Detailed Information About the Luco Hybrid OSA Appliance

The Luco Hybrid OSA Appliance® is the result of over 30 years of research on sleep apnea, UARS, and sleep-related bruxism. There are a number of innovations in this advanced device that place it in a class of its own.

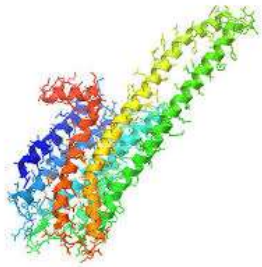
This information document covers how the appliance actually works in detail. I am very proud to have developed the only FDA cleared treatment (of any kind) in the treatment of sleep-related bruxism and associated tension/migraine type headaches, as well as in the treatment of obstructive sleep apnea and upper airway resistance syndrome.

Dr. Ken Luco

Sleep-related bruxism is a genetic disorder affecting around 12% of the adult population. It affects men and women equally and the symptoms can vary widely between individuals.

The gene identified to date is the HTR2a gene on chromosome 13. In SRB, there are too many copies of the gene termed “polymorphism”. This gene creates a protein that forms receptors in the nervous system for serotonin, a neurotransmitter (Figure 1). With SRB, there too many serotonin receptors present.

Figure 1 The HTR2A Receptor

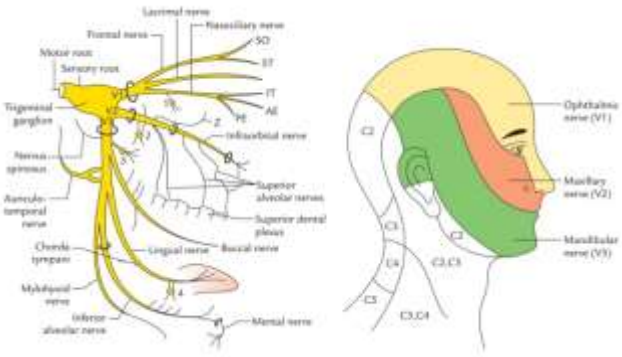


As a result, a cranial reflex (reflex located in the brain or brainstem) called the masseter inhibitory reflex (MIR) is affected. The MIR is activated when biting into something hard unexpectedly. Immediately, the masseter muscle contraction stops. Once the object is removed, chewing slowly resumes to normal. This reflex protects the teeth from damage that could occur if chewing continued.

The HTR2a gene’s role is to suppress nerve activity. In SRB, with too many receptors, the MIR is suppressed. This results in loss of this protective reflex while sleeping and the resulting damage to the teeth, periodontal structures, muscles, TMJ, and jaws. Biting forces in SRB are 4-6x greater than when chewing food.

The Luco Hybrid OSA Appliance® has a patented forward bite that places all the bite force upon the 1st bicuspids and eyeteeth. This activates a different reflex called the periodontal masseter reflex (PMR) that bypasses the suppressed MIR resulting in re-activation of the MIR. This restores the protection for the teeth and jaw structures.

Figure 2 The Trigeminal Nerve



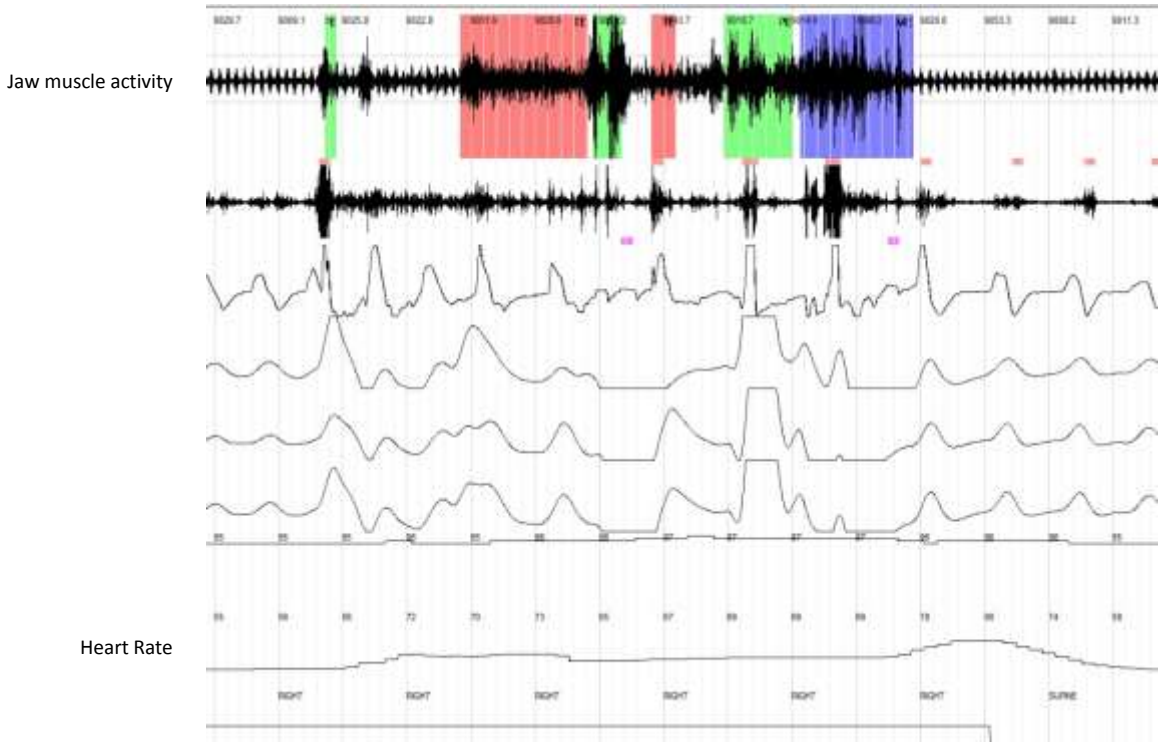
The other unique feature of SRB is has a direct effect on one of the most powerful cranial reflexes, the “trigeminal cardiac reflex” or TCR. The TCR characteristically results in a rapid drop in heart rate, blood pressure, intracranial pressure and increased or decreased stomach acid production when activated and is a serious concern during surgery of the face.

The trigeminal nerve has three branches, the ophthalmic, the maxillary and the mandibular (Figure 2). The TCR is activated by stimulation of any of the three branches either peripherally (on the outside) or internally (at the trigeminal ganglion or brainstem). It occurs in less than 10ms.

SRB is unique in that the TCR stimulation occurs at the trigeminal ganglion level, which has the opposite effect of the other areas. A rapid increase in heart rate (tachycardia), blood pressure (hypertension), cranial pressure (pressure within the brain), and increase in acid production in the stomach with acid reflux (GERD).

The Luco Hybrid OSA Appliance® 's forward bite has another significant function. A recent endodontic (root canal) study demonstrated that when root canal therapy was performed on the 1st bicuspids and eyeteeth, the TCR was activated normally, reducing heart rate etc. With the forward bite of the Luco Hybrid OSA Appliance® the TCR stimulation seen in SRB is reversed by the normal stimulation of the TCR at the 1st bicuspids and eyeteeth. Figure 3 is a screenshot of a sleep study recording SRB's stimulation of heart rate.

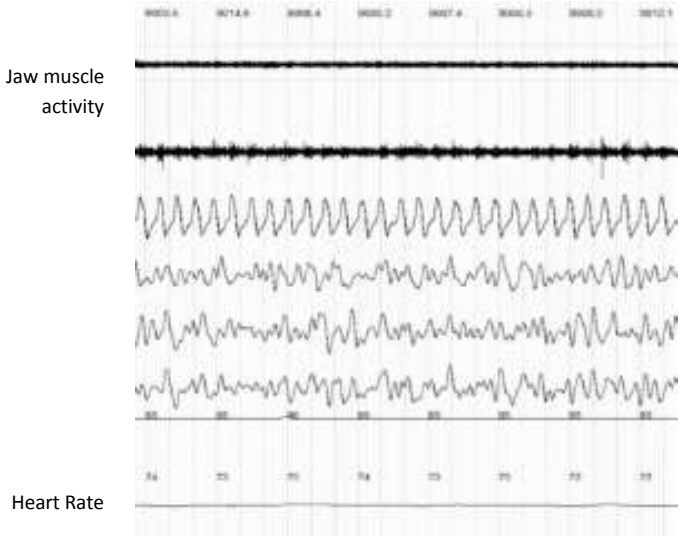
Figure 3 Sleep-related bruxism's effect on heart rate



In figure 3, the heart rate increases form 55 bpm to 90 bpm in response to the SRB events (shown in red, blue and green). It is medically accepted that there must be an increase in heart rate of 20% or more before it can be said the TCR has been activated. In Figure 3, there was an increase of 35% indicating a significant stimulation of the TCR has occurred. Heart rates can exceed 130 bpm with some patients.

With the Luco Hybrid OSA Appliance®, heart rate returns to normal. The following screen shot is the same patient while wearing the device.

Figure 4 Tracing while wearing the Luco Hybrid Device



Notice the muscle activity has stabilized as well as the heart rate.

This is a direct result of the TCR being acted peripherally, neutralizing the stimulation at the level of the Trigeminal ganglion seen in t Figure 3.

Now that we have shown how the Luco Hybrid OSA Appliance® treats sleep-related bruxism, let us look at how it treats obstructive sleep apnea and upper airway resistance syndrome.

OSA

The Luco Hybrid OSA Appliance® is classified as an "anterior repositioning appliance" as it moves the lower jaw forward and down. This is not a unique feature, there are many OSA appliances that work this way.

With OSA, the tongue and muscles in the pharynx (throat) relax. In people who are overweight, there are fat deposits in the throat constricting it. If the patient has a long soft palate, that can also contribute. Narrow upper jaws, resulting from years of allergies and mouth breathing, crowds the tongue forcing it back. A large tongue can obstruct the airway. All of these factors independently can result in some degree of OSA. When combined, the OSA increases in severity and complexity.

Mandibular advancement appliances (MAD) work by moving the tongue down and forward. They also activate a series of pharyngeal (throat) reflexes that move the tongue forward or prevent it from falling back onto the soft palate (Figure 5).

Figure 5 Obstructive Sleep Apnea

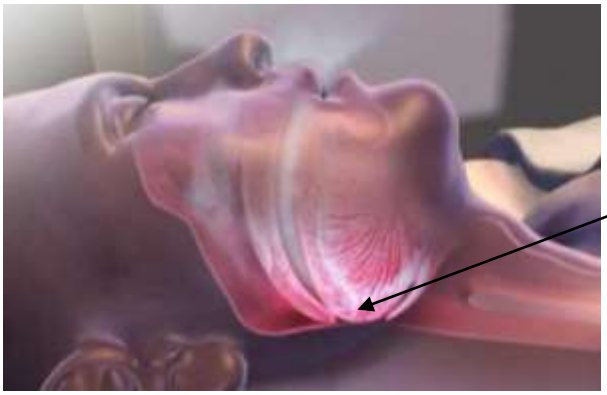


Figure 6 OSA Appliance Working

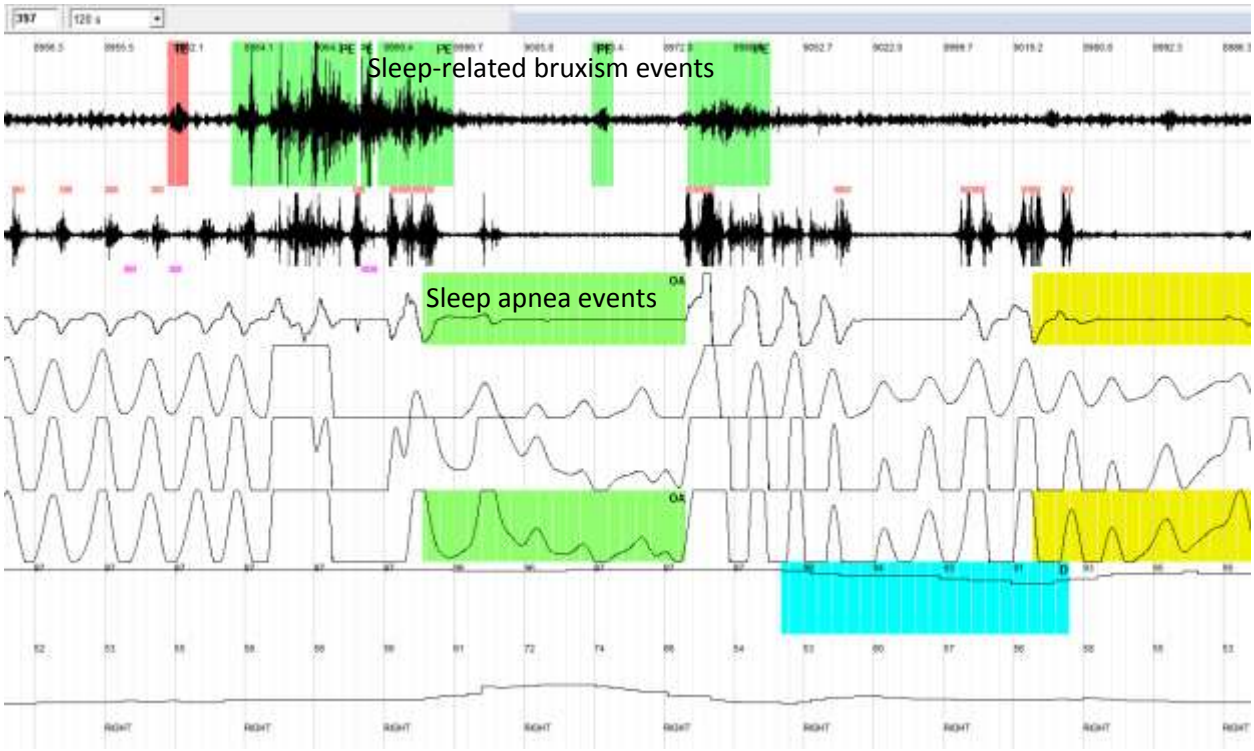
In figure 5, the tongue has fallen back and blocked the airflow into the lungs, resulting in an apnea or cessation of breathing.

In figure 6, the OSA appliance holds the lower jaw (and tongue, which is attached to the lower jaw) forward, opening the airway and relieving the sleep apnea.

It should be noted that all MAD type OSA appliances work this way including the Luco Hybrid OSA Appliance® .

Where the Luco Hybrid OSA Appliance® treats OSA differently is when sleep-related bruxism and sleep apnea occur together at the same time. This occurs in 25% of OSA cases. The Luco Hybrid OSA Appliance® can be adjusted to treat *both conditions* providing relief from both. It is the only FDA cleared device capable of doing this.

Figure 7 Sleep tracing of sleep apnea and sleep-related bruxism



In figure 7, it can be seen that both OSA and SRB can occur in the same patient. When they do it is termed secondary sleep-related bruxism and is different from the primary one shown in figure 3. It is different as it occurs seconds before or after an apnea event and researchers feel that it is acting to protect the patient by arousing them from sleep to re-start breathing.

Sleep-Related Bruxism and Medications

SRB has been shown to be activated or worsened by some medications. The most commonly prescribed are the selective serotonin re-uptake inhibitors (SSRI) and selective serotonin norepinephrine re-uptake inhibitors (SSRNI) used to treat depression and mood disorders. These medications act to prevent the body from breaking down serotonin, freeing more up in the brain and nervous system. It is not clearly known how

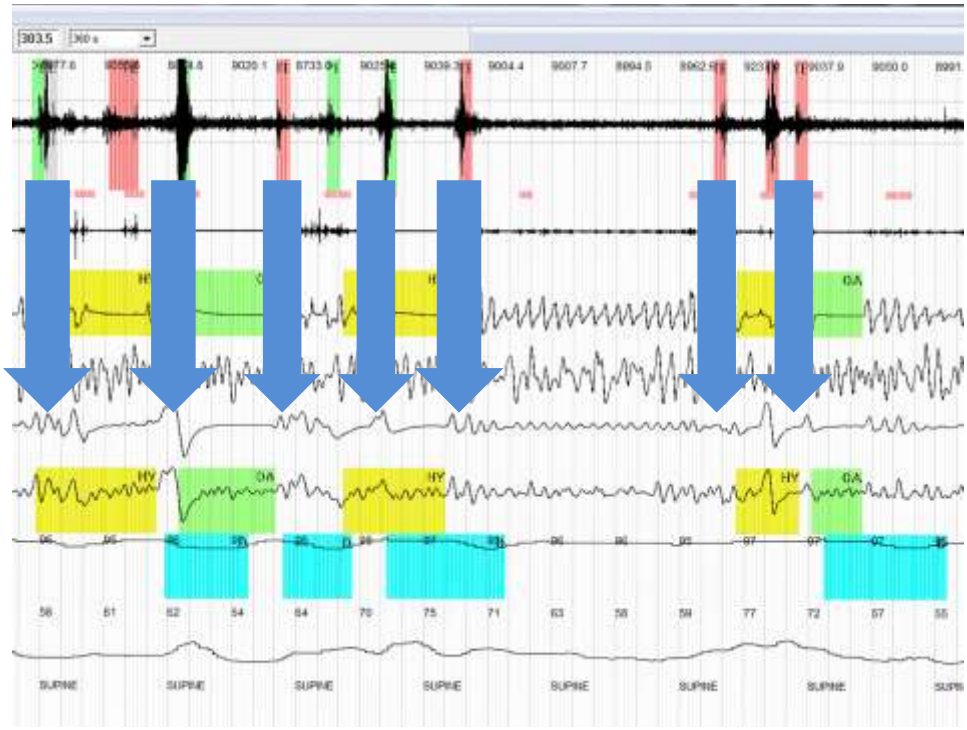
this treats depression but it does. Unfortunately, with SRB, there are too many receptors for serotonin and more extensive, pronounced inhibition of the masseter inhibitory reflex occurs. This only worsens the SRB and makes treatment that much more difficult.

In my experience, patients on SSRIs or SSNRIs take longer to respond to treatment with the Luco Hybrid OSA Appliance®. Where primary SRB takes 2-3 weeks to control, with these medications, it can take several months of treatment.

To compound the problem, SRB has been shown to cause depression as does OSA. These and other sedative type medications can make both conditions, if present and undiscovered, much worse.

In a severe case this can be seen clearly in figure 8 below:

Figure 8 Secondary SRB occurring with Severe OSA



The SRB events occur mostly just before or just after the OSA event marked in green and yellow. Notice the associated increases in heart rate in response to activation of the TCR by the SRB events.

In Summary…

I hope this more detailed description is helpful in understanding these serious conditions as well as how the Luco Hybrid OSA Appliance® is effective in treating both. For OSA, snoring and UARS, you must have a sleep study with medical supervision and be referred to your dentist for this treatment. For SRB, your dentist can diagnose and treat this condition without medical oversight. If you suffer from both, it is considered medical and requires medical oversight.

For more information, please visit our websites at:

www.lucohybridosa.com www.sleepbruxism.ca

and begin

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