ORAL APPLIANCE THERAPY: THE GOOD AND BAD NEWS ABOUT IT

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OUTLINE

- No Financial Disclosures
- Private practice focused on Dental Sleep Medicine
- Grants from Non-Profit organizations:
  - University of British Columbia
  - S. Wah Leung Foundation
  - SickKids Foundation
  - Canadian Institutes of Health Research (CIHR)

- Dental and TMJ side effects of OAT – The Bad News
- Cardiovascular Effects of OAT – The Good News
- The role of combination therapy – is there a balance?
CPAP and MAS appear to be effective – CPAP better controls AHI.
- MAS has a 30% lower rate of treatment success.
- Both CPAP and MAS are cost-effective among patients with moderate to severe OSA, little data on MAS.
- To properly address these studies we need Cardiovascular Event Risk – little data!

**Efficacy of MAS**

<table>
<thead>
<tr>
<th>Definition of success</th>
<th>No. of studies</th>
<th>Average success rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHI &lt; 5/hour</td>
<td>8</td>
<td>42%</td>
</tr>
<tr>
<td>AHI &lt; 10/hour</td>
<td>30</td>
<td>52%</td>
</tr>
<tr>
<td>AHI &lt; 50% compared to baseline</td>
<td>10</td>
<td>65%</td>
</tr>
</tbody>
</table>

Ferguson et al, Sleep 2006
Efficacy CPAP vs MAS

Symptomatic Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Effect of MAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Snoring</td>
<td>Very high subjective response rate. Objective reduction in snoring intensity and frequency</td>
</tr>
<tr>
<td>Sleepiness</td>
<td>Improved ESS. No difference between MAS and CPAP</td>
</tr>
<tr>
<td>Quality of life</td>
<td>Improved QoL. No difference between MAS and CPAP</td>
</tr>
<tr>
<td>Mood</td>
<td>Few studies. Improved scores. Inconsistent differences between MAS and CPAP</td>
</tr>
</tbody>
</table>

Adapted from Cistulli. Ferguson, Sleep 2006; Naismith, JCSM 2005; Engleman, AJRCCM 2002; Hoekema J Dent Res 2008

- Acquiring insight into the patient's perspectives about attributes of a potential treatment modality can provide vital information to practitioners to help inform the choice of optimal treatment.
- Matching therapy to patient preferences may help identify the most appropriate treatment, and this may achieve greater likelihood of adherence.
Health Outcomes

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Effect of MAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objective Sleepiness</td>
<td>Improved MSLT. MAS = CPAP on MWT</td>
</tr>
<tr>
<td>24hr Blood Pressure</td>
<td>Reduced blood pressure. MAS = CPAP*</td>
</tr>
<tr>
<td>Endothelial function</td>
<td>Improved endothelial function after 1 year of MAS use, despite residual AHI (19%)</td>
</tr>
<tr>
<td>Psychomotor speed</td>
<td>Improved psychomotor speed</td>
</tr>
<tr>
<td>Driving simulator performance</td>
<td>Improved performance MAS = CPAP</td>
</tr>
</tbody>
</table>


Endothelial Function

- In mild-severe OSA, MAS improved long term cardiovascular risk markers despite of residual apneas (Itzhaki, Chest 2007)

<table>
<thead>
<tr>
<th>Biochemical data</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine, mg/dL</td>
<td>0.8 ± 0.1</td>
<td>1.1 ± 1</td>
<td>1.1 ± 1.24</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>Total cholesterol, mg/dL</td>
<td>205 ± 36.4</td>
<td>290 ± 40.2</td>
<td>172 ± 34.7</td>
<td>0.0009</td>
<td></td>
</tr>
<tr>
<td>LDL, mg/dL</td>
<td>143 ± 37.7</td>
<td>190 ± 36.1</td>
<td>114 ± 30.4</td>
<td>0.025</td>
<td></td>
</tr>
<tr>
<td>HDL, mg/dL</td>
<td>43 ± 16.4</td>
<td>45 ± 12.2</td>
<td>34 ± 11.9</td>
<td>0.0007</td>
<td></td>
</tr>
<tr>
<td>Triglycerides, mg/dL</td>
<td>150 ± 75.6</td>
<td>142 ± 63.2</td>
<td>190 ± 50.2</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>Fasting glucose, mg/dL</td>
<td>104 ± 30.3</td>
<td>96 ± 18.7</td>
<td>90 ± 5.1</td>
<td>NS</td>
<td></td>
</tr>
<tr>
<td>TBARS, nmol MD/mg/dL</td>
<td>0.6 ± 0.2</td>
<td>1.8 ± 1.4</td>
<td>1.8 ± 1.2</td>
<td>0.05</td>
<td></td>
</tr>
</tbody>
</table>

Oral Appliance impact on Cardiovascular Health
MAS improves nocturnal dip in blood pressure

![Graph showing the improvement in nocturnal blood pressure with MAS therapy.]

Gotsopoulos, et al. Sleep Breath 2006
Otsuka, Almeida, Leone, et al. Sleep 2004

Cardiovascular Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>OA</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>127.3</td>
<td>123.7*</td>
<td>RDI 5-21</td>
</tr>
<tr>
<td>DBP</td>
<td>91.0</td>
<td>81.9*</td>
<td>Gauthier, SleepMed 2011</td>
</tr>
</tbody>
</table>

MAS improves blood pressure after 3.3 years

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>MAS</th>
<th>CPAP</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>24hr mean systolic</td>
<td>126.5</td>
<td>126.7</td>
<td>127.3</td>
<td>AHI 5-30</td>
</tr>
<tr>
<td>24hr mean diastolic</td>
<td>76.3</td>
<td>76.3</td>
<td>76.7</td>
<td>Barnes, AJRCCM 2004</td>
</tr>
<tr>
<td>Night diastolic</td>
<td>69.4</td>
<td>67.2*</td>
<td>69.9</td>
<td></td>
</tr>
</tbody>
</table>

* MAS significantly improved the nocturnal diastolic blood pressure and increased the proportion of subjects with a normal night-time dip in blood pressure.
Cardiovascular outcomes depend probably not only on decrease of AHI, but also on treatment adherence.

Barnes, AJRCCM 2004

Iftikhar et al, JCSM 2013

OA treatment for mild to moderate sleep apnea improves BP control. Reductions in both SBP and DBP, as well as in nocturnal SBP were seen with OA treatment.

Although the reductions in BP with OA were modest, these effects were comparable to those reported with CPAP treatment.
Health Outcomes CPAP vs OA
Phillips et al, AJRCCM, 2013

- 108 patients mild-severe OSA

**Conclusions:**
- Health outcomes MAD = CPAP
- Greater efficacy of CPAP
- Greater compliance of MAD,
- Resulting in similar effectiveness

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Important health outcomes were similar after 1 month of optimal MAD and CPAP treatment in patients with moderate-severe OSA.

The results may be explained by greater efficacy of CPAP being offset by inferior compliance relative to MAD, resulting in similar effectiveness.
Sleepiness Improvement
MAS = CPAP

OSA Quality of Life Improvement
MAS = CPAP

General Quality of Life Domains
Improvement MAS = CPAP but
MAS greater than CPAP

Bodily pain; Vitality; Mental health and Mental component

Driving performance
MAS = CPAP

No overall changes
in Blood Pressure
MAS = CPAP

Hypertensive Improvement
between 2 to 4 mmHg
MAS = CPAP

126 patients mod-severe OSA – 108 finished.
Physicians need to know

- Evidence based
- Send papers
- Partner with them
- Show reciprocal respect
- They are your referral source!

What about long term !!!!

'I still can't believe he's not snoring.'
There is some evidence that MAS changes Blood pressure and Endothelial Function in OSA

There is small evidence that MAS treatment reduces cardiovascular risk/mortality

Continuous Positive Airway Pressure Treatment of Mild to Moderate Obstructive Sleep Apnea Reduces Cardiovascular Risk

AJRCCM, 2007

Note the word treated
not CPAP treatment

Buchner et al. AJRCCM, 2007

Treatment
CPAP treatment was recommended to patients with moderate or severe OSA and to patients with mild OSA accompanied by severe daytime sleepiness. An alternative intrasal protrusive appliance was offered to patients who refused CPAP or to those with mild OSA without severe hypersomnolence. Patients who refused mechanical devices remained untreated.

RESULTS
A total of 449 patients (384 male, 65 female) were recruited. Treatment for OSA was initiated in 364 patients (CPAP in 296, bilevel positive airway pressure in 48, and intrasal protrusion devices in 20). Eighty-five patients refused treatment. Patient baseline characteristics are listed in Table 1. Briefly, BMI was

Why did they not exclude 20 MAS patients?
A. They believe MAS = CPAP
B. MAS made the statistics significant
(B) treated versus untreated patients with mild–moderate OSA

(C) treated versus untreated patients with mild–moderate OSA without pre-existing cardiovascular disease.

Based on this study, there is some weak evidence that MAS may decreases cardiovascular risk

Conclusions
This observational study shows benefits of OSA treatment on cardiovascular outcome in mild-moderate OSA. OSA treatment is associated with a marked cardiovascular risk reduction of at least 38% (upper end of 95% CI) independent from age, gender, and preexisting cardiovascular comorbidities. As a component of primary or secondary prevention, OSA therapy should be considered even in mild forms of OSA.

At 79 months follow-up
Efficacy in Moderate to Severe OSA

Positive correlation between the baseline AHI and the reduction of the AHI with the use of a MAS.

Moderate to severe OSA should not be excluded from MAS therapy.

Morbidity and Mortality

Studies have shown that MAS improves inflammatory markers, endothelial function, microvascular reactivity and blood pressure to similar levels of CPAP.

Despite the presence of residual apneas.
Cardiovascular outcomes depend probably not only on decrease of AHI, but also on treatment adherence.

**Efficacy x Effectiveness**

![Graph showing relationship between treatment adherence and cardiovascular outcomes](image)

**Barnes, AJRCCM 2004**

**Mandibular advancement devices (MADs)** represent the main non-continuous positive airway pressure (non-CPAP) therapy for patients with obstructive sleep apnoea (OSA).

- CPAP more effectively diminishes AHI, while increasing data suggest fairly similar outcomes in relation to symptoms and cardiovascular health from these treatments.

**European Respiratory Journal 2012; 39:1241-1247**

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

Marie Marklund, Johan Verbraeckens and Winfried Randerath

- Mandibular advancement devices (MADs) represent the main non-continuous positive airway pressure (non-CPAP) therapy for patients with obstructive sleep apnoea (OSA).
- CPAP more effectively diminishes AHI, while increasing data suggest fairly similar outcomes in relation to symptoms and cardiovascular health from these treatments.

**Efficacy**

**Table 1—Clinical End Points of Treatment of OSA with Oral Appliances and CPAP**

<table>
<thead>
<tr>
<th>End Points</th>
<th>O-A</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement in severity of snoring</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Improvement in AHI</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Improvement in oxygen saturation</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Reduction in sleep fragmentation</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Improvement in daytime somnolence</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Improvement in sleep duration</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Improvement in sleep latency</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Improvement in wake latency</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Improvement in mood</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Improvement in quality of life</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Improvement in motor vehicle accident rate</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

*An indication of the relative efficacy of oral appliances and CPAP is denoted by: + (small benefit), ++ (moderate benefit), +++ (large benefit), 7 denotes an unmeasurable end point.

**Chan & Cistulli, 2007**

**9 RCT MAS x Placebo**

**10 RCT MAS x CPAP**
Comparison of overall treatment performance.

Chan & Cistulli, 2009
Tooth and TMJ Side-effects of OA

Temporary
- Frequency is 6 to 86%
- Resolved within several days to several weeks or with OA adjustments
- Salivation, TMJ pain, myofascial pain, tooth pain, dry mouth, gum irritation and morning-after occlusal changes.

Permanent
- Tooth movement, skeletal changes and occlusal alterations

Temporary
- A Green Oral Appliance
  - Environmental friendly
  - OA coated in green residue → non compliance
  - Calcium Stearato from soap and high calcium water


Discontinued OA due to or presence of TMJ symptoms (% of patients)

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmidt-Nowara 1991</td>
<td>1.4%</td>
</tr>
<tr>
<td>Clark GT 1993</td>
<td>20.0%</td>
</tr>
<tr>
<td>Clark GT 1996</td>
<td>4.7%</td>
</tr>
<tr>
<td>Bernhold M 1998</td>
<td>4.0%</td>
</tr>
<tr>
<td>Raphaelson MA 1999</td>
<td>16.6%</td>
</tr>
<tr>
<td>Pantin CC 1999</td>
<td>6.0%</td>
</tr>
<tr>
<td>McGown 2001</td>
<td>37%</td>
</tr>
<tr>
<td>Johnston 2002</td>
<td>42%</td>
</tr>
<tr>
<td>Rose 2002</td>
<td>9%</td>
</tr>
<tr>
<td>Mehta 2001</td>
<td>7%</td>
</tr>
<tr>
<td>Pitis 2002</td>
<td>48% x 70%</td>
</tr>
<tr>
<td>Marklund 2007</td>
<td>11% x 21%</td>
</tr>
<tr>
<td>Hammond 2007</td>
<td>23%</td>
</tr>
<tr>
<td>Gindre 2008</td>
<td>~26%</td>
</tr>
<tr>
<td>Vezina 2011</td>
<td>12% x 9%</td>
</tr>
</tbody>
</table>

Variability between studies 1.4 to 70% !!
% of Patients - TMJ symptoms

<table>
<thead>
<tr>
<th></th>
<th>Jaw Discomfort</th>
<th>Vertical Opening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitsis, AJRCCM, 2002</td>
<td>48% x 70%</td>
<td>4 mm x 14 mm</td>
</tr>
<tr>
<td>Marklund, JSleepRes, 2007</td>
<td>11% x 21%</td>
<td>TMJ Sounds</td>
</tr>
<tr>
<td></td>
<td>Frequent users</td>
<td>Infrequent user</td>
</tr>
</tbody>
</table>

Does Propulsion Mechanism Influence the Long-term Side Effects of Oral Appliances in the Treatment of Sleep-Disordered Breathing?

Conclusions: traction-based appliances are similar to compression-based devices with regard to secondary effects and compliance.

<table>
<thead>
<tr>
<th></th>
<th>Traction</th>
<th>Compression</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 16 (9M/7F)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 32 (31M/1F)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Early TMJ Pain</td>
<td>12.8 (0-32)</td>
<td>12.2 (0-95)</td>
</tr>
<tr>
<td>Early Masticatory Muscle Pain</td>
<td>0 (0-6)</td>
<td>8.5 (0-62) **</td>
</tr>
<tr>
<td>Residual TMJ Pain</td>
<td>0 (0-5)</td>
<td>0 (0-83)</td>
</tr>
<tr>
<td>Residual Masticatory Muscle Pain</td>
<td>0 (0-24)</td>
<td>0 (0-83)</td>
</tr>
</tbody>
</table>

Measurements in mm from a visual analog scale from 0 to 100mm

Vezina et al. CHEST 2011; 140(5):1184–1191

How to measure TMD? Symptoms or physiological aspects? Which symptoms are important?
Physiology
Condyle position and morphology

Maximal Open
Oral Appliance

No significant changes in the morphology of the TMJ.

The anterior displacements of the condyle were within the physiological limits of the TMJ.

Almeida FR et al. Sleep, 2002

How to Measure TMD?

Helkimo Anamnetic Dysfunction Index

34 patients evaluated over a period of 36±17 months

Significant decrease of TMJ symptoms

Tinnitus

9 patients presented tinnitus at beginning of treatment
7 patients reported a decrease in this symptom

Giannasi, Almeida et al. Sleep and Breath 13(4):375-81

How to measure TMD – Research Diagnostic Criteria

AXIS 1

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I</td>
<td>Myofascial Pain</td>
</tr>
<tr>
<td>Group II</td>
<td>Disc Displacement</td>
</tr>
<tr>
<td>Group III</td>
<td>Arthralgia</td>
</tr>
<tr>
<td>Total TMD</td>
<td>Any group</td>
</tr>
</tbody>
</table>

AXIS 2

Grade | Description |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>No temporomandibular pain in the prior 6 months</td>
</tr>
<tr>
<td>Grade I</td>
<td>Low disability–low intensity pain</td>
</tr>
<tr>
<td>Grade II</td>
<td>Low disability–high intensity pain</td>
</tr>
<tr>
<td>Grade III</td>
<td>High disability – moderately limiting</td>
</tr>
<tr>
<td>Grade IV</td>
<td>High disability – severely limiting</td>
</tr>
</tbody>
</table>

*Deo et al. (1986)
86 OSA Patients were evaluated for TMD (RDC)

75% of the patients presented chronic pain related to TMD.


Incidence of TMD /RDC in OSA patients - Subjective

- 511 patients with clinical symptoms of OSA
- Mean AHI 32.5 ± 30.6
- Self-reported questionnaire on jaw symptoms

<table>
<thead>
<tr>
<th>Total</th>
<th>AHI &lt; 15</th>
<th>AHI &gt;15</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least one (1) jaw symptom (% of patients)</td>
<td>19%</td>
<td>25%</td>
</tr>
</tbody>
</table>

Higher incidence amongst patients with major indication is oral appliance (milder).


Is TMD a contra-indication for oral appliance?

Treat only 25% of these patients?

GO FISHING !!!!
**Oral Appliance impact on TMD**

Research Diagnostic Criteria Evaluation at 14, 21 and 58 months (15 pts 5yr)

<table>
<thead>
<tr>
<th>N = 15 completed 58 mo.</th>
<th>Baseline</th>
<th>After 14 months</th>
<th>After 21 months</th>
<th>After 58 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMD (any group)</td>
<td>20% (3)</td>
<td>13% (2)</td>
<td>7% (1)</td>
<td>7% (1)</td>
</tr>
<tr>
<td>Group I myofascial pain</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Group II disc displacement</td>
<td>20% (3)</td>
<td>13% (2)</td>
<td>7% (1)</td>
<td>7% (1)</td>
</tr>
<tr>
<td>Group III Arthralgia</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Martinez-Gomis, J et al, Angle Orthod 2010; 80(1):30-6

No significant variation of TMD was found over the treatment period, **DESPITE** changes in the occlusion.

Martinez-Gomis, J et al, Angle Orthod 2010; 80(1):30-6

**Long-term oral appliance therapy in obstructive sleep apnea syndrome: a controlled study on temporomandibular side effects**

Clin Oral Invest. 2011

Parallel randomized controlled study

- Occurrence of TMDs and the risk of developing pain and function impairment of the temporomandibular complex during 2 year treatment with OA or CPAP.

- The influence of mandibular protrusion on these variables.

Doff and colleagues concluded

1. Only at 2 months timeline, the occurrence of pain-related TMDs was higher in OA (24%) vs CPAP (6%).
2. OA resulted in more TMD pain compared to CPAP (odds ratio 2.33).
3. No limitation in mandibular function in both groups during the entire follow-up.
4. Oral appliances resulted in transient and non-serious pain-related TMD, more than CPAP.
5. Since increase in pain related to initial use of OA was transient, it should not be considered a contra-indication.
6. TMDs and the risk of developing impairment of the temporomandibular complex appear limited with long term oral appliance use.

Oral Appliance impact on patients with previous TMD

- Include only patients with positive Temporomandibular Disorders evaluated by the Research Diagnostic Criteria (RDC)
- Patients divided randomly into
  - Support Therapy
  - Placebo Therapy

Support Therapy

Coordinated exercises to stretch mandibular muscles
Control pain and restore movements

Support Therapy

Lateral Pterygoid and TMJ
Stretching Temporal and Masseter

Placebo Therapy

There were no patients with cervicalgia
Instructions

- Both therapies were effective.
- Do two times a day
  - Before use at night
  - After use in the morning
- 3 sets of 5 repetition each

Cunali, S&B 2011

Treatment Outcomes - Compliance

![Graph showing compliance percentages for different therapies over time](image)

Figure 6. Mandibular advancement device compliance at various stages of the study based on diaries and presented as percentage of nights used in the previous month.

Cunali, S&B 2011

Treatment Outcomes - Pain

![Graph showing pain levels for different therapies](image)

Similar to the findings from Doff and colleagues

Cunali, S&B 2011
MAS decreased subjective pain, compared to baseline and CPAP.

Intensity of the Pain

Mandibular Exercises Improve Mandibular Advancement Device Therapy for Obstructive Sleep Apnoea. Cunali, S&B 2011

- Non-indication of the OA in TMD cases should be re-examined.
- Jaw exercise may be decisive in OA treatment in TMD patients
  - Reducing TMJ side effects
  - Improving compliance
  - Improving quality of life
  - Reducing previous TMD
Conclusion

- There is an increase in temporary TMJ side effects related to MAS.
- There is little/no long-term TMJ side effects.
- Dentist can prescribe simple exercises to improve TMD symptoms.

Changing the subject

OA Side Effects

- Temporary
  - Frequency is 6 to 86%
  - Resolved within several days to several weeks or with OA adjustments
  - Salivation, TMJ pain, myofascial pain, tooth pain, dry mouth, gum irritation and morning-after occlusal changes.

- Permanent
  - Tooth movement, skeletal changes and occlusal alterations
Dental, skeletal and occlusal changes

Permanent long-term side effects


Title: Watchers in the Woods
What the brain does not know, the eye cannot see (Sir William Osler)

Artist: Bev Doolittle
What about CPAP dental side effects in post orthodontic therapy patients?
<table>
<thead>
<tr>
<th>Therapy</th>
<th>Age</th>
<th>Duration</th>
<th>AHI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthodontics</td>
<td>Pre</td>
<td>13Y2M</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>14Y9M</td>
<td>19M</td>
</tr>
<tr>
<td>nCPAP</td>
<td>Base</td>
<td>16Y2M</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Titration</td>
<td>18Y11M</td>
<td>33M</td>
</tr>
<tr>
<td>Surgery</td>
<td>Pre</td>
<td>19YOM</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Post</td>
<td>19Y1M</td>
<td>Mx/Md</td>
</tr>
</tbody>
</table>
There are no careful studies evaluating CPAP side effects on maxillary growth in children or adolescents.

Question 1

Patients with previous orthodontic treatment may be more prone to dental side-effects.

Dental Side Effects

4 years of OSA treatment
Four Years of Nasal Mask
Question 2

When there is a constant pressure, i.e. 6 hours/night 7 days/week,
Even extra-oral forces will likely move teeth and/or other facial structures

(nasal pillows effect on nasal ala)
Hypothesis

Long-term use of a nCPAP could directly affect the maxilla as well as anterior teeth position in ADULTS.

Demographic data

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>46</td>
<td></td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>41 / 5</td>
<td></td>
</tr>
<tr>
<td>Age (year)</td>
<td>56.3 ± 13.4</td>
<td>56.3 ± 13.4</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.8 ± 5.6</td>
<td>26.8 ± 5.6</td>
</tr>
<tr>
<td>AHI (event/h)</td>
<td>42.0 ± 18.6</td>
<td>42.0 ± 18.6</td>
</tr>
<tr>
<td>nCPAP pressure (average)</td>
<td>7.2 ± 1.7</td>
<td>7.2 ± 1.7</td>
</tr>
<tr>
<td>Duration of nCPAP use (months)</td>
<td>35.0 ± 6.7</td>
<td>35.0 ± 6.7</td>
</tr>
<tr>
<td>Compliance (h/day)</td>
<td>6.0 ± 0.9</td>
<td>6.0 ± 0.9</td>
</tr>
<tr>
<td>Compliance (days/week)</td>
<td>6.5 ± 0.8</td>
<td>6.5 ± 0.8</td>
</tr>
</tbody>
</table>

Cephalometric variables

<table>
<thead>
<tr>
<th></th>
<th>Pre-nCPAP Mean SD</th>
<th>Follow-up Mean SD</th>
<th>Amount of change Mean SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interarch relationship</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNA (º) **</td>
<td>84.3 ± 3.6</td>
<td>83.2 ± 3.9</td>
<td>-1.1 ± 1.6</td>
</tr>
<tr>
<td>SNB (º) *</td>
<td>77.8 ± 3.9</td>
<td>77.5 ± 4.0</td>
<td>-0.3 ± 0.9</td>
</tr>
<tr>
<td>ANB (º) **</td>
<td>6.3 ± 2.2</td>
<td>5.7 ± 2.5</td>
<td>-0.6 ± 1.1</td>
</tr>
<tr>
<td>SNPg (º) *</td>
<td>78.1 ± 4.0</td>
<td>77.6 ± 4.1</td>
<td>-0.5 ± 0.9</td>
</tr>
<tr>
<td>Convexity (A-NPo) (mm) *</td>
<td>7.7 ± 3.1</td>
<td>6.9 ± 3.7</td>
<td>-0.7 ± 1.7</td>
</tr>
<tr>
<td>Tooth position U1 - SN (º) *</td>
<td>103.3 ± 9.1</td>
<td>102.1 ± 9.8</td>
<td>-1.2 ± 3.2</td>
</tr>
</tbody>
</table>

* p<0.05; ** p<0.01
Changes are expressed as follow-up minus baseline values

Craniofacial Changes after Two Years of nCPAP Use in OSA Patients

- Major changes occurred in the maxilla
- The use of a nCPAP machine for more than 2 years may change craniofacial form by reducing maxillary and mandibular prominence and/or by altering the relationship between the dental arches.


Dental Side Effects

CASE 8

10 years of oral appliance wear

Intraoral Records

1992

2002

Case 8
Lower Arch Changes

TRD for 10 yrs.

Superimposition on Lower Arch

Constriction of Molars

Expansion of Canines & 1st Premolars

Anterior Crowding was corrected

After 10 Years of TRD Wear

- Retroclination of maxillary incisors
- Proclination of mandibular incisors
- Mesial tipping of mandibular molars
- Overbite decreased from 8.0mm to 7.5mm
- Overjet increased from 3.5mm to 4.0mm
Question 3

Do not think that because a specific appliance does not touch teeth, or if it applies less pressure that there will be no dental side-effects.

If adherence is high, there will likely be dental side-effects.

Dental Side Effects of Mandibular Advancement Devices

The most commonly measurement used to assess dental side effects

Overbite and Overjet changes

Almeida FR AJODO, 2006
What does the literature say

<table>
<thead>
<tr>
<th>Author</th>
<th>N</th>
<th>years</th>
<th>∆ OB</th>
<th>∆ OJ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marklund 2001</td>
<td>75</td>
<td>2.5</td>
<td>-0.5</td>
<td>-0.6</td>
</tr>
<tr>
<td>Robertson 2001</td>
<td>100</td>
<td>2.5</td>
<td>-1.02</td>
<td>-1.06</td>
</tr>
<tr>
<td>Rose 2002 / 2008</td>
<td>34/24</td>
<td>2.5/2.5</td>
<td>-1.13/2.5</td>
<td>-1.3/2.5</td>
</tr>
<tr>
<td>Almeida 2006 (model/ceph)</td>
<td>70</td>
<td>7.6</td>
<td>-1.9 / -2.8</td>
<td>-1.2 / -2.6</td>
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<tr>
<td>Marklund 2006</td>
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<td>5.4</td>
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<td>Hammond 2007</td>
<td>64</td>
<td>2.1</td>
<td>-0.3</td>
<td>-0.2</td>
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<tr>
<td>Martinez-Gomis 2010</td>
<td>12</td>
<td>5.0</td>
<td>-0.8</td>
<td>-1.1</td>
</tr>
<tr>
<td>Doff 2010 (ceph)</td>
<td>51</td>
<td>2.0</td>
<td>-1.0</td>
<td>-1.7</td>
</tr>
<tr>
<td>Vezina 2011</td>
<td>48</td>
<td>3.6</td>
<td>lower Incº 5.79 / 4.67</td>
<td></td>
</tr>
<tr>
<td>Doff 2012 (model)</td>
<td>51</td>
<td>2.0</td>
<td>-1.2</td>
<td>-1.5</td>
</tr>
</tbody>
</table>

Long-term Sequellae of Oral Appliance Therapy in Obstructive Sleep Apnea

Part 1 - Cephalometric Analysis
Part 2 - Study Model analysis

Almeida FR, Lowe AA, Farbood M, Sung JO, Otsuka R, Fastlicht S and Tsuiki S

Almeida FR AJODO, 2006

Favorable
29 (41.4%)

Unfavorable
31 (44.3%)

Change
60 (85.7%)

No Change
10 (14.3%)

70 OSA Patients

Small
13

Intermediate
13

Large
3

Small
8

Intermediate
15

Large
8

Predictors of Side Effects (ΔOB -1.9mm)

Changes in mm

OB OJ LFH

ΔOB < 1 mm

ΔOB 1 to 4 mm

ΔOB > 4 mm

*p < 0.05

Duration of OA Wear

SNMP

SNA

OB

< 6 yrs 6-8 yrs >8 yrs

Almeida FR AJODO, 2006
Our study found that over a mean period of 7.4 years of OA use, about 85% of the patients had some bite changes.

Note that the mean period of evaluation was 7.4 years (range 4-12 years)

Almeida FR et al, AJODO, 2006

Predictors of Side Effects
Marklund M. AJODO, 2006

- The amount of dental changes were related to baseline OJ
- Soft elastomeric appliance showed less changes in some cases

Length of use:
- Overbite decreased in beginning of treatment but then kept unchanged
- Overjet decreased at 2.5 and 5 years interval

Does Propulsion Mechanism Influence the Long-term Side Effects of Oral Appliances in the Treatment of Sleep-Disordered Breathing?

<table>
<thead>
<tr>
<th>Parallel, Non-randomized</th>
<th>Traction</th>
<th>Compression</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 16 (9M/7F)</td>
<td>27.3 %</td>
<td>19.2 %</td>
</tr>
<tr>
<td>Change of posterior teeth contact (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N = 32 (31M/1F)</td>
<td>25.0 %</td>
<td>19.2 %</td>
</tr>
<tr>
<td>Change of anterior teeth contact (%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BUT these changes were measured with a questionnaire: subjective

Vezina et al. CHEST 2011; 140(5):1184–1191
Does Propulsion Mechanism Influence the Long-term Side Effects of Oral Appliances in the Treatment of Sleep-Disordered Breathing?

<table>
<thead>
<tr>
<th>Traction</th>
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</thead>
<tbody>
<tr>
<td>N = 16</td>
<td>N = 32</td>
</tr>
<tr>
<td>9M/7F</td>
<td>31M/1F</td>
</tr>
<tr>
<td>Controls</td>
<td>N = 9</td>
</tr>
</tbody>
</table>

- Change lower incisal angle: 5.79 - 4.67 - 2.54
- Change upper incisal angle: -0.65 - 0.75 - 0.55

No significant difference despite changes in the appliance design.

Vezina et al. CHEST 2011; 140(5):1184–1191

Long-term oral appliance therapy in obstructive sleep apnea syndrome: a controlled study on dental side effects

- N = 103
  - 51 on MAS After 2 years 29 on MAS
  - 52 on CPAP 34 on CPAP

<table>
<thead>
<tr>
<th></th>
<th>MAS</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΔOAB</td>
<td>-1.2</td>
<td>-0.1</td>
</tr>
<tr>
<td>Δ OJ</td>
<td>-1.5</td>
<td>-0.2</td>
</tr>
</tbody>
</table>

Occlusal contact points cuspid-incisor region (n).

<table>
<thead>
<tr>
<th></th>
<th>MAS</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>2.5</td>
<td>3.2</td>
</tr>
<tr>
<td>Follow-up</td>
<td>2.2</td>
<td>3.0</td>
</tr>
</tbody>
</table>

Occlusal contact points pre-molar and molar region (n).

<table>
<thead>
<tr>
<th></th>
<th>MAS</th>
<th>CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>6.8</td>
<td>6.9</td>
</tr>
<tr>
<td>Follow-up</td>
<td>5.1 *</td>
<td>6.4 *</td>
</tr>
</tbody>
</table>

“Oral appliance therapy should be considered as a lifelong treatment, and there is a risk of dental side effects to occur.”
Although there are few studies comparing different types of MAS design, the literature shows that there is NO difference between MAS designs and dental side-effects, but maybe on the amount of protrusion.

Important is likely the amount of protrusion, the length of the evaluation and the accuracy of the measurements.

<table>
<thead>
<tr>
<th>Author</th>
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<tr>
<td>Vezina 2011</td>
<td>48</td>
<td>-1.0</td>
<td>-1.5</td>
</tr>
<tr>
<td>Doff 2012 (models)</td>
<td>51</td>
<td>-2.0</td>
<td>-2.3</td>
</tr>
<tr>
<td>Pleka (abstract AADSM 2012)</td>
<td>77</td>
<td>11.1</td>
<td>-1.9</td>
</tr>
</tbody>
</table>

Mean overjet change (mm)

![Graph showing mean overjet change (mm)]

Ref 1,3,6-9,11,13,15,18
Mean overbite change (mm)

- Fritsch et al. 2001 (Herbst or Monoblock, 22 users)
- Ringqvist et al. 2003 (Monoblock, 30 users)
- Fransson et al. 2004 (Monoblock, 64 users)
- Battagel et al. 2005 (Herbst, 30 frequent users)
- Almeida et al. 2006 (Klearway, n=70)
- Marklund 2006 (Monoblock, 51 frequent users)
- Hammond et al. 2007 (Somnomed, 45 users)
- Rose et al. 2002 (Adjustable activator, 34 frequent users)
- Ghazal et al. 2008 TAP, n=24)
- Martinez-Gomis et al. 2010 (Herbst, 15 users)

Mean overbite change (mm)

- Fritsch et al. 2001 (Herbst or Monoblock, 22 users)
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- Martinez-Gomis et al. 2010 (Herbst, 15 users)

Long-Term Side-effects

77 patients (62 males)
Average age 47.5 at beginning of treatment
Average treatment length 11.1 years (8-19)

Table 2 - Significant Treatment Effects (p<0.001)

<table>
<thead>
<tr>
<th>Treatment Effect</th>
<th>Change (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overbite</td>
<td>-2.3±1.6</td>
</tr>
<tr>
<td>Overjet</td>
<td>-1.9±1.9</td>
</tr>
<tr>
<td>Mandibular crowding</td>
<td>-1.3±1.8</td>
</tr>
<tr>
<td>Mandibular intercanine width</td>
<td>+0.7±1.5</td>
</tr>
<tr>
<td>Mandibular intermolar width</td>
<td>+1.1±1.4</td>
</tr>
</tbody>
</table>

Pliska, Nam, Chen, Lowe and Almeida, 2012
Overbite

Mixed-effect polynomial regression analysis
The amount of change in OB decreases with time

Overjet

The amount of change in OJ continues as long as the patient wears a mandibular advancement splint.
Baseline OJ>3mm will have a decrease in 0.2mm/year
Combining OB and OJ (11.1 years)

<table>
<thead>
<tr>
<th>Study</th>
<th>Correlation</th>
<th>OB</th>
<th>OJ</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>OB ≤ 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OB ≤ 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;3</td>
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<tr>
<td>&gt;3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Correlations

The change in OJ was greater with a greater AHI.

The greater the baseline OB the greater the OB changed.

The greater the baseline OB and OJ correlated with a greater chance to have a normal occlusion after 11.1 years.
Patient Perspective

The clinical relevance of these dental changes to the patient can ONLY be judged individually within the scope of the entire assessment. (Ghazal and Rose 2008)

Most of the patients were unaware of these changes. (Marklund 2006)

Occlusion is Dynamic

The development of a new occlusal equilibrium over time.


An orthodontic oral appliance

A randomized, controlled pilot study

Marie Marklund; Per Erik Legrell

Results: Four of nine patients in the orthodontic OA group increased their overjet by 0.4 mm, while none of the 10 patients in the OA group experienced that effect.

Conclusion: Only the orthodontic OA increases the overjet; this design may therefore be beneficial to patients at risk of negative effects on their bite during OA treatment.

Caveat: an elastomeric device was used, and this technique may not be applicable with other devices.
Both exercises significantly increased the total bite force in the morning compared with the period of no exercise.

None of the exercises did normalize bite force or contact area in the evening.

- Patient’s perceptions do not correlate with objective measurements
- Patients do not realize occlusal changes, unless these are brought by the general dentist.
- Patients usually consider the dental side effects to be unimportant compared to the benefits of a reduction in daytime sleepiness and other sleep apnea symptoms (Marklund, 2007)
Clinical Case

- Penny is worried that this may damage the central incisors and I was curious as to how to restore her posterior teeth.

- Could you explain and help me understand occlusion management for restorative dentistry for a person who wears this type of appliance.

Main Concerns

- Restore in Centric Relation
- Effects on the TMJ (remodeling)
- Short / long-term prognosis of mandibular dentition
- Lack of anterior guidance
- Occlusal vertical dimension

AHI – 81/hour
AHI – 23/h with oral appliance
Patients with untreated severe disease showed a higher incidence of fatal cardiovascular events (1.06 per 100 person-years) and non-fatal cardiovascular events (2.13 per 100 person-years).

Conclusion

Mas causes minimal impact on TMJ.

Mas changes OJ in 0.2mm/year long-term.

Despite posterior open bite, a decrease on overbite or overjet are common, these side-effects do not increase sleepiness or CV risks.
Patients with untreated severe disease showed a higher incidence of fatal cardiovascular events (1.06 per 100 person-years) - non-fatal cardiovascular events (2.13 per 100 person-years).

OSA and Cardiovascular Events

12 years follow-up ~ 2,000 patients

Marin JM et al. Lancet. 2005

3.5 fold increase in cardiovascular incidents

When will a posterior open bite cause it?

When will proclination of lower anterior incisors (OA) or retroclination of upper incisors (CPAP) cause it?

When will lack of ideal occlusion cause this increase in morbidity and mortality?

Do not stop therapy because of tooth movements.

WHY?

DO NOT STOP ON TRACKS
Do not stop OA therapy because of tooth movements.

"Get over it" – Dr. Alan Lowe

Informed Consent

Always

An evaluation of patients’ willingness to trade symptom-free days for asthma-related treatment risks: A discrete choice experiment. McTaggart-Cowan J Asthma 2008

Patients desired treatments that offered more symptom-free days

BUT

They are willing to trade days without symptoms in exchange for a reduction in adverse events
Effective treatment of a life-threatening disease such as OSA supersedes the maintenance of baseline occlusion.

Even if major tooth movements are seen, the discontinuation of treatment should occur only if the patient accepts another treatment modality.

There is a need for careful follow-up, to increase adherence and to monitor side-effects.
Future Directions

- Long term studies comparing:
  - Exercises for TMJ
  - Exercises to decrease occlusal side effects
  - Investigate other approaches, e.g. use of a retainer during the day
  - Evaluate amount of use and side effects, maybe 3 days CPAP, 3 days OA is the answer
  - Understand better correlation of amount of mandibular protrusion and side-effects

Patient Centered Medicine

It is time for us to understand better patient preferences and maybe evaluate combination of therapies
CPAP - FAQ

- Do I have to bring my CPAP with me on vacation?
- Is there an alternative treatment?
- How much does it cost?
- Will it work?

Offer MAS therapy for compliant CPAP users

Symptomatic improvement

With treatment efficacy disclosure, patients tend to use the more effective, but many alternated about 8 days/month (70% of nights on CPAP)
Short-term Efficacy Alternating with CPAP

Epworth sleepiness scale had significantly improved when allowing patients to use both treatments.

ESS on CPAP = 8.5
ESS on MAS + CPAP = 5.5

MAS reduced at least 50% AHI in 74% of patients
MAS is safe to be used as a short-term alternative to CPAP.

Positional Therapy and Oral Appliance Therapy

Olivier M. Vanderveken, MD, PhD
Department ENT, Head and Neck Surgery
Antwerp University Hospital
University Antwerp
BELGIUM

Deputy Editor Journal of Dental Sleep Medicine (JDSM)
Member ORANGE group

Results

![Graph showing AHIs at different stages: Baseline, MAD, SPT, MAD + SPT, with statistical significances marked.]

* statistically significant (p < 0.05) as compared to baseline;
$ statistically significant (p < 0.05) as compared to PSG with MAD;
∞ statistically significant (p < 0.05) as compared to PSG with SPT
Conclusion

- Large number of patients can use an MAS
- MAS is less effective than CPAP in the reduction of AHI and ODI
- MAS is equally effective to CPAP in the reduction of symptoms
- MAS is equally effective to CPAP in the improvement of cardiovascular markers (BP, endothelial function).

MAS Utility

MAS are not as effective as CPAP, but is an optional treatment for snorers, mild, moderate and severe OSA

Treatment plans involving and valuing patient participation in chronic disease management leads to improved treatment adherence and a higher quality of life and life expectancy.

Efficacy vs Effectiveness

<table>
<thead>
<tr>
<th>Table 1—Clinical End Points of Treatment of OSA With Oral Appliances and CPAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>End Points</td>
</tr>
<tr>
<td>Improvement in AHI</td>
</tr>
<tr>
<td>Improvement in sleep fragmentation</td>
</tr>
<tr>
<td>Improvement in subjective and objective measures of disease outcome</td>
</tr>
<tr>
<td>Reduction in BP</td>
</tr>
<tr>
<td>Improvement in neurobehavioral function</td>
</tr>
<tr>
<td>Improvement in quality of life</td>
</tr>
<tr>
<td>Reduction in motor vehicle accident risk</td>
</tr>
</tbody>
</table>

*An indication of the relative efficacy of oral appliances and CPAP is denoted by + = small benefit, ++ = moderate benefit, and +++ = large benefit. 7 denotes an unmeasured end point.

Chan A et al, Chest 2007
Adherence

Is there a difference in objectively measured treatment adherence?

Is there a similar mean disease alleviation between PAP and MAS treatment for patients with moderate to severe OSA?

Adherence and preference of CPAP versus MAS in Obstructive Sleep Apnea patients: a randomized trial.

Objective Adherence
Inclusion and Exclusion Criteria

- AHI from 15 – 50/hr
- Naïve to treatment
- Have enough teeth for MAS
- No major CV comorbidities
- Not professional drivers

• Start recruitment in January 2015

• Patients will receive an autoCPAP and MAS for free after the completion of the trial

• 20 patients in each site
Thank you

Dr. Fernanda R Almeida DDS, MSc, PhD
Assistant Professor - University of British Columbia
Chair of Research Committee for the AADSM
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Where to get training

www.aadsm.org
Barriers of Oral Appliance Therapy
- No standardization (industry development)
- Differences in efficacy
- Complex Protocol
- Different side-effects

Oral appliances have a high effectiveness, and should be considered as a first line therapy for OSA patients, who prefer OA to CPAP.

The Role of Dentists in a Sleepy World
- Seek more training
- Ask the right questions to your patient
- Refer to physician
- Treat if comfortable or refer to a colleague
- Do not criticize side effects
- Manage side effects if other treatments are provided