Conflict of Interest Disclosures
Robert R. Rogers, DMD

<table>
<thead>
<tr>
<th>Type of Potential Conflict</th>
<th>Details of Potential Conflict</th>
</tr>
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<tbody>
<tr>
<td>Grant/Research Support</td>
<td>NONE</td>
</tr>
<tr>
<td>Consultant</td>
<td>NONE</td>
</tr>
<tr>
<td>Speakers’ Bureau</td>
<td>NONE</td>
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<td>Financial support</td>
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<td>Other</td>
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Advanced Course
Dental Sleep Medicine
The acquisition and processing of oxygen is the primary mission of any air-breathing vertebrate. Chewing, walking, reproducing and thinking are all fine, but first one must breathe.
It's All About Air, Stupid

2

3

4
It's All About Air, Stupid
At the Same Time...

How Hard Could it Be???

Trying To Breathe

Overview
- Quick Review
- Research Update
- Jurisprudence
- Medical consequences
- Device design
- Trouble shooting
- Positional therapy
- Nasal Breathing

ADVANCED COURSE
- Home Monitoring
- In-Lab Titration
- Bite Changes
- AM Splints
- Combination Therapy
- Pediatrics
- Insurance Coding
- Marketing
### Basic Concepts

<table>
<thead>
<tr>
<th>Sleep-Disordered Breathing: Complete / partial collapse of airway</th>
<th>Team Concept: Dentist</th>
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</thead>
<tbody>
<tr>
<td>Consequences: CVD</td>
<td>Others</td>
</tr>
<tr>
<td>Neurocognitive</td>
<td>Side Effects: Major</td>
</tr>
<tr>
<td>Social</td>
<td>QOL</td>
</tr>
<tr>
<td>QOL</td>
<td>OAT Mechanism of Action</td>
</tr>
<tr>
<td>Treatment Options: Behavioral</td>
<td>Minor</td>
</tr>
<tr>
<td>Medical (including OAT)</td>
<td>Surgical</td>
</tr>
<tr>
<td>Surgical</td>
<td></td>
</tr>
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</table>

### Oral appliances function to create and maintain a patent upper airway during sleep

- **Mandibular Repositioning Devices**
- **Tongue Retaining Devices**
- **Combination OA / CPAP**

### AASM Review Paper

#### Mechanism of Action

**Cephalometry (upright and supine):**
- Lower tongue position
- Reduce mandibular plane to hyoid distance (MPH)
- Advance mandible and widen upper oropharynx (retropalatal, retroglossal) in most subjects

**CT, MRI, Endoscopy:**
- Increase pharyngeal airway size
Ferguson K, et al. Oral appliances for snoring and obstructive sleep apnea: A Review. SLEEP 2006;29(2):244-262

- Evidence-based review from 1995-2005
- Structured search revealed 141 articles
- 87 suitable for inclusion in evidence base
- 15 level I and II RCT’s, 5 with placebo-controlled treatment

Abstract

- Success (AHI ≤ 10) averaging 52% (mild, mod, severe OSA)
- Mild-moderate OSA: 57 – 81%
- Severe OSA: 14-61%
- Positive effect on sleepiness and quality of life
- Neurocognitive outcomes inconsistent
- Mechanism related to opening the upper airway (imaging and physiologic monitoring)

- Adherence median 77% after 1 year
- Minor adverse effects frequent, major adverse effects uncommon
- Minor tooth movement and small changes in occlusion in some patients after prolonged use
- Less efficacious than CPAP in reducing AHI, but preferred and utilized more (self-report)
- More effective than UPPP after 1 year


An American Academy of Sleep Medicine Report

Recommendations are based on the Review Paper produced by a Task Force established by the AASM Standards of Practice Committee

Abstract

- Indicated for treatment of mild to moderate OSA in patients who prefer them to CPAP or who fail CPAP
- CPAP is indicated whenever possible to treat severe OSA prior to considering oral appliances
- Should be fitted by qualified dental personnel
- Follow-up PSG needed to verify efficacy
- Follow-up with attending dentist needed on periodic basis
Literature Reviews
Lim J, et al. Cochrane Review; 2004
Cistulli P, et al. Sleep Med Reviews; 2004
Hoffstein V. Sleep Breath; 2006

Clinical Guidelines
Epstein L. et al. Clinical guideline for the evaluation, management and long-term care of obstructive sleep apnea in adults. JCSM; 2009

Jurisprudence
We Walk the Line

Informed Consent
ADA Tells Us:

“The dentist should inform the patient of the proposed treatment and any reasonable alternatives in a manner that allows the patient to become involved in a treatment decision.”

Attorneys Tell Us:

“Patients have the right to make informed choices regarding their treatment...

...and failing to provide patients with relevant information is malpractice if an unfavorable outcome should occur and the patient was not informed of the possibility in advance.”

Legal Perspective
Compliance with local licensing requirements (scope of licensure)

Issues of professional liability (standard of care)

Due to the nature of oral appliance therapy, certain aspects of treatment fall within the scope of practice of physicians and certain others dwell within the scope of practice of dentists.

The fabrication, fitting and adjusting of dental appliances is generally limited to the practice of dentistry and falls outside the legal practice of medicine.

Physicians should recognize the liability they assume if they engage in placing and managing oral appliances.
For dentists, the caveat relates to diagnosis, which must take place prior to appliance utilization.

In the instance where a dentist treats “snoring” without a definitive medical diagnosis, the dentist creates significant legal exposure for him/herself.

Any healthcare provider who exceeds the scope of a professional license risks civil and criminal liability.

Those who practice within the scope of licensure but do not satisfy the standard of care also risk liability.

Presently, diagnosis falls into the realm of medicine while management of oral appliance therapy dwells within that of dentistry.

May differ from company to company

Check with your company

Understand required protocol
  - PSG diagnosis, MD referral?
  - FDA approved appliance?
  - Follow-up?
Medical Consequences

OSA is thought to be more prevalent than asthma and adult diabetes, possibly affecting more than 18 million Americans.


Public health advocates think it may be as big a public health hazard as smoking.


OSA and Cardiovascular Disease

OSA increases the risk of heart failure by 140%, the risk of stroke by 60%, and the risk of coronary heart disease by 30%.

## Cardiovascular Disease

### Proposed Mechanisms

- Sustained sympathetic activation
- Changes in intrathoracic pressure
- Oxidative stress
- Vascular inflammation resulting from the nocturnal hypoxia and re-oxygenation cycles
- Other possible factors include coagulation abnormalities, endothelial damage, platelet activation and an increase in inflammatory mediators

## Cardiovascular Disease

### Role of Metabolic Syndrome

<table>
<thead>
<tr>
<th>Cardiovascular Disease</th>
<th>Role of Metabolic Syndrome</th>
</tr>
</thead>
</table>
| Direct link not established. However, 60% of patients with sleep apnea had metabolic syndrome, compared with 40% of patients without sleep apnea. | Components:  
• Obesity  
• Diabetes  
• Dyslipidemia  

Parish JM, et al. Relationship of metabolic syndrome and obstructive sleep apnea. JCSM 2007;3:399-72

## Cardiovascular Disease

### Role of Endothelial Dysfunction

<table>
<thead>
<tr>
<th>Cardiovascular Disease</th>
<th>Role of Endothelial Dysfunction</th>
</tr>
</thead>
</table>
| Proposed mechanism:  
Initiating/propagating vascular endothelial dysfunction through hypoxemia, reactive oxygen species (ROS), sympathetic activation  
Endothelial dysfunction may lead to:  
Vasoconstriction, vascular smooth muscle proliferation, hypercoagulability, thrombosis and eventually to cardiovascular events. |
Endothelial Dysfunction

Dysfunctional endothelium characterized by:

- Imbalance in production of vasoactive hormones
- Increased adherence of inflammatory mediators to endothelial cells
- Hypercoagulability
- Known risk factor for cardiovascular events

Contemporary Conjecture

Activation of the sympathetic nervous system through hypoxia and hypercapnia triggers an inflammatory response cascading in several downstream consequences including hypertension, diabetes, dyslipidemia and endothelial dysfunction all of which represent significant risk factors for cardiovascular morbidity.

Itzhaki S, Dorchin H, Clark G. Chest 2007;131;740-749

The effects of 1-year treatment with a Herbst mandibular advancement splint on OSA, oxidative stress, and endothelial function

- With OA use, mean AH1 decreased significantly from 29 to 19 after one year
- ESS decreased from 12.4 to 7.8 after one year
The effects of 1-year treatment with a Herbst mandibular advancement splint on OSA, oxidative stress, and endothelial function

- Endothelial function improved to levels that were not significantly different from controlled reference levels, even though apneic events were not completely eliminated
- Thiobarbituric acid-reactive substance (TBARS) decreased from 18.8 to 15.5 after one year

OSA and Brain Damage


The potentially harmful medical consequences of untreated sleep-disordered breathing: the evidence supporting brain damage

A literature review exploring the association of episodic hypoxia (EH) and brain damage

The evidence suggests that EH as seen during SDB causes:
- Damage to the brain; gray/white-matter loss
- Alteration in autonomic/motor regulation
- Damage to higher cognitive functions
- Retention of deficits after treatment suggests long-term injury
Snoring is associated with an increased risk of experiencing stroke. A recent article found that heavy snoring could cause carotid artery atherosclerosis.


Premise for Pathogenesis

The premise for the pathogenesis has been confirmed in a rabbit study, in which vibrational stimuli effected the carotid endothelial cells by triggering an inflammatory cascade that produced the atherosclerosis.


Oral Appliance Design – Does it Matter?
Pick a Workhorse

Most good OA's will effectively treat the majority of patients

- FDA approved
- Strong
- Adjustable
- Pt. / Dr. friendly
- Supported by research

Pick a Workhorse – cont’d.

- Using one OA much of the time allows for "effective familiarity"
- Repairs
- Increase / Decrease OVD
- Alter protrusive capability
- Ability to add PAP
How and Why
I Do What I Do

TAP Appliances for 75%
- FDA approved
- Well studied
- Fairly durable
- OVD adjustable (chairside)
- Infinite protrusive adjustability (chairside)
- Pt. / Dr. friendly
- Limited tongue space

The other 25%
Additional Tongue Space
EMA
SomnoDent
Herbst
SUAD
PM Positioner
Others …

Large Tongue

Compromised Dentition
TRD
TSD
EMA
Troubleshooting (Side effects & Solutions)

**Short-term changes (MRD’s):**
- Hypersalivation
- Dry mouth
- Pain in teeth or muscles
- Tooth mobility
- Dislodgment of dental work
- Posterior openbite
- Pain in TMJ
- Soft tissue irritation
- Allergic reactions

**Long-term changes (MRD’s):**
- Soft tissue
- Hard tissue
- Temporomandibular joint

Heavy Bruxism
SUAD

Claustrophobia
EMA
SUAD
SomnoDent
Herbst
### Hypersalivation

**Cause:**
- Foreign body (appliance) in mouth

**Solution:**
- Resolves in several weeks
- Towel inside pillowcase

### Dry mouth

**Cause:**
- Mouth breathing
- Lip incompetency

**Solution:**
- Artificial saliva, (Salivart™)
- Biotene™ products
- Different appliance design

### Tooth pain: Individual teeth

**Possible cause:**
- Distorted impression
- Chipping of stone model
- Interproximal wedging

**Solution:**
- Identify tooth and adjust
- Reduce interproximal wedges
- Retake impression

### Tooth pain: Posterior teeth

**Possible cause:**
- Clenching on posterior stops
- Uneven posterior contact

**Solution:**
- Adjust posterior stops
- Removed posterior stops

### Mobility: Anterior teeth

**Cause:**
- Muscle forces against appliance components
- Compromised dentition originally?

**Solution:**
- Relief facial of maxillary anterior
- Relieve lingual of mandibular anterior
- Discontinue therapy

### Dislodgment of Restorations

**Cause:**
- Ill-fitting restorations
- Excessive retentive force

**Solution:**
- Selectively reduce retention
- Better initial exam
- Discontinue therapy
### Posterior Openbite: A.M.

**Possible cause:**
- Edema in joint space
- Exacerbated by shortening of the internal lateral pterygoid muscle?
- Anterior tooth movement

**Possible solution:**
- Exercises (clenching, gum, leaf gauge)
- Daytime bite splint

### Anterior Openbite: A.M.

**Possible cause:**
- Edema in joint space with advancement onto posterior teeth due to pronounced Curve of Spee (?)
- Extrusion of posterior teeth?

**Possible solution:**
- Exercises as before
- Daytime bite splint

### Posterior Openbite: Afternoon

**Observation:**
Occasionally, a posterior openbite can resolve in the morning but recur in the afternoon.

**Reason:**
Related to recurring shortening of the internal pterygoid muscle??

**Solution:**
Same as before

### Research: Occlusal Alteration

Occlusal alteration ranges from 14% to 86% in published studies

Patients are often not aware of occlusal alterations

Clinical significance???

### TMJ / Muscle Pain

**Cause:**
- Rapid joint / muscle movement
- Excessive joint / muscle movement
- Mandibular eccentricity
- Bruxism

**Solution:**
- Advance slower
- Retrude to comfortable position
- Correctly align mandible, new bite registration
- Posterior stops?
- Symptomatic treatment
Mandibular Eccentricity

Mark Midline Don't Deviate

Soft Tissue Irritation

Areas:
Buccal mucosa
Tongue
Gingiva

Cause:
Hardware
Acrylic shell
Appliance design

Solutions:
Identify / adjust irritating components when possible
Change appliance design
Allergic Reaction

Cause:
- Metal: ie, nickel
- Latex
- Methylmethacrylate
- Dyes

Solution:
- Avoid offending materials
- Seal or cover offending materials
- Consider new burs with each adjustment
- Different appliance design
- Differential diagnoses?

Allergy to Methylmethacrylate

Long-Term Changes with MRD’s

Soft tissue changes
- Irritation

Hard tissue changes
- Tooth movement
- Occlusal alteration

Temporomandibular joint area
- Repositioning of condyle
Hard Tissue Changes

Teeth can move due to forces applied during the night:

Pressures from:
- Muscular forces
- Appliance retention forces
- Opening OVD
- Incomplete coverage of dental arch
- Transept will fibers activated?

What Can Move?

- Individual teeth
- Blocks of teeth
- Upper incisors: lingual movement
- Lower incisors: labial movement
  - Results in decreased overbite and overjet
  - Posterior openbite
  - Anterior fremitus
- Opening interdental contacts: lower arch

Temporomandibular Joint

Repositioning of condyle due to:

- Fluid buildup in posterior joint space?
  - Short-term / Long-term
- Stretching / foreshortening of muscles and ligaments?
Occlusal Change

Daily Transient Change:
Posterior openbite
Anterior fremitus
Due to:
Condylar repositioning
Anterior tooth movement
Generally resolves in several hours or less

Permanent change:
Posterior openbite
Anterior fremitus
Due to:
Condylar repositioning
Anterior tooth movement
Posterior tooth movement
Permanent in nature
Resolution requires prosthetic / orthodontic therapy
Minimized through daily exercises / splint use?

Does It Matter?

Many patients are unaware of occlusal change,
And once aware, many patients are unconcerned

What is the clinical significance of occlusal change?

Cost  Benefit

Decreased Risk of:
Heart attack
Stroke
Depression
Diabetes
Automobile accidents
Accidents in the workplace
Poor Quality of life
Others…
Occlusal Changes

<table>
<thead>
<tr>
<th>Minimize? Prevent?</th>
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<tbody>
<tr>
<td>Daily Exercises</td>
</tr>
<tr>
<td>Clenching</td>
</tr>
<tr>
<td>Gum chewing</td>
</tr>
<tr>
<td>Eccentric stretching</td>
</tr>
<tr>
<td>Posterior pressure on mandible</td>
</tr>
<tr>
<td>Daily Splint Therapy</td>
</tr>
<tr>
<td>Bite tabs</td>
</tr>
<tr>
<td>Leaf gauge</td>
</tr>
<tr>
<td>Morning Repositioner</td>
</tr>
</tbody>
</table>

Splint Therapy

- Leaf Gauge
- Bite Tabs
- Morning Positioners

Morning Positioners

ThermAcryl PLUS
Treatment Augmentation

- In-lab PSG titration
- Positional therapy
- Combination therapy

In-Lab Titration

- Of 57 subjects treated with an OA (mild, mod, severe) 64.9% were treated successfully; AHI < 10 and AHI decrease at least 50% from baseline
- 55% successfully treated with self-titration at home
- 32% of self-titrated failures became successes with added in-lab PSG titration

Krishnan V, Collop N, Scherr S. Chest 2008, 133; 1135-1141
An evaluation of a titration strategy for prescription of oral appliances for OSA

In-Lab Titration

- Success rate improved 27% over home titration (AHI <10 and 50% decrease in AHI, resolution of symptoms)
- Mean advancement 2mm
- Sleep efficiency not affected
- “In order to determine accurate success rates for OAT, future research studies must include in-lab PSG titrations”
Positional Therapy

Positional therapy refers to the use of sleep related postural changes to positively impact breathing during sleep.

By avoiding supine sleep, positional therapy improves the patency of the upper airway in those with positional OSA.

The evidence-base for positional therapy is emerging but not completely developed.
**OA + Positional therapy**

**Patient: Kevin W.**

<table>
<thead>
<tr>
<th>Date</th>
<th>Disposition</th>
<th>AHl (sup. 38, lat. 12)</th>
<th>Nadir SpO2</th>
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<tbody>
<tr>
<td>04/2007</td>
<td>Diagnosis</td>
<td>22</td>
<td>82%</td>
</tr>
<tr>
<td>01/2008</td>
<td>Oral Appliance</td>
<td>25 (all supine sleep)</td>
<td>82%</td>
</tr>
<tr>
<td>03/2008</td>
<td>OA + Pos’Tx</td>
<td>4 (side sleep only)</td>
<td>84%</td>
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**The Best of Both Worlds**

**Combination Therapy**

**Consider the Fundamentals of CPR**
- Advance and stabilize the mandible
- Apply positive airway pressure

**Combining the Advantages of OA’s and CPAP**
- Near universal efficacy
- Superior mask anchorage
- No need for straps / headgear
- Additional airway splinting
- Lower pressures (?)

---

**CPAP PRO**
Orally Delivered PAP (OPAP)

Strapless Concept
No lower OA component

MRD with strut to accept PAP interface
Patient self-fits pillows

Pillows are fixed in position with heat-sensitive adhesive

Prototype Machined Parts
Fabrication

[Images of a facial mask and a nasal cannula]

[Image of a person in a wheelchair with a nasal cannula]

[Image of a person wearing a mask over their mouth]

10/23/2009
HOME MONITORING AND DENTAL SLEEP MEDICINE

Indications for Unattended Portable Monitoring (PM)

PM may be indicated for diagnosis of OSA in patients where in-lab PSG is not possible due to immobility, safety, critical illness.

PM may be indicated to monitor response to non-CPAP treatments for OSA including oral appliance therapy, upper airway surgery and weight loss.
Classification of Testing Devices

- **Type 1**: standard polysomnography; minimum of seven parameters: EEG, EO, EMG, ECG along with monitors to measure airflow, respiratory effort, O2 saturation. Must be attended.
- **Type 2**: standard polysomnography; unattended.
- **Type 3**: minimum of four channels including airflow, respiratory effort, heart rate, O2 saturation.
- **Type 4**: continuous monitoring of one or two parameters, typically airflow, O2 saturation.

Uses in Dental Sleep Medicine

- Screen and refer for diagnostic PSG; should not screen and treat.
- Titration of therapeutic jaw position prior to referral for follow-up PSG.

Pediatrics: Don't Forget The Kids
Sleep-Disordered Breathing

27% of children affected by habitual snoring
2 – 3% of all children have OSA

Consequences of Undiagnosed and Untreated Childhood OSA

• Impaired growth
• Neurocognitive dysfunction
• Behavioral dysfunction
• Cardiorespiratory failure
• Accidents/injuries

Childhood Sleep-Disordered Breathing

Differs significantly from that of adults in regard to symptoms, pathogenesis, diagnosis, treatment and outcome
Sleep-Disordered Breathing
May be present in children who do not exhibit loud regular snoring, disturbed sleep architecture, oxygen desaturations or daytime sleepiness.

Nocturnal Symptoms
• Louder breathing noise rather than distinct snoring (occasional snoring)
• Restless sleep
• Increased sweating
• Parasomnias
• Mouth breathing
• Nocturia
• Attention deficit hyperactivity disorder (ADHD??)

Daytime Symptoms
• Mouth breathing
• Disturbances of concentration
• Decreased performance in school
• Behavioral difficulties; motor restlessness
• Occasional daytime sleepiness
Pathogenesis

• Upper airway narrowing is multifactorial, but adenotonsillar hyperplasia is most often responsible
• Obesity is only occasionally significant independently of adenotonsillar hyperplasia

Treatment

• Removal of hypertrophi ed adenoids and tonsils will reverse symptoms in most but not all children
• Palatal expansion may be effective

Insurance Benefits

Claim Requirements:
• Copy of PSG showing OSA
• Referral letter from MD
• Letter of medical necessity
• Documentation of CPAP intolerance
• Medical model protocol
Insurance Coding

- Health Care Procedure Coding System (HCPCS)
- Durable Medical Equipment (DME)
  - E0485: non-custom oral appliance
  - E0486: custom oral appliance
- Evaluation and Management (E/M)
  - Consultation Visit: 99241 – 99245
  - New Patient Visit: 99201 – 99205
  - Established Patient Visit: 99211 – 99215

Insurance Coding

To Qualify for Coding Levels
- Understand the 3 key components and how time effects them
- Design patient encounters to conform to coding requirements
- Record keeping to support coding level

Practice Building
Ride the Trend

Opportunities

- Your Own Practice
- Other Dentists
- Sleep Disorders Communities
- The General Public (The Consumer)

Opportunities: Your Own Practice

- Case Finding – med hx, ask...
- Brochures
- Posters
- Conversation
- Statement Stuffers
- Educate Staff
Opportunities: Other Dentists

- Copy referral/follow-up letters
- Brochures
- AASM practice parameters, research
- Conversation
- Lecture
- Support their efforts
- Become “The Expert”!!

Opportunities: Sleep Disorder Communities

- (MD’s, Sleep Labs, Home Healthcare Company’s)
  - Create a relationship
  - Give a lecture
  - Attend meetings
  - Observe PSG’s

Opportunities: Sleep Disorder Communities (Continued)

- Business cards, brochures, an OA
- Discuss insurance issues
- AASM practice parameters, research
- Referral/follow-up letters
- Become “The Expert”!!
### Opportunities: The General Public

- Advertising
- Direct mail
- Public speaking
- Conversation
- Carry business cards
- Website
- AWAKE
- Become “The Expert” !!

### In Summary

- Get organized, make a plan
- Use AADSM resources
- Network
- Get Board Certified
- Stick with it