An Overview of Oral Appliances and their Clinical Indications

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Functional Classification of Oral Appliances

• Categorized by Modes of Action
  – Soft Palate Lifters
  – Tongue Retainers
  – Mandibular Repositioners

Department of Oral and Maxillofacial Surgery, University of Pennsylvania Health System
and University of Pennsylvania School of Dental Medicine
Mandibular Repositioning Devices

- Sleep and Nocturnal Apnea Reducer (SNOAR)
- SnoreGuard
- Nocturnal Airway Patency Appliance (NAPA)
- Herbst Appliance

Anatomy of Sleep Apnea

Picture of the airway corresponding to the 70% setting.

The appliance is adjusted to provide ~70% of the maximum mandibular advancement.

Klearway

Somnomed Mandibular Advancement Splint

SnoreGuard

Oasys

Department of Oral and Maxillofacial Surgery, University of Pennsylvania Health System and University of Pennsylvania School of Dental Medicine
Mandibular Repositioning Appliance
Design Variations

- Method of Retention
- Flexibility of Material
- Adjustability
- Vertical Opening
- Freedom of Jaw Movement
- Lab vs. Office Fabrication

Department of Oral and Maxillofacial Surgery, University of Pennsylvania Health System and University of Pennsylvania School of Dental Medicine
What is the efficacy of OA in the treatment of snoring & obstructive sleep apnea in the short & long term?

Do patients use OA in the treatment of snoring & obstructive sleep apnea in the short & long term?

What are the short- & long-term side effects, adverse effects, & complications of using OA in the treatment of snoring & obstructive sleep apnea?

What are the long-term side effects, adverse effects, & complications of using OA in the treatment of snoring & obstructive sleep apnea?

What device selection & procedure are best for implementing OA in the treatment of snoring & obstructive sleep apnea?
American Academy of Sleep Medicine Task Force


• What is the efficacy of OA in the treatment of snoring & obstructive sleep apnea in the short & long term?
  - Studies of MRA therapy with success as AHI ≤ 5: success rate = 42%
  - 30 studies of MRA therapy with success as AHI < 10: success rate = 52%
  - 10 studies of MRA therapy with success as AHI reduced by 50%: success rate = 65%

  Improvement in minimum O₂ sat ranged from 1 - 11%, but not always clinically significant
  - Snoring: improved in intensity & frequency by bed partner reporting. Also reduced in all but 1 study using objective measures, but not always statistically significant. Need better objective assessment in future research.

EDS: Most often self-reported. Many studies showed improvement, but not always statistically significant. Need better objective assessment in future research.


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• What is the efficacy of OA in the treatment of snoring & obstructive sleep apnea in the short & long term?
  - Variables affecting OA efficacy
    - Severity of the OSA: 9 studies analyzed success of treatment by severity of OSA
      - Mild-moderate OSA success rates: 57-81%
      - Severe OSA success rates: 14-61%
    - Amount of mandibular protrusion: <10 studies. OSA improves with more advancement. Possible increased occlusal changes with increased protrusion.
    - Presence of positional sleep apnea: 3 studies showed greater success rates of OA with positional apnea. 2 studies found no relationship.
    - BMI: Several studies, but not all, showed inverse relationship between BMI & OA success.

Materials and Methods

- 134 consecutive patients from 1993-1998
  - 80 patients completed the post-insertion PSG and follow-up appointments
- All appliances adjusted to achieve approximately 50-75% of normal protrusion and increase vertical dimension 2-5 mm
- Post-therapy study done at 3 months with the appliance both in and out while sleeping
- Success = RDI < 20 or a reduction in RDI > 50%

Results

- No significant weight changes
- Decreased RDI
- Less frequent oxygen desaturation
- Decreased Snoring

Effect of CPAP and Dental Appliance Therapy on Patients with Sleep Apnea

A Retrospective Study of a Mandibular Advancement Device, the Klearway Appliance, for the Treatment of Sleep Apnea

Initial patient pool: 348 patients treated with the Klearway appliance from 1/1/95 to 2/1/2004.

Exclusion criteria:
- Lack of pre- and post-insertion polysomnography studies at Hospital of University of Pennsylvania.
- Co-morbidities affecting the sleep study.
- An initial RDI < 5 without the appliance.
- Surgery for sleep apnea between studies.
- Polygraph studies with and without the appliance greater than 6 months apart.
- Weight change of greater than 10% of body mass between polysomnography studies.
- 64 subjects were identified that had full records of pre- and post-appliance insertion at HUP.

Of the 64 subjects, 41 patients met the inclusion criteria, of which 7 had multiple polysomnography studies.

Snoring was evaluated as snoring or no snoring by patient report. Partial responses or reductions in snoring were not included in the questionnaire. A two-tailed paired t-test was used to analyze the data.
A Retrospective Study of a Mandibular Advancement Device, the Klearway Appliance for the Treatment of Sleep Apnea

Paul Madlock D.M.D., M.D., David Stanton D.M.D., M.D., Douglas Ditty D.M.D., M.D., and Joli Chou D.M.D., M.D.

<table>
<thead>
<tr>
<th>Patient Number</th>
<th>Sleep Apnea RDI</th>
<th>Pre-appliance RDI</th>
<th>Post-appliance RDI</th>
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</thead>
<tbody>
<tr>
<td>Mild &amp; Moderate</td>
<td>14.2</td>
<td>14.2</td>
<td>8.36</td>
</tr>
<tr>
<td>Moderate</td>
<td>20.1</td>
<td>20.1</td>
<td>10.8</td>
</tr>
<tr>
<td>Severe</td>
<td>48.9</td>
<td>48.9</td>
<td>20.7</td>
</tr>
<tr>
<td>All subjects</td>
<td>26.1</td>
<td>26.1</td>
<td>12.6</td>
</tr>
</tbody>
</table>

No significant improvement in oxyhemoglobin nadir

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• By what mechanism do OA improve snoring & obstructive sleep apnea?
  – Several studies using upright cephalometry have shown increases in PAS or reductions in the MPH
  – A few studies utilizing CT or MRI Imaging have also demonstrated increases in the pharyngeal
    area's size and volume.

Cephalometrics
Do patients use OA in the treatment of snoring & obstructive sleep apnea in the short & long term?

- Not well studied.
- Generally relies on self-reporting.
- Ranges from 100% to 25% for MRA


What short- & long-term side effects, adverse effects of complications occur with the use of OA in the treatment of snoring & obstructive sleep apnea

Mandibular Repositioning Device
Side effects and Complications

Oral Appliance Therapy
Side effects and Complications

• Minor and Temporary Effects:
  – Excessive Salivation
  – Transient discomfort - teeth, TMJ, muscles of mastication
  – Dry mouth
  – Soft tissue irritation
  – Temporary, minor bite disharmonies (morning-after occlusal changes)

• Moderate to Severe and Continuous:
  – Significant TMJ discomfort / dysfunction
  – Myofascial pain
  – Tongue pain (tongue devices only)
  – Gagging (mostly soft palate lifters)
  – Dry mouth and salivation
  – Permanent occlusal changes

Occlusal Changes
Oral Appliance Therapy
Side effects and Complications

Occlusal Changes

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• How do OAs compare to nasal CPAP, surgery & other therapies for the treatment of snoring & obstructive sleep apnea in terms of efficacy, treatment adherence, and preference?
SnoreGuard
Randomized Crossover Study
Ferguson et al. Chest 1996; 109: 1269-75

- SnoreGuard compared to CPAP in 27 patients with mild to moderate OSA.
- Patients had 4 months of therapy with one modality and crossed-over to 4 months of therapy with the other.
- 2 drop-outs: 25 patients completed the study.

Snoring was eliminated by CPAP in all but remained in 6 SG patients (24%).
CPAP more effective in reducing EDS.
Reported compliance was the same.
Significant side effects were more common with CPAP.

Treatment Success (RDI < 10)
SnoreGuard | CPAP
---|---
12 (48%) | 13 (62%)

Compliance Failure (unable/unwilling)
SnoreGuard | CPAP
---|---
6 (24%) | 8 (38%)

Treatment Failure (RDI > 10 or symptoms)
SnoreGuard | CPAP
---|---
7 (28%) | 0

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- What device selection & procedures are best for implementing OA in the treatment of snoring & obstructive sleep apnea?
Practice Parameters for the Treatment of Snoring & Obstructive Sleep Apnea with Oral Appliances: An Update for 2005
An American Academy of Sleep Medicine Report
Kushida, CA, Morgenthaler, TI, Limer, MR, et. al. SLEEP, 2006, 29(2); 240-243

• Diagnosis
• Appliance Fitting
• Treatment
• Follow-up

Diagnosis

3.1.1 The presence or absence of OSA must be determined before initiating treatment with oral appliances to identify those patients at risk due to complications of sleep apnea and to determine the effectiveness of subsequent treatment. Detailed diagnostic criteria for OSA are available and include clinical signs, symptoms and the findings identified by polysomnography. The severity of sleep related respiratory problems must be established in order to make an appropriate treatment decision. (Standard)

Kushida, CA, Morgenthaler, TI, Litner, MR, et. al. SLEEP, 2006, 29(2); 240-243

An American Academy of Sleep Medicine Report


The diagnosis of SDB, particularly the potentially life-threatening medical disorder, OSA, as well as the differential diagnosis of narcolepsy, periodic limb movements of sleep, insufficient sleep syndrome, and other medical conditions that also exhibit EDS, should be made by a qualified sleep specialist. (Standard)

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Appliance Fitting

- 3.2.1 Oral appliances should be fitted by qualified dental personnel who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures. Dental management of patients with OSA should be overseen by practitioners who have undertaken rigorous training in sleep medicine and other sleep related breathing disorders with focused emphasis on the proper protocol for diagnosis, treatment, and follow-up. (Option)*

- 3.2.2 Although cephalometric evaluation is not always necessary for patients who will use an oral appliance, appropriately trained professional should perform these examinations when they are deemed necessary. (Option)

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Treatment Objectives

- 3.3.1.1 For patients with primary snoring without features of OSA or upper airway resistance syndrome, the treatment objective is to reduce the snoring to a subjectively acceptable level. (Standard)

- 3.3.1.2 For patients with OSA, the desired outcome of treatment includes the resolution of the clinical signs and symptoms of OSA and the normalization of the apnea-hypopnea index and oxyhemoglobin saturation. (Standard)

- 3.3.2 Oral appliances are appropriate for use in patients with primary snoring who do not respond to or are not appropriate candidates for treatment with behavioral measures such as weight loss or sleep position change. (Guideline)*

- 3.3.3 Although not as efficacious as CPAP, oral appliances are indicated for use in patients with mild to moderate OSA who prefer OAs to CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change. (Guideline)*

- 3.3.4 Patients with severe OSA should have an initial trial of nasal CPAP because greater effectiveness has been shown with this intervention than with the use of oral appliances. Upper airway surgery (including tonsillectomy and adenoidectomy, craniofacial operations and tracheostomy) also is appropriate for oral appliances in instances for whom these operations are predicted to be highly effective in treating sleep apnea. (Guideline)
Follow-up

3.4.1 Follow-up sleep testing is not indicated for patients with primary snoring. (Guideline)

3.4.2 To ensure satisfactory therapeutic benefit from OAs, patients with OSA should undergo polysomnography or an attended cardiorespiratory (Type 3) sleep study with the oral appliance in place after final adjustments of fit have been performed. (Guideline)

3.4.3 Patients with OSA who are treated with oral appliances should return for follow-up office visits with the dental specialist. Once a patient has achieved and maintains a good, consistent compliance with therapy, dental specialist follow-up at every 6 months is recommended for the first year, and at least annually thereafter. The purpose of follow-up is to monitor patient adherence, evaluate device deterioration or maladjustment, evaluate the health of oral structures and integrity of the occlusion, evaluate the patient for signs and symptoms of worsening OSA, and continue medical evaluation. The dental specialist should have frequent and close communication with the pulmonologist. This is a unique situation in which the pulmonologist is treating the patient for sleep-disordered breathing and the dental specialist is treating the patient for OSA with an oral appliance. The pulmonologist may recommend a change in medication to improve symptoms and may counsel the oral surgeon about medical conditions that are unique to each device. In addition, oral appliances can be rendered ineffective by patient alteration of the device. (Option)

3.4.4 Patients with OSA who are treated with oral appliances should return for periodic follow-up office visits with the referring clinician. The purpose of follow-up is to assess the patient for signs and symptoms of worsening OSA. Close communication with the dental specialist is most conducive to good patient care. An objective reevaluation of respiration during sleep is indicated in sign or symptoms of OSA worsen or recur. (Option)

Protocol for Oral Appliance Therapy

- Evaluation of appliance for 2-3 months
- Repeat polysomnography
- Repeat evaluation by both pulmonologist and Dentist/OMFS

Design Variations

- Adjustability
- Method of Retention
- Flexibility of Material
- Freedom of Jaw Movement
- Lab vs. Office Fabrication
- Vertical Opening

What is the best Appliance?

One that works, and that the patient will use.

Mandibular Repositioning Appliances

Overall, those with mild to severe OSA have a 52% chance of being able to control apnea using an appliance

Oral appliances (OA) are on the whole less effective than CPAP but may be better accepted by patients

OA are not recommended as a first line treatment in patients with severe OSA (AHI>40)

Patients with severe OSA might consider an OA of they have failed CPAP or upper airway surgery, recognizing that the results of OA therapy in severe OSA are unpredictable.
Future Directions

• Titration of amount of jaw protrusion at sleep center
• Home PSG monitoring to assess efficacy of advancement
• ?Use in children & adolescents – probable effect on facial growth.