment with FDA-approved RLS drugs.2 Part III demonstrated a strong connection between patient belief about the Relaxis system and its therapeutic effect, which supports the theory that RLS dysphoria originates within the brain and not within the legs themselves.7 Part IV compared sham pads used in the Relaxis trials with placebo pills used in RLS drug trials and demonstrated that sham pads and placebo pills had comparable effects.8

The Relaxis system is available as a rechargeable battery-powered system or as a wall-plug powered system. It is a prescription medical device cleared by the FDA to treat the symptoms of RLS.

References

1. Staff. FDA clears sensory Medical’s RelaxisTM, First device for Restless Legs Syndrome - Device is Only Non-Pharmacologic approach for improving RLS patients’ sleep quality [Web Page]. 2014. Available at: http://bit.ly/1ypSgHb


The role of technologists is expanding. Many clinical tasks such as DME disbursement, compliance monitoring, sleep hygiene training, patient education, and much more, are now being shifted to experienced technologists. Technologists in other fields such as Neurodiagnostics, Nursing, and Respiratory Care also work with sleep disorder patients and fulfill these duties. Oregon Tech is again in the forefront of providing online academic programs to meet the required educational preparation for the field of sleep. Contact us to learn how you can become a Certified Clinical Sleep Health (CCSH) professional.

Certificate and Associate degree programs available Fall 2014, and students can start programs any term.

Current licensure in a medically related field and employment in a facility that treats patients with sleep disorders is required for entrance into the Clinical Sleep Health professional program. An equal-opportunity institution.

For more information:
Jane Perri, PhD, RPSGT
PSG/CSH Program Director
jane.perri@oit.edu
937-750-5416
www.oit.edu/csh

Hands-on education for real-world achievement.