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DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
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REPLY TO
ATTENTION OF

OTSG/MEDCOM Policy Memo 18-043

MCDS

03 AUG 2018

Expires 3 August 2020

MEMORANDUM FOR All U.S. Army Dental Care Personnel

SUBJECT: Dental Sleep Medicine Therapy (Obstructive Sleep Apnea and Severe Snoring Oral Appliance Therapy) in the U.S. Army Dental Care System

1. References:

a. AR 40-501, Standards of Medical Fitness, 14 June 2017.

b. Army Directive 2016-07 (Redesign of Personnel Readiness and Medical Deployability), 1 Mar 2016.

c. American Academy of Sleep Medicine/American Academy of Dental Sleep Medicine Clinical Practice Guidelines for Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015.

d. U.S. Army Dental Clinical Practice Guidelines, 2017.

2. Purpose: Provide Dental Sleep Medicine (DSM) therapy guidance for Army Sleep Medicine treatment plans.

3. Background: Management of obstructive sleep apnea (OSA) and severe snoring (SS) are areas where Army Dentistry can support Army Medicine by enhancing the health and readiness of the force. Research indicates poor sleep quality impairs the ability to perform complex cognitive tasks, degrades physical performance and alertness, and increases fatigue and depression. Positive airway pressure devices are the gold standard for the management of OSA. However, these devices are not tolerated by all patients and are not suitable for all forward deployed environments. Active Duty Service Members (ADSMs) with unmanaged OSA and those that share quarters with unmanaged SS suffer from poor sleep quality. Oral appliances have proven efficacy in the management of OSA and SS for a majority of indicated patients. Oral appliance therapy (OAT) for these patients will improve worldwide deployment readiness and mission performance.

4. Proponent: The proponent for this policy is the Chief, Dental Policy Division, Dental Directorate, MEDCOM G-3/5/7.

5. Policy:

a. The Army Dental Care System (ADCS) will support Army sleep medicine physicians by fabricating the Food and Drug Administration (FDA) approved oral appliances to help manage OSA and SS in ADSMs.

b. The Dental Health Activity (DENTAC) Commander will appoint, on orders, a Chief, Dental Sleep Medicine, and provide a copy of these orders along with contact information to the Chief, Department of Sleep Medicine or MTF Commander, if the installation lacks a Department of Sleep Medicine.

c. The Chief of Dental Sleep Medicine will internally manage OSA and SS referrals from the Department of Sleep Medicine or designated sleep medicine physicians, advise on credentialing and privileging of DENTAC providers and laboratory personnel, execute quality control on cases referred to the Army Dental Lab (ADL) for fabrication, and ensure cases are referred back to the sleep physicians after oral appliances are titrated for maximum therapeutic benefit. Only providers credentialed and privileged for OSA and/or SS appliances may provide these services without supervision.

d. Army Dental Treatment Facilities (DTFs) will exercise right of first refusal. If dental sleep medicine referrals cannot meet specialty appointment access to care standards, the patients will be given the option to be seen in the Tricare referral network with a qualified DSM provider. These referrals will authorize only MicrO2, Herbst, or TAP (dream or elite) oral appliances to ensure follow-on care can be managed at Army DTFs or in forward deployed areas.

e. Diagnosis of OSA and SS must be based upon a polysomnogram (PSG) and evaluation by a credentialed sleep medicine physician. Dental providers that suspect a patient has a sleep-disordered breathing condition will refer the patient to their primary care manager for evaluation. For the purpose of this policy, SS is defined as PSG quantified snoring without OSA which results in disturbed sleep of a bed partner or other military personnel when sleeping in close quarters, and is determined by the sleep medicine physician to be readiness limiting.

f. Sleep medicine physicians will submit referrals through the DTF to the Chief, DSM, via the referral management office using the Military Health System electronic health record as the preferred method. Alternative referral methods include Relay Health, SF 513, or encrypted email. The Health Insurance Portability and Accountability Act compliant method of referral will be determined at the local level by the two providers and will be standardized for the installation. The referral will include a request/prescription for oral appliance therapy, the diagnosis (OSA or SS), the AHI (Apnea Hypoapnea Index) and date of the PSG. The diagnosis, AHI, PSG, and name of the referring physician will be recorded in the dental treatment record to facilitate communication and referral back to sleep medicine when the prescriptive care is

complete.

g. Privileged dental providers will make full arch impressions and protrusive bite registration for OSA/SS patients or capture equivalent digital records. All cases will be digitally submitted or shipped to the ADL within the next business day of capture. Direct shipment to laboratories other than ADL is not approved if the ADL is funding the appliance. Cases must be approved by a privileged dental sleep medicine provider, and the DD Form 2322 (Dental Laboratory Work Authorization), or other approved laboratory prescription signed prior to shipment. Additional signatures by the clinic or unit Lab Officer are not required.

h. The ADL will support fabrication of oral appliances as prescribed by the sleep medicine physician working in conjunction with a privileged DSM provider when an approved laboratory prescription is submitted. The DD Form 2322, or other approved laboratory prescription, must be supported with a copy of the referral from the sleep medicine physician, the referral will include the date of the PSG, the AHI, the readiness limiting diagnosis, and a request for oral appliance therapy evaluation/treatment. If a MicrO2 appliance is requested, a ProSomnus prescription will also be attached. Herbst appliances require a Great Lakes Orthodontics prescription. Transmission of digital scans of the arches and bite are preferred, but Polyvinyl Siloxane impressions and a bite registration are acceptable for the MicroO2 or Herbst. Only stone models and a George gauge bite registration are acceptable for the TAP appliances.

i. Army Chief of DSM will post changes to regulatory guidance impacting DSM as well as DSM Short Course opportunities, outcome tracking, and strategic communications on the Army Dentistry Portal, DSM Community the following link https://info.dencom.army.mil/CMT/default.aspx.

j. The proper Code on Dental Procedure and Nomenclature (CDT) for delivery of a customized oral appliance to manage sleep disordered breathing is W7881. The proper CDT code for delivery of prefabricated oral appliances to manage sleep disordered breathing is W7880. One code per appliance is taken, not one per arch.

k. Privileging for dental sleep medicine procedures is at the discretion of the DENTAC Commander. Dental sleep medicine is a core privilege for Comprehensive Dentists and Prosthodontists. Other providers that seek privileging may attend the 5-day Army Dentistry Dental Sleep Medicine Short Course and pass the cumulative credentialing exam, or obtain 25 or more American Dental Association Continuing Education Recognition Program or Academy of General Dentistry Program Approval for Continuing Education certified continuing education (CE) hours on dental sleep medicine. After completing required CE hours, the provider requesting privileges must then evaluate, deliver, and follow-up a series of DSM patients under supervision of a privileged provider until they are recommended by that provider and privileged by the Commander.

MCDS
SUBJECT: Dental Sleep Medicine Therapy (Obstructive Sleep Apnea and Severe Snoring Oral Appliance Therapy) in the U.S. Army Dental Care System

l. Army Dentistry leadership and Consultants to The Surgeon General will monitor the sleep medicine evidence base, ensuring Army Dentistry delivers FDA-approved oral appliances that have optimal outcomes in standardization, efficacy, comfort, and compliance for ADSMs to ensure maximum readiness impact in both garrison and deployed environments.

m. Evaluation, delivery and follow-on care will comply with U.S. Army Dental Clinical Practice Guidelines, section 32.0, Obstructive Sleep Apnea. When a titrated therapeutic benefit is achieved, the Chief of Dental Medicine will refer the ADSM back to the referring sleep medicine physician for continuation of care. If evaluation or follow-on care reveals noncompliance or contraindication for OAT, the ADSM will be referred back to the sleep medicine physician to discuss alternate treatment options as clinically appropriate.

FOR THE COMMANDER:

Richard R Beauchemin
RICHARD R. BEAUCHEMIN
Interim Chief of Staff

PPG-TAB A: AMPLIFICATION OF THE MINIMAL STANDARDS OF FITNESS FOR DEPLOYMENT TO THE CENTCOM AOR; TO ACCOMPANY MOD THIRTEEN TO USCENTCOM INDIVIDUAL PROTECTION AND INDIVIDUAL/UNIT DEPLOYMENT POLICY

1. General. This PPG-TAB A accompanies MOD THIRTEEN, Section 15.C. and provides amplification of the minimal standards of fitness for deployment to the CENTCOM area of responsibility (AOR). Individuals possessing a disqualifying medical condition must obtain an exception to policy in the form of a medical waiver prior to being medically cleared for deployment. The list of deployment-limiting conditions is not comprehensive; there are many other conditions that may result in denial of medical clearance for deployment based upon the totality of individual medical conditions and the medical capabilities present at that individual's deployed location. "Medical conditions" as used here also include those health conditions usually referred to as dental, psychological, and/or emotional.

A. Uniformed Service Members must meet Service standards of fitness according to Service regulations and policies, in addition to the guidance in the parent MOD 13. See MOD THIRTEEN REF E, F, G, H, I, P, and KK.

B. DoD civilian personnel with disqualifying medical conditions could still possibly deploy based upon an individualized medical assessment and approved medical waiver from the appropriate CENTCOM waiver authority (which shall be consistent with subparagraph 4.g.(3)(c) of DoDD 1404.10 and The Rehabilitation Act of 1973, as amended).

C. DoD Contract personnel will be evaluated for fitness according to DoDI 3020.41 (REF J).

D. Regardless of underlying diagnosis, waivers for disqualifying medical conditions will be considered only if all the following general conditions are met:

1. The condition is not of such a nature or duration that an unexpected worsening or physical trauma is likely to have a grave medical outcome or negative impact on mission execution.

2. The condition is stable and reasonably anticipated not to worsen during the deployment in light of the physical, physiological, psychological, and nutritional effects of assigned duties and location.

3. The condition does not require frequent clinical visits (more than quarterly), ancillary tests, or significant physical limitations, and does not constitute an increased risk of illness, injury, or infection.

4. There is no anticipated need for routine evacuation out of theater for continuing diagnostics or evaluations.

5. Any required, ongoing health care or medications anticipated to be needed for the duration of the deployment are available to the applicant in theater within the Military Health System or equivalent. Medication must have no special handling, storage, or other requirements (e.g., refrigeration, cold chain, or electrical power requirements). Medication must be well tolerated within harsh environmental conditions (e.g. heat or cold stress, sunlight) and should not cause significant side effects in the setting of moderate dehydration.

6. Individuals must be able to perform all essential functions of the position in the deployed environment, with or without reasonable accommodation, without causing undue hardship. In evaluating undue hardship, the nature of the accommodation and the location of the deployment must be considered. Further, the member's medical condition must not pose a significant risk of substantial harm to the member or others taking into account the condition of the relevant deployed environment, with particular consideration of areas of armed conflict in the AOR. See REF I.

7. The medical condition does not prevent the wear of personal protective equipment, including protective mask, ballistic helmet, body armor, and chemical/biological protective garments.

8. The medical condition does not prohibit required theater immunizations or medications.

9. The medical condition is not anticipated to significantly impair one's duty performance during the duration of the deployment.

2. Evaluating providers must consider that in addition to the individual's assigned duties, severe environmental conditions, extremes of temperature, high physiologic demands (water, mineral, salt, and heat management), poor air quality (especially particulates), limited dietary options, sleep deprivation/disruption, and emotional stress may all impact the individual's health. If maintaining an individual's health requires avoidance of these extremes or conditions, they should not deploy.

3. Evaluation of functional capacity to determine fitness in conditions of physiologic demand is encouraged for conditions which may impair normal functionality. This includes such things as a complete cardiac evaluation, to include stress imaging, when there is coronary artery disease or an official functional capacity exam (FCE) for orthopedic issues. The evaluating provider should pay special attention to any conditions which may present a hazard to the individual or others and/or preclude performing functional requirements in the deployed setting. Also, the type, amount, suitability, and availability of medications in the theater environment must be considered as potential limitations. Pre-deployment processing centers may vary in medical examination/screening procedures; individuals should contact their respective mobilization site for availability of a processing checklist.

4. The guidance in this document should not be construed as authorizing use of defense health program or military health system resources for health evaluations unless otherwise authorized. Generally, Defense Health Agency and Military Health System resources are not authorized for the purpose of pre-deployment or travel medicine evaluations for contractor employees IAW REF J. Local command, legal, contracting and resource management authorities should be consulted for questions on this matter.

5. Shipboard operations which are not anticipated to involve operations ashore are exempt from the deployment-limiting medical conditions listed below and will generally follow Service specific guidance. However, sovereign laws of some nations within the CENTCOM AOR may prohibit entry of individuals with certain medical conditions. Contingency plans for emergency evacuation of individuals with diagnoses that could result in or complicate medical care in theater following evacuation should be coordinated with and approved by the CENTCOM Surgeon prior to entering the AOR.

6. The general guidance from MOD THIRTEEN section 15.C applies to:

A. All personnel (uniformed service members, government civilian employees, volunteers, and DoD contractor employees) deploying to theater must be medically, dentally and psychologically

fit for deployment and possess a current Periodic Health Assessment (PHA) or physical. Fitness specifically includes the ability to accomplish tasks and duties unique to a particular operation and the ability to tolerate environmental and operational conditions of the deployed location.

B. The existence of a chronic medical condition may not necessarily require a waiver to deploy. Personnel with existing conditions, **other than those outlined in this document**, may deploy if either:

1. An approved medical waiver, IAW Section 15.C.3, is documented in the medical record.

OR

2. The conditions in Para. 1.D.1-1.D.9 are met. To determine stability and assess need for further care, for most conditions 90 days is considered a reasonable timeframe, subject to the examining provider's judgment. The exception to this is noted in paragraph 7.G. Psychiatric Conditions.

7. Documented medical conditions precluding medical clearance. A list of all possible diagnoses and their severity that may cause an individual to be non-deployable would be too expansive. *The medical evaluator must carefully consider whether the climate, altitude, nature of available food and housing, availability of medical, behavioral health, dental, surgical, and laboratory services, or whether other environmental and operational factors may be hazardous to the deploying person's health.* The following list of conditions should not be considered exhaustive. Other conditions may render an individual medically non-deployable (see paragraph 6). Medical clearance to deploy with any of the following documented medical conditions may be granted, except where otherwise noted, IAW MOD THIRTEEN Section 15.C. If an individual is found deployed with a pre-existing non-deployable condition and without a waiver for that condition, a waiver request to remain deployed should be submitted to the respective Component Surgeon. If the waiver request is denied, the individual will be redeployed out of the CENTCOM AOR. **Individuals with the following conditions will not deploy without an approved waiver:**

A. Specific Medical Conditions / Restrictions:

1. Asthma or other respiratory conditions that have a Forced Expiratory Volume-1 $\leq$ 50% of predicted despite appropriate therapy, that have required hospitalization in the past 12 months, or that requires daily systemic (not inhaled) steroids. Respiratory conditions that have been well controlled for 6 months and are evaluated to pose no risk of deterioration in the deployed environment may be considered for waiver.

2. Seizure disorder, either within the last year or currently on anticonvulsant medication for prior seizure disorder/activity. Persons on a stable anticonvulsant regimen, who have been seizure-free for one year, may be considered for waiver.

3. Diabetes mellitus, type 1 or 2, on pharmacotherapy or with $HgA_1C > 7.0$.

a. Type 1 diabetes or insulin-requiring type 2 diabetes.

b. Type 2 diabetes, on oral agents only, with no change in medication within the last 90 days and HgA1C ≤ 7.0 does not require a waiver if a calculated 10-year coronary heart disease risk percentage (see paragraph 7.B.7) is less than 15%. If the calculated 10-year risk is 15% or greater, further evaluation is required prior to waiver submission. See B.8. for more detailed instructions.

c. Newly diagnosed diabetics will require 90 days of stability, either on oral medications or with lifestyle changes, before a waiver will be considered. They

should also have documentation of a complete initial diabetic evaluation (eye exam, foot exam, nutrition counseling, etc.).

4. History of heat stroke. Those with no multiple episodes, persistent sequelae, or organ damage, and no episode within the last 24 months, may be considered for waiver.

5. Meniere's disease or other vertiginous/motion sickness disorder, unless well controlled on medications available in theater.

6. Recurrent syncope for any reason. Waiver request should include the etiology and diagnosis of the condition.

7. Endocrine conditions requiring replacement or adjustment therapies must be stable, require no laboratory monitoring or specialty consultation, and require only routine follow-up which must be available in the deployed location or by specific arrangement. Hormonal preparations must be administered by oral or transdermal routes, be within clinically appropriate dose parameters, have no special storage requirements, and not produce side effects which interfere with the normal performance of duties or require additional medications to manage.

8. Any musculoskeletal condition that significantly impairs performance of duties in a deployed environment. If there are concerns, an official functional capacity exam (FCE) should be performed and results included with the waiver request.

9. Migraine headache, when frequent or severe enough to disrupt normal performance of duties. Waiver submission should note history, frequency, severity, and functional impact of headaches, as well previous and current treatment regimens. Neurology evaluation and endorsement encouraged.

10. Nephrolithiasis, recurrent or currently symptomatic.

11. Pregnancy.

12. Obstructive sleep apnea (OSA). The OSA is diagnosed with an attended, in-laboratory polysomnography (PSG) with a minimum of 2 hours of total sleep time, that yields an apnea-hypopnea index (AHI), and/or respiratory disturbance index (RDI), of greater than 5 / hour. Unattended, home PSG is not acceptable for deployment purposes. For individuals previously diagnosed with OSA, updated or repeat PSG is not required unless clinically indicated (i.e. significant change in body habitus, corrective surgery or return of OSA symptoms). Individuals treated with an oral appliance require PSG documentation that OSA is controlled with its use. Individuals who are treated with automatic positive airway pressure (APAP), continuous positive airway pressure (CPAP) and bi-level positive airway pressure (BPAP) are acceptable as long as the condition being treated is OSA and not a more complex respiratory disorder. Complex OSA, central sleep apnea or OSA that requires advanced modes of ventilation such as adaptive servo-ventilation (ASV) or average volume assured pressure support (AVAPS) is generally non-deployable. Individuals using PAP therapy should deploy with a machine that has rechargeable battery back-up and sufficient supplies (air filters, tubing and interfaces/masks) for the duration of the deployment. Individuals deploying with PAP therapy to a location where the sleep environment has unfiltered air will typically not be granted waivers if a waiver is otherwise required per the guidance below. The following guidelines are designed to ensure that individuals with OSA are adequately treated and that their condition is not of the severity that would pose a safety risk should they be required to go without their PAP therapy for a significant length of time.

a. Symptomatic OSA (i.e. excessive daytime sleepiness) of any severity, with or without any treatment**.**

b. Asymptomatic mild OSA (diagnostic AHI and RDI < 15/hr): Deployable with or without treatment (PAP or otherwise). **No waiver required.**

c. Moderate OSA (diagnostic AHI or RDI ≥15/hr and < 30/hr): **No waiver required** to deploy if successfully treated (CPAP or otherwise), except to Afghanistan, Iraq, or Yemen.

d. Severe OSA (AHI or RDI ≥ 30/hr): Once successfully treated (PAP or otherwise), requires a waiver for deployment to any location in the AOR.

e. For moderate and severe OSA, adherence to positive airway pressure (PAP) therapy must be documented prior to deployment. Adherence is defined as PAP machine data download (i.e. compliance report) that reveals the machine is being used for at least 4 hours per night for greater than 70% of nights over the previous 30-day period.

13. History of clinically diagnosed traumatic brain injury (mTBI/TBI) of any severity, including mild. Waiver may not be required, but pre-deployment evaluation, which may include both neurological and psychological components, is needed per ref HH.

a. Individuals who have a history of a single mild Traumatic Brain Injury may deploy once released by a medical provider after 24-hours symptom free.

b. Individuals who have sustained a second mTBI within a 12-month period, may deploy after seven days symptom free and release by a medical provider.

c. Individuals who have had three clinically diagnosed TBIs (of any severity, including mild) since their last full neurological and psychological evaluation are required to have such an evaluation completed prior to deployability determination.

14. BMI > 35 with or without any significant comorbidity. Military personnel in compliance with Service body fat guidelines do not require a waiver. Morbid obesity (BMI > 40 or weight greater than 300 pounds) can generally not be supported. Civilians and contractors should submit a body fat worksheet with the waiver request. A BMI calculator is located at http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm

15. Any medical conditions (except OSA-see 10 above) that require certain durable medical equipment or appliances (e.g., nebulizers, catheters, spinal cord stimulators) or that requires periodic evaluation/treatment by medical specialists not readily available in theater.

B. Cardiovascular Conditions:

1. Symptomatic coronary artery disease. Also, see B.8.

2. Myocardial infarction within one year of deployment. Also, see B.8.

3. Coronary artery bypass graft, coronary artery angioplasty, carotid endarterectomy, other arterial stenting, or aneurysm repair within one year of deployment. Also, see B.8.

4. Cardiac dysrhythmias or arrhythmias, either symptomatic or requiring medication, electro-physiologic control, or automatic implantable cardiac defibrillator or other implantable cardiac devices**.**

5. Hypertension if controlled with a medication or lifestyle regimen that has been stable for 90 days and requires no changes does not require a waiver. Single episode hypertension found on predeployment physical should be accompanied by serial blood pressure checks (3 day BP checks) to ensure hypertension is not persistent.

6. Heart failure or history of heart failure.

7. Civilian personnel who are 40 years of age or older must have a 10-year CHD risk percentage calculated (online calculator is available at http://tools.acc.org/ASCVD-Risk-Estimator/). If the individual's calculated 10-year CHD risk is 15% or greater, the individual should be referred for further cardiology work-up and evaluation, to include at

least one of the following: graded exercise stress test with a myocardial perfusion scintigraphy (SPECT scan) or stress echocardiography as determined by the evaluating cardiologist. Results of the evaluation (physical exam, Framingham results, etc.) and testing, along with the evaluating cardiologist's recommendation regarding suitability for deployment, should be included in a waiver request to deploy.

8. Uncontrolled hyperlipidemia. Lipid screening should be accomplished IAW Service specific guidelines for lipid assessment. All others (e.g. civilians, contractors) ≥35 years old should have a lipid screening profile performed prior to deployment. While hyperlipidemia should be addressed IAW clinical treatment guidelines, hyperlipidemia values that are outside any of the following (Total Cholesterol > 260, LDL > 190, Triglycerides > 500), either treated or untreated, requires a waiver to be submitted.

C. Infectious Disease:

1. Blood-borne diseases (Hepatitis B, Hepatitis C, HTLV) that may be transmitted to others in a deployed environment. Waiver requests for persons testing positive for a blood borne disease should include a full test panel for the disease, including all antigens, antibodies, viral load, and appropriate tests for affected organ systems**.**

2. Confirmed HIV infection is disqualifying for deployment, IAW References I and T, service specific policies, and agreements with host nations. Note that some nations within the CENTCOM AOR have legal prohibitions against entering their country(ies) with this diagnosis.

3. Latent tuberculosis (LTBI). Individuals who are newly diagnosed with LTBI by either TST or IGRA testing will be evaluated for TB disease with at least a symptom screen and chest x-ray, and will have documented LTBI evaluation and counseling for consideration of treatment. Those with untreated or incompletely treated LTBI, including those with newly diagnosed LTBI, previously diagnosed LTBI, and those currently under treatment for LTBI will be provided information regarding the risks and benefits of LTBI treatment during deployment (see paragraph 15.G.6.C). Individuals meeting the above criteria **do not require a waiver** for deployment. Active duty TST convertors who have documented completion of public health nursing evaluation for TB disease and counseling for LTBI treatment described above **may deploy without a waiver** as long as all Service specific requirements are met.

4. History of active tuberculosis (TB). Must have documented completion of full treatment course prior to deployment. Those currently on treatment for TB disease may not deploy.

5. A CENTCOM waiver cannot override host or transit nation infectious disease or immunization restrictions. Active duty must comply with status of forces agreements; civilian deployers should contact the nation's embassy for up-to-date information.

D. Eye, Ear, Nose, Throat, Dental Conditions:

1. Vision loss. Best corrected visual acuity which does not meet minimum occupational requirements to safely perform duties. Bilateral blindness or visual acuity that is unsafe for the combat environment per the examining provider.

2. Refractive eye surgery. Personnel who have had laser refractive surgery must have a satisfactory period for post-surgical recovery before deployment. There is a large degree of patient variability which prevents establishing a set timeframe for full recovery. The attending ophthalmologist or optometrist will determine when recovery is complete.

a. Personnel are non-deployable while still using ophthalmic steroid drops post-

procedure**.**

b. Personnel are non-deployable for three months following uncomplicated photorefractive keratectomy (PRK) or laser epithelial keratomileusis (LASEK), or one month for laser-assisted in situ keratomileusis (LASIK) unless a waiver is granted.

c. Waiver request should include clearance from treating ophthalmologist or optometrist.

3. Hearing loss. Service members must meet all Service-specific requirements. Individuals must have sufficient unaided hearing to perform duties safely, hear and wake up to emergency alarms unaided, and hear instructions in the absence of visual cues such as lip reading. If there is any safety question, Speech Recognition In Noise Test (SPRINT) or equivalent is a recommended adjunct.

4. Tracheostomy or aphonia.

5. Patients without a dental exam within 12 months of deployment, or those who are likely to require evaluation or treatment during the period of deployment for oral conditions that are likely to result in a dental emergency.

a. Individuals being evaluated by a non-DoD civilian dentist should use a DD Form 2813, or equivalent, as proof of dental examination.

b. Individuals with orthodontic equipment require a waiver to deploy. Waiver requests to deploy should include a current evaluation by their treating orthodontic provider and include a statement that wires with neutral force are in place.

E. Cancer:

1. Cancer for which the individual is receiving continuing treatment or which requires frequent subspecialist examination and/or laboratory testing during the anticipated duration of the deployment.

2. Precancerous lesions that have not been treated and/or evaluated and that require treatment/evaluation during the anticipated duration of the deployment.

3. All cancers should be in complete remission for at least a year before a waiver is submitted.

F. Surgery:

1. Any medical condition that requires surgery (e.g., unrepaired hernia) or for which surgery has been performed and the patient requires ongoing treatment, rehabilitation or additional surgery to remove devices (e.g., external fixator placement).

2. Individuals who have had surgery requiring follow up during the deployment period or who have not been cleared/released by their surgeon (excludes minor procedures).

3. Individuals who have had surgery (open or laparoscopic) within 6 weeks of deployment.

4. Cosmetic, bariatric, or gender reassignment procedures are disqualifying until fully recovered with all follow-up and revisions complete, to include adjuvant counselling, medical treatment, and Service requirements. Special dietary and hygienic requirements cannot be reliably accommodated and may be independently disqualifying.

G. Psychiatric Conditions: Diagnostic criteria and treatment plans should adhere to Diagnostic and Statistical Manual of Mental Disorders, Fourth or Fifth edition (DSM-

IV/5) and current professional standards of care. Waiver submission should include information on applicant condition, including history and baseline symptoms of known disorders, severity of symptoms with and without treatment, and likelihood to recur or deteriorate in theater if exposed to operational activity. See reference KK. Waiver required for all conditions listed below (list is not inclusive).

1. Psychotic and bipolar-spectrum disorders are strictly disqualifying.
2. Any DSM IV/5-diagnosed psychiatric disorder with residual symptoms, or medication side effects, which impair social and/or occupational performance.
3. Any behavioral health condition that poses a substantial risk for deterioration and/or recurrence of impairing symptoms in the deployed environment.
4. Any behavioral health condition which requires periodic (beyond quarterly) counselling or therapy.
5. Chronic insomnia that requires regular or long-term use of sedative hypnotics / amnestics, benzodiazepines, and/or antipsychotics.
6. Anxiety disorders requiring use of benzodiazepines for management, or featuring symptoms of panic or phobia.
7. Post-Traumatic Stress Disorder, when not completely treated or when therapy includes use of benzodiazepines without additional anxiety diagnosis. Waiver submission should note if condition is combat-related, and, if so, comment on impact that return to theater could have on applicant well-being and performance.
8. Gender dysphoria, while not intrinsically disqualifying, does require underlying psychiatric, endocrine, and/or surgical issues (as applicable) to be stable and resolved, and all Service requirements must be met. Due to complex needs, those actively undergoing gender transition are generally disqualified until the process, including all necessary follow-up and stabilization, is completed.
9. Bulimia and anorexia nervosa.
10. Attention Deficit Disorder(ADD)/Attention Deficit Hyperactivity Disorder (ADHD). Evaluation and diagnosis should be appropriate per DSM IV/5 criteria, particularly if Class II stimulants are used for treatment. Specific clinical features or objective testing results should be included in waiver application for stimulant use. Dosages for medications should likewise be appropriate and justified by clinical presentation.
11. Psychiatric hospitalization within the last 12 months.
12. Suicidal Ideation or Suicide Attempt with the last 12 months.
13. Enrollment in a substance abuse program (inpatient, service specific substance abuse program or outpatient) within the last 12 months measured from time of discharge / completion of the program.
- **a.** A post-treatment period of demonstrated stability is required, the length of which will depend on individual patient factors.
- **b**. Substance abuse disorders (not in remission), actively enrolled in Service Specific substance abuse programs are not eligible for waiver.

14. Use of antipsychotics or anticonvulsants for stabilization of DSM IV or DSM-5 diagnoses.
15. Use of 3 or more psychotropics (e.g. antidepressants, anticonvulsants, antipsychotics, benzodiazepines) for stabilization, particularly if used to offset side-effects of other BH therapy.
16. Psychiatric disorders with fewer than three months of demonstrated stability from the last change in treatment regimen, including discontinuation.

17. Psychiatric disorders newly diagnosed during deployment do not immediately require a waiver or redeployment. Disorders that are deemed treatable, stable, and having no impairment of performance or safety by a credentialed mental health provider do not require a waiver to remain in theater.

a. Exceptions include diagnoses featuring bipolar, psychotic, or suicidal features. These individuals should be redeployed at soonest opportunity via medical evacuation with appropriate escorts and per TRANSCOM guidelines.

b. Diagnoses requiring the prescription of CSA-scheduled controlled substances will require an approved waiver to obtain routine refills of medication.

H. Medications – although not exhaustive, use of any of the following medications (specific medication or class of medication) is disqualifying for deployment, unless a waiver is granted:

1. Any medication which, if lost, misplaced, stolen, or destroyed, would result in significant worsening or grave outcome for the affected individual before the medication could be reasonably replaced.

2. Any medication which requires periodic laboratory monitoring, titrated dosing, or special handling/storage requirements, or which has documented side effects, when used alone or in combination with other required therapy, which are significantly impairing or which impose an undue risk to the individual or operational objectives.

3. Blood modifiers:

a. Therapeutic Anticoagulants: warfarin (Coumadin), rivaroxaban (Xarelto).

b. Platelet Aggregation Inhibitors or Reducing Agents: clopidogrel (Plavix), anagrelide (Agrylin), Dabigatran (Pradaxa), Aggrenox, Ticlid (Ticlopidine), Prasugrel (Effient), Pentoxifylline (Trental), Cilostazol (Pletal). Note: Aspirin use in theater is to be limited to individuals who have been advised to continue use by their healthcare provider for medical reasons; such use must be documented in the medical record.

c. Hematopoietics: filgrastim (Neupogen), sargramostim (Leukine), erythropoietin (Epogen, Procrit).

d. Antihemophilics: Factor VIII, Factor IX.

4. Antineoplastics (oncologic or non-oncologic use): e.g., antimetabolites (methotrexate, hydroxyurea, mercaptopurine, etc.), alkylators (cyclophosphamide, melphalan, chlorambucil, etc.), antiestrogens (tamoxifen, etc.), aromatase inhibitors (anastrozole, examestane, etc.), medroxyprogesterone (except use for contraception), interferons, etoposide, bicalutamide, bexarotene, oral tretinoin (Vesanoid).

5. Immunosuppressants: e.g., chronic systemic steroids.

6. Biologic Response Modifiers (immunomodulators): e.g., abatacept (Orencia), adalimumab (Humira), anakinra (Kineret), etanercept (Enbrel), infliximab (Remicade), leflunomide (Arava), etc.

7. Antiretrovirals used for Pre-Exposure Prophylaxis (PrEP): e.g. tenofovir disoproxil fumarate/emtricitabine (Truvada), tenofovir alafenamide (Vemlidy)

8. Any CSA Schedule I-V controlled substance, including but not limited to the following:

a. Benzodiazepines: lorazepam (Ativan), alprazolam (Xanax), diazepam (Valium), flurazepam (Dalmane), clonazepam (Klonopin), etc.

b. Stimulants: methylphenidate (Ritalin, Concerta), amphetamine/dextroamphetamine (Adderall), dextroamphetamine (Dexedrine),

dexmethylphenidate (Focalin XR), lisdexamfetamine (Vyvanse), modafinil (Provigil), armodafinil (Nuvigil), etc.

c. Sedative Hypnotics/Amnestics: zolpidem (Ambien, Ambien CR), eszopiclone (Lunesta), zaleplon (Sonata), estazolam (Prosom), triazolam (Halcion), temazepam (Restoril), etc. Note: single pill-count issuances for operational transition do not generally require a waiver.

d. Narcotics/narcotic combinations: oxycodone (Oxycontin, Percocet, Roxicet), hydrocodone (Lortab, Norco, Vicodin), hydromorphone (Dilaudid), meperidine (Demerol), tramadol (Ultram), etc.

e. Cannabinoids: marijuana, tetrahydrocannabinol (THC), dronabinol (Marinol), etc. Note that possession or use may be a criminal offense in the CENTCOM AOR.

f. Anorexiants: phendimetrazine (Adipost), phentermine (Zantryl), etc.

g. Androgens and Anabolic Steroids: testosterone (Axiron, AndroGel, Fortesta, Testim), oxymetholone (Anadrol-50), methyltestosterone (Methitest), etc. Preparations used in accordance with standards outlined in 7.A.7 above do not require separate waiver. All injected preparations require waiver.

9. Antipsychotics, including atypical antipsychotics: haloperidol (Haldol), fluphenazine (Prolixin), quetiapine (Seroquel), aripiprazole (Abilify), etc.

10. Antimanic (bipolar) agents: e.g., lithium**.**

11. Anticonvulsants, used for seizure control or psychiatric diagnoses.

a. Anticonvulsants (except those listed below) which are used for *non-psychiatric* diagnoses, such as migraine, chronic pain, neuropathic pain, and post-herpetic neuralgia, are not intrinsically deployment-limiting as long as treated conditions meet the criteria set forth in this document and accompanying MOD THIRTEEN. No waiver required. Exceptions include:

b. Valproic acid (Depakote, Depakote ER, Depacon, divalproex, etc.).

c. Carbamazepine (Tegretol, Tegretol XR, etc.).

d. Lamotrigine (Lamictal)

12. Varenicline (Chantix).

13. Botulinum toxin (Botox): Current or recent use to control severe pain.

14. Insulin and exenatide (Byetta).

15. Injectable medications of any type, excluding epinephrine (Epipen), though underlying allergy may require separate waiver.

SPECIAL ARTICLE

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Dental Sleep Medicine Standards for Screening, Treating, and Managing Adults with Sleep-Related Breathing Disorders

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Oral appliance therapy (OAT) has been used to manage sleep-related breathing disorders (SRBDs), such as obstructive sleep apnea (OSA) and snoring, for more than 20 years. However, dental sleep medicine standards of clinical practice have not been clearly defined. SRBD prevalence rates have grown to double digits, presenting an increased need for dentists proficient in dental sleep medicine. A standardized approach to patient management, which underscores the collaborative nature necessary between dentists and physicians, is needed. These standards provide guidance for patient examination, patient screening, education, and treatment management including follow-up care. Although this paper introduces best practices for the practice of dental sleep medicine as it currently exists, the reader should recognize the fluid and dynamic nature of dental sleep medicine and understand that periodic updates to these standards will be required.

Keywords: best practice, obstructive sleep apnea, oral appliance therapy, sleep-related breathing disorders, standard

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INTRODUCTION

Sleep-related breathing disorders (SRBDs) are one of six classifications of sleep disorders identified in the International Classification of Sleep Disorders, Third Edition (ICSD-3),[1] the American Academy of Sleep Medicine's (AASM) clinical text for the diagnosis of sleep disorders. Obstructive Sleep Apnea (OSA) is a SRBD associated with upper airway collapse. OSA has an estimated prevalence of 12% (includes both diagnosed and undiagnosed).[2] There is abundant literature to support the utility of oral appliances (OAs; also known as mandibular advancing devices) as an effective treatment of OSA in adults.[3-6] There is limited evidence to suggest that mandibular advancement (also referred to as functional appliance therapy in the orthodontic literature) and maxillary expansion can be effective treatment modalities in the management of pediatric OSA.

The American Academy of Dental Sleep Medicine (AADSM) recognizes the inconsistency of the sleep medicine curricula in US and Canadian dental schools. The AADSM and others offer educational opportunities to provide dentists with the requisite knowledge to effectively treat and manage OSA patients. Yet, despite these efforts, there are no uniform standards on the practice of dental sleep medicine.

In 2015, the AASM and AADSM issued the *Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy*.[7] This guideline offers clarity on the desired qualifications of a dentist participating in the treatment and ongoing management of OSA and snoring. The guideline stipulates that a dentist should have at least one of the following: (1) diplomate certification in dental sleep medicine by a non-profit organization; (2) designation as the dental director of a dental sleep medicine facility accredited by a nonprofit organization; or (3) obtain the designation of "qualified dentist." The qualified dentist is encouraged to continue their education in dental sleep medicine and seek either diplomate and/or dental director status. Throughout this paper, our use of the designation "qualified" includes the diplomate certified dentist, the dental director of an accredited facility, as well as the dentist who has completed the qualified dentist requirements established in the 2015 clinical practice guideline.

To ensure high-quality patient care is provided, qualified dentists treating and managing patients in whom SRBDs have been diagnosed should adhere to standards of care in an ethical and medicolegal framework, including following best practices for informed consent, risk management, quality assurance, and record keeping. Patient care should be delivered within the scope of the qualified dentist's competence in a patient-centered environment that recognizes the diversity of patient populations. The qualified dentist treating and managing patients with SRBDs should educate the patient and appropriate caregivers as to the etiology of SRBDs according to evidence-based practices, critical thinking, and outcomes assessments. Finally, the qualified dentist should identify known risk modifiers and work with patients and other health care professionals to effectively

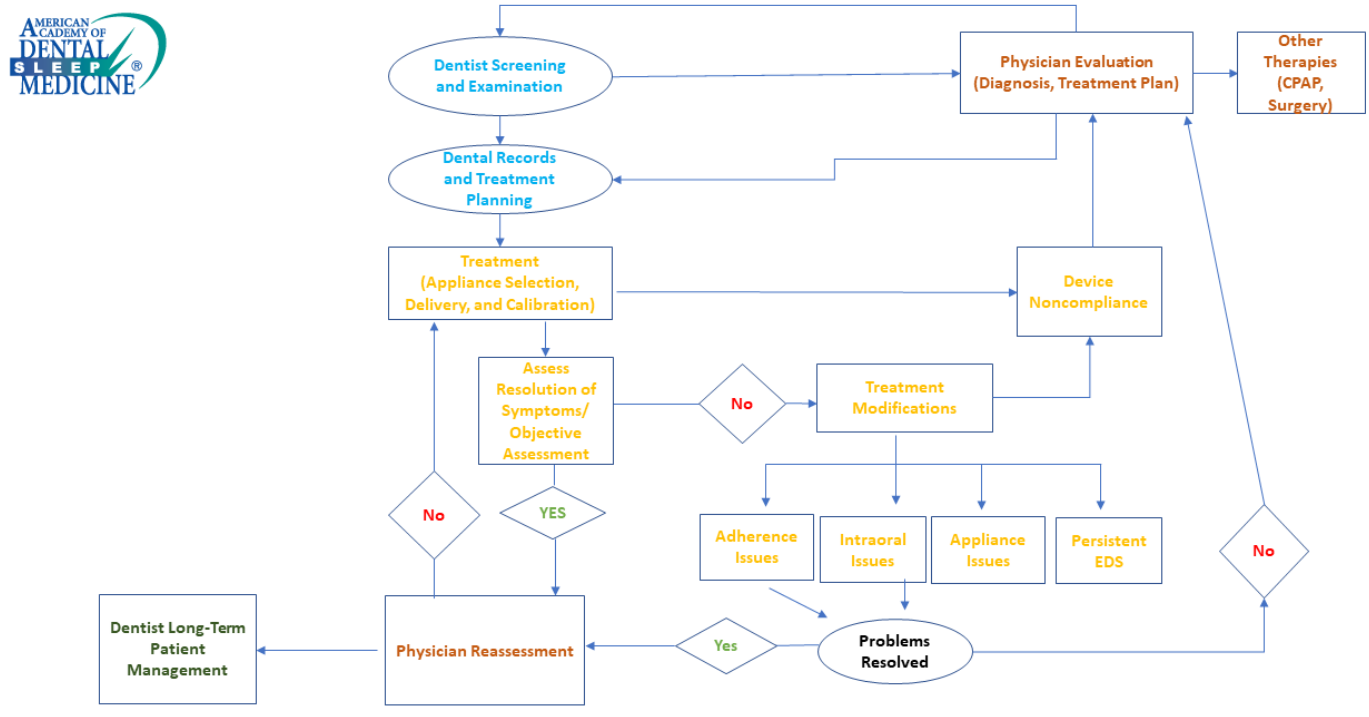
manage the SRBD through evidence-based practices.[8]

In the fall of 2017, the AADSM commissioned a task force of experts in dental sleep medicine to create a document that would appropriately define the scope of dental sleep medicine practice. The task force included five American Board of Dental Sleep Medicine (ABDSM)-certified dentists. The task force developed these standards based on a review of relevant literature, including prior and current guidelines and, collectively, established this framework for the scope of dental sleep medicine practice. The AADSM Board of Directors approved the final manuscript.

The goal of this paper is to establish clear guidelines for the qualified dentist using oral appliance therapy (OAT) as a treatment for OSA. Accordingly, this paper demonstrates how a qualified dentist should identify an adult patient suspected of an SRBD and then details a clinical care pathway for the management and treatment of the SRBD (see Figure 1). This paper describes standards for patient examination, screening and education, treatment management, and follow-up care. Standardization will encourage and promote a methodical approach to patient care, which, in collaboration with the physician, will enable the qualified dentist to deliver the best possible care.

There are two pathways that may lead a dental patient to evaluation for an SRBD, subsequent diagnosis, and OAT. A patient may initiate a visit to the qualified dentist and be screened, or a physician may refer a patient to the qualified dentist. In the first instance, a patient's visit to a qualified dentist should include a screening process that may identify any number of findings often associated with a SRBD. In consultation with the patient, the qualified dentist should then refer the suspected SRBD patient to a physician for evaluation and assessment. In the second instance, a physician who has diagnosed SRBD in a patient may prescribe an OA and then refer the patient to a qualified dentist for dental assessment and initiation of OAT.

FIGURE 1: Clinical Pathway for the Management and treatment of SRBD



CPAP = Continuous Positive Airway Pressure; EDS = Excessive Daytime Sleepiness

SCREENING

When patients present to the dental office, the qualified dentist should employ various screening tools to supplement the general examination process to collect information on the typical demographic and anatomic factors associated with OSA.

The goal of the initial screening is to assess the patient or bed partner's perception of both nocturnal and daytime symptoms (eg, snoring, witnessed apneas, gasping, sleepiness) as to the likelihood of an SRBD. In the adult population, the Epworth Sleepiness Scale and Berlin and STOP-BANG questionnaires are examples of questionnaires that collectively focus on subjective and objective criteria and are valuable tools for the initial screening process. The Epworth Sleepiness Scale, although not specific for SRBDs, is widely used[9] and may be requested by private payers. The Berlin questionnaire[10] includes a question on hypertension, which is of value when correlated with number of medications for hypertension.[11] A high score on the STOP-BANG questionnaire indicates a high probability of moderate to severe OSA. [12] Ultimately, this information is collated to help the qualified dentist determine whether the patient should be referred to a physician.

When using questionnaires for initial screening, certain criteria should trigger a referral to a physician for evaluation and diagnosis; among these is increased body mass index, witnessed apneas, excessive daytime sleepiness, and the presence of medical comorbidities. Frequently, a patient will present to the dental office with the belief that there are no concerns other than simple snoring; however, all snoring is abnormal and should be taken as a serious symptom in patients.[13, 14]

The qualified dentist should record the patient's chief complaint(s), the medical and family histories, and current medications. Screening questionnaires can be particularly valuable in identifying patients at increased risk for SRBDs when correlated with the history of current sleep problems, medical history, family medical history, medications, and dental history and findings. Numerous medications may significantly affect a patient's sleep schedule, as well as negatively affect respiratory patterns while asleep.[15] Oral and facial anatomic considerations, including pharyngeal crowding, sleep bruxism, and enamel erosion associated with gastroesophageal reflux are also associated with SRBDs.[16-18] This information, understood in context with the screening process, may further clarify the need for physician referral.

Although screening tools provide valuable information to identify patients at risk for an SRBD, they are not a substitute for an objective sleep apnea test. Ultimately, the diagnosis of a SRBD should be determined by a physician.

PHYSICAL EXAMINATION

The qualified dentist should perform a thorough oral examination to identify key physical features associated with SRBDs. During the initial portion of the examination, it is also important to record baselines for each patient including BMI, blood pressure, and neck circumference. These baselines may be used in the future to monitor changes in the patient's physical status and their success or failure with OAT.

A comprehensive examination should include visualization and descriptive assessment of the craniofacial complex including the upper airway. Systematically, the qualified dentist commences with visualization of the posterior pharyngeal wall. Key structures that should be evaluated include the soft palate, the uvula, and the palatine tonsils. Researchers, including Mallampati, Friedman, and Brodsky, developed descriptive assessments of these soft-tissue entities.[19-21] It should be noted that a primary site of upper airway obstruction occurs in these retropalatal tissues.[22, 23] Additionally, the nose should be evaluated for deviations, valvular collapses, and possible obstructions. If either nasal or pharyngeal patency is compromised, the patient should be referred for an ear, nose, and throat evaluation.

The tongue often has a significant role in upper airway obstruction. Tongue size and occlusal positioning may provide additional evidence as to the likelihood of oropharyngeal crowding. Additionally, the appearance of the tongue, including color, shape, tonicity, and surface texture, should be noted.

The hard and soft tissues of the oral cavity, including the hard palate, alveolar processes, teeth, gingiva, and frenal (lingual and facial) attachments, should also be assessed during the comprehensive oral examination. The number and location of teeth, along with the morphological integrity, is significant and may dictate not only whether the patient is a candidate for an OA, but future OA selection as well. An associated periodontal assessment is suggested to assist the qualified dentist further in appliance selection. Special consideration should be given to periodontally involved teeth, especially those with severely compromised support. The inclusion of such teeth in the appliance framework could compromise appliance retention and efficacy should any of these teeth be lost in the future. The use of radiographic imaging also assists the qualified dentist in determining the integrity of the dentition, candidacy for oral appliance therapy, and identifying skeletal and/or soft tissue presentations often associated with SRBDs.

There may be an association between temporomandibular disorders and SRBDs.[24] A thorough examination of the temporomandibular joint (TMJ) area should include a complete muscle examination including the masseter, temporalis, sternocleidomastoid muscles, and

associated superficial muscles. Along with a manual examination of the TMJ muscles, it should be determined if the patient presents with normal joint function, reducing or nonreducing joint disease, or crepitus. The severity of pain should also be referenced prior to fabrication of an OA. As the joints are evaluated, the patient's range of motion, including lateral and protrusive movement and deviations, should also be noted.

A thorough dental assessment is necessary and should include Angle classification, overbite and overjet, and noting any deviations from what is considered normal. Evaluation of dental midlines, crossbites, wear facets, intra-arch spacing and/or crowding, as well as occlusal and interproximal contacts, should also be documented for reference. Long-term appliance wear is often associated with changes in the dental occlusion and a record of pre-treatment dental schematics can be valuable in assessing any variations.

Should the qualified dentist anticipate the patient's condition will be managed with an OA, the qualified dentist may obtain both intraoral and extraoral photographs as a record of the pretreatment dental condition. Additionally, dental study casts, or a digital form of such, will be needed to create the OA and may be retained as part of the patient's record for as long as state regulations require.

A comprehensive facial and oral examination of the patient should provide the qualified dentist with the necessary information to both discern whether an OA is appropriate for the patient and to assist with proper appliance selection.

PATIENT EDUCATION

The effective management of SRBDs requires the qualified dentist to provide the patient with an overview of the disease process, as well as an understanding of how oral appliances treat SRBDs. OSA is the result of neuro-anatomical factors and pathophysiological processes that either singularly, or collectively, fail to maintain the patency, or opening, of the upper airway. Patient education should include the role of these processes as well as highlighting risk factors related to demographics, ethnicity, and sex. Additionally, patients should be informed about disease processes including comorbid conditions arising from or associated with OSA.

The patient undergoing OAT should be informed of their SRBD severity including an understanding of the resulting apnea-hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) from objective sleep apnea testing. The patient should also be informed that OAT success may be affected by fragmented sleep, oxygen desaturation, and other coexisting sleep disorders.

Additionally, the qualified dentist should explain risk modifiers that may mitigate disease severity. The patient should be advised that the risk of disease severity or treatment success may be negatively influenced by using tobacco, alcohol, caffeine, or recreational substances.[25, 26] The effect of both weight loss and weight gain should be discussed with the patient.[27] The educated and informed patient may choose to reduce the effects of disease by modifying behaviors that increase SRBD risk or severity.

Additionally, patients should be educated about the importance of sleep hygiene. The patient should understand the effect of ambient room lighting, temperature, the use of electronics in bed, and animals on the bed, as well as the importance of regular sleep schedules. Although these considerations may not directly affect OA efficacy, they can collectively fragment sleep and aggravate daytime sleepiness concerns. Improper sleep hygiene can also indirectly reduce patient perception of OA benefit in terms of sleep quality and daytime function.

DIAGNOSIS

The qualified dentist may interpret and collate findings as part of an extensive screening process and should refer a patient suspected of an SRBD to the physician for evaluation and appropriate medical diagnosis. The physician who diagnoses the SRBD, or the treating physician, is responsible for providing a prescription for OAT to the qualified dentist prior to the initiation of OAT.

Once an OA has been prescribed, the physician should refer the patient, accompanied by a letter of medical necessity and a copy of the study, to the qualified dentist for OAT. The importance of bidirectional referral patterns should be recognized, with the qualified dentist referring to the physician and the physician referring to the qualified dentist. Optimal outcomes are often best realized when the qualified dentist, physician, and any other auxiliary providers collaborate to achieve the shared goal of treatment.

TREATMENT OPTIONS

When an SRBD is diagnosed by a managing physician, it becomes necessary to collaborate with the physician to develop a properly sequenced treatment and/or referral plan as appropriate, to begin management of the disease using OAT or other agreed-on treatment modalities.

Positive airway pressure (PAP) therapy has long been considered the gold-standard treatment for OSA, and patients with OSA successfully treated with PAP therapy should be encouraged to continue this treatment course. Many patients will come to the qualified dentist having struggled with PAP adherence, so it is likely that the qualified dentist will be sent referrals from physicians for this reason.

An oral appliance is prescribed by the physician to

treat SRBDs. The OA may be a first-line therapy[28] or may be used when previous treatment efforts have fallen short of maximum efficacy.[29] Several studies have demonstrated that OAs and PAP therapy were comparable in improving daytime somnolence, hypertension, neurocognitive function, quality-of-life indices, and cardiovascular mortality.[5, 30]

Some patients using PAP may find the pressure too high, leading to PAP adherence issues. Combination therapy, in which an OA is used in concert with PAP, may allow for lower pressure and improve PAP adherence.[31] Combination therapy may reduce the upper airway resistance and allow a more comfortable and lower pressure required to sustain patency of the airway. The use of customized masks and interfaces can be fabricated by qualified dentists to facilitate the use of combination therapy. Some patients may also elect to alternate between PAP and OAT to accommodate lifestyle needs or to minimize the side effects of either therapy.

Depending on the severity of the SRBD, another treatment option includes surgery, such as maxillofacial surgery or otolaryngologic surgery.[32, 33] However, the most effective treatment plans for resolution of SRBDs are comprehensive and multidisciplinary in nature. For many patients, this will include discussions about weight reduction, positional therapy, and/or behavioral modification (modification or elimination of certain lifestyle habits).

OAT INITIATION

After OAT is prescribed, the qualified dentist should use his or her knowledge and understanding of the patient's health history, dental history, dental and skeletal anatomy, and temporomandibular disorder history to develop a treatment plan to utilize an OA.

Initiating OAT includes obtaining informed consent and a letter of medical necessity and should allow for modification of the treatment plan as needed to obtain the desired therapeutic result. Informed consent is the process by which the treating dentist discloses appropriate information to a competent patient so that the patient is able to make a voluntary choice to accept or refuse treatment. The qualified dentist should provide the patient an opportunity to ask questions about the risks of treatment as well as educate the patient as to the risks associated with no treatment. Informed consent also requires that the qualified dentist informs the patient about alternate therapies to OAT, such as PAP therapy, positional therapy, maxillofacial surgery, or otolaryngologic surgery. Upon agreement to a plan of treatment, the patient should sign the informed consent in front of the qualified dentist or other dental staff. The qualified dentist should then countersign and date the document, which should be kept as part of the patient's record of care.

OA SELECTION

Selection of an OA, as well as the initial protrusive position, will be at the discretion of the qualified dentist based on the aforementioned criteria (ie,. dental history and physical examination).

The 2014 consensus paper by the AADSM describes the purpose, function, and physical features of an effective OA.[34] An effective OA is defined as a custom-fabricated, Food and Drug Administration (FDA)-cleared device that is designed to maintain airway patency during sleep for the management of OSA.[34] An effective OA helps to protrude and stabilize the mandible to preserve the patency of the upper airway during sleep. Custom, adjustable dual-arch OAs have been shown to be highly efficacious for treating primary snoring and mild-moderate OSA and may have significant benefit in more severe disease where other treatment modalities are not effective.[35]

The qualified dentist's selection of an appropriate OA should include both the patient's preferences as well as the qualified dentist's assessment. Appliance selection should consider craniofacial structures, and oral, dental, and periodontal tissues. Other elements to consider include the patient's cognitive ability, manual dexterity, visual acuity, range of motion, and nasal patency, as well as number, location, and health of remaining teeth. The clinical tooth height, undercuts, current dental restorative conditions, and anticipated dental restorative needs, along with allergies and or sensitivities, are also to be considered because they may limit the type and material to be used in the fabrication of an OA. Patient preferences to consider could include perceived comfort, ease of use and financial considerations.

OA FABRICATION

The fabrication of the OA begins with accurate digital or analog impressions and a protrusive bite record. The various types of protrusive bite records may be used and customized to accommodate an individual's dental, muscular, and anatomic range. Although the qualified dentist has discretion as to the initial position of the OA, literature suggests a range of 25% to 75% as a comfortable and yet therapeutic range.[36-38]

OA DELIVERY

The qualified dentist should verify the fit and comfort of the OA. Following successful OAT insertion, the qualified dentist or staff should review the adjustment protocol, homecare instructions, and the warranty specific to the OA selected. It is recommended that a written copy of the instructions and warranty be signed and dated by the patient and a staff member, with one copy being provided to the patient and the other retained in the medical record.

The qualified dentist should provide appropriate

provisions to maximize comfort and minimize the development of dental changes including, but not limited to, occlusal irregularities and interdental spacing. Additionally, the qualified dentist should take appropriate measures to attenuate the possible development of jaw discomfort and muscle fatigue. These provisions may include morning exercises, the use of a morning repositioning device, and associated palliative care.[39] It is appropriate to follow up with the patient after OA delivery to ascertain whether the patient has any immediate concerns.

OA CALIBRATION

Typically, within the first 30 days, the patient should return to the qualified dentist to assess the comfort and efficacy of the OA. The qualified dentist may elect to advance the OA setting based on multiple factors including the initial assessment of the patient's range of motion, level of severity, patient comfort, and subjective report of initial response.[40]

The qualified dentist will need to determine an appropriate endpoint to the OA advancement process. OA advancement is based on the patient's range of motion and comfort, with consideration of evidence supporting 50% to 75% of the patient's maximum protrusive range. Excessively increasing the patient's protrusive position has not been shown to guarantee improved efficacy and may worsen the patient's sleep-disordered breathing.[36] However, individuals who fail to achieve a satisfactory decrease in snoring or the AHI/RDI/REI may show further improvement with continued gradual advancement.

As such, the qualified dentist and physician should have a mutually agreed-upon process that enables the OA to be assessed objectively. The use of objective data by the qualified dentist to verify the therapeutic position of the OA may be appropriate and used within the scope of practice as defined by the dentist's state dental practice act.[41] The American Dental Association's (ADA's) *Policy on Dentistry's Role in Treating Obstructive Sleep Apnea, Similar Disorders* states that unattended cardiorespiratory portable monitors (type 3 or 4) may help define the optimal target position of the mandible.[42] The AASM and AMA have published policies that state that a home sleep apnea test (HSAT) must be ordered by a physician, even in the instance of determining appliance efficacy.[43,44] Ultimately, any decisions regarding the use of HSATs, and the resulting objective data, should be made in concert with the patient, the treating physician, and qualified dentist, and should be made in the interest of furthering the patient's sleep assessment.

Upon final calibration of the OA, the qualified dentist should refer the patient back to the physician for assessment of OAT outcome. The qualified dentist should provide the physician any notes and/or findings that may contribute to the physician's assessment. Should the physician deem the calibrated position to be sub-therapeutic, the physician and qualified dentist should discuss the possibility of further calibration or alternative treatment.

LONG-TERM FOLLOW-UP/MANAGEMENT

Patients who utilize OAT should be evaluated by the qualified dentist every 6 months for the first year and at least annually thereafter. The annual recall examination should verify OA efficacy and occlusal stability, check the structural integrity of the OA, and ensure that there is maintenance of previously resolved symptoms such as snoring and daytime sleepiness. The qualified dentist should inquire about patient comfort and adherence to therapy and screen for possible side effects. If side effects are noted, their presence should be documented, as well as any management and manner of resolution. Should the annual assessment reveal symptoms of worsening OSA or the potential need for additional adjustments to the OA, then the qualified dentist shall communicate this and any other relevant subjective or objective findings to the patient's physician.[40]

OAs should be evaluated by the qualified dentist on a yearly basis for signs of wear, fractures, and bacterial and/or fungal growth, and should be replaced according to the patient's needs. In the event of damage, loss of the OA, or significant changes to the patient's dentition, a new OA may need to be fabricated. The new OA may require some additional calibration to restore the patient to the previously determined therapeutic position. As such, the patient's physician should be notified of the delivery of the new OA and may then decide if an additional objective assessment is required.

In some instances, a long-time user of an OA, for whom there is not a qualified dentist of record, may present to a new qualified dentist seeking repair or replacement of a worn or damaged OA. This patient should be managed as a new patient, and the qualified dentist should seek out the previous diagnosing physician's notes and sleep studies. The qualified dentist should use clinical judgement and consider re-establishing the patient with the former physician or assist the patient in establishing a relationship with a new physician. The physician can then determine what evaluation is appropriate and provide the qualified dentist with a current letter of medical necessity.

OA REPLACEMENT

Patients requesting a replacement OA should undergo a comprehensive evaluation by their qualified dentist prior to fabrication of a new appliance. The patient's physician should be alerted of the request and should be given the opportunity to reassess the patient, modify treatment if necessary, and provide a new letter of medical necessity.

For a patient in whom there was a previous diagnosis

and treatment with an OA by another practitioner, a new comprehensive evaluation should be completed. Continuity of care should be maintained, and fabrication of a new OA should proceed based on the last available diagnostic sleep study. However, direct communication with the patient's physician should be initiated to request guidance regarding the need for an updated sleep study and/or face-to-face evaluation with the physician.

SIDE EFFECTS

The potential for side effects[1,4,39] must be explained to the patient by the qualified dentist and discussed prior to initiating treatment and again as needed throughout treatment. The potential for TMJ-related side effects, intraoral tissue-related side effects, occlusal changes, damage to teeth or restorations, and appliance issues are among the topics that should be reviewed by the qualified dentist prior to treatment.[39] Because informed consent must be reviewed with the patient and signed prior to initial treatment, it is recommended that the review of informed consent be completed by the qualified dentist to allow opportunity for discussion of all patient questions and concerns.

Management of reported side effects[39] should be well documented and tailored to the individual patient's needs. The presence of side effects should be discussed as it pertains directly to an individual patient's clinical history. If side effects negatively affect adherence or effectiveness of the OAT, if the patient is intolerant to OAT or if the qualified dentist recommends treatment be discontinued, the qualified dentist must consult or inform the patient's physician.[39]

DISCUSSION

As an evolving field of dental practice, there are increasing numbers of qualified dentists electing to participate in the treatment and management of SRBDs. Although there are expanding educational opportunities for the qualified dentist, there does not exist, to our knowledge, a standard of practical care. These standards were developed to provide the qualified dentist with a clear and concise guide to the management of SRBDs in the adult population. Commencing with patient intake, screening, OA design and delivery, and moving to treatment execution and long-term patient management, this standard is not intended to be all inclusive. Emerging technologies and new explorations in the field will necessitate periodic updates to these standards. For example, orthodontic advances in the use of skeletal anchorage techniques may provide additional dental therapeutic modalities for adults. As well, there is increasing evidence that the presence of inflammatory markers in OSA and periodontitis may be bi-directional.[45] Though not currently widely used, there are also new systems that use PSG to monitor patients during customized OA titration.[46] New ways to objectively monitor OA adherence are also being explored[47], including ways for this data to be accessible to providers in real time. To keep up to date, the qualified dentist practicing dental sleep medicine should participate in an ongoing, comprehensive educational strategy best suited to their individual learning.

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Dr. Schwartz reports serving in an advisory capacity as part of Resmed's dental panel, owning public stock in Resmed, serving as part of an advisory group for Prosomnus, and having a financial stake in Prosomnus. The other authors report no conflicts of interest.

SPECIAL ARTICLES

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Management of Side Effects of Oral Appliance Therapy for Sleep-Disordered Breathing

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As the field of oral appliance therapy (OAT) to manage obstructive sleep apnea has evolved over the past 30 years, side effects of therapy have become increasingly recognized. Although the most commonly observed side effect is unwanted tooth movement, a number of other side effects have been reported through anecdotes, case reports, and observational studies. Members of the American Academy of Dental Sleep Medicine developed a set of consensus recommendations to guide dentists in the management of side effects as a consequence of OAT. Thirteen expert clinicians were appointed to the panel, which used the modified RAND/UCLA Appropriateness Method to review the body of evidence on OAT side effects and to establish the recommendations. Clinicians are encouraged to use these recommendations in conjunction with their clinical expertise to minimize the side effects of OAT. The recommendations are based on knowledge to date and are expected to evolve over time. Future research should aim at timely identification of these side effects for positive treatment outcomes.

Keywords: malocclusion, mandibular advancement, mandibular repositioning, mouth diseases and therapeutics, oral device, orthodontic appliance, sleep apnea (obstructive and snoring), tooth disease

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INTRODUCTION

The American Academy of Dental Sleep Medicine (AADSM) and American Academy of Sleep Medicine recently updated their clinical practice guideline for the treatment of obstructive sleep apnea (OSA) and snoring with oral appliance therapy (OAT).[1] The guideline included the following recommendation: "We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence."

The management of side effects is essential to maximize treatment adherence and the clinical effectiveness of oral appliances. The guideline further states that although multiple manuscripts refer to side effects, the overall evidence is limited and of low quality.

The field of dental sleep medicine lacks a set of published guidelines that clinicians and dentists can refer to for the management of side effects associated with OAT. Most of the information available to clinicians is derived from individual lecturers and is anecdotal. In an effort to begin to address this gap in knowledge, the AADSM Board of Directors convened a panel of experts to develop consensus-based recommendations for managing the most common side effects encountered in OAT.

BACKGROUND

OSA has a reported prevalence of 2% to 8% in older literature, with more recent estimates suggesting that more than 18 million adults in the United States have sleep apnea, a leading cause of excessive daytime sleepiness. An oral appliance, while effective in ameliorating the respiratory events of OSA, often causes alterations in occlusal (tooth) contacts and mandibular positioning as well as other side effects. During the Advanced Course in Oral Appliance Therapy in 2009, the AADSM first catalogued some of these side effects and proposed solutions for their management. This was originally published in *Dialogue* and was considered a work in progress.[2]

The purpose of this consensus paper is to update those recommendations and to develop a touchstone reference for practitioners and researchers seeking guidance on the management of side effects of OAT for sleep-disordered breathing.

METHODS

Expert Panel Selection

In accordance with the recommendations of the RAND Appropriateness Method,[3] the Consensus Conference panel comprised 13 voting members. All panel members were dentists who were trained and experienced in the overall care of oral health, the temporomandibular joint (TMJ), dental occlusion, and associated oral structures with focused emphasis on the proper protocol for diagnosis, treatment,

and follow-up of patients being managed with OAT for sleep-disordered breathing. All panelists were required to complete conflicts of interest disclosures before being officially invited to participate.

In addition, the American Academy of Sleep Medicine, the American Dental Association, and the American Dental Education Association were invited to identify a representative of their respective associations to attend the consensus conference as nonparticipating observers. These observers were permitted to pose questions during the conference but did not participate in the voting or the development of the recommendations.

Literature Search and Review

A literature search was performed using a combination of keywords and Medical Subject Heading terms in PubMed. Disorder-related keywords used were *sleep apnea, obstructive and snoring, tooth disease, malocclusion, mouth diseases,* and *therapeutics*. These were combined with treatment keywords including *mandibular advancement, mandibular repositioning, oral device,* and *orthodontic appliance*. The search strategy was limited to humans and articles in English. Search results were retrieved for literature published through February 23, 2016, resulting in a total of 181 articles. The panelists reviewed the abstracts to identify articles that included side effects of OAT for sleep-disordered breathing and treatment options to manage side effects. Articles that were not relevant were discarded. The panel also conducted a "spot check" of the literature in June 2016 to identify missing publications. The final number of articles accepted in support of this endeavor was 143.

The full text of all accepted publications was made available to the panel members for review.

Survey of American Board of Dental Sleep Medicine Diplomates and AADSM Committee Members

Concurrent with the literature review, a comprehensive list of the side effects and possible treatment options was developed. Because knowledge about oral appliances varies among providers, an online survey of dentists was conducted to ensure that common side effects and possible treatment strategies were not overlooked.

The survey was designed to capture the percentage of patients in each respondent's practice who were managed with OAT, the common side effects encountered with OAT, the frequency of each of these side effects, and commonly used treatment options to manage each side effect.

In late summer of 2016, the survey was sent to all Diplomates of the American Board of Dental Sleep Medicine and all AADSM committee members: 149 of 295 (51%) responded to the survey; 113 (76% of respondents) submitted complete responses and 36 (24% of respondents) submitted partial responses. All responses were reviewed, whether or not the entire survey was completed.

Survey responses were used in conjunction with relevant literature to inform the panel during the voting process (described in the next paragraphs). To facilitate the literature review, panel discussion, and voting, the side effects were assigned to 1 of 6 groups: (1) TMJ-related side effects, (2) intraoral tissue-related side effects, (3) cephalometric changes, (4) occlusal changes, (5) damage to teeth or restorations, and (6) appliance issues.

Modified RAND Appropriateness Method

The RAND Appropriateness Method[3] uses a detailed search of the relevant scientific literature, followed by 2 rounds of anonymous voting by panelists, to arrive at consensus on the appropriateness of a treatment. For this conference, panelists voted on the appropriateness of each treatment recommendation proposed for all side effects. The first round of voting was conducted via email prior to the face-to-face conference. The second round of voting occurred at the conference after discussion of the available evidence and round 1 voting results. In a modification of RAND Appropriateness Method, the panel completed a third round of voting to rate the priority level of all treatment options that the panel agreed were "appropriate" in round 2 voting.

Round 1 Voting

Prior to the conference, panel members independently reviewed the accepted publications and the results of the online survey. Based on their review of this material and their clinical expertise, each member voted to indicate level of agreement with the following statement: *"Based on the available evidence, [Treatment option] is appropriate to manage [Side effect] in patients using oral appliances."* Each panel member expressed their level of agreement with each statement using a 9-point Likert scale where 1 meant "strongly disagree," 5 meant "neither disagree nor agree," and 9 meant "strongly agree."

Median values of panel scores were calculated for each treatment option according to the following categories: scores of 1–3 indicated *inappropriateness* of the treatment option, scores 4–6 described *uncertainty* about the appropriateness of the treatment option, and scores 7–9 signified *appropriateness* of the treatment option. Panel agreement occurred when at least 10 panelists voted within a single category.

For this initial round of voting, panel members were instructed not to discuss the evidence or their votes with one another to ensure independence and anonymity.

Conference Proceedings: Voting Rounds 2 and 3

At the conference, panelists reviewed the results of round 1 voting for each treatment option proposed for each side effect and discussed the available evidence and their clinical experience in treating each side effect. During these discussions, panelists agreed that Cephalometric Changes should be dropped as a category of changes. The 2 side effects included in this category were "increased facial height" and "altered mandibular position." The results of the online survey conducted prior to the consensus conference suggested to the panel that few practitioners note these side effects, and panelists speculated that clinicians do not routinely obtain or analyze lateral cephalograms. Furthermore, the cephalometric changes documented are most likely a manifestation of occlusal changes that result from OAT, rather than separate and independent side effects.

At the conclusion of each discussion, panelists completed round 2 voting for all treatment options proposed for each of the side effects, following the same procedures as round

1 voting. Only those treatment options for which the panel agreed was appropriate in round 2 voting were retained in the final recommendations. Panel agreement on treatment options whose median scores fell into the *inappropriate* or *uncertain* categories, were dropped from further consideration.

A third round of voting was conducted to categorize the treatment options retained after round 2 voting as a "first-line," "second-line," or "uncommon but appropriate" treatment option for each side effect. The "uncommon but appropriate" category was created to acknowledge the possibility that, in infrequent circumstances, an "uncommon" treatment option would be indicated only after the other treatment options were either ineffective, exhausted, or not appropriate for that specific patient.

Development of Recommendations

Upon completion of round 3 voting, the panel members discussed the voting results and developed the recommendations. The final recommendations were submitted to the AADSM Board of Directors for endorsement.

In view of the availability of many titratable oral appliances (degree of protrusion and other settings) this document should not be considered a comprehensive or exhaustive list of side effects or corresponding options for treating the side effects secondary to OAT.

It is expected that these guidelines will be most beneficial to the novice practitioner in the field of dental sleep medicine and will serve to highlight the breadth of adverse effects of OAT and to provide strategies for managing them. In developing these recommendations, the panel was careful to consider various clinical scenarios but elected to address the most common situations, rather than the most esoteric, that clinicians would encounter. The panelists stress that this document should be used in conjunction with the clinical expertise of the practicing dentist and that individual patient needs may necessitate deviation from these recommendations.

RECOMMENDATIONS

Prior to initiating OAT, the treating dentist should document pretreatment tooth positions with baseline records including dental casts, intraoral photographs, and a record of occlusal relationships. Patients must be informed of potential side effects prior to initiating treatment and informed consent must be secured.

Side effects must be assessed and recorded at all follow-up visits, including occurrence, management, and/or resolution. The dentist should refer to the baseline records to identify changes in tooth position and should immediately disclose to the patient such changes and their possible consequences. Other patient concerns should be noted and managed accordingly. If the patient expresses discomfort with continuing OAT, discussion regarding alternative treatment options should occur and be documented.

If the recommendation is made to permanently discontinue OAT, this decision should be made in consultation with the local treating physician to ensure that adequate alternative therapy is available to manage OSA.

Table 1—Side effects.

Temporomandibular joint-related side effects
• Transient morning jaw pain
• Persistent temporomandibular joint pain
• Tenderness in muscles of mastication
• Joint sounds
Intraoral tissue-related side effects
• Soft tissue and tongue irritation
• Gingival irritation
• Excessive salivation/drooling
• Dry mouth
Occlusal changes
• Altered occlusal contacts/bite changes
• Incisor changes
• Decreased overjet and overbite
• Alterations in position of mandibular canines and molars
• Interproximal gaps
Damage to teeth or restorations
• Tooth mobility
• Tooth fractures or damage to dental restorations
Appliance issues
• Appliance breakage
• Allergies to appliance material
• Gagging
• Anxiety

The following side effects and their recommended treatment options are grouped according to similarity in type (see **Table 1**).

In addition to the tailored treatment options recommended for each side effect, the panel recognized that a set of common management techniques should be considered as well, often as first-line therapy. These common techniques are summarized in the following paragraphs, and are identified in the following recommendations when appropriate.

Common Management Considerations

A number of treatment modalities have utility across a broad spectrum of known oral appliance side effects. For consistency and clarity, these are described as follows:

Palliative Care

Palliative care is supportive in nature and intended to manage patient discomfort during the healing phase. It may include any/all of the following options: reassurance, rest, ice, soft diet, topical or systemic pain relief products or anti-inflammatory medication, massage and physiotherapy.

Watchful Waiting

Watchful waiting is the ongoing process of careful and diligent observation, with the possibility of additional assessment along the way, in an effort to better understand the side-effect process. Documentation of findings must be included in the patient's record, and follow-up of concerns at subsequent visits should occur and be recorded regarding persistence, resolution, or management of side effects.

Morning Occlusal Guide

Morning occlusal guide encompasses many custom-made appliances and prefabricated devices used in the effort to

reposition the mandible into its habitual pretreatment position. These devices may function by utilizing biting force to re-seat the condyles to help reestablish/maintain the appropriate occlusal relationship in the morning following each night of OAT. Some of these custom devices may function by reversing changes that may have occurred in tooth position or work to exercise or stretch muscles of mastication as well. They are intended to address the occlusal discrepancy noted after removal of the oral appliance each morning.

Before the patient begins using the oral appliance, the morning occlusal guide is fabricated chairside or by a laboratory, and is often made of hard acrylic, thermoplastic, or compressible materials. The guide must be adapted to the patient's maxillary and mandibular teeth in habitual occlusion, or to dental casts in maximum intercuspation.

Intended to address the occlusal discrepancy noted after removal of the oral appliance each morning, morning occlusal guides also help patients to monitor their condition by allowing them to ascertain whether their mandible is correctly aligned every morning. Each morning after the sleep appliance is worn, the patient should bite into the guide until the maxillary and mandibular teeth are fully seated for as long as it takes the teeth to re-establish occlusion. In the event that the patient is unable to attain proper habitual occlusion, the patient should contact the oral appliance provider.

Daytime Intraoral Orthotic

The daytime intraoral orthotic encompasses many custom-made appliances and prefabricated devices that are retained by either the maxillary or mandibular dentition/implants. These devices are intended to deprogram masticatory muscles, re-seat the mandibular condyles, and/or reduce the magnitude and frequency of bruxism events as well as its consequences. Distinctive from the morning occlusal guide, this device is intended for more active therapy of preexisting or iatrogenically created conditions affecting the TMJ or the masticatory musculature.

Verification and/or Correction of Midline Position

Verification and/or correction of midline position describes an effort to ascertain and maintain the appropriate lateral position of the mandible in its forward position, often similar in lateral dimensions to the nonprotruded (non-treatment) position.

Verification and/or Correction of Occlusion

Verification and/or correction of occlusion describes an effort to ascertain balanced occlusal forces on the oral appliance both bilaterally and anteriorly-posteriorly. This balance may be altered as the mandibular position is advanced or as muscles alternatively relax or contract with use. This may also encompass consideration of changes to the vertical dimension of the oral appliance.

Habitual Occlusion

Habitual occlusion refers to the position of closure between the dental arches in which the patient feels the teeth fit most comfortably with minimal feeling of stress in the muscles and joints.

Note: The term "habitual occlusion" refers to the patient's most comfortable position of jaw closure at any specific time. Many terms have been used to describe the interarch relationship of the maxilla and mandible, often with the intent of providing a reproducible position for restorative purposes. Terms such as centric relation, centric occlusion, maximum intercuspation position, bite of convenience, and intercuspation position have also been used. This paper favors the term "habitual occlusion" because as many as 85% of patients using OAT for more than 5 years demonstrate altered occlusal relationships from baseline.[4]

Isometric and Passive Jaw Stretching Exercises

Isometric and passive jaw stretching exercises include instructing patients to move the mandible against resistance both vertically and laterally and to stretch the mandibular range of motion assisted by the fingers, targeting the masticatory muscles. Examples would include instructing a patient to move the mandible against gentle resistance both vertically and laterally within their physiologic range of motion and using finger pressure to stretch the lateral pterygoid, temporalis, and masseter muscles. These have been shown to decrease the level of discomfort and improve adherence to OAT.[5] Duration and frequency of exercises will be dependent on the ease with which the patient is able to reestablish occlusion.

Conservative Titration

Conservative titration refers to the minimum amount of advancement of the appliance required to manage sleep-disordered breathing. Aarab et al. demonstrated that the number of side effects increases as protrusion exceeds 50%.[6] Moreover, research reveals that both 50% and 75% protrusion can be equally effective in groups of patients with mild to moderate OSA.[7]

Side Effects

The following subsections list each side effect, grouped by category, and describe the recommendations that the panel put forth to manage each one.

Temporomandibular Joint-Related Side Effects

Note: Several online survey respondents mentioned the terms "TMJ degeneration" and "myofascial pain" as potential side effects. A careful review of the literature revealed no instances where these side effects were verifiably reported to have occurred. Furthermore, the panel found that oftentimes in the literature, the terms myofascial pain, myalgia, muscle pain, and muscle tenderness were used interchangeably. It must be noted that these terms often have specific diagnostic criteria and are often used with various definitions across disciplines (physical therapy, physical medicine, etc.). Inaccurate or improper use of these terms in the sleep apnea oral appliance literature has led to confusion regarding diagnosis, prevalence, and management of these conditions among oral appliance users.

Transient Morning Jaw Pain

"Watchful waiting, palliative care, isometric contraction and passive jaw exercise, and decreasing the titration rate are considered first-line treatments to manage transient jaw pain."

Transient jaw pain includes pain or discomfort occurring in the morning upon oral appliance removal that disappears spontaneously during the day or with prescribed exercises or techniques. It also refers to pain or discomfort of short duration, generally less than a few weeks, that might occur intermittently during use of an oral appliance but more likely during acclimation and titration stages. It is considered to be mild in nature, originating in muscles of mastication and unlikely to cause OAT abandonment.

First-line treatment is usually conservative. Watchful waiting or active surveillance entails that the dental provider rule out pain or dysfunction originating in the TMJ and monitor the patient for a worsening of symptoms. Palliative care, in addition to the options mentioned in the Common Management Considerations section, will include patient reassurance that symptoms are likely to decrease, muscle massage, application of heat, and relaxation techniques.[8,9] Isometric contraction and passive jaw exercise[9] may be employed in an effort to alleviate muscle tenderness by a variety of techniques. Decreasing the rate of advancement may also be helpful in improving symptoms.[6]

Symptoms of pain or discomfort that continue or worsen through the day, last more than a few weeks, or interfere with a patient's normal daily function should be considered persistent and may hinder long-term adherence to OAT.

Persistent Temporomandibular Joint Pain

"Palliative care, isometric contraction and passive jaw stretching exercises, verifying or correcting midline positions, appliance adjustment, decreasing the titration rate, decreasing advancement, and conducting a temporomandibular disorder work-up and management are considered first-line treatments to manage persistent temporomandibular joint pain. Placing posterior stops or anterior discluding elements, decreasing wearing time and temporarily discontinuing use of oral appliance therapy are considered second-line treatments. If these treatment options are insufficient or inappropriate, using a daytime intraoral orthotic, prescribing a steroid dose pack, recommending a different oral appliance design, referring to a dental specialist or additional health care provider, and permanently discontinuing oral appliance therapy may also be appropriate."

It is important to document the findings at the initial presentation of persistent joint pain and then at each subsequent visit until symptoms resolve. Reassurance to the patient is essential, as most studies have found that TMJ pain and discomfort—both baseline discomfort and discomfort associated with oral appliance use—decrease with continued oral appliance use.[9–12]

Palliative care for persistent TMJ pain includes resting the joints as much as possible, intermittently applying ice to the affected joints and adopting a soft diet until the pain resolves. The judicious use of anti-inflammatory and pain medication may aid with resolution. Isometric contraction and passive jaw stretching exercises may be beneficial.

Maxillary and mandibular midlines may not be coincident when the patient protrudes without the appliance. It is important to verify that the midline relationship when the appliance is fully seated matches the relationship when the patient protrudes without the oral appliance. Oral appliances that have independent right and left side advancement mechanisms may be adjusted if necessary to re-establish the midline relationship or to provide relief of symptoms. If the TMJ pain is unilateral, decreasing the advancement on the affected side may help. If the dentist is not able to resolve the cause of the persistent TMJ pain, it may be advisable to conduct a thorough examination for TMJ disorder to identify the cause of the pain, with documentation of both muscle and joint function and levels of discomfort during palpation, function, and movement.

Decreasing the advancement rate may facilitate TMJ accommodation to the repositioned mandible. If the appliance has already been advanced to maximum protrusive position, reducing the amount of advancement may be beneficial. Aarab et al. reported that tenderness in muscles of mastication was more prevalent at 50% and 75% maximum protrusion than at 25% maximum protrusion. However, this approach must be balanced against decreasing the optimal therapeutic effect.[6]

Second-line treatment includes the addition of posterior acrylic stops that may increase patient comfort in appliance designs whose contact is otherwise limited to the anterior region. An anterior stop that produces posterior disclusion may be added to appliance designs with flat contact of the maxillary and mandibular elements.

Additional second-line treatment includes instructing the patient to decrease their time wearing the oral appliance. Decreased wearing time may mean wearing the appliance fewer hours each night or fewer nights per week. In the case of severe pain that is affecting the patient's quality of life and sleep, temporary discontinuation of the appliance may be indicated.

If TMJ pain persists despite the aforementioned measures, it may be appropriate to recommend a different oral appliance design. If the existing appliance rigidly holds the mandible, a design that facilitates more jaw movement may improve the pain. Conversely, some patients may benefit from a more rigid design if the existing design permits too much freedom of movement. Refractory temporomandibular symptoms related to OAT are uncommon. These patients may sometimes benefit from a daytime intraoral orthotic and/or referral to a dental practitioner with advanced education in facial pain disorders.

Appropriate options in occasional circumstances include the use of steroid packs or permanent discontinuation of OAT. A steroid pack may be recommended for limited use and in accordance with pharmacologic recommendations. The decision to permanently discontinue oral appliance use is a collaborative decision that should include the patient's local treating physician to ensure that adequate alternative therapy is available.

Tenderness in Muscles of Mastication

"Palliative care, watchful waiting, verifying or correcting midline positions, use of a morning occlusal guide, and isometric contraction and passive jaw stretching exercises are considered first-line treatments to manage tenderness in the muscles of mastication. Decreasing oral appliance advancement, vertical dimension, and the rate of forward titration, modifying the acrylic, and temporarily discontinuing use of oral appliance therapy are considered second-line treatments. If these treatment options are insufficient or inappropriate, recommending a different oral appliance design, referring to a dental specialist or additional health care provider, and permanently discontinuing oral appliance therapy may also be appropriate. In very rare instances, increasing oral appliance advancement may be indicated."

Initial care is usually conservative. Palliative care, in addition to the options mentioned in the Common Management Considerations section, includes muscle massage, application of heat, and relaxation techniques. If inflammation is suspected, the application of cold packs to the affected area may be helpful. Watchful waiting may also be an appropriate first-line treatment. The verification and/or correction of midline position may allow for a more comfortable position for the muscles and other soft tissues. Pain or dysfunction may be attributed to an imbalance in the protractive forces particularly when using an appliance where two separate lateral titration mechanisms are utilized. A morning occlusal guide as described under the Common Management Considerations section may also be considered as an adjunctive therapy to help with muscle tenderness. Isometric and passive jaw stretching exercises may be employed in an effort to alleviate muscle tenderness.

If tenderness in the muscles of mastication continues despite the aforementioned measures, second-line treatments include decreasing the rate of forward titration, decreasing oral appliance advancement, reducing vertical dimension, modification of the acrylic, and temporarily discontinuing use of OAT. A decrease in the titration rate may be appropriate if the optimal mandibular position has not yet been attained. Chen et al. investigated side effects of the Klearway appliance and noted that muscle tenderness in the lateral pterygoid region was more common during the active titration phase.[13] Therefore, it may be beneficial to advance the appliance at a rate lower than usually prescribed. For example, if the patient is instructed to advance the appliance 0.25 mm twice a week, it may be helpful to decrease the advancement to 0.25 mm once a week.

If the appliance has already been advanced to maximum protrusive position, reducing the amount of advancement may be beneficial. Aarab et al. reported that tenderness in muscles of mastication was more prevalent at 50% and 75% maximum protrusion than at 25% maximum protrusion. However, this approach must be balanced against decreasing the optimal therapeutic effect.[6]

Another option to consider is to decrease the vertical dimension of the appliance by judicious adjustment of the acrylic on the occlusal surfaces. With the aid of articulating paper, even contact is verified on all occlusal surfaces after the vertical dimension has been reduced. Acrylic modifications to appliances with dorsal "fins" include reducing the lingual aspect of the fins. This may serve to permit more lateral movement and decrease muscle tenderness.

In order to alleviate persistent muscle tenderness, it may be necessary to temporarily discontinue use of the mandibular advancement appliance until inflammation subsides. Palliative measures, as described previously, may hasten resolution of symptoms, after which oral appliance use may be resumed. Upon resumption of wear, it may be useful to decrease the amount of mandibular advancement and proceed at a slower titration rate until therapeutic benefit is achieved.

In rare instances, it may be appropriate to advance the oral appliance. The decision to advance the appliance may come from subjective information such as the patient reporting continued snoring or nonrestorative sleep. Objective data from home sleep apnea testing or polysomnography revealing continued apneas and/or hypopneas may also indicate the need for advancement or further evaluation and treatment planning.

Recommendation of a different oral appliance design may be necessary if the clinician judges that muscle tenderness is a result of an appliance design that maintains the jaws in a rigid relationship. When choosing an oral appliance design, it may be appropriate to consider appliance designs that permit lateral movement of the jaws if a patient has evidence of lateral bruxism.

The practitioner may also consider referral to an additional health care provider such as a physical therapist to help alleviate muscle tenderness. If, after repeating the TMJ examination, the clinician is unable to determine the cause of muscle tenderness, referral to a dentist who has undergone advanced education in facial pain may be appropriate.[14] Additionally, it is important to recognize that some pain conditions are exacerbated by comorbid conditions and/or changes in the effectiveness of medications such as selective serotonin reuptake inhibitors; thus, consultation with the patient's primary care provider, local treating physician, or other medical specialist may be necessary to appropriately manage muscle tenderness secondary to OAT.

If none of the aforementioned options serve to manage the patient's muscle tenderness sufficiently to continue with OAT, permanent discontinuation of OAT may be necessary.

Joint Sounds

"Watchful waiting is considered first-line treatment to manage joint sounds caused as a result of using an oral appliance. If this treatment option is insufficient or inappropriate, temporary or permanent discontinuation of oral appliance therapy may also be considered."

TMJ sounds secondary to OAT are usually transient and resolve with time.[9,15,16] When they occur, first-line treatment is watchful waiting. This involves recording the type and location of the sounds and what movement or activity elicits the sounds. Patient reassurance and counseling includes a frank discussion about the uncertainty of joint sound resolution, either with continued use of the oral appliance or after discontinuation. If the joint sounds are accompanied by persistent TMJ pain, however, temporary or permanent discontinuation of the oral appliance may be warranted.

Intraoral Tissue-Related Side Effects

Soft Tissue and Tongue Irritation

"Palliative care and appliance modification are considered first-line treatments to manage soft tissue and tongue irritation side effects. Temporarily discontinuing use of the oral appliance is considered second-line treatment. If these treatment options are insufficient or inappropriate, orthodontic wax and switching to a different oral appliance design may also be considered appropriate."

Intraoral soft-tissue side effects including tongue irritation related to OAT are usually transient and minor if addressed promptly.[17,18] Mechanical trauma of the soft tissue is not unique to oral appliances used to treat sleep apnea. It commonly occurs with other oral devices such as dentures and orthodontic appliances. Techniques for treating soft-tissue issues and tongue irritation related to these other dental appliances will also be applicable to appliances used to treat sleep apnea. Palliative care, in addition to the options mentioned in the Common Management Considerations section, includes patient reassurance and application of topical medications. Appliance modification should focus on recontouring the appliance material to remove sharp, protruding, or offensive features that may impinge on the soft tissues. It may also involve the addition of material for the purpose of creating a physical protective barrier or more physiologic contour.

In infrequent instances, orthodontic wax may be recommended for use by the patient as needed over intrusive appliance components that cannot be recontoured or removed.

If intraoral soft-tissue side effects persist despite the aforementioned measures, consider discontinuing use of the oral appliance temporarily in order to remove the potential irritant and promote more rapid soft-tissue recovery. The patient should be encouraged to use continuous positive airway pressure or consult with their local treating physician about alternative OSA treatment during the oral appliance holiday. Use of the oral appliance is resumed after the offending tissue irritation has resolved.

In occasional circumstances, a different oral appliance design may be selected that positions device components in a way that interferes less with the soft tissues.

Gingival Irritation

"Modification of the appliance and palliative care are considered first-line treatments to manage gingival irritation. Discontinuing oral appliance therapy temporarily is considered second-line treatment."

Appliance modification refers to removal of or adjustment to appliance material (such as acrylic or hardware) that may impinge on the gingival tissues. In addition to the options mentioned in the Common Management Considerations section, palliative care includes documentation of gingival health and attachment level.

If gingival irritation persists despite the aforementioned measures, it may be beneficial to discontinue use of the oral appliance temporarily in order to remove the potential irritant and promote more rapid gingival healing. The patient should be encouraged to use continuous positive airway pressure or consult with their local treating physician about alternative OSA treatment during the oral appliance holiday. Use of the oral appliance is resumed after the gingival irritation has resolved.

Excessive Salivation

"Watchful waiting is considered first-line treatment to manage excessive salivation/drooling. Modification to the appliance is considered second-line treatment. If these treatment options are insufficient or inappropriate, prescribing medications to decrease salivary input may also be appropriate."

Numerous studies have demonstrated that oral appliances are well tolerated despite excessive salivation/drooling and only rarely preclude use.[19–23] Excessive salivation is reported very often but generally decreases with time. Patients should be informed in advance of possible excessive salivation and helped to understand that it is typically transient over the first few weeks. Hypersalivation has not been associated with any specific appliance design. Reassurance often suffices to manage excessive salivation/drooling.

Excessive salivation/drooling as a side effect of OAT is generally benign and initial care can be very conservative. Watchful waiting entails recognizing the problematic annoyance to patients and reassuring them that in most cases this issue will subside in a matter of days or weeks. In some cases, when the problem is minimal, patients may simply accommodate to it. Documentation of findings should be included in the patient's record and follow-up of concerns at subsequent visits should occur and be recorded.

Modification to the appliance may be considered in certain instances if it appears that the shape or design of the appliance may be contributing to the excessive salivation/drooling. Decreasing vertical dimension may be appropriate when it is deemed that it will allow for more effective lip seal or greater ease in swallowing. In certain cases, a mouth shield or oral obturator can be added to the appliance to prevent seepage of oral fluids.

Certain medications are known to decrease salivation and can be utilized if the practitioner is well versed in the use of such medications and is certain that the patient's medical history does not contraindicate such use. Consultation with the patient's local treating physician is advisable.

Dry Mouth

"Palliative care, watchful waiting, and decreasing vertical dimension of the device to encourage lip seal, are considered first-line treatments to manage dry mouth. Modification of the appliance and techniques for discouraging mouth breathing are considered second-line treatments. If these treatment options are insufficient or inappropriate, avoiding commercial mouth rinses with alcohol or peroxide, mouth-taping, and referring to an additional health care provider may also be considered appropriate."

Many studies have demonstrated that oral appliances are well tolerated despite dry mouth and only occasionally preclude use.[19,20,23] Dry mouth is reported very often and may continue with time. Patients should be informed in advance of possible dry mouth, especially against the background of nasal airway resistance. Dry mouth was not associated with any specific appliance design.

Dry mouth as a side effect of OAT is generally benign and initial care can be very conservative. Watchful waiting entails recognizing the problematic annoyance to patients and reassuring them that in most cases this issue may subside in a matter of days or weeks, or they may simply accommodate to it. When patients are struggling to continue appliance use due to dry mouth, conservative palliative care can be initiated by decreasing vertical dimension of the appliance to encourage lip seal or keeping water by the bed for adequate hydration during the night.

When it is believed that medications are responsible for dry mouth, consultation with the patient's local treating physician may be beneficial to see if medications can be changed. Limiting tobacco, alcohol, caffeine, and sugary/acidic foods prior to bedtime may be effective in preventing dry mouth during sleep. Similarly, avoidance of commercial mouth rinses with alcohol and peroxide may be effective.

Techniques for discouraging mouth breathing can be considered in certain instances. When nasal airway resistance appears to be leading to mouth breathing during sleep, evaluation and treatment by an otolaryngologist may be effective. If the nasal airway is patent and the patient is amenable, suitable medical tape may be placed over the lips to prevent excessive lip separation. It is prudent to place the tape vertically over the lips to allow passage of air around the sides of the tape should mouth breathing become necessary.

Occlusal Changes

Altered Occlusal Contacts/Bite Changes

"Watchful waiting, jaw stretching exercises, and use of a morning occlusal guide are considered first-line treatments to manage altered occlusal contacts or bite changes. Chewing hard gum in the mornings and making modifications to the appliance are considered second-line treatments. If these treatment options are insufficient or inappropriate, discontinuing oral appliance therapy temporarily or permanently may also be appropriate."

A direct relationship has been demonstrated between the amount of protrusion and the magnitude of the forces sustained by the dental structures. Forces to the maxilla from the oral appliance are directed distally and intrusively to the posterior segments. However, forces to the mandible are directed anteriorly and intrusively to the anterior segments. These force vectors help to explain the occlusal and skeletal side effects associated with the use of oral appliances.[24] The clinician should strive for conservative titration of the appliance, because it has been demonstrated that the number of side effects can be larger, starting at 50% protrusion position.[6] Moreover, research shows that 50% and 75% protrusion can be equally effective in groups of patients with mild to moderate OSA.[25]

Development of posterior open bites is a common occurrence with OAT.[9,18,26–30] In a 5-year follow-up study of 45 patients, Ueda et al. noted that the number of occlusal contacts decreased in 67% of patients.[28] Most of these changes occurred in the premolar and molar regions. In a study of 51 patients using oral appliances, Doff et al. recorded a significant decrease in the number of posterior occlusal contacts after 2 years of OAT.[30] Patients tolerate or are even unaware of such changes and do not discontinue treatment as a consequence.[9,26,27,31,32]

Initial care is usually conservative and includes watchful waiting. Although there is very little literature addressing the use of any method to prevent or correct the amount of occlusal changes, the daily usage of the morning occlusal guide is recommended.

Jig exercises and jaw stretching exercises can also be used, as described by Ueda et al.[33] Jaw exercises may relieve masticatory muscle stiffness and accelerate the repositioning of the mandible to the normal position, in addition to preventing or minimizing the occlusal functional changes in susceptible patients.[33] Anecdotal evidence suggests that chewing gum in the morning may help reestablish habitual occlusion and is suggested as second-line therapy because chewing gum has potentially very few side effects.[34]

In other instances, modification of the appliance by strategic acrylic relief can be considered if altered occlusal contacts appear to be caused by an ill-fitting appliance or if the clinician seeks to reduce the pressure on specific teeth to prevent or minimize potential bite changes.

At times it may be appropriate to temporarily or permanently discontinue OAT. Discontinuation of OAT should only be considered if an alternative treatment is acceptable.[12]

In all cases, decisions to accept or to correct the occlusal changes should be guided by the extent of the problem, acceptability of treatment alternatives, and the concerns of the patient.

Incisor Changes

"Watchful waiting, use of a morning occlusal guide and modification to the appliance are considered first-line treatments to manage incisor angulation and position changes. If these treatment options are insufficient or inappropriate, recommending a different oral appliance design and discontinuing oral appliance therapy permanently may also be appropriate treatment options."

Among the earliest and persistently reported alterations in occlusion secondary to OAT were changes in maxillary and mandibular incisor position and angulation.[4,18,35–38] Pliska et al. reported that anterior crossbites of at least 1 tooth, but more commonly of 4 anterior teeth, occurred in 62% of patients followed for an average of 11 years.[39] Changes in incisor angulation are difficult to quantify without lateral cephalograms, but alterations in incisor anteroposterior position can be documented by serial diagnostic casts.

Changes in incisor angulation and position are generally manifested as changes in overjet and overbite that are perceived by patients and clinicians alike. First-line treatment includes watchful waiting. Modification to the appliance may also be considered first-line treatment to decrease pressure on the incisors. Forces from OAT are directed palatally to maxillary incisors and labially to mandibular incisors and increase nearly linearly with increases in mandibular advancement.[24] Relief of the acrylic contacting the labial surfaces of maxillary incisors and lingual surfaces of mandibular incisors may reduce reciprocal forces on the incisors while wearing an oral appliance. For patients with shallow overbites and minimal overjet, similar acrylic modification to Klearway appliances has been recommended.[13]

Occasionally, it may be necessary to change to a different oral appliance design to decrease or eliminate undesirable forces on the incisors. If the incisor changes are unacceptable and previous treatments are ineffective, permanent discontinuation of OAT may be necessary, but not before consultation with the patient's local treating physician to ensure treatment alternatives to manage OSA are in place.

Decreased Overjet and Overbite

"Watchful waiting, isometric contraction and passive jaw stretching exercises, and use of a morning occlusal guide are considered first-line treatments to manage decreased overjet and overbite. Chewing hard gum in the morning is considered second-line treatment."

Studies suggest a likelihood as high as 85.7% of a decrease in overjet and overbite in patients managed with OAT.[4] Although patients are often unaware of and tolerant of these changes, patients must nonetheless be informed of these risks prior to initiating OAT.

Due to patient acceptance of general changes in overjet and overbite, initial management is usually conservative; first-line treatment consists of watchful waiting.

Morning occlusal guides are considered first-line treatment for decreased overjet and overbite and are widely used. First-line treatment also includes the use of isometric and passive jaw stretching exercises, which may facilitate reestablishment of habitual occlusion.[33]

Chewing hard gum, bilaterally, is recommended as second-line treatment. Though only anecdotal evidence supports this recommendation, this may be an effective treatment to accomplish the same objectives as mandibular exercises.[34]

Alterations in Position of Mandibular Canines and Molars

"Watchful waiting and use of a morning occlusal guide are considered first-line treatments to manage altered positions of mandibular canines and molars."

In the early 2000s, mesial shifting of mandibular molars and canines was recognized as a side effect of OAT in follow-up studies of up to 2.5 years.[19,27,40,41] Analysis of plaster study casts,[4,27,42] cephalometric radiographs, and 3-dimensional computer-assisted study model analysis noted mesial shifting of the canines and molars in as many as 27% of subjects.[13,28,43] In most of these studies, oral appliances completely covered the dentition, and yet dental alterations occurred regardless.[4,19,41] In a study of an oral appliance fabricated from either soft elastomeric material or hard acrylic, significant mesial shifting of first molars and premolars occurred in both groups, although the change was greater in the hard acrylic group.[41]

Other alterations in the positions of the molars and canines have been noted and include changes in arch width and canine rotations. Changes varied by arch, right or left side position, and Angle classification.[4,13,41] Alterations in molar and canine position continue with prolonged OAT.[13,39] Although altered canine and molar positioning may develop in many patients, occlusal changes led to patient nonadherence in only 12.4% of patients surveyed at follow-up after an average of 5.7 years.[44]

Watchful waiting is the first-line treatment of occlusal changes, and evaluation of the patient's dental alignment should continue as long as the patient is using the oral appliance. Evaluations are suggested every 6 months for the first year, and reevaluation at least annually thereafter.[45] If the changes are of concern to the patient, alternative therapies should be reviewed with the patient. If the patient declines to continue OAT, the local treating physician should be notified to ensure continued appropriate management of the patient's OSA.

Morning occlusal guides are also considered first-line therapy for management of the mesial shift of mandibular canines and molars. They may also be used as a record of the patient's pretreatment habitual occlusion.

Inter-Proximal Gaps

"Watchful waiting, use of a morning occlusal guide, adjusting ball clasps and making modifications to the appliance are considered first-line treatments to manage interproximal gaps. If these treatment options are insufficient or inappropriate, use of a distal

wrap-around retainer and restoration of contact areas may be appropriate."

Open interproximal contacts serve as food traps and may concern patients. Development of open contacts has been documented with OAT and is associated with longer oral appliance use.[4] They occur with greater frequency in patients who are Angle Class 1 and are more prevalent in the mandibular arch.[4,42]

First-line treatment includes watchful waiting and the use of a morning occlusal guide to prevent occlusal changes.

If the oral appliance relies on ball clasps for retention, adjustment or removal of retentive clasps may decrease the occurrence of interdental gaps, but it is noteworthy that interproximal gaps have occurred even when the device was acrylic retained and did not utilize ball clasps.[42]

Modification of the device may include adding a small amount of base material to strategic areas of the oral appliance in an effort to reposition the teeth to close open contacts and counteract the forces placed on these teeth by mandibular advancement. For example, placement of material on the oral appliance lingual to the maxillary incisors, labial to the mandibular incisors, or distal to the last teeth in the arch are strategies to accomplish this effect. Judicious reduction of interproximal acrylic "fins" that aid in retention may also decrease the occurrence of interproximal gaps by reducing the interproximal forces from the wedging effect of these retentive fins.

Daytime use of a distal wrap-around retainer, such as a vacuum-formed acrylic splint, to maintain or recapture initial tooth position may also be considered. An orthodontic-type retainer with a distal wrap-around spring may also be effective in closing or preventing interproximal gaps.

If appliance modification is not effective and a periodontal problem develops or the patient continues to complain about food trapping, restoration of the contact area may be required to prevent loss of periodontal support of the teeth. However, because continued use of OAT may lead to re-creating the interproximal spaces, a restorative approach may not be an effective long-term solution.[4]

Damage to Teeth or Restorations

Tooth Mobility

"Palliative care and modifying the appliance are considered first-line treatments to manage tooth mobility. Decreasing the titration rate is considered second-line treatment. If these treatment options are insufficient or inappropriate, daytime/fixed splinting of teeth may also be appropriate."

Palliative care may be sufficient for managing discomfort associated with tooth mobility, tooth tenderness, gingival discomfort, and hypersensitivity. Nonsteroidal anti-inflammatory drugs or other pain relievers may be used to manage the pain of mobility.

Modification of the internal surface of the device in the area of tooth mobility may be necessary to alleviate the discomfort as well as to reduce mobility. The use of various fit-checking materials can help identify areas of increased pressure on affected teeth. Decreasing the oral appliance advancement rate during initial calibration may allow adaptation to the forces of protrusion that are transmitted to the teeth.

Temporary discontinuation of OAT may be helpful in alleviating discomfort associated with the mobile teeth. Palliative measures may hasten resolution of symptoms, after which oral appliance use may be resumed. Upon resumption of wear, it may be useful to decrease the amount of mandibular advancement and proceed at a slower titration rate until therapeutic benefit is achieved. The elimination or modification of anterior ramps, if used on the opposing arch, may also be helpful. Tooth mobility that is detected after the appliance has been advanced to the target protrusion may be addressed by temporarily reducing the protrusive position to allow mobile teeth to adapt to the forces and potentially stabilize before resuming gradual return to the target protrusion.

If mobility does not respond to aforementioned treatments, daytime use of a pressure or vacuum-formed clear retainer, or alternatively bonded resin splinting, may be considered in cases of persistent tooth mobility. Changing to a different oral appliance design may ultimately be necessary.

Tooth Fractures or Damage to Dental Restorations

"Modifying the appliance and referral to a general/restorative dentist are considered first-line treatments to manage tooth fractures or damage to dental restorations. If these treatment options are insufficient or inappropriate, recommending a different oral appliance design may also be appropriate."

Fractures and damage to restorations or teeth may be a direct result of the stresses on the teeth and restorations caused by appliance clasps or other forms of retention. These may also occur indirectly from OAT as a result of changes to the bite, causing increased stresses on the dentition, especially on anterior teeth.

Bite changes from long-term OAT include reduction of overjet that may result in an increase in forces on anterior teeth, causing chipping or fractures.[46] Although anecdotal evidence supports the occurrence of occasional fracture of teeth or restorations, no published studies were identified that describe the frequency of this side effect.

If the dental sleep medicine dentist is also the patient's general or restorative dentist, treatment of tooth chipping or fractures may involve conservative recontouring of rough edges, bonding, or more definitive restoration when warranted. When dental damage occurs, particular attention should be paid to possible occlusal prematurities emerging as a result of the changing overjet/overbite relationship. Selective occlusal adjustment may be considered to reduce the risk of additional chipping or fractures.

When damage to teeth is the direct result of stresses from the appliance, the internal surface of the appliance should

be modified to eliminate forces that potentially caused the fracture of the tooth and/or dental restoration. Any clasps or tight-fitting acrylic adjacent to the damaged tooth or restoration should be adjusted to eliminate stress on that portion of the tooth structure or restoration. This area of the appliance should also be modified sufficiently to permit proper restorative treatment and to reduce the possibility of recurrence.

Ultimately, if the dental sleep medicine dentist is not also the patient's general or restorative dentist, the patient should be referred to their primary dental care provider if restoration of the dentition is needed for cosmetic or functional reasons.

If the appliance design or material has contributed to the fracture of a tooth or dental restoration, a different appliance design and/or material may be indicated to redirect force vectors and retention features from the damaged area.

Appliance Issues

Appliance Breakage

"Repairing or replacing the appliance is considered first-line treatment to manage appliance breakage. If these treatment options are insufficient or inappropriate, recommending a different oral appliance design may also be appropriate."

Appliance breakage is a relatively common problem across the field of dental sleep medicine. Some appliances may be more prone to these problems, and it behooves the prescriber to gain experience and knowledge to help avoid and/or mitigate this treatment complication. Several articles describe appliance breakage or broken components (clasps, acrylic flanges, etc.).[32,47,48] In a 2-year follow-up study of patients treated with a Herbst appliance, Battagel and Kotecha reported that 60% had experienced appliance breakage with subsequent repair and 40% required a replacement appliance.[32] Martínez-Gomis et al. noted that most breakages occurred in the telescopic mechanism of the Herbst appliance.[47]

When an oral appliance has suffered wear or breakage due to fatigue or acute stress, the clinician must judge if repair of the defective appliance is feasible or, if not, recommend replacement of the device. If appliance breakage occurs repeatedly, further investigation is warranted to determine if the underlying cause of the breakage is due to patient behavior or anatomic variation that may be incompatible with that appliance design. If so, replacement of the oral appliance with a different design would be appropriate.

Allergies to Appliance Materials

"Removing the allergenic material and temporary discontinuation of oral appliance use are considered first-line treatments to manage allergies to appliance material. If these treatment options are insufficient or inappropriate, referring to another health care provider may also be considered as a treatment option."

It may be difficult at times to recognize that intolerance to OAT may be due to an allergic response to appliance materials. Moreover, a patient may perceive an allergic response when none actually exists. The clinician will need to distinguish if a true allergic reaction has occurred or if the symptoms are caused by pressure irritation or other irritation from the device or its components. Sometimes the patient will report mucosal dryness, redness, or irritation and mistake these conditions as an allergic response to the appliance.[8]

If the offending allergen can be identified, through allergy testing if necessary, the clinician should ascertain if the appliance can be fabricated without the allergenic material, or replace the appliance with a different design that is fabricated with nonallergenic materials. For example, nickel, a common component in stainless steel, may elicit a hypersensitivity reaction within the first week in some patients. Altering the appliance by substitution of nonallergenic metals such as chrome, gold, and titanium should also be considered.

If the allergenic material cannot be identified, the dentist should inquire about the new or ongoing use of adjunctive intraoral products that might cause the reaction. Such products include but are not limited to toothpastes, mouth rinses, or lozenges. Inquiry regarding materials used to clean the device may also lead to identification of allergens, as common device-cleaning agents can be noxious and offensive to the soft tissues.

Note that some tissue reactions might occur that are not true allergies. If these irritations are significant enough, however, they need to be managed in the same manner as an allergen. Methyl methacrylate acrylic is a common substance used in the fabrication of most oral appliances. If a device is manufactured with inadequate curing (heat/pressure), the material is more porous, less dense, and contains more unlinked monomer. In susceptible individuals, methyl methacrylate acrylic may cause irritation, which can be exacerbated by inadequately cured acrylic.

It is always prudent, if simple measures are ineffective at relieving the irritation/reaction, to refer the patient to another health care provider such as an allergist or dermatologist, or where unavailable, an otolaryngologist or primary care physician for clinical evaluation and testing.

Gagging

"Modification to the appliance is considered first-line treatment to manage gagging. Deprogramming the gag reflex is considered second-line treatment. If these treatment options are insufficient or inappropriate, recommendation of a different oral appliance design may also be appropriate."

Initiation of the gag reflex may be elicited by an oral appliance. Some patients describe this sensation as a feeling of bulkiness from the appliance causing "choking" and "difficulty breathing."[49] Difficulty with swallowing might also activate the gag reflex. In addition, appliances that hold the mandible rigidly may precipitate feelings of anxiety, gagging or panic.

First-line treatment to help mitigate gagging symptoms include modifications to the oral appliance acrylic to decrease

its bulk by thinning the acrylic or trimming it back to the level of the cementoenamel junction if this can be accomplished without affecting appliance retention.[50] Second-line treatment includes desensitization techniques. Use of anesthetic rinse, spray, or gel may alleviate the initial sense of crowding or eliminate the soft-tissue triggers that may give rise to gagging. These as well as other desensitizing techniques may be managed directly by the dental provider or with the help of those more specifically trained in these areas. Cognitive behavioral therapy may also be effective, managed by those specifically trained in its use.

If appliance modifications and/or desensitization techniques fail to resolve the gagging, the practitioner may consider different oral appliance designs that are less bulky, provide more tongue space, permit free lateral movement of the mandible, or allow uninhibited opening and closing.

Anxiety

"Watchful waiting and use of desensitization techniques are considered first-line treatments to manage anxiety. If these treatment options are insufficient or inappropriate, recommending a different oral appliance design and referring to a different health care provider may also be appropriate."

If a specific device holds the mandible tightly in an immovable position, feelings of anxiety, gagging, or panic may ensue. A common phrase within the literature to describe anxiety as a side effect of OAT was the sense of a "suffocation" that led to discontinuation of oral appliance use.[44] "Choking" and "difficulty breathing" were also noted by some researchers to yield levels of anxiousness sufficient to discontinue OAT.[49]

When anxiety presents as a side effect of OAT, watchful waiting may suffice in order to provide the patient an opportunity to accommodate to the appliance. Desensitization techniques may also prove helpful. One technique consists of asking the patient to wear the appliance for a specified time, such as 1 hour, prior to bedtime until the patient establishes an acceptable level of tolerance for the appliance.

A different oral appliance design may be necessary as some features may be more tolerable for anxiety-prone patients. Examples include appliances that allow free lateral movement of the mandible or uninhibited jaw opening and closing or appliances with less bulk that may facilitate easier swallowing.

If success is not achieved through any of the preceding recommendations, it would be prudent to work with the local treating physician to consider alternative definitive or adjunctive therapy including surgery.

SUMMARY OF THE LITERATURE

The recommendations of the consensus panel on the management of the side effects of OAT are based on their clinical expertise and experience and a body of literature that included more than 140 articles. The articles included 29 randomized controlled trials in addition to numerous prospective cohort studies, retrospective studies, reviews, systematic reviews, and meta-analyses. The studies spanned a period of more than 20 years of research on OAT from 1992[51] to 2016.[52] The findings represent diverse populations: Europe,[12] North America,[9] New Zealand,[53] Australia,[54] Asia,[55] and South America.[5]

Side effects were recorded from studies comparing one appliance design to another,[17,18,50,55,56] OAT to continuous positive airway pressure,[37,57–60] different protrusive positions in the same appliance,[6,7] OAT versus placebo,[54] and OAT versus uvulopalatopharyngoplasty.[25] The literature included a report on side effects in subjects who had been wearing an oral appliance for a minimum of 8 years[39] and others in whom use of an oral appliance had been at least 2 years.[11,18,30,40,61] Most side effect reports were derived from patient self-report through questions at examination, mail or phone questionnaires, or a combination of these methods. The reporting periods ranged from several days after commencing OAT to several years. Side effects that are quantifiable have been extensively and systematically studied using imaging techniques[27,62,63] or analysis of dental casts.[13,39,41,42]

Although most studies describe the type and frequency of side effects, only a few comment on strategies used to mitigate the side effects, and informative details are lacking.[55,56,62,64,65] Even fewer studies investigate interventions to minimize side effects.[5,29,33]

Reports of discomfort or pain in the teeth, muscles, TMJ, tongue, or other oral structures are common. However, only a limited number of studies describe using structured clinical examination methods to evaluate the prevalence and/or incidence of dysfunction and/or pain in the TMJ, muscles of mastication, and teeth or oral structures.[9,11,12,25,40,61,66–69]

Although research in the field of dental sleep medicine has advanced considerably over the past two decades, more information is needed to develop evidence-based guidelines on the most effective treatment options to manage the side effects of OAT for sleep-disordered breathing.

DISCUSSION AND FUTURE DIRECTIONS

Some side effects of OAT are common, causing permanent alterations in dental occlusion and, less often, soft-tissue or TMJ pain, which may negatively affect long-term adherence with therapy. Although guidelines exist for long-term follow-up of all patients using OAT to treat OSA—a lifelong disease with age-related increase in severity—sparse information is available to guide clinicians on how to address side effects related to OAT. The current literature is rife with descriptions of side effects but is lacking in the clarification of causative factors and methods to minimize these adverse effects. Few published data clarify what interventions are most effective, and the recommendations offered are rarely evidence driven. Available studies suggest that side effects may be related to oral appliance design, materials, and amount of mandibular advancement, and long-term studies describe a progressive increase in occlusal side effects with ongoing use of OAT.

Current evidence supports watchful waiting as the major treatment for OAT-related side effects unless discomfort is

present. Most interventions are palliative, involve modification of the oral appliance, or require no active therapy. Many of the side effects were thought to be best addressed prophylactically with use of a morning occlusal guide to help prevent occlusal alterations or to minimize transient muscle contraction. However, it must be noted that despite the widespread use of this technique, no evidence to date has demonstrated its effectiveness.

At this conference, consensus on recommended treatment options was reached among the panelists based on limited empirical evidence. Decisions were often informed by clinical experience and the results of an online survey of practitioners of dental sleep medicine. It is anticipated that these recommendations will highlight specific questions that need clarification and will encourage researchers to design studies to advance the field.

Standardization of both the definition of OAT success as well as clinical and outcome measures in OAT research would enable meaningful comparison across studies. Investigation is needed to clarify factors that lead to the onset and progression of side effects such as appliance design features, appliance materials, vertical and sagittal mandibular positioning, and duration of OAT. Anthropomorphic and imaging studies may help identify patients at greater risk for the occurrence of side effects.

Ultimately an understanding of how the management of OAT side effects influences OAT adherence will ensure that patients with sleep-disordered breathing are optimally treated. More evidence is needed to identify the most effective strategies for minimizing or preventing the occurrence of untoward side effects. Outcomes of research that focuses on these issues are expected to lead to revisions of these recommendations in the future.

These recommendations have been endorsed by the AADSM.

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SPECIAL ARTICLES

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Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015

An American Academy of Sleep Medicine and American Academy of Dental Sleep Medicine Clinical Practice Guideline

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Introduction: Since the previous parameter and review paper publication on oral appliances (OAs) in 2006, the relevant scientific literature has grown considerably, particularly in relation to clinical outcomes. The purpose of this new guideline is to replace the previous and update recommendations for the use of OAs in the treatment of obstructive sleep apnea (OSA) and snoring.

Methods: The American Academy of Sleep Medicine (AASM) and American Academy of Dental Sleep Medicine (AADSM) commissioned a seven-member task force. A systematic review of the literature was performed and a modified Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process was used to assess the quality of evidence. The task force developed recommendations and assigned strengths based on the quality of the evidence counterbalanced by an assessment of the relative benefit of the treatment versus the potential harms. The AASM and AADSM Board of Directors approved the final guideline recommendations.

Recommendations:

1. We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). (STANDARD)
2. When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)
3. We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)
4. We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)
5. We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)
6. We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

Conclusions: The AASM and AADSM expect these guidelines to have a positive impact on professional behavior, patient outcomes, and, possibly, health care costs. This guideline reflects the state of knowledge at the time of publication and will require updates if new evidence warrants significant changes to the current recommendations.

Keywords: obstructive sleep apnea, snoring, oral appliance, mandibular advancement, positive airway pressure

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SUMMARY

Since the publication of the initial position statement by the American Academy of Sleep Medicine (AASM) in 1995, the clinical use of oral appliances (OAs) for the treatment of snoring and obstructive sleep apnea (OSA) has markedly increased. The most recent AASM practice parameters on the treatment of snoring and OSA with oral appliances was published in 2006 as "Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005" with the accompanying systematic review paper "Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review." Since these publications, the scientific literature on OAs has grown considerably, particularly related to clinical outcomes after use of OAs. The purpose of this guideline is therefore to replace the recommendations in the 2006 guideline for the use of OAs in the treatment of OSA and snoring.

Methods

To develop this guideline, the AASM and American Academy of Dental Sleep Medicine (AADSM) commissioned a task force of seven members, three sleep medicine physicians and two dentists, with expertise in the use of OAs, and two

AASM research staff members experienced in guideline development. None of the task force members had any conflicts that would preclude participation in this effort. Eleven PICO (patient, population or problem, intervention, comparison, and outcomes) questions were developed based on both the questions raised in the 2006 AASM review paper and practice parameter and review of systematic reviews, meta-analyses, and guidelines published since then (Table 1). The AASM Board of Directors approved the final list of PICO questions before the targeted literature search was performed.

The literature search was performed by the AASM research staff using the PubMed and Embase databases. Though the search yielded all types of articles with various study designs, for most PICO questions the analysis was limited to only randomized controlled trials (RCTs). The RCTs that were cited in the 2006 AASM review paper and 2006 practice parameter paper were included for data analysis if they met the study inclusion criteria. For PICO questions 7 and 11, due to lack of RCTs, we relied on prospective observational studies. The PubMed database was searched from January 1, 2004, through July 31, 2012, and was updated again on February 28, 2013, to capture the latest literature. A total of 324 citations were identified in PubMed and supplemented by pearling. A total of 53 citations were identified in Embase, yielding a total of 377 citations from both databases.

Meta-analysis was performed with Review Manager 5.2 software to compare various types of OAs used to treat snoring and OSA. Oral appliances were categorized into the following types: custom, titratable; custom, non-titratable; non-custom, titratable; and non-custom, non-titratable. Meta-analysis was performed for each PICO question by pooling data across studies for each outcome measure. All analyses were performed using the random effects model. The result of each meta-analysis is shown as a forest plot.

The assessment of evidence quality was performed according to a modified Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process. The final assessment, as defined in Table 3, was determined for each treatment and outcome measure. The results are reported as evidence profiles for each PICO question that include the number of studies, study design, limitations, inconsistency, indirectness, imprecision, and other considerations that went into determining the quality of evidence for each outcome of interest. The task force then developed recommendations for the efficacy of OA treatment for snoring and OSA. Strengths of recommendation were assigned to these statements based on the quality of the evidence and counterbalanced by an assessment of the relative benefits of the treatment versus the potential risks as delineated in Table 4.

This guideline refers to a "qualified dentist" as the dental provider of choice to provide oral appliance therapy. The successful delivery of oral appliances requires technical skill, acquired knowledge, and judgment regarding outcomes and risks of these therapies. The need to append the word "qualified" stems from two things: (1) all of the studies conducted to evaluate the efficacy and risks of oral appliances were conducted by dentists with considerable experience in dental sleep medicine, and (2) the unfortunate fact that training in dental sleep medicine is uncommon. Therefore, not all dentists have the training or experience required to deliver knowledgeable care, and application of the literature to practice dental sleep medicine.

The American Academy of Dental Sleep Medicine (AADSM) is one of several organizations that has begun to address this issue over the past decade via the development and delivery of educational programs in dental sleep medicine along with the development of a certifying examination in dental sleep medicine that is now administered and maintained by the American Board of Dental Sleep Medicine (ABDSM). As physicians diagnose and subsequently refer patients with OSA to select dentists to evaluate for delivery of oral appliance therapy, they should seek qualified dentists who have a valid state license and proof of liability coverage and possess additional training or experience in this area of care. Although not all-inclusive, desirable qualifications include that the dentist have at least one of the following: certification in dental sleep medicine by a non-profit organization, designation as the dental director of a dental sleep medicine facility accredited by a non-profit organization, or a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school in the last two years.

OSA is a chronic disorder and therefore would be best diagnosed and followed by a sleep physician in cooperation with any other healthcare providers the patient may be going to for treatment (their primary care physician, a qualified dentist, ENT, etc.). For the purposes of this guideline, a sleep physician is defined as a physician who is either sleep board-certified or sleep board-eligible. A multicenter, prospective, comparative effectiveness study showed that board-certified sleep physicians and accredited centers improved patient-centered outcomes for OSA patients. Also, most of the RCTs that were reviewed to develop the recommendations in this current guideline were conducted by sleep physicians and investigators as defined by the above criteria.

Results

Our assessment of the efficacy of different OAs, as compared to each other and to PAP for different levels of OSA severity (mild, moderate, and severe), was based on very limited evidence. Most of the studies accepted for inclusion in this guideline did not provide sub-analyses of results based on different levels of OSA severity. Therefore, the recommendations presented below do not provide guidance for treating OSA patients with specific levels of severity. Meta-analyses performed using the limited available evidence indicates that OAs can significantly reduce the apnea hypopnea index/respiratory disturbance index/respiratory event index (AHI/RDI/REI) across all levels of OSA severity in adult patients. There was no statistically significant difference in the mean reduction in AHI before and after treatment using OAs versus CPAP across all levels of OSA severity. Moreover, there was no significant difference between OAs and CPAP in the percentage of mild OSA patients achieving their target AHI/RDI/REI (< 5, < 10, > 50% reduction) after treatment. For patients with moderate to severe OSA, however,

the odds of achieving the target AHI were significantly greater with CPAP than with OAs.

Our assessment of factors that may be used to predict treatment success in adults with OSA was also based on very limited evidence. We found that treatment success was usually defined as a reduction in the AHI/RDI/REI to a specific level (e.g., post-treatment AHI/RDI/REI < 5, > 50% reduction in AHI/RDI/REI). However, there were no reported factors that consistently predicted treatment success. Specifically, there was conflicting evidence for the use of age, gender, neck circumference, body mass index (BMI), and cephalometric measurements to predict treatment success. Patient preference for OA versus CPAP should be considered by the treating sleep physician before therapy is prescribed. The strength of each recommendation was not only made based on the quality of evidence, but also incorporated patient preference along with other factors such as cost, value, and other patient-related factors.

Summary of Recommendations

1. We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). (STANDARD)

Quality of Evidence: High

Values and Trade-Offs: Oral appliances (OAs) reduce the frequency and intensity of snoring, improve sleep quality for both patients who snore and their bed partners, and improve quality of life (QOL) measures. Though the available evidence on these outcomes is limited, we gave this a STANDARD strength of recommendation, as the possible benefits from treatment of primary snoring clearly outweigh the risk. Insufficient evidence exists to conclude that treatment of primary snoring improves other health-related outcomes, or to compare objective sleep quality during use of oral appliances versus other treatments. Therefore, OAs should be recommended for patients who snore who fail conservative measures (such as weight loss, positional therapy, and avoiding alcohol) and request further treatment. Diagnosis of primary snoring should be rendered by a sleep physician and not a dentist, as snoring is frequently accompanied by OSA, and misdiagnosis can have serious implications for the patient.

2. When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: The overall grade for the body of evidence exploring the impact of custom vs. non-custom OAs to treat OSA varies between low and moderate depending on the physiologic sleep outcome measures. A systematic review of the evidence has shown that custom, titratable OAs reduce the AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation to a greater extent than do non-custom OAs. The evidence supports the use of custom, titratable OAs over other types of appliances. Although the reduction in AHI and ODI are similar for both custom, titratable and custom, non-titratable OAs, the confidence interval for the effect of the custom, titratable OAs is considerably smaller than for the custom, non-titratable appliances. Both types of custom appliances are more effective than non-custom OAs.

Neither custom nor non-custom OAs have been shown to significantly affect sleep architecture and sleep efficiency. However, the overall improvement in other physiologic sleep parameters with the use of custom OAs in adult patients with OSA should result in an improvement in daily function and quality of life.

The available data also suggest that OAs effectively improve daytime sleepiness. The mean change in the Epworth Sleepiness Scale (ESS) with custom, titratable OAs is moderate. The reduction in subjective daytime sleepiness achieved with custom titratable OAs is not inferior to that reported with CPAP therapy. In contrast, very limited data suggest that custom, non-titratable OAs do not produce a significant change in ESS. Insufficient data are available to assess objective measures of sleepiness or wakefulness following OA therapy.

The evidence indicates that OAs are also effective in improving QOL. Specifically, custom, titratable OAs provide moderate improvement in QOL outcomes. The data on QOL is very limited for custom, non-titratable OAs, and therefore their use cannot be recommended to improve QOL.

3. We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)

Quality of Evidence: Moderate

Values and Trade-Offs: A review of the evidence suggests that adherence rates using OAs are greater than those observed with CPAP. However, no randomized controlled trials have assessed objective OA adherence rate as compared with CPAP. The subjective reporting of adherence rate is prone to bias, and needs to be interpreted with caution as patients may overestimate their OA use. However, a patient whose OSA does not improve with the use of CPAP or is intolerant to CPAP may benefit from the use of an OA. Overall, the discontinuation of therapy due to side effects occurs less when using OAs versus CPAP to treat adult patients with OSA.

The overall grade for the body of evidence on the impact of OAs to treat obstructive sleep apnea (OSA) varies between low and moderate depending on the physiologic sleep outcome measures. A systematic review of the evidence has shown that OAs reduce AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation. However, OAs have shown no significant effect on sleep architecture and sleep efficiency. The overall improvement in physiologic sleep parameters with the use of OAs in adult patients with OSA should result in an improvement in daily function and quality of life. Although OAs have been shown to improve physiologic sleep parameters, continuous positive airway pressure (CPAP), in our meta-analyses, was found to be superior to OAs

in reducing the AHI, arousal index, and oxygen desaturation index and improving oxygen saturation, and therefore, should still generally be the first-line option for treating OSA. The improvement in QOL produced by custom, titratable OAs is not inferior to that reported with CPAP therapy. The quality of evidence for the use of these OAs to improve QOL is moderate, whereas the quality of evidence comparing OAs to CPAP is low. The custom, titratable OAs improve QOL, but as with CPAP, reduced QOL may persist despite otherwise adequate therapy.

The available data regarding the impact of OAs on blood pressure are more limited (overall grade for the body of evidence is low) than the data addressing blood pressure change with CPAP. For example, the role of OAs in patients with resistant hypertension has not yet been evaluated. However, the available data suggest that OAs may be as effective as CPAP in at least select patient populations to lower blood pressure and therefore should not preclude the use of either therapy or diminish the other established benefits that accrue from treatment of OSA. Of note, no RCTs have assessed the impact of OA therapy on other cardiovascular endpoints.

In summary, OAs may be effective in improving sleep parameters and outcomes of OSA, and there is little likelihood of harm. Although they are not as efficacious as PAP therapy, the benefits of using OAs outweigh risks of not using OAs. Thus, a STANDARD strength of recommendation to use OAs was provided.

4. We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: Beneficial treatment effects may be reduced by treatment-related side effects, and most OA therapy side effects are dental. A wide range of devices made from a variety of materials and having different characteristics are utilized in clinical practice. Literature on dentists performing interventions to prevent failure of OA therapy is limited, although the topic is mentioned in the results and discussion sections of some publications. Therefore, the overall evidence in support of the above recommendation was considered low. Nevertheless, minimization of side effects may improve adherence and thereby patient outcomes. Several studies demonstrated dental interventions to mitigate side effects. Additionally, knowledge of dental materials and a variety of dental devices including the knowledge of the patients' dental status will likely ensure fewer side effects. A qualified dentist will be able to screen for many problems and choose and/or build the OA with features to minimize the side effects of the therapy. A qualified dentist will have the skills to choose the proper OA and make necessary modifications to accommodate patients who, among other things, may have allergies to metals or acrylics, are strong teeth grinders, or have anatomical deviations. The patient's history and exam, appliance preference, and review of any side effects should be taken into account to avoid device breakage, allergic reactions, or discomfort that leads to frustration or discontinuation of the therapy.

5. We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: The overall grade of evidence for support of follow-up evaluations and testing by sleep physicians is low due to a lack of evidence. However, the discussion sections in most research studies report significant improvement in OA efficacy when changes were made to the appliances based on data obtained either during or after the sleep studies. While insufficient evidence exists to produce a meta-analysis, the available data suggest that subjective feedback is not sufficient to determine the optimal setting of the OA in the management of OSA. Without objective data the patient may, unnecessarily, remain sub-optimally treated. Follow-up sleep testing by sleep physicians should also be considered for OA-treated patients who develop recurrent symptoms, show substantial weight changes, or receive diagnoses of comorbidities relevant to OSA.

6. We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

Quality of Evidence: Low

Values and Trade-Offs: A review of the evidence suggests that patients may benefit from periodic follow-up visits with a physician and with a qualified dentist. Several studies have demonstrated that adjustments made to the OA by a dentist, based on data obtained from PSGs and home sleep apnea tests conducted by a physician, may result in greater long-term improvement in OSA. The absence of periodic follow-up visits may result in suboptimal improvement in OSA or side effects that increase risk for discontinuation of therapy.

1.0 INTRODUCTION

Snoring and obstructive sleep apnea (OSA) are common sleep disorders resulting from repetitive narrowing and collapsing of the upper airway. Untreated OSA is associated with multiple adverse health outcomes including systemic hypertension, coronary artery disease, stroke, atrial fibrillation, increased motor vehicle accidents, congestive heart failure, daytime sleepiness, decreased quality of life, and increased mortality.[1] Snoring is also a significant social problem and contributes to decreased quality of life for bed partners through disrupted sleep.[2] Snoring itself may have a negative health impact, such as increased risk for cardiovascular disease.[3]

In recent years, oral appliances (OAs) have become an increasingly common treatment modality for OSA and snoring. Although positive airway pressure (PAP) remains the most common and most efficacious treatment for sleep disordered breathing, OAs offer effective therapy for many patients with OSA. These devices offer advantages over PAP in that they do not require a source of electricity and are less cumbersome, especially with travel. Oral appliances are well tolerated in most patients, and therapeutic adherence may be better than CPAP.[4]

Since the publication of the initial position statement by the American Academy of Sleep Medicine (AASM) in 1995, the clinical use of OAs for the treatment of snoring and obstructive sleep apnea has markedly increased. The most recent AASM practice parameters on the treatment of snoring and OSA with oral appliances was published in 2006 as "Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005" with the accompanying systematic review paper "Oral Appliances for Snoring and Obstructive Sleep Apnea: A Review."[5,6] Since the publication of the previous review paper and practice parameters, the scientific literature on oral appliances has grown considerably, particularly related to clinical outcomes after use of OAs, and hence the recommendations in this guideline will replace the recommendations in the 2006 guideline for the use of OAs in the treatment of OSA and snoring.

This guideline refers to a "qualified dentist" as the dental provider of choice to provide oral appliance therapy. The successful delivery of oral appliances requires technical skill, acquired knowledge, and judgment regarding outcomes and risks of these therapies. The need to append the word "qualified" stems from two things: (1) all of the studies conducted to evaluate the efficacy and risks of oral appliances were conducted by dentists with considerable experience in dental sleep medicine, and (2) the unfortunate fact that training in dental sleep medicine is uncommon. Therefore, not all dentists have the training or experience required to deliver knowledgeable care, and application of the literature to practice dental sleep medicine.

The American Academy of Dental Sleep Medicine (AADSM) is one of several organizations that has begun to address this issue over the past decade via the development and delivery of educational programs in dental sleep medicine along with the development of a certifying examination in dental sleep medicine that is now administered and maintained by the American Board of Dental Sleep Medicine (ABDSM). As physicians diagnose and subsequently refer patients with OSA to select dentists to evaluate for delivery of oral appliance therapy, they should seek qualified dentists who have a valid state license and proof of liability coverage and possess additional training or experience in this area of care. Although not all-inclusive, desirable qualifications include that the dentist have at least one of the following: certification in dental sleep medicine by a non-profit organization, designation as the dental director of a dental sleep medicine facility accredited by a non-profit organization, or a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school in the last two years.

OSA is a chronic disorder and, therefore, would be best diagnosed and followed by a sleep physician in cooperation with any other healthcare providers the patient may be going to for treatment (their primary care physician, a qualified dentist, ENT, etc.). For the purposes of this guideline, a sleep physician is defined as a physician who is either sleep board-certified or sleep board-eligible. A multicenter, prospective, comparative effectiveness study showed that board-certified sleep physicians and accredited centers improved patient-centered outcomes for OSA patients.[7] Also, most of the RCTs that were reviewed to develop the recommendations in this current guideline were conducted by sleep physicians and investigators as defined by the above criteria.

2.0 BACKGROUND

2.1 Nomenclature, Types, and Definition of an Effective Oral Appliance

Oral appliances are devices intended to protrude and stabilize the mandible to maintain a patent airway during sleep.[8] A custom OA is "fabricated using digital or physical impressions and models of an individual patient's oral structures. As such, it is not a primarily prefabricated item that is trimmed, bent, relined, or otherwise modified. It is made of biocompatible materials and engages both the maxillary and mandibular arches."[8] Non-custom OAs, commonly known as "boil and bite devices," are primarily prefabricated and usually partially modified to an individual patient's oral structures. There are also custom-made and non-custom-made OAs that hold the tongue forward and are called tongue retaining devices (TRDs), and these have to be distinguished from the OAs. There was insufficient evidence to assess the efficacy of TRDs for the treatment of adult patients with OSA.

In addition to being custom- or non-custom-made, OAs are either titratable or non-titratable. Titratable OAs have a mechanism that allows for varying amounts of mandibular protrusion. The increasing protrusion of the mandible is considered analogous to the titration of continuous positive airway pressure (CPAP). Non-titratable OAs hold the mandible in a single protrusive position, and no changes are possible over the course of treatment.

The American Academy of Dental Sleep Medicine (AADSM) published a definition of an *effective* OA in March 2013,

Table 1—PICO Questions.

1. In adult patients with primary snoring, do oral appliances (OAs) improve snoring, sleep quality, including the bed partner's sleep quality, and/or quality of life measures compared to other therapies or no treatment?
2. In adult patients with obstructive sleep apnea (OSA) (irrespective of underlying severity of OSA, and for each mild, moderate, or severe OSA), do oral appliances improve the apnea hypopnea index (AHI)/respiratory disturbance index (RDI)/respiratory event index (REI), oxygen saturation, arousal index, and/or sleep architecture compared to other therapies or no treatment?
3. In adult patients with OSA, do OAs improve cardiovascular endpoints, such as hypertension, coronary artery disease, myocardial infarction, and/or arrhythmias, as compared to other therapies or no treatment?
4. In adult patients with OSA, do OAs improve quality of life measures, and/or objective and subjective daytime sleepiness, as compared to other therapies or no treatment?
5. In adult patients with OSA, do titratable OAs improve AHI/RDI/REI, oxygen saturation, arousal index, and/or sleep architecture and do they improve long-term management of OSA with outcome measures such as AHI/RDI/REI, sleep quality, quality of life measures, cardiovascular endpoints, and/or subjective/objective measures of sleepiness compared to non-titratable OAs?)
6. In adult patients with OSA, do OAs lead to mild or serious side effects compared to those treated with other therapies or no treatment?
7. In adult patients with OSA, do follow-up oximetries, home sleep apnea tests, polysomnograms, or follow-up with a sleep physician improve long-term management with OAs as compared to no follow-up?
8. In adult patients with OSA, does follow-up with dentists/sleep specialists improve adherence and reduce side effects associated with OAs compared to those who do not have follow-up?
9. In adult patients with OSA, does OA use show better adherence than that reported by subjective or objective measures for PAP therapy?
10. In adult patients with OSA, do different types of OAs have variable effectiveness in controlling sleep-disordered breathing as measured by the AHI/RDI/REI and/or other outcome measures such as sleep quality, quality of life measures, cardiovascular endpoints, and/or objective/subjective daytime sleepiness?
11. In adult patients with OSA, what are the factors that predict success with OAs compared to other therapies or no treatment?

focusing on custom-titratable OAs.[8] This definition was developed at a consensus conference attended by a group of experienced dental sleep medicine researchers and clinicians using a modified RAND Appropriateness Method. The definition was unanimously approved by the conference attendees and then subsequently approved by the AADSM Board of Directors. A manuscript detailing the conference, the process, the literature search, grading, and review has also been published.[8]

Currently, there is no universal terminology to describe oral appliances that are used to treat OSA. The plethora of terms is potentially confusing. Commonly used terms include, but are not limited to: mandibular advancement device (MAD), mandibular repositioning device (MRD), mandibular advancement splint (MAS), and mandibular advancement appliance (MAA). Throughout this guideline paper, we use the term "oral appliance (OA)" to refer to all of these different types. We will, however, specify whether they are custom or non-custom made and whether they are titratable or non-titratable OAs. A preferred term chosen by the AADSM may lead to less confusion in the field.

3.0 METHODS

3.1 Expert Task Force

To develop this guideline, the AASM and AADSM commissioned a Task Force of seven members, three sleep medicine physicians and two dentists with expertise in the use of oral appliances, and two AASM research staff members experienced in guideline development. Prior to being appointed to the Task Force, the content experts were required to disclose all potential conflicts of interest (COI) according to the AASM's COI policy. None of the task force members had any conflicts that would preclude participation in this effort. The Task Force members performed an extensive review of the scientific literature to draft recommendations and supporting text for the use of OAs in the treatment of snoring and OSA.

3.2 PICO Questions

PICO (patient, population or problem, intervention, comparison, and outcomes) questions were developed based on both the questions raised in the 2006 AASM review paper[5] and practice parameter[6] and review of systematic reviews, meta-analyses, and guidelines published since then (Table 1). The PICO format is an established framework for subsequently guiding literature searches targeted at addressing the PICO questions and developing evidence-based clinical practice recommendations. After a thorough review, editing, and approval of these questions by the task force members, the AASM Board of Directors approved the final list of PICO questions before the targeted literature search was performed.

3.3 Literature Search

The Task Force members performed an extensive review of the scientific literature to retrieve articles which addressed at least one of the eleven PICO questions. The literature search was performed by the AASM research staff using the PubMed and Embase databases. Though the search yielded all types of articles with various study designs, for most PICO questions the analysis was limited to only randomized controlled trials (RCTs) as RCTs are considered a higher quality of evidence than observational, nonrandomized, or before-after interventional studies. The RCTs that were cited in the 2006 AASM review paper[5] and 2006 practice parameter paper[6] were included for data analysis if they met the study inclusion criteria. For PICO questions 7 and 11, due to lack of RCTs, we relied on prospective observational studies. The literature search in PubMed was conducted using a combination of MeSH terms and keywords. The MeSH terms were: Sleep Apnea Syndromes, Snoring, Orthodontic Appliances, and Mandibular Advancement/Instrumentation.

The keywords were: sleep apnea, sleep apnoea, sleep-related breathing disorders, sleep-disordered breathing, oral, intraoral, dental, orthodontic, mandibular, tongue-retaining, tongue-stabilizing, occlusal, titratable, titrated, appliance(s), splint(s), device(s), OA, or snoring. The limits of the search (criteria that all had to be met) were: humans, English, all adults (no pediatrics), and RCTs. The RCT limitation was not used for PICO questions 7 and 11. The PubMed database was searched from January 1, 2004, through July 31, 2012, for any relevant literature published since the last guideline. This search was updated again on February 28, 2013, to capture the latest literature. A total of 324 citations were identified in PubMed and supplemented by pearling (i.e., checking the reference sections of search results for articles otherwise missed). The literature search in Embase was performed using a combination of disorder and treatment terms. The disorder terms were: sleep apnea, sleep apnoea, sleep apnea syndrome, sleep-related breathing disorders, or sleep-disordered breathing. The treatment terms were: orthodontic device, mandible reconstruction, oral, intraoral, dental, orthodontic(s), mandibular, tongue retaining, tongue-stabilizing, occlusal, titratable, or titrated. The presence of any one of these terms in the title or abstract of a publication would identify a potentially relevant article for inclusion in data analysis. The limits of the search were: humans, English, adults, and RCTs. The RCT limitation was not used for PICO questions 7 and 11. The Embase database was searched from January 1, 2004, through August 31, 2012. This search was updated again on February 28, 2013, to capture the latest literature and cross-checked with the results from the PubMed search to find any previously unidentified articles. A total of 53 citations were identified in Embase, yielding a total of 377 citations from both databases.

Abstracts from these articles were assessed by two task force members to determine whether they met inclusion criteria. However, if there were any questions on whether the abstract met the inclusion criteria, the article was reviewed in detail to determine whether to accept or reject. Articles were included for evaluation if they focused on treatment of snoring and/or OSA with OAs, and included only adult subjects. Included articles also had to address at least one of the eleven "PICO" questions identified ahead of the review process. Articles were accepted if they used either the apnea hypopnea index (AHI) or the respiratory disturbance index (RDI) as determined by an overnight polysomnogram (PSG) or the respiratory event index (REI) as determined by a home sleep apnea test. However, there were 3 articles that did not necessarily meet the above criteria, but were still included in our analysis.[9–11] In two studies by Gauthier et al., RDI was defined as the combination of apneas, hypopneas and arousals per hour of sleep,[9,10] while Gotsopoulos et al. defined AHI as the combination of apneas, hypopneas, and arousals per hour of sleep.[11] The Task Force acknowledges that there are limitations to the direct comparisons made in this guideline due to the variety of ways AHI, RDI, and REI are defined and scored among the studies included. Articles were excluded if they focused on diagnosis, described the use of OAs to treat central or complex sleep apnea, or if they were studies on pediatric patients. A total of 51 articles met these criteria and were used for data extraction, meta-analysis, and grading.

3.4 Meta-Analysis

Meta-analysis was performed with Review Manager 5.2 software to compare various types of OAs used to treat snoring and OSA. Oral appliances were categorized into the following types: custom, titratable; custom, non-titratable; non-custom, titratable; and non-custom, non-titratable. Meta-analysis was performed for each PICO question by pooling data across studies for each outcome measure. All analyses were performed using the random effects model. The result of each meta-analysis is shown in a forest plot. Individual studies in the meta-analysis are identified in a table that includes the mean and standard deviation (SD) of the outcome measure and the number of patients. The pooled results are expressed as the total number of patients and mean difference between the experimental treatment and the control or between the baseline and final values of the outcome measure. The center of the black diamond at the bottom of the plot indicates the mean difference (i.e., average response or magnitude of effect) across all studies. The width of the black diamond represents the 95% confidence interval of the mean difference. The zero line represents no effect. If the black diamond does not touch the zero line, and lies beyond the clinical decision threshold, the treatment is considered either effective or ineffective depending on which side of the zero line the diamond lies.

It should be noted that for a number of PICO questions there was insufficient evidence to perform meta-analyses for certain comparisons and outcome measures. For example, the efficacy of OAs was only compared with CPAP, as there was insufficient evidence to compare OAs to other therapies, such as conservative treatment or surgery. Therefore, the content of this guideline includes comparisons, outcome measures, and recommendations for which there was sufficient evidence. It should also be noted that meta-analysis of head-to-head studies was only performed when comparing the efficacy of OAs to CPAP. Due to insufficient head-to-head studies comparing different types of OAs (e.g., custom, titratable vs. custom, non-titratable), data on the efficacy of specific device types were pooled across studies and compared side by side. The meta-analyses are presented in the Appendix.

3.5 Quality of Evidence

The assessment of evidence quality was performed according to a modified Grading of Recommendations Assessment, Development, and Evaluation (GRADE) process.[12] The GRADE system differs from other grading systems in that each study is not only evaluated for study design and risk of bias, but, additionally, an estimate of effect is generated for each outcome. The quality of evidence reflects the degree of confidence that the estimates of the effects are correct, and the quality of a body of evidence for each outcome is assessed as opposed to evaluating individual studies. Multiple aspects of quality are assessed including study limitations, imprecision, inconsistency of results, indirectness of evidence, and likeliness of publication bias.

A risk of bias analysis was performed on all RCTs. Analyzing risk of bias includes reviewing aspects of conduct such as blinding, allocation concealment, loss to follow-up, or selective outcome reporting that could affect the quality of evidence. The GRADE process allows for the downgrading of the quality

Table 2—A summary of GRADE's approach to rating quality of evidence.

Study Design	Initial Quality of a Body of Evidence	Downgrade if	Upgrade if	Quality of a Body of Evidence
Randomized trials	High →	Risk of bias −1 Serious −2 Very serious Inconsistency −1 Serious −2 Very serious Indirectness −1 Serious −2 Very serious Imprecision −1 Serious −2 Very serious Publication bias −1 Serious −2 Very serious	Large effect +1 Large +2 Very large Dose response +1 Evidence of a gradient All plausible residual confounding +1 Would reduce a demonstrated effect +1 Would suggest a spurious effect if no effect was observed	High (four plus: ⊕⊕⊕⊕) Moderate (three plus: ⊕⊕⊕⊖) Low (two plus: ⊕⊕⊖⊖) Very Low (one plus: ⊕⊖⊖⊖)
Observational studies	Low →			

Table 3—Final assessments of level of bodies of evidence.

High:	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate:	We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
Low:	Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of effect.
Very low:	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Table 4—AASM strengths of recommendations.

	Overall Quality of Evidence			
Assessment of Benefits versus Harms/Burdens	**High**	**Moderate**	**Low**	**Very Low**
Benefits clearly outweigh harms/burdens	STANDARD	STANDARD	GUIDELINE	OPTION
Benefits closely balanced with harms/burdens OR Uncertainty in the estimates of benefits versus harms/burdens	GUIDELINE	GUIDELINE	OPTION	OPTION
Harms/burdens clearly outweigh benefits	STANDARD	STANDARD	STANDARD	STANDARD

of evidence due to risk of bias. The grading of evidence also includes an analysis of imprecision, indirectness, and inconsistency. Imprecision refers to wide confidence intervals around the estimate of effect when there are relatively few patients and few events. Indirectness occurs when the question being addressed is different than the available evidence in terms of population, intervention, comparator, or outcome. There is inconsistency when there is unexplained heterogeneity of the results. A summary of the GRADE approach to rating quality of evidence is presented in Table 2.

All studies were assessed for study design and limitations to validity (bias) for each outcome of interest. Subsequently, the body of evidence for each outcome was assessed and graded, taking into account the results of the meta-analysis (if applicable) and other factors as described above. The final assessment, as defined in Table 3, was determined for each treatment and outcome measure. The results are reported as evidence profiles, for each PICO question, that include the number of studies, study design, limitations, inconsistency, indirectness, imprecision, and other considerations that went into determining the quality of evidence for each outcome of interest. Also reported are the number of patients that were studied, the overall effect that was calculated in the meta-analysis (reported as the *mean difference* [MD]), and a qualitative assessment of the relative importance of the outcome. Task force members and AASM staff extracted the data and graded the studies. The GRADE summary of findings reports, along with the meta-analyses, are presented in the Appendix.

3.6 Strength of Recommendations

The task force then developed recommendations for the efficacy of OA treatment for snoring and OSA. Strengths of recommendation were assigned to these statements based on the strength of evidence and counterbalanced by an assessment of the relative benefits of the treatment versus the potential risks as delineated in Table 4. Particularly noteworthy on this table is that when the harm or burden clearly outweighs the benefit, a STANDARD strength of recommendation *against* the proposed therapy is given regardless of the overall quality of evidence.

Sections titled "Values and Trade-offs" appear under each individual recommendation to explain the rationale leading to each recommendation. These sections are an integral part of the GRADE system and offer transparency to the process.

Table 5—Summary of recommendation statements.

Recommendation Statement	Strength of Recommendation	Quality of Evidence	Benefits versus Harms/Burdens Assessment
The Use of Oral Appliances for Treatment of Primary Snoring in Adults			
We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea).	STANDARD	High	Benefits clearly outweigh harms
The Use of Oral Appliances for Treatment of Obstructive Sleep Apnea in Adults			
When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices.	GUIDELINE	Low	Benefits clearly outweigh harms
We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy.	STANDARD	Moderate	Benefits clearly outweigh harms
We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence.	GUIDELINE	Low	Benefits clearly outweigh harms
We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances.	GUIDELINE	Low	Benefits clearly outweigh harms
We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician.	GUIDELINE	Low	Benefits clearly outweigh harms

3.7 Approval and Interpretation of Recommendations

A draft of the guideline was available for public comment for a two-week period on the AASM and AADSM websites. The task force took into consideration all the comments received and made decisions about whether to revise the draft based on the comments. The revised guideline was submitted to the AASM and AADSM Board of Directors who subsequently approved these recommendations.

The recommendations in this guideline define principles of practice that should meet the needs of most patients in most situations. This guideline should not, however, be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably expected to obtain the same results. The ultimate judgment regarding propriety of any specific care must be made by the clinician (sleep physician and dentist), in light of the individual circumstances presented by the patient, available diagnostic tools, accessible treatment options, and resources.

The AASM expects this guideline to have an impact on professional behavior, patient outcomes, and, possibly, health care costs. This clinical practice guideline reflects the state of knowledge at the time of publication and will be reviewed every few years and updated if new evidence warrants significant changes to the recommendations.

4.0 RECOMMENDATIONS

All figures, including meta-analyses and GRADE profile reports, are presented in the Appendix. Table 5 shows a summary of the recommendation statements organized by strength of recommendation, including the quality of evidence and the assessment of the harm/benefit balance of the recommendation.

Our assessment of the efficacy of different OAs, as compared to each other and to PAP for different levels of OSA severity (i.e., mild, moderate, and severe), was based on very limited evidence. Most of the studies accepted for inclusion in this guideline did not provide sub-analyses of results based on different levels of OSA severity. Therefore, the recommendations presented below do not provide guidance for treating OSA patients with specific levels of severity. Meta-analyses performed using the limited available evidence indicate that both OAs and CPAP can significantly reduce the apnea hypopnea index/respiratory disturbance index/respiratory event index (AHI/RDI/REI) across all levels of OSA severity in adult patients (see Figures 1–6). There were statistically significant differences in the mean reduction in AHI before and after treatment using OAs versus CPAP for mild-to-moderate and severe levels of OSA severity. Based on a single retrospective study by Holley in 2011, however, there was no significant difference in the percentage of mild OSA patients achieving their target AHI/RDI/REI (< 5, < 10, > 50% reduction) after treatment between OAs and CPAP.[13] For patients with moderate to severe OSA, however, the odds of achieving the target AHI was significantly greater with CPAP than with OAs.[13] In an RCT conducted by Randerath in 2002, the odds of achieving the target AHI of < 10 in mild to moderate adult patients was significantly greater with CPAP than OA therapy.[14] CPAP remains the first-line or primary therapy for the treatment of adult patients with severe OSA. OA therapy should be reserved for use in severe OSA patients who did not benefit from CPAP therapy or were intolerant to CPAP.[15,16]

Our assessment of factors that may be used to predict treatment success in adults with OSA was also based on very limited evidence. We found that treatment success was usually defined as a reduction in the AHI/RDI/REI to a specific level (e.g., post-treatment AHI/RDI/REI < 5, > 50% reduction in AHI/RDI/

REI). However, there were no reported factors that consistently predicted treatment success. Specifically, there was conflicting evidence for the use of age, gender, neck circumference, body mass index (BMI), and cephalometric measurements to predict treatment success.

It should be noted that conclusions drawn from side-by-side comparisons of the meta-analyses should be interpreted with caution in instances where a meta-analysis based on a limited number of RCTs for one appliance type was compared against a meta-analysis of several RCTs for another appliance type.

There was insufficient evidence to compare the efficacy of OAs to other therapies besides CPAP. Patient preference for OAs versus CPAP should be considered by the treating sleep physician before therapy is prescribed. The strength of each recommendation was not only made based on the quality of evidence, but also incorporated patient preference along with other factors such as cost, value, and other patient-related factors.

4.1 Primary Snoring

4.1.1 Snoring Indices

Oral appliances are effective for the treatment of primary snoring in adult patients without obstructive sleep apnea (Quality of evidence: *High*) The efficacy of OAs for the treatment of primary snoring in adult patients with OSA was previously addressed in the AASM Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005.[6] The existing evidence at that time supported a STANDARD strength of recommendation for use of OAs in the treatment of primary snoring without features of OSA or upper airway resistance syndrome. The prior evidence found these devices reduced subjective snoring. Since that time, additional trials have further supported this recommendation and have explored additional benefits of oral appliance therapy among these patients.

Two RCTs that assessed the effect of OAs in patients with primary snoring were identified.[17,18] An RCT conducted by Johnston et al. determined that snoring occurred on fewer nights per week; 1.90 (95% CI: 1.32, 2.48).[17] Cooke et al. observed fewer snores per hour; 278 (95% CI: 375.30, 180.70).[18] While the overall quality of this evidence is high, these trials utilized different snoring scales.

A meta-analysis was performed comparing snoring loudness before and after treatment with an OA. The results are shown in Figure 7. Two trials found snoring loudness was reduced while using an OA; 3.31 (95% CI: 1.84, 4.77).[17,18]

The summary of findings table for snoring indices is presented in Figure 8.

4.1.2 Quality of Life

There was insufficient evidence to determine the efficacy of OAs for the improvement in quality of life (QOL) in patients with primary snoring.

4.1.3 OAs vs. CPAP

There was insufficient evidence to compare the efficacy of OAs to CPAP for the reduction in primary snoring. In a prospective, randomized crossover trial, Robertson et al. found that changes in the Snoring Outcomes Survey were similar with the OA and nasal CPAP. The authors also observed that the OA was superior to CPAP in improving sleep quality among bed partners. More patients in this trial also preferred the OA over CPAP for long-term treatment of snoring.[19]

4.1 Recommendation: We recommend that sleep physicians prescribe oral appliances, rather than no therapy, for adult patients who request treatment of primary snoring (without obstructive sleep apnea). (STANDARD)

Values and Trade-Offs: Oral appliances reduce the frequency and intensity of snoring, improve sleep quality for both patients who snore and their bed partners, and improve quality of life (QOL) measures. Though the available evidence on these outcomes is limited, we gave this a STANDARD strength of recommendation, as the possible benefits from treatment of primary snoring clearly outweigh the risk. Insufficient evidence exists to conclude that treatment of primary snoring improves other health-related outcomes, or to compare objective sleep quality during use of oral appliances versus other treatments. Therefore, OAs should be recommended for patients who snore who fail conservative measures (such as weight loss, positional therapy, avoiding alcohol) and request further treatment. Diagnosis of primary snoring should be rendered by a sleep physician and not a dentist, as snoring is frequently accompanied by OSA, and misdiagnosis can have serious implications for the patient.

4.2 OSA

4.2.1 Physiologic Sleep Parameters

The evidence on the efficacy of all OAs for the improvement in physiologic sleep outcome measures is summarized in Figure 40.

The evidence on the efficacy of custom and non-custom OAs for the improvement in physiologic sleep outcome measures is summarized in Figures 41 and 42, respectively.

The evidence on the efficacy of custom, titratable and custom, non-titratable OAs for the improvement in physiologic sleep outcome measures is summarized in Figures 43 and 44, respectively.

The evidence on the efficacy of OAs vs. CPAP for the improvement in physiologic sleep outcome measures is summarized in Figure 45.

4.2.1.1 Apnea-Hypopnea Index/Respiratory Disturbance Index/Respiratory Event Index (AHI/RDI/REI)

4.2.1.1.1 All Appliance Types

Oral appliances reduce the AHI in adult patients with OSA. (Quality of evidence: *Moderate*) Since the previous practice parameter published in 2006, several RCTs evaluating the effect of OAs on AHI have been published including studies comparing OAs to CPAP.

Thirty-four RCTs with 1,301 patients assessed the effect of OAs on AHI and found an overall improvement in AHI.[4,9–11,14,17,20–47] A meta-analysis was performed on all included trials that compared AHI pre- and post-treatment with OAs. The results

are shown in Figure 9. In weighted analysis, the mean reduction in AHI was 13.60 events/h (95% CI: –15.25, –11.95) with an OA compared to the control group without OA.

Twenty-five of the 34 RCTs included in the meta-analysis reported greater than 50% reduction in AHI with the use of OAs in adult OSA patients.[11,20,21,23–25,27–36,38–44,46,47]

4.2.1.1.2 Custom vs. Non-Custom OAs

Custom OAs reduce AHI and RDI in adult patients with OSA. (Quality of evidence: *Moderate*) Thirty-three RCTs including 1,259 patients that assessed AHI with the use of custom OAs were identified.[4,9–11,14,17,20–28,30–47] Overall, custom OAs were found to substantially reduce the AHI. Meta-analysis (Figure 10) showed the mean reduction in AHI/RDI/REI for custom OAs to be 13.89 events/h (95% CI: 15.57, 12.20). Twenty-eight of the 33 RCTs included in the meta-analysis reported a greater than 50% reduction in AHI with the use of custom OAs in adult OSA patients.[9–11,20,21,23–25,27,28,30–47] Five RCTs reported a mean decrease in AHI of up to 25 events/h with the use of custom OAs.[30,34–36,44]

Non-custom OAs reduce AHI/RDI/REI in adult patients with OSA. (Quality of evidence: *Low*) Two RCTs including 42 adult patients with OSA that assessed AHI with the use of non-custom OAs were identified.[29,45] Small improvements in AHI were reported. Meta-analysis (Figure 11) showed the mean reduction in AHI for non-custom OAs to be 6.28 events/h (95% CI: –13.13, 0.56). It should be noted that the meta-analysis reports wide confidence intervals surrounding the mean reduction in AHI for each of the 2 RCTs that studied the efficacy of non-custom OAs.

A comparison of the results of the meta-analyses cited above suggests that custom OAs achieve a greater reduction in AHI in adult patients with OSA than non-custom OAs.

4.2.1.1.3 Custom, Titratable vs. Custom, Non-Titratable OAs

Custom, titratable OAs reduce AHI/RDI/REI in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis (Figure 12) of 27 RCTs including 1,054 patients showed the mean reduction in AHI/RDI/REI for custom, titratable OAs to be 13.80 events/h (95% CI: 15.74, 11.87).[4,9–11,14,20–22,24–27,30–42,44,47] Twenty-two of the 27 RCTs included in the meta-analysis reported greater than 50% reduction in AHI with the use of custom, titratable OAs in adult OSA pati ents.[9–11,20,21,24,25,27,30–36,38–42,44,47] Five RCTs reported a mean decrease in AHI of up to 25 events/h with the use of custom titratable OAs.[30,34–36,44] In an RCT conducted by Tan et al., the first 10 subjects were treated with a custom, non-titratable OA; but 2 subjects complained of inadequate nocturnal oral respiration and were unable to tolerate the device.[43] Therefore, the patients in the study were switched to a custom, titratable device for the remainder of the study.[43] For this reason, the study was excluded from the meta-analyses of custom, titratable and custom, non-titratable OAs.

Custom, non-titratable OAs reduce AHI/RDI/REI in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis (Figure 13) of 6 RCTs including 164 adult patients with OSA showed the mean reduction in AHI for custom, non-titratable OAs to be 12.51 events/h (95% CI: 15.23, 9.80).[17,23,24,28,45,46] Four of the 6 RCTs included in the meta-analysis reported greater than 50% reduction in AHI with the use of custom, non-titratable OAs.[23,24,28,46]

A comparison of the results of the meta-analyses cited above suggests that custom, titratable and custom, non-titratable OAs achieve an equivalent reduction in AHI in adult patients with OSA.

4.2.1.1.4 OAs vs. CPAP

CPAP reduces AHI/RDI/REI more than OAs in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis performed on 15 RCTs (9 of them published since the 2006 practice parameters paper) evaluated 491 patients assigned to an OA and 481 assigned to CPAP to assess the effect of these devices on AHI.[4,14,20–22,28–30,33–36,40,43,44] The results are shown in Figure 14. In weighted analysis, OAs produced a significant mean reduction in AHI, however the mean reduction in AHI was 6.24 events/h (95% CI: 8.14, 4.34) greater with CPAP than with OA.

A study by Gagnadoux et al. evaluating the effectiveness of OA vs. CPAP over a 2-month treatment period noted a complete response (> 50% reduction in AHI to < 5 events/h) in 73.2% of patients with CPAP and 42.8% with OA.[30] The odds of achieving an AHI ≤ 5 events/h was 49 times greater, and the odds of achieving an AHI ≤ 10 events/h was 89 times greater with the OA treated group compared to the control group, based on one RCT. The odds of achieving an AHI ≤ 5 events/h after treatment was 3.6 times greater.[30] Ferguson et al. reported that achieving an AHI ≤ 10 events/h was 1.9 times greater with CPAP than with OA.[4] The treatment duration with OA and CPAP in the above studies varied between 6 weeks and 4 months.

4.2.1.2 Oxygen Saturation

4.2.1.2.1 All Appliance Types

Oral appliances modestly improve minimum oxygen saturation in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis was performed on all included trials that compared pre- and post-treatment oxygen saturation when treated with OAs vs. control group without OA. The results are shown in Figure 15. In a weighted analysis of 22 RCTs that assessed 946 adult OSA patients treated with OAs, the mean improvement in oxygen saturation was 3.09% (95% CI: 2.43, 3.76).[4,9–11,14,22,26,27,29,31–41,45,47] The greatest improvements in minimum oxygen saturation with the use of OAs were reported by Hoekema et al. in 2007 and 2008; 13.0% (95% CI: 7.02, 18.98) and 12.1% (95% CI: 6.89, 17.31), respectively.[34,35] Custom, titratable appliances were used in these studies.[34,35] Nine of the 22 RCTs included in the meta-analysis did not show a statistically significant improvement in oxygen saturation with the use of OAs.[4,14,26,27,29,37,41,45,47]

4.2.1.2.2 Custom vs. Non-Custom OAs

Custom OAs modestly improve minimum oxygen saturation in adult patients with OSA. (Quality of Evidence: *Moderate*) A meta-analysis of 21 RCTs including 908 adult patients with OSA showed the mean increase in minimum oxygen saturation for custom OAs to be 3.22% (95% CI: 2.54, 3.90).[4,9–11,14,22,26,27,31,32,34–41,45,47] The results are shown in Figure 16. Eight of the 21 RCTs included in the meta-analysis did not show a statistically significant improvement in oxygen saturation with the use of custom OAs.[4,14,26,27,37,41,45,47]

Non-custom OAs do not significantly improve minimum oxygen saturation in adult patients with OSA. (Quality of evidence: *Moderate*) Two RCTs including 42 adult patients with OSA investigated changes in minimum oxygen saturation with non-custom OAs.[29,45] Meta-analysis (Figure 17) of these 2 studies revealed a statistically insignificant mean decrease in minimum oxygen saturation of 0.29% (95% CI: –3.22, 2.64).

4.2.1.2.3 Custom, Titratable vs. Custom, Non-titratable OAs

Custom, titratable OAs modestly improve minimum oxygen saturation in adult patients with OSA. (Quality of Evidence: *Moderate*) Meta-analyses were performed on 20 RCTs including 851 adult patients with OSA that assessed the impact of custom, titratable OAs on minimum oxygen saturation during their sleep.[4,9–11,14,22,26,27,31,32,34–41,47] The results are shown in Figure 18. The weighted analysis showed a mean increase of 3.15% (95% CI: 2.46, 3.84) in minimum oxygen saturation using custom, titratable OAs.

Custom, non-titratable OAs modestly improve minimum oxygen saturation in adult patients with OSA. (Quality of evidence: *Low*) A meta-analysis (Figure 19) of 3 RCTs including 57 patients showed a mean increase in minimum oxygen saturation of 4.70% (95% CI: –3.83, 13.22) when using custom, non-titratable OAs to treat adult patients with OSA.[41,45,47] Zhou et al. reported a statistically significant improvement in minimum oxygen saturation,[47] while Vanderveken et al. and Rose et al. found no significant improvement.[41,45]

A comparison of the results of the meta-analyses cited above suggests that custom, titratable and custom, non-titratable OAs achieve an equivalent improvement in minimum oxygen saturation in adult patients with OSA.

4.2.1.2.4 OAs vs. CPAP

CPAP improves minimum oxygen saturation slightly better than OAs in adult patients with OSA. (Quality of evidence: *Moderate*) Nine RCTs (5 of them published since the 2006 practice parameters paper) evaluated a total of 346 adult patients with OSA randomized to OA and 354 to CPAP to evaluate the effect on oxygen desaturation.[4,14,22,29,33–36,40] Meta-analysis (Figure 20) revealed the improvement in oxygen saturation was better with CPAP than with an OA (mean difference 3.11% [95% CI: 1.74, 4.48] higher with CPAP than with an OA). Of the 9 RCTs included in the meta-analysis, Ferguson et al. reported the greatest improvement in minimum oxygen saturation with the use of CPAP over OAs: 11.9% (95% CI: 6.71, 17.09).[4] Conversely, RCTs conducted by Hoekema et al. reported no significant differences in minimum oxygen saturation with OAs compared to CPAP.[34–36]

4.2.1.3 Arousal Index

4.2.1.3.1 All Appliance Types

Oral appliances reduce the arousal index in adult patients with OSA. (Quality of evidence: *Moderate*) Fourteen RCTs (6 of them published since the 2006 practice parameters paper) assessed 704 adult patients with OSA randomized to OAs vs. a control group and found an overall reduction in arousal index with OAs.[11,14,20–24,27,31,32,38–40,43] A meta-analysis (Figure 21) comparing the pre- and post-treatment arousal index with OAs compared to the control group showed a mean reduction of 10.78 arousals/h (95% CI: 8.02, 13.54). All RCTs reported a statistically significant reduction in arousal index using OAs. The findings by Barnes et al. and Randerath et al., while statistically significant, were considered clinically insignificant using custom OAs.[14,22] All other RCTs reported clinically significant reductions in arousal index using custom OAs.[20,21,27,31,32,44–46,49] Aarab et al., Blanco et al., and Ghazal et al. reported > 50% reduction in arousal index using OAs.[21,23,31] Deanne et al. performed an RCT comparing an OA to a tongue retaining device and found that the OAs reduced the arousal index from 33.23 ± 16.41 arousals/h to 21.09 ± 9.27 arousals/h, p = 0.004, while the tongue retaining device decreased it to 21.09 ± 10.56 arousals/h, p = 0.001.[27]

4.2.1.3.2 Custom vs. Non-Custom OAs

Custom appliances have an impact on lowering arousal index. (Quality of Evidence: *Moderate*) Since all of the custom appliances evaluated for improvement in arousal index were custom, titratable appliances, the meta-analysis results for all OAs above also apply to custom appliances. (Figure 21)

There was insufficient evidence to assess the efficacy of non-custom OAs for improvement in arousal index in adult patients with OSA.

4.2.1.3.3 Custom, Titratable vs. Custom, Non-titratable OAs

Custom, titratable appliances have an impact on lowering arousal index. (Quality of Evidence: *Moderate*) Twelve RCTs assessed 648 adult patients with OSA randomized to OAs vs. a control group and found an overall reduction in arousal index with OAs.[11,14,20–22,24,27,31,32,38–40] A meta-analysis (Figure 22) comparing the pre- and post-treatment arousal index with OAs compared to the control group showed a mean reduction of 10.44 arousals/h (95% CI: 7.45, 13.44). An RCT conducted by Randerath et al. was the only study that reported a statistically insignificant reduction in arousal index using OAs.[14] In an RCT conducted by Tan et al., the first 10 subjects were treated with a custom, non-titratable OA; but 2 subjects complained of inadequate nocturnal oral respiration and were unable to tolerate the device.[43] Therefore, the patients in the study were switched to a custom, titratable device for the remainder of the study.[43] For this reason, the study was excluded from the meta-analyses of custom, titratable and custom, non-titratable OAs.

Custom, non-titratable appliances have an impact on lowering arousal index. (Quality of Evidence: *Low*) A meta-analysis (Figure 23) of 2 RCTs[23,24] assessed 32 adult patients with OSA found a mean reduction in arousal index of 14.59 arousals/h (95% CI: 12.48, 16.71).

A comparison of the results of the meta-analyses cited above suggests that custom, titratable and custom, non-titratable OAs achieve an equivalent reduction in arousal index in adult patients with OSA.

4.2.1.3.4 OAs vs. CPAP

CPAP reduces the arousal index more than OAs in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis (Figure 24) of 6 RCTs (3 of them published since the 2006 practice parameters paper) assessed 274 adult patients with OSA randomized to OAs vs. 272 randomized to CPAP.[14,20–22,40,43] A meta-analysis demonstrated that CPAP was moderately better than an OA in reducing the overall arousal index (mean

difference in arousal index reduction was 3.57 arousals/h (95% CI: 1.64, 5.51) better with CPAP than OA). Barnes et al. reported the most significant differences in the mean reduction in arousal index between the use of OAs and CPAP; 5.50 arousals/h (95% CI: 5.82, 5.18).[22] Aarab et al., Phillips et al., Randerath et al., and Tan et al. reported no significant difference between OAs and CPAP.[14,20,21,40,43]

4.2.1.4 Oxygen Desaturation Index (ODI)

4.2.1.4.1 All Appliance Types

Oral appliances lower the ODI in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis (Figure 25) of 6 RCTs (3 of them published since the 2006 practice parameters paper) that included 399 adult patients with OSA found a mean reduction in ODI of 12.77 events/h (95% CI: 8.69, 16.85).[17,22,31,40,46,47] Four out of the 6 RCTs included in the meta-analysis reported > 50% reduction in ODI using OAs.[31,40,46,47] In an RCT of 2 different OAs, Ghazal et al. noted an improvement in ODI from 16.0 events/h (4–22) to 8.0 events/h (1–12), $p < 0.05$ in one appliance and 14.0 events/h (2–16) to 4.0 events/h (0.8–19), $p < 0.05$ in the other.[31]

4.2.1.4.2 Custom vs. Non-Custom OAs

Custom appliances have an impact on lowering ODI. (Quality of Evidence: *Moderate*) Since all of the appliances evaluated for improvement in ODI were custom appliances, the meta-analysis results for all OAs above also apply to custom appliances (Figure 25).

There was insufficient evidence to assess the efficacy of non-custom OAs for improvement in ODI in adult patients with OSA.

4.2.1.4.3 Custom, Titratable vs. Custom, Non-Titratable OAs

Custom, titratable OAs lower the ODI in adult patients with OSA. (Quality of Evidence: *Moderate*) Meta-analysis (Figure 26) of 4 RCTs including 322 adult patients with OSA showed the mean reduction in ODI for custom, titratable OAs to be 9.95 events/h (95% CI: 16.25, 3.66).[22,31,40,47]

Custom, non-titratable OAs lower the ODI in adult patients with OSA. (Quality of evidence: *Moderate*) Three RCTs including 77 patients investigated changes in ODI with custom, non-titratable OAs.[17,46,47] Meta-analysis (Figure 27) showed the mean reduction in ODI for custom, non-titratable OAs to be 15.65 events/h (95% CI: 26.86, 4.44). Zhou et al. reported the most significant decrease in ODI with the use of a custom, non-titratable OA; 25.00 events/h (95% CI: 28.81, 21.19).[47]

A comparison of the results of the meta-analyses cited above suggests that custom non-titratable OAs achieve an equivalent reduction in ODI with custom titratable OAs in adult patients with OSA.

4.2.1.4.4 OAs vs. CPAP

CPAP reduces the ODI slightly more than OAs in adult patients with OSA. (Quality of evidence: *Low*) Three RCTs (2 of them published since the 2006 practice parameters paper) evaluated the effectiveness of OAs vs. CPAP for the treatment of adult patients with OSA.[22,30,40] Meta-analysis (Figure 28) of 234 patients randomized to an OA vs. CPAP found CPAP was slightly better at reducing the ODI compared to OAs with a mean difference in ODI of 4.76 events/h (95% CI: 2.37 to 7.15) All RCTs included in the meta-analysis reported a statistically significant difference in reduction of ODI favoring CPAP over an OA.[22,30,40]

4.2.1.5 Sleep Architecture

4.2.1.5.1 All Appliance Types

Oral appliances have no significant effect on sleep architecture in adult patients with OSA. (Quality of evidence: *Low*) A meta-analysis (Figure 29) of 17 RCTs including 636 adult patients with OSA found no clinically significant differences in REM% pre and post OA treatment (1.67, 95% CI: 0.51, 2.84).[4,9–11,14,20–24,27,29,31,32,35,38,43]

There was insufficient evidence to assess the effects of OA therapy on other measures of sleep architecture (e.g., % sleep stage time) in adult patients with OSA.

4.2.1.5.2 Custom vs. Non-Custom OAs

Custom OAs do not have a significant effect on % of REM sleep. (Quality of evidence: *Low*) A meta-analysis (Figure 30) of 16 RCTs including 620 adult patients with OSA found a clinically insignificant weighted mean increase in REM of 1.58% (95% CI: 0.64, 2.53) using custom OAs.[4,9–11,14,20–24,27,31,32,35,38,43]

Non-custom OAs do not have a significant effect on % of REM sleep. (Quality of evidence: *Moderate*) An RCT conducted by Ferguson et al. including 19 adult patients with OSA found an insignificant weighted mean increase in REM of 5.70% (95% CI: −0.56, 11.96) using a non-custom OA.[29]

4.2.1.5.3 Custom, Titratable vs. Custom, Non-Titratable OAs

Custom, titratable OAs do not have a significant effect on % of REM sleep. (Quality of evidence: Low) A meta-analysis (Figure 31) of 14 RCTs including 561 adult patients with OSA found an insignificant weighted mean increase of 1.24% (95% CI: −0.09, 2.56).[4,9–11,14,20–22,24,27,31,32,35,38]

Custom, non-titratable OAs do not have a significant effect on % of REM sleep. (Quality of evidence: Moderate) A meta-analysis (Figure 32) of 2 RCTs including 32 adult patients with OSA found an insignificant weighted mean increase of 0.97% (95% CI: 0.41, 1.53).[23,24]

4.2.1.5.4 OAs vs. CPAP

OAs and CPAP do not significantly improve % of REM sleep in adult patients with OSA. (Quality of evidence: *Low*) A meta-analysis (Figure 33) of 8 RCTs (3 of them published since the 2006 parameters paper) evaluated the effectiveness of OAs vs. CPAP in 244 adult patients with OSA randomized to CPAP and 244 randomized to an OA. The analyses found no significant differences in the % of REM sleep; 0.72 (95% CI: −1.09, 2.52).[4,14,20–22,29,30,36,43]

There was insufficient evidence to assess the effects of OAs vs. CPAP on other measures of sleep architecture (e.g., % sleep stage time) in adult patients with OSA.

4.2.1.6 Sleep Efficiency

4.2.1.6.1 All Appliance Types

Oral appliances have no significant effect on sleep efficiency in adult patients with OSA. (Quality of evidence: *Moderate*) A

meta-analysis (Figure 34) of 17 RCTs (7 of them published since the 2006 practice parameters paper) looked at 721 adult patients with OSA to evaluate sleep efficiency. There were no significant improvements in sleep efficiency; 0.95 (95% CI: −0.21, 2.12).[4,9–11,22–24,27,29,31,32,35,38,39,43,45,47] Deanne et al. performed an RCT comparing an OA vs. a tongue retaining device (TRD) and found no significant differences in sleep efficiency (baseline 80% ± 11% to 78% ± 17% with OA, p = ns vs. TRD at 79% ± 11%, p = ns).[27]

4.2.1.6.2 Custom vs. Non-Custom OAs

Custom OAs have no significant effect on sleep efficiency in adult patients with OSA. (Quality of Evidence: *Low*) A meta-analysis (Figure 35) was performed on 16 RCTs including 679 adult patients with OSA that assessed the impact of custom OAs on sleep efficiency.[4,9–11,22–24,27,31,32,35,38,39,43,45,47] The weighted analyses showed an insignificant mean improvement in sleep efficiency for custom appliances to be 0.98% (95% CI: −0.22, 2.18). RCTs conducted by Barnes et al., Ghazal et al., Gauthier et al., Gotsopoulos et al., and Zhou et al. reported statistically significant increases in sleep efficiency using custom OAs.[9–11,22,31,47]

Non-custom OAs have no significant effect on sleep efficiency in adult patients with OSA. (Quality of evidence: *Moderate*) A meta-analysis (Figure 36) was performed on 2 RCTs including 42 adult patients with OSA that assessed the impact of non-custom OAs on sleep efficiency.[29,45] The results show no significant change in sleep efficiency. The weighted analyses showed the mean decrease in sleep efficiency for non-custom OAs to be 0.30% (95% CI: −4.02, 4.62).

4.2.1.6.3 Custom, Titratable vs. Custom, Non-Titratable OAs

Custom, titratable OAs have an insignificant impact on sleep efficiency in adult patients with OSA. (Quality of Evidence: *Low*) A meta-analysis (Figure 37) was performed on 13 RCTs including 584 patients with OSA that assessed the efficacy of custom, titratable OAs for sleep efficiency.[4,9–11,22,24,27,31,32,36,38,39,47] The weighted analysis showed the mean increase in sleep efficiency to be 0.87% (95% CI: −0.43, 2.17).

Custom, non-titratable OAs have an insignificant impact on sleep efficiency in adult patients with OSA. (Quality of Evidence: *Moderate*) A meta-analysis (Figure 38) was performed on 4 RCTs including 71 patients with OSA that assessed the efficacy of custom, non-titratable OAs for sleep efficiency.[23,24,45,47] The weighted analysis showed the mean increase in sleep efficiency to be 2.71% (95% CI: −2.32, 7.73).

4.2.1.6.4 OAs vs. CPAP

OAs and CPAP do not significantly improve sleep efficiency in adult patients with OSA (Quality of evidence: *Moderate*) A meta-analysis (Figure 39) of 5 RCTs (1 of them published since the 2006 practice parameters paper), that evaluated 190 patients randomized to OAs and 191 to CPAP, found no significant difference between the 2 therapies in improving sleep efficiency; 0.37% (95% CI: −0.47, 1.21).[4,22,29,36,43]

4.2.2 Daytime sleepiness

4.2.2.1 All Appliance Types

Oral appliances reduce daytime sleepiness in adult patients with OSA. (Quality of evidence: *Moderate*) This is an expansion of the recommendations in the 2006 AASM Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances. Since publication of the 2006 practice parameters, several high quality clinical trials have established the benefits of oral appliance therapy in improving daytime sleepiness in patients with OSA.

Compared with no treatment or non-therapeutic (sham) therapy, treatment with OAs significantly improved daytime sleepiness. In meta-analysis (Figure 46) of 25 studies that measured subjective somnolence as an outcome of OA therapy, the mean reduction in the ESS was 3.81 (95% CI: 4.39, 3.23).[9–11,17,22–26,28,30,31,33–40,43–45,47,48] In a study comparing a custom OA set at 75% of the maximum mandibular advancement to a similar OA that did not advance the mandible, Blanco et al. found that daytime somnolence was improved with therapy.[23] ESS scores improved more in the advanced group, decreasing from 14.7 ± 5.1 before treatment to 5.1 ± 1.9 after 3 months of treatment (p < 0.05).[23] There was not a significant reduction in ESS among the non-advanced group (16.3 ± 2.5 to only 13.6 ± 6.7, p = NS).[23] Similarly, Gauthier et al. conducted an RCT of patients using OAs for the treatment of OSA and, after a mean follow-up period of 40.9 months, reported a decrease in ESS from 13.9 ± 1.3 to 9.3 ± 1.2 for one custom, titratable OA and from 13.9 ± 1.3 to 9.9 ± 1.3 for the other.[9] In contrast, an RCT conducted by Johnson et al. did not observe that OAs led to significant improvements in daytime sleepiness when compared to placebo.[17] The investigators utilized a fixed, non-titratable OA, which may explain the discrepancy between their observed treatment effect and other trials exploring the impact of OAs.[17] In that RCT, the ESS changed from 13.9 ± 6.4 at baseline to 11.6 ± 6.7 with an OA and 12.7 ± 6.3 with placebo (p = 0.414).[17] However, 45% of those using an OA achieved a normal ESS (< 10) following treatment.[17]

The evidence on the efficacy of OAs for the improvement of subjective daytime sleepiness is summarized in Figure 51.

4.2.2.2 Custom vs. Non-Custom OAs

Custom oral appliances reduce daytime sleepiness in adult patients with OSA. (Quality of evidence: *Moderate*) Twenty-five RCTs including 948 patients were identified that evaluated the change in ESS with the use of custom OAs.[9–11,17,22–26,28,30,31,33–40,43–45,47,48] Reductions in ESS were modest. Meta-analysis (Figure 47) showed the mean reduction in ESS score for custom OAs to be 1.95 (95% CI: 2.03, 1.88). Phillips et al., in one of the largest studies with 108 subjects, found a significant (p < 0.01) reduction in ESS from a baseline of 9.1 ± 0.4 to 7.2 ± 0.4.[40] Others such as Hoekema et al. reported larger improvements in ESS score (12.9 ± 5.6 to 4.8 ± 5.4).[35]

Non-custom oral appliances do not significantly reduce daytime sleepiness in adult patients with OSA. (Quality of evidence: *Moderate*) A single RCT including 23 patients assessed the effects of non-custom OA therapy on sleepiness in adult patients with OSA. The study reported an insignificant mean reduction in ESS of 1.0 (95% CI: −3.62, 1.62).

The evidence on the efficacy of custom and non-custom OAs for the improvement of subjective daytime sleepiness is presented in Figures 52 and 53, respectively.

4.2.2.3 Custom, Titratable vs. Custom, Non-Titratable OAs

Custom, titratable oral appliances reduce daytime sleepiness in adult patients with OSA. (Quality of evidence: *Moderate*) Nineteen RCTs including 768 patients were identified that evaluated the change in ESS with the use of custom, titratable OAs.[9–11,22,24–26,30,31,33–40,44,47] Reductions in ESS were modest. Meta-analysis (Figure 48) showed the mean reduction in ESS score for custom, titratable OAs to be 3.95 (95% CI: 4.61, 3.28).

Custom, non-titratable oral appliances reduce daytime sleepiness in adult patients with OSA. (Quality of evidence: *High*) Eight RCTs including 156 patients were identified that evaluated the change in ESS with the use of custom, non-titratable OAs.[17,23–25,28,45,47,48] Meta-analysis (Figure 49) showed the mean reduction in ESS score for custom, non-titratable OAs to be 3.65 (95% CI: 5.18, 2.13).

The evidence on the efficacy of custom, titratable and custom, non-titratable OAs for the improvement of subjective daytime sleepiness is summarized in Figures 54 and 55, respectively.

4.2.2.4 OAs vs. CPAP

OAs are equivalent to CPAP in reducing subjective daytime sleepiness in adult patients with OSA. (Quality of evidence: *Low*) Meta-analyses were performed on 10 RCTs that compared measures of daytime sleepiness between OAs and CPAP (Figure 50).[22,28,30,33–36,40,43,44] The weighted analysis of 10 trials comparing changes in the ESS between OAs and CPAP found an insignificant increase of 0.08 (95% CI: −0.21, 0.38) in post-treatment measures of subjective sleepiness between these 2 therapies.

In an RCT of patients with mild to moderate OSA, Barnes et al. compared the impact of OAs and CPAP on daytime sleepiness.[22] Both treatments led to clinically and statistically significant improvements in daytime sleepiness, with greater effects noted with CPAP therapy.[22] Compared with placebo, both treatments significantly improved subjective sleepiness as measured by the ESS ($p < 0.001$ for both OAs and CPAP).[22] There was no difference in the measured treatment effect between the 2 interventions.[22] The investigators did not observe improvements in objective sleepiness with either treatment.[22] However, the mean sleep latency on baseline maintenance of wakefulness testing (MWT) was normal among the cohort (30.7 ± 0.9 minutes), and only 18.4% had objective somnolence prior to therapy.[22] Alertness, as measured by a visual analog scale, was improved with CPAP ($p < 0.001$) but unchanged with OAs.[22] In an RCT, Hoekema et al. found that OAs performed similarly to CPAP in improving daytime sleepiness.[36] Specifically, ESS changed from 12.9 ± 5.6 at baseline to 6.9 ± 5.5 following treatment with an OA, compared with a change from 14.2 ± 5.6 to 5.9 ± 4.8 with CPAP.[36]

The evidence on the efficacy of OAs vs. CPAP for the improvement of subjective daytime sleepiness is presented in Figure 56.

4.2.3 Quality of Life

4.2.3.1 All Appliance Types

Oral appliances improve quality of life measures in adult patients with OSA. (Quality of evidence: *Moderate*) This is an expansion of the statements and associated recommendations provided in the 2006 AASM Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances. Since the publication of the 2006 practice parameters, several high quality clinical trials have established the benefits of OA therapy in improving QOL measures in patients with OSA.

Compared with no treatment or non-therapeutic (sham) therapy, treatment with OAs significantly improved QOL measures. A meta-analysis of 8 RCTs exploring the impact of OAs on QOL was performed.[22,23,26,28,31,35,37,40] The results are shown in Figure 57. Oral appliances were associated with significant improvements in QOL measures. In a weighted analysis, the mean improvement in the SF-36 scores was 6.41 (95% CI: 5.08, 7.75). In a study comparing a custom OA set at 75% of the maximum mandibular advancement to a similar OA that did not advance the mandible, Blanco et al. found that QOL was improved with therapy.[23] After 3 months of treatment, the overall FOSQ scores also improved by 27.1% from baseline in the mandibular advancement group ($p < 0.001$, effect size 0.90).[23] In comparison, the non-advanced group experienced a −1.7% decline in FOSQ.[23] Similarly, Gauthier et al. conducted an RCT of patients using OAs for the treatment of OSA.[10] After a mean follow-up period of 40.9 months, mean overall FOSQ scores improved from 13.9 ± 0.8 to 17.2 ± 0.6 ($p \leq 0.01$).[10]

The evidence on the efficacy of OAs for the improvement in QOL is summarized in Figure 61.

4.2.3.2 Custom vs. Non-Custom OAs

Custom appliances improve quality of life in patients with obstructive sleep apnea in adult patients with OSA. (Quality of Evidence: *Moderate*) The meta-analysis for all appliance types applies to custom OAs as all of the appliances were custom made (Figure 57).

There was insufficient evidence to assess the efficacy of non-custom OAs for improvement in QOL.

4.2.3.3 Custom, Titratable OAs vs. Custom, Non-Titratable OAs

Custom, titratable appliances improve quality of life. (Quality of Evidence: *Moderate*) Six RCTs including 2,223 patients were identified that evaluated the change in SF-36 with the use of custom, titratable OAs.[22,26,31,35,37,40] Meta-analysis (Figure 58) showed the mean reduction in SF-36 score for custom, titratable OAs to be 6.84 (95% CI: 5.42, 8.26).

Custom, non-titratable appliances do not improve quality of life in adult patients with OSA. (Quality of Evidence: *Low*) Two RCTs including 102 patients were identified that evaluated the change in SF-36 with the use of custom, non-titratable OAs.[23,28] Meta-analysis (Figure 59) showed no significant improvement in QOL for custom, non-titratable OAs; −0.95 (95% CI: −4.55, 2.64).

The evidence on the efficacy of custom, titratable and custom, non-titratable OAs for the improvement in QOL is summarized in Figures 62 and 63.

4.2.3.4 OAs vs. CPAP

OAs are nearly equivalent to CPAP for improving QOL in adult patients with OSA. (Quality of evidence: *Low*) Meta-analyses were performed on 4 RCTs that compared measures of QOL between OAs and CPAP (Figure 60) and found that

both therapies performed similarly; a clinically insignificant weighted mean improvement in SF-36 scores of 2.18 (95% CI: 1.10, 3.25) with CPAP compared to OAs.[22,28,36,40] In an RCT of patients with mild to moderate OSA, Barnes et al. compared the impact of OAs and CPAP on several functional outcomes. Both treatments led to clinically and statistically significant improvements in QOL, with greater effects noted with CPAP therapy. Neither treatment was superior to placebo for changes in neuropsychologic function or improvements in mood.[22] In an RCT, Hoekema et al. found that OAs performed similarly to CPAP in improving QOL.[36] Specifically, FOSQ scores improved from 13.7 ± 3.1 to 16.6 ± 2.8 with OAs and from 13.9 ± 3.7 to 16.7 ± 3.1 with CPAP therapy.[36] Phillips et al. observed that baseline FOSQ scores improved from 16.3 ± 0.2 to 17.3 ± 0.2 with CPAP and 17.3 ± 0.2 with an OA.[40] In addition, SF-36 scores related to Bodily Pain, Vitality, Social Function, Mental Health, and Mental Component had similar improvements with both therapies.[40]

The evidence on the efficacy of OA vs. CPAP for the improvement in QOL is presented in Figure 64.

4.2.4 Hypertension

4.2.4.1 All Appliance Types

Oral appliances have a modest impact on reducing blood pressure in adult patients with OSA. (Quality of evidence: *Moderate*) This is a new clinical question that was not addressed in the 2006 AASM Practice Parameters for the Treatment of Snoring and Obstructive Sleep Apnea with Oral Appliances: An Update for 2005.[6] Since that time, several RCTs exploring the effect of OA therapy on cardiovascular outcomes, specifically blood pressure (BP) measures have been conducted.

A meta-analysis was performed on all included trials that compared pre- and post-treatment BP recordings between OAs and non-therapeutic (sham) or no treatment. The results are shown in Figures 65 and 66. In a weighted analysis, the mean reduction in systolic BP was 2.09 mmHg (95% CI: 0.96, 3.22). Oral appliances lead to a greater reduction in diastolic BP recordings, with a mean decrease of 3.15 mm Hg (95% CI: 2.03, 4.26).

Seven RCTs including 343 patients that assessed BP measures as an outcome were identified.[9,10,22,32,40,44,48] Overall, OAs were found to lower the systolic, diastolic, and mean BP. However, these reductions were modest at best. An RCT by Gotsopoulos et al. compared the effect on BP of 4 weeks of an OA vs. a non-therapeutic OA.[32] Compared to controls (non-therapeutic OA), OAs led to a 1.8 ± 0.5 mm Hg greater reduction in the mean 24-hour diastolic BP ($p = 0.001$).[32] However, there was no difference in the mean 24-hour systolic BP between the two OAs. Both systolic and diastolic BP measures during wake were improved with OAs compared to non-therapeutic controls.[32] Specifically, the mean awake systolic BP decreased by 4.4 mm Hg in those treated with OAs, compared to only 1.4 mm Hg in those receiving non-therapeutic OAs ($p = 0.003$).[32] Similarly, OA therapy produced a greater reduction in the mean diastolic BP while awake compared to controls (–3.3 mm Hg vs. –0.1 mm Hg, $p < 0.0001$).[32] Gauthier et al. observed significant reductions in BP with OA therapy, specifically, a mean reduction in diastolic BP of 10.1 mm Hg and a mean reduction in systolic BP of 4.3 mm Hg.[10] Other trials found less robust improvements in BP recordings.[22,40]

The evidence on the efficacy of OAs for the improvement in hypertension is summarized in Figure 71.

4.2.4.2 Custom vs. Non-Custom OAs

Custom OAs modestly reduce blood pressure in adult patients with OSA. (Quality of evidence: *Moderate*) The meta-analyses for all appliance types apply to custom OAs as all of the appliances were custom made (see Figures 65 and 66).

There was insufficient evidence to assess the efficacy of non-custom OAs for the reduction in BP in adult patients with OSA.

4.2.4.3 Custom, Titratable vs. Custom, Non-Titratable OAs

Custom, titratable OAs modestly reduce blood pressure in adult patients with OSA. (Quality of evidence: *Moderate*) Six RCTs including 307 patients were identified that assessed the impact of custom, titratable OAs on systolic BP.[9,10,22,32,40,44] A meta-analysis (Figure 67) of these studies showed the mean reduction in systolic BP for custom, titratable OAs to be –2.37 mm Hg (95% CI: –3.55, –1.20). In a group (n = 12) with higher baseline systolic BP, Trzepizur et al. reported decrease in mean systolic BP from 149.3 ± 3.7 to 140.5 ± 7.4 mm Hg.[44] In a larger group (n = 67) with a lower baseline systolic BP, Gotsopoulos et al. reported a modest reduction from a baseline of 127.3 ± 1.3 to 125.2 ± 1.3 mm Hg.[32]

Six RCTs including 307 patients were identified that assessed the impact of custom, titratable OAs on diastolic BP.[9,10,22,32,40,44] A meta-analysis (Figure 68) of these studies showed the mean reduction in diastolic BP for custom, titratable OAs to be –2.77 mm Hg (95% CI: –3.88, –1.67). After 2.5 to 4.5 years of treatment, Gauthier et al. reported an improvement in diastolic BP from a baseline of 92.0 ± 3.0 to 81.9 ± 2.3 mm Hg.[10] Gotsoupolos et al. reported a more modest change over a shorter treatment period from 77.7 ± 0.9 to 76.4 ± 0.9 mm Hg.[32]

Custom, non-titratable OAs modestly reduce BP in adult patients with OSA. (Quality of evidence: *High*) One RCT including 36 patients investigated changes in systolic and diastolic BP with custom, non-titratable OAs.[48] There were no significant changes found. The mean reduction in systolic BP for a custom, non-titratable OA was –2.30 mm Hg (95% CI: –7.20, 2.60). The mean reduction in diastolic BP for a custom, non-titratable OA was –2.20 mm Hg (95% CI: –6.22, 1.82).

The evidence on the efficacy of custom, titratable and custom, non-titratable OAs for the improvement in hypertension is summarized in Figures 72 and 73, respectively.

4.2.4.4 OAs vs. CPAP

OAs are nearly equivalent to CPAP in reducing blood pressure in adult patients with OSA. (Quality of evidence: *Low*) In a meta-analysis (Figures 69 and 70) of 3 RCTs comparing OA to CPAP, OAs were nearly equivalent to CPAP in lowering the systolic BP; 0.54 (95% CI: 0.32, 0.76) and diastolic BP; 0.24 (95% CI: –0.50, 0.020).[22,40,44] Trzepizur et al. reported no significant difference in post-treatment BP changes between OAs and CPAP.[44] Similarly, Phillips et al. found that neither treatment produced significant improvements in BP measures.[40]

The evidence on the efficacy of OA vs. CPAP for the improvement in hypertension is summarized in Figure 74.

4.2.5 Adherence

The adherence with oral appliances is better overall than with CPAP in adult patients with OSA. (Quality of evidence: Low) A meta-analysis was performed on 11 RCT studies (Figure 75) that evaluated the adherence rate with OA compared to CPAP, with 9 studies published since the last practice parameters paper in 2006.[22,28,30,33–36,40,44,49,50] Overall, the absolute difference between the mean subjective adherence rate for OA users was 0.70 (95% CI: 0.11, 1.30) more hours per night than the objective adherence rate among CPAP users. Though CPAP adherence was assessed objectively from the download data, OA adherence was assessed subjectively based on patients' self-reports or by reviewing self-entered information in their diaries. The adherence rate for the devices was based on 4 hours a night use, 70% of the time. There were no RCT studies that assessed OA adherence rate objectively.

Among patients randomly assigned to CPAP or OAs, Barnes et al. found CPAP was used 4.2 ± 0.3 nights/week for an average of 3.6 ± 0.3 h/night compared to 5.3 ± 0.3 nights/week for 5.5 ± 0.3 h/night with OAs.[22] Three of the 11 trials included in the meta-analysis clearly showed that adherence rates with OAs were superior to CPAP (> 1 more hour of use).[22,40,44] Seven of the remaining 8 studies also observed an increase use of OAs compared with CPAP.[28,30,33,34,36,49,50] However, these differences were less robust (less than or equal to 1 hour improvement in adherence rate compared to CPAP). It should be noted that all included trials compared subjective reports of OA use to objective measures of CPAP use. Although measures to obtain objective oral appliance adherence data do exist, they are not widely used. Therefore, few objective data exist to include in this clinical practice guideline.

The evidence comparing adherence with the use of OAs vs. CPAP is summarized in Figure 76.

4.2.6 Assessment of Side Effects

Side effects, serious enough to cause patients to discontinue use of their oral appliance, are less common than side effects causing adult patients with OSA to discontinue the use of CPAP. (Quality of evidence: *Moderate*) The purpose of follow-up is to monitor patient adherence, evaluate OA deterioration or maladjustment, evaluate the health of the oral and craniofacial structures and integrity of the occlusion, and assess the patient for signs and symptoms of worsening OSA. Intolerance and improper use of the OA are potential problems for patients using OAs, which require patient effort to use properly. OAs may aggravate temporomandibular disorder (TMD) and may cause dental misalignment and discomfort that are unique to each device. In addition, OAs can be rendered ineffective by patient alteration of the device. Specific side effects differ widely in types and severity, but most are of a dental nature: sore teeth, gum problems, sore jaw muscles, excessive salivation, difficulty chewing in the morning, dry mouth, and change in occlusion.[13,28,35,57,58] Doff et al. reported that changes in craniofacial morphology should be anticipated in OSA patients using an OA for 2 years when compared with CPAP therapy. These changes were predominantly dental in nature.[51] Long-term use of an OA resulted in small but significant dental changes compared with CPAP. In the OA group, overbite and overjet decreased 1.2 ± 1.1 mm and 1.5 ± 1.5 mm, respectively.[51] It should be noted, however, that in a prospective study conducted by Tsuda et al. to assess the craniofacial changes in adult subjects with OSA after CPAP use found that use of nasal CPAP for > 2 years resulted in a significant retrusion of the anterior maxilla, a decrease in maxillary-mandibular discrepancy, a setback of the supramentale and chin positions, a retroclination of maxillary incisors, and a decrease of convexity.[52] However, significant correlations between the craniofacial changes, demographic variables, or the duration of CPAP use could not be identified. None of the patients self-reported any permanent change of occlusion or facial profile.[52]

A meta-analysis (Figure 77) was performed on 9 studies that evaluated the discontinuation of therapy due to side effects resulting from the use of OAs.[4,21–23,29,31,35,40,43] The results showed that the odds of experiencing a side effect leading to discontinuation of therapy with OAs are 6.65:1 (95% CI: 2.51, 17.62).

A meta-analysis (Figure 78) was performed on 8 RCT studies of OAs versus CPAP and discontinuation of therapy from side effects.[4,20–22,29,35,40,43] The overall odds of discontinuing therapy due to the use of an OA vs. CPAP are 0.54:1 (95% CI: 0.26, 1.12) indicating that the risk of side effects resulting in the discontinuation of OA therapy is less than those resulting in the discontinuation of CPAP. Ferguson et al. reported that patients "had fewer side effects and greater patient satisfaction than with CPAP."[13,29] Aarab et al. reported 2 patients discontinuing OA therapy (vs. 6 patients with CPAP) because they reported experiencing more side effects than benefits.[21] The overall quality of evidence for these 8 RCT studies was moderate, with 299 patients in the OA group and 298 patients in the CPAP group. The treatment duration for all the 8 RCT studies varied from 1–12 months. A total of 14 patients withdrew from OA therapy and 25 withdrew from CPAP use.

In a study conducted by Ghazal et al., it was mentioned that "patients who complained of wearing discomfort had the fit of their OA and retention checked…PSG was carried out once the patient had tolerated the OA for at least 5 nights per week."[31] A study conducted by Rose et al. reported that subjective assessments of the OAs must be made after they are worn.[41] Patients in the study described loss of retention during the night, TMJ pain, gingival irritations, and tenderness in the masseter region.[41] More dental sessions were required for these patients.

Cunali et al. reported that temporomandibular disorder (TMD) has been the most common contraindication for OAs as a treatment for OSA.[26]

The evidence on the frequency of discontinuation of side effects from the use of OAs in adult patients with OSA is summarized in Figure 79.

The evidence comparing the frequency of occurrence of side effects with the use of OAs vs. CPAP in adult patients with OSA is summarized in Figure 80.

4.2a Recommendation: When oral appliance therapy is prescribed by a sleep physician for an adult patient with obstructive sleep apnea, we suggest that a qualified dentist use a custom, titratable appliance over non-custom oral devices. (GUIDELINE)

Values and Trade-Offs: The overall grade for the body of evidence exploring the impact of custom vs. non-custom OAs to treat OSA varies between low and moderate depending on the physiologic sleep outcome measures. A systematic review of the evidence has shown that custom, titratable OAs reduce the AHI, arousal index, and oxygen desaturation index, and increase oxygen saturation to a greater extent than do non-custom OAs. The evidence supports the use of custom, titratable OAs over other types of appliances. Although the reduction in AHI and ODI are similar for both custom, titratable and custom, non-titratable OAs, the confidence interval for the effect of the custom, titratable OAs is considerably smaller than for the custom, non-titratable appliances. Both types of custom appliances are more effective than non-custom OAs.

Neither custom nor non-custom OAs have been shown to significantly affect sleep architecture and sleep efficiency. The overall improvement in physiologic sleep parameters with the use of custom OAs in adult patients with OSA should result in an improvement in daily function and quality of life.

The available data also suggest that OAs effectively improve daytime sleepiness. The mean change in the Epworth Sleepiness Scale (ESS) with custom, titratable OAs is moderate. The reduction in subjective daytime sleepiness achieved with custom titratable OAs is not inferior to that reported with CPAP therapy. In contrast, very limited data suggest that custom, non-titratable OAs do not produce a significant change in ESS. Insufficient data are available to assess objective measures of sleepiness or wakefulness following OA therapy.

The evidence indicates that OAs are also effective in improving QOL. Specifically, custom titratable OAs provide moderate improvement in QOL outcomes. The data on QOL is very limited for custom, non-titratable OAs, therefore, their use cannot be recommended.

4.2b Recommendation: We recommend that sleep physicians consider prescription of oral appliances, rather than no treatment, for adult patients with obstructive sleep apnea who are intolerant of CPAP therapy or prefer alternate therapy. (STANDARD)

Values and Trade-Offs: CPAP is superior to OAs in the measured outcomes and, therefore, should be the first-line option for treating OSA. A review of the evidence suggests that adherence rates using OAs are greater than those observed with CPAP. However, no randomized controlled trials have assessed objective OA adherence rate as compared with CPAP. The subjective reporting of adherence rate is prone to bias and needs to be interpreted with caution, as patients may overestimate their OA use. However, a patient whose OSA does not improve with the use of CPAP or is intolerant to CPAP may benefit from the use of an OA. Overall, the discontinuation of therapy due to side effects occurs less when using OAs versus CPAP to treat adult patients with OSA. Therefore, OAs can be offered to patients with OSA who strongly prefer alternate therapies due to side effects or inability to use CPAP.

OAs were not compared to other alternate therapies as there were not sufficient head-to-head studies to analyze.

The overall grade for the body of evidence on the impact of OAs to treat obstructive sleep apnea (OSA) varies between low and moderate depending on the physiologic sleep outcome measures. A systematic review of the evidence has shown that OAs reduce AHI, arousal index, oxygen desaturation index, and increase oxygen saturation. However, OAs have shown no significant effect on sleep architecture and sleep efficiency. The overall improvement in physiologic sleep parameters with the use of OAs in adult patients with OSA should result in an improvement in daily function and quality of life. Although OAs have been shown to improve physiologic sleep parameters, CPAP appears, in our meta-analyses, to be superior to OAs in reducing the AHI, arousal index, and oxygen desaturation index and improving oxygen saturation, and therefore should still generally be the first-line option for treating OSA. The improvement in QOL produced by custom, titratable OAs is not inferior to that reported with CPAP therapy. The quality of evidence for the use of these OAs to improve QOL is moderate, whereas the quality of evidence comparing OAs to CPAP is low. The custom, titratable OAs improve QOL, but as with CPAP, reduced QOL may persist despite otherwise adequate therapy.

The available data regarding the impact of OAs on blood pressure are more limited (overall grade for the body of evidence is low) than the data addressing blood pressure change with CPAP. For example, the role of OAs in patients with resistant hypertension has not yet been evaluated. However, the available data suggest that OAs may be as effective as CPAP in at least select patient populations to lower blood pressure and, therefore, should not preclude the use of either therapy or diminish the other established benefits that accrue from treatment of OSA. Of note, no RCTs have assessed the impact of OA therapy on other cardiovascular endpoints.

In summary, OAs may be effective in improving sleep parameters and outcomes of OSA, and there is little likelihood of harm. Although they are not as effective as PAP therapy, the benefits of using OAs outweigh risks of not using OAs. Thus, a STANDARD strength of recommendation to use OAs was provided.

4.2c Recommendation: We suggest that qualified dentists provide oversight—rather than no follow-up—of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)

Values and Trade-Offs: Beneficial treatment effects may be reduced by treatment-related side effects, and most OA therapy side effects are dental. A wide range of devices made from a variety of materials and having different characteristics, are utilized in clinical practice. Literature on dentists performing interventions to prevent failure of OA therapy is limited, although the topic is mentioned in the results and discussion sections of some publications. Therefore, the overall evidence in support of the above recommendation was considered low. Nevertheless, minimization of side effects may improve adherence and thereby patient outcomes. Several studies demonstrated dental interventions to mitigate side effects. Additionally, knowledge of dental materials and a variety of dental devices including the knowledge of the patients' dental status will likely ensure fewer side effects. A

qualified dentist will be able to screen for many problems and choose and/or build the OA with features to minimize the side effects of the therapy. A qualified dentist will have the skills to choose the proper OA and make necessary modifications to accommodate patients who, among other things, may have allergies to metals or acrylics, are strong teeth grinders, or have anatomical deviations. The patient's history and exam, appliance preference, and review of any side effects should be taken into account to avoid device breakage, allergic reactions, or discomfort that leads to frustration or discontinuation of the therapy.

4.2.7 Long-term Management

Follow-up evaluations and sleep testing improves long-term management of adult patients with OSA. (Quality of evidence: *Low*) Although insufficient data was attained to produce a meta-analysis, several studies demonstrated that adjustments made to the OA, based on data obtained from PSGs and home sleep apnea tests (a 7-channel unattended test recording chest and abdominal movement, oxygen saturation, oro-nasal airflow, heart rate, body position, and parapharyngeal noise was utilized by Rose et al.), resulted in greater success.[41] Gagnadoux et al. compared CPAP and OAs after one-night PSG titration of both treatments. Titration of the OA was designed to optimize its efficacy. The results showed a 70% success with OA therapy vs. an 82% success with CPAP.[30] In a study conducted by Hoekema et al., participants used an OA (or CPAP) for 8 weeks, and the effect was assessed with a PSG.[36] For those with an AHI ≥ 5, the OA was adjusted and another PSG was performed. This sequence was repeated until the AHI was < 5 or the adjustments caused discomfort. Of the total OA population 76.5% were effectively treated (69.2% of the severe patients were considered effectively treated and 84.0% of the non-severe patients were considered effectively treated).[36] Aarab et al. demonstrated that, through PSG, an effective reduction in AHI was seen at 25% (1 patient), 50% (7 patients) and at 75% (12 patients).[21]

4.2d Recommendation: We suggest that sleep physicians conduct follow-up sleep testing to improve or confirm treatment efficacy, rather than conduct follow-up without sleep testing, for patients fitted with oral appliances. (GUIDELINE)

Values and Trade-Offs: The overall grade of evidence for support of follow-up evaluations and testing by sleep physicians is low due to a lack of evidence. However, the discussion sections in most research studies report significant improvement in OA effectiveness when changes were made to the appliances based on data obtained either during or after the sleep studies. While insufficient evidence exists to produce a meta-analysis, the available data suggest that subjective feedback is not sufficient to determine the optimal setting of the OA in the management of OSA. Without objective data the patient may, unnecessarily, remain suboptimally treated. Follow-up sleep testing by sleep physicians should also be considered for OA-treated patients who develop recurrent symptoms, show substantial weight changes, or receive diagnoses of comorbidities relevant to OSA.

4.2e Recommendation: We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

Values and Trade-Offs: A review of the evidence suggests that patients may benefit from periodic follow-up visits with a physician and with a qualified dentist. Several studies have demonstrated that adjustments made to the OA by a dentist, based on data obtained from PSGs and home sleep apnea tests conducted by a physician, may result in greater long-term improvement in OSA. The absence of periodic follow-up visits may result in suboptimal improvement in OSA or side effects that increase risk for discontinuation of therapy.

5.0 FUTURE DIRECTIONS

Since the publication of the previous practice parameters on the use of OAs for the management of OSA, a considerable amount of literature has been published on the efficacy of OA treatment using different types of appliances. Nevertheless, there are a number of unresolved issues that require additional consideration. Suggestions for future research are summarized below.

- There should be a consistent and standardized nomenclature when referring to OAs. We suggest that future studies should use the term "oral appliance" rather than use terms such as splints.
- Future studies should consider clinically relevant protocols when assessing custom, non-titratable OAs and when comparing different types of OAs. Methods that use more than one non-titratable OA at difference protrusive positions, or cut apart and reposition appliances do not replicate the methods clinicians expect to use with non-titratable OAs. Clinicians expect to fabricate a non-titratable OA at one protrusive position and leave it there for the course of treatment. Titration protocols that use a titratable OA during sleep to pre-determine an effective protrusive position prior to the fabrication of a non-titratable OA may be valuable.
- As the current data indicate benefits with custom titratable OAs to treat OSA compared to other types of OAs, future studies evaluating outcome measures related to OSA treatment should consider using only custom titratable OAs to compare with other therapies such as CPAP.
- A consistent and objective measure of snoring is needed when evaluating treatment benefit.
- Standard protocols are needed to document adverse effects related to OAs.
- Subjective reporting of adherence by patients is the current method of assessing OA adherence. As this is prone for reporting bias and with a lack of randomized control trials assessing objective OA use, future efforts and studies are needed to obtain objective OA adherence data, similar to CPAP. There are several recent non-RCTs published that report on the use of objective adherence

monitors in OAs. Further RCTs are needed to evaluate the efficacy of these monitors and also to compare it with the CPAP objective adherence rate.

- Larger and longer RCTs examining the benefits of OA treatment to cardiac, metabolic, and neurocognitive health will also be valuable to clinicians contemplating OA treatment for their patients.
- Studies are needed to assess the long-term outcomes associated with OA therapy in adult patients with OSA.
- Current data demonstrates that mild side effects are associated with OA therapy when compared to CPAP therapy. Few research studies conduct head to head comparisons of devices and many devices have little research investigating side effects at this time. Further research demonstrating an association between specific devices and associated side effects would be useful.
- While evidence is low in assessing the relationship of dental involvement, side effects, and adherence to OA therapy, the discussion section of many RCTs describe incidences of patients requiring additional follow up visits with dentists to make the OAs more comfortable. It is reasonable to conclude that a mitigation of side effects will increase patient adherence with therapy. There were no RCT studies assessing objective OA adherence rate because reliable technology was not available until recently. The subjectively reported adherence in RCTs is prone to bias. Future studies, utilizing newly developed technologies that produce objective data are needed.
- Studies are needed to assess the effects of mandibular exercises and other methods to mitigate side effects associated with OAs.
- Knowing the predictive factors for OA success to treat OSA will be helpful for a clinician. However, studies to date have had significant study methodology limitations, resulting in predictive factors that are not consistent in all studies. Also, some of these factors cannot be readily accessed or be used by the clinician. Future studies evaluating for predictive factors for success of OSA treatment with OAs are needed, and ideally these factors should be readily accessed and applied by the clinician.
- Also, future studies evaluating cost benefit analysis and effectiveness are needed compared to CPAP.

While significant progress has been made in defining an effective OA for the treatment of patients with OSA, this guideline underscores the need to enhance the quantity, quality, and scope of future studies to optimize patient care strategies.

NOTES

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REVIEW ARTICLES

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Efficacy versus Effectiveness in the Treatment of Obstructive Sleep Apnea: CPAP and Oral Appliances

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Obstructive sleep apnea (OSA) is a chronic disorder and effective long-term treatment is necessary to prevent associated health risks. Standard treatment remains continuous positive airway pressure which is highly efficacious but has well-recognized limitations, with suboptimal patient acceptance and adherence rates, which in turn obviates the desired health benefits. The leading alternative device treatment is oral appliances. Patients often report preferring oral appliances to CPAP treatment, with better usage rates. However, unlike CPAP, inter-individual variability in the efficacy of oral appliance therapy means that patients are often left with some residual OSA. Despite discrepancies in efficacy (apnea-hypopnea index [AHI] reduction) between CPAP and oral appliances, randomized trials show similar improvements in health outcomes between treatments, including sleepiness, quality of life, driving performance, and blood pressure. Similar results in terms of health outcomes suggests that although the two treatments have different efficacy and treatment usage profiles, these result in similar overall effectiveness. In this narrative review, we discuss efficacy versus effectiveness in relation to CPAP and oral appliance treatment of OSA.

Keywords: obstructive sleep apnea, treatment effectiveness, efficacy, CPAP, oral appliances

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Efficacy and effectiveness are important concepts to distinguish when evaluating treatment performance. Treatment efficacy refers to how well an intervention works under ideal circumstances whereas, effectiveness is how well an intervention performs in the real world where conditions are not controlled. Therefore treatment effectiveness is particularly important in management of chronic disease. Obstructive sleep apnea (OSA) is a common sleep disorder characterized by repetitive upper airway obstruction leading to intermittent hypoxia and sleep fragmentation. There has been a dramatic increase in OSA prevalence over the last two decades, attributable to the obesity epidemic, with at least moderate OSA now evident in 17% of middle-aged men and 9% of middle-aged women.[1] OSA is associated with excessive daytime sleepiness and lower quality of life as well as increased risk of workplace and motor vehicle accidents, hypertension and cardiovascular disease, type 2 diabetes, and all-cause mortality.[2–9] Therefore effective management of this chronic disorder is imperative to not only improve symptoms but to prevent long-term health risks. Standard care is the highly efficacious treatment, continuous positive airway pressure (CPAP). This therapy involves delivery of pressurized air to the upper airway during sleep via a nasal mask interface and tube connected to a pump. The pressurized air acts to splint open the upper airway preventing it from collapsing during sleep. The effectiveness of this therapy is therefore dependent upon its ability to overcome airway collapse (efficacy) as well as the time course over which a patient applies it during sleep (compliance). While the efficacy of CPAP is generally high, in the real world long-term health effects of CPAP are likely to be compromised by low compliance and suboptimal hours of treatment use. Treatment usage as a proportion of the total sleep period when a patient is vulnerable to OSA is often overlooked as a confounder of efficacy. However, treatment usage compared to sleep time is an important aspect of real-world effectiveness. Importantly, treatment effectiveness warrants consideration when comparing effects of other OSA treatment options which may not have the same level of efficacy as CPAP but may have a better usage profile. In this review we discuss efficacy and effectiveness between first line OSA treatment CPAP and the leading alternative device treatment, oral appliances.

EFFICACY VERSUS EFFECTIVENESS IN OSA

Efficacy, in the context of OSA, reflects the ability of treatment to prevent the occurrence of obstructive breathing events during periods when the treatment is being physically applied. This is assessed by the number of obstructive breathing events *per hour of sleep* or apnea-hypopnea index (AHI). An AHI < 5 events/h indicates absence of disease or a completely efficacious treatment. In a fully compliant patient (using treatment for 100% of sleep time) efficacy measured as AHI on treatment ($AHI_{Treatment}$) will give an accurate reflection of OSA treatment effectiveness. However sleep time off treatment becomes an important consideration when compliance is suboptimal. The potential impact of suboptimal CPAP compliance on AHI has been considered using formulas that adjust $AHI_{Treatment}$ for sleep time off treatment when AHI can presumably revert to untreated levels ($AHI_{Untreated}$).[10,11] When the untreated portion of the night with OSA reoccurrence is taken into consideration, CPAP effectiveness can dramatically decrease depending on OSA severity and total sleep time. Good CPAP adherence is generally set at a benchmark of 4 h/night; however, the rationale for this benchmark is not overly evidence based. Moreover when taking into consideration sleep time off treatment, 4 h of CPAP use during an 8-h sleep period may only reduce

the AHI by 50% due to reoccurrence of moderate OSA during the remaining 4 h without CPAP.[10] In this case, the true AHI is poorly represented by $AHI_{Treatment}$. It has therefore been proposed that treatment comparisons should be made on overall effectiveness after adjustment of efficacy for hours of usage over total sleep time.[12] In this context, although other OSA treatments such as surgery and oral appliances may be less efficacious, they offer more favorable compliance profiles (100% in the case of surgery), which may be an important determinant of the overall effectiveness, and may correlate more strongly with downstream health outcomes.

CPAP COMPLIANCE AND EFFECTIVENESS

Adequate CPAP compliance, based on reported average usage rates, is generally accepted as > 4 h on ≥ 70% if nights.[13] However, even with strategies to enhance patient acceptance and usage, only ~50% of patients use CPAP ≥ 4 h per night after 6 months.[14] The proportion of patients maintaining this minimally acceptable level of CPAP usage further drops to 17% after 5 years.[15] Furthermore this 4-h threshold is arbitrary and not necessarily adequate to convey benefits for *all* important health outcomes. In reality, a dose response relationship has been observed between hours of CPAP use and a range of subjective and objective health benefits with differing benefit thresholds for different outcomes.[16–18] For example, normalization of subjective sleepiness (ESS), objective sleepiness (multiple sleep latency test), and disease specific functional status (functional outcomes of sleep questionnaire [FOSQ]) requires 4, 6, and 7.5 h, respectively, of nightly CPAP usage.[18] In hypertensive OSA patients, ≥ 5.6 h of CPAP usage is required to sustain a long-term reduction in blood pressure.[19] CPAP usage > 6 h per night shows greatest reduction in mortality risk.[20] Therefore to maximize treatment benefits for all important health outcomes, CPAP needs to be consistently used for the majority, if not all, of the sleep period. Given that this is generally not a reality for most CPAP users, there is a clear rationale for conducting comparative effectiveness trials against alternative less efficacious treatments which may still be equally effective at improving health outcomes due to higher compliance rates.

ORAL APPLIANCES IN TREATMENT OF OSA

Oral appliances are the leading device alternative to CPAP. Oral appliances cover the upper and lower dental arches and are configured so that the lower jaw is held forward in a more protruded position. The action of mandibular advancement results in an increase in pharyngeal airway space and reduces airway collapsibility.[21,22] Oral appliances have a demonstrated role in improving snoring, obstructive apneas and hypopneas, and oxygen desaturation measures.[23] Oral appliances also have demonstrated benefit on health outcome measures such as daytime sleepiness and blood pressure.[23,24] However unlike CPAP which will prevent airway collapse in most people as long as sufficient pressure is applied, therapeutic response to oral appliance treatment shows intra-individual variability. In general terms, over a third of patients will show a complete response to oral appliance therapy with a reduction in AHI to < 5/h (or no OSA). Another third will have a clinically important response showing > 50% reduction in AHI,[25] although AHI remains > 5/h and a third will not achieve > 50% reduction in AHI. There are many factors which may contribute to differences in therapeutic response to oral appliance therapy including differences in devices and treatment protocols but also craniofacial, upper airway, and obesity characteristics of the patient.[25] Currently there is no validated clinical method to reliably pre-select patients who will receive sufficient benefit from oral appliance therapy from those who show minimal therapeutic response. Uncertainty around efficacy has essentially restricted oral appliance implementation to milder cases of OSA with consideration only in more severe OSA if CPAP fails.[26]

COMPARISON OF HEALTH EFFECTS OF CPAP AND ORAL APPLIANCE THERAPY

Although CPAP is clearly superior to oral appliances in terms of eliminating obstructive breathing events and improving nocturnal oxygen saturation,[27] this is not the case for health outcomes. In randomized controlled trials comparing CPAP to oral appliance treatment, CPAP consistently demonstrates normalization of AHI, whereas average AHI remains in the range of mild OSA on oral appliance treatment.[28–35] However the superiority of CPAP in terms of efficacy is generally not carried through to the actual health outcomes of treatment. A summary of randomized controlled trials comparing CPAP and oral appliances with commonly reported health outcomes is summarized in Table 1. Subjective daytime sleepiness, assessed by the Epworth Sleepiness Scale, does not differ following CPAP and oral appliance treatment.[36] This has also been shown in objective tests of sleepiness[32,37] and simulated driving performance.[35,38] Furthermore, in terms of cardiovascular outcomes there is no demonstrated difference between treatments in short-term effects on blood pressure.[29,34,35] In a small study both CPAP and oral appliances were found to improve endothelial function to the same degree.[39] To date short-term treatment studies comparing CPAP and oral appliance overall consistently show minimal to no difference in health outcome measures despite demonstrating a higher $AHI_{Treatment}$ with oral appliances. Longer term studies are lacking, although a recent 6-year observational study of untreated and treated (either CPAP or oral appliance) OSA patients found OSA treatment reduced the cardiovascular mortality rates regardless of whether CPAP or oral appliance treatment was used.[40]

A likely explanation for similarity in key health outcomes is that oral appliances are more consistently used for a greater proportion of the total sleep period, compared to CPAP. Greater usage may counterbalance the lower treatment efficacy and result in overall equivalent treatment effectiveness. Oral appliances were preferred to CPAP in four of six crossover trials asking for treatment preference at the end of the trial.[30–32,35] This preference for oral appliance treatment may translate to significantly more hours of usage. A review of reported treatment times in oral appliance studies suggests usage remains at a median of 77% of nights after one year of treatment.[41] However, it has been possible to objectively verify CPAP usage by data download for many years, while comparison to oral appliance

Table 1—Efficacy and effectiveness of oral appliances versus CPAP: AHI and health outcome results from randomized trials.

Study	Study Design	N	Baseline AHI	Treatment AHI		Health Outcomes			
						Daytime Sleepiness		Health-Related Quality of Life	Blood Pressure
				CPAP	OA	Subjective (ESS)	Objective		
Aarab, 2010	parallel	57	20.9 ± 9.8	1.4 ± 13.1	5.8 ± 14.9	↔	N/A	↔	N/A
Barnes, 2004	crossover	80	21.5 ± 1.6	4.8 ± 0.5	14.0 ± 1.1	↔	↔ (MWT)	N/A	↔
Engleman, 2002	crossover	48	31 ± 26	8 ± 6	15 ± 16	CPAP	CPAP (MWT)	CPAP	N/A
Ferguson, 1997	crossover	20	26.8 ± 11.9	4.0 ± 2.2	14.2 ± 14.7	↔	N/A	N/A	N/A
Gagnadoux, 2009	crossover	59	34 ± 13	2 (1–8)#	6 (3–14)#	↔	↔ (OSLER)	OA	N/A
Hoekema, 2008	parallel	103	40.3 ± 27.6	2.4 ± 4.2	7.8 ± 14.4	↔	N/A	↔	N/A
Lam, 2007	parallel	101	23.8 ± 1.9^	2.8 ± 1.1	10.6 ± 1.7	CPAP	N/A	CPAP	↔
Phillips, 2013	crossover	108	25.6 ± 12.3	4.5 ± 6.6	11.1 ± 12.1	↔	N/A	↔	↔
Tan, 2002	crossover	21	22.2 ± 9.6	3.1 ± 2.8	8.0 ± 10.9	↔	N/A	↔	N/A

#Median (interquartile range). ^Mean ± standard error. Summary of AHI data with CPAP and oral appliances (OA) in randomized trials comparing treatments. Summary of commonly reported health assessments are presented. "CPAP" or "OA" indicates superior results were found with that treatment, ↔ indicates equivalent findings observed with both treatments. AHI data is mean ± standard deviation, unless otherwise indicated. ESS, Epworth Sleepiness Score; MWT, maintenance of wakefulness test; OSLER, oxford sleep resistance test.

usage has been limited to self-report until recently. Therefore, even though self-reported oral appliance usage appears to exceed that of objectively downloaded CPAP usage, it has been difficult to compare usage profiles between therapies. The recent advent of objective compliance monitors for oral appliances in the form of small embedded temperature-sensing chips[42] now makes verification of usage patterns possible. Initial studies of objective oral appliance usage confirm good usage of > 7 hours a night in the initial 3 months of oral appliance treatment[42] which is maintained at > 6 hours per night after one year.[43] Furthermore the discrepancy of over an hour between subjective and objective CPAP usage[13] does not seem to be apparent with oral appliance treatment, with initial studies reporting < 30 minutes difference between subjective estimates and objective data.[43] Regardless, initial evidence from oral appliance compliance monitors lends support to greater usage of oral appliance therapy than CPAP.

SLEEP ADJUSTED RESIDUAL AHI (SARAH INDEX) FOR ASSESSMENT OF TREATMENT EFFECTIVENESS

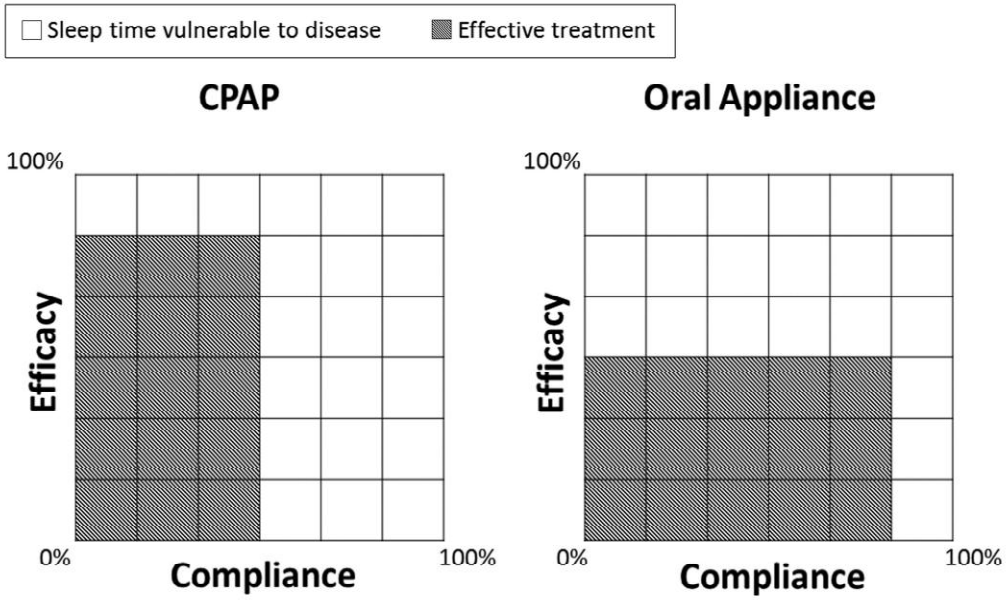
Evidence of equivalent health outcomes between oral appliances and CPAP suggest that real-world treatment effectiveness is not captured by the efficacy measure $AHI_{Treatment}$. However this is the metric on which clinical decisions are primarily made, although it is well recognized that CPAP is not used for all hours of sleep. The different treatment profiles of CPAP (high efficacy/low adherence) and oral appliances (moderate efficacy/high adherence) may conceptually result in similar profiles of treatment effectiveness. In the schematic in Figure 1, two identical sleep periods in which OSA can occur is represented by a grid (white boxes) for which CPAP and oral appliance are applied. Treatment effectiveness is a composite of efficacy (represented on the y axis of the grid) and hours of treatment usage (represented on the x axis). In this example MAS is only half as efficacious as CPAP, but compliance is two-fold greater. Despite these different treatment profiles, both treatments have similar overall effectiveness in relieving OSA (shaded area). This conceptual example likely reflects many patients in the real world, for whom CPAP is highly efficacious but treatment usage is modest, while oral appliances may have more modest efficacy but are used for relatively more of the sleep period. Potentially a more representative measure of treatment effectiveness than $AHI_{Treatment}$ should also take into account hours ON treatment ($AHI_{Treatment}$) *and* hours OFF treatment ($AHI_{Untreated}$) for the TOTAL sleep period. We adopt the formula of Ravesloot and colleagues,[12] which accounts for these additional factors in order to assess a more accurate measure of treatment effectiveness, which we have called the Sleep Adjusted Residual AHI or SARAH Index. Potentially such an index which incorporates these currently overlooked factors could be a more accurate measure of treatment effectiveness and will better align with downstream health benefits. The formula is expressed below:

$$\text{Sleep Adjusted Residual AHI (SARAH Index)} = \frac{[AHI_{Treatment} \times Hours_{Treatment}] + [AHI_{Untreated} \times Hours_{Untreated}]}{Hours_{Total\ Sleep\ Time}}$$

COMPARISON OF AHI AND SLEEP ADJUSTED RESIDUAL AHI (SARAH INDEX) IN CPAP AND ORAL APPLIANCE TREATMENT

We have previously published a large cross-over study (108 completers) of one month each of optimized CPAP and oral appliance treatments.[35] This study found that oral appliances were non-inferior to CPAP across a range of health outcomes in predominantly moderate-severe patients. There were no between-treatment difference in cardiovascular (24-h

Figure 1—Comparison of treatment effectiveness profile of CPAP and oral appliances.



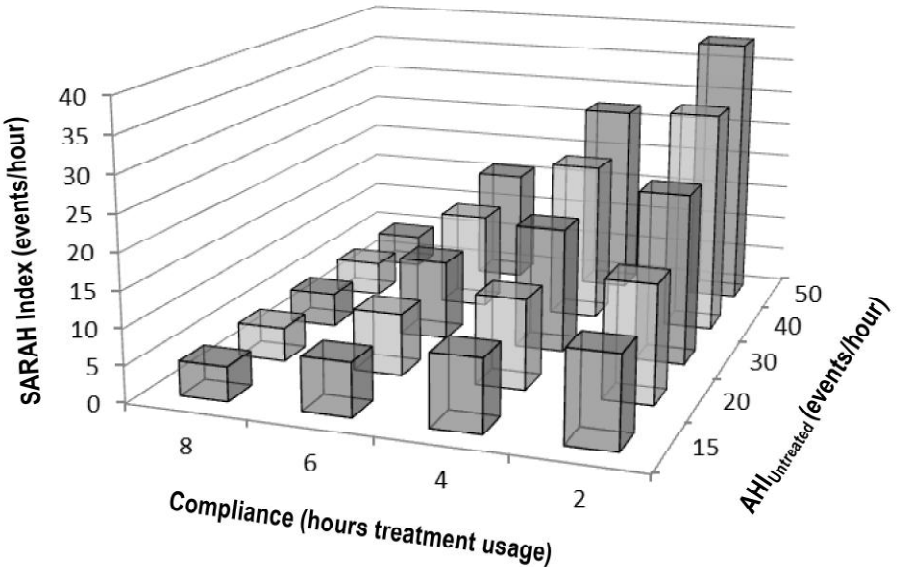
Efficacy (y axis) reflects the ability of treatment to prevent obstructive breathing events when it is physically applied. Compliance (x axis) reflects the hours the treatment is applied for over the total sleep time when obstructive events can occur. "Effectiveness" requires both efficacy and compliance and the balance of these likely reflects over health outcomes. This schematic illustrates the scenario of an oral appliance which is only half as efficacious as CPAP but has two-fold greater compliance which results in equivalent effectiveness (shaded area).

blood pressure, arterial stiffness), neurobehavioral (subjective sleepiness, driving simulator performance), or quality of life outcomes. In a subgroup of hypertensive patients, blood pressure during sleep reduced from baseline with both treatments, but more importantly, with no difference between them. In comparing the efficacy profiles of the two treatments, as expected, polysomnography confirmed OSA resolution on CPAP, whereas residual mild OSA was evident with oral appliance treatment (AHI 4.5 ± 6.6 vs. 11.1 ± 12.1/h). However, self-reported compliance favored oral appliances at an average 1.3 h more usage per night than CPAP. These efficacy and compliance profiles of CPAP and oral appliance treatment suggest that superior CPAP efficacy may be offset by greater oral appliance usage. We now use real data from this trial to compare AHI and SARAH Index between CPAP and oral appliance treatments across the spectrum of OSA severity.

Median treatment AHI on CPAP from this trial was 4.7/h (i.e., elimination of OSA). We have used $AHI_{Treatment}$ of 4.7/h to calculate the SARAH Index at different levels of treatment usage hours for an 8-h sleep period (healthy sleep time range[44]). Figure 2 shows the results from calculation of SARAH Index across a range of OSA severity ($AHI_{Untreated}$). If CPAP is used for the total 8-h sleep, OSA is indeed resolved (AHI = 4.7) for all levels of OSA severity. However, it is recognized that as many as 50% of CPAP treated patients are using their treatment < 4 h of total sleep time.[15] Using this example of an 8-h sleep period, the graph demonstrates that patients using their device for 4 and 2 h per night have at least mild OSA assessed by the SARAH Index, with much higher levels in those with more severe OSA. As total sleep time decreases, the SARAH Index reduces; however, for an average 8-h sleep period, the majority of CPAP users would be effectively under-treated based on known compliance rates. As CPAP usage further declines long term, CPAP treatment effectiveness may additionally become worse over time. This graph illustrates that when taking into consideration CPAP hours used over sleep time, OSA may not be well controlled, and even moderate-severe OSA may still be present in more severe and less compliant patients who sleep for longer periods. The SARAH Index calculation raises the possibility that despite high efficacy, CPAP users may not be effectively treated in practice.

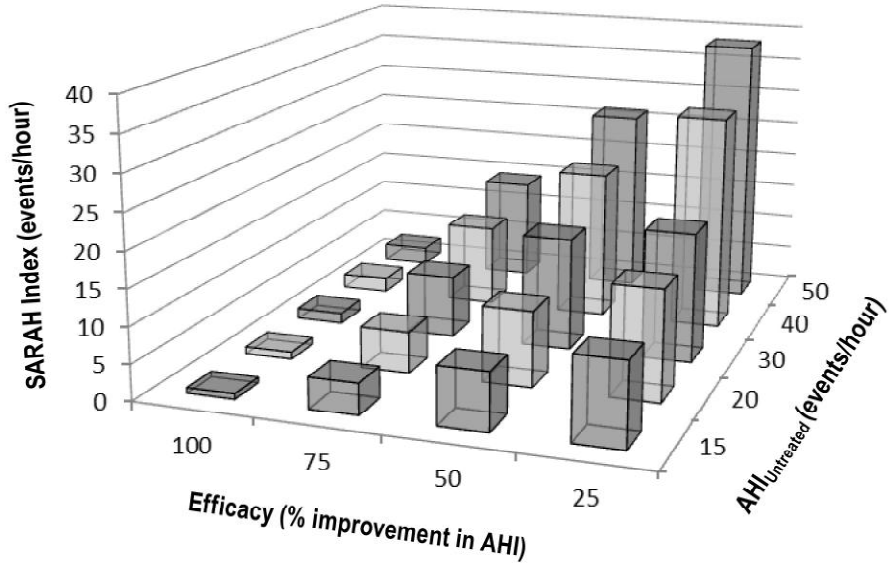
Oral appliance usage data from this same trial[35] found median reported usage time to be 95% of total sleep time. We have used this 95% compliance rate to assess oral appliance treatment effectiveness by the SARAH Index. With good self-reported usage of nearly 100% of sleep time the influencing factor on treatment effectiveness for oral appliances is their efficacy, expressed as a percentage improvement in OSA from baseline levels. We show SARAH Index for different OSA severities across different levels of oral appliance efficacy of 25%, 50%, 75%, and 100% improvement in Figure 3. Oral appliance treatment effectiveness expressed by SARAH Index varies with efficacy and OSA severity. We have shown in a large audit of oral appliance treated patients that the majority (70%) will have ≥ 50% improvement in OSA using an oral appliance.[45] If we compare Figures 2 and 3, CPAP and oral appliance treatment effectiveness measured by the SARAH Index, conceptually we can see that many patients may be effectively undertreated with either treatment. However, with half of all CPAP treated patients using it < 4 h per night and two-thirds of oral appliance treated patients reducing OSA by at least half, theoretically many patients with incomplete efficacy on oral appliance may be no worse off than when on fully efficacious CPAP in terms of treatment effectiveness.

Figure 2—CPAP effectiveness assessed by the Sleep Adjusted Residual AHI (SARAH Index).



This figure illustrates SARAH Index for different levels of OSA severity ($AHI_{Untreated}$) for varying hours of treatment usage for an average 8-h sleep time. An $AHI_{Treatment}$ of 4.7 events/h is used (elimination of OSA). When taking into consideration CPAP hours used over sleep time, OSA may not be well controlled in moderate-severe patients using CPAP 4 hours or less for 8 h of sleep.

Figure 3—Oral appliance effectiveness assessed by the Sleep Adjusted Residual AHI (SARAH Index).



In contrast to CPAP, oral appliance hours of usage are reported to be high (95% of sleep time). However efficacy levels are variable with oral appliances. This figure illustrates SARAH Index for different levels of efficacy (% improvement in AHI). The majority of patients have 50% or greater improvement in $AHI_{Treatment}$ using an oral appliance. Therefore by SARAH Index calculation, many patients may not be worse off on oral appliance treatment despite $AHI_{Treatment}$ > 5/hour compared to CPAP used for minimal hours compared to total sleep time.

POTENTIAL CONFOUNDERS OF EFFECTIVENESS CALCULATION

Although treatment efficacy is not an adequate indicator of health benefit, effectiveness measures, such as the calculation presented as the SARAH Index, also have potential limitations. The formula assumes that OSA will return to baseline levels once treatment is removed before the end of the sleep period. Withdrawal of CPAP results in return of OSA.[46–48] However, short-term carryover effects after CPAP removal may occur resulting in reduced OSA despite being without treatment. Sustained effects of CPAP may be due to an ongoing increase in pharyngeal volume and airflow due to reduced soft tissue edema as a consequence of CPAP use.[49,50] The evidence for existence and duration of CPAP washout effects has been recently reviewed.[51] Studies re-assessing OSA after CPAP

withdrawal for several nights to weeks find lower AHI levels then recorded at baseline, potentially more evident in severe OSA patients,[48] although this is not always observed.[47,52,53] Regardless of baseline severity, AHI does appear to deteriorate between the first and seventh night of CPAP withdrawal.[54] Furthermore, although some CPAP washout effect is observed in studies, the extent and duration is highly variable and potentially confounded by issues of night to night variability in measurement of sleep-disordered breathing.[55,56] In particular, it is unknown whether such a phenomenon occurs within a single night. In terms of oral appliances, OSA levels return to baseline after a week of a placebo oral appliance (no active advancement).[57] However residual effects of mandibular advancement once the lower jaw returns to normal position, or a washout effect, may be less plausible with oral appliances than CPAP.

This effectiveness assessment also does not take into account differences in OSA severity due to body position and sleep stage. OSA may become more severe in the supine position and REM sleep and treatment effectiveness, particularly of oral appliances, may vary under these conditions.[45] CPAP removal after several hours may leave the patient exposed to the portion of the night with more concentrated REM sleep, and hence more severe OSA. Treatment carryover effects and OSA variability due to body position and sleep stage are not captured in the simple assessment of time on versus off treatment at $AHI_{Treatment}$ and $AHI_{Baseline}$, and would be difficult to do so routinely. However, whether this approximation of effectiveness will be more clinically useful than relying only on a potentially false reassurance of $AHI_{Treatment}$ needs further assessment. If proven to give a more reliable measure of effectiveness, another obstacle to adopting an index such as SARAH Index would be related to technological limitations with estimating sleep time in the home setting. Although the growing adoption of lifestyle wearable devices that monitor aspects of sleep may prove useful in this regard.

CONCLUSIONS AND FUTURE DIRECTIONS

Although effectiveness, as a combined measure of real world usage and efficacy, is difficult to accurately assess, proposed formulas which account for sleep time on and off treatment potentially may be a more accurate marker of health outcome responses. However this remains to be assessed in prospective trials. There is limited evidence of comparative effectiveness of CPAP and oral appliance treatments longer-term. If equivalent short-term health outcomes are found to be sustained in the long term, this opens up treatment options for patients with this chronic disease. Comparative-effectiveness and Patient-Centered Outcomes Research aims to help patients (and their healthcare providers) to make informed decisions about health and healthcare options base on outcomes that are important to them.[58] We propose a greater emphasis on treatment effectiveness rather than efficacy as part of a chronic disease management approach. Future comparative effectiveness research of CPAP and Oral appliance treatment could allow patients more freedom to choose their preferred treatment over all aspects of treatment effectiveness and health outcomes.

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CHEST

Original Research

SLEEP DISORDERS

Efficacy of an Adjustable Oral Appliance and Comparison With Continuous Positive Airway Pressure for the Treatment of Obstructive Sleep Apnea Syndrome

Aaron B. Holley, MD; Christopher J. Lettieri, MD, FCCP; and Anita A. Shah, DO

Background: **We sought to establish the efficacy of an adjustable oral appliance (aOA) in the largest patient population studied to date, to our knowledge, and to provide a comparison with continuous positive airway pressure (CPAP).**
Methods: **We conducted a retrospective analysis of patients using an aOA. Results of overnight polysomnography with aOA titration were evaluated and compared with CPAP. Predictors of a successful aOA titration were determined using a multivariate logistic regression model.**
Results: **A total of 497 patients were given an aOA during the specified time period. The aOA reduced the mean apnea-hypopnea index (AHI) to 8.4 ± 11.4, and 70.3%, 47.6%, and 41.4% of patients with mild, moderate, and severe disease achieved an AHI < 5, respectively. Patients using an aOA decreased their mean Epworth Sleepiness Score by 2.71 (95% CI, 2.3-3.2; *P* < .001) at follow-up. CPAP improved the AHI by −3.43 (95% CI, 1.88-4.99; *P* < .001) when compared with an aOA, but when adjusted for severity of disease, this difference only reached significance for patients with severe disease (−5.88 [95% CI, −8.95 to −2.82; *P* < .001]). However, 70.1% of all patients achieved an AHI < 5 using CPAP compared with 51.6% for the aOA (*P* < .001). On multivariate analysis, baseline AHI was a significant predictor of achieving an AHI < 5 on aOA titration, and age showed a trend toward significance.**
Conclusions: **In comparison with past reports, more patients in our study achieved an AHI < 5 using an aOA. The aOA is comparable to CPAP for patients with mild disease, whereas CPAP is superior for patients with moderate to severe disease. A lower AHI was the only predictor of a successful aOA titration.** ***CHEST 2011; 140(6):1511–1516***

Abbreviations: AASM = American Academy of Sleep Medicine; AHI = apnea-hypopnea index; aOA = adjustable oral appliance; CPAP = continuous positive airway pressure; ESS = Epworth Sleepiness Score; MMP = maximum mandibular protrusion; OA = oral appliance; OSAS = obstructive sleep apnea syndrome; PSG = polysomnography; TAP = Thornton Adjustable Positioner

An oral appliance (OA) is a device that fits within the oral cavity and prevents upper airway collapse in patients with obstructive sleep apnea syndrome (OSAS). A recent American Academy of Sleep Medicine (AASM) guideline concluded that OAs are less effective than continuous positive airway pressure (CPAP) but are a reasonable alternative for patients with mild to moderate obstructive sleep apnea (OSA) in specific situations.[1,2] For patients with severe OSA, a trial of CPAP is required prior to their use, and

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surgery may be preferred over an OA for CPAP failures. Predicting which patients will have a successful OA titration and treatment response is difficult.[1,2]

The studies used to establish these guidelines are limited by small sample sizes, select patient populations, and the absence of device titration during polysomnography (PSG). The two largest trials enrolled only 256[3] and 263[4] patients. Trials included patients who failed or had a contraindication to CPAP,[4-6] which may bias the results toward a less responsive population. Most study protocols for performing a PSG with an OA in place did not include active titration during the study.[4,7,8] Given these limitations, the published data likely underestimate the efficacy of an OA and leave clinicians uncertain as to which patients might benefit from their use.

At the Walter Reed Army Medical Center sleep clinic, an adjustable OA (aOA) is often ordered for patients who are set to deploy, even if they are already using CPAP. This provides an opportunity to study a large patient population not biased by a high proportion of CPAP failures. In addition, all patients have their aOA setting optimized by titration during PSG. We analyzed data from patients who were given an aOA by our clinic to clarify their role in the treatment of OSAS, with the expectation that our success rate would be higher than previously published estimates.

Materials and Methods

Patients

This protocol was approved by the institutional review board at our hospital's Department of Clinical Investigations, IRB reference No. 05-17048EX-355294-1. Because the study was retrospective in nature and all patient identifiers were removed from the database, patient consent was not required. Using this protocol, we performed a retrospective review of all patients who were given an aOA by a provider from our clinic. All patients had an AHI > 5, and patients with Cheyne-Stokes respirations, central sleep apnea, and the obesity-hypoventilation syndrome were not given an aOA in our clinic. Patients with an edentulous jaw, known temporomandibular joint disease, and acute periodontal disease were not offered an OA. Data on craniofacial characteristics, BMI, age, Epworth Sleepiness Score (ESS), and comorbid hypertensive disease were abstracted from the initial sleep clinic visit.

Many patients in our clinic deploy to austere environments where electricity is not available. Reliance on CPAP may result in duty restrictions or separation from service, so from 2004 to 2006 it was standard practice to prescribe both CPAP and an OA for patients diagnosed with OSAS who were expected to deploy. Patients did not have to try or fail CPAP prior to being given an OA. Patients were advised to use CPAP whenever possible, whereas the OA was reserved for travel to locations that could not support a CPAP unit.

All patients diagnosed with the OSAS at our institution undergo education regarding the health effects of untreated OSA and the need for adequate therapy. Whether they are given CPAP, an OA, or both, they are trained in the proper care for and maintenance of their device(s). We provide serial clinical evaluations after therapy is initiated, during which methods to maximize adherence are discussed. When applicable, active sinus disease is adequately treated prior to initiating OA therapy.

Oral Appliance

All patients received a Thorton Adjustable Positioner (TAP) (Airway Management, Inc; Dallas, Texas), an aOA designed for PSG titration and used for the treatment of snoring and OSAS. The TAP is a custom-made, two-piece appliance that fits over the upper and lower teeth. It aims to prevent the tongue and soft tissues of the throat from collapsing into the airway by forward protrusion of the lower jaw. The TAP has an anterior dial that allows adjustment to achieve maximum comfort and efficacy. Each turn is equal to 0.25 mm of additional jaw protrusion.

After receiving a diagnosis of OSAS, patients were followed by a board-certified sleep medicine physician. They were referred to one of two dentists, each specifically trained in sleep medicine, to be fitted for an individually customized device. After the maximum mandibular protrusion (MMP) was estimated, the dentist then fit the appliance, instructed the patient on how to adjust and care for the device, and counseled the patient on side effects. The initial setting was usually at 70% to 80% of the MMP.

After being fitted, patients began an at-home adjustment protocol with the aOA set in a neutral position. Patients were instructed to advance the device 0.25 mm (one turn) each night as tolerated, with the goal of optimizing subjective sleep quality. In the event of discomfort, the device was regressed 0.5 mm (two turns) and subsequent advancement was resumed at a slower pace. Using the setting that the patient settled on during the at-home titration protocol and the patient's sleep diary, the degree of mandibular advancement that optimized sleep quality was estimated.

Follow-up PSG with aOA titration was scheduled after subjective improvement in sleep quality. At follow-up PSG, the aOA was set to 1 mm of mandibular advancement less than the number of turns used at home, and incrementally advanced to eliminate respiratory events (apneas, hypopneas, and snoring). If the patient was uncomfortable at a given number of turns, the technician was instructed to dial back two turns and to cease advancing the device for the remainder of the study. Technicians were instructed not to advance the device past the MMP. After their titration PSG, patients used the number of turns that provided the lowest AHI, provided side effects were tolerable.

Polysomnography

The diagnosis of OSA was made by an attended, overnight level I polysomnogram in all subjects. The apnea-hypopnea index (AHI) was used to define the severity of OSA in accordance with the AASM criteria, as follows[9,10]:

- Mild AHI: 5-15/h
- Moderate AHI: > 15-30/h
- Severe AHI: > 30/h

Hypopneas were defined by the AASM alternative criteria.[10] For the overnight CPAP titration on PSG, patients were titrated according to AASM guidelines.[11]

All PSGs were scored by a certified sleep technician in accordance with the published AASM guidelines[10] and interpreted by a board-certified sleep physician. Relevant PSG data were abstracted, including oxygen saturation nadir, total time with oxygen saturation < 90%, and AHI in both the supine and lateral positions. Patients were labeled as having "positional" sleep apnea if the AHI in the lateral position was < 5 and was 50% lower than that seen in the supine position. For aOA titration studies, the time,

AHI, and amount of rapid eye movement sleep at the maximum number of turns were recorded. For CPAP titration studies, the final pressure and the AHI at that pressure were recorded.

Treatment Success

Because a CPAP titration is considered unsuccessful unless an AHI <5 is achieved,[11] we used an AHI <5 as our criterion for success when we compared the aOA to CPAP. Many OA studies cited in the AASM practice guideline used an AHI <10[1,3,4,7,12-16] to define success, so success rates according to this standard are also provided.

Statistical Analysis

All means are followed by SD. Comparisons between categorical variables were performed using χ^2 and McNemar χ^2 analyses. Differences between means were compared using the paired samples and independent samples *t* tests. To identify baseline demographic, polysomnographic, and physical examination predictors of an AHI <5 on an aOA titration, logistic regression was performed. Variables were entered into models if they reached a *P* value of $<.10$ in univariate analysis or if association was assumed clinically (Statistical Package for Social Sciences 17.0; SPSS Inc; Chicago, Illinois).

Results

A total of 720 consecutive patients were given an OA at our clinic between August 1996 and March 2009. Of these, 96 were excluded because they were given a fixed device that could not be adjusted. This left 624 patients who received an adjustable appliance during the specified time period, and 497 had data from their aOA titration available for analysis. The 127 patients who received an adjustable appliance but did not have data available for the aOA titration were younger (39.3 ± 9.0 y vs 41.3 ± 9.0 y; $P = .03$) and had more subjective sleepiness according to the ESS (14.2 ± 5.0 vs 12.9 ± 5.1; $P = .02$), when compared with the 497 patients with data. There was no significant difference in AHI, oxygen nadir, or percent time below an oxygen saturation of 90% on the initial PSG and no difference in BMI, percent of patients with positional OSA, gender, or OSA severity between the two groups. Baseline demographics and PSG data for the 497 patients who had an aOA titration are listed in Table 1. The average time between diagnostic PSG and aOA titration was 296.5 ± 315.7 days.

Tables 2 and 3 list the results of the aOA titration. An ESS was documented at the time of the aOA titration and the diagnostic PSG for 330 patients. Presumably, they had been given and were using their aOA in the interim. The average time between studies for these 330 patients was 297.3 ± 317.2 days, and the ESS was 13.0 ± 5.0 prior to the diagnostic PSG and 10.4 ± 5.3 at the time of the aOA titration (-2.7; 95% CI, -2.2 to -3.1; $P < .001$).

There were 378 patients who had both CPAP and aOA titrations available for comparison, and titrations with the aOA were completed an average of 232 ± 355 days after those with CPAP. Most patients (98.7%) had their CPAP titrations performed first. Results for the CPAP titration studies are shown in Table 4. When compared with the aOA, CPAP

Table 1—*Baseline Characteristics*

Age	41.3 ± 9.0
BMI	28.7 ± 4.4
Men	86.4
HTN	28.7
ESS	12.9 ± 5.1
Mallampati	
1	7.3
2	17.4
3	50.0
4	25.3
Retrognathia/micrognathia	63.5
Diagnostic PSG results	
AHI	30.0 ± 24.8
Supine	23.7 ± 17.9
Side	13.6 ± 17.5
Positional	37.4[a]
Spo_2 nadir	83.8 ± 7.5
Spo_2% TST <90%	5.1 ± 10.0
Mild OSA	33.4
Moderate OSA	30.8
Severe OSA	35.8

Data are presented as mean ± SD or %. AHI = apnea-hypopnea index; ESS = Epworth Sleepiness Score; HTN = physician diagnosis; OSA = obstructive sleep apnea; PSG = polysomnogram; Spo_2 = oxygen saturation by pulse oximetry; TST = total sleep time (in min).
[a]AHI 50% less on side when compared with supine, and AHI <5 on side.

Table 2—*aOA Titration Results*

AHI[a]	8.3 ± 11.4
AHI supine	12.4 ± 13.5
AHI side	6.7 ± 13.3
Spo_2 nadir	85.1 ± 7.3
Spo_2% TST <90%	3.3 ± 8.8
REM at final turns	84.4
Time at final turns, min	221.4 ± 124.1
AHI <5[a]	53.8
AHI <10[a]	73.9
Mild OSA (n = 186)	
AHI[a]	5.2 ± 7.3
AHI <5[a]	69.9
AHI <10[a]	86.0
Moderate OSA (n = 144)	
AHI[a]	7.4 ± 8.1
AHI <5[a]	47.9
AHI <10[a]	75.0
Severe OSA (n = 167)	
AHI[a]	12.3 ± 15.4
AHI <5[a]	41.9
AHI <10[a]	60.5

Data are presented as mean ± SD or %. aOA = adjustable oral appliance; REM = rapid eye movement sleep. See Table 1 legend for expansion of other abbreviations.
[a]Data reflect AHI at final turn.

Table 3—*Improvements With aOA*

Measure	Improvement	95% CI	*P* Value
Mean AHI reduction at final turn			
Overall	−21.6	19.4-23.8	< .001
Mild	−4.46	3.3-5.6	< .001
Moderate	−13.5	12.0-15.0	< .001
Severe	−44.5	40.7-48.4	< .001
Change in O_2 saturation nadir			
Overall	+1.27	0.5-2.1	.001
% Time SpO_2 < 90%			
Overall	−1.88	0.8-3.0	.001

O_2 = oxygen. See Table 1 and 2 legends for expansion of other abbreviations.

improved the AHI by −3.43 (95% CI, 1.88-4.99; $P < .001$). When adjusted for severity of disease, the difference in AHI improvement between CPAP and an aOA was −1.9 (95% CI, −3.8 to 0.02; $P = .053$), −1.7 (95% CI, −4.0 to 0.7; $P = .17$), and −5.88 (95% CI, −8.95 to −2.82; $P < .001$) for mild, moderate, and severe disease, respectively. On CPAP titration, 70.1% (268 of 378) of patients achieved an AHI < 5 at final pressure, compared with 51.6% (195 of 378) at final turn on their aOA titration ($P < .001$ for difference). When the same comparison was done, adjusting for disease severity, success rates (AHI < 5) for CPAP vs aOA were 76.2% vs 62.3% ($P = .15$), 71.0% vs 50.8% ($P = .001$), and 63.4% vs 39.9% ($P < .001$) for mild, moderate, and severe disease, respectively.

Results for the univariate analysis are shown in Table 5, and multivariate modeling in Table 6. Patients who achieved an AHI < 5 on their aOA titration were younger, had a lower BMI, and had less severe OSA as measured by the AHI and degree of nocturnal hypoxia. They were also more likely to be women. On multivariate analysis, only baseline AHI retained significance, whereas age showed a trend toward significance. Using an AHI < 10 as the dependent variable, AHI at baseline remained the only significant predictor in multivariate modeling (OR, 0.98; 95% CI, 0.97-0.99; $P = .002$).

Table 4—*CPAP Titration Results*

AHI at final pressure	5.6 ± 10.9
Final CPAP pressure	8.7 ± 2.9
AHI < 5 at final pressure	69.1
AHI < 10 at final pressure	84.3
Mild OSA (n = 113)	
AHI at final pressure	3.8 ± 7.4
AHI < 5 at final pressure	76.2
AHI < 10 at final pressure	85.7
Moderate OSA (n = 114)	
AHI at final pressure	5.7 ± 11.0
AHI < 5 at final pressure	70.7
AHI < 10 at final pressure	87.7
Severe OSA (n = 151)	
AHI at final pressure	6.8 ± 12.8
AHI < 5 at final pressure	62.9
AHI < 10 at final pressure	80.1

Data are presented as mean ± SD or %. CPAP = continuous positive airway pressure. See Table 1 legend for expansion of abbreviations.

Discussion

We found that the majority of patients using an aOA achieved an AHI < 5 on the PSG titration, and the ESS decreased significantly after an aOA was prescribed. In multivariate analysis, only AHI remained a significant predictor of aOA success. Although CPAP was superior for patients with severe OSA, the difference in AHI reduction between the aOA and CPAP was not significant for patients with mild and moderate disease.

In comparison with previous studies, the OA success rate at our clinic was higher. The AASM guidelines[1,2] and a recent review[17] both quote a summary success rate from the literature, using AHI < 10, of just over 50%. Our population's success rate using the same criteria was 73.6%. The largest studies performed to date quote success rates of 54%,[3,4] 51%,[7] and 49.1%[12] using an AHI < 10, and 36%[8] using an AHI < 5 as the definition for success, all considerably lower than our rates. Our success rate for patients with severe disease was also higher than previously seen.[1,2,4,17]

The absence of a statistically superior AHI reduction with CPAP in comparison with the aOA in a large group of patients with mild and moderate disease is an important addition to the existing literature. Other investigators have reported mixed results for the comparison of CPAP to an OA for this outcome. Most have found significant differences favoring CPAP for mild to moderate disease,[12,14,15,18,19] but a few have not.[13,16]

All of the variables identified as predictors in our univariate analysis have been cited in the literature before.[1,17] Evaluations of predictors performed by different investigators have varied based on the outcomes predicted, the definitions used for positional apnea, the type of analysis performed (linear vs logistic regression), and whether cephalometric and other variables were included in the models.[4,7,20-24] This makes comparisons difficult, and the lack of prospective validation limits the inferences that can be made from the existing data on predictors of success.

We cannot determine with certainty why our aOA success rates were higher than those seen previously, but we believe there are two possible reasons. First, our patients' aOAs were titrated during the follow-up PSG, which is a relatively new technique that is only briefly mentioned in the 2006 AASM guidelines.[1,25,26]

Table 5—*Univariate Analysis for Successful aOA Titration*

Variable	AHI < 5	AHI > 5	*P* Value
Age	40.0 ± 8.8	42.9 ± 8.8	< .001
BMI	28.1 ± 4.7	29.3 ± 4.0	.007
ESS	12.9 ± 5.0	12.9 ± 5.2	.99
Spo_2% TST < 90%	3.6 ± 7.7	7.1 ± 12.3	.003
AHI	24.3 ± 20.2	36.5 ± 27.8	< .001
Retrognathia/micrognathia	64.0	62.6	.78
Women	16.8	9.3	.014
Positional[a]	43.1	31.8	.18

Data are presented as mean ± SD or %. See Table 1 and 2 legends for expansion of abbreviations.
[a]AHI 50% less on side when compared with supine, and AHI < 5 on side.

Although previous studies routinely allowed a variable period of time for self-adjustment,[4,7,8,12,22,27] very few specifically stated that they followed up with an in-laboratory titration. Most follow-up PSGs with the OA in place appear to have occurred at a single device setting without changes during the study. Titration in the laboratory likely provided a superior improvement in the AHI for our patients. Second, because the 1995[28,29] and 2006 AASM OA guidelines state that OAs should be considered second line, and that patients with moderate[28,29] or severe[1,2,28,29] disease should have a trial of CPAP prior to using an OA, previous studies only included patients with moderate or severe disease if they had already failed CPAP.[4,24] Even for those studies that did not explicitly state whether patients failed CPAP prior to using an OA, given the guidelines it is reasonable to assume that a portion of the patients enrolled had tried and failed CPAP. Because many of the patients seen at our clinic had not failed CPAP when their OA was prescribed, that population was not subject to the same degree of selection bias.

Our study has several limitations. Because it was retrospective, we were not able to collect variables that others found predictive of OA success, to include the maximum jaw protrusion and the cephalometric analysis that was done at the initial dental visit. Our population includes a large portion of active duty military members, so our findings may not generalize to a civilian population with different demographics and anthropomorphic features. Although the long time interval between diagnostic PSG and aOA titration likely reflects issues with timely access to dental care and PSG wait times, if the patient lost weight during this period or made additional adjustments to treatment, this could bias our results toward a better aOA titration. We also have no data on side effects, treatment preferences, adherence, or clinical failures, so it is not possible to perform a risk-benefit analysis for aOA therapy.

Table 6—*Multivariate Logistic Regression*

Variable	OR	95% CI	*P* Value
Age	0.97	0.95-1.00	.06
BMI	0.97	0.91-1.01	.20
Spo_2% TST < 90%	1.00	0.97-1.03	.94
AHI	0.98	0.97-0.99	< .001
Female	1.88	0.88-4.02	.11

See Table 1 legend for expansion of abbreviations.

In summary, in the largest patient population studied to date, we found a higher aOA success rate than previously seen. Based on our results, an aOA would be a reasonable, first-line alternative to CPAP for patients with mild disease. For patients with moderate to severe disease, our higher success rates call into question the recommendation that a CPAP failure is required prior to using an adjustable OA. Future studies should focus on measuring aOA adherence and side effects along with patient treatment preferences so that a comprehensive comparison with CPAP can be conducted.

Acknowledgments

Author contributions: All authors confirm that the study objectives and procedures were honestly disclosed and the procedures were followed so that the results are valid and could be generalized to a similar population.
Dr Holley: wrote the manuscript, performed all statistical analyses, edited the manuscript, and contributed to database construction. He is the primary guarantor of the manuscript.
Dr Lettieri: contributed to intellectual design and project initiation, data collection, database construction, and editing and writing the manuscript.
Dr Shah: contributed to database construction and editing and writing the manuscript.
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And here is the interview COL Lettieri did regarding the article: (2012)
https://americansleepandbreathingacademy.com/the-battle-for-oral-appliance-legitimacy

Transcript –

If you're living in a fox hole, CPAP is highly inconvenient. Army physicians took this simple truth and turned it into a study that has buoyed the case for adjustable oral appliances.

CPAP compliance can be challenging under ideal conditions. Add the dust, sand, and lack of electricity under combat conditions, and therapy adherence can be virtually impossible.

Major Aaron B. Holley, MD, FACP, ran an ICU unit in Afghanistan for 6 months where he treated combat-related injuries. He saw the harsh Arab landscape firsthand, a place where proper sleep is not a priority. Even in cases of clearly identified sleep apnea, most troops could not afford to give up pack space for CPAP devices and batteries.

Back home at Walter Reed National Military Medical Center (WRNMC), Bethesda, Md, Holley and Lt Col Christopher J. Lettieri, MD, FACP, FCCP, FAASM, continued their work to improve sleep for veterans. They believed that if oral appliances (OAs) were as effective as they were convenient, they could ultimately contribute to a stronger fighting force.

Lettieri, Holley, and additional colleagues attempted to find the answer to this question, ultimately publishing research in the CHEST Journal. The study, titled "Efficacy of an Adjustable Oral Appliance and Comparison with CPAP for the Treatment of Obstructive Sleep Apnea Syndrome", confirmed excellent results among mild to moderate sleep apnea sufferers.

Accidents and Explosions
Not surprisingly, the quality of sleep among soldiers can be a shambles during combat deployment. Explosions and less-than-ideal sleeping arrangements are unavoidable, but combined with sleep apnea can be even worse. "We know that most injuries are not battle related," says Lettieri, a co-author of the study. "We have accidents, and if soldiers are sleep deprived, they are going to lack focus and be more prone to accidents."

It's a problem on U.S. roadways, but the stakes are even higher when lethal machinery is mixed in. "If you are driving a 40-ton tank around, you can't afford to make bad decisions," adds Lettieri, program director, Sleep Medicine Fellowship, WRNMC. "Research shows that chronic low-level sleep deprivation impairs reasoning, decision-making, and slows reaction time. You don't want that in a combat-deployed troop."

Beyond the obvious benefits of reduced accidents and convenient placement in a ruck sack, they found that even post traumatic stress disorder (PTSD) may be affected by poor sleep. "We have all these guys coming back with PTSD, and we broke it down into guys who were injured, and those who were not," explains Lettieri. "Among guys who did not sustain a combat injury, almost universally they had some underlying sleep disorder."

"When I was over there, we were sleeping next to an air field," adds Holley. "It's the nature of deployment that you don't get a fixed and regular sleep schedule. Even if you take out PTSD and the anxiety of being subjected to mortars and rockets, you still have a situation where people are getting disturbed and fragmented sleep at best."

Between 2004 and 2006, the Walter Reed sleep clinic gave out oral appliances and CPAP to service men and women on active duty. "When they went to a place without electricity, it would cause problems and sometimes even prevent some people from being able to go overseas," explains Holley. "The dusty dirty environment made CPAP too difficult to keep clean. Filters in the machines were frequently going down and having problems."

Large Pool Yields Better Findings

Armed with findings from one of the largest patient populations to date, Army researchers found that adjustable OAs are nearly as effective as CPAP treatment for patients with mild to moderate OSA, and are more effective than fixed oral appliances—particularly in patients with moderate to severe OSA.

"Historically, CPAP has been the primary treatment for OSA, but only half of patients tolerate this therapy," says Lettieri, an Army medical director, and the chief of Sleep Medicine in the Pulmonary, Critical Care and Sleep Medicine Department at WRNMMC. "This new data offers a fresh look at adjustable oral appliances as an initial treatment for OSA in both the military and civilian sectors."

The military is interested in the potential of adjustable OAs, also called mandibular advancement devices, as alternatives to CPAP systems since some active duty service members deploy to remote environments where electricity is not always available. In these cases, reliance on CPAP may result in duty restrictions or separation from service. "Adjustable OAs would eliminate duty assignment limitations associated with CPAP, allowing soldiers to travel to remote areas as needed," adds Lettieri.

The study in CHEST evaluated and compared results of overnight sleep studies in which patients used adjustable OAs or CPAP devices. Researchers found that a significantly higher percentage of patients using an adjustable OA experienced successful reduction of their AHI score to below five apneic events per hour, compared to past reports (62.3% versus 54%).

In most research trials of oral appliances, patients receive oral appliances after they have already failed with CPAP. It amounts to a selection bias because patients have already failed, and researchers often never really know why they failed. "We thought our data set was unique because a fair proportion of our patients did not fail CPAP since they were given both at the same time," explains Holley. "The problem with doing this in the real world is you run into cost limitations. It is not cheap to do either of these therapies individually, never mind giving both to everyone up front. This is true in the military or civilian world."

Changing Perceptions

Holley contends that physician "CPAP followers" are fairly devoted, tending to favor the humidification features of the modality. "Some docs are comfortable with what they are comfortable with, regardless of the evidence, even when it is compelling," laments Holley. "It takes time to change people's minds. How much will change with this study is hard to say. I would hope we have at least shifted the thought process and debate so that pulmonologists like me are more likely to not automatically go to CPAP for mild to moderate. It really does work just about as well as CPAP for people who have mild to moderate disease."

Lettieri and Holley believe the study will (and should) contribute to a shift toward considering OAs earlier in the patient experience. More comparisons with CPAP are necessary, but Holley admits it can be difficult to level the playing field. “CPAP is electronic with a smart card that records compliance,” he says. “We know exactly how well it’s working. The struggle with studying oral appliances is that you must rely on self reporting from patients as to how much they use it. We can prove that oral appliances work, but the next thing to prove is if patients actually wear them more than CPAP. We suspect they do, but we have yet to prove it.”

Building the case is something that Lettieri is content to do. As a 40-year-old physician in a relatively young field, he has seen awareness grow exponentially, and he has helped the military change its perceptions. At Walter Reed, the size of the sleep lab has doubled in recent years and the staff has tripled. Consults have gone from 70 per month to often 70 in a day.

In a culture where sleep deprivation is part of the culture, Lettieri admits that raising awareness has not always been easy. “When I enlisted, the recruiting slogan was ‘We do more by 9:00 a.m. than most people do all day,’” he muses. “We get up early and operate at night. There is a sleep-when-you-can mentality. Americans as a whole keep shortening their average sleep time at night. Since the 1970s, we have about 1.3 hours less per night. The military is even worse.”

SIDEBAR: Military Intelligence

As program director of the Sleep Medicine Fellowship at Walter Reed National Medical Center, Bethesda, Md, Lt Col Christopher J. Lettieri, MD, FACP, FCCP, FAASM, has seen the evolution of sleep medicine. In a culture where sleep deprivation is often considered a badge of honor, the 40-year-old Lettieri has succeeded by educating top brass and soldiers alike with a powerful message: Well-rested soldiers are more effective in the field of battle.

Nowadays, the sleep lab at Walter Reed is a full-fledged sleep disorders center that is recognized as a center of excellence. In addition to pulmonologists, neurologists, pediatricians, and even psychiatrists are applying for fellowship training. Sleep Diagnosis & Therapy sat down with Lettieri to talk about the explosion in sleep awareness and the implications for the military.

How tough is it to get proper rest in the military?

Lettieri: If you are talking about deployment, your sleep quality gets worse because you go from the relatively quiet environment to sleeping among a bunch of other people. There is more noise, radios, helicopters, explosions, and the constant stress.

Is sleep apnea more or less common in the military population?

Lettieri: Sleep apnea is common in general, and it’s common in the military. Even though we tend to be younger and more physically fit, we still have a lot of sleep apnea.

Why is that?

Lettieri: Some of it is anatomic, but a lot of it has to do with chronic low level sleep deprivation. You lose your ability to maintain tone of your upper airways. Back when I was a fellow, I did a research study called, “Obstructive Sleep Apnea Syndrome: Are We Missing an At Risk Population.” Across America, most people thought about sleep apnea in the 55 year-old overweight guy snoring in your waiting room. But really you see it in younger, thinner people. And if you don’t think about it, you’re going to miss the diagnosis.

Are physicians outside of the sleep realm starting to think about sleep apnea outside of the stereotypical patient categories?
Lettieri: With some of my prior research, and in a lot of the lectures I do now, I am trying to get people to think about it in the less typical person, such as the younger girl with chronic headaches and depression. Or the young guy who has unexplained fatigue and ADHD. I've always thought we had a lot of it in the military because of this chronic low level sleep deprivation.

Are there examples among fit combat soldiers?
Lettieri: We have had young, active duty guys who get diagnosed with sleep apnea. If it is toward the earlier part of the war, what do you do with them? You cannot bring CPAP in the theater with you. If you're living in a fox hole, where are you going to plug it in?

Are CPAPs possible at the larger bases?
Lettieri: Even with the more mature theaters we have now, where everybody has laptops plugged in and lamps, you still can't plug in a CPAP. The Central Command that runs the war said you can't bring it.

So what do you do now? You've got a young guy, and if you tell him he has sleep apnea, he may be out of a job. The alternative is oral appliances.

When did oral appliances emerge as a viable alternative?
Lettieri: A couple of years ago, when we started this, oral appliances were largely considered an alternative to CPAP. You could consider oral appliances if they had a really mild disease, or really hated CPAP.

What do you with young guys who have severe disease?
Lettieri: You can't say, 'Well you're out of the army.' So we pushed the envelope way beyond what was accepted, because we didn't want anyone to be forced out of the Military because of sleep apnea" At one point, we had more experience with oral appliances than most of the country combined. We had to get this message out, so we published two papers almost back to back.

Why did you focus so much on the oral appliances?
Lettieri: We did it largely to conserve the military fighting strength. On one hand, we want to find alternatives to CPAP, because while it is great, lots of people don't like it.

Across the country, it's a constant battle with better adherence. You can say that with all medical care, but the difference with CPAP is it has an integrated compliance monitoring device. So we look at this thing and we can tell exactly when the person used it. Some people abandon therapy, and roughly only half of people on CPAP have regular use of their therapy. That's terrible.

CPAP may be great, but if people aren't going to use it, we've got to have another treatment option. For us on a more personal note, we also have to maintain the fighting strength. We must be able to send people into combat.

You don't diagnose sleep apnea, and then let soldiers go out with an untreated medical disorder. That is not good for anybody. In that case, you are taking very sleepy people and putting them in harm's way, and you're going to see more accidents.

How effective are oral appliances?
Lettieri: Nothing's perfect by any means, but even half of the people with severe disease got what we considered to be adequate therapy. It depends on where you draw your line in the sand.

"We use strict criteria for what we consider to be effective therapy. It would be hard to argue with this criteria, so most people would have to agree that adjustable oral appliances work." If we realize that only half the people are actually using their CPAP anyway, then you're no worse off. Even if CPAP were completely effective, half the people are not going to use it.

What do you think of non adjustable or fixed devices?
Lettieri: The problem is that you get one shot to fix them. We found that they are OK, but only for really mild disease. Anyone with moderate to severe, you need adjustable. And these are ones you can titrate, just like you do when adding a higher dose of a medication or a range of pressures with CPAP. Adjustable ones ought to be used, and are probably more cost effective in the long term because more people get adequate therapy.

SSC Warrior Edition Quizzes

101: Sleep Introduction

1. Which of the following is INCORRECT:
   a. Moderate OSA is defined as having an AHI between 15 and 30.
   b. Moderate oxygen desaturation with OSA is defined as being between 80-84%.
   c. REM sleep is considered to be deep sleep.
   d. Healthy adults should have about 50% N2 sleep.

2. A 1999 study at Mayo Clinic regarding the effects of sleep apnea and snoring on the bed partners sleep showed.
   a. In spite of all of the men in the study having sleep apnea, there was no effect on their bed partner's sleep.
   b. The bed partners were all found to have sleep apnea as well.
   c. The bed partners' sleep was negatively affected by the introduction of CPAP therapy on their spouse halfway through the night.
   d. OSA and snoring were shown to negatively effect the bed partners' sleep, and use of CPAP by the man improved the sleep of the spouses.

3. The most powerful cue for our circadian rhythm, and whether our brain thinks we should be awake or asleep, is:
   a. Melatonin secretion.
   b. Light and dark.
   c. Time of day.
   d. Cortisol secretion.

4. With regard to Sleep Hygiene:
   a. It is important to have your bedroom dark.
   b. Try to get to bed at the same time each night.
   c. Give yourself enough time for sleep and make it a priority.
   d. All of the above.

5. A patient who does not get adequate deep sleep (N3 sleep) may:
   a. Feel physically fatigued or tired.
   b. Report symptoms such as muscle aches and pains.
   c. In a child, may have "failure to thrive" or stunted growth.
   d. All of the above.

102: Sleep Apnea in Adults & Children

1. “Sleep apnea” includes the following varieties, **except**:
   a. Mixed.
   b. Central.
   c. Episodic.
   d. Obstructive.

2. “Complex sleep apnea,” defined as the emergence of central sleep apnea events when a person with obstructive sleep apnea is placed on CPAP,
   a. Is usually treated first with BiPAP, and if that’s not effective then Adaptive Servo Ventilation (ASV).
   b. May respond to oral appliance therapy, although this is virtually unknown at this point.
   c. May not be treated with oral appliance therapy.
   d. Both A & B.

3. The #1 killer in the world is heart disease. Of those who will die of heart disease in the USA:
   a. Approximately half will die from “sudden cardiac death.”
   b. More than half will be children.
   c. Most will have had an initial, non-fatal, heart attack.
   d. A very small percentage will be women.

4. Because sleep apnea is typically worse in older, heavier, men, it is possible that younger, thinner, women may be more likely diagnosed with other problems rather than being referred for a sleep study. Some of those problems include:
   a. Chronic fatigue syndrome.
   b. TMJ syndrome.
   c. Depression.
   d. All of the above, and more.

5. All of the following are true regarding OSA, **except**:
   a. OSA is typically worse in supine sleep.
   b. OSA is typically worse in REM sleep.
   c. Only people with an Epworth Sleepiness Scale score over 10 have OSA.
   d. In children, and AHI of 1.5 of greater is considered significant.

103: Diagnosis of OSA & Screening Your Patients

1. When should the sleep screening form be discussed with the patient or patient's parent?
   a. Only when the Epworth Sleepiness Scale score is > 10.
   b. Only when there are at least 3 items marked positive.
   c. The form should always be discussed, regardless of what is marked.
   d. At recall appointments.
   e. Only when the doctor believes that a sleep study is indicated.

2. Who do we refer for sleep studies?
   a. Adults with an Epworth Sleepiness Scale score over 10.
   b. Children who's parents report the child having symptoms.
   c. We never refer for sleep studies. We refer the patient "to have a conversation with a sleep physician" to see if their issue might be sleep related.
   d. Medical doctors.
   e. Any patient who snores.

3. CPAP:
   a. Works by blowing the airway open in all dimensions.
   b. Is almost always effective, but a high percentage of people cannot tolerate it.
   c. May be used in conjunction with an oral appliance to reduce the necessary pressure to open the airway.
   d. Is usually titrated in the sleep lab, but there are also "auto-set" CPAP units that do not require in lab titration.
   e. All of the above.

4. In 2015 the AASM in conjunction with the AADSM published new guidelines for oral appliance therapy. These guidelines state all of the following **except**:
   a. Oral appliances often result in TMJ problems, especially in more severe OSA cases.
   b. Oral appliance therapy may be chosen by the physician as first line therapy.
   c. It is recommended that there is objective follow up of oral appliance therapy.
   d. It is recommended that a "qualified dentist" be involved.
   e. It is recommended that patients in OAT have long term follow up, with periodic visits.

5. Intra-oral signs of POSSIBLE OSA include all of the following, **except**:
   a. Wear of the anterior teeth (possibly from thrusting the jaw forward while sleeping).
   b. Scalloping of the lateral borders of the tongue (possibly from pushing the tongue forward).
   c. Periodontal bone loss.
   d. Mandibular tori.
   e. All of the above are POSSIBLY related to OSA.

104: Oral Appliances for OSA, Part 1

1. Jamison's 5 types of mandibular repositioning appliances include all of the following, **except**:
   a. Pull (EMA, Narval, Silent Night, etc.)
   b. Push (All styles of Herbsts)
   c. Tongue positioners (all styles that incorporate tongue retention)
   d. Anterior pull/push (TAP, MDSA, Silencer, etc.)
   e. Interlocking (Dorsal, SomnoMed Air, MicroO2, etc.)
   f. Adjustable monoblock (Moses, PM Positioner, Klearway, etc.)

2. A good appliance choice for a patient who has evidence of lateral bruxism might be a:
   a. Push style.
   b. Pull style.
   c. Interlocking.
   d. Adjustable monoblock.
   e. A or B

3. For a patient who "sleeps with their mouth open" you might select a:
   a. Push style.
   b. Pull style.
   c. Interlocking.
   d. Adjustable monoblock.
   e. It depends on whether or not the patient wants to be able to open their mouth easily.

4. A good appliance choice for a patient who is missing several lower, posterior teeth would be:
   a. Push style.
   b. Pull style.
   c. Interlocking.
   d. Adjustable monoblock.
   e. A, C or D

5. Some things to consider when deciding on a oral appliance design include all of the following, **except**:
   a. Does the patient have evidence of lateral bruxism?
   b. Does the patient travel from a long way away?
   c. Do you trust the patient to return for follow up?
   d. What will the patient's insurance cover?
   e. Reported sensitivity to metal.
   f. Missing teeth or poor retentive features.
   g. Previous experience with oral appliance therapy.
   h. History of TMJ issues.
   i. All of the above are considerations.

105: Oral Appliances for OSA, Part 2

1. Possible reasons to use a temporary oral appliance include all of the following, **except**:
   a. Temporary appliances can't cause side effects like tooth movement or bite changes.
   b. When a patient breaks their custom appliance during the repair period.
   c. When the patient travels and doesn't want to risk losing their custom appliance.
   d. When the patient needs treatment immediately, but has pending dental work that contraindicates fabrication of a custom appliance.
   e. For use OVER "invisalign style" trays to treat the OSA and straighten the teeth simultaneously.

2. For a patient that has no evidence of lateral bruxism, has no missing teeth, good retentive features, and sleeps with their mouth closed:
   a. They will likely be able to tolerate any appliance design.
   b. Only an "all hard" tray design should be used.
   c. They may not tolerate a monoblock style appliance due to lack of ability to move laterally.
   d. A custom appliance will most likely be far more successful than a well executed temporary appliance.
   e. If they have pending dentistry they should not be treated till the dentistry is completed.

3. If a patient has had prior experience with oral appliance therapy;
   a. You might consider fitting them with the same appliance design and brand if they were particularly successful with that type of appliance before.
   b. If they had a negative experience with a prior attempt at OAT, regardless of whether you think the appliance choice was appropriate or not, you might consider a different design.
   c. Learn from their past experience and use this knowledge with your appliance choice and initial position decision.
   d. Prior therapy has no relation to future therapy and should not be included in your decision making process.
   e. All but D.

4. For patients with a history of or a current TMJ problem, according to Dr. Spencer;
   a. Such patients should not be treated, even if they are CPAP intolerant.
   b. If there is adequate retention, a Pull style appliance may be appropriate.
   c. If there is minimal retention, a Push style appliance may be appropriate.
   d. The EMA can be helpful due to the "squishy" nature of the bands.
   e. All but A.

5. With combination therapy:
   a. Make sure that the patient is using a newer CPAP/BiPAP unit.
   b. The best appliance is a custom made full acrylic face mask attached to an OA.

c. The goal is to reduce the needed pressure of the PAP unit buy using an OA simultaneously with PAP.
d. Masks that attach to the oral appliance are better because insurance covers their routine replacement, and they reduce pressure on the teeth.
e. Most physicians and DME providers are not aware that combination therapy can be done or that insurance will pay for both an OA and PAP.
f. Both C & E.

106: Avoiding Side Effects

1. If your OAT patient presents or calls you with report of “jaw pain:”
   a. You need to have them discontinue use of the OA immediately.
   b. Suspect that most likely you have brought the jaw too far forward, too fast.
   c. You need to first determine if the jaw pain is more muscular or in the TMJ.
   d. It is most likely due to your appliance design choice.
   e. Jaw pain does not happen with OAT.

2. According to Dr. Spencer’s “non-intuitive rule of thumb” of jaw pain during OAT:
   a. Patient’s may develop “jaw pain” due to “fighting” the appliance as they try to protect their airway.
   b. Monoblock appliances are more likely to cause jaw pain.
   c. Pain in the TMJ is usually from OVER protrusion of the mandible.
   d. Pain in the masseter/temporalis is usually due to too low of vertical.
   e. Jaw pain during OAT is best treated with anti-inflammatories before bed.

3. With regard to predicting problems before they occur;
   a. Patients who are lateral bruxers may develop muscular pain using an appliance that does not allow lateral motion.
   b. Patients with a reducing disc displacement may experience a more difficult time getting their occlusion to return to normal.
   c. Patients with a non-reducing disc displacement may experience symptoms from a previously asymptomatic condition.
   d. Patients who have never had jaw clicking are more likely to develop jaw clicking.
   e. A, B & C.

4. All of the following are ways to help avoid side effects, **except**:
   a. Do a good exam of the TM joints and muscles in advance and note any issues.
   b. Choose that one appliance that the manufacturer/lab rep says “never causes side effects.”
   c. Make sure that you ask the lab to “wrap the distal” for the most distal teeth to help avoid spaces from opening.
   d. Ask all of your patients to floss daily and check their occlusion at bedtime, and report to you any changes.
   e. Choose an appliance design that makes sense for the patient based on your exam and their history.

5. With regard to avoiding bite changes:
   a. If you give the patient a leaf gauge it is possible that they may use it incorrectly.
   b. Fitting the patient with a thermal plastic morning repositioner you should only cover the front 4 to 6 teeth, ensuring posterior contact of the teeth.
   c. Patients should be asked to “check their bite” before bed every night.
   d. Once bite changes have occurred they are usually permanent.
   e. All but D.

107: Parafunction or Protective Function?

1. The pharyngeal airway in humans:
   a. Is collapsable while we are awake.
   b. Is more likely to collapse if it is short.
   c. Is held open while we are awake via reflex, but may collapse while sleeping.
   d. If less than 5mm on a CBCT at it's smallest diameter indicates OSA.
   e. Is most likely to collapse at the nasopharynx.

2. In 1986 Jeff Okeson showed that there was a correlations between "clench index," AHI and:
   a. RDI.
   b. Sleeping posture (side versus back).
   c. ODI.
   d. 2nd molar interferences.
   e. Lack of canine guidance.

3. Everyone believes that clenching and grinding is caused by "stress." Dr. Spencer believes that this might be true, but in some people it may be the stress of:
   a. Taxes.
   b. Jerks at work.
   c. Suffocating to death.
   d. Politics.
   e. Plate tectonics.

4. In children, multiple studies have shown a correlation between OSA and:
   a. Enuresis.
   b. ADHD.
   c. Reduction of the OSA, and bruxism, with tonsilloadenoidectomy.
   d. Reduction of the OSA, and enuresis, with palatal expansion.
   e. All of the above.

5. A case study showed that when a person with severe bruxism, and sleep apnea, was put on CPAP:
   a. There was improvement of the sleep apnea, but no change in the bruxism.
   b. There was improvement of the sleep apnea, and a complete eradication of tooth grinding events.
   c. There was no improvement of the sleep apnea, but a complete eradication of tooth grinding events.
   d. There was no improvement of the sleep apnea or the bruxism.
   e. The bruxism was not improved because only night guards improve bruxism.

6. Dr. Gilles Lavigne, in a pilot study, showed that use of a flat plane nightguard in patients with OSA could:
   a. Significantly improve the sleep apnea.
   b. Had no positive or negative effect on the patient's sleep apnea.

c. Significantly reduce rhythmic masticatory muscle activity while sleeping.
d. Be associated with risk of aggravation of respiratory disturbances.
e. Eliminate bruxism.

201: From Screening to Final Follow UP

1. The main problem with the Epworth Sleepiness Scale is:
a. it asks how likely someone is to fall asleep, and some people just feel tired or fatigued, but don't fall asleep.
b. there is not a direct correlation between falling asleep and having sleep apnea, and people may be sleeping for many different reasons (for example due to certain medications).
c. most insurance companies in the United States do not consider the Epworth Sleepiness Scale to be valid.
d. woman tend to report being fatigued, rather than sleepy or falling asleep, so women tend to score lower on the Epworth Sleepiness Scale.
e. a, b and d

2. If a patient fills out the screening form and basically marks all "no" and has a low Epworth, you or your team should:
a. file the information for possible future discussion or follow up, but not discuss with the patient.
b. throw it away and do not discuss as the patient clearly does not have any issues.
c. discuss with the patient why you had them fill the information out and thank them for doing so, giving them the opportunity to perhaps mention family members who may have some of the issues.
d. refer the patient for a sleep evaluation with a sleep doctor.

3. When a patient appears to be at risk for possible OSA (based on responses on the screening form, your clinical exam and patient history) an appropriate next step COULD be:
a. asking the patient if they would be open to having an initial consult with a sleep doctor.
b. asking the patient if you could talk to their family physician about ordering a possible home sleep study.
c. providing a home sleep test or pulseoximetry as an additional screening tool.
d. discussing positional therapy or ENT evaluation.
e. All of the above COULD be appropriate under specific circumstances.

4. A home sleep study:
a. can be an affordable alternative to an in lab study.
b. can only rule IN sleep apnea, it cannot rule it out.
c. that is "negative" (no indication of OSA) could be an indication for an in lab study if the patient is symptomatic or has comorbidities.
d. gives basically the exact same information as an in lab study.
e. a, b and c

5. After you have referred a patient for a sleep consultation, all of the following are likely outcomes, EXCEPT:
a. the sleep physician does not believe that a sleep study is indicated.

b. the patient is found to have sleep apnea, and CPAP is prescribed as first line therapy.
c. the patient is found to have sleep apnea, and stimulant medications are prescribed as first line therapy.
d. the patient is found to not have sleep apnea.
e. the patient is found to have sleep apnea and an oral appliance is prescribed as first line therapy.

202: Exam and Records

1. Once the patient has been diagnosed with sleep apnea and referred to you for oral appliance therapy, your clinical exam should provide you
f. with the information that you feel is most important for you to make your appliance selection and determine if there are any potential issues that could increase the chance side effects, pain or dysfunction.
g. with the information about issues that have been correlated with a greater risk of sleep apnea, such as neck circumference and BMI.
h. a clinical exam is not important.
i. the clinical exam notes from the referring physician should be obtained and this will be sufficient.
j. None of the above.

2. A patient with a reducing disc displacement
a. has a disc which is moving in to place when the patient opens their mouth, usually with a palpable click or pop.
b. is most likely aware that their jaw is clicking IN to place, and is out of place the majority of the time.
c. should have the nature of the disc displacement clearly explained to them, using the "TMJ Tutor," the cadaver videos, or in some other way.
d. may be more at risk of a bite change with oral appliance therapy.
e. All but b

3. Critical items to discuss during your informed consent include, but are not limited to,
a. possible bite/occlusal changes (and how to avoid them).
b. possible tooth movement (and how to avoid it).
c. appliance therapy not working as effectively as desired or not at all.
d. loosening or dislodging of dental restorations.
e. All of the above.

4. While there are many ways to take a bite registration for an oral appliance, Dr. Spencer when discussing use of the George Gauge recommends,
a. Dr. Spencer does not recommend use of the George Gauge.
b. use of the 2mm fork in all but anterior open bite cases.
c. confirming that the midline has not accidentally been shifted.
d. starting at a "comfortably protruded" position.
e. b, c and d

5. Something you may ask the dental laboratory to do in order to avoid separation of teeth is,
a. fabricate your appliance on a fully adjustable articulator and provide a face bow transfer.
b. wrap the distal of the second molars (or most distal tooth).
c. extend the flange of the appliance on the buccal to cover soft tissue.
d. add extra ball clasps.

e. reinforce the fins of “interlocking style” appliances.

203: Fitting

1. Prior to fitting the oral appliance you may
f. check the fit of the appliance on the models and look for any issues.
g. tell the patient that the appliance is probably going to fit really tight, and it's probably going to feel pretty uncomfortable.
h. remove some unnecessary bulk from the appliance.
i. confirm a day or two before the fitting appointment that you have received the appliance.
j. All of the above

2. All of the following are true regarding fitting of an oral appliance, EXCEPT:
a. It's a good idea to allow the appliance to be seated on the teeth for 15-20 seconds before asking the patient about tightness.
b. People who have used CPAP, in general, tend to not complain as much about minor comfort issues with the oral appliance.
c. Posterior teeth tend to be more sensitive to pressure and tightness than anterior teeth.
d. It's a good idea to tell the patient that it may take several weeks for them to get use to wearing the oral appliance through the night.
e. Dr. Spencer will typically seat and fit the upper tray first.

3. After fitting the upper and lower trays of the appliance, one should also check:
a. that the impressions were accurate.
b. that the posterior supports of the appliance, if applicable, are hitting on both sides.
c. that the initial protrusive position of the appliance is appropriate.
d. that the occlusion on each individual tray, against the opposing teeth, is even.
e. b and c

4. Fitting a morning repositioner is HIGHLY recommended. Dr. Spencer's favorite style of a morning repositioner is made with a thermal plastic material, chairside, and only fits on the anterior teeth. Dr. Spencer feels this design is superior to others due to:
a. the posterior teeth being able to fully occlude allowing for proprioception of the maximum intercuspation position.
b. the low cost of the material.
c. the properly fabricated device also serving as an index/record of the position of the upper anterior teeth, the lower anterior teeth, and the maxillo/mandibular relationship prior to beginning oral appliance therapy.
d. the ease of patient use.
e. both a and c.

5. At the end of the fitting appointment it is important to:
a. set up a follow up appointment.
b. let the patient know that they should contact you if they have any problems.
c. review the potential side effects, particularly tooth movement and bite changes, and review how to avoid these problems.

d. ask the patient what questions they have.
e. all of the above.

204: Follow Up

1. Follow up with oral appliance therapy,
f. is typically not necessary.
g. requires use of home sleep testing and other devices owned by the dentist.
h. is critical to long term success and minimizing side effects.
i. depends solely upon subjective reports from the patients.
j. should focus on comfort issues only and not objective measures of improvement.

2. If a patient says they have “jaw pain,”
a. they are most likely describing TMJ pain due to the appliance being too far forward.
b. you need to determine if the pain is coming from their TMJ or their muscles.
c. they are most likely describing muscle pain due to the appliance bing too far forward.
d. they are most likely describing tooth pain related to the tightness of the appliance.
e. none of the above.

3. A patient who is having muscle or TMJ pain related to “fighting the appliance” due to their airway not being protected will typically report
a. that their jaw pain is only in the afternoons.
b. that they are not sleeping well and that they are still snoring.
c. that they are sleeping well and that their snoring is much better.
d. that the appliance is “too tall” and that they cannot close their lips easily.
e. that their TMJ pain only hurts when the appliance is in place.

4. A patient is ready to be referred back to the prescribing physician when
a. they report that they are feeling better and snoring less.
b. you believe that you are in the best possible position, although the patient is not able to give you good subjective feedback.
c. it is never necessary to refer a patient back to the prescribing physician as the dentist can just do a home sleep study.
d. they are having jaw discomfort and you believe it is due to the airway not being adequately protected and would like to titrate the appliance live in the sleep lab.
e. a, b and d would all be reasons to refer a patient back to the prescribing physician.

5. At the final follow up you should
a. go over, again, the possible side effects of tooth movement and bite changes and what the patient can do to avoid these.
b. discuss when you would like the patient to come back for a recall and explain to them the importance of these appointments.
c. let the patient know that their medical insurance, if applicable, may help pay for a new oral appliance every so many years.
d. review the follow up sleep study and make any last adjustments, if applicable.
e. all of the above

General Information:

☐ Definitions

- **Apnea** - Complete cessation of breathing for at least 10 seconds
- **Hypopnea -** Decrease in tidal volume associated with a fall in oxygen saturation (4%) or arousal response
- **Arousal -** Shift in EEG for at least 3 seconds (in REM sleep requires also increase in EMG or movement)

☐ Apnea Hypopnea Index (AHI)

- **Normal:** less than 5 events per hour
- **Mild:** 5-15 events per hour
- **Moderate:** 16-30 events per hour
- **Severe:** over 30 events per hour

☐ Oxygen Saturation

- Normally, the blood oxygen level should be above 90%. With obstructions, you can have varying degrees of desaturations. The severity of the problem depends on how much of a drop below 90%:
  - ⇒ Mild problem: 85-90%
  - ⇒ Moderate problem: 80-84%
  - ⇒ Severe problem: below 80%

☐ Abbreviations

- Apnea Index **AI**
- Apnea Hypopnea Index **AHI**
- Respiratory Disturbance Index **RDI (RDI = AHI + RERA)**
- Oxygen Desaturation Index **ODI**
- Respiratory Effort Related Arousal **RERA**

What to look for on a Sleep Study:

- Total sleep time (TST) and sleep efficiency (TST/total recording time = efficiency)
- Sleep stages (within normal ranges)
    - N1 = 5%
    - N2 = 50-55%
    - N3 (formally known as stage 3 and 4) = 10-20% (less N3 as we get older)
    - REM = 20-25%
- Ventilation summary
    - Obstructive Apneas
    - Central Apneas
    - Obstructive Hypopneas
    - Apnea/Hypopnea Index (AHI)
    - Respiratory Disturbance Index (RDI)
- Positional and REM data
    - Apneas, hypopneas, AHI (and maybe RDI) in
        - Supine
        - Lateral
        - REM
        - Supine REM
- Oxygenation
    - Lowest saturation (nadir)
    - Time below 90%
- Heart rate
- Limb Movements
- Sleep Doctor's "impression" and recommendations

Comparing one sleep study to another:

- Compare apples to apples
    - PSG to a PSG
        - How long since the last PSG?
        - Same lab?
        - Same reading doctor?
    - PSG to HST, or HST to PSG—not apples to apples = tough to make conclusions
    - HST to HST
        - How long since the last HST?
        - Same device?
- Was anything different from the last study (baseline) to this study?
    - Weight gain?
    - Different sleep posture?
    - Different recording/sleep time?
    - Look at more than just the AHI
        - Change in apneas?
        - Hypopneas?
        - O2 saturation?

How to Read a Sleep Study Report
Jamison Spencer DMD MS

Sleep study reports come in a lot of variety. Some reports will be "just the facts." Others will have TONS of data. Here are the things that are important for us to review as dentists, and what we should point out to our patients.

Is it an in lab test, a home sleep test, or are you looking at the CPAP titration?

The first thing you need to determine is what type of study report you are looking at. You want to be looking at a baseline study, not the CPAP (continuous positive airway pressure) titration. Here are the different types of studies:

1. In lab polysomnogram, or PSG. This is the gold standard test and is performed with the patient going to a sleep lab, getting wired up, and spending the night in the lab while a technician attends the study.
2. A "home sleep test" or "out of center sleep test" (OCST). These are small devices that are usually sent home with the patient or sometimes mailed to them. They usually consist of a pulse-oximeter, 1 or 2 strain gauges, and a nasal cannula. Some home test units can also measure brain waves or have another means to determine if the patient is actually asleep or not (most home units only assume the patient is asleep…making them less accurate).
3. A "split night study." This is an in lab PSG where the first part of the night is the diagnostic phase, and then, IF the patient shows significant sleep apnea, the patient is awoken and placed on CPAP. The rest of the night is used to find the optimal CPAP pressure to treat the sleep apnea.
4. CPAP titration study. This is an in lab PSG where the entire night is used to adjust the CPAP. Usually in these reports there will be an initial sentence about what the baseline PSG showed.

Once you know that you are looking at the baseline PSG or OCST, here are the things you want to look for:

1. **AHI:** What was the overall Apnea/Hypopnea Index (AHI)? The AHI is the measure of how bad the patient's sleep apnea is. The scale of AHI is:
   - < 5 = normal (in an adult. In a child > 1.5 indicates clinically significant sleep apnea)
   - 5-15 = mild
   - 15-30 = moderate
   - >30 = severe

Now, let's take this AHI number and break it down a bit. Obstructive apneas and central apneas are added together to get the "A" in the AHI. Central sleep apnea is where the brain doesn't tell the person to try to breathe. [As a brief note, pure central sleep apnea is very, very rare, BUT if you ever see a patient with a high percentage of central sleep apnea, instead of obstructive, you will want to review the goals of oral appliance therapy with their physician, as oral appliance therapy typically will not affect central sleep apnea—neither does CPAP.] Hypopneas are the "H." A hypopnea is a reduction in ventilation by at least 50% that also results in a decrease of the O2

saturation by 4% of more. In other words, a hypopnea is shallow breathing that results in desaturation. These are usually obstructive in nature, like partly kinking a hose, but not completely blocking the flow.

I enjoy showing the patient the difference between an apnea and a hypopnea by drawing on the back of one of the forms. I say, "in the sleep lab, or in your home study, you had a nasal cannula in your nose. Normally when you see these things they are to give someone extra oxygen. In this case, the cannula was measuring your breathing in and out. On the computer screen it would look like this:

I'll tell the patient that this, an apnea, happened "X number of times" throughout the whole night. This number will usually, but not always, be in the report. This is not the "index" but the actual number of obstructive and central apneas that occurred throughout the night. If the number of apneas is not specified in the report, then you can't show this.

I will then show the patient what a hypopnea would look like on the computer screen in the sleep lab:

I'll tell the patient that this, a hypopnea, occurred "X number of times" throughout the whole night.

By showing the patient the difference between and apnea and a hypopnea, it helps them to understand their problem better, and makes the severity of their sleep apnea make more sense…because the AHI does not tell the whole story.

Speaking of story, here's a little mathematical story problem for you:

Patient A's study shows that he had 60 obstructive apneas throughout the night. He had 30 hypopneas throughout the night. He slept 6 hours total. Therefore his AHI is (60 + 30) / 6 = 15.

Patient B's study shows that he had 30 obstructive apneas throughout the night. He had 60 hypopneas throughout the night. He slept 6 hours total. Therefore his AHI is (30 + 60) / 6 = 15.

Wait a second! They both have an AHI of 15 even though one had half as many actually episodes of stopping breathing? Yep!

Now let's take this to the extreme. What is the AHI if the patient had 120 apneas for the night, 0 hypopneas for the night, and slept 6 hours? (180 + 0) / 6 = 30.

What is the AHI if the patient had 0 apneas for the night (literally NEVER stopped breathing), 180 hypopneas for the night, and slept 6 hours? (0 + 180) / 6 = 30.

What? So BOTH of these patients have "severe sleep apnea," even though the second one NEVER stopped breathing?! That's correct.

So why do we care? I believe it is important to show the patient what is going on with them so that they better understand their problem. If you are told that you have severe sleep apnea and that you stop breathing 30 times per hour, but your wife of 20 years says that she has only rarely noticed you stopped breathing, are you going to believe the report? Probably not. So it is important to explain to the patient that even though they have been told that they "stop breathing X times per hour" (which is what they will think the AHI is) that they don't actually completely stop breathing all of those times (unless of course they have 0 hypopneas throughout the night).

It's also important for us to look at this as I believe, through experience, that we tend to have an easier time treating patients with more hypopneas than apneas. That doesn't mean that we don't treat people with lots of apneas, but it just means that we might "lower their expectations" a little of oral appliance therapy completely resolving their apneas.

2. **Sleep Position:** In conjunction with the AHI you will also usually find information about sleep position and the

AHI when the patient is sleeping supine versus on their side. For most people their obstructive sleep apnea is worse on their back (supine). For some people you will notice that their problem almost exclusively occurs when they sleep supine. When you notice this, you should talk to the patient about this fact and encourage them to sleep as much as possible on their side, including once they get their oral appliance.

3. **O2 Saturation:** What is the O2 saturation nadir (lowest point), and how much time did the patient spend with an O2 saturation below 90%?

This is a pretty obvious one to us as to why it is important. However, most patients will not realize what the O2 saturation means. Explain to them that our blood O2 levels, at this elevation, should be above 95% most of the time. Explain that if they were in a hospital and their O2 level went below 90, alarms would go off! Then tell them that their O2 level dropped to a low of X and was below 90 X% of the night.

4. **Sleep Stages:** How much time the patient spent in the different levels of sleep during the study. Non REM sleep stages are referred to as N1, N2 and N3. Here are the "ideal" percentages:
    - N 1 is "light sleep" or "transitional sleep." This should only account for about 5-10% of the total sleep time.
    - N2 is "restful sleep." This should be about 45-55% of the total sleep time. When people have reduced deep sleep and REM sleep, they usually have increased N1 and N2 sleep.

- N3 is "deep sleep" or "slow wave sleep." This should be about 10-20% (much more in children, and becomes less as we get older).
- REM is Rapid Eye Movement sleep, or "dream sleep." We should have about 20-25% of our sleep be REM sleep. In REM sleep the muscles have much less tone (some will say paralyzed), and as such obstructive sleep apnea tends to be worse in REM sleep.

While there are a lot of things that are fascinating about how sleep works, here are the simple things you need to know and share with your patients.

First, if they have reduced deep sleep (N3) they will feel physically tired. They may also have muscle pain, or even "fibromyalgia" type symptoms.

Second, if they have reduced REM sleep they will feel mentally tired. They may also have memory problems and a "clouded intellect."

For some of our patients you will be the first one to go over the baseline sleep study with them. For many of our patients it was months or years ago that their doctor reviewed their sleep study with them, so they have likely forgotten much of the information. Going over this information with the patient will help them, and you, to understand their problem much better and make them, in my opinion, more likely to stick with treatment.

Each sleep lab and sleep doctor will present their data a little different, but you should be able to find the above information in all sleep studies and help the patient to understand it.

We DO NOT base our appliance selection on any of this information. ALL oral appliances work the same way…they keep the mandible from falling back, or keep it slightly forward. The data WILL help us to know how bad the patient's obstructive sleep apnea is so that we will better know how to treat them and how important it will be for them to return to their physician for objective follow up and adjustment of the oral appliance in the sleep lab.

Follow Up Sleep Study:

I believe that ALL patients should be referred back to the referring physician (the one who wrote the prescription for the oral appliance) <u>for consideration of a follow up sleep study</u> with the oral appliance in place. IF the physician does decide to have a follow up sleep study, I also believe that it is ideal to have the appliance adjusted in the sleep lab by the sleep techs (you will normally need to teach them how to do this and have written protocols for this).

When comparing a baseline study to a follow up study, make sure that you compare apples to apples, and look for:

- PSG to a PSG is apples to apples, but
    - How long has it been since the last PSG?
    - Were both studies at the same lab?
    - Were both studies read by the same doctor?
- PSG to HST, or HST to PSG = not apples to apples = tough to make conclusions

- HST to HST may be apples to apples, but
    - How long since the last HST?
    - Is the same HST device being used (if not, probably not apples to apples)?

Once you understand the differences between the technical aspects of the baseline study versus the follow up study, look for the following things that may be different from the baseline study to the follow up study:

- How long has it been since the baseline study? Sleep apnea usually gets worse as we get older.
- Has there been any weight gain? Sleep apnea usually gets worse with weight gain.
- Different sleep posture? Sleep apnea is usually worse in the supine position.
- Look at more than just the AHI
    - Was there a change in the number of apneas?
    - Was there a change in the number of hypopneas?
    - Was there a change in the average O2 saturation? The nadir?

I have had several patients that prior to me referring them back to the physician for consideration of a follow up sleep study with adjustment of the appliance in the sleep lab, the patient reported feeling fantastic and having a major improvement of their snoring. However, when they went in for the follow up sleep study the report came back that they didn't do as well as I would have liked. In almost all of these cases I was able to compare the baseline study to the follow up study and find the reasons that we didn't see a big change in the AHI, even though the patient felt much better. The most common things I've seen that made the follow up study numbers not as good as I would have liked were:

- It had been 5 or more years since the baseline study.
- The patient had gained significant weight.
- The patient slept mostly non-supine on their baseline study, and mostly on their back on their follow up study.

The bottom-line is that it is important for us as dentists to understand what is presented in sleep study reports AND when follow up studies are completed to make sure that we compare the follow up study to the baseline study, and make sure that our objective data appears to be consistent with the subjective data of what the patient is reporting to us.

Sleep Study Review Sheet

Metric	Baseline Study	OA Study
Type of study (PSG, HST, split, etc)		
Date of study		
Patient BMI		
Total sleep time (TST)		
Sleep efficiency		
% N1		
% N2		
% N3		
% REM		
% Supine sleep		
% Non-supine sleep		
% Supine REM sleep		
Overall AHI		
Number of apneas		
Number of hypopneas		
RDI		
Number of RERA’s		
Average oxygen saturation		
Oxygen saturation nadir		
Supine AHI		
Non-Supine AHI		
Other notes		

POLYSOMNOGRAM INTERPRETATION REPORT

Patient Name:
Sex:
D.O.B.:
Age:

Sleep Architecture: Testing began at 11:38:17 PM and ended at 5:31:10 AM, for a total time in bed (TIB) of 5:52:53. Sleep period time (SPT) was 5:52:53 and the total sleep time (TST) was 5:21:58 which resulted in sleep efficiency (TST/TIB) of 91.2%. The sleep latency was 0:00:00 and the REM Latency was 1:59:58. There were 2 periods of REM observed on this study night as well as 18 awakenings and 103 stage shifts.

Sleep Staging & Body Position: Sleep stage distribution expressed as a percentage of TST was as follows; Stage 1: 14.7%, Stage 2: 28.7%, Stage 3/4: 39.4%, and REM: 17.1%. Sleep expressed as a percentage of TST was observed in the supine (5.5%), right-lateral (0.0%), left-lateral (94.4%), and prone (0.0%) body positions.

Respiratory Parameters: There were 25 apneas (25 obstructive apneas, 0 central apneas & 0 mixed apneas) and 104 hypopneas. The RDI was 26.5 during Non-REM sleep and 12.0 in REM sleep. The RDI was 88.0 in the supine position, N/A in the right-lateral position, 20.3 in the left-lateral position and N/A in the prone position.

Oximetry: Mean SpO2 during sleep time (TST) was 93.8% and the minimum SpO2 during sleep time (TST) was 88.0%. Oxygen saturation was between 90-100% for 97.2%.

Arousal & Limb Movement Summary: The arousals consist of spontaneous EEG, respiratory, and limb movement arousal events. Of the total arousals, 43 were of a spontaneous nature (8.0 events/hour). A total of 80 arousals were associated with respiratory events (14.9 events/hour) and 0 were associated with limb movements (0.0 events/hour). There were a total of 1 for a total limb movement index of 0.2 events/hour.

Interpretation: This study demonstrated severe supine dependent obstructive apnea. Snoring was present intermittently. No limb movements of clinical significance were seen. The EKG showed sinus rhythm. Sleep architecture was normal.

Recommendation: A trial of CPAP is indicated.

EMA DEVICE TITRATION

STANDARD PROTOCOL: The patient was studied with attended Polysomnography. Electrophysiologic sleep parameters included: frontal (F4/M1 or F3/M2), Central (C4/M1 or C3/M2) and occipital (O2/M1 or O1/M2), electroencephalogram (EEG), right and left electroculogram (EOG), and submentalis electromyogram (EMG). Cardiac rhythm was continually recorded (ECG). Periodic limb movements were monitored by anterior tibialis electromyogram (EMG). Airflow was detected by oronasal thermistor and pressure transducer. Respiratory effort was determined by measurement of chest and abdomen motion using Respiratory Inductance Plethysmography. Arterial pulse oximetry (SpO_2) was measured with a Nonin 3 second sampling rate from the finger. Analog data was digitized, transferred from the hard drive to the local area network, and after being analyzed, the results are archived. Raw data was manually scored in 30-second epochs for sleep stages using AASM Manual for the Scoring of Sleep and Associated Events 2012. Apneas were scored on the basis of absence of airflow from a thermistor for ≥10 seconds, respectively. Hypopneas were scored on the basis of reduction of nasal pressure amplitude of ≥ 30%, for a duration of ≥ 10 seconds, desaturation of ≥ 3% below pre-event baseline or the event is associated with arousal and 90 % of event meets amplitude criteria. The Apnea Hypopnea Index (AHI) was computed as a total of all respiratory events divided by the total sleep time in hours.

REFERRING PHYSICIAN:

PRIMARY CARE PHYSICIAN:

CHIEF COMPLAINT: Obstructive sleep apnea.

HISTORY OF PRESENT ILLNESS: This is a 47-year-old male status post baseline polysomnography in December of 2008, which showed moderate obstructive sleep apnea with an AHI of 24 events/hour. He underwent CPAP titration, which eliminated sleep-disordered breathing. He was intolerant to CPAP therapy and, hence, fit with a mandibular advancement device.

PAST MEDICAL HISTORY: Headaches, gastroesophageal reflux disease.

MEDICATIONS: Valtrex.

EMA DEVICE TITRATION

PHYSICAL EXAM RISK FACTORS:

BMI: 32.2.
Class IV Mallampati airway.
Neck circumference: 20 ½ inches.

TECHNICAL NOTES:

The study was excellent.
One episode of nocturia.
Moderate snoring was reduced but not eliminated using the EMA appliance.
The patient was titrated from a 19-mm yellow, to a 19-mm blue, to a 17-mm yellow, to a 17-mm blue, to a 15-mm yellow band.

MORNING QUESTIONNAIRE:

Estimated sleep onset latency: 5 minutes, same as usual.
Estimated total sleep time: 7 hours, longer than usual.
The patient remembered 4 awakenings.
The patient felt well rested in the morning.
Overall, thought it was a typical night's sleep.

SLEEP ARCHITECTURE:

Total sleep time: 356 minutes.
Sleep efficiency: 82%.
Sleep onset latency: 19 ½ minutes.
REM latency: 93 minutes.

Sleep hypnogram reveals fragmented sleep, with 3 distinct REM periods.

Sleep Stage Distribution: Slightly decreased slow-wave sleep.

N1: 5% total sleep time.
N2: 56% total sleep time.
N3: 6% total sleep time.
Stage REM: 33% total sleep time.

BODY POSITION:

100% of the night spent in the supine position.

EMA DEVICE TITRATION

LIMB MOVEMENTS:

Periodic Limb Movement Index is 36.9 events/hour, of which 1.2 events/hour are associated with arousals.

Arousal Index: 26.3 events/hour, of which the majority is nonspecific in origin.

RESPIRATORY: The patient had persistent obstructive sleep apnea, despite the mandibular advancement device. Using a 17-mm blue band the patient slept 63 minutes, including time in the supine position, as well as in stage REM sleep.

Total obstructive apneas: 4.
Total hypopneas: 17.

Apnea-Hypopnea Index (AHI): 20 events/hour.

OXYGENATION: On the aforementioned band:

Mean SpO_2: 93%.

SpO_2 Nadir: 89%.

Time spent with saturations less than 88%: 2.6% of total sleep time.

EEG NOTES: None.

EKG: Sinus arrhythmia.

CONCLUSIONS:

1) The patient's obstructive sleep apnea persisted, despite the mandibular advancement device.
2) The patient had mild nocturnal hypoxemia.
3) The patient had moderate periodic limb movement disorder.
4) The patient had abnormal sleep architecture.

EMA DEVICE TITRATION

RECOMMENDATIONS:

1) Consider restarting CPAP therapy in an attempt to treat the patient's underlying obstructive sleep apnea and nocturnal hypoxemia.
2) Alternatively, can consider using the mandibular advancement device using a 17-mm blue band and supplemental oxygen at 2 L/minute.
3) Consider treatment of his periodic limb movement disorder to help consolidate sleep.
4) The patient should follow up as scheduled at
   as well as at
5) Please feel free to call with any questions.

Spencer Study Club

Sleep Study Review Sheet: CASE 1

Metric	Baseline Study	OA Study
Type of study (PSG, HST, split, etc)	PSG	PSG
Date of study	12-2007	11-2012 (5 years)
Patient BMI	???	32.2
Total sleep time (TST)	5:21:58	4:56, 63 minutes at optimal band
Sleep efficiency	91.2%	82%
% N1	14.7%	5%
% N2	28.7%	56%
% N3	39.4%	6%
% REM	17.1%	33%
% Supine sleep	5.5%	100%
% Non-supine sleep	94.4%	0%
% Supine REM sleep	???	???
Overall AHI	24	20
Number of apneas	25	4 (at optimal band, 63 minutes)
Number of hypopneas	104	17 (at optimal band, 63 minutes)
RDI	???	???
Number of RERA's	???	???
Average oxygen saturation	93.8%	93%
Oxygen saturation nadir	88%	89%
Supine AHI	88	20 (all sleep was supine)
Non-Supine AHI	20.3 (left lateral)	NA (no non supine sleep)
Other notes	sleep doctor notes "severe supine dependent obstructive sleep apnea"	no mention or consideration of supine dependent sleep apnea

Name:
Date:
DOB:
Referring Physician:

Recording Technique: Electrophysiologic signals were digitalized, acquired and reviewed using the Embla system. The entire study was attended and staged in 30-second epochs by sleep center technologists; using the recommended scoring criteria for hypopnea with 4 % desaturation's from the "AASM manual for the scoring of sleep and associated events". Digitalized signals include EEG (F4-M1, C4-M1,02-M1), EOG, submental EMG, heart rate, left and right leg EMG, oral/nasal pneumotach pressure transducer, oral/nasal thermistor, respiratory inductance plethysmography, pulse oximetry, snoring. And, when applicable, nasal CPAP or BIPAP pressure/flow.

Clinical Indications: sleep apnea

Sleep Results: total recording time 495 minutes, total sleep time 427 minutes, sleep efficiency 87%, sleep latency 18 minutes

Sleep Architecture: all sleep stages noted with a shift to lighter NREM stages. REM sleep 15%, REM latency shortened at 59 minutes.

Respiratory Analysis: mild obstructive sleep apnea, AHI 11, low oxygen 81%.

Electromyographic Findings: without findings of a periodic limb movement disorder.

EKG: normal sinus rhythm

Impressions: mild OSA

Final diagnosis: 1. obstructive sleep apnea.

Recommendations: 1. CPAP titration and trial. The patient has a clinic follow-up scheduled to review test results and treatment recommendations.

POLYSOMNOGRAHY REPORT

Patient:	**Study Date:**	**MR#:**
DOB:	**BMI:**	**Rec ID:**
Height:	**Age:**	**Tech:**
Weight:	**Gender:**	**Scorer:**
		ESS:

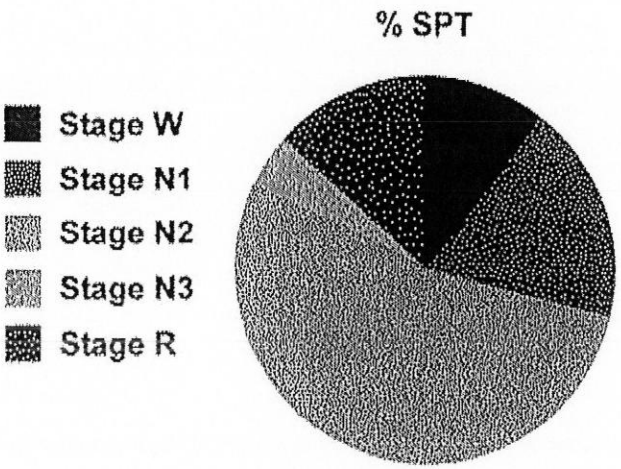
Referring Physician:
Interpreting Physician:

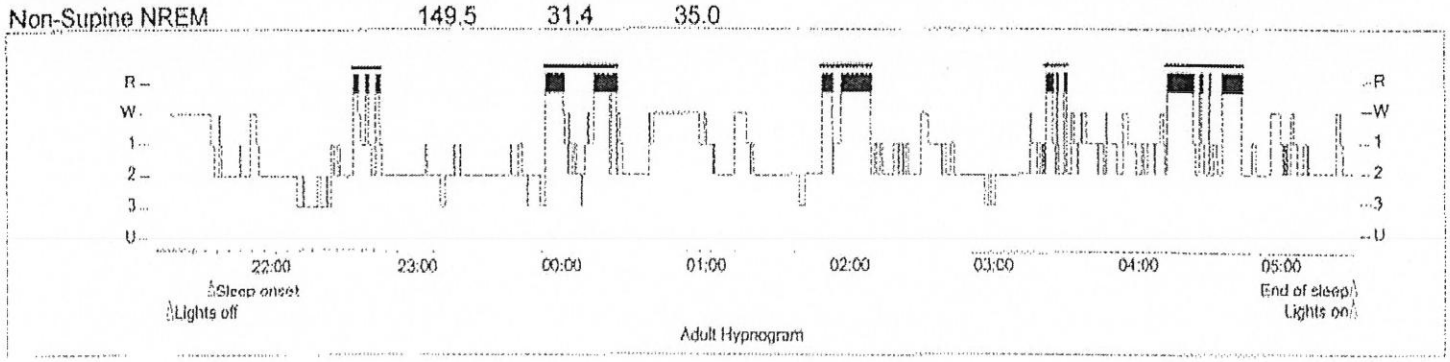
SLEEP SUMMARY

Lights Out:	21:24:51	
Lights On:	5:38:21	
Total Recording Time:	493.5	min
Total Sleep Time:	427.0	min
Sleep Period Time:	476.0	min
Percent Sleep Efficiency:	86.5	%
Sleep Latency:	17.5	min
Stage R Latency:	59.0	min
Number of Awakenings (NW):	22.0	

SLEEP STAGE SUMMARY

STAGE	Duration (min)	% SPT	%TST
Stage W	66.0	*	*
WASO	49.0	*	*
Wake During Sleep (WDS)	49.0	10.3	*
Stage N1	88.5	18.6	20.7
Stage N2	253.0	53.2	59.3
Stage N3	22.5	4.7	5.3
Stage R	63.0	13.2	14.8
Total NREM	364.0	76.5	85.2
Supine	239.5	50.3	56.1
Supine REM	25.0	5.3	5.9
Supine NREM	214.5	45.1	50.2
Non-Supine	187.5	39.4	43.9
Non-Supine REM	38.0	8.0	8.9
Non-Supine NREM	149.5	31.4	35.0





Patient: MR#: Study Date:

RESPIRATORY DISTURBANCE SUMMARY

AHI 10.8

	Apnea			Hypopnea	Total	
	# Obst.	# Central	# Mixed	#	#	Index
REM Events	20	0	0	6	26	24.8
Supine	20	0	0	6	26	62.4
Non-Supine	0	0	0	0	0	0.0
NREM Events	14	0	0	37	51	8.4
Supine	11	0	0	33	44	12.3
Non-Supine	3	0	0	4	7	2.8
Wake Events	0	0	0	0	0	0.0
Supine	0	0	0	0	0	0.0
Non-Supine	0	0	0	0	0	0.0
TOTAL EVENTS	34	0	0	43	77	9.4
REM+NREM Event Total	**34**	**0**	**0**	**43**	**77**	**10.8**
Supine Event Total (Sleep + Wake)	31	0	0	39	70	15.1
Non-Supine Event Total (Sleep + Wake)	3	0	0	4	7	2.0

APNEA INDEX 4.8
HYPOPNEA INDEX 6.0

AROUSAL SUMMARY

	Count	Index
Apnea	9	1.3
Hypopnea	7	1.0
Snore	0	0.0
Desaturation	7	1.0
Spontaneous	70	9.8
Limb Movement	8	1.1
Periodic Limb Movement	0	0.0
Respiratory RLM	1	0.1
TOTAL	102	14.3

OXYGEN SATURATION SUMMARY

	Mean	Max	Min
Sleep	94.6	98.0	81.0
REM	94.7	98.0	81.0
NREM	94.6	98.0	81.0
Wake	95.1	99.0	85.0
All Stages	94.7	99.0	81.0

Occurrence of Cheyne Stokes breathing: No

Minutes TRT SaO2 < 90%: 9.0
Minutes TRT SaO2 < 88%: 4.2

LIMB MOVEMENT SUMMARY

	Count	Index
Limb Movements	17	2.4
Periodic Limb Movements	0	0.0
Respiratory Related LLM	3	0.4
TOTAL	20	2.8

EKG SUMMARY

	Mean	Max	Min
Sleep	64.0	87.0	49.0
REM	66.7	82.0	52.0
NREM	63.5	87.0	49.0
Wake	64.7	91.0	48.0
All Stages	64.1	91.0	48.0

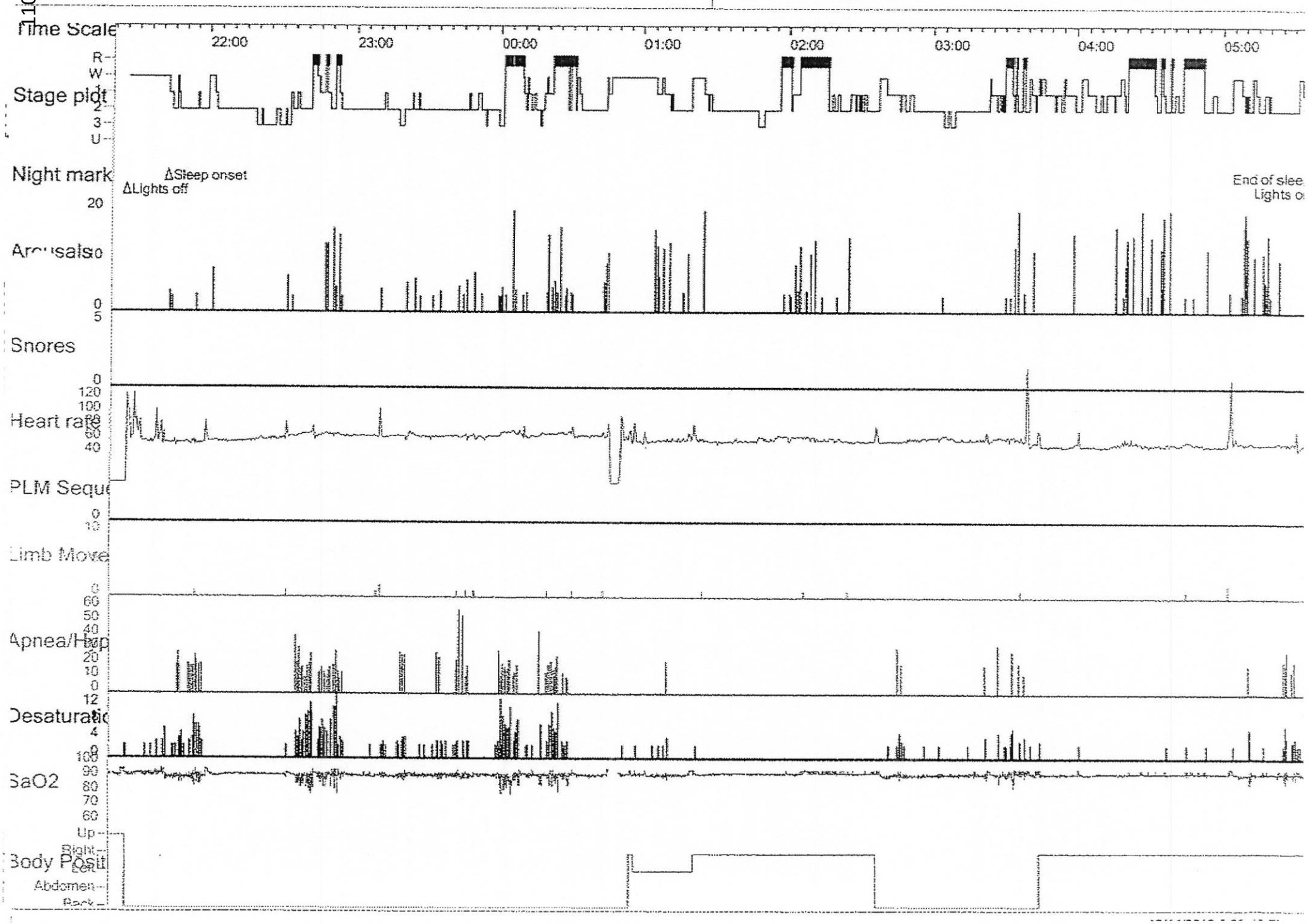
Bradycardia:	No
Asystole:	No
Sinus tachycardia during sleep:	No
Narrow complex tachycardia:	No
Wide complex tachycardia:	No
Atrial fibrillation:	No
Arrhythmia:	

	Count	Index
Desaturations 4% or >	114	13.9
NREM Desaturations	86	14.2
REM Desaturations	28	26.7
Wake Desaturations	0	0.0

Lowest Desaturation (All Stages): 81.0%

NOTE: Scoring rules for limb movement and respiratory events are scored based on the criteria listed in the AASM Manual for the Scoring of Sleep and Associated Events.

Recording Code:
Recording Date:
Patient Name:
Birth date:
MedRec.:



EMA DEVICE TITRATION

DOB:
DOS:

STANDARD PROTOCOL: The patient was studied with attended Polysomnography. Electrophysiologic sleep parameters included: frontal (F4/M1 or F3/M2), Central (C4/M1 or C3/M2) and occipital (O2/M1 or O1/M2), electroencephalogram (EEG), right and left electroculogram (EOG), and submentalis electromyogram (EMG). Cardiac rhythm was continually recorded (ECG). Periodic limb movements were monitored by anterior tibialis electromyogram (EMG). Airflow was detected by oronasal thermistor and pressure transducer. Respiratory effort was determined by measurement of chest and abdomen motion using Respiratory Inductance Plethysmography. Arterial pulse oximetry (SpO_2) was measured with a Nonin 3 second sampling rate from the finger. Analog data was digitized, transferred from the hard drive to the local area network, and after being analyzed, the results are archived. Raw data was manually scored in 30-second epochs for sleep stages using AASM Manual for the Scoring of Sleep and Associated Events 2012. Apneas were scored on the basis of absence of airflow from a thermistor for ≥10 seconds, respectively. Hypopneas were scored on the basis of reduction of nasal pressure amplitude of ≥ 30%, for a duration of ≥ 10 seconds, desaturation of ≥ 3% below pre-event baseline or the event is associated with arousal and 90 % of event meets amplitude criteria. The Apnea Hypopnea Index (AHI) was computed as a total of all respiratory events divided by the total sleep time in hours.

REFERRING PHYSICIAN:

PRIMARY CARE PHYSICIAN:

CHIEF COMPLAINT: Suspected sleep apnea.

HISTORY OF PRESENT ILLNESS: This is a 60-year-old female previously diagnosed with obstructive sleep apnea on 10/12/2013, with an AHI of 11 events/hour. There was no significant limb-movement abnormality. She had no significant nocturnal hypoxemia.

PAST MEDICAL HISTORY: Unknown.

EMA DEVICE TITRATION

DOB:
DOS:
PAGE 2

MEDICATIONS:

1) Verapamil.
2) Vitamin D3.
3) Multivitamins.
4) Omega-3 fatty acids.
5) Calcium.

PHYSICAL EXAM RISK FACTORS:

BMI: 21.7.
Class II Mallampati airway.
Neck circumference: 12 ¼ inches.

TECHNICAL NOTES:

The study was excellent.
Two episodes of nocturia.
Moderate snoring was present.
The patient was titrated from a 19-mm blue, to a 17-mm blue, to a 15-mm blue, to a 14-mm yellow, to a 15-mm blue band.

MORNING QUESTIONNAIRE:

Estimated sleep onset latency: 5 minutes, same as usual.
Estimated total sleep time: 6 hours, same as usual.
The patient remembered 4 awakenings.
The patient felt awake, but not alert.
Overall, thought it was a worse night's sleep than usual.

SLEEP ARCHITECTURE:

Total sleep time: 392 minutes.
Sleep efficiency: 91%.
Sleep onset latency: 1 minute.
REM latency: 56 minutes.

Sleep hypnogram reveals fragmented sleep, with 6 short REM periods.

EMA DEVICE TITRATION

DOB:
DOS:
PAGE 3

SLEEP ARCHITECTURE (cont'd):

Sleep Stage Distribution: Within normal limits.

N1: 0% total sleep time.
N2: 46% total sleep time.
N3: 31% total sleep time.
Stage REM: 23% total sleep time.

BODY POSITION:

84% of the night spent in the supine position.
16% of the night spent in the non-supine position.

LIMB MOVEMENTS:

Periodic Limb Movement Index is 2.1 events/hour, of which 0 events/hour are associated with arousals.

Arousal Index: 13.3 events/hour, of which the majority is nonspecific in origin.

RESPIRATORY: The patient had persistent sleep-disordered breathing, despite the dental appliance. Using 14-mm blue bands, the patient slept 72 minutes, including time in stage REM sleep, as well as in the supine position.

Total obstructive apneas: 1.
Total hypopneas: 14.

Apnea-Hypopnea Index (AHI): 12.5 events/hour.

OXYGENATION: Using a 14-mm blue band:

Mean SpO_2: 93%.

SpO_2 Nadir: 88%.

Time spent with saturations less than 88%: 2.4% of total sleep time.

EEG NOTES: None.

EKG: Normal sinus rhythm with occasional PVCs.

EMA DEVICE TITRATION

DOB:
DOS:
PAGE 4

CONCLUSIONS:

1) The patient had persistent sleep-disordered breathing, despite the dental appliance.
2) The patient had no significant limb-movement abnormality.
3) The patient had fragmented sleep architecture with a shortened REM latency.

RECOMMENDATIONS:

1) Consider a trial of CPAP therapy in an attempt to further treat the patient's underlying sleep-disordered breathing.
2) If she were to use the dental appliance, would recommend 14-mm blue bands, as that appeared to work best during the study.
3) Consider a trial of a sedative/hypnotic to help consolidated sleep.
4) The patient should follow up as scheduled
   as at the
5) Please feel free to call with any questions.

MediByte™ Snoring Report

Pre-treatment Summary Report

Patient Name:		**Patient ID:**	
Date of Birth:		**Chart Code:**	
Weight:		**Study Date:**	
Height:		**Age:**	
BMI:		**Sex:**	
Waist: 0"	**Hip:** 0"	**Waist-Hip Ratio:** 0.00	**Referring Physician:**

Comments: Wearing appliance

Total Recording Time(TRT) : 357.9 minutes

Respiratory and Snoring Events	Total#	Index	Duration (sec.) Mean	Min.	Max.
Central Apneas	0	0.0	0.0	0.0	0.0
Obstructive.Apneas	18	3.0	44.2	17.3	117.7
Mixed Apneas	0	0.0	0.0	0.0	0.0
Hypopneas	12	2.0	60.5	10.7	114.2
AH	30	5.1	50.7	10.7	117.7
Snoring	1460	246.9	0.7	0.2	2.4
Desaturations	23	3.9	48.7	19.5	99.5
RERAs	0	0.0	0.0	0.0	0.0

Cardiac

Avg HR:	66.0	Min HR:	52.0	Max HR:	95.0

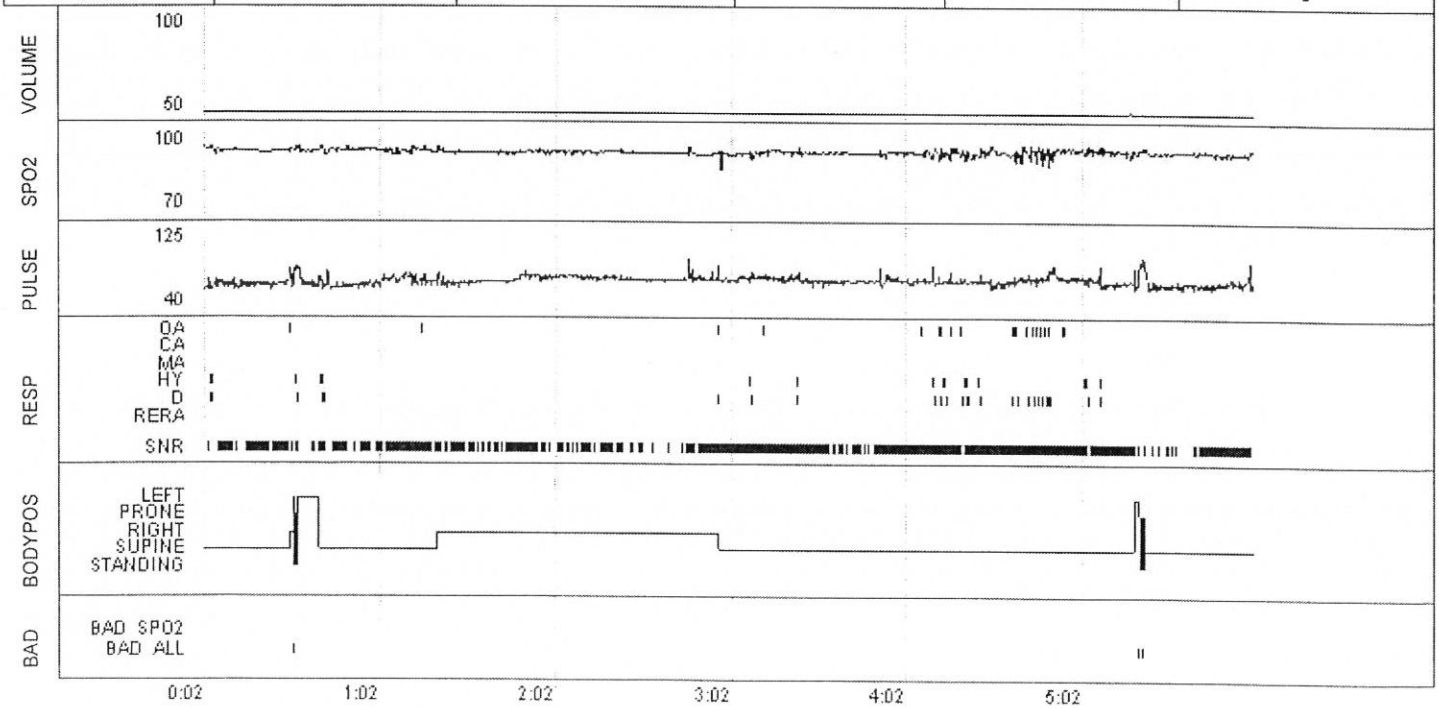
Oximetry

Mean SpO2	94.2%
Min SpO2	85.0%
Max SpO2	98.0%
% Time SpO2 in Range	
90-100 %	99.8%
80-89 %	0.2%
70-79 %	0.0%
60-69%	0.0%
50-59%	0.0%
< 50 %	0.0%

Body Position	**Supine**	**Prone**	**Left Side**	**Right Side**	**Total Non Supine**
% Time in Pos	69.9%	0.1%	2.5%	27.4%	29.9%
Snoring events	1217	1	14	227	242
AH events	27	0	0	2	2
AHI	6.5	0.0	0.0	1.2	1.1

Snoring Volume Table dB(A)

Body Position	**Supine**	**Non-Supine**	**Right Side**	**Left Side**	**Prone**
Min	-	-	-	-	-
Max	-	-	-	-	-
Mean	-	-	-	-	-



**Respiratory events are defined in the Assisted Scoring User Settings and in the User Guide. Final clinical decisions and degree of accuracy are the sole responsibility of the clinician using this software.*

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Sleep Study Review Sheet—CASE 2-PSG to PSG to HST

Metric	Baseline Study	OA Study	Medibyte
Type of study (PSG, HST, split, etc)	PSG	PSG	HST
Date of study	11/2013	3/2014 (4 months)	4/2014
Patient BMI	21	21	16.7 (wrong on report)
Total sleep time (TST)	427 minutes	392 minutes (72 with optimal band)	357 minutes recording
Sleep efficiency	87%	91%	NA
% N1	20.7	0%	NA
% N2	59.3	46%	NA
% N3	5.3	31%	NA
% REM	14.8%	23%	NA
% Supine sleep	56.1%	84%	69.9%
% Non-supine sleep	43.9%	16%	29.9%
% Supine REM sleep	5.9%	???	NA
Overall AHI	10.8	12.5 (in the 72 minutes)	5.1
Number of apneas	34	1 (in the 72 minutes)	18
Number of hypopneas	43	14 (in the 72 minutes)	12
RDI	???	???	5.1
Number of RERA's	???	???	0
Average oxygen saturation	94.6%	93%	94.2%
Oxygen saturation nadir	81%	88%	85%
Supine AHI	15.1	???	6.5
Non-Supine AHI	2.0	???	1.1
Other notes			

PATIENT:
REFERRING PHYSICIAN:
EXAM DATE:
EMPI:

DOB:
ACCOUNT:
MR:

SEX:
IP/OP:

Job Number: **Version: 0**

NOCTURNAL POLYSOMNOGRAPHY

STUDY PROTOCOL:

Standard placements for central and occipital electroencephalogram recording as well as submental electromyogram and horizontal electro-oculogram recording were used. The anterior tibialis muscles were monitored for evidence of nocturnal myoclonus. Saturation was monitored by finger oximetry. Air flow was monitored by a nasal pressure transducer and an oral thermocouple. Chest and abdominal wall motion were monitored by piezo crystal belts. Single lead electrocardiogram was recorded continuously. The apnea-hypopnea index was derived by dividing the total number of respiratory events by the total sleep time in hours. Hypopneas were defined as decrease in air flow or effort associated with a desaturation or arousal. Standard definitions for apneas were used (International Classification of Sleep Disorders 1997). Standard scoring for sleep staging was used (Rechtschaffen and Kales). Snoring was monitored by nasal pressure transducer. The signal averaging time for oximetry channel was 4 seconds.

REASON FOR REQUEST: This is a 70-year-old male with a previous history of severe obstructive sleep apnea syndrome who presents for a repeat CPAP titration with a history of hypersomnia and witnessed apneas.

INTERPRETATION: Nocturnal polysomnography was performed in the usual manner. The study was conducted as a split night. Total recording period before initiation of CPAP was approximately 300minutes (146 minutes of sleep time). The entire study lasted for 479 minutes with the total sleep time of 268 minutes for a sleep efficiency of 56%. Sleep onset latency was normal at 18 minutes. REM latency was prolonged at 456 minutes.

SLEEP STAGE ARCHITECTURE: Stage 1 sleep occupied 22% of total sleep time, stage 2 70.7%, and REM sleep 7.3%.

VENTILATION SUMMARY: During the initial portion of the study the patient had 213 apneas and hypopneas recorded together. The apnea-hypopnea index was severely elevated at 87.2 with some snoring identified as well. The patient was supine for the initial portion of the study prior to the initiation of CPAP. With respect to the patient's breakdown in sleep-disordered breathing, he had 9 obstructive apneas, 76 central apneas and 90 mixed apneas as well as 38 hypopneas. CPAP was initiated at a beginning pressure of 5 cm of water and titrated to an ending CPAP pressure of 13 cm with normalization of the apnea-hypopnea index to 2 but the patient did not achieve supine positioning during REM sleep at the very end of the study. At an ending CPAP pressure of 13 cm, the patient had the oxygen desaturation nadir of 90%. The patient appeared to tolerate CPAP only fair.

PATIENT:
EMPI:

Job Number: **Version:**

NOCTURNAL POLYSOMNOGRAPHY

OXYGENATION: The study was conducted on room air with an oxygen saturation prior to lights out of 98%. During the study the patient had a mean hemoglobin oxygen saturation of 91% with an oxygen desaturation nadir of 76% prior to initiation of CPAP. The patient spent approximately 44 minutes with oxygen saturations less than 90%. It appeared primarily associated with the diagnostic portion of the study prior to initiation of CPAP.

LEG MOVEMENTS: Leg movements were monitored and there was no clear evidence for periodic limb movement disorder.

CARDIAC SUMMARY: The patient remained in normal sinus rhythm during the study.

IMPRESSION:

1. SEVERE OBSTRUCTIVE SLEEP APNEA SYNDROME WITH AN OVERALL APNEA-HYPOPNEA INDEX OF 87.2 DURING THIS SPLIT-NIGHT STUDY. THE PATIENT WAS TITRATED ON CPAP TO 13 CM WITH NORMALIZATION OF THE APNEA-HYPOPNEA INDEX. THE PATIENT DID ACHIEVE REM SLEEP AT THIS ENDING CPAP PRESSURE BUT NOT CONCURRENTLY IN THE SUPINE POSITION. THE PATIENT SPENT MINIMAL TIME IN THE SUPINE POSITION AT THIS ENDING CPAP PRESSURE OF 13 CM.
2. DEPRESSED SLEEP EFFICIENCY.
3. NORMAL SLEEP ONSET LATENCY.
4. PROLONGED REM LATENCY.
5. SLEEP STAGE ARCHITECTURE WAS REMARKABLE FOR AN INCREASE IN STAGE 1 AND STAGE 2 AND A DECREMENT OF REM SLEEP. THERE WAS NO SLOW-WAVE SLEEP OBSERVED.
6. SIGNIFICANT HYPOXEMIA ASSOCIATED WITH SLEEP-DISORDERED BREATHING PRIOR TO INITIATION OF CPAP.
7. NO CLEAR EVIDENCE FOR PERIODIC LIMB MOVEMENT DISORDER.
8. THE PATIENT REMAINED IN NORMAL SINUS RHYTHM DURING THE STUDY.

RECOMMENDATIONS:
1. Follow up with
2. I would recommend CPAP at 14 cm of water pressure with a C-Flex of 3 and mask of choice with a passover humidifier. During this study the patient used a Fisher-Paykel nasal mask. The size is not known to me.

TAPS DEVICE TITRATION

DOB:
DOS:

MEDICARE/MEDICAID STANDARD PROTOCOL: The patient was studied with attended Polysomnography. Electrophysiologic sleep parameters included: frontal (F4/M1 or F3/M2), Central (C4/M1 or C3/M2) and occipital (O2/M1 or O1/M2), electroencephalogram (EEG), right and left electroculogram (EOG), and submentalis electromyogram (EMG). Cardiac rhythm was continually recorded (ECG). Periodic limb movements were monitored by anterior tibialis electromyogram (EMG). Airflow was detected by oronasal thermistor and pressure transducer and respiratory effort was determined by measurement of chest and abdomen motion using Respiratory Inductance Plethysmography. Arterial pulse oximetry (SpO_2) was measured with an internal Nellcor OxiMax 3 second sampling rate from the finger. Analog data was digitized, transferred from the hard drive to the local area network, and after being analyzed, the results archived on CD-ROM. Raw data was manually scored in 30-second epochs for sleep stages using AASM Manual for the Scoring of Sleep and Associated Events 2012. Apneas were scored on the basis of absence of airflow from a thermistor for ≥10 seconds, respectively. Hypopneas were scored on the basis of reduction of nasal pressure amplitude of ≥ 30%, for a duration ≥ 10 seconds, desaturation of ≥4% below pre-event baseline and 90% of event meets amplitude criteria. The Apnea Hypopnea Index (AHI) was computed as a total of all respiratory events divided by the total sleep time in hours.

REFERRING PHYSICIAN:

PRIMARY CARE PHYSICIAN:

CHIEF COMPLAINT: Obstructive sleep apnea.

HISTORY OF PRESENT ILLNESS: This is a 77-year-old male status post split night polysomnography on 11/26/2007, which showed severe obstructive sleep apnea with an AHI of 87.2 events/hour. He was intolerant to CPAP therapy.

PAST MEDICAL HISTORY: Unknown.

MEDICATIONS: Unknown.

TAPS DEVICE TITRATION

DOB:
DOS:
PAGE 2

PHYSICAL EXAM RISK FACTORS:

BMI: 26.4.
Class IV Mallampati airway.
Neck circumference: 16 inches.

TECHNICAL NOTES:

The study was excellent.
Four episodes of nocturia.
Moderate snoring was noted.
The patient was titrated from a position of 4 turns, to 8 turns, to 12 turns, to 16 turns, to 20 turns, back to 16 turns, and the addition of supplemental oxygen was added at 4:08 a.m. at 2 L/minute.

MORNING QUESTIONNAIRE:

Estimated sleep onset latency: 1 hour, much longer than usual.
Estimated total sleep time: 4 hours, shorter than usual.
The patient remembered 5 awakenings.
The patient felt awake and wide alert.
Overall, thought it was a worse night's sleep than usual.

SLEEP ARCHITECTURE:

Total sleep time: 300 minutes.
Sleep efficiency: 63%.
Sleep onset latency: 30 minutes.
REM latency: 128 minutes.

Sleep hypnogram reveals fragmented sleep, with 4 short REM periods.

Sleep Stage Distribution: Decreased slow-wave and stage REM sleep.

N1: 5% total sleep time.
N2: 81% total sleep time.
N3: 4% total sleep time.
Stage REM: 10% total sleep time.

BODY POSITION:

35% of the night spent in the supine position.
65% of the night spent in the non-supine position.

TAPS DEVICE TITRATION

DOB:
DOS:
PAGE 3

LIMB MOVEMENTS:

Periodic Limb Movement Index is 11.2 events/hour, of which 0.4 events/hour are associated with arousals.

Arousal Index: 10.2 events/hour, of which the majority is nonspecific in origin.

RESPIRATORY: At a position of 8 turns, the patient slept 51 ½ minutes, including time in stage REM sleep; however, not in the supine position.

Total obstructive apneas: 0.
Total hypopneas: 0.

Apnea-Hypopnea Index (AHI): 0 events/hour.

OXYGENATION: At a position of 8 turns:

Mean SpO_2: 89%.

SpO_2 Nadir: 80%.

Time spent with saturations less than 88%: 6.4% of total sleep time.

EEG NOTES: Alpha intrusion.

EKG: Normal sinus rhythm.

CONCLUSIONS:

1) The patient's obstructive sleep apnea was eliminated using the TAPS appliance.
2) The patient had persistent mild nocturnal hypoxemia.
3) The patient had mild periodic limb movement disorder.
4) The patient had fragmented sleep architecture.

TAPS DEVICE TITRATION

DOB:
DOS:
PAGE 4

RECOMMENDATIONS:

1) TAPS appliance at a position of 8 turns.
2) Supplemental oxygen at 2 L/minute via nasal cannula to be worn along with the appliance.
3) Consider treatment of his periodic limb movement disorder to help consolidate sleep.
4) The patient should follow up as scheduled
5) Please feel free to call with any questions.

Spencer Study Club

Sleep Study Review Sheet—Case 3

Metric	Baseline Study	OA Study
Type of study (PSG, HST, split, etc)	PSG, split night study	PSG
Date of study	11/2007	3/2014 (6.5 years)
Patient BMI	???	26.4
Total sleep time (TST)	146 minutes pre CPAP 268 minutes total	300 minutes, 51 minutes at optimal position (“8 turns”)
Sleep efficiency	56% total	63%
% N1		5%
% N2		81%
% N3		4%
% REM		10%
% Supine sleep		35%
% Non-supine sleep		65%
% Supine REM sleep		
Overall AHI	87.2	0 (at optimal position)
Number of apneas	9 obstructive, 76 central, 90 mixed	0
Number of hypopneas	38	0
RDI		
Number of RERA’s		
Average oxygen saturation	91%	89%
Oxygen saturation nadir	76%	80%
Supine AHI		No supine sleep in optimal position
Non-Supine AHI		

Metric	Baseline Study	OA Study
Other notes		Note that low oxygen continued, so the MD recommended supplemental oxygen to be used with the appliance. The optimal position was 4 turns (1mm) advanced from the initial position. The patient did NOT improve with further advancement.

SPLIT-NIGHT POLYSOMNOGRAPHY (PSG) REPORT

Patient Name:			
Sex:	Male	**Study Date:**	6/21/2015
D.O.B.:	8/15/1978	**Subject Code:**	20/9008
Age:	36	**Referring Physician:**	SVIENE, CYNTHIA
Height:	70.0 in	**Sleep Specialist:**	
Weight:	185.0 lbs	**Recording Tech:**	RICHARD KOONCE, RPSGT
B.M.I.:	26.5	**Scoring Tech:**	RICHARD KOONCE, RPSGT

INDICATIONS FOR STUDY: EDS snoring and non restorative sleep

PHYSICIAN INTERPRETATION:
The PSG was technically adequate.
IMPRESSION:
1. Obstructive Sleep Apnea (OSA) severe at AHI of 55
2. Optimal CPAP titration found at 6 cm pressure with REM supine noted and significant REM rebound found

RECOMMENDATIONS:
1. Discuss treatment options at the CPAP treatment group class.
2. Options include positive airway pressure (PAP), positional therapy (encouraged lateral sleep with wedges, etc.), treatment of snoring (including aggressive treatment of allergies and/or nasal congestion if present), or a dental orthotic.
3. Weight optimization should be encouraged as appropriate.
4. Surgical options are typically reserved for patients with moderate to severe disease who are refractory to other therapeutic options.
5. If PAP is selected for therapy, would consider auto titrating PAP (APAP) 5-15 cmH2O as treatment option.
   Please include the following information when placing a consult under "Durable Medical Equipment": age, OSA diagnosis with AHI, sleep study date, main symptoms, PAP pressure settings, accessories (heated humidification and tubing, compliance monitoring with data card and modem, mask interface of choice) with refill of supplies for lifetime/99 months.
6. Educate patient about not operating vehicles, using dangerous equipment, or firing a weapon when sleepy.
7. Educate patient about the potential increase in sleep disordered breathing with alcohol ingestion.

SLEEP ARCHITECTURE, RESPIRATORY MEASURES, BODY POSITION, OXIMETRY, AND CO2 KINETICS:

Diagnostic portion of study: Sleep onset was prolonged at **17.7** minutes. REM latency was normal at **50.0** minutes. REM was present during the diagnostic portion of the study. Overall sleep architecture was normal. During the diagnostic portion of the study, total sleep time was **125.0** minutes of a total of **163.1** minutes in bed time yielding a decreased sleep efficiency of **76.7%.** The patient demonstrated a severe degree of sleep fragmentation with a total arousal index of **61.0**/hr. The majority of these arousals were secondary to Sleep Disordered Breathing (SDB) with an Apnea-Hypopnea Index (AHI) of **55.2**/hr. The Respiratory Event-Related Arousal (RERA) index was **0.0**/hr, yielding a Respiratory Disturbance Index (RDI) of **55.2**/hr. Supine RDI was **55.2**/hr. The patient slept **100.0**% of the time in the supine position. The lowest oxygen saturation during this portion of the study was **83.0**%. The patient spent **4.9** minutes with an oxygen saturation below 89%. The oxygen desaturation index (ODI) was **38.9**/hr. Carbon dioxide (TcCO2 or ETCO2) was not monitored during this study. Mild-Moderate snoring was noted.

Titration portion of study: CPAP was begun at 6 cm. H_2O pressure and titrated up to 6 cm. H_2O pressure. Snoring was controlled at 6 cm. H_2O pressure. Sleep disordered breathing and sleep continuity appeared best controlled at 6 cm. H_2O pressure. Control of sleep

disordered breathing was observed during supine REM sleep at this pressure. Overall sleep architecture was improved. There was marked REM rebound to nearly 30 % of the treatment portion of the study

PERIODIC LIMB MOVEMENTS: Prior to treatment, the patient had a Periodic Limb Movements of Sleep (PLMS) index of **0.0**/hr and a PLMS arousal index of **0.0**/hr. During the CPAP titration, the PLMS index was **0.0**/hr with **0.0**/hr resulting in arousal from sleep.

ELECTROCARDIOGRAM (EKG)/HEART RATE: Throughout the study, the EKG revealed no abnormalities.

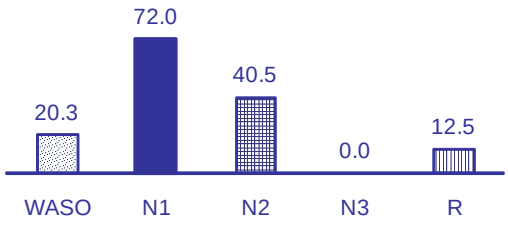
ELECTROENCEPHALOGRAM (EEG): Throughout the study, no epileptiform or seizure activity noted.
PSG PARAMETERS:
Technical and digital specifications and scoring rules comply with the American Academy of Sleep Medicines *AASM Manual for Scoring Sleep, 2012.* EEG derivation is the RECOMMENDED derivation. Hypopnea definition is the RECOMMENDED definition. Respiratory disturbance index (RDI) = AHI + RERA/hour. RERA is scored by nasal pressure and inductance plethysmography.

John D Roehrs, MD FCCP
Pulmonary, Critical Care, Sleep Staff
ABIM sleep certified

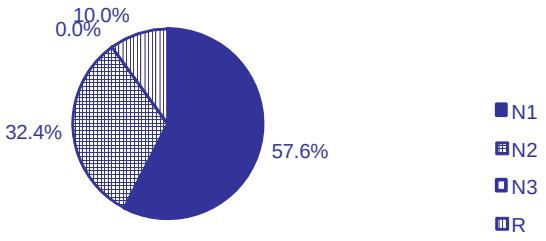
DIAGNOSTIC ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

Sleep Architecture	
Lights out clock time (hr:min):	9:58 PM
Lights on clock time (hr:min):	12:42 AM
Total Recording Time (TRT):	163.1
Sleep Period Time (SPT):	145.3
Total Sleep Time (TST):	125.0
Sleep Efficiency:	76.7%
Sleep latency (SL):	17.7
Total Stage Changes (after sleep onset):	72
Awakenings (after sleep onset):	10
WASO:	20.3
REM Periods:	1
REM Latency:	50.0
REM Latency (less Wake time):	37.5



Stage Distribution (in min.)



Sleep Stage (%TST)

Sleep Stage	Latency (min)
N1:	0.0
N2:	2.5
N3:	N/A
R:	50.0

Stage Latency = 0.0 denotes start of sleep.

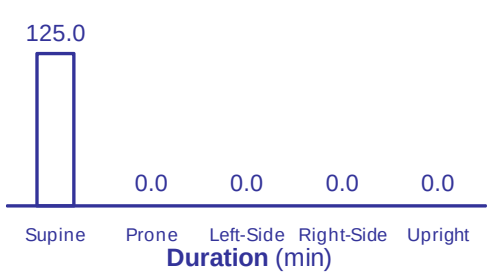
DIAGNOSTIC ANALYSIS

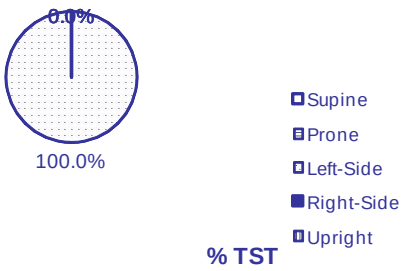
Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

RESPIRATORY EVENTS	Cen. Apneas	Obs. Apneas	Mxd. Apneas	Hypopneas	Total Apneas	Apnea+ Hypopnea	RERA	All Resp. Events *
Count:	3	6	0	106	9	115	0	115
Index (events / hr.):	1.4	2.9	0.0	50.9	4.3	**55.2**	0.0	55.2
Mean Duration (sec.):	17.9	24.4	N/A	27.3	22.2	26.9	N/A	26.9
Longest Event (sec.):	25.1	43.2	N/A	73.0	43.2	73.0	N/A	73.0
REM Count:	0	0	0	14	0	14	0	14
Non-REM Count:	3	6	0	92	9	101	0	101
REM Index:	0.0	0.0	0.0	67.2	0.0	67.2	0.0	67.2
Non-REM Index:	1.6	3.2	0.0	49.1	4.8	53.9	0.0	53.9

* Note: Does not contain Cheyne Stokes Breathing, Hypoventilation, or Periodic Breathing.

RESPIRATORY EVENTS (by Body-Position)	Supine Sleep		Prone Sleep		Left-Side Sleep		Right-Side Sleep		Upright Sleep	
	Count	Index	Count	Index	Count	Index	Count	Index	Count	Index
Duration (hrs:min:sec):	125.0		0.0		0.0		0.0		0.0	
Obstructive Apneas:	6	2.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Central Apneas:	3	1.4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mixed Apneas:	0	0.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Hypopneas:	106	50.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
RERAs:	0	0.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total:	115	55.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A





BODY-POSITION RESULTS

DIAGNOSTIC ANALYSIS

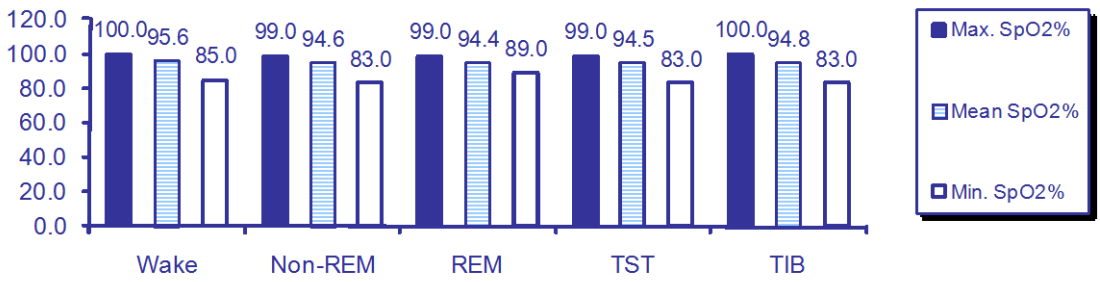
Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

AROUSALS	Resp. Count	Resp. Index	Spontaneous Count*	Spontaneous Index*	Total Count	Total Index
Total Sleep Time:	103	49.4	24	11.5	127	61.0
Non-REM	94	50.1	23	12.3	117	62.4
REM:	9	43.2	1	4.8	10	48.0

* EEG Arousal activity not associated with Respiratory or PLM events.

LIMB MOVEMENTS (by sleep stage)	LM w/ Arousals		LM w/o Arousals		Total LMs		PLM Series	
	Count	Index	Count	Index	Count	Index	Count	Index
Total Sleep Time:	0	0.0	0	0.0	0	0.0	0	0.0
N1:	0	0.0	0	0.0	0	0.0	0	0.0
N2:	0	0.0	0	0.0	0	0.0	0	0.0
N3:	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
R:	0	0.0	0	0.0	0	0.0	0	0.0

OXYGEN DESATURATION EVENTS	Count	Index
Total Sleep Time:	81	38.9
Wake (after sleep onset):	4	11.8
Non-REM:	71	37.9
REM:	10	48.0
Total Recording Time:	85	31.3



Oximetry Trend Graph

DIAGNOSTIC ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

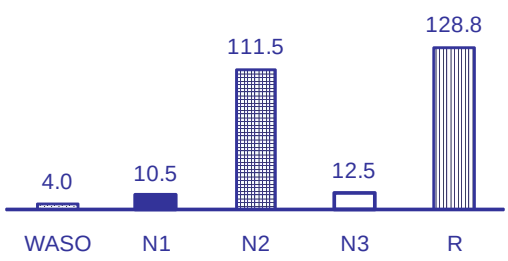
OXYGEN SATURATION	Wake	Non-REM	REM	TST	TIB
Max. SpO2%:	100.0	99.0	99.0	99.0	100.0
Mean SpO2%:	95.6	94.6	94.4	94.5	94.8
Min. SpO2%:	85.0	83.0	89.0	83.0	83.0
SpO2% <= 88% (min.)	0.4	3.1	0.0	3.1	3.5
% Time in range					
90 – 100%:	97.4%	93.8%	97.3%	94.2%	94.9%
80 – 89%:	2.6%	6.2%	2.7%	5.8%	5.1%
70 – 79%:	0.0%	0.0%	0.0%	0.0%	0.0%
60 – 69%:	0.0%	0.0%	0.0%	0.0%	0.0%
50 – 59%:	0.0%	0.0%	0.0%	0.0%	0.0%
< 50%:	0.0%	0.0%	0.0%	0.0%	0.0%
% Artifact / Bad Data:	0.0%	0.0%	0.0%	0.0%	0.0%

HEART RATE RESULTS	Wake	Non-REM	REM	TST	TIB
Max. HR (bpm):	86.0	84.0	78.0	84.0	86.0
Mean HR (bpm):	67.2	63.9	65.7	64.1	64.8
Min. HR (bpm):	59.0	56.0	57.0	56.0	56.0
% Time in range					
> 100 (bpm):	0.0%	0.0%	0.0%	0.0%	0.0%
90 – 100 (bpm):	0.0%	0.0%	0.0%	0.0%	0.0%
80 – 89 (bpm):	1.1%	0.1%	0.0%	0.1%	0.3%
70 – 79 (bpm):	16.6%	7.0%	12.3%	7.5%	9.6%
60 – 69 (bpm):	81.1%	74.9%	73.4%	74.7%	76.2%
50 – 59 (bpm):	1.2%	18.1%	14.3%	17.7%	13.9%
< 50 (bpm):	0.0%	0.0%	0.0%	0.0%	0.0%
% Artifact / Bad Data:	N/A	N/A	N/A	N/A	N/A

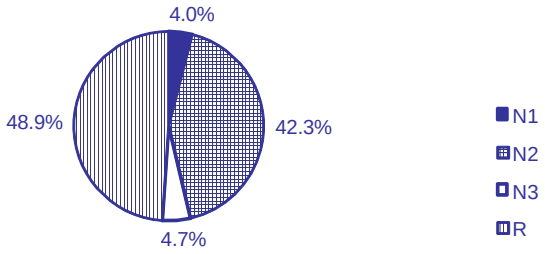
TREATMENT ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

Sleep Architecture	
Lights out clock time (hr:min):	12:49 AM
Lights on clock time (hr:min):	5:32 AM
Total Recording Time (TRT):	282.6
Sleep Period Time (SPT):	267.3
Total Sleep Time (TST):	263.3
Sleep Efficiency:	93.2%
Sleep latency (SL):	15.2
Total Stage Changes (after sleep onset):	42
Awakenings (after sleep onset):	5
WASO:	4.0
REM Periods:	3
REM Latency:	8.5
REM Latency (less Wake time):	8.0



Stage Distribution (in min.)



Sleep Stage (%TST)

Sleep Stage	Latency (min)
N1:	0.0
N2:	4.0
N3:	75.0
R:	8.5

Stage Latency = 0.0 denotes start of sleep.

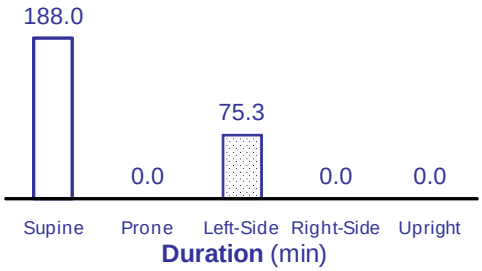
TREATMENT ANALYSIS

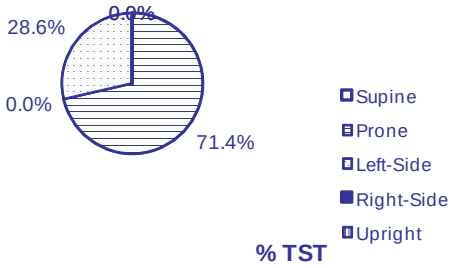
Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

RESPIRATORY EVENTS	Cen. Apneas	Obs. Apneas	Mxd. Apneas	Hypopneas	Total Apneas	Apnea+ Hypopnea	RERA	All Resp. Events *
Count:	1	0	0	3	1	4	0	4
Index (events / hr.):	0.2	0.0	0.0	0.7	0.2	**0.9**	0.0	0.9
Mean Duration (sec.):	14.9	N/A	N/A	16.7	14.9	16.3	N/A	16.3
Longest Event (sec.):	14.9	N/A	N/A	22.2	14.9	22.2	N/A	22.2
REM Count:	0	0	0	0	0	0	0	0
Non-REM Count:	1	0	0	3	1	4	0	4
REM Index:	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Non-REM Index:	0.4	0.0	0.0	1.3	0.4	1.8	0.0	1.8

* Note: Does not contain Cheyne Stokes Breathing, Hypoventilation, or Periodic Breathing.

RESPIRATORY EVENTS (by Body-Position)	Supine Sleep		Prone Sleep		Left-Side Sleep		Right-Side Sleep		Upright Sleep	
	Count	Index	Count	Index	Count	Index	Count	Index	Count	Index
Duration (hrs:min:sec):	188.0		0.0		75.3		0.0		0.0	
Obstructive Apneas:	0	0.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Central Apneas:	1	0.3	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Mixed Apneas:	0	0.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Hypopneas:	3	1.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
RERAs:	0	0.0	N/A	N/A	N/A	0.0	N/A	N/A	N/A	N/A
Total:	4	1.3	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A





BODY-POSITION RESULTS

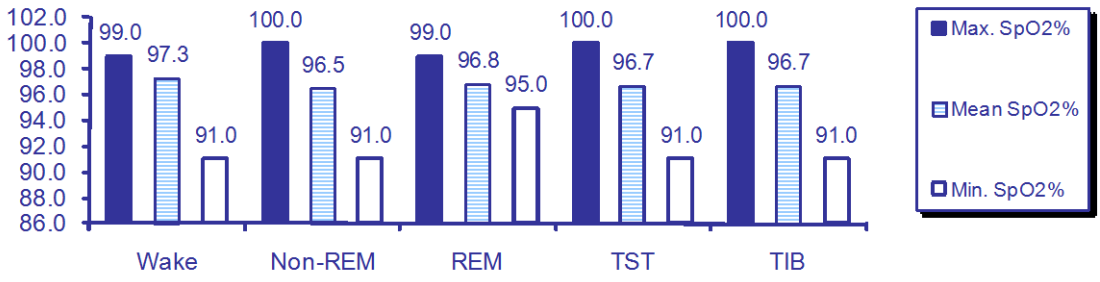
TREATMENT ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

AROUSALS	Resp. Count	Resp. Index	Spontaneous Count*	Spontaneous Index*	Total Count	Total Index
Total Sleep Time:	3	0.7	12	2.7	15	3.4
Non-REM	3	1.3	9	4.0	12	5.4
REM:	0	0.0	3	1.4	3	1.4

* EEG Arousal activity not associated with Respiratory or PLM events.

LIMB MOVEMENTS (by sleep stage)	LM w/ Arousals		LM w/o Arousals		Total LMs		PLM Series	
	Count	Index	Count	Index	Count	Index	Count	Index
Total Sleep Time:	0	0.0	0	0.0	0	0.0	0	0.0
N1:	0	0.0	0	0.0	0	0.0	0	0.0
N2:	0	0.0	0	0.0	0	0.0	0	0.0
N3:	0	0.0	0	0.0	0	0.0	0	0.0
R:	0	0.0	0	0.0	0	0.0	0	0.0



Oximetry Trend Graph

TREATMENT ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

OXYGEN SATURATION	Wake	Non-REM	REM	TST	TIB
Max. SpO2%:	99.0	100.0	99.0	100.0	100.0
Mean SpO2%:	97.3	96.5	96.8	96.7	96.7
Min. SpO2%:	91.0	91.0	95.0	91.0	91.0
SpO2% <= 88% (min.)	0.0	0.0	0.0	0.0	0.0
% Time in range					
90 – 100%:	100.0%	100.0%	100.0%	100.0%	100.0%
80 – 89%:	0.0%	0.0%	0.0%	0.0%	0.0%
70 – 79%:	0.0%	0.0%	0.0%	0.0%	0.0%
60 – 69%:	0.0%	0.0%	0.0%	0.0%	0.0%
50 – 59%:	0.0%	0.0%	0.0%	0.0%	0.0%
< 50%:	0.0%	0.0%	0.0%	0.0%	0.0%
% Artifact / Bad Data:	0.0%	0.0%	0.0%	0.0%	0.0%

HEART RATE RESULTS	Wake	Non-REM	REM	TST	TIB
Max. HR (bpm):	87.0	81.0	80.0	81.0	87.0
Mean HR (bpm):	60.0	58.6	57.1	57.9	58.0
Min. HR (bpm):	54.0	50.0	46.0	46.0	46.0
% Time in range					
> 100 (bpm):	0.0%	0.0%	0.0%	0.0%	0.0%
90 – 100 (bpm):	0.0%	0.0%	0.0%	0.0%	0.0%
80 – 89 (bpm):	3.0%	0.0%	0.0%	0.0%	0.2%
70 – 79 (bpm):	2.5%	0.4%	0.2%	0.3%	0.4%
60 – 69 (bpm):	22.5%	14.6%	12.6%	13.6%	14.2%
50 – 59 (bpm):	71.9%	85.0%	85.9%	85.4%	84.5%
< 50 (bpm):	0.0%	0.1%	1.3%	0.7%	0.6%
% Artifact / Bad Data:	N/A	N/A	N/A	N/A	N/A

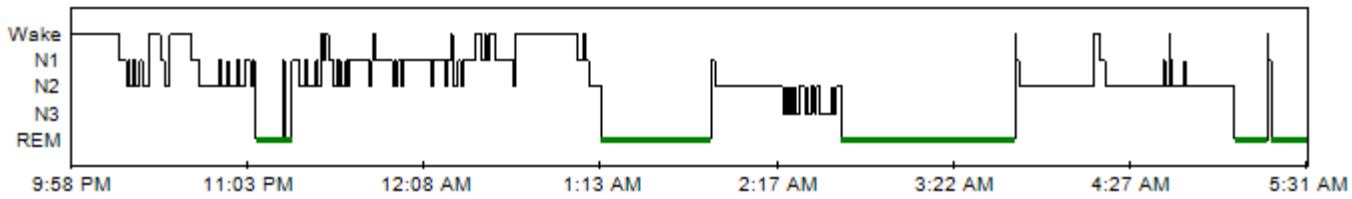
TREATMENT ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

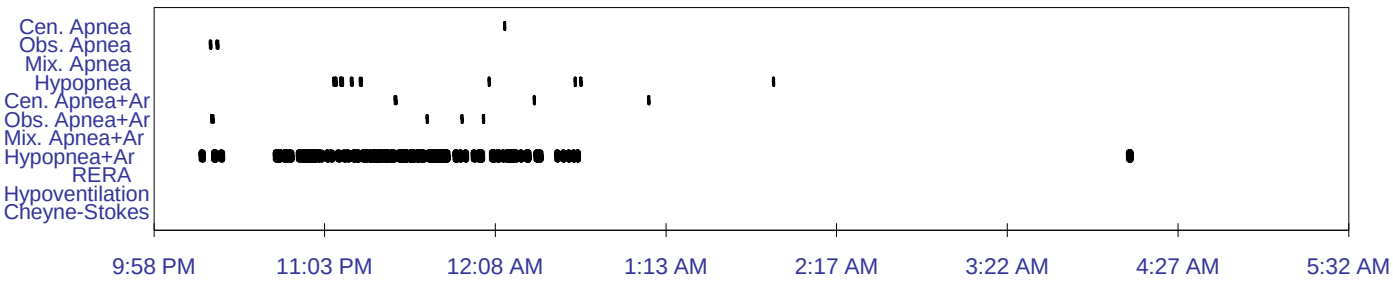
Therapy Device Titration Chart

Treatment		TIME			RESPIRATORY								OXIMETRY		
Level	TIB	REM	Non-REM	Obs.	Cen.	Mixed	All	A + H	**AHI**	**RERA**	**All**	**RDI**	Max.	Min.	Mea
(cm. H2O)		(hrs:min:sec)		Apnea	Apnea	Apnea	Hypn's	TOTAL			**Resp**		SpO2%	SpO2%	SpO2
CPAP 6	4:42:28	2:08:50	2:14:30	0	1	0	3	4	0.9	0	4	0.9	100.0	91.0	96.7

Hypnogram



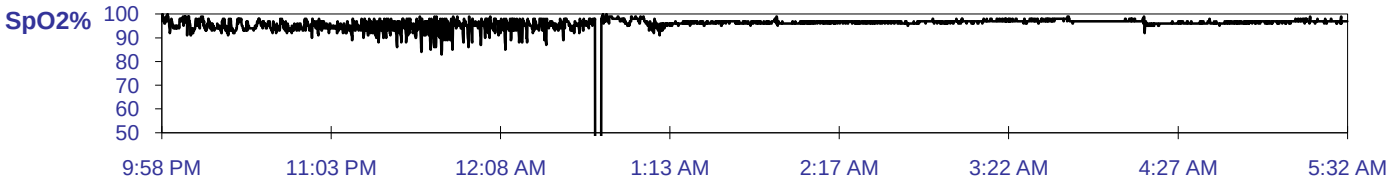
Respiratory Events

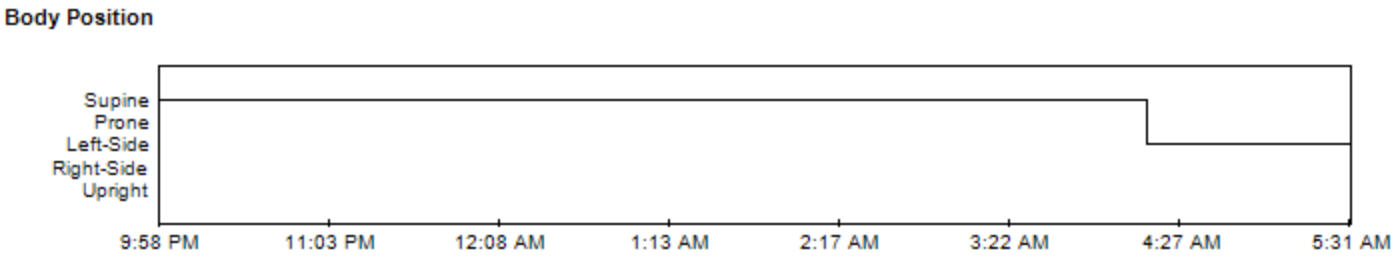


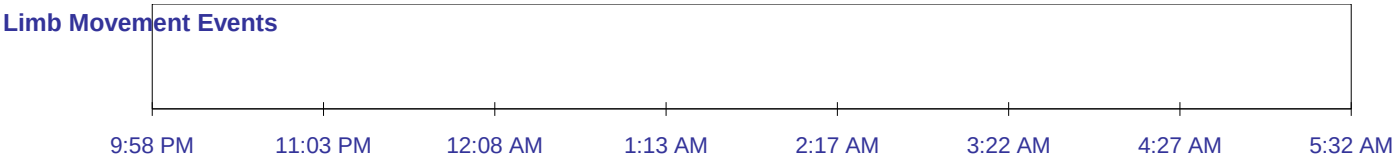
Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015

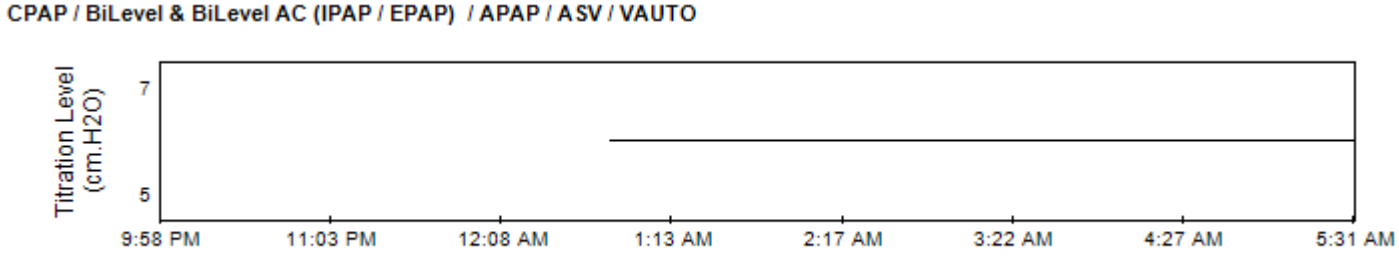
TREATMENT ANALYSIS

Patient Name: Subject Code: 20/9008 Study Date: 6/21/2015









Patient Profile

Patient Information

Patient Name: **Mr**
Patient ID:
Reference ID:
Date of Birth: **15 August 1978** Age: **37**
Gender: **Male**

Contact Details

Address:
Telephone Numbers:
E-Mail:

Insurance

Insurance Carrier: Membership Number: Member Since: **10/9/2015**

Doctor

Treating Doctor: Clinic:
Referring Doctor: Clinic:

Equipment Information

Flow Generator: Flow Generator Serial Number: Owner: **Yes**
Flow Generator Software Version:
Humidifier: Humidifier Serial Number: Owner: **Yes**
Data Module: Data Module Serial Number: Owner: **Yes**
Data Module Software Version:
Mask:
Data Card: **No**

Statistics

9/1/2015 - 11/5/2015 **Device: AirSense 10 AutoSet (S/N: 23151469539)**

Device Settings

Therapy Mode: **AutoSet**
EPR: **FULL_TIME**
EPR Level: **1.0 cmH2O**
Ramp Time: **45.0 Minutes**
Essentials: **ON**
Minimum Pressure: **5.0 cmH2O**
Maximum Pressure: **15.0 cmH2O**

Pressure - cmH2O

Median: **5.6**
95th Percentile: **6.8**
Maximum: **7.3**

Leak - L/min

Median: **0.0**
95th Percentile: **3.6**
Maximum: **32.4**

Respiratory Indices - events/hr

Apnea Index: **0.8**
Hypopnea Index: **0.9**
AHI: **1.7**
Obstructive: **0.0**
Central: **0.5**
Unknown: **0.0**
RERA Index: **0.0**
% Time in CSR: **0.0**

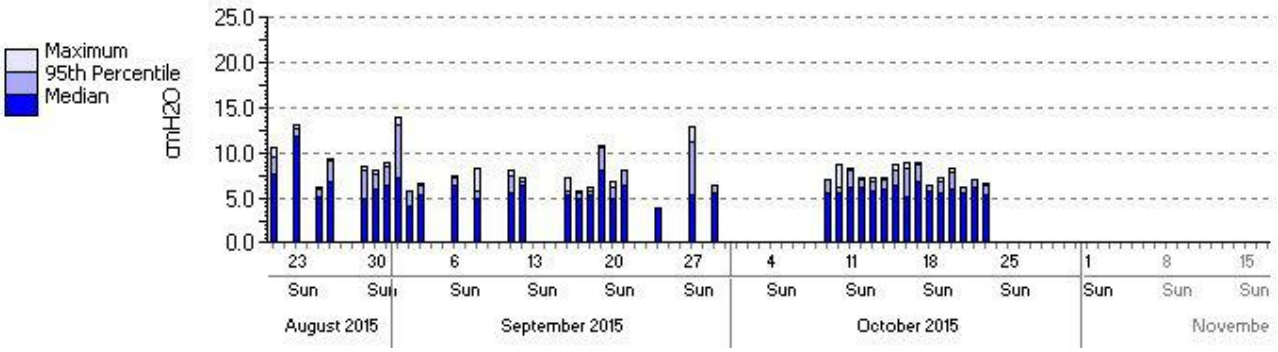
Total Usage

Used Days >= 4 hrs : **2**
Used Days < 4 hrs : **29**
% Used Days >= 4 hrs : **3**
Days not used: **35**
Total days: **66**
Total hours used: **54:38**
Median daily usage: **1:23**
Average daily usage: **0:49**

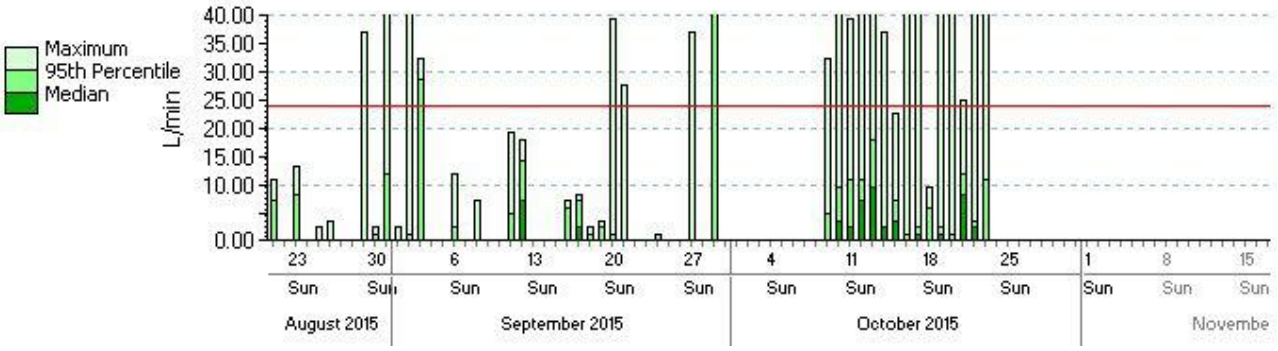
Summary Graphs

9/1/2015 - 11/5/2015 **Device: AirSense 10 AutoSet (S/N: 23151469539)**

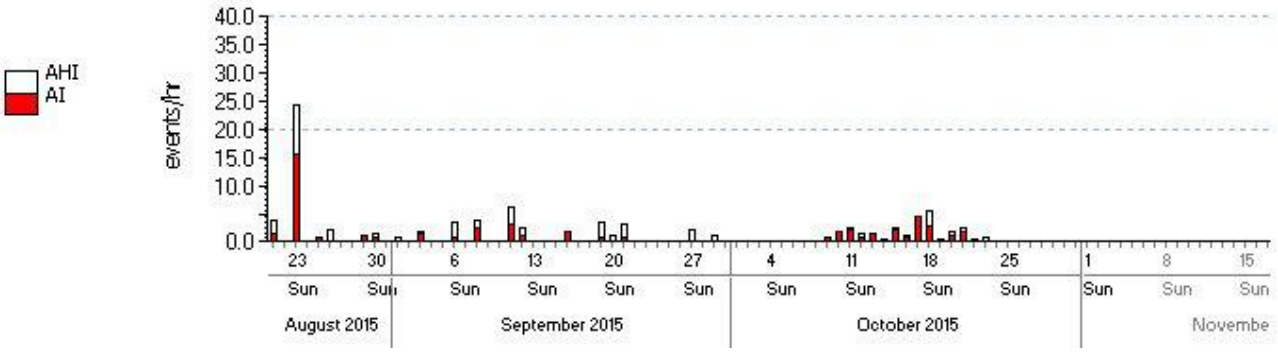
Pressure



Leak

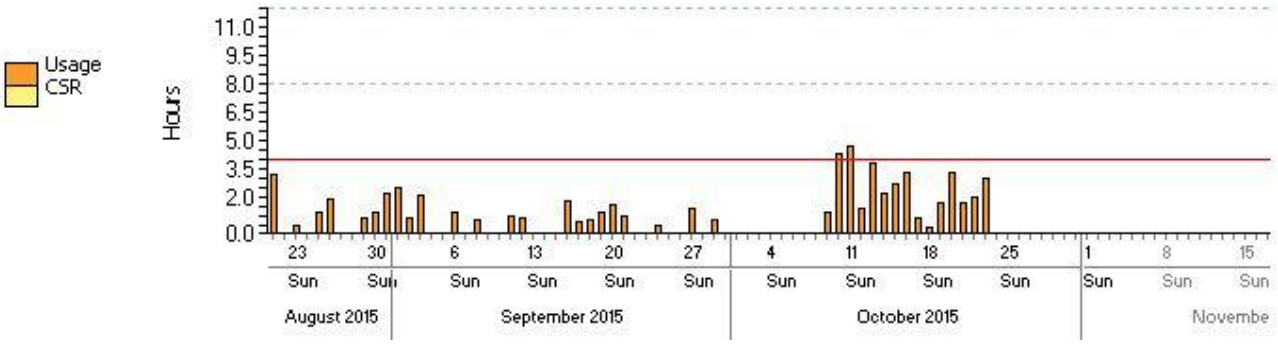


AHI & AI



Usage

Total Usage & Cheyne-Stokes



Case # 4

Patient Name:			
Sex:	Male	**Study Date:**	5/3/2017
D.O.B.:	8/15/1978	**Subject Code:**	20/9008
Age:	38	**Referring Physician:**	MYSLIWIEC, VINCENT
Height:	70.0 in	**Sleep Specialist:**	
Weight:	215.0 lbs	**Recording Tech:**	GARB, LEANNA
B.M.I.:	30.8	**Scoring Tech:**	GARB, LEANNA
Epworth Score		**Insomnia Severity Index**	

INDICATIONS FOR STUDY: Evaluate OSA with a MAD.

PSG PARAMETERS:
Technical and digital specifications and scoring rules comply with the American Academy of Sleep Medicines *AASM Manual for Scoring Sleep, 2012*. EEG derivation is the RECOMMENDED derivation. Hypopnea definition is the RECOMMENDED definition. Respiratory disturbance index (RDI) = AHI + RERA/hour. RERA is scored by nasal pressure and inductance plethysmography.

PHYSICIAN INTERPRETATION:
The PSG was technically adequate.

SLEEP CONTINUITY AND SLEEP ARCHITECTURE: Sleep onset was normal at 1.4 minutes. REM latency was decreased at **46.0** minutes. Sleep stage analysis revealed **12.5**% stage N1 (normal), **48.3**% stage N2 (normal), **1.8**% stage N3 (decreased), and **37.4**% REM (increased). Wake after sleep onset (WASO) was normal at **43.0** minutes. Overall sleep architecture was normal. Total sleep time was **367.5** minutes of a total of **411.9** minutes in bed time yielding a normal sleep efficiency of **89.2**%**.** The patient demonstrated a abnormal degree of sleep fragmentation with a total arousal index of **24.7**/hr.

RESPIRATORY MEASURES AND BODY POSITION: The Apnea-Hypopnea Index (AHI) was **15.8**/hr. The total number of hypopneas was **97** and the total number of apneas was **0** (**0** central and **0** obstructive). The Respiratory Event-Related Arousal (RERA) index was **0.0**/hr, yielding a Respiratory Disturbance Index (RDI) of **15.8**/hr. Supine RDI was **26.3**/hr, prone RDI was **N/A**/hr**,** left side RDI was **2.9**/hr and right side RDI was **N/A**/hr**.** Mild snoring was noted. The patient slept **55.2**% of the time in the supine position and supine REM was observed.

OXIMETRY AND CO2 KINETICS: The lowest oxygen saturation during the study was **88.0**%**.** The patient spent **0.5** minutes with an oxygen saturation below 89%. The oxygen desaturation index (ODI) was **0.0**/hr. Carbon dioxide (TcCO2 or ETCO2) was not monitored during this study.

PERIODIC LIMB MOVEMENTS: The patient had a Periodic Limb Movements of Sleep (PLMS) index of **0.0**/hr and a PLMS arousal index of **0.0**/hr.

ELECTROCARDIOGRAM (EKG)/HEART RATE: The EKG revealed no abnormalities.

ELECTROENCEPHALOGRAM (EEG): No epileptiform or seizure activity noted.

IMPRESSION:

1. Obstructive Sleep Apnea (OSA)
   Not controlled in the supine position, AHI 26/hr
   Controlled in the non supine position, AHI 3/hr
2. Increased REM (decreased latency, increased percent of total sleep time

RECOMMENDATIONS:

1. Discuss treatment options during an appointment in the Sleep Disorder Center with Dr. Brock or Mysliwiec.
2. Investigate etiology of increased REM.
3. Educate patient about not operating vehicles, using dangerous equipment, or firing a weapon when sleepy.
4. Educate patient about the potential increase in sleep disordered breathing with alcohol ingestion.

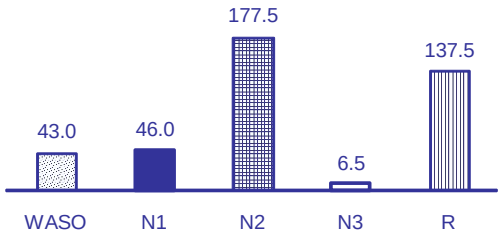
//SIGNED//

COL(ret.) William C. Frey, MD, D, ABSM, D, ABIM
Pulmonary, Critical Care, Sleep Staff

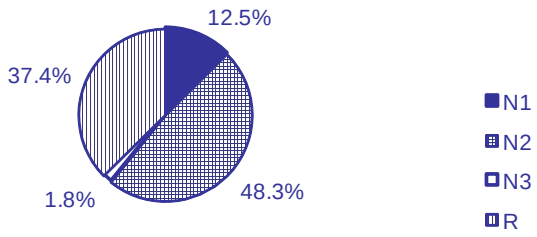
Patient Name: Subject Code: 20/9008 Study Date: 5/3/2017

Sleep Architecture	
Lights out clock time (hr:min):	10:31:37 PM
Lights on clock time (hr:min):	5:23:32 AM
Total Recording Time (TRT; in min.):	411.9
Sleep Period Time (SPT)*:	6:50:31
Total Sleep Time (TST; in min.):	367.5
Sleep Efficiency:	89.2%
Sleep latency (SL):	0:01:24
Total Stage Changes (after sleep onset):	151
Awakenings (after sleep onset):	33
WASO (min.):	43.0
REM Periods:	6
REM Latency*:	0:13:00
REM Latency (less Wake time)*:	0:12:30

* Time formats are in hrs:min:sec



Stage Distribution (in min.)



Sleep Stage (%TST)

Sleep Stage	Latency (min)
N1:	0.0
N2:	1.0
N3:	271.0
R:	13.0

Stage Latency = 0.0 denotes start of sleep.

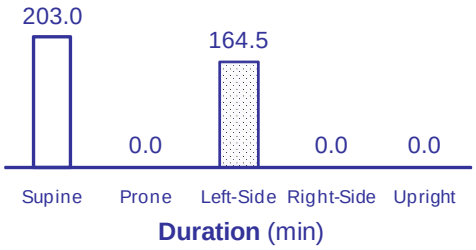
Patient Name: Subject Code: 20/9008 Study Date: 5/3/2017

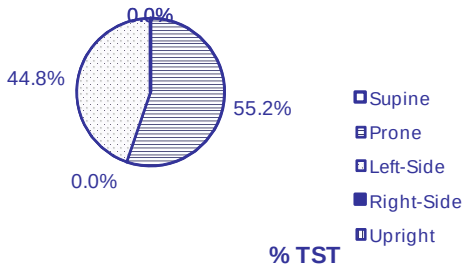
RESPIRATORY EVENTS	Cen. Apneas	Obs. Apneas	Mxd. Apneas	Hypopneas	Total Apneas	Apnea+ Hypopnea	RERA	All Resp. Events *
Count:	0	0	0	97	0	97	0	97
Index (events / hr.):	0.0	0.0	0.0	15.8	0.0	**15.8**	0.0	15.8
Mean Duration (sec.):	N/A	N/A	N/A	13.0	N/A	13.0	N/A	13.0
Longest Event (sec.):	N/A	N/A	N/A	38.4	N/A	38.4	N/A	38.4
REM Count:	0	0	0	41	0	41	0	41
Non-REM Count:	0	0	0	56	0	56	0	56
REM Index:	0.0	0.0	0.0	17.9	0.0	17.9	0.0	17.9
Non-REM Index:	0.0	0.0	0.0	14.6	0.0	14.6	0.0	14.6

* Note: Does not contain Cheyne Stokes Breathing, Hypoventilation, or Periodic Breathing.

RESPIRATORY EVENTS (by Body-Position)	Supine Sleep		Prone Sleep		Left-Side Sleep		Right-Side Sleep		Upright Sleep	
	Count	Index	Count	Index	Count	Index	Count	Index	Count	Index
Duration (hrs:min:sec):	3:23:00		0:00:00		2:44:30		0:00:00		0:00:00	
Obstructive Apneas:	0	0.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Central Apneas:	0	0.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Mixed Apneas:	0	0.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Hypopneas:	89	26.3	N/A	N/A	8	2.9	N/A	N/A	N/A	N/A
RERAs:	0	0.0	N/A	N/A	0	0.0	N/A	N/A	N/A	N/A
Total*:	89	26.3	N/A	N/A	8	2.9	N/A	N/A	N/A	N/A

* Note: Does not contain Cheyne Stokes Breathing, Hypoventilation, or Periodic Breathing.





BODY-POSITION RESULTS

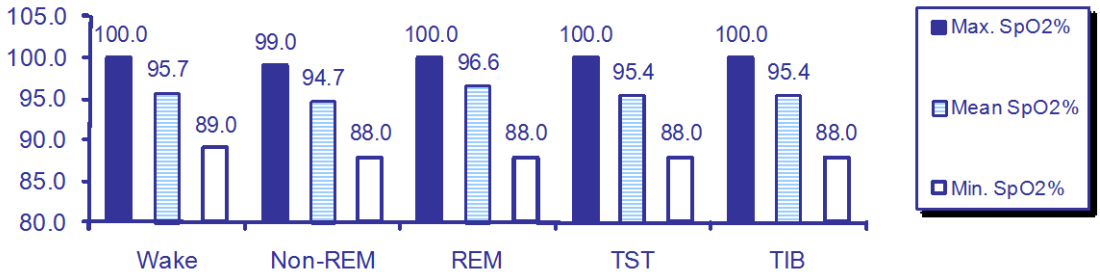
Patient Name: Subject Code: 20/9008 Study Date: 5/3/2017

AROUSALS	Resp. Count	Resp. Index	Spontaneous Count*	Spontaneous Index*	Total Count	Total Index
Total Sleep Time:	65	10.6	86	14.0	151	24.7
Non-REM	38	9.9	56	14.6	94	24.5
REM:	27	11.8	30	13.1	57	24.9

* EEG Arousal activity not associated with Respiratory or PLM events.

LIMB MOVEMENTS (by sleep stage)	LM w/ Arousals Count	LM w/ Arousals Index	LM w/o Arousals Count	LM w/o Arousals Index	Total LMs Count	Total LMs Index	PLM Series Count	PLM Series Index
Total Sleep Time:	0	0.0	0	0.0	0	0.0	0	0.0
N1:	0	0.0	0	0.0	0	0.0	0	0.0
N2:	0	0.0	0	0.0	0	0.0	0	0.0
N3:	0	0.0	0	0.0	0	0.0	0	0.0
R:	0	0.0	0	0.0	0	0.0	0	0.0

OXYGEN DESATURATION EVENTS	Count	Index
Total Sleep Time:	0	0.0
Wake (after sleep onset):	0	0.0
Non-REM:	0	0.0
REM:	0	0.0



Oximetry Trend Graph

Patient Name: Subject Code: 20/9008 Study Date: 5/3/2017

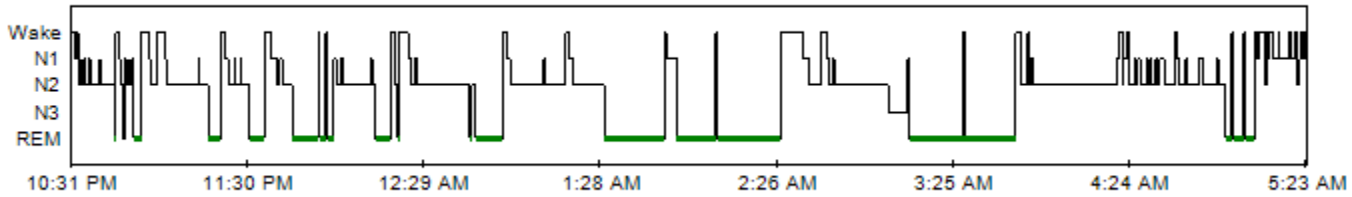
OXYGEN SATURATION	Wake	Non-REM	REM	TST	TIB
Max. SpO2%:	100.0	99.0	100.0	100.0	100.0
Mean SpO2%:	95.7	94.7	96.6	95.4	95.4
Min. SpO2%:	89.0	88.0	88.0	88.0	88.0
SpO2% <= 89% (min.)	0.2	0.3	0.2	0.5	0.6
	% Time in range				
90 – 100%:	90.3%	98.9%	99.7%	99.2%	98.3%
80 – 89%:	1.4%	1.1%	0.3%	0.8%	0.9%
70 – 79%:	0.0%	0.0%	0.0%	0.0%	0.0%
60 – 69%:	0.0%	0.0%	0.0%	0.0%	0.0%
50 – 59%:	0.0%	0.0%	0.0%	0.0%	0.0%
< 50%:	0.0%	0.0%	0.0%	0.0%	0.0%
% Artifact / Bad Data:	8.3%	0.0%	0.0%	0.0%	0.9%

HEART RATE RESULTS	Wake	Non-REM	REM	TST	TIB
Max. HR (bpm):	95.0	87.0	81.0	87.0	95.0
Mean HR (bpm):	67.8	62.7	58.1	61.0	61.7
Min. HR (bpm):	48.0	50.0	45.0	45.0	45.0
		% Time in range			
> 100 (bpm):	0.0%	0.0%	0.0%	0.0%	0.0%
90 – 100 (bpm):	0.7%	0.0%	0.0%	0.0%	0.1%
80 – 89 (bpm):	8.0%	0.0%	0.0%	0.0%	0.9%
70 – 79 (bpm):	16.9%	0.3%	2.0%	0.9%	2.7%
60 – 69 (bpm):	56.6%	82.0%	34.3%	64.2%	63.4%
50 – 59 (bpm):	9.3%	17.7%	52.5%	30.7%	28.4%
< 50 (bpm):	0.2%	0.0%	11.0%	4.1%	3.7%
% Artifact / Bad Data:	8.3%	0.0%	0.0%	0.0%	0.9%

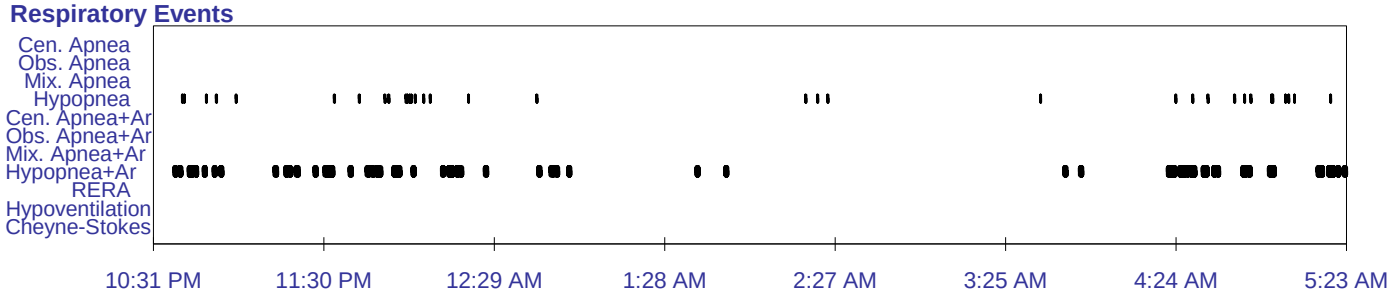
CARDIAC EVENTS	Brady.	Asystole	Tachy.	Narrow Complex Tachy.	Wide Complex Tachy.	Atrial Fibrillation	Accel.	Decel.
Count :	0	0	0	0	0	0	0	0
Shortest Event (min:sec):	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Longest Event (min:sec):	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Sum Duration (min:sec):	0:00:00	0:00:00	0:00:00	0:00:00	0:00:00	0:00:00	0:00:00	0:00:00
Absolute Max. Rate (bpm):	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Absolute Min. Rate (bpm):	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Patient Name: Subject Code: 20/9008 Study Date: 5/3/2017

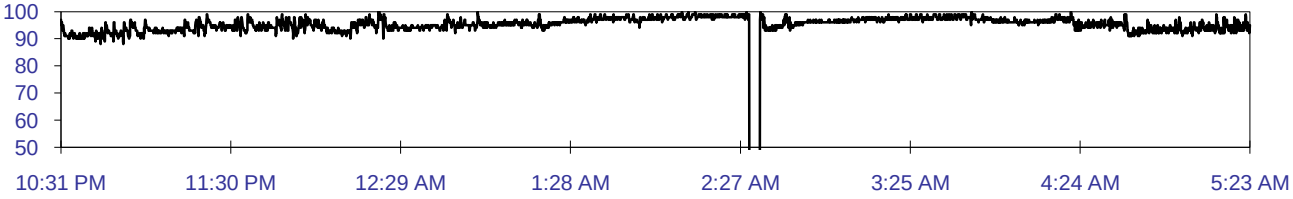
Hypnogram



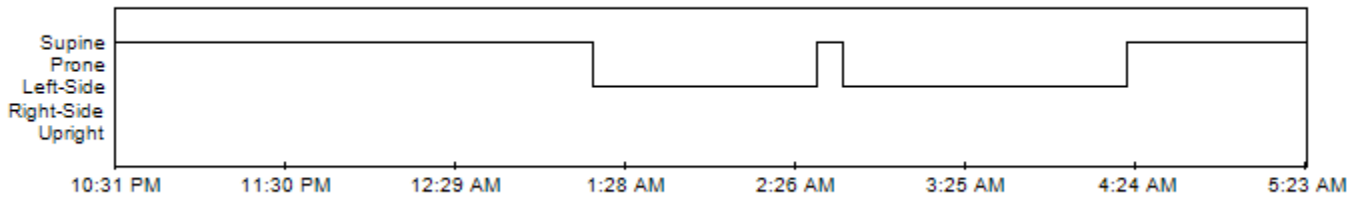
Respiratory Events



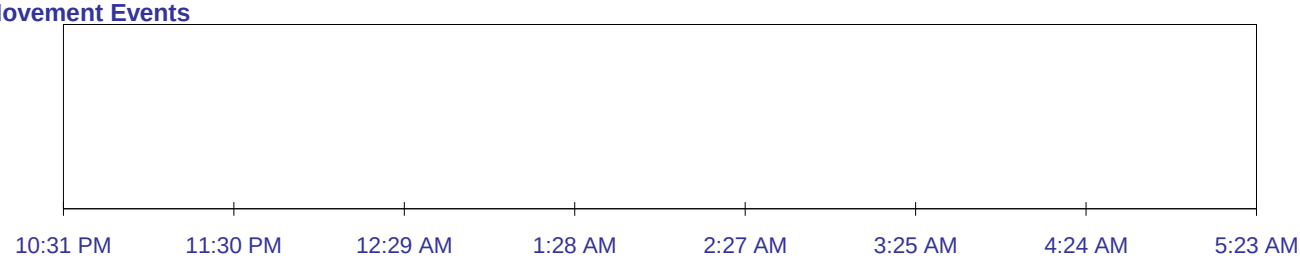
SpO2%



Body Position



Limb Movement Events



Spencer Study Club

Sleep Study Review Sheet

Metric	Baseline Study	OA Study
Type of study (PSG, HST, split, etc)		
Date of study		
Patient BMI		
Total sleep time (TST)		
Sleep efficiency		
% N1		
% N2		
% N3		
% REM		
% Supine sleep		
% Non-supine sleep		
% Supine REM sleep		
Overall AHI		
Number of apneas		
Number of hypopneas		
RDI		
Number of RERA’s		
Average oxygen saturation		
Oxygen saturation nadir		
Supine AHI		
Non-Supine AHI		
Other notes		

OAT PE Instructions

Read all case summaries for familiarization

Read and discuss the complete case with your group and come to an agreement on a clinical COA.

Prepare to present and defend your COA to the class

Pick one of the 3 other scenarios and complete the questionnaire and exam form to match it.
(Add up to 3 abnormal wild card findings)

BPT execute the exams on the other students later in the course.

OAT PE Desired End State

Students are familiar with forms and all 4 case scenarios

All students are prepared to defend the chosen COA
Including, but not limited to
- – if OAT is indicated
- – What type of appliance is best indicated
- – Significant findings/justifications

Questionnaire and exam form filled out to fit one of the other scenarios.

We will discuss afterwards and you will execute the exams on each other today or tomorrow AM.

Case 1

A patient presents with a diagnosis of OSA and an Rx for oral appliance therapy. The patient tried CPAP, but was intolerant due to claustrophobic associations with the mask. The AHI was 10, with a supine AHI of 12 and a REM AHI of 12 with REM sleep being 20% of the total sleep time. The patient sought care due to reports of severe snoring when sleeping in the barracks disturbing others. His Epworth Sleepiness Scale score was 4.

Upon examination, the patient's maximum mandibular range of motion was 45mm without deviation or deflection. No joint noises were noted. Lateral excursion was 12mm to the right and 12mm to the left. Periodontal condition is WNL with no pocketing or tooth mobility beyond physiologic. The patient is missing teeth 1, 5, 12, 16, 17, 21, 28 and 32. Other dental and intraoral examination findings are WNL. There is evidence of lateral bruxism with significant wear of the canines and buccal cusps of the 2nd premolars. Muscle palpation was WNL.

Questions:

Would this patient be a candidate for oral appliance therapy? If yes, what appliance would you choose and why. If no, why not?

What other recommendations might you give to this patient?

Case 2

A patient presents with a diagnosis of OSA and an Rx for oral appliance therapy. The patient has not tried CPAP, but told the sleep doctor that she would prefer to try an oral appliance first. Her AHI was 7, with a supine AHI of 7 and a REM AHI of 10 with REM sleep being 15% of the total sleep time. Her BMI is 20. The patient sought care due to reports of loud snoring which disturbs the sleep of others. Her Epworth Sleepiness Scale score was 2. However, when asked about feeling "tired or fatigued" she reported feeling fatigued on a daily basis.

Upon examination, the patient's maximum mandibular range of motion was 48mm without deviation or deflection. No joint noises were noted. Lateral excursion was 10mm to the right and 10mm to the left. Periodontal condition is WNL with no pocketing or tooth mobility beyond physiologic. The patient is missing teeth 1, 2, 4, 16, 17, and 32. A 3 unit bridge from 3-5 has been treatment planned. A crown on tooth #30 needs to be replaced, and there is a radiolucency at the apex of tooth #29 and the tooth tested non vital. Referral for Endodontic consult has been made but the patient has not seen the endodontist yet. Other dental and intraoral examination findings are WNL. There is no evidence of lateral bruxism or clenching. Muscle palpation was WNL.

Questions:

Would this patient be a candidate for oral appliance therapy? If yes, what appliance would you choose and why. If no, why not?

What other recommendations might you give to this patient?

Case 3

A patient presents with a diagnosis of OSA and an Rx for oral appliance therapy. The patient has not tried CPAP, but the physician believes that an oral appliance is better suited for readiness issues. The AHI is 20, with a supine AHI of 35 and a REM AHI of 40 with REM sleep being 10% of the total sleep time. The patient sought care initially due to excessive daytime sleepiness. The patient's Epworth Sleepiness Scale score was 18.

Upon examination, the patient's maximum mandibular range of motion is 52mm without deflection or deviation. Lateral excursion is 12mm both to the left and to the right. Midlines are coincident. There are no joint noises. There is localized moderate to severe periodontal bone loss involving 7-10 with class 2+ mobility. The patient is missing teeth 1, 16, 17 and 32 (extracted as a teenager). Other dental and intraoral examination findings are WNL. There is no tenderness to palpation of the muscles of mastication.

Questions:

Would this patient be a candidate for oral appliance therapy? If yes, what appliance would you choose and why. If no, why not?

2. What other recommendations might you give to this patient?

Case 4

A patient presents with a diagnosis of OSA and an Rx for oral appliance therapy. The patient tried CPAP, but was intolerant due to mask leak and aerophagia. The AHI was 15, with a supine AHI of 25 and a REM AHI of 10 with REM sleep being 2% of the total sleep time. The patient sought care due to bed partner report of witnessed apneas. The Epworth Sleepiness Scale score was 6.

Upon examination, the patient's maximum mandibular range of motion was 48mm with deviation to the right. A distinct click/pop was noted on the right side. Lateral excursion was 10mm to the right and 8mm to the left, with a click on the right in left lateral excursion. Periodontal condition is WNL with no pocketing or tooth mobility beyond physiologic. The patient is missing teeth 1, 5, 12, 16, 17, 21, 28 and 32. Other dental and intraoral examination findings are WNL. There is no evidence of lateral bruxism, but there are minor wear facets. There is slight tenderness to palpation of the right masseter. Other palpation is WNL.

Questions:

Would this patient be a candidate for oral appliance therapy? If yes, what appliance would you choose and why. If no, why not?

2. What other recommendations might you give to this patient?

DENTAL SLEEP MEDICINE EXAM
Patient Questionnaire

PATIENT INFORMATION (To be completed by patient or guardian if a minor) **Date:** _____

Patient Name: _____ **Rank:** _____

Date of Birth: _____ **Age:** _____ **Gender:** M / F

Home #: _____ **Work#:** _____ **Email:** _____

Service: USAF / USA / USN / USMC / Retired / Family Member / Other: _____

Who referred you for this evaluation? _____

Epworth Sleep Scale: 0= never 1=slight chance 2= moderate chance 3= strong chance of dozing

Situation	Chance of Dozing			
Sitting and reading	0	1	2	3
Watching TV	0	1	2	3
Sitting, inactive in a public place (eg. Theater or meeting)	0	1	2	3
As passenger in car for an hour without a break	0	1	2	3
Lying down to rest in afternoon when circumstances permit	0	1	2	3
Sitting and talking to someone	0	1	2	3
Sitting quietly after lunch without alcohol	0	1	2	3
In a car, while stopped for a few minutes in traffic	0	1	2	3

Total = _____

Sleep History

In the last four weeks: Time spent sleeping on typical night: _____ Time it took to fall asleep: _____

Did you have trouble: Falling asleep Staying asleep **Why?** _____

I woke up _____ times per night. Reason: _____ Time it took to fall back asleep? _____

Your typical night's sleep was: Good Fair Poor Sound Light Restless Very restless

Do you have a regular/consistent sleep schedule? Y N **Swinging Shifts?** Y N **Do you snore?** Y N **Loudly?** Y N

Date of last sleep study?_____ **Results of sleep study?** Mild OSA Mod OSA Severe OSA Other: _____

Do you use CPAP? Y N **If not, why?** _____

_____

What is your preferred sleep position(s) Side Back Stomach

Do you take sleep aid medications? Y N **If yes, what /how often?**_____

After a typical night's sleep, I felt refreshed and rested. Always Most nights Sometimes Rarely Never

Nasal Airway / Breathing Assessment

Do you have chronic allergies or other issues (i.e. obstructions) that make breathing through the nose difficult? Y N

_____

In the past three months, how often have the following conditions been a concern or problem?

Rarely = once or twice; Frequently = 2-3 times per month; Very frequently = 2-3 times per week; Always = Most days

Nasal congestion, stuffiness, obstruction:	None	Rarely	Frequently	Very frequently	Always
Difficulty breathing through nose while sleeping:	None	Rarely	Frequently	Very frequently	Always
Difficulty breathing through nose during exercise:	None	Rarely	Frequently	Very frequently	Always
Difficulty breathing through nose in general:	None	Rarely	Frequently	Very frequently	Always

Have you ever worn a dental device while sleeping? Y N **If yes, what type/what for/when do you wear it?** _____

_____

Do you have any unusual jaw movements? Y N Describe: _____

Do you have ongoing or intermittent pain to the face, head, jaw, and/or teeth? Y N If yes, describe: _____

_____

Have you been told you had TMJ, TMD, TMJD? Y N If yes, has this been examined by a dentist/TMD specialist? Y N

- Are you currently being treated for TMD ? Y N If yes, describe: _____
- Do you currently have symptoms? Y N If yes, describe: _____

  _____
- How often do they occur (daily, 1-2 times a week, etc.)? _____
- How long do your symptoms last? _____

Do you wake-up with jaw pain, stiffness, or fatigue? Y N How often? _____

Do you clench or grind your teeth during sleep? Y N Don't know How do you know? self-aware dentist others

Do you notice any jaw (joint) sounds? Y N If yes, is it: Popping/clicking Grating/grinding Other _____

- Does the jaw (joint) noise cause pain? Y N Sometimes How often? _____
- Has your jaw ever locked open (unable to close) or locked closed (unable to open)? Y N
- Does your jaw lock on a recurring basis? Y N If yes, how often? _____

Do you have any additional information to add? _____

_____

ORAL APPLIANCE THERAPY EVALUATION
Clinical Findings

Patient Last name, DOB:_____ Dentist: _____ Date:_____

TMJ

Pain to Palpation? Y N Location: R L Both Severity: Mild Moderate Severe

Crepitus: None R L Severity: Mild Moderate Severe

Click or Pop: Right: None Opening Reciprocal Intermittent Painful

Left: None Opening Reciprocal Intermittent Painful

Is there pain on loading (tongue blade test)? No Yes Location: R L

MUSCLE PALPATION

Codes: 0 = Non Painful, 1 = Tenderness, 2 = Painful, 3 = Pain with withdrawal

	Right	Left		Right	Left
Masseter	_____	_____	Temporalis	_____	_____
Temporalis Tendon	_____	_____	Med Pterygoid	_____	_____
Lateral Pterygoid	_____	_____	Digastric	_____	_____

(Pain on Resisted Protrusion, Not Palpation)

AIRWAY EVALUATION

Nasal Airway - Septum: WNL Deviated Inf Turbinate: WNL Enlarged/Obstructive

Alar Rim Test: WNL Collapse - R L Both Cottle Test: Negative Positive

Oropharyngeal Airway - Tonsillar Size: Absent Barely visible WNL Enlarged Kissing

Mallampati Score: _____

Uvula Size: Normal Enlarged Missing

Gag Reflex: Present Muted Absent

Lingual Frenum: Normal Short Extremely Short

MANDIBULAR MOVEMENT

Deflection / Deviation None Opening : R L Closing: R L

Protrusive Movement _____ mm Maximum Opening _____mm

Right Lateral Movement _____ mm George Gauge Range: _____ to _____

Left Lateral Movement _____ mm

Pain w/Mandibular Movement Y N Location:_____

INTRAORAL EXAMINATION

Oral Hygiene: Poor Fair Good Salivary Flow: Adequate Abnormal: _____

Mucosal Ridging? Y N Tongue Scalloping? Y N Trauma: _____

Soft tissue screening: WNL Findings: _____

Tori: Palatal R Man L Man Exostoses? Y N Removal indicated prior to tx? Y N

Palatal Vault: Normal High Flat Hard tissue screening: WNL Findings: _____

Perio Attach Loss: None Mild Moderate Severe / Generalized Localized: _____

Tooth mobility: Physiologic Generalized Localized: _____

Tooth Wear: Attrition Erosion Abrasion Abfraction None Mild Moderate Severe Posterior Anterior

Clinical Crown Height: Posterior: WNL Short Long Anterior: WNL Short Long

Angle Molar Class : R: I II III L: I II III Canine Class: R: I II III L: I II III

Overbite: ___mm / Overjet: ___ mm Crossbites or Openbite? _____

Other Dental Concerns Prior to treatment: _____

_____

Occlusal and Proximal Contacts (documented no later than delivery appointment):

X = Missing tooth O = Holds Shimstock // between #s = Diastema/No Resistance to Floss

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
32	31	30	29	28	27	26	25	24	23	22	21	20	19	18	17

INITIAL TREATMENT NOTES

Indicated for Oral Appliance Therapy? Y N Contraindication (s) If No _____

Initial Target Protrusive Bite Registration (Select one) : **1)** Comfort - End to End + _____

2) ____ **%** of Protrusive ROM ____ mm or George Gauge # ___ **3)** Confirmed during PSG or HST

Dental Midlines at Target Protrusion Coincident? Y N If not, Draw Midlines _____

Appliance Selected Herbst / MicrO2 / TAP (Dream) / TAP (Elite) AM Aligner Fabricated ? Y N

Prefabricated MAD Delivered? Y N Apnea Guard / MyTAP / Other _____

Full Arch Impression Medium (circle one) PVS / Alginate / Digital Scan / Other _____

Records emailed or shipped within 24 hours Y N Reason if not sent_____

Delivery of Appliance Scheduled ___ /_____ /____ Reason if not scheduled _____
DD MMM YY

INFORMED CONSENT FOR THE TREATMENT OF SNORING AND/OR OBSTRUCTIVE SLEEP APNEA WITH ORAL APPLIANCES

1. Snoring and Obstructive Sleep Apnea are breathing disorders that occur during sleep due to narrowing or total closure of the airway. Snoring occurs during the partial closure of the airway and may be problematic to those in shared sleeping quarters. However, snoring may indicate a more serious disorder, Obstructive Sleep Apnea (OSA). OSA is a serious condition where the airway totally closes many times during the night and can significantly reduce oxygen levels in the body and disrupt sleep. In varying degrees, this can result in excessive daytime sleepiness, reduced reaction time and brain function, high blood pressure and increased risk of heart attack, stroke, and death. OSA is also associated with increased risk of depression and chronic pain.
2. Because any sleep disordered breathing may potentially represent a health risk, all individuals are advised to consult with their physician and/or sleep specialist for a diagnosis. The patient must have a referral from their sleep medicine physician for dental evaluation for an oral appliance that can help manage OSA.
3. Oral appliances may be helpful in the treatment of snoring and sleep apnea. Those diagnosed with mild or moderate OSA are better candidates for improvement with this therapy than those severely affected. Oral appliances are designed advance the mandible, keeping the tongue forward, thereby opening the airway space in the throat. While clinical research shows that oral appliances have substantially reduced snoring and OSA for many people, there are no guarantees this therapy will be successful for every individual.
4. Some patients initially may have difficulty tolerating the appliance in their mouth, but usually adapt in a short time period. Likewise, some patients may develop temporary adverse side effects such as excessive salivation, difficulty swallowing, sore jaws, teeth and gums, and a slight change in their bite. However, these usually diminish within an hour after appliance removal. On rare occasion, a permanent bite change or dislodgement of ill-fitting restorations may occur and require dental evaluation.
5. It is advised that the oral appliance should be checked twice during the first year and then once a year to ensure proper fit and that the mouth and jaw joint be examined at that time to assure a healthy condition. If any unusual symptoms occur, it is recommended that the appliance not be worn until an office visit is scheduled to evaluate the situation. If this occurs, the patient should immediately contact their dental clinic.
6. Individuals who have been diagnosed as having OSA may notice that after sleeping with an oral appliance they feel more refreshed and alert during the day. This is only subjective evidence of improvement and may be misleading. The only way to accurately measure whether the appliance is keeping the oxygen level sufficient is to have a consultation with the sleep specialist and a follow-up sleep test while wearing the appliance.
7. The dentist should complete an exam to include "baseline" records e.g. models of the teeth, x-rays, etc. Your dentist may also require the patient to follow up with their referring physician or other specialists e.g. Sleep Specialist, ENT, Oral and Maxillofacial Surgeon, Orthodontist etc.

By signing below I, the patient, indicate that I have read and understood this information concerning oral appliance therapy for the treatment of snoring and/or OSA. I have had the opportunity to discuss the treatment concerning the oral appliances. I authorize treatment and confirm that I have received a copy of this consent form.

_____ _____

Patient Signature Date

_____ _____

Doctor Signature Date

Dr. Spencer's Prescription for Better Sleep…

Sleepy time: Try to have a regular bedtime…and give yourself enough time for sleep.

Light: Limit exposure to bright light, including computer/iPad screens, the last hour or so before bed.

Tip: www.justgetflux.com This program dims your screen and removes blue light at night (based on when you tell it to come on).

Environment: Keep your sleep environment…

- DARK…dim or cover lights from alarm clocks and chargers.
- Quiet…either silent, or you might consider PINK NOISE as it has been shown to help increase deep sleep.

  Tip: www.simplynoise.com is a pink noise generator that my wife and I use every night.
- Stop snoring! A snoring bed partner will disturb your sleep…and may lead to their untimely death…so don't ignore it!! If YOU are the snorer, do something about it!!!

  Tip: Not sure if you snore (the cats don't tell you), there's an app for that! www.snorelab.com.
- Comfortable…have the temperature of the room comfortable or use blankets to get comfortable. When you have a bed partner you will need to make the temperature comfortable for both of you.

Exercise: Daily exercise will help you sleep more deeply…and is good for you on a bunch of other levels too. Exercise right before bed isn't ideal for most people, but it is better to exercise at night rather than not exercising at all.

Priority: Make sleep a priority. Sleep is one of the 3 pillars of health, along with nutrition and exercise. Improving your quality of sleep can have a tremendously positive effect on your overall health and wellbeing.