Sleep Appliances: Introduction and Overview

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Learning Objectives

1. History of Oral Appliances
2. Patient Selection (What are we able to treat, ie. Base of tongue, Cpap Intolerant)
3. Types of Oral Appliances
   ◦ Mechanism of Action
   ◦ Designs of Appliances
   ◦ Materials
4. Treatment Protocol to achieve optimum airway (Maximum efficacy)(Exam, insertion, titration follow-up/maintence)
5. Case Studies
6. Reimbursement/Insurance
7. Summary (Benefits)
History of Oral Appliances
Patient Selection: Who can benefit from Oral appliance therapy

- Patients with a base of tongue that obstructs the airway
- Patients who are C-Pap Intolerant
“Oral appliances are an alternative for OSAH”

“It is appropriate to recommend oral appliance therapy to patients with mild symptomatic OSAH, and those patients who are unwilling or unable to tolerate CPAP therapy

Cochrane Database 2006
Types of Oral Appliances

There are approximately 100 intraoral appliances that have FDA clearance for the treatment of apnea and snoring. Clinical success is ultimately determined by the skill of the dentist.

Six design principles:

1. The more space created for tongue in the mouth the less likely it is to collapse on the airway during sleep.
Mechanism of Action
Oral Appliance Design

- Ideal appliance-2 separate parts-upper and lower joined at the side with screw or strap to slowly advance mandible forward in 1mm increments or less (Medicare guidelines)
- Insurances compensate for FDA approved oral appliances
- Various names include: Dorsal, EMA, Respire, Somnodent, OASYS, TAP, Klearaway, Silent Nite, Herbst
- Need adequate number of teeth
- Ideal plastic-Hard plastic on outside, thermoplastic on inside-improves patient comfort
Types of Oral Appliances

Six design principles to be considered when selecting the appropriate appliance:

1. The more space created for tongue in the mouth the less likely it is to collapse on the airway during sleep.
2. Oral airway dilation is the primary goal. There is more to an oral appliance than just mandibular advancement.
3. Stimulation of protrusive tongue reflexes is a desirable effect of an oral sleep appliance.
4. Facilitation of nasal breathing with the lips together during sleep is preferred to oral breathing with the mouth open.
5. Comfort of the appliance.
Types of Oral Appliances

Common sense principles for registering the maxillo-mandibular relationships are:

1. The maximum vertical that the lips can be comfortably closed during sleep so the patient is nose breathing.

2. The maximum comfortable protrusive position presumably with the proper combination of vertical and protrusive to stent the airway open.
SomnoMed

The SomnoMed MAS™ is a Mandibular Advancement Splint (MAS) that treats snoring and mild to moderate OSA by moving the lower jaw forward slightly. This forward movement tightens the soft tissue and muscles of the upper airway, which prevents obstruction of the airway while you sleep. The tightening created by the device also prevents the tissues of the upper airway from vibrating as air passes over them – the most common cause of loud snoring. The SomnoMed MAS™ is a custom-made device, consisting of upper and lower dental plates with a unique patented fin-coupling component, which allows normal mouth opening and closing. The device is adjustable which improves the efficacy and comfort level of treatment, as the jaw is moved only as far as is required to alleviate the condition.

The SomnoMed MAS™ design has a number of key features that are significant improvements on existing MAS oral appliances. These improvements make the device both comfortable and effective. The SomnoMed MAS™ is a highly effective solution for the majority of patients with mild to moderate OSA who prefer oral Somnomed appliances to CPAP therapy, who do not respond to, are not appropriate candidates for, or fail CPAP treatment attempts. Our exceptional levels of patient acceptance, compliance, and treatment efficacy of the SomnoMed MAS™ are backed by a large body of clinical research. In clinical studies 91% of patients reported substantial improvement in sleep quality, 87.5% of patients reported nightly use, and 96% of patients stated they would like to continue to use the SomnoMed MAS™. The SomnoMed MAS™ moves the lower jaw forward slightly which tightens the soft tissues and muscles of the upper airway, preventing obstruction during sleep. The tightening also prevents tissues of the upper airway vibrating as air passes over them.

FDA Approval received July 2005
The design of the Full Breath Solution focuses on inhibition of tongue movement; inhibiting the rise and backward movement of the tongue so that it does not block the airway during sleep. With a single arch appliance designed to provide subtle yet effective adjustments, the Full Breath Solution improves airflow 100% of the time and stops snoring with 95% of all patients.
The SUAD is also a custom-made appliance that is made of a heat-sensitive acrylic and is reinforced by a metal framework. The SUAD adjustment mechanism (Herbst) is positioned on the sides of the device and consists of a piston that slides within a tube. The appliance is comfortable on the teeth and the mechanism allows good freedom of movement of the jaw. Therefore it is used frequently in patients who tend to grind their teeth heavily. The position of the jaw can be adjusted by using small rings that slide over the piston and when the tube is positioned over the piston it will advance the jaw the width of the ring. Small elastics (rubber bands) are used to keep the jaw from falling open during the night although the patient is able to partially open the mouth, which can improve comfort when using the appliance.
HOW THE TAP WORKS

The Thornton Adjustable Positioner (TAP®) is a custom-made two piece adjustable appliance that is worn while sleeping. The trays of the appliance snap over the upper and lower teeth and hook together. The design is based on the same principle as cardiopulmonary resuscitation, CPR. The airway must be opened to allow air to pass through the throat. The TAP® holds the lower jaw in a forward position so that it does not shift nor fall open during the night. This prevents the airway from collapsing. The more you pull your jaw forward, the more your airway will open.

The TAP® is the only mandibular advancement device that can be adjusted easily by the patient or practitioner while in the mouth. This feature allows the patient to always be in control of their treatment. The unique design also allows the patient to fine-tune their treatment position at home to achieve maximum results.

Most patients experience relief the very first night they wear their TAP®. Although it may take up to a week to get used to wearing a TAP® appliance, this is a small hurdle for patients. Nine in ten patients wear the device all night, every night – making the TAP® a highly effective solution for both snoring and sleep apnea.

Features

Patient-friendly
• Superior results
• Easy to fit
• Infinitely adjustable
• Precise control of advancement
• Interchangeable hooks
• Freedom for lateral movement
• More room for tongue
• Allows lips to close

The TAP® can help prevent conditions linked to sleep apnea:

> Chronic daytime sleepiness
> High blood pressure
> Heart attack
> Stroke
> Heartburn, reflux
> Morning headaches
> Depression

FDA Approval: Approved for both snoring and OSA Date of FDA Approval: August 21, 1997 FDA Registration Number: K972061
Dorsal

The Dorsal, has been one of the most popular sleep appliances in the history of sleep appliance therapy with its original design dating back to the mid 1980's.

Date of FDA Approval: March, 2011
FDA Registration Number: K103076
The EMA® - Custom appliance is a simple, patient-friendly oral appliance created for noninvasive treatment of snoring and OSA. The primary treatment mechanism of opening the bite and gently moving the mandible forward is achieved with the use of interchangeable elastic straps that offer varying degrees of mandibular advancement. The flexibility of these elastic straps provides unsurpassed lateral movement and overall TMJ comfort. The 2 mm thick pressure formed bases offer orthodontic retention (resulting in no tooth movement) and maximum anterior tongue space because there are no projections in the palate.

The Elastic Mandibular Advancement (EMA®) appliance uses elastic force to advance the mandible. Hand plastic trays are pressure formed to the patient's models and utilize the undercut areas of the teeth for retention. This insures that there will be no movement of the patient's teeth. Bite planes are used to open the bite. Mandibular advancement is achieved with different length straps. The elastic pull can also be adjusted to suit the patient's musculature. The straps provide complete lateral movement.

The EMA® - Custom is available only to dental professionals
FDA Approval: Approved for both Snoring and OSA
Date of FDA Approval: Sept. 29, 1997
FDA Registration Number: K971794
Klearway™ is a fully-adjustable oral appliance used for the treatment of snoring and mild to moderate Obstructive Sleep Apnea. Fabricated of thermoactive acrylic resin, Klearway becomes pliable for easy insertion and confirms securely to the dentition for an excellent fit while significantly decreasing soft tissue and tooth discomfort. Small increments (0.25mm) of forward lower jaw advancement are initiated by the patient under the direction of a dentist and this helps avoid rapid jaw movements that can cause significant patient discomfort. The appliance does not encroach on tongue space. Once warmed under hot water and inserted, the acrylic resin hardens as it cools to body temperature and firmly affixes itself to both arches. Lateral and vertical jaw movement is permitted which enables the patient to yawn, swallow, and drink water without dislodging the appliance.

FDA Approval: Approved for both Snoring and OSA
Date of FDA Approval: May 25, 1995
FDA Registration Number: K950763
The Moses™ was invented and fabricated by incorporating 3 very specific dimensions. Below is a description of all three dimensions and how they contribute to the efficacy of this oral airway dilator:

**Tongue Management:** No other device on the market incorporates Tongue Management into their device. The design of The Moses™ promotes the activation of involuntary sub-conscious reflexes using a clever but simple design in the mandibular lingual acrylic. So rather than pull the tongue out of the airway, the acrylic design guides it to optimum position to the roof of the mouth. Gone are uncomfortable pins, posts and gadgets that prevent the tongue from coming forward. There is nothing in the mouth that restricts the tongue from advancing forward. The Moses™ increases tongue space and prevents collapse of tongue on the airway.

**Mandibular Advancement:** With The Moses™, it is not necessary to extend the mandible to a position that is uncomfortable and painful for the patient. The combination of Tongue Management and Mandibular Advancement means you can be conservative when advancing the mandible. Now that the tongue is out of the airway, the mandible does not need to be protruded significantly. As a result, you will also reduce problems associated with TMD.

**Patient Compliance:** The most important dimension of The Moses™ is compliance. If the device works well and is comfortable, we know the patient will want to wear it every night. While wearing The Moses™ the patient can easily talk, drink, open wide and close their lips. They no longer have the discomfort of dry mouth in the mornings. Eliminated are the claustrophobic locked jaw and mouth breather designs of earlier MADs. After a short time, you forget it is in! Patients wear it because they feel better now that their symptoms are reduced or permanently diminished.

The combination of all 3 dimensions of The Moses™ means the success doesn't rely heavily on one attribute to stop symptoms. Since the tongue is stimulated to a forward position, you don't have to aggressively extend the mandible in order stop snoring or reduce the AHI. The mandibular position of The Moses™ is comfortable for the patient. Bottom line: It works and is very comfortable, therefore the patient wears it and gets help every night!

FDA 510K number: The Moses Appliance - K093710
The OASYS Oral/Nasal Airway System™ is the first dental device to be reviewed by both the dental and ENT divisions of the FDA and to be approved as a dental device for treatment of snoring and sleep apnea through mandibular repositioning and also as a nasal dilator for reduction of nasal resistance and improved nasal breathing.

**The OASYS Oral/Nasal Airway System™ functions to:**
- Act as a mandibular repositioner
- Act as a nasal dilator
- Allow mouth breathing to occur, if required.

**The OASYS Oral/Nasal Airway System™ is designed to achieve these functions with the following goals:**
- Maintain maximize the intraoral volume.
- Minimize the force on the teeth.
- Have no components that extend extra orally through the lips.
- To reduce upper airway resistance.

**THE OASYS ORAL/NASAL AIRWAY SYSTEM REDUCES THE FORCES ON THE TEETH BY DESIGN.**

The OASYS Oral/Nasal Airway System™ fits securely onto the lower arch only. The upper flange extends in front of the upper arch and under the upper lip. This maintains a slippage during mandibular movements during usage.

There is a nature give to the wires that creates a yielding give when the mandible pulls back on the device. Provided is an upper splint that distributes the forces through the entire arch. Together these act to reduce the forces on the teeth.

**MAXIMAL INTRAORAL VOLUME**

The OASYS Oral/Nasal Airway System™ maintains maximal tongue space by positioning the connectors and adjustment components outside of the dental arch leaving the palate and anterior oral space completely free for the tongue to position itself up and forward. There is usually even an open space for the tip of the tongue to go between the incisor teeth.

**SYNERGISTIC FUNCTION FOR MAXIMAL RESULTS**

The OASYS Oral/Nasal Airway System™ maintains the patentcy of the oropharyngeal airway by functioning as a mandibular repositioner and as a nasal dilator by maintaining a stretch in the nasal labial tissue to dilate the internal nares.

FDA Registration Number: K030440
Adjustable PM Positioner

The Adjustable PM Positioner™ utilizes materials and a design that minimize office chair-time and provide the patient control of adjusting the jaw position under the dentist’s supervision. Research studies have shown that this appliance is successful in treating 77% of patients with moderate obstructive sleep apnea. The appliance fits over all maxillary and mandibular teeth and is made of a special acrylic material (Bruxeze™) that softens in hot water to provide a combination of comfort, strength, and retention. This material has proven to be very durable. Expansion screws are located on the right and left buccal areas to allow maximum space for the tongue and easy anterior-posterior positioning of the mandible to achieve optimal effectiveness. This design permits ample lateral and protrusive movement to maintain jaw comfort. The device uses a unique method of retention consisting of small projections of acrylic within the device that comfortably grip the undercut areas of two posterior teeth in each quadrant. Therefore, no metal clasps are necessary. Clinical Research Associates gave the Adjustable PM Positioner™ its highest rating for appliances tested.
The APM Ultra is the next generation Adjustable PM Positioner. The APM Ultra has incorporated many design features that will increase patient comfort and acceptance in addition to effectiveness. The design features include:

Made of a comfortable heat-sensitive acrylic  
Retention by projections of acrylic (no clasps)  
Open in the anterior for easy breathing through the mouth (or nose)  
Excellent freedom of jaw movement (6 mm in lateral excursion)  
Smaller expansion screws on R and L buccal segments  
Smaller overall size with shorter periphery and increased tongue space

FDA Approval: Approved for both snoring and OSA  
Date of FDA Approval: Feb. 8, 1996  
FDA Registration Number: K955503
Silencer

The Silencer Professional is a laboratory fabricated fully adjustable oral appliance for the treatment of sleep apnea and snoring. The appliance features a titanium precision attachment, which controls the anatomical settings of the appliance. It is capable of anteroposterior adjustment as well as vertical adjustment through a range of 10mm, in both dimensions. The design of the precision attachment also allows lateral movement of the mandible which respects and protects the TMJ. The titanium Halstrom Hinge is made of implant grade titanium and carries a five-year warranty.

There are three component materials in the Silencer. The body of the appliance is constructed of elastomer, a pliable material which offers the patient a much greater degree of comfort than harder acrylic materials. For additional support, to the dentition as well as the temporomandibular joint, hard acrylic "bite pads" are placed in the molar regions. A commercially pure titanium articulating component grants the appliance the many adjustment characteristics that make the Silencer unique - kind to the tissues, the teeth, and the temporomandibular joint.

FDA Approval: Approved for both snoring and OSA Date of FDA Approval: Nov 29, 1995 FDA Registration Number: K954530
Herbst

The Herbst Appliance has been proven to be effective on chronic snoring and mild to moderate obstructive sleep apnea sufferers. This appliance allows patients to move laterally and vertically without disengaging the appliance. Also, if it is determined that the initial position does not provide the anticipated relief of the condition, the mandible can easily be moved forward by two options of adjustability. The first option is traditional hardware with sets of 1, 2 and 3 mm shims for advancing those increments only. The second being the Telescopic version allowing the clinician to advance in ¼ mm increments by making one full turn of the protrusion collar up to 6-8mm from the start position. The appliance can be fabricated from hard acrylic, thermoactive and soft materials and is tooth retained via friction grip or clasps. The Herbst Appliance is a mandibular repositioner that has been in use many years for orthodontic and TMJ therapy prior to its modification for treatment of sleep disordered breathing.

The greatest advantage of the Herbst appliance is that it allows for very quick, easy and accurate mandibular protrusive adjustability. This is accomplished through simple manipulation of the rod/sleeve plunger mechanism. Vertical opening varies is 5 mm and there is limited freedom of movement for the mandible in a lateral direction. Bilateral interarch elastics are recommended to keep the jaw closed during sleep.

FDA Approval: The Acrylic Splint Herbst Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea

Date of FDA Approval: January 8, 2009 FDA Registration Number: K083209
The Silent Nite® appliance is prescribed by more dentists for the initial treatment of snoring. Persons with mild sleep apnea also may be treated when surgical and other medical treatments are ineffective or not desired. A soft/hard frame material is available for increased patient comfort.

FDA Approval: Approved for Snoring and OSA
Date of FDA Approval: September 18, 1997
FDA Registration Number: K972424
Snore Guard®, an oral appliance easily assembled at chair side, comprises a structure shaped to conform to the upper dental arch of the user and to create a ramp behind the lower anteriors. This ramp prevents the user's jaw from receding; in addition, the tongue seeks an opening between the upper and lower portion of the Snore Guard, thus keeping the air passage of the throat open.

It is made of two polycarbonate thermoplastics fused together under high pressure. This unique combination of materials allows stability of the unit while providing ease of wear and insertion. Snore Guard has been marketed since 1989 with a 95% reported success rate for reducing snoring. Snore Guard's design allows the user to breathe orally while promoting nasal breathing. It also permits lateral movement of the mandible.

FDA Approval: Approved for Snoring
Date of FDA Approval: April 14, 1989
FDA Registration Number: K882303
The SNOR-X is a mouth guard that gently holds the tongue forward during sleep, keeping the upper airway open and free from obstruction. The prevention of this obstruction relieves snoring. SNOR-X is made of two pieces, a tongue sleeve and a plastic ring that goes around the device and is held in place by notches on each side of the sleeve. The patient places their tongue into the tongue sleeve and squeezes the front end of the device to create a gentle suction that holds the tongue in an extended position. The patient can adjust the extension of the tongue for comfort and effectiveness. Air vents are sculpted onto the upper surface of the device to facilitate mouth breathing.

The SNOR-X is constructed of medical grade silicone, requires no laboratory fabrication and is available in several stock sizes. It maintains tongue protrusion by way of negative pressure created in the anterior vacuum bulb. An extraoral lip guard prevents retrolapse of the tongue during sleep and also allows for a degree of protrusive adjustability of the tongue. The SNOR-X is not retained on the teeth in any manner and allows total freedom of movement.

FDA Approval: Approved for snoring. Not approved for OSA Date of FDA Approval: Oct. 17, 1995 FDA Registration Number: K954324
Oral Appliance Types

- Boil-and-Bite (OTC) (insert photo)
  - Advantages:
  - Disadvantages:

- Custom-Fabricated (insert photo)
  - Advantages:
  - Disadvantages:
Tongue retained

Insert photo—Glidewell labs has photo

Advantages:
Disadvantages:
Boil – and – Bite Mouthguard

- Material: ethylene vinyl acetate
- The material is placed over the dental arch once it has been softened and has cooled sufficiently but before it rehardens.
- The material should then be evenly manipulated against the dental arches.
Custom Fabricated Mouthguards

- Three main methods for custom fabrication of mouthguards
  - The First involves taking an impression and sending this together with the prescription for the custom fabricated oral appliance to the laboratory
  - hard acrylic resin or a softer, resilient polymer (plastic) material.
Custom Fabricated Mouthguards (cont.)

- Three main methods for custom fabrication of mouthguards
  - Method #2, impressions are still taken and the resulting stone models are used with vacuum-formed material to create a temporary sleep appliance either in the office or in a laboratory.
  - Method #3, chairside technique where a temporary oral sleep appliance can be created in one visit without impressions. Using single use arch forms that are placed using a silicone mold and then light-cured.
Mouthguard Variants: Effectiveness

- Patrick van Noort ranked the effectiveness of protective mouthguards, finding laminated mouthguards with outer hard layers and an inner soft layer the most effective and stock mouthguards to be the least effective.
Adverse Effects: Oral Appliance

**MAJOR:**
- Posterior open bite in am
- Tooth movement
- Jaw discomfort (TMJ) - if healthy TMJ – usually resolves within 10-30 minutes upon awakening

**MINOR:**
- Excessive salivation, dry mouth,
- Transient malocclusion
- TMD

Approximately 90 % of patients who continue with treatment consider the benefits of treatment outweigh the adverse effects as described above
Oral Appliance Advantages

- Reduction in frequency and loudness of snoring
- Improved quality of sleep
- Reduced daytime sleep
- Improved airflow
- Smaller and more portable CPAP—more ideal for travel
- Comfortable fit
Combination therapy:

- OA and positional therapy
- Oa and surgery
- Oa and pap
- Sometimes a combination of airway splinting and pap – best results
Test Efficacy of Oral Appliances

1. Insertion of oral appliance: Adaptation period 2 weeks
2. Titration period: 2-3 months. Instruct patient to start adjusting oral appliance after a few weeks if snoring persists. Advance mandible slowly in order not to cause a problem for the temporomandibular joint.
3. Cessation of snoring – Home study
   When patient reports that snoring has decreased, and Epworth test decreases, then home study is advised
Case Selection
Case #1-Patient:B.G.

Female Age: 69
BMI: 30 Neck: 15in
Occupation: Retired
Referred By: Sleep Physician
Chief Complaint: C-Pap Intolerance
Airway Soft Tissue:
Mallampati = Class 4
Pharyngeal Space Grade = 3
Uvula is enlarged and the tongue retracts into airway on opening
Patient 1

Pre-Treatment:
Epworth : 8
PSG: AHI: 7.0
REM AH1: 18, Supine AH1: 14
REM-Supine AH1: 30.0
Nadir SaO2: 73.0%
Mean SaO2: 73.0%

Post Treatment:
Epworth : 2
PSG: AHI: 3.8
REM AH1: 17.0  Supine AH1: 4.6
Nadir SaO2: 87.0%
Mean SaO2: 94.0%
Patient 2

Male  Age: 67
BMI: 39.6   Neck: 17in
Occupation: Retired
Referred By: Sleep Physician
Chief Complaint: C-Pap Intolerance
Airway Soft Tissue:
Mallampati = Class 3
Pharyngeal Space Grade = 2
Uvula obstructs airway and the tongue retracts into airway on opening
Patient 2

Pre-treatment
Epworth Pre-Tx: 8
PSG: AHI: 14.9
REM AHI: 56.4  Supine AHI: 35.6
Lowest SaO2: 81.0%
14 Desaturation events below 90%

Post treatment PSG: AHI: 4.2
REM AHI: 17.7  Supine AHI: 13.6
Min SpO2: 89.0%
Mean SpO2: 94.2%
Max SpO2: 97.0%
1 Desaturation event below 90%
Insurance Reimbursement

- Treatment is covered by most Medical and Dental insurance plans.
- Treatment by In-Network Dentist is typically covered at 80%.
- Pre-Authorization is required by most insurance plans for the Oral Appliance.
- Oral Appliances covered by Medicare are
Indemnity Plan

- Private contract between patient and insurance company
- Patient can see any provider
- In network vs out of network
- Some plans exclude dentists from being in-network with medical plan
Gap Waiver

Insurance company may give written permission for the beneficiary to receive benefits from and out-of network provider, at in-network rates, if there is no qualified in-network provider within reasonable geographic distance.
Managed Care Plans

- Preferred provider organization (PPO)
- Health maintenance organization (HMO)
- Point of Service (POS)
Government Plans
(Medicare)

Medicare B-PHYSICIANS SERVICES
Medicare DME POS-includes oral appliances
Medicare B: Services include examination, consultation, imaging, follow up
Medicare DME POS
May provide benefits for OA on a case by case basis
Does not provide prior approval
Summary

- Every patient’s airway is unique. By having the ability to adjust forward repositioning and caudal displacement of the mandible, we can customize oral appliances to individual patients. While observing the anatomy of the anterior wall of the oral pharynx is important when determining ideal amounts of the mandibular advancement and vertical opening, other factors need to be considered. Multiple sites of closure, failure of muscles to respond, and other unknown factors could keep us from obtaining successful treatment.