Mandibular Advancement Devices
Indications and Complications for Obstructive Sleep

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Disclosures

- None related to presentation
- Personal financial support from a non-commercial source relevant to medicine, within past 3 years
  - Research
    - Inspire Medical hypoglossal nerve implant
  - Consultant
    - Inspire Medical New Product Development
  - Medtronic Ent
  - Siesta Medical
  - Medtronic ENT hyoid to mandible suspension
  - Patents
  - Tongue suspension (Aspire “advance”) owned by Phillips Respironics with no financial ownership
Case 1

- 48 year old male executive
  - Severe disruptive snoring
  - Fatigue but denies problems driving
  - AHI 28/hr, low SaO2 of 85%
  - Poorly tolerated CPAP
  - Failed an OTC thermoplastic oral device
Clinical Algorithm to Assess Likely Benefit/Risk

- Exam
  - No major nasal abnormalities
  - Tonsil = T0
  - Modified Mallampati = Grade 3
  - Full dentition, Angle Class II (no bridges but 1 crown)
  - 8+ mm protrusive range
  - No palpable TMJ pain or limited ROM
  - BMI 32 kg/M2
  - Good cervico/mental angle (hyoid to mandible position)
Evidence Based Clinical Options

• Conservative Medical Therapies
• Mandibular Advancement Devices
• Surgery

• How to Proceed???
Guidelines Oral Appliances (3)

Oral appliances for obstructive sleep apnoea (Review)

Lim J, Lasserson T, Fleetham J, Wright J

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Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances

An American Sleep Disorders Association Report
Sponsored by the Practice Committee of the American Sleep Disorders Association

Michael T. Strollo, MD, Andrew Gottlieb, MD, Sander Zeilstra, DDS, Othmar Strohmenger, MD, Richard Minihan, MD, Samuel Polumbic, Jr., MD, Gerald Rosen, MD, Patricia J. Skatrud, Jr., MD, Valerio Woollen, MD

Non-CPAP therapies in obstructive sleep apnoea: mandibular advancement device therapy

Marie Marklund*, Johan Verbraecken and Winfried Randerath

• Newer and Older Differ in Recommendations

Cochrane 2005

AASM 2005

Summary (AASM, 2005)

- Goal is resolution of clinical signs and symptoms and the **normalization of AHI**
- Snoring not responsive to behavioral measures such as weight loss or sleep-position change.
- Since effect less than CPAP, only indicated for mild to moderate OSA who prefer OAs or who do not respond to CPAP
- Excluded severe OSA
Oral Appliances fail to “NORMALIZE” AHI

CPAP vs OA Mild to Moderate OSA  Barnes et al ARRCCM 170:656,2004
Health Outcomes of CPAP versus OA: A RCT

• Oral appliance have a partial effect on AHI even when not accounting for adherence (Hr/night and nights/week)
Health Outcomes of CPAP versus OA: A RCT

- However, in other health outcomes = Equivalent results
  - HTN, sleepiness, driving simulator,
  - Quality of life (SF -36): OA>CPAP (p< 0.05)
Effectiveness = Effect + Adherence

- CPAP has greater effect
- Oral Appliances in many subgroups have better adherence
- Key is to identify which groups have better adherence
Summary (ERS Task Force, 2010)

• MADs reduce AHI and EDS versus placebo
• CPAP > OA on AHI yet data show symptoms and cardiovascular health are equivalent
• Recommendation Level A = MADs recommended for patients with mild to moderate OSA with a proven increase in upper airway size and for those who do not tolerate CPAP

i.e. Oral Appliances can be first line treatment
Types of Oral Appliances

1. Tongue Retaining Devices (TRD)
2. Mandibular Advancement (MAD)
   1. Adjustable
   2. Fixed
3. Manufacturing Type
   1. Custom fit (generally meet criteria)
   2. Boil and bite (generally do not)

Critical Elements are Fit and Function
TRD

Mandibular Advancement

Herbst

Klearway

Silencer

TAP
Tongue Retaining versus MAD

- Very few studies on TRD (some data suggests may make OSA worse in some)
- Possible use in edentulous patient

Adjustable versus Non-adjustable

- Device and provider specific
- Some studies show equivalence
Custom versus Thermoplastic

• Friedman (level 4) 40% versus 21% success
• Vanderveken (RCT) 60% versus 31%
• Primary reason: Poor retention
• Secondary: Size and excess vertical opening
Therapeutic Features: Protrusion

Dose-Dependent Effects of Mandibular Advancement on Pharyngeal Mechanics and Nocturnal Oxygenation in Patients With Sleep-Disordered Breathing*

Therapeutic Features: Vertical Opening

- Lengthens and narrows posterior airway space
- Goal is to minimize vertical opening

ARRCCM 166 860 2002

Effect of Vertical Dimension on Efficacy of Oral Appliance Therapy in Obstructive Sleep Apnea

Andrew J. Pitsis, M. Ali Darendelier, Helen Gotsopoulos, Peter Petocz, and Peter A. Cistulli
• Major predictor was change in retropalatal space in success but not failure group.
• Temporary device used during DISE
• Statistical but not clinical predictor
Tolerance and Adherence

Type D “distressed” personality, defined as a combination of negative affectivity and social inhibition.

Cephalometric, facial morphometrics, CT scans, Pharyngometry all fail to predict outcomes.
Clinical Pathway (Positive Predictors)

1. Snoring >> EDS (for OSA patients)
2. Adequate dentition
3. Enthusiasm for use of device (not Type D)
4. Good protrusive range (7-10 mm)
5. Avoid morbidly obese (desaturation and greater lateral wall component to collapse)
Dentist

- Good working relationship with dentists and sleep physicians
Side effects

• Pain from temporomandibular joint(s) and/or teeth (47 %), excessive salivation (38 %), different feeling in teeth upon withdrawal of the MAD (36 %), dry mouth (33 %), and sensitive teeth (29 %).

• Change in dentition/occlusion

• Change in TMJ
“transient” side effects:

• Dental:
  – Decreased overjet/ overbite
  – Changes in incisor inclination

• Temporomandibular Dysfunction:
  – Due to mandibular forward positioning
  – Seen in mostly FIXED appliances
  – Most studies poorly controlled
Prospective, randomized
n=103
OA (TAP) vs. CPAP
Followed over 2 years
TAP: Set to 50% maximum protrusion, titrated to either symptom improvement or discomfort
<table>
<thead>
<tr>
<th>Clinical diagnosis (RDC/TMD)</th>
<th>T0</th>
<th>T2</th>
<th>T15</th>
<th>T27</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CPAP (n=52)</td>
<td>OA (n=51)</td>
<td>Total (n=103)</td>
<td>CPAP (n=50)</td>
</tr>
<tr>
<td>No TMD</td>
<td>40</td>
<td>33</td>
<td>73</td>
<td>36</td>
</tr>
<tr>
<td>1a: myofascial pain</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2a: disc displacement with reduction</td>
<td>7</td>
<td>14</td>
<td>21</td>
<td>9</td>
</tr>
<tr>
<td>2b: disc displacement without reduction with limited opening</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3a: Arthralgia</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3c: Osteoarthrosis of the temporomandibular joint</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>1a+ 2a</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1a+ 3a</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>2a+ 3a</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2a+ 3c</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Total TMD (%)</td>
<td>23</td>
<td>35</td>
<td>29</td>
<td>28 (15)</td>
</tr>
<tr>
<td>Pain-related TMD (%)</td>
<td>4</td>
<td>8</td>
<td>6</td>
<td>6 (12)</td>
</tr>
</tbody>
</table>

*a Only those clinical diagnoses or combinations of diagnoses which were prevalent during the study

b Diagnoses or combinations of diagnoses in italic represent pain-related diagnoses

c Within parenthesis, the percentage increase (†) or decrease (¶) in the occurrence of TMD compared to the preceding check-up is described
• N = 103
• T= baseline, 2 mo, 1 yr, 2 yr
• Assessed change in occlusion
  – Decrease in overjet and overbite
  – Decreased number of posterior occlusal contacts
  – Decrease in overbite is associated with mandibular protrusion
<table>
<thead>
<tr>
<th>Variable</th>
<th>Oral appliance ($n=29$)</th>
<th>CPAP ($n=34$)</th>
<th>Difference ($p$ value$^c$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>49.7±8.9</td>
<td>50.6±10.1</td>
<td>NS</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>22/7</td>
<td>32/2</td>
<td>NS$^d$</td>
</tr>
<tr>
<td>Apnea-hypopnea index (no./h)</td>
<td>35.6±22.3</td>
<td>44.2±27.9</td>
<td>NS</td>
</tr>
<tr>
<td>Body mass index (kg/m$^2$)</td>
<td>31.4±5.7</td>
<td>33.7±5.7</td>
<td>NS</td>
</tr>
<tr>
<td>Therapeutic use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nights per week</td>
<td>6.9±0.4</td>
<td>6.7±1.1</td>
<td>NS</td>
</tr>
<tr>
<td>Hours per night</td>
<td>7.1±0.8</td>
<td>6.7±1.3</td>
<td>NS</td>
</tr>
<tr>
<td>Number of teeth</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper arch</td>
<td>12.7±1.5</td>
<td>13.1±1.8</td>
<td>NS</td>
</tr>
<tr>
<td>Lower arch</td>
<td>13.1±1.4</td>
<td>13.0±1.5</td>
<td>NS</td>
</tr>
<tr>
<td>Occlusal contact points cuspid–incisor region (no.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>2.5±1.7</td>
<td>3.2±2.0</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>2.2±1.8</td>
<td>3.0±1.9</td>
<td>NS</td>
</tr>
<tr>
<td>Difference ($p$ value$^b$)</td>
<td>NS</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Occlusal contact points (pre)molar region (no.)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>6.8±2.6</td>
<td>6.9±2.6</td>
<td>NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>5.1±2.3</td>
<td>6.4±2.3</td>
<td>NS</td>
</tr>
<tr>
<td>Difference ($p$ value$^c$)</td>
<td>$p&lt;0.00$</td>
<td>$p=0.03$</td>
<td></td>
</tr>
<tr>
<td>Delta overbite (mm)</td>
<td>$-1.2±1.1$</td>
<td>$-0.1±0.6$</td>
<td>$p&lt;0.00$</td>
</tr>
<tr>
<td>Delta overjet (mm)</td>
<td>$-1.5±1.5$</td>
<td>$-0.2±0.7$</td>
<td>$p&lt;0.00$</td>
</tr>
<tr>
<td>Anterior–posterior movement (mm)</td>
<td>$-1.3±1.5$</td>
<td>$-0.1±0.6$</td>
<td>$p&lt;0.00$</td>
</tr>
</tbody>
</table>

*Values are means ± standard deviations

$^a$Unpaired $t$ test

$^b$Paired $t$ test

$^c$Fisher's exact test

CPAP: continuous positive airway pressure, NS: not significant
Side Effects and Technical Complications:
Angle Orthodontist, Vol 80, No 1, 2010

- \(N=40\)
- Set to 70% maximum protrusion, titrated to cessation of snoring or increased symptoms
- \(T=6\) wks, 6 mo, 5 yrs
- Results:
  - Mild occlusal changes occur (mainly in initial 2 years)
  - Has no real effect on patients with previous TMD diagnosis
  - Appliance failure resulted in unscheduled visits
    - Patients discontinued use
    - Increased cost
    - Delay in effective treatment
Five Years of Sleep Apnea Treatment with a Mandibular Advancement Device
Side Effects and Technical Complications

Jordi Martínez-Gomis, Eva Willsart, Lluis Nogues, Maribel Pazuelo, Maria Somoza, and Carmen Munsterio

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Abstract

Objective: To determine the variation in prevalence of temporomandibular disorders (TMD), other side effects, and technical complications during 5 years of sleep apnea treatment with a mandibular advancement device.

Materials and Methods: Forty patients diagnosed with obstructive sleep apnea received an adjustable appliance at 70% of the maximum protrusion. The protrusion was then progressively increased. TMD (diagnosed according to the Research Diagnostic Criteria for TMD), overjet, overbite, occlusal contacts, subjective side effects, and technical complications were recorded before and a mean of 14, 21, and 58 months after treatment and analyzed by the Wilcoxon test (P < .05).

Results: Fifteen patients still used the oral appliance at the 5-year follow-up, and no significant variation in TMD prevalence was observed. Subjective side effects were common, and a significant reduction was found in overjet, overbite, and in the number of occlusal contacts. Furthermore, the patients made a mean of 2.5 unscheduled dental visits per year and a mean of 0.8 appliance repairs/relines per year by a dental technician. The most frequent unscheduled visits were needed during the first year and were a result of acrylic breakage on the lateral telescopic attachment, poor retention, and other adjustments to improve comfort.

Conclusions: Five-year oral appliance treatment does not affect TMD prevalence but is associated with permanent occlusal changes in most sleep apnea patients during the first 2 years. Patients seek several unscheduled visits, mainly because of technical complications.

Keywords: Sleep-disordered breathing, Oral appliance, Craniomandibular disorders, Adverse effects, Device failure
FREQUENT EVALUATIONS

Recommendations for Use of Oral Appliances

- Dental follow-up at regular intervals
- Monitor compliance
- Evaluate status of the device
- Health of the oral structures
- Occlusion
- Assess for signs and symptoms of worsening OSA
18-35% edentulous
40% Gingivitis peridontal pockets
2% Active TMJ pain, clicking limited mouth opening protrusion

Findings 36% contraindicated
50% remaining needed periodontal care
Contraindications

1. No dentition or poor dentition (highly dependent on number, placement, and condition of remaining teeth)
2. Acute temporomandibular joint dysfunction (TMJD) symptoms (case-by-case basis)
3. TMJD arthritis
4. Psychological aversion to structures in the oral cavity
5. Limited dexterity
6. Limited mental capacity
Contraindications

7. Advanced Periodontal (gum) Disease and/or other periodontal issues (such as attachment)
8. Myofacial Pain Dysfunction (MPD), Trigeminal Neuralgia?
9. Money – may not be covered by some medical insurance policies, therefore considered an out of pocket expense
1. Muscle spasms, pain, TMJ
2. Excess salivation or xerostomia (usually transient)
3. Tooth, crown movement, damage
4. Permanent change in bite (anterior migration of mandible) i.e., “teeth don’t fit together like they used to”
5. Can’t tolerate: Mouth sores, periodontal (gum) complications, root resorption
6. Ingestion/aspiration of broken OA pieces
Additional Parameters
(AASM 2005)
Oral Appliance Parameter - Sleep Studies  AASM 2005

• OSA must be evaluated before initiating OA to identify patients at risk of OSA related complications and to provide a baseline to establish the effectiveness of treatment (i.e PSG)

• Follow-up sleep testing is not indicated for patients with primary snoring.

• Patients with OSA should undergo follow up PSG or Type 3 sleep study after final adjustments
Oral Appliance Parameter AASM 2005

• Oral appliances should be fitted by qualified personnel (1995) (qualified dental personnel (2005,Option) ) who are trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion and associated oral structures.

• Dental management of OAs should be by practitioners who have serious training in sleep medicine with focused emphasis on the proper protocol for diagnosis, treatment, and follow up. (2005,Option)
Oral Appliance Parameter AASM 2005

• Patients with OSA should
  – follow-up dental visits every 6 months for the first year and then annually
  – device deterioration or maladjustment, evaluate oral health, occlusion, assess for worsening OSA, intolerance, and improper use.

• OA may aggravate temporomandibular joint disease and may cause dental misalignment and discomfort