Myerson SleepBetter EMA Oral Appliance: Instructions for the Dentist

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Myerson has served dentistry for over 90 years with a special emphasis on removable oral appliances. The Myerson SleepBetter campaign is intended to promote acceptance worldwide of oral appliances to treat snoring and OSA.

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Table of Contents

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Introduction

Obstructive sleep apnea (OSA) afflicts over 40 million Americans. Only a fraction of this number are diagnosed, and even fewer are treated effectively. This is a major health issue, as the consequences of untreated sleep apnea include elevated blood pressure, hypercholesterolemia, increased risk of stroke, elevated blood sugar with risk of diabetes, gastroesophageal reflux, anxiety, irritability, and depression. Excessive daytime sleepiness can be fatal: more people are killed by sleepy drivers than by drunken drivers. It is worth noting that approximately one in four truck drivers is affected by OSA.

Besides outright OSA, at least 80 million Americans snore. Snoring is not just an embarrassing or cosmetic concern. Snoring is a sign of restricted airflow during sleep. This restricted airflow and impeded breathing often results in excessive daytime sleepiness, causes a higher rate of headaches in snorers than in non-snorers, diminishes the overall quality of life, and adversely affects the sleep quality of the snorers' bed partners. Many snorers are banished to a separate bedroom.

Snoring and OSA affect all ages. Even though the prototypical snorer or obstructed airway patient may be an older and overweight male, women and children are affected, too. OSA in children produces symptoms similar to attention deficit or hyperactivity disorder (ADHD) Even slender men, women, and children may have OSA due to an inherited small airway or to tonsils, adenoids, or other airway obstructions.

Compressed Positive Air Pressure (CPAP) devices are considered the gold standard for treatment of OSA and snoring, but CPAP is not always effective or practical. Common problems experienced by CPAP users include nasal congestion, mask leaks with air blowing into the eyes, air leaking out of the mouth, aerophagia (air inflating the stomach), mask dermatitis, and sinusitis. In addition, the noise of a CPAP pump prevents some patients and their bed partners from initiating sleep, and movement during the night can displace the mask. CPAP also requires a dependable and convenient source of 110-volt electricity and distilled water for the humidifier, which are not always available to travelers. OSA patients and snorers need an alternative to use when they are intolerant to CPAP and when CPAP is not practical. The Myerson SleepBetter EMA custom oral appliance (“EMA”) can fill this need.

Medical authorities support use of the EMA appliance. The American Academy of Sleep Medicine (AASM) now recommends oral appliances like the EMA as a front line of treatment for snoring and mild to moderate sleep apnea, and in cases where CPAP has not been tolerated. Furthermore, the FDA has approved the EMA for the treatment of both obstructive sleep apnea and snoring.

Patient Assessment

Every health history must include questions that can reveal the presence of sleep disorders such as OSA or significant snoring. Particularly relevant questions are:

- How many hours of sleep do you get per night?
- Is your usual sleep quality good, fair, or poor?
- Do you snore?
- Has anyone noticed you breathing heavily, holding your breath, or gasping during sleep? (i.e., breathing heavily followed by silence and then a gasp for air.)
- Are you still tired or sleepy when you wake in the morning?
- Do you remain sleepy during the day?
- Would you nap during the day if you had the opportunity?
- Have you ever fallen asleep while driving?
- Have you had an overnight sleep study?

When a sleep disorder is suspected, direct conversation with the patient is essential. Since so many systemic disorders are associated with OSA, consultation with the patient's physician is recommended. Depending on your assessment, this type of consultation may be as simple as sending a checkoff form with a self-addressed stamped envelope to the patient's physician (see "Attachment A"), which confirms the medical necessity for treatment of sleep apnea and M.D. approval for use of an oral sleep appliance. This form can be useful when the patient's medical insurance company balks at coverage, and if your professional liability insurance requests proof that you are treating sleep apnea patients only with physician referral or approval.

Obstructive sleep apnea is a medical, rather than dental, disorder and is usually covered by medical insurance when billed on the appropriate medical claim forms with appropriate diagnosis and treatment codes. However, many insurance companies absolutely require prior authorization before any treatment is initiated with an oral sleep apnea appliance treatment plan before they will provide any benefits. Also, be aware that most insurance companies require confirmation of the presence and severity of the disorder with overnight polysomnography before they will authorize payment of benefits. You may need to request a copy of the summary of any previous sleep studies from the patient's sleep specialty clinic or sleep laboratory.

Basic physical assessment primarily involves measuring the patient's range of mandibular motion and quality of jaw movement. If the patient can open smoothly to 40 millimeters interincisally and protrude the jaw 5 millimeters comfortably, and these movements can be performed without significant TMJ clicking or crepitus, it is reasonably likely that the appliance will be tolerated comfortably.

Adequate dental retention is essential. The EMA can only be used over intact, non-mobile teeth without periodontal involvement. Dental restorations must be secure, as any removable oral appliance can displace loose crowns, inlays, onlays, or veneers. Having adequate numbers of secure teeth for retention of the EMA is particularly important in the maxillary anterior and premolar region and in the mandibular premolar and molar areas.

Impressions and Bite Registration

It is essential to have accurate impressions that extend to cover all surfaces of all erupted teeth, the buccal and labial vestibules of both entire arches, at least two-thirds of the palate, and the lingual surfaces of the mandibular alveolar arch. This may require modifying impression trays by adding compound or wax to the palatal area of the tray to be sure the impression material reaches the vertical extent of a high palate. Mandibular trays may need to be trimmed to fit around bony exostoses ("tori"). Pour the impressions in dental stone, not plaster, and add adequate bases to provide resistance to breakage during shipping and to allow secure mounting in an articulator.

A good bite registration will simplify and minimize appliance adjustments at the insertion and follow-up appointments. One excellent technique is to warm a sheet of baseplate wax, roll it tightly, and bend it to match the mandibular arch form. Press the anterior area back lingually to allow visualization of the maxillary and mandibular dental midlines. Have the patient open wide, and then press the wax onto the lower occlusal surfaces. Have the patient close slowly into the wax, keeping the midlines aligned and stopping with approximately 8 to 10 millimeters of anterior open bite. Ask the patient to open wide again, remove the wax carefully and immediately chill it in cold water to avoid distorting it. You may trim the buccal extensions with a very sharp knife and reinsert the bite registration into the mouth, to confirm that the teeth seat fully into the wax and that the midlines remain aligned.

Send both stone models and the wax bite registration to an authorized EMA dental laboratory (go to www.myersontooth.com for a complete list of authorized EMA dental laboratories). An EMA laboratory can construct an appliance without a bite registration, but constructing the appliance to such arbitrary dimensions often complicates the construction and extends the time required for the delivery of the appliance.

EMA Delivery

When the patient returns for delivery of the appliance, remove the upper and lower components of the appliance from their plastic bag and thoroughly rinse any residual disinfectant from them. Try each section in separately, before attaching elastic straps to either component. Confirm that each component seats fully in both anterior and posterior areas and that each is adequately retentive. Inform the patient that, because of pressure on the periodontal membranes, the appliance may seem uncomfortable for the first 5 minutes or so. Any reported pressure on an individual tooth persisting after 5 to 10 minutes of appliance wear may be due to an inaccurate impression or excessive wedging of acrylic into the occlusal aspect of the interproximal areas. Such areas may be conservatively relieved with an acrylic bur.

Remove the appliance components from the mouth and attach #1 yellow straps on both sides. Then reinsert the appliance and check the occlusion on the occlusal pads with articulating paper. An articulating paper plier can be very helpful in positioning the paper over the pads from a lingual approach. Occlusion must be checked in the protruded position. Since the TMJ eminentia are not always symmetric, balanced occlusion in the retruded position may be substantially different from that of the protruded position.

Have the patient practice placing and removing the appliance, to be sure that they can do so comfortably. Explain that placement is to be done by pressing the EMA onto the teeth with the fingers, not by popping the appliance into the mouth and biting into it. Careless insertion can break the EMA. Removal is also to be done with the fingers, reaching toward the back on both sides simultaneously, hooking the buccal flanges with the fingertips or fingernails, and pulling both sides off the teeth at once. Forceful removal of the appliance by pulling only one side off the teeth again risks breakage.

If the patient expresses TMJ or muscular discomfort, first check the evenness of occlusion on the bite pads. If discomfort is in the right TMJ, the right bite pad may be too high. Reducing the height should give the patient instant relief. If discomfort persists despite balanced occlusion on the pads, start treatment with #1 white straps instead of the firmer yellow straps. Starting patients with long and soft elastic straps and gradually moving to stiffer and/or shorter straps enhances comfort and acceptance of the appliance.

If the appliance is too tight, relieve the interior problem areas with an acrylic bur. If the appliance is too loose, it can be tightened by adding a tiny amount of acrylic to the buccal interproximal areas, seating the appliance in the mouth for one minute, and then removing the appliance and curing it in a pressure pot. Do not attempt a complete in-the-mouth reline of the EMA, as this will thicken the appliance excessively.

Demonstrate strap placement to the patient. Explain that gripping the EMA in the palm of the hand can be risky, as inadvertently squeezing the appliance can break it at the midline. Always start by holding the appliance only by the side on which you are working, near to the button. Catch the hole in one end of a strap with the pointed end of the teardrop-shaped lower button. Then stretch the strap anteriorly, along the side of the appliance, until it snaps over the rounded end of the button. Pulling away from the appliance can break the tip of the button or even break the button off the appliance. Be sure to explain this clearly to the patient. Blue or clear straps must be heated in very hot water, preferably in a cup of water that has been microwaved to nearly boiling temperature, to soften the straps and prevent button or appliance breakage. Connect both straps to the mandibular section of the EMA first, and then attach the straps to the maxillary section.

Give the assembled appliance to the patient with the #1 yellow straps (again, #1 white if the #1 yellow straps caused TMJ or muscle pain), and send along a pair of #2 yellow straps, which are shorter than the starter straps. Ask the patient to wear the starter straps each night for a week and then, if comfortable, to change to the #2 yellow straps. You may ask the patient to call your office after the first week to confirm that they have been comfortable with the starter straps before changing them.

Instruct the patient in how to clean and take care of the appliance when it is not being worn and reappoint for two to three weeks out. See Attachment B for sample handout care instructions.

Tell the patient that their bite may feel different in the morning, after wearing the EMA all night. This is due to muscle stiffness, as the lateral pterygoid muscles remain short during appliance wear and keep the condyles forward in their fossae overnight. The bite change is not a result of tooth movement. If bite changes persist for more than ten minutes or so each morning, have the patient chew sugar-free gum for five to ten minutes to stretch out the muscles and restore the bite. Tell the patient to call your office if their bite does not feel normal a short time after doing this.

EMA elastic strap size and elasticity; vertical dimension

EMA elastic straps (see photo below) come in five lengths:

EMA Elastic Strap	Description	Length in mm
#1	Extra long	21.0
#2	Long	19.0
#3	Medium	17.0
#4	Short	15.5
#5	Extra short	14.0

Shorter straps provide more protrusion. Unless you specify otherwise, the lab will set the buttons of the EMA appliance 25 mm apart with the models mounted to your wax bite. When placing a #1 strap, (21 mm) on the appliance, the mandible will be advanced 4 mm. With a #5 strap, (14 mm) on the appliance, the EMA produces 11 mm advancement. If the patient has a large range of mandibular advancement, i.e. 9 to 16 mm protrusion, instruct the lab to construct the EMA with the buttons 27 mm apart. This will help avoid having to send the appliance back to the lab to reset the buttons for further protrusion.

EMA elastic straps also come in four levels of elasticity:

EMA Elastic Strap Color	Description	Durometer
White	Soft	60
Yellow	Medium	70
Blue	Firm	80
Clear	Extra Firm	90

If the patient does well with a particular strap length and stiffness combination, the straps should last from two to six weeks before requiring replacement.

If the patient does well the first night or two but sleep quality then diminishes or snoring returns, the strap may have stretched an eighth of an inch or more and may need to be replaced with a stiffer, more durable strap. If sleep quality is not optimal and the strap is not stretched excessively, try a strap that is one step shorter. If this is uncomfortable, go to a stiffer strap but drop back one strap size. For example, if a patient does well with #2 yellow straps for a night or two but strap stretching then reduces sleep quality, try #2 blue straps. If these feel uncomfortable even after wearing the strap for a few minutes, try a #1 blue or clear. It is common to need to increase the stiffness by one or two colors while dropping back to a strap that is one step longer.

Try to stay with longer straps whenever possible. Shorter straps increase the vertical vector of force and can pop the appliance off the teeth, and shorter straps tend to stretch out faster than long straps. If the patient requires shorter straps but the appliance continues to pop off during the night or the straps stretch out too quickly, take a new bite in the patient's treatment position. Send the bite with the appliance and both of the patient's dental models to the laboratory that constructed the appliance. The

laboratory technician can move the buttons farther apart to 21 mm centers or 19 mm centers, to accommodate #1 or #2 straps, as you choose.

With jaw pain, TMJ pain, or headaches, always suspect an occlusal imbalance and adjust the bite pads as necessary. Pain usually is on the side where the pad is high. In stubborn cases of pain or appliance ineffectiveness, you may round the occlusal surfaces of the pads to create less surface area for the patient to contact, which can reduce bruxism on the appliance.

Vertical opening can be just as important as mandibular advancement. If titration of mandibular protrusion with strap changes does not produce optimal treatment results, add vertical opening by cleaning and roughing up the occlusal surfaces of the mandibular bite pads. Add up to 3 or 4 mm of orthodontic acrylic to the bite pads, pressure cure or soak in very warm water. You may also use light-cure laboratory composite, which will adhere to the pads. The new bite pad does not need to be flat. If the extra height is uncomfortable, round the occlusal surfaces but check the occlusion carefully. Then place longer and/or softer straps on the appliance, to maintain patient comfort.

The patient may complain of lip incompetence and nighttime “drooling” with elevated bite pads. This is usually a very temporary problem as the lips generally relax and regain full closure during sleep after a few weeks.

Follow-up Appointments

At the first follow-up appointment, have the patient fill out a follow-up form. See Attachment C. Discuss the patient's progress and comfort. Palpate the TMJs for clicking or crepitus. You will often find that preexisting TMJ noises are diminishing with nightly use of the EMA. Check the retention and cleanliness of the appliance.

Palpate the TMJs, masseter, temporalis, and sternocleidomastoid muscles for tenderness. Tenderness often indicates unbalanced occlusion or of excessive mandibular protrusion. Some patients can easily protrude several millimeters immediately after delivery of the appliance, while others may find that even small changes are uncomfortable, requiring incremental changes in strap length or stiffness. Select straps and adjust or elevate the bite pads as described on the previous page. Attach the selected straps, reinsert the EMA, and let the patient sit with it for a few minutes to confirm comfort. Confirm that the mandible appears to be adequately protruded.

Send several pairs of the selected straps home with the patient and encourage changing to a new pair of straps whenever the button holes have stretched to be oval rather than round, or whenever the old straps have stretched an eighth of an inch or more when compared to new straps of the same number. Patients often go through straps quickly for the first several weeks after starting appliance wear. Straps will last longer after the jaw has become used to the protruded position. If the patient has been doing extremely well, you may reappoint the patient for six months out and ask them to call your office sooner if they have any problems. If you have any concerns about the effectiveness or comfort of the appliance at this point, change the straps and/or adjust the bite pads as described above and reappoint the patient for one or two weeks out for an additional follow-up appointment.

Persistent difficulty with comfort or appliance effectiveness often relates to lingual bulk or contours that interfere with tongue posture. In these cases, coat the lingual surfaces of both upper and lower EMA components with pressure indicating paste, reinsert, and have the patient go through some phonetic exercises. These include counting aloud from sixty to seventy, pronouncing a number of words containing “L” sounds (e.g., lollipop, little, lilac, lascivious) and “G” sounds (e.g. garage, garbage, grungy, gradual) and swallowing some water. Explain that you are not concerned with how well they can pronounce these sounds but you want their tongue to go through its full range of movement. Remove the EMA and examine any areas where the paste has been wiped cleanly from the appliance, conservatively relieve these areas with an acrylic bur, and polish. Repeat if necessary. This procedure often results in shortening the distolingual margins, thinning and polishing all lingual and palatal margins, lowering the plastic over the mandibular premolar lingual cusp tips, and trimming away the lingual bulk of the occlusal pads. In especially difficult cases, you may need to paste and adjust two or three times. Some practitioners do this routinely at the first recheck appointment, and doing so may reduce the level of protrusion and vertical dimension necessary for successful treatment.

When the patient is comfortable and the appliance appears to be effective, consider a follow-up polysomnogram or home study to provide objective evidence of efficacy. Whether or not a follow-up overnight study is done, the current standard is to see the EMA patient on a six-month interval for the first year and annually after that. It is very important to tell the patient to call you if their bite is not returning to normal within 30 minutes after removal of the appliance in the morning.

Attachment A: Sample consultation form with the patient's physician

PATIENT NAME: _____ BIRTH DATE: _____

DOCTOR: Please check one or more, sign and date, and return in the enclosed envelope. Feel free to add comments and any other pertinent information.

___ At this patient's most recent examination, no evidence of significant sleep apnea was found. Construction of an intraoral anti-snoring appliance is approved.

___ This patient requires a new examination before approval of an oral anti-snoring or sleep apnea appliance. Please have the patient call my office to schedule an examination appointment.

___ The level of severity of this patient's sleep apnea indicates that an intraoral anti-snoring or sleep apnea appliance is a reasonable treatment choice.

___ A follow-up polysomnogram with the appliance in place is indicated to demonstrate efficacy of the appliance and to adjust the appliance to optimize its effect.

___ This patient requires further evaluation by a sleep specialist/pulmonologist/sleep center.

___ I have scheduled/referred her/him as follows for further evaluation. _____
_____

OR

___ Please refer this patient to an appropriate sleep center before with constructing an intraoral anti-snoring appliance.

___ Intraoral anti-snoring or sleep apnea appliances are contraindicated for this patient due to:

_____

_____

___ Additional Comments on Back

Signed _____M.D. Date_____

Attachment B: Sample care instructions to be sent with patient

Wear and Care Instructions for your EMA appliance

You may notice an increase in flow of saliva at first, which will subside after a few nights' wear. Later, your mouth may become dry at times. You may sip water while wearing the appliance, so long as the straps have not become loose.

You may also experience tooth soreness and jaw muscle fatigue, due to clenching the teeth as well as pulling you lower jaw forward. This is normal, and will subside as your mouth becomes accustomed to the appliance. If one or two teeth are extremely sore or if the gums become sore, please call our office. We will adjust the EMA appliance as needed.

The elastic straps on either side of the appliance are the key to the success of your appliance. We will work with you to determine the best strength and size for you. You can help us with this process by telling us when you feel that optimum comfort and effect have been reached. Some patients' jaw muscles relax quickly and do not need the straps changed frequently, but other patients stretch the straps out in one week or less. The straps may need to be changed more frequently during the first month or two. The straps need to be changed if you start holding your breath or gasping in your sleep again, or if snoring worsens. When changing the straps on the appliance it is very important that you hold the appliance only by the side on which you are changing the strap, close to the button. DO NOT hold your appliance in the palm of your hand or squeeze it as you could break it.

If you are using blue or clear straps, warm them in very hot water, preferably in a cup of water that has been microvwaved to nearly boiling, before attaching them to your appliance. Hook the strap over the point on the button, then pull forward or backward

ALONG THE SIDE of the appliance to hook it on. DO NOT pull OUTWARD as you attach the straps, or you could pull the buttons from the appliance.

Please remember to always BRUSH and FLOSS your teeth every night before placing your appliance in your mouth. Good oral hygiene is very important when wearing an appliance to bed.

Clean your appliance every morning in cool or lukewarm water with a denture toothbrush and toothpaste. We suggest using denture toothpaste such as DentuCreme® or Fresh 'N Brite®. If white film begins to form on the appliance or if it picks up odors, soak it in a denture cleaning solution such as Polident® or Efferdent® in warm, not hot, water. Heat can warp your appliance. You may leave the straps on during cleaning. DO NOT soak the appliance in mouthwash or expose it to alcohol in any way. Rinse the appliance, shake it off, and store it dry during the day.

If your bite feels off for more than a few minutes in the morning, be aware that this is due to shortening of some of smaller jaw muscles overnight. Chew sugar-free gum for five or ten minutes in the morning to restore your bite. If your bite still feels off, call our office.

Take your appliance to every dental appointment, so your dentist can make sure that new dental work does not interfere with the fit of the appliance. If you have major dentistry done, such as crowns, bridges, or veneers, you may need a new sleep appliance.

Please call our office if your appliance gets loose and comes off your teeth too easily, especially if it comes off during the night. You can break it if you bite down while it is out of place. Also, call us if your teeth remain sore for more than a half-hour after removing the appliance in the morning or if you develop any sore areas on the soft tissues of your mouth. GOOD LUCK AND SLEEP BETTER!

Attachment C: Sample follow-up patient questionnaire

Snoring & Sleep Apnea Recheck

SUBJECTIVE: _____

_____

_____

OBJECTIVE: Straps currently in use: #1 #2 #3 #4 #5 White Yellow Blue Clear

that produce ___ mm ___ underjet ___ overjet & ___ mm anterior open bite

Maxillary appliance is: ___ retentive ___ loose Mandibular appliance is: ___ retentive ___ loose

Mandibular Range of Motion:

Vertical: ___ Pain/Noise Right lateral: ___ Pain/Noise Left lateral: ___ Pain/Noise Protrusion: ___ Pain/Noise

	L R B		L R B
R TMJ	__ Smooth __ Click __ Crepitus	L TMJ	__ Smooth __ Click __ Crepitus
R TMJ	__ None __ Mild __ Mod __ Severe	L TMJ	__ None __ Mild __ Mod __ Severe
R Masseter	__ None __ Mild __ Mod __ Severe	L Masseter	__ None __ Mild __ Mod __ Severe
R Temporalis	__ None __ Mild __ Mod __ Severe	L Temporalis	__ None __ Mild __ Mod __Severe
R SCM	__ None __ Mild __ Mod __ Severe	L SCM	__ None __ Mild __ Mod __Severe

Posterior teeth are: ___ intact ___ in full occlusion ___ in light occlusion ___ out of occlusion

Comments:_____

_____

Assessment:

___ Doing well with sleep appliance therapy ___ is not yet at maximum improvement

___ Requires additional mandibular advancement ___ requires additional vertical dimension

___ Firmer straps would provide greater durability and stability of mandibular position

___ Needs repair of the ___ maxillary ___ mandibular section of the appliance

___ Needs tightening of the ___ maxillary ___ mandibular section of the appliance

___ Needs appliance: ___ blocked ___ bonded together

Comments:_____

_____

Plan & Procedures:

___ Balanced occlusion ___ Trimmed palatal extension ___Trimmed lingual peripheries

___ Increased vertical dimension by ___ millimeters

___ Polished ___ Ultrasonically cleaned ___ Tightened the ___ maxillary ___ mandibular ___

___ Returned the appliance to the laboratory for _____

___ Changed straps to #____ __White ___Yellow ___Blue ___Clear

___ Gave patient ___ pairs of _____ straps and ___ pairs of _____ straps

___ Pasted lingual surface of appliance with PIP and adjusted

___ Told patient to call in _____ with an update

___ Referred patient back to sleep clinic for follow-up polysomnography

___ Dispensed Watch-PAT and instructed in use

Next visit in: ___ Weeks ___ Months ___ Year for a reevaluation appointment.

Name: _____ Date: _____ Page: _____

Myerson SleepBetter EMA custom oral appliance photo

Photo courtesy of Glidewell Laboratories (Newport Beach, CA)