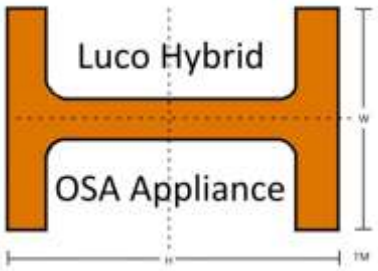
By Rx only



The Luco Hybrid OSA Appliance®

Prescriber Manual

For the Treatment of Obstructive Sleep Apnea and Upper Airway Resistance Syndrome

Prescriber Manual Version 2019.07.20.001

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Preamble:

This manual provides detailed information on the use of the Luco Hybrid OSA Appliance (LHOA) in the treatment of obstructive sleep apnea (OSA) and upper airway resistance syndrome (UARS).

As with all mandibular advancement appliances, knowledge in orthodontic/orthopedic appliances is helpful but not essential. For experienced practitioners in OSA, this device is a valuable addition to your existing appliance protocol as it does not require any special records or bite registrations to manufacture.

As an added benefit, this device also treats sleep-related bruxism and is highly resistant to breakage, significantly reducing repairs and remakes. I am confident that most dental practitioners can learn and master the use of the LHOA for the treatment of OSA/UARS and incorporate this effective treatment into their practices,

Sincerely,

Dr. Ken Luco

Indications for Use

FDA	Indication for Use
K130797	For the treatment of mild to moderate obstructive sleep apnea in adults
K130797	For the treatment of primary snoring in adults
K160477	For the treatment of sleep-related bruxism in adults
K160477	To aid in the treatment of associated tension/migraine type headaches in adults

Risks Associated with Mandibular Advancement Appliances

Most complications with mandibular advancement (MAD) appliances are minor and temporary. Hypersalivation, dry mouth, dental pain, gingival irritation, myofascial pain and temporomandibular dysfunction (TMD) and all reported in the literature. The latter two are directly associated with sleep-related bruxism, which often occurs with OSA/UARS. Minor tooth movements can and do occur with all MAD devices but do not affect ability to chew. Most changes are considered minor and, in most cases are positive (decrease overbite, overjet).

Contraindications for Use

This appliance should not be used on patients diagnosed with central apnea, have severe respiratory disorders, have loose teeth or advanced periodontal disease or are under the age of 18 years. You should not use this appliance if the patient has a known allergy to chrome, cobalt or acrylic [methyl methacrylate]. It should be used on patients with poorly controlled epilepsy. It should be used with caution on patients with hypertrophy of the masseter and/or temporalis muscles (excessively developed muscles as a result of untreated parafunction/excessive gum chewing). Patients suffering from Fibromyalgia should be treated with caution (may be treated by dentists with advanced knowledge of this disorder).

Warnings

Use of this device may cause movement or changes in dental occlusion and may cause gingival or dental soreness. It may cause pain or soreness of the TMJ and associated musculature. In rare cases, it may cause obstruction of oral breathing and it may cause excessive salivation or dry mouth during sleep.

Responsibility

The prescribing dentist is responsible to ensure that the contraindications, warnings and precautions are carefully considered before prescribing this treatment. Every case must be assessed individually to determine what the best and safest course of treatment is.

Care should be exercised when using any mandibular advancement appliance on patients with pre-existing TMJ problems, chronic myofascial pain, fibromyalgia or have a history of chronic neck and back pain, as this group of appliances can exacerbate symptoms for some of these patients.

Patients who are claustrophobic may not tolerate this or any oral appliance therapy.

History and Examination

The patient should complete a history of their general health as well as regarding their sleep condition. Questions should include their history of headaches, traumas such as sports injuries to the head and neck, motor vehicle accidents etc. as these patients likely have a concurrent neuromuscular condition with their sleep disorder. TMD, chronic myofascial pain and fibromyalgia all affect how you will go about treating their sleep disorder. Patients with diabetes and hypothyroidism both are associated with neuromuscular problems and again should be treated with caution. The Epworth or other scale should be administered.

Patients taking SSRI (selective serotonin reuptake inhibitor) medications, SNRI (selective serotonin/norepinephrine inhibitor) medications, methylphenidate, or barbiturates should be carefully screened for sleep-related bruxism as these medications can initiate and exacerbate sleep-related bruxism. Sleep-related bruxism is a known cause of myofascial pain and TMD. Patients on these medications should be informed of the increased likelihood of sleep-realted bruxism and associated signs and symptoms and managed as sleep-related bruxism/OSA patients (see the separate manual for this).

Once you have reviewed the patient's history with the patient (and preferably with their spouse as well), you are ready to examine the patient. You should have a dedicated form to record your OSA examination to ensure consistency in your exams as well as not to miss important information. On our website you will find downloadable PDF examination forms, patient history forms, and other forms you can use and customize for your practice.

Your examination should provide you with the information to determine if the patient has sleep apnea, sleep-related bruxism and/or snoring and a detailed history of headaches. This is essential in your treatment planning.

First and foremost, ensure that your consent form is signed before starting. We recommend you have your staff clip it to the front of the file or flag clearly on your patient screen so there is no doubt.

Bite Registrations for OSA and UARS

Bite registrations are taken using a guide such as the George Gauge or Andra Gauge as these gauges allow accurate positioning of the mandible as well as a clinical record of adjustment made to the device. It is not important which system is used for the bite registration, the selected position is far more important.

Most patients can tolerate some mandibular protrusion with a minimum of problems. A 65-70% advancement of the mandible is generally far enough to achieve an open airway. Vertical opening is also a factor and, as a rule, the deeper the overbite, the less vertical opening is required. There is a minimum amount of posterior opening (in the molar regions) needed, to ensure that there is no molar contact (Appendix A). The LHOA has a 10mm screw for further advancement beyond this, if needed. Increasing the vertical is sometimes preferable to advancement and can easily be accomplished with composite resin on the bite pads as needed.

I would like to stress again the importance of proper screening for sleep-related bruxism as it occurs commonly with OSA in a secondary form. Please see the separate manual on treating OSA and sleep-related bruxism concurrently.

Checking the Appliance Prior to Insertion

Prior to patient arrival, try on the upper and lower appliances to the working casts. You do not want a snap fit; it should easily slide on and off. If it is a snap fit, adjust the areas shown below:

Figure 1 Adjusting the Upper

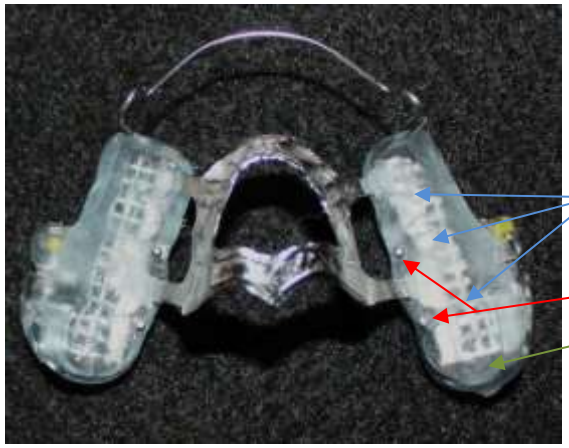
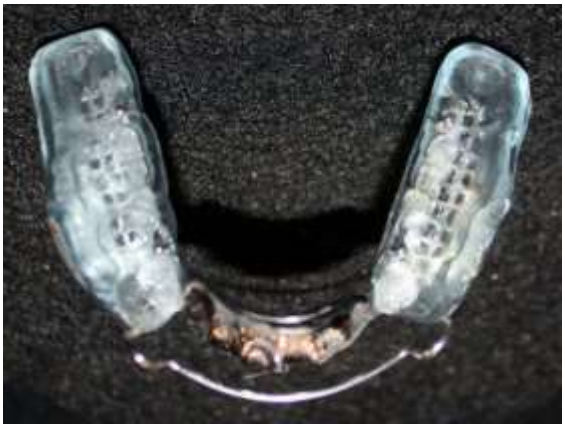


Figure 2 Adjusting the Lower Fit



The lower is adjusted similarly by removing excess interproximal acrylic and loosening the ball clasps.

If there are edentulous spaces on either the upper or lower area, the acrylic may need to be reduced or reshaped to allow the appliance to seat easily.

Insertion of the LHOA

Try in each part separately, fine adjusting as needed, until they fit snugly and comfortably. Once this is completed, insert both parts of the device. Ask the patient if there are any uncomfortable areas (tightness, pressure etc.). Adjust as needed. Check retention of both by asking the patient to open about half way. If the back of the lower appliance lifts, remove and tighten the posterior ball clasps (molars) by gently bending inward by 0.25 to 0.5mm. Try in both again and recheck the fit.

Next, ask the patient to gently bite and then slide their jaw, over the appliance slowly forward and back. Ask them if both wings of the lower are contacting the retaining blocks of the upper simultaneously. If not, remove and advance the non-touching side 1-2 turns and try in and repeat. Continue until the patient reports it is hitting evenly.

Finally, check the bite. The only contact should be on the upper bite pads with complete disclusion of the molar regions. Left and Right pads should contact simultaneously. If one pad is hitting harder or first, mark with thick bite paper and lightly reduce the acrylic of the lower appliance and repeat until the patient reports even contact.

Recheck even wing contact and, if correct, remove the appliance. Pass the patient a hand mirror and demonstrate placement of the appliance. Hold the mirror for them and ask them to place and remove it. Repeat until they are proficient and comfortable placing it.

At this point instruct on home care and provide them with a manual and storage case.

Reappoint them in 7-10 days.

The 7 Day Check

Ask how the patient is doing. Ask if they recall any dreams as these are a sign of REM sleep which OSA/UARS patients are usually deficient in. Ask about refreshing sleep or any difficulties with the appliance. Ask if there is any reported snoring. If so, advance the appliance 2-3 turns.

Have them place the appliance observing they are comfortable with this. Inability to place the device is often a sign they are not using it. Again, check the bite and wing contacts are even and, if not, adjust as needed.

The 14 Day Check

Ask how the patient is doing. Ask if they recall any dreams as these are a sign of REM sleep which OSA/UARS patients are usually deficient in. Ask about refreshing sleep or any difficulties with the appliance. Ask if there is any reported snoring. Adjust if needed. If not, they are ready to be returned to the referring sleep lab.

Contacting the Sleep Lab

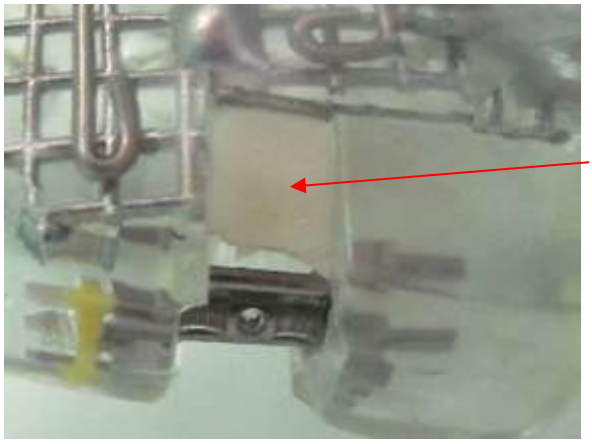
OSA/UARS are medical conditions with significant morbidity. It is essential that the patient undergo a sleep study with the appliance in, to verify its effectiveness. Stress this with the patient and contact the sleep lab for follow up. This simple step will demonstrate to the sleep lab that you are conscientiously following the guidelines and can generate more referrals.

Final Adjustments

Once the patient has been seen at the sleep lab and the treatment verified (a written document from the sleep lab, not the patient's word), they should be seen one last time.

Check the fit one last time. If you advanced the screws on the appliance, it is advisable to lock them, to prevent them from slipping. Figure 3 shows how this is easily accomplished in minutes.

Figure 3 Locking the Adjustment Screw



Place a small amount of composite resin (a good use for outdated material) and shape as shown.

Take care to leave the screw exposed should future adjust be needed.

Opening the screw dislodges the composite allowing it to be replaced at the new setting.

Long Term Reassessment/Commitment

OSA is often a lifelong illness. Use of a MAD type appliance can be for many years. It is essential that you monitor these patients over time. At least yearly is recommended, to ensure compliance and if adjustments are required. People gain and lose weight. Do they need to be that far forward? Or could they be a bit further out? Did they lose a tooth?

It is critical that you inform and note in their file that you advised them to contact you if they need adjustments (dental work, tooth loss etc.) and that you want to see them yearly.

The LHOA usually lasts for up to 4-5 years and most insurance companies will replace them at 5 years. It is good practice to replace these at this time. Use the existing appliance as a spare and make a new one. If one is lost or left behind somewhere, they can wear the old one for a while. This is comforting to most patients as they come to rely on these appliances for quality sleep.

Non-Compliance

It is a fact. 5% of the population causes 95% of the problems. And they all have sleep apnea! Non-compliance is something you will always have to deal with occasionally.

At a yearly recall, have the patient place their appliance in. They should have no problem placing it, literally throwing into their mouth. If they are having trouble telling the upper from the lower, this is a sure sign of non-compliance. Ask them how often they are using the device as you feel it is not often. If they have a million excuses, this is also a sign of non-compliance. Ask their spouse. They often will gladly tell you they don't wear the appliance as snoring is a good motivator.

You have an ethical and legal obligation to contact the referring sleep lab and inform them of any non-compliant patients. OSA/UARS have many associated serious conditions if untreated.

Contact the sleep lab and inform them of non-compliance and that you advise an alternate form of treatment. Send a copy of the letter to the patient and that you are suspending treatment for non-compliance. You do not want this patient in your practice.

Trouble Shooting

Problem	Recommended Mitigation
The patient experiences tooth soreness	Check the bite carefully and query the patient as to which side touches first. Check that you don't have a ball clasp too tight on a tooth. On the lower appliance, tighten the labial bow slightly and you can sometimes loosen the ball clasp's on the bicuspids
The patient reports a sore jaw in the morning	Check there masseter muscles and then recheck the bite carefully. Ensure there are no molar contacts which will encourage sleep bruxism. Query the patient: are they chewing a lot of gum? Did they injure themselves biting something hard unexpectedly? Often there is an underlying cause of jaw pain independent of your treatment. If the bite and wings seem fine, remeasure the patient's protrusive movement. Often their muscles will relax allowing a greater range of movement and your 75% advancement will have been lost. Advance to the *new* 75%.
The patient reports having a very dry mouth at night	Instruct the patient to keep a glass of water bedside. They can drink water without removing the appliance. Suggest Biotene's or similar products for xerostomia if the problem persists.
The patient drops the appliance on a hard floor and bends a wire [very hard to do]	If you are a proficient wire bender you might be able to undo this. Or you can take new impressions and send it to the lab for repair. It is near impossible to know exactly where the wire is distorted.
The tongue is sore on one side in the morning	This is usually caused by the lower appliance lifting during sleep. Tightening the ball clasps is usually all that is needed
The lower lifts up when they open their mouth wide	If you have advanced the appliance 3 to 4 mm ahead of starting position, the curve in the wing can dislodge the device. The curve at the upper one third of the wing can be straightened which will help this problem.
The patient reports a sore neck on waking	Query the patient as to what type of pillow they use and how they sleep. Recommending a good RMT or PT in the area is often greatly appreciated. Recommend a "side-sleeper" pillow and a back pad to prevent supine sleep

Appendix A

Stress Distribution with a Molar Bite

When we bite, stress is placed on the teeth, periodontal ligaments, jaw bones and TMJ. Research has shown that *where* we bite affects where this stress is distributed.

Figure 4 Molar Bite

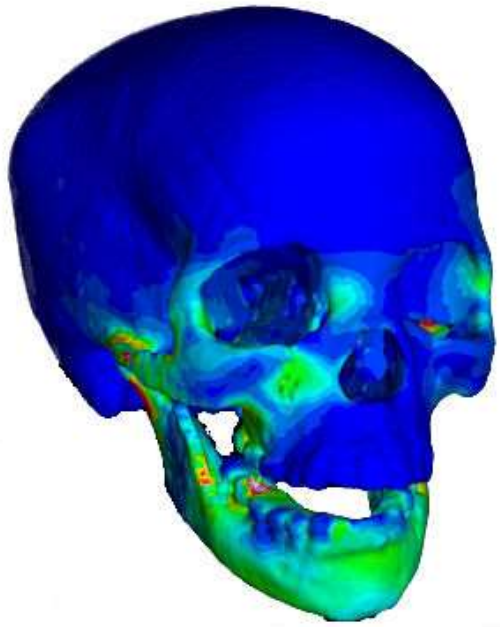


Figure 4: When biting on the molar region, the areas marked in red revive the highest amount of stress or pressure. This includes the oblique angle, the ramus, the TMJ, under the eyes.

The majority of stress in in the jaws is focused within the mandible. Of concern, the TMJ are heavily loaded with this type of bite.

Figure 5 Cuspid Bite

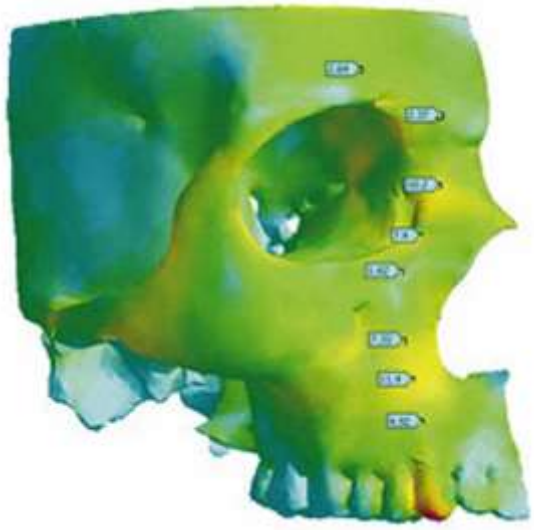


Figure 5: When biting in the cuspid area. The only high stress region is the tip of the cuspid (which is the strongest tooth we have). The stress is evenly distributed up and over the cranium.

The LHOA has a patented forward bite that distributes the stress as in Figure 5.

The lack of molar contact of the LHOA prevents pressure on the TMJ. This also activates the periodontal masseter reflex that reactivates the masseter inhibitory reflex.

Figure 6 the Luco Hybrid Device