Virginia Department of Health Professions

FEBRUARY 18, 2022
BOARD ROOM 2

VIRGINIA BOARD OF DENTISTRY
REGULATORY-LEGISLATIVE COMMITTEE MEETING AGENDA
FRIDAY, FEBRUARY 18, 2022
PERIMETER CENTER, 9960 MAYLAND DRIVE, SECOND FLOOR CONFERENCE CENTER, HENRICO, VA 23233

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Dentistry**

Meeting: Public hearing	
Meeting Details	
Date / Time	2/18/2022 1:00 pm
Type	Physical Location Only
Location	Department of Health Professions Perimeter Building, 9960 Mayland Drive, 2nd Floor, Board Room 4, Henrico, VA 23233
Board Website	http://www.dhp.virginia.gov
Agenda document	agency has not posted
Disability Friendly? Yes	**Deaf interpreter available upon request?** Yes
Purpose of the meeting To received public comment on proposed regulations on training in infection control	
Meeting Scope	[X] Public hearing to discuss a proposed change to regulation [ ] Discuss particular regulations / chapters [ ] General business of the board
This meeting is a public hearing to discuss the following proposed change(s) Training in infection control	

Contact Information	
Name / Title:	Sandra Reen / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, 23233
Email Address:	sandra.reen@dhp.virginia.gov
Telephone:	(804)367-4538 FAX: (804)527-4428 TDD: ()-

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Dentistry**

Meeting: Public hearing	
Meeting Details	
Date / Time	2/18/2022 1:15 pm
Type	Physical Location Only
Location	Department of Health Professions Perimeter Building, 9960 Mayland Drive, 2nd Floor, Board Room 4, Henrico, VA 23233
Board Website	http://www.dhp.virginia.gov
Agenda document	agency has not posted
Disability Friendly? Yes	**Deaf Interpreter available upon request?** Yes
Purpose of the meeting To receive public comment on proposed regulations for digital scan technicians	
Meeting Scope	[X] Public hearing to discuss a proposed change to regulation [ ] Discuss particular regulations / chapters [ ] General business of the board
This meeting is a public hearing to discuss the following proposed change(s) Training and supervision of digital scan technicians	

Contact Information	
Name / Title:	Sandra Reen / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, 23233
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Telephone:	(804)367-4538 FAX: (804)527-4428 TDD: ()-

VIRGINIA BOARD OF DENTISTRY
REGULATORY-LEGISLATIVE COMMITTEE MEETING MINUTES
October 22, 2021

TIME AND PLACE:	The meeting of the Regulatory-Legislative Committee was called to order at 1:00 p.m., on October 22, 2021.
PRESIDING:	Patricia B. Bonwell, R.D.H., PhD, Chair
COMMITTEE MEMBERS PRESENT:	Jamiah Dawson, D.D.S. J. Michael Martinez de Andino, J.D.
COMMITTEE MEMBERS ABSENT:	Alf Hendricksen, D.D.S.
OTHER PARTICIPATING BOARD MEMBERS:	Nathanial C. Bryant, D.D.S.
STAFF PRESENT:	Sandra K. Reen, Executive Director, Board of Dentistry Donna M. Lee, Discipline Case Manager, Board of Dentistry Barbara Allison-Bryan, M.D., Chief Deputy Director, Department of Health Professions Elaine Yeatts, Senior Policy Analyst, Department of Health Professions Rebecca Schultz, Policy Specialist, Department of Health Professions
COUNSEL PRESENT:	James E. Rutkowski, Assistant Attorney General
ESTABLISHMENT OF A QUORUM:	With four Board members present, a quorum was established. Ms. Reen read the emergency evacuation procedures.
PUBLIC COMMENT:	Dr. Bonwell explained the parameters for public comment and opened the public comment period. Dr. Bonwell also stated that written comments were distributed to the Board members and copies were placed on the table for the public. **Alexander T. Vaughan, D.D.S., Dental Director, Virginia Total Sleep** – Dr. Vaughan stated he reviewed the summary of findings contained in the Board's agenda and noted that in 2017 the ADA adopted a statement that laid out the role that dentists can play in the screening and treatment of sleep related breathing disorders which was amended last week and has not yet been published. He said the American Academy of Dental Sleep Medicine and the ADA are in full agreement that ordering and administration of home sleep apnea testing is within the scope of the practice of dentistry, and that the diagnosis of sleep apnea is performed by physicians. Dr. Vaughan brought two FDA approved home sleep apnea tests to show the Committee and demonstrated the finger test. He suggested that an advisory panel be convened to advise the Board on developing a regulation regarding sleep apnea testing.

APPROVAL OF MINUTES: Dr. Bonwell asked if there were any edits or corrections to the May 17, 2021 minutes. Mr. Martinez moved to approve the minutes as presented. The motion was seconded and passed.

REGULATORY ACTIONS CHART: Ms. Yeatts reported that she and Ms. Reen communicated with the Governor's Office this week about the long period of time the regulations for amendment of the restriction on advertising dental specialties and the action on making a technical correction have been pending. She also stated the regulations on training in infection control were advanced to the Office of the Secretary of Health and Human Resources for review.

COMMITTEE DISCUSSION/ACTION:

Report on Sleep Studies/Diagnosis/Testing – Ms. Yeatts and the Committee commended Ms. Schultz on the charts and information she provided for consideration regarding sleep studies.

Ms. Schultz reviewed and answered questions regarding the information she gathered from the various states pertaining to whether or not it is within the scope of practice for dentists to order home sleep apnea tests.

Ms. Yeatts stated she recently attended a meeting of the Advisory Board on Polysomnographic Technology, and it was determined that dentists can be a part of the treatment for patients with sleep apnea, and that dentists cannot diagnose sleep apnea because there are multiple physical aspects that must be considered.

Dr. Allison-Bryan explained home tests are very simple tests and very few physicians would accept the results to determine sleep apnea. She stated a physician would do different tests and reminded the Committee that a home test is not the same as a polysomnography. She supported having dentists and physicians work together to treat patients.

After discussion, the Committee agreed by consensus to recommend that the Board convene an advisory panel to develop proposed language on the role of dentists in addressing sleep apnea.

Discussion of Dental Assistants Using Scalers - Ms. Sacksteder discussed the chart addressing the policies gathered from Virginia's surrounding states which address the use of a scaler to remove cement and the level of dental assistant that could perform that task.

Ms. Reen stated that the majority of public comments received on this topic were from dental hygienists who are opposed to dental assistants using scalers. The Committee discussed that dental assistants could remove cement by using floss, wipes, and non-cutting instruments.

Dr. Bryant moved to recommend that in Guidance Document 60-7 under the subheading "Restorative Services" where it reads "remove excess cement from coronal surface of teeth" add the words "by using a non-cutting instrument". The motion was seconded and passed.

Proposed Update Guidance Document 60-7 – Delegation to Dental Assistants - Ms. Reen said this is an opportunity to identify any other proposed changes or updates in this document, noting that it was last updated in 2018. Dr. Bryant proposed the following additional changes:

- Under the subheading "Restorative Services" delete the words "rubber dams: place and remove";
- Under the subheading "Hygiene" the sentence that reads "polish coronal portion of teeth with rotary hand piece and rubber prophy cup or brush" delete the word "rotary" and replace it with "slow speed";
- Under the heading "Duties that may be delegated to dental assistants I and II under indirect supervision of a dental hygienist" the sentence that reads "polish coronal portion of teeth with rotary hand piece and rubber prophy cup or brush" delete the word "rotary" and replace it with "slow speed"; and
- Under the heading "Duties that may only be delegated to dental assistants II under direct supervision of a dentist" the sentence that reads "apply base and cavity liners/perform pulp capping procedures" add the word "indirect" after the word "perform".

Mr. Martinez moved to recommend that Guidance Document 60-7 be adopted as amended. The motion was seconded and passed.

Proposed Guidance Document on Sedation Inspections and Permits – Ms. Sacksteder introduced this draft guidance document, stating it was discussed and developed by an advisory committee which included dentists and inspectors who undergo or conduct sedation inspections. She then asked for discussion.

Ms. Yeatts proposed the following edits:

- Under the heading "Periodic Office Inspection for Administration of Sedation and Anesthesia", in the second bullet, add the word "a" after the words "if there was".
- Under the heading "Periodic Office Inspection for Administration of Sedation and Anesthesia, in the third bullet, first sentence, after the word "their" add the word "preliminary". In the second sentence; delete the word "shall" and insert the words "should attempt to". Revise the fourth sentence to read "The inspector will note corrections in his final report."
- Under the heading "OMS Requirement", in the first bullet, delete the word "shall" and insert the word "does". In the second bullet, first sentence, delete the word "shall" and insert the word "must". In the second bullet, second sentence, delete the word "shall" and insert the word "must". In the third bullet, delete the word "shall" and insert the word "must".

Dr. Dawson moved to recommend to the Board that the amended Guidance Document on Sedation Permits be adopted. The motion was seconded and passed.

Proposed Workgroup - Dr. Bonwell asked the Committee to return to the May 17, 2021 Minutes on page 2 in the agenda book. She pointed out the discussion of forming a workgroup to discuss a regulatory proposal that would allow patients receiving active appliances, including orthodontics, be examined in person by a dentist. She stated Ms. Reen did not receive any names of prospective participants for the workgroup. After discussion, it was agreed by consensus to address this at the next Board meeting.

NEXT MEETING: No date scheduled.

ADJOURNMENT: With all business concluded, the Committee adjourned at 2:45 p.m.

Patricia B. Bonwell, R.D.H., PhD, Chair

Date

Sandra K. Reen, Executive Director

Date

Sandra Reen

From: Sandra Reen
Sent: Tuesday, January 25, 2022 5:53 PM
To: 'PRISBY Stephen'
Subject: Sleep apnea testing

Hello Stephen:
I hope you are having a great day in Oregon.
Would you please send the following question to our membership for me?

Do you have any statute, regulation or policy addressing the role of dentists in addressing sleep apnea testing (home sleep tests and polysomnographic testing) and addressing sleep disorders? Please send me any information you have.

Thank you!

Sandy

Sandra K. Reen
Executive Director
Virginia Board of Dentistry
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
804-367-4538

Sandra Reen

Subject: FW: AADA Member Question For You

From: Brad Edmonds <brad@dentalboard.org>
Sent: Tuesday, January 25, 2022 6:08 PM
To: Sandra.Reen@dhp.virginia.gov
Subject: RE: AADA Member Question For You

We have an FAQs document linked from our home page, www.dentalboard.org. It is just an opinion; guidance on how the board will interpret the statutes and regs when asked a particular question:

"The Board opines that it is within the scope of practice for a dentist to order/administer a home sleep test; however, a definitive diagnosis of sleep apnea must be made by a licensed physician prior to the prescription and fabrication of an intra-oral sleep disorder appliance. It is outside the scope of dental practice to order or prescribe an intra-oral sleep disorder appliance as a result of a sleep study being interpreted by a dentist. Additionally, it is always outside beyond the scope of dental practice for a dentist to prescribe a CPAP. It is, however, permissible for a dentist to fabricate and prescribe an antisnoring appliance without the consultation of a physician. See July, 2011 minutes and August, 2017 minutes."

Bradley W. Edmonds, Executive Director
Board of Dental Examiners of Alabama
2229 Rocky Ridge Road
Birmingham, Alabama 35216
(205) 985-7267
Fax: (205) 823-9006

Sandra Reen

Subject: FW: AADA Member Question For You

From: Ryan Edmonson <ryan.edmonson@dentalboard.az.gov>
Sent: Wednesday, January 26, 2022 11:10 AM
To: Sandra K. Reen <Sandra.Reen@dhp.virginia.gov>
Cc: PRISBY Stephen * OBD <Stephen.PRISBY@obd.oregon.gov>
Subject: Fwd: AADA Member Question For You

Good Morning Sandy and Sic Semper Tyrannis,

Neither Arizona's statutes, nor its rules address sleep apnea or sleeping disorders.

Respectfully,

Ryan P. Edmonson

Executive Director

Arizona State Board of Dental Examiners
1740 West Adams Street, Suite 2470

Phoenix, Arizona 85007
P: 602.542.4493
C: 602.540.0341
E: ryan.edmonson@dentalboard.az.gov
W: https://dentalboard.az.gov/

The Role of Iowa Dentists in Managing Sleep-Related Breathing Disorders

In October 2017, the American Dental Association (ADA) House of Delegates approved a policy statement on the "Role of Dentistry in the Treatment of Sleep-Related Breathing Disorders (SRBDs)." Subsequently, the Iowa Dental Board convened a work group to examine the ADA policy and develop clarifications to provide information to Iowa dentists in the management of patients diagnosed with SRBDs and in identifying undiagnosed patients at risk of having these disorders. The work group developed a set of recommendations for the "Role of Iowa Dentists in the Management of Sleep-Related Breathing Disorders."

It is understood that the field of dental sleep medicine is constantly evolving, and that due to changes in knowledge and technology, future modifications to these recommendations may be necessary. These non-binding recommendations are provided for informational purposes only and do not constitute requirements of the Iowa Dental Board.

Note: In these recommendations, "physician" refers to a licensed medical provider with an MD, DO, PA (physician assistant) or NP (nurse practitioner) degree. "Sleep physician" refers to licensed medical provider (MD or DO) who is board-certified in sleep medicine, and also refers to a PA or NP who works with the board-certified provider.

The dentist's role in the treatment of SRBDs includes the following:

1. Dentists are encouraged to screen patients for SRBDs as part of a comprehensive medical and dental history and to recognize symptoms such as daytime sleepiness, choking during sleep, snoring or witnessed apneas and other risk factors such as obesity, macroglossia, Mallampati class 3 or 4, or hypertension. If risk for SRBD is determined, patients should be referred to a sleep physician[1] or their managing physician for follow-up evaluation and diagnosis.

   Working with a licensed physician (preferably a sleep physician), dentists may elect to administer pulse oximetry as part of initial screening for SRBD the scoring and interpretation of such testing as well as the patient's diagnosis should be the sole responsibility of the physician.

   Dentists' use of unattended Home Sleep Apnea Testing devices for screening should be considered within the scope of practice of a qualified dentist, defined as a dentist treating SRBDs who continually updates his or her knowledge and training with related continuing education. Data from the HSAT ***must*** be interpreted by a licensed medical provider, preferably a sleep physician, which may be accomplished by a face to face or telehealth visit.

2. In children, screening through history and clinical examination may identify signs and symptoms of dysmorphic growth and development, and other risk factors that may lead to airway issues. If risk for SRBDs is determined, intervention through medical/dental referral or evidenced based treatment may be appropriate to help treat the SRBD and/or develop an optimal physiologic airway and breathing pattern.

3. Oral appliance therapy (OAT) is an appropriate treatment for the spectrum of SRBDs in adults including diagnosed primary snoring, upper airway resistance, and obstructive sleep apnea. For all patients, a diagnosis rendered by a medical provider is required. When the diagnosis is obstructive sleep apnea, the patient must have a written or electronic prescription (work order) by the patient's medical provider for OAT.

4. When OAT is prescribed by a physician through written or electronic order for an adult patient with obstructive sleep apnea, a dentist knowledgeable in the practice of dental sleep medicine should evaluate the patient for the appropriateness of providing a suitable oral appliance.[2] If an oral appliance is deemed appropriate, the dentist should fabricate the oral appliance.

5. Dentists should obtain appropriate patient consent for treatment after obtaining baseline pre-treatment records. The written consent should review the proposed treatment plan, all available options, potential side effects of using OAT, and importance of follow-up care with both the dentist and the patient's physician.

6. Dentists treating SRBDs with OAT should be capable of recognizing and managing the potential side effects through treatment or proper referral.

7. Dentists who provide OAT to patients should adjust the Oral Appliance (OA) for treatment efficacy. Patient symptoms and objective data may be utilized to monitor or improve treatment efficacy.

   As titration of OAs has been shown to improve the final treatment outcome and overall OA success, dentists may use pulse oximetry or an unattended home sleep apnea testing device to help define the optimal target position of the mandible. A dentist trained in the use of these devices may assess the objective interim results for the purposes of OA titration.

   In no instance should the dentist rely on the outcomes of these devices to make the independent determination that the SRBD has been optimally treated. The patient's physician has ultimate responsibility for judging treatment efficacy.

8. Dentists should maintain regular communications with the patient's physician and other healthcare providers such as the patient's general dentist to inform them of the patient's treatment progress and recommended follow-up treatment.

9. Follow-up sleep evaluation and communication with the patient's physician is indicated to assess obstructive sleep apnea (OSA) improvement or to confirm oral appliance treatment efficacy. Dentists should monitor and re-assess treatment efficacy at least annually.

   In addition, dentists are strongly encouraged to closely communicate with the training physician/sleep physician or medical provider to see what information, or what frequency of information they would prefer.

   Provider should follow patient who is on OAT at least one time per year, as a safeguard to ensure everything is as optimal as could be medically.

   Treated patients who develop recurring OSA-relevant symptoms or comorbidities should be referred to their physician for follow-up sleep evaluation and alternative treatment if necessary.

10. Surgical procedures may be considered as a secondary treatment for OSA when CPAP or OAT is inadequate or not tolerated. In selected cases, surgical intervention may be considered as a

primary treatment. This decision should be made by the surgeon in collaboration with the patient's physician.

11. Training in dental sleep medicine is necessary for the dentist to provide safe, quality care to patients using oral appliances for SRBDs. Dentists treating SRBDs should take a minimum of 6 hours of related continuing education per licensing period in order continually update their knowledge and training.

[1] Patient's medical insurance may necessitate referral being made to the primary care or other managing physician.

[2] This may include the dentist's use of unattended home sleep apnea testing devices with a trial oral appliance to determine if the patient's sleep breathing sufficiently improves with jaw advancement. In no instance should the dentist rely on the outcomes of this testing to make the independent determination that the SRBD will be optimally treated. The patient's physician has ultimate responsibility for judging treatment efficacy of the final custom-fabricated oral appliance.

Sandra Reen

Subject: FW: AADA Member Question For You
Attachments: 20.3.10 sleep medicine memo w attch.pdf

From: Arthur Hickham <ahickham@lsbd.org>
Sent: Tuesday, January 25, 2022 6:16 PM
To: Sandra.Reen@dhp.virginia.gov
Subject: RE: AADA Member Question For You

Sandy,

Louisiana has no statute or rule addressing sleep medicine. We were asked by the American Academy of Dental Sleep Medicine to opine on several questions. If you are interested attached is a memo to my Board with the letter from the AADSM attached. All four questions were answered in the affirmative by my Board.

Rusty

MEMO

The American Academy of Dental Sleep Medicine ("AADS") has asked the Board to answer four questions regarding whether a dentist can order a portable monitor for sleep apnea (also known as a home sleep apnea test) .The questions are attached hereto as Exhibit A. The Board has referred the questions to this committee to review.

The Board is required by statute to issue "declaratory orders and rulings as to the applicability of any statutory provision or of any rule or order of the agency. Declaratory orders and rulings shall have the same status as agency decisions or orders in adjudicated cases." La. R.S. 49:962.

In determining whether it is within the scope of practice for a dentist to order such devices, the definition of "dentistry" as defined by the law should be kept in mind. La. R.S. 37:751(6) defines dentistry as follows:

> "Dentistry" means the evaluation, diagnosis, prevention, or treatment, including nonsurgical, surgical, or related procedures, of diseases, disorders, or conditions of the oral cavity, maxillofacial areas or the adjacent and associated structures and their impact on the human body provided by a dentist within the scope of his education, training, and experience, in accordance with the ethics of the profession and applicable law.

The AADS has issued a policy statement on a dentist's role in treating sleep-related breathing disorders, attached as Exhibit B and which provides:

> Dentists should verify oral appliance treatment efficacy using objective data only as permitted within their scope of practice and as defined by their state dental practice acts.

In other words, when a dentist makes an appliance for the treatment of sleep apnea, how far forward the jaw should be moved and how well the appliance is working should be monitored with a home sleep apnea test. These tests usually monitor nasal and oral airflow as well as respiratory effort and use an oximeter finger probe.

The American Dental Association has taken the position that dentists who are treating sleep apnea with an oral appliance as ordered by a physician can and should order home sleep apnea tests (also known as portable sleep apnea tests). The ADA position paper it attached as Exhibit C and provides:

> Dentists who provide OAT [oral appliance therapy] to patients should monitor and adjust the Oral Appliance (OA) for treatment efficacy as needed, or at least annually. As titration of OAs has been shown to affect the final treatment outcome and overall OA success, the use of unattended cardiorespiratory (Type 3) or (Type 4) portable monitors may be used by the dentist to help define the optimal target position of the mandible. A dentist trained in the use of these portable monitoring devices may assess the objective interim results for the purposes of OA titration.

However, the American Medical Association takes a different view, asserting in a policy paper that the ordering of sleep apnea tests constitutes the practice of medicine. See Exhibit D.

The American Association of Sleep Medicine has also taken the position that only a physician can order sleep apnea tests. See Exhibit E.

The Standards of Practice Committee of the American Academy of Dental Sleep Medicine has recognized this conflict in its article "Dental Sleep Medicine Standards for Screening, Treating, and Managing Adults with Sleep-Related Breathing Disorders," attached as Exhibit F. The article states:

> The qualified dentist will need to determine an appropriate endpoint to the OA [oral appliance] advancement process.... 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. 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. 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. 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.

Given the differing positions taken on the issue it is not surprising that the Board has been asked to weigh in on the issue.

AMERICAN ACADEMY OF DENTAL SLEEP MEDICINE®

January 10, 2020

RECEIVED
Exhibit A
JAN 15 2020
LOUISIANA STATE BOARD OF DENTISTRY

J. Jerome Smith, DDS
President, Louisiana Board of Dentistry
PO Box 5256
Baton Rouge, LA 70821-5256

Dear Dr. Smith:

On behalf of the American Academy of Dental Sleep Medicine, I am requesting clarification on the scope of practice in Louisiana as it relates to the treatment of sleep apnea with oral appliance therapy.

As you may be aware, *The Role of Dentistry in the Treatment of Sleep Related Breathing Disorders* published by the ADA encourages dentists to screen patients for sleep-related breathing disorders and refer those at risk to the appropriate physician for diagnosis. The ADA policy also indicates that dentists who provide oral appliance therapy may use unattended cardiorespiratory portable monitors, commonly referred to as home sleep apnea tests, HSAT or HST, to help determine the optimal position of the appliance.

As the largest professional organization exclusively representing dentists who are trained to screen, treat and manage patients with sleep apnea, we are asking you to verify whether licensed dentists in your state may do the following:

1. Is it within a dentist's scope of practice to dispense portable monitors when ordered by physicians for patients at risk for sleep apnea? The test results are provided to a physician for interpretation and diagnosis.

2. Is it within a dentist's scope of practice to order portable monitors for patients identified by the dentist as being at risk for sleep apnea? The test results are provided to a physician for interpretation and diagnosis.

3. Is it within a dentist's scope of practice to use a portable monitor to help determine the optimal effective position of a patient's oral appliance?

4. If a dentist does not use a portable monitor to determine the optimal effective position, is it within a dentist's scope of practice to order a portable monitor to verify the effectiveness of an oral appliance? The test results are provided to physicians for interpretation and therapeutic effectiveness is determined by physicians.

The information you provide will be included on the AADSM website as a resource to our members. Please send your responses, as well as any questions, to Coreen Vick, Director of Clinical Services of the American Academy of Dental Sleep Medicine, at cvick@aadsm.org or 630-686-9875.

Sincerely,
Nancy L. Addy, DDS
President

CC: Arthur Hickham Jr. - Executive Director, Louisiana Board of Dentistry

Exhibit A

1001 Warrenville Road,
Suite 175
Lisle, IL 60532
Phone: 630-686-9875
Fax: 630-686-9876
Web: AADSM.org

Sandra Reen

From: Anderson, Bridgett (HLB) <bridgett.anderson@state.mn.us> on behalf of Anderson, Bridgett (HLB)
Sent: Wednesday, January 26, 2022 10:25 AM
To: Sandra Reen
Subject: Sleep Dentistry

We require the sleep study done by a physician and not a dentist, but we regulate it as the standard of care and do not have it in laws/ rules.

Hope you are well! Miss you Sandy!

In the Service of Health,

Bridgett Anderson LDA, MBA
Executive Director

Minnesota Board of Dentistry
335 Randolph Avenue, Suite 250
St. Paul, MN 55102
Phone 612-617-2250 | Fax 651-797-1373
Toll- Free 888-240-4762 | Direct 612-548-2127

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MINNESOTA
BOARD OF DENTISTRY

Sandra Reen

From: MSBDE Executive Director <executivedirector@dentalboard.ms.gov> on behalf of MSBDE Executive Director
Sent: Wednesday, January 26, 2022 8:46 AM
To: Sandra.Reen@dhp.virginia.gov
Subject: Dentists-Sleep apnea

Though Mississippi does not have a direct regulation regarding sleep apnea, the Board made a Board Determination to allow dentists to add the treatment of sleep apnea and prescribing such devices within the dentist scope of practice.

Regards,

Chris L. Hutchinson; BBA, MBA, LLBL, MAPP

Executive Director
Mississippi State Board of Dental Examiners
Suite 100, 600 East Amite Street
Jackson, MS 39201-2801
Telephone: 601-944-9622
Fax: 601-944-9624
Email:executivedirector@dentalboard.ms.gov

Sandra Reen

Subject: FW: Sleep apnea testing

From: PRISBY Stephen * OBD <Stephen.PRISBY@obd.oregon.gov>
Sent: Tuesday, January 25, 2022 6:07 PM
To: Sandra Reen <Sandra.Reen@dhp.virginia.gov>
Subject: Re: Sleep apnea testing

Here you go for Oregon!

Treating Sleep-Related Disordered Breathing

As more and more dentists are treating Sleep-Related Disordered Breathing (SRDB), the Board is starting to see an increase in the number of complaints related to dentists treating Obstructive Sleep Apnea (OSA) and SRDB. Dentists can (and do) play an essential role in the multidisciplinary care of patients with certain sleep related breathing disorders, and are well-positioned to identify patients at greater risk of SRDB and OSA.

Since sleep-related disordered breathing can be caused by a number of multifactorial medical issues, a physician's diagnoses of SRDB (based on a patient's medical history, symptoms from a medical evaluation, and findings from either polysomnography or a home sleep apnea test) is necessary before a dentist can treat the SRDB. Oral Appliance Therapy (OAT) can improve OSA in adult patients, especially those who are intolerant of Continuous Positive Airway Pressure (CPAP), and dentists are the only health care provider with the knowledge and expertise to provide OAT.

Working in conjunction with physicians, dentists can help treat these disorders. Dentists have long been aware of the importance of the maintenance of their patient's airway. Many dentists and their hygienists regularly screen their patient's Mallimpati score, and grade their patient's tonsils to evaluate a patient's airway. But again, dentists may not diagnose SRDB and sleep apnea; a physician must make the diagnosis and then prescribe oral appliance therapy before the dentist can treat it.

In children, a dentist can refer the patient to a pediatric otolaryngologist for evaluation and treatment of suspected airway obstruction caused by hypertrophic tonsils.

It is the Board's position that the diagnosis of SRDB or OSA is outside the scope of the practice of dentistry, and the diagnosis must be made by a physician prior to oral appliance therapy by a dentist. ■

South Carolina
Department of Labor, Licensing and Regulation

Board of Dentistry

110 Centerview Drive
Post Office Box 11329
Columbia, SC 29211-1329
Phone: (803) 896-4599
FAX: (803) 896-4719

Henry D. McMaster
Governor

Emily H. Farr
Director

July 20, 2021

Board of Dentistry: Position on Ordering of Home Sleep Test

At the South Carolina Board of Dentistry meeting on July 9, 2021, the Board voted to approve the proposed policy regarding dental ordering of home sleep test:

> If screening suspicions dictate, a licensed dentist in South Carolina may order a Home Sleep Test (HST), which will be read, interpreted and a diagnosis be rendered by a South Carolina licensed sleep physician, with results, diagnosis and therapeutic recommendations provided by that physician as part of the dentist's ongoing care of their patients.

Parties interested in further information regarding the policy may contact the Board office at contact.dentistry@llr.sc.gov. Committee meeting minutes can be found on the Board website at https://www.llr.sc.gov/bod/minutes/minutes.aspx.

Licensees and other members of the public needing assistance are encouraged to visit the Board website at www.llr.sc.gov or contact the Board office at 803-896-4599 or at contact.dentistry@llr.sc.gov.

Sincerely,

South Carolina Board of Dentistry

Sandra Reen

Subject: FW: AADA Member Question For You

From: WV Board of Dentistry Susan Combs <wvbde@suddenlinkmail.com>
Sent: Wednesday, January 26, 2022 8:27 AM
To: sandra.reen@dhp.virginia.gov
Subject: FW: AADA Member Question For You

I do not believe there is anything specific in WV laws or rules.

Susan M. Combs
Executive Director
West Virginia Board of Dentistry
PO Box 1447
Crab Orchard, WV 25827
(304)252-8266
FAX (304)253-9454

Sandra Reen

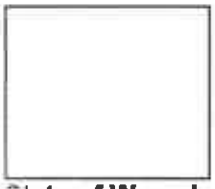
Subject: FW: AADA Member Question For You

From: Emily Cronbaugh <emily.cronbaugh@wyo.gov>
Sent: Friday, January 28, 2022 2:26 PM
To: Sandra K. Reen <sandra.reen@dhp.virginia.gov>
Subject: Fwd: AADA Member Question For You

HI Sandy! For Wyoming, the Board debated this topic at their November 9, 2018 meeting and concluded: The treatment of sleep apnea without a medical consultation and diagnosis is outside the scope of practice of dentistry in Wyoming.

I hope this helps!

Emily



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JDSM

SPECIAL ARTICLE

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

Standards of Practice Committee of the American Academy of Dental Sleep Medicine: Mitchell Levine, DMD (Chair)[1]; Kathleen M. Bennett, DDS[2]; Michelle K. Cantwell, DMD[3]; Kevin Postol, DDS[4]; David B. Schwartz, DDS[5]

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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 **Citation:** Levine M, Bennett K, Cantwell M, Postol K, Schwartz D. Dental sleep medicine standards for screening, treating, and managing adults with sleep-related breathing disorders. *J. Dent Sleep Med.* 2018;5(3):61-68.

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

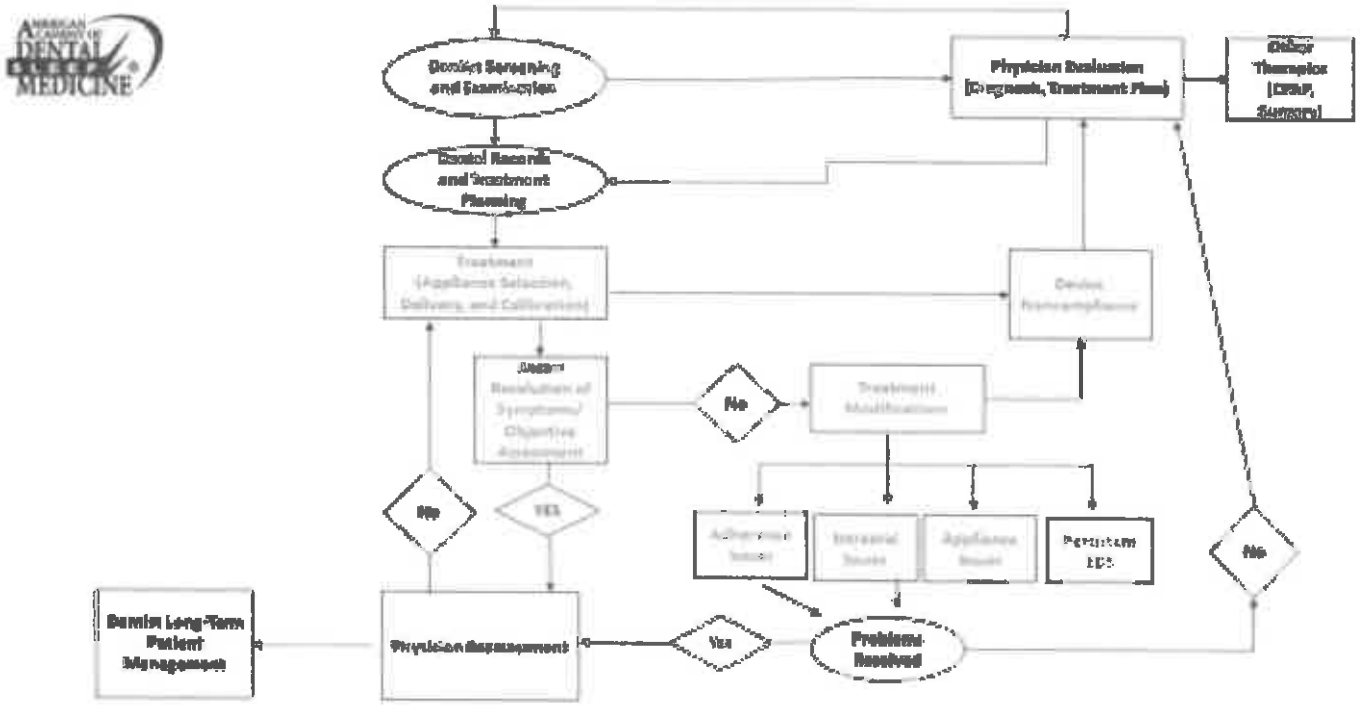
according to evidence-based practices, critical thinking, and outcomes assessments. Finally, the qualified dentist should identify known risk modifiers and work with patients and other health care professionals to effectively

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.

ACKNOWLEDGMENTS

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SUBMISSION & CORRESPONDENCE INFORMATION

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DISCLOSURE STATEMENT

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.

AADSM Treatment Protocol:
Oral Appliance Therapy for Sleep Disordered Breathing

1. Medical Assessment [1, 2, 3, 11]
   Either;

   - In order to practice within the limits of their license as designated by their state the dentist refers the patient to the physician for diagnosis of SDB – be it snoring, UARS or Obstructive Sleep Apnea. Following diagnosis, the physician sends the patient back to the dentist for OAT as appropriate. Or;
   - Referral by Physician for oral appliance therapy if appropriate.

2. A copy of the diagnostic sleep study is forwarded to the dentist.

3. The dentist is to assess the patient through a complete clinical examination, including determining the current health and prognosis of oral tissues that might be affected by the use of a mandibular advancement appliance. Evaluation of a recent radiographic survey when indicated is important to a complete examination. The dentist is to recommend the choice of appliance [4,5,6,7,8,9,10] and disclose relevant fees. Rationale for appliance therapy should be explained to the patient and documented.

4. Communicate your proposed treatment plan, progress and follow up notes, as well as other pertinent information, with the patient's physician and appropriate healthcare providers on a regular basis.

5. Informed consent must be obtained prior to appliance delivery. 6. Dentist to initiate therapy and titrate [9, 11] the OA to achieve optimum results based on resolution of patient symptoms and / or obtaining objective data during titration with the use of portable monitors.

7. Following optimal titration[9, 11], the dentist refers the patient back to the physician for assessment of OA treatment of SDB. If the OA treatment is sub-therapeutic, the dentist consults with the physician to discuss further treatment options.

8. Patients diagnosed with primary snoring may be treated without follow-up objective data.

9. Follow-up protocol should include a patient evaluation at six months after successful titration and at least annually thereafter. The annual recall exam should evaluate efficacy, patient compliance, side effects, symptoms as well as the structural integrity of the oral appliance and the need for possible additional titration. Continual annual assessment and the need for possible additional titration is communicated with the patient's physician.

10. Knowledge of various appliances is strongly recommended, as no one appliance is effective for treatment of all patients. Dentists who treat SDB are encouraged and have a responsibility to pursue additional education in the field.

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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

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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.**

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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

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.

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; $P = .002$).

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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An Individually Adjustable Oral Appliance vs Continuous Positive Airway Pressure in Mild-to-Moderate Obstructive Sleep Apnea Syndrome*

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Background: **For the treatment of nonsevere obstructive sleep apnea syndrome (OSAS), mandib ular advancement devices (MADs) are employed as an alternative to nasal continuous positive airway pressure (CPAP) therapy. However, very few specific data on the effectiveness of MADs in this group of patients are available. We therefore compared an individually adjustable intraoral sleep apnea device (ISAD) that permits movements of the lower jaw in three dimensions, with CPAP in the treatment of patients with an apnea/hypopnea index (AHI) < 30/h.** ***Methods:*** **In a randomized crossover study, 16 men and 4 women (mean SD age, 56.5 10.2 years; body mass index, 31.2 6.4; AHI, 17.5 7.7/h) were treated for 6 weeks with each modality.**

Results: **In the initial phase, a significant improvement in AHI (baseline, 17.5 7.7/h; ISAD, 10.5 7.5/h [p < 0.05]; CPAP, 3.5 2.9/h [p < 0.01]) and in breathing-related arousals (base line, 8.9 6.1/h; ISAD, 3.7 3.3/h [p < 0.01]; CPAP, 1.4 1.6/h [p < 0.01]) was achieved with both modalities. Considering all 20 subjects, after 6 weeks of treatment, normalization of the respiratory parameters was seen only with CPAP. However, 30% of the patients had a lasting reduction in AHI to < 10/h with the ISAD also. The patients considered the ISAD to be easier to use (scale of 1 to 6: ISAD, 1.8 1.1; CPAP, 3.1 1.5 [p < 0.05]), and indicated greater utilization of the device in comparison with CPAP.**

Conclusion: **Even in patients with mild-to-moderate OSAS, CPAP is the more effective long-term treatment modality. In the individual case, the better compliance seen with the ISAD may be advantageous.** ***(CHEST 2002; 122:569–575)***

Key words: continuous positive airway pressure; mandibular advancement device; orthodontic appliances; positive pressure ventilation; sleep apnea, obstructive

Abbreviations: AHI apnea/hypopnea index; ASDA American Sleep Disorders Association; BMI body mass index; CPAP nasal continuous positive airway pressure; ISAD intraoral sleep apnea device; MAD mandibular advancement device; NS not significant; OSAS obstructive sleep apnea syndrome; Sao_2 min minimal oxygen saturation in relation to respiratory disturbances during total sleep time; TST total sleep time

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Despite its effectiveness in the treatment of the obstructive sleep apnea syndrome (OSAS), na sal continuous positive airway pressure (CPAP) is not fully accepted by all patients.[1,2] Therefore, attempts have been made to employ oral appliances alterna tively.[3–13] The aim of such treatment is to enlarge the anteroposterior diameter of the retroglossal space, and thus reduce pharyngeal collapse. Of particular interest in this context are mandibular advancement devices (MADs), which are orthodontic appliances capable of advancing the lower jaw.[14–16] In contrast to tongue-retaining appliances, MADs are more readily accepted by the patient.[14] Schmidt-Nowara et al[14] investigated 68 patients treated with a dental orthosis for an average of 7 months. An improvement in snoring and sleep quality on the basis of subjective parameters was found, together with a reduction in the apnea/hypopnea index (AHI) that, however, dld not go to 20/h with treatment. Eveloff et al,[12] studying a "Herbst MAD," found a decrease in AHI from 34.7 5.3 to 12.9 2.4/h. Bloch et al,[6] using

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two different MADs (a single-piece and a two-piece appliance), found a reduction in AHI to 10/h in 88% of the patients, at least with one device. In contrast, Millman et al[8] found only 10 responders to treatment with an "adjustable mandibular advance ment Herbst appliance" in 24 patients who had previously undergone uvulopalatopharyngoplasty. Recently, Mehta et al,[17] in a placebo-controlled study, reported that 62.5% of the patients treated with a "mandibular advancement splint" showed at least a "partial response."

Only few data obtained from prospective random ized studies comparing MADs with CPAP are cur rently available. Clark et al[18] found a reduction in respiratory disturbances of 39% with an "anterior mandibular positioning device," and 50% with CPAP. However, the AHI with CPAP was reduced only to 11.15 3.93/h.[18] Moreover, comparison of the two treatment modes in this study was not done in randomized fashion. Ferguson et al[19] performed a randomized crossover study with a nonadjustable oral appliance. Respiratory disturbances and daytime symptoms showed significantly greater improvement with CPAP than with an MAD.[19] After 4 months of treatment using an adjustable anterior mandibular positioner, the same authors recorded a decrease in AHI from 25.3 15.0 to 14.2 14.7/h, correspond ing to 44% of the baseline value.[20] In seven patients, the AHI remained 10/h. Although a clearly greater improvement in the respiratory disturbances was seen with CPAP, no relevant differences were ob served between the two modalities in terms of sleep profile, and there was no improvement vs baseline in sleep profile. With regard to compliance, the oral appliance also proved to be clearly superior to CPAP treatment.[20]

In contrast to uncontrolled studies, which report large reductions in AHI, the above-mentioned con trolled studies failed to find such a positive effect of an MAD on sleep-related disturbances. On the basis of these data, the use of MADs was recommended only in patients with nonobstructive snoring or mild sleep apnea.[21] In severe OSAS, MADs should only be used if the we therefore carried out a randomized crossover study to compare—for the first time, as far as we are aware—an MAD with CPAP applied over the long term exclusively in patients with an AHI 30/h in accordance with the recommendations of the American Sleep Disorders Association (ASDA). Our aim was to investigate the effectiveness and acceptance of an adjustable orthodontic device per mitting jaw movements in three dimensions (an intraoral sleep apnea device [ISAD]), in comparison with CPAP.

Materials and Methods

Patients

Twenty patients (16 men and 4 women; mean SD age, 56.5 10.2 years; body mass index [BMI], 31.2 6.4), who had been referred to a university sleep laboratory for the diagnosis and treatment of OSAS were investigated between January 1999 and December 1999. Inclusion criteria were an AHI of 5/h minimum and 30/h maximum (mean, 17.5 7.7/h) measured in two diagnostic polysomnographies, and clinical symptoms of OSAS. The patients were submitted to two diagnostic measure ments to ensure that, in the event of appreciable night-to-night variability, only patients with an AHI 30/h were admitted. Exclusion criteria were an AHI 30/h, temporomandibular joint disorders, bruxism, and patients with gaps in their dentition precluding fitting of the device. We studied only patients with mild-to-moderate OSAS, so as to comply with ASDA recommen dations.[21] Patients with more severe OSAS were not included since MADs are recommended in this group only if CPAP is not accepted. Since the diagnosis of OSAS and the need for treat ment were established for the first time in all participants, refusal of CPAP could not legitimately be used as an inclusion criterion. All patients gave their informed consent. The study was approved by the ethics committee of the University Witten/Herdecke.

Devices

The ISAD (IST; Hinz; Herne, Germany) is an oral appliance for the noninvasive treatment of sleep-disordered breathing. Two thin thermoplastic parts, worn on the upper and lower jaws, are connected by two adjustable telescopic guide rods (Scheu Dental; Iserlohn, Germany) in the vestibule. The ISAD works by advancing and slightly depressing the mandible and tongue while imparting a slight vertical clockwise rotation. Prior to customizing the device, any pathology of the temporomandibular joints was excluded by a manual functional examination, with particular attention being paid to excursive movements. After obtaining an impression of the upper and lower teeth, the dentist determined the amount of mandibular advancement and the size of the bite opening with a construction bite obtained with the George Gauge instrument.[22] The maximum forward protrusion of the mandible was measured, and this amount

articulator[23] (Fig 1).

CPAP Devices

Patients were treated with commercially available CPAP de vices (Max II, MAP, Martinsried, Germany; Somnotron, Wein mann, Hamburg, Germany; and Vector, Hoffrichter, Schwerin, Germany). The treatment pressure was increased in incremental steps of 1 cm H_2O/h until respiratory disturbances were mini mized and respiration related arousals were reduced to 5/h. The mean CPAP treatment pressure was 7.4 0.9 cm H_2O.

Design

Following the diagnostic polysomnographies, manual CPAP titration, and customized fitting of the ISAD, the patients underwent, in randomized crossover fashion, 1 night of polysom nography with CPAP (CPAP, first night) and 1 night with the ISAD (ISAD, first night), which was then followed by 6 weeks of home treatment with CPAP and 6 weeks with the ISAD or *vice versa*. During the initial 6 weeks of treatment with the ISAD, patients need to adapt to the device, so the amount of protrusion was not adjusted during this period. Eight patients began treat

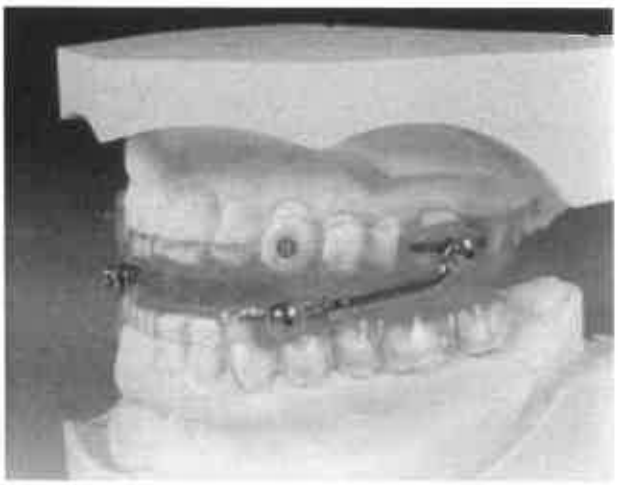

Figure 1. The ISAD is comprised of two thermoplastic parts with elevated vertical dimension achieved by acrylate plates and adjustable telescopic guide rods for nocturnal forward protrusion of the mandible.

ment with CPAP, and 12 patients began treatment with the ISAD. At the end of each period of treatment, polysomnography was carried out in the sleep laboratory (CPAP, 6 weeks; ISAD, 6 weeks), and the patients were interviewed to record the effect and acceptance of each of the modalities.

Polysomnography

The following parameters were recorded: submental or pretibial electromyography, EEG C4A1 or C3A2, electro-oculography, respi ratory effort (thoracic and abdominal impedance plethysmography), respiratory flow (thermo-elements), CPAP pressure (pressure sen sor signal at the mask), snoring (laryngeal microphone), and oxygen saturation (finger pulse oximetry). Body position was not recorded. The results of polysomnography were analyzed by chest specialists in accordance with the guidelines of Rechtschaffen and Kales and the ASDA criteria.[24,25] Arousals were defined as respiration induced when they occurred at the earliest with the onset, at the latest 2 s after the end, of an apnea or hypopnea.

A hypopnea was defined as a reduction of flow or effort of 50% in comparison with baseline for at least 10 s or any reduction of flow and effort *and* a decrease in oxygen saturation of at least 4%. To quantify snoring, the number of epochs (30 s per page) with evidence of microphone signals for at least 2 s outside of movement artifacts were counted as previously described.[26–28] Also calculated was the minimal oxygen saturation in relation to respiratory disturbances during the total sleep time (TST) [Sao_2 min].

Statistics

The statistical calculations for significant differences between baseline and the treatment modes, with rejection of the null hypothesis at a p 0.05, were carried out with the analysis of variance with Bonferroni correction. Comparisons between re sponders and nonresponders to ISAD treatment were effected with the Mann-Whitney test.

Results

With CPAP, a significant improvement in the respiratory parameters (AHI, snoring, Sao_2 min) and sleep quality (total number of arousals and respira tion-induced arousals) was achieved at both measur ing time points (first night and 6 weeks; Table 1). The AHI decreased from 17.5/h 7.7 to 3.5 2.9/h (first night) and 3.2 2.9/h (6 weeks) [p 0.01 in each case]; the arousal index decreased from 21.8 9.9 to 15 7.5/h (first night) and 14.1 5.1/h (6 weeks) [p 0.05 in each case]; and the respiration induced arousals decreased from 8.9 6.1 to 1.4 1.6/h (first night) and 2.3 4.3/h (6 weeks) [p 0.01 in each case; Table 1].

With ISAD also, a significant decrease in AHI from 17.5 7.7 to 10.5 7.5/h (p 0.05) and in respiration-induced arousals from 8.9 6.1 to 3.7 3.3/h (p 0.01) was observed on the first night. For the overall group, long-term treatment

Table 1—*Study Data

Variables Baseline CPAP Night 1 CPAP 6 wk ISAD Night 1 ISAD 6 wk

AHI, per h of TST 17.5 7.7 3.5 2.9‡ 3.2 2.9‡ 10.5 7.5† 13.8 11.1 Snoring, epochs/h 54.5 25.9 13.9 8.0‡ 10.3 5.0‡ 28.8 11.1‡§ 36.4 17.7‡ Sao_2 min, % 83.6 4.6 88.7 2.7‡ 89 3.4‡ 85 3.9 85.3 3.1§ TST, min 333.8 44.2 281.1 85.6† 324.8 48.9 337.2 34.9 327 45.4 Wake after sleep onset, min 35.9 26.4 45.3 32.8 39.4 24.9 19.7 9.6 39.9 31 Sleep stage 1, % TST 15.2 9.5 13.6 12.1 12 7.2 11.8 7.3 15 7.9 Sleep stage 2, % TST 53.6 9.9 50.1 12.3 55 6.8 52.1 8 54.4 10 Sleep stages 3 and 4, % TST 14.2 10.6 18.6 14.6 16.2 9.1 16.5 8.9 14.1 10.8 Rapid eye movement, % TST 15.1 5.9 13.3 8.2 15.3 6.8 18.5 5 14.8 7.3 Arousals, per h of TST 21.8 9.9 15 7.5† 14.1 5.1† 16.3 6.4 17 5.1 Respiration-induced arousals, per h of TST 8.9 6.1 1.4 1.6‡ 2.3 4.3‡ 3.7 3.3‡ 6 5.6

*Data are presented as mean SD.
†Significantly different from baseline (p 0.05).
‡Significantly different from baseline (p 0.01).
§Significantly different from CPAP at the corresponding measurement (p 0.05).
Significantly different from CPAP at the corresponding measurement (p 0.01).

with the ISAD showed a small improvement in AHI that, however, did not reach the level of significance (Table 1). Treatment with the ISAD significantly reduced snoring both in the first night and after 6 weeks (baseline, 54.5 25.9 epochs per hour; first night, 28.8 11.1 epochs per hour [p 0.01]; six weeks, 36.4 17.7 epochs per hour [p 0.01]). After 6 weeks, AHI with CPAP was significantly lower than with the ISAD (CPAP, 3.2 2.9/h; ISAD, 13.8 11.1/h [p 0.01]). At both measuring points, snoring was significantly lower with CPAP as compared with the ISAD (Table 1).

The study population was classified into three subgroups by baseline AHI (10/h, 10 to 20/h, and 20/h). In the two more seriously affected groups, AHI and snoring improved significantly after the first night and after 6 weeks with CPAP. In patients with AHI 10/h, the reduction in respira tory disturbances did not reach the level of signifi cance. There were no significant differences in AHI between baseline and treatment with the ISAD in either of the subgroups (Fig 2). However, with the ISAD, snoring significantly improved in the two more seriously affected groups in the first night: the subgroup with AHI of 10 to 20/h snoring baseline, 44.4 13.8 epochs per hour; first night, 26.4 8.2 epochs per hour [p 0.01]; 6 weeks, 33.8 12.8 epochs per hour (not significant [NS]); and the subgroup with AHI 20/h snoring baseline, 67.1 26.5 epochs per hour; first night, 28.1 2.7 epochs per hour (p 0.01); 6 weeks, 41.7 13.5 epochs per hour (NS).

To study the influence of weight on the efficacy of the appliances, the population was classified accord ing to BMI (27, 27 to 30.5, and 30.5). The AHI showed a tendency to improve in the subgroup with BMI 27 with both modalities, and significant improvements were seen in the other groups receiv ing CPAP. Moreover, the ISAD brought about a significant reduction in AHI in patients with a BMI 30.5 both on the first night and after 6 weeks of treatment (Fig 3).

In 6 of the 20 patients investigated (30%), long term treatment with the ISAD resulted in a reduc tion in AHI to 10/h, which was interpreted as signifying efficacy, and was statistically significant

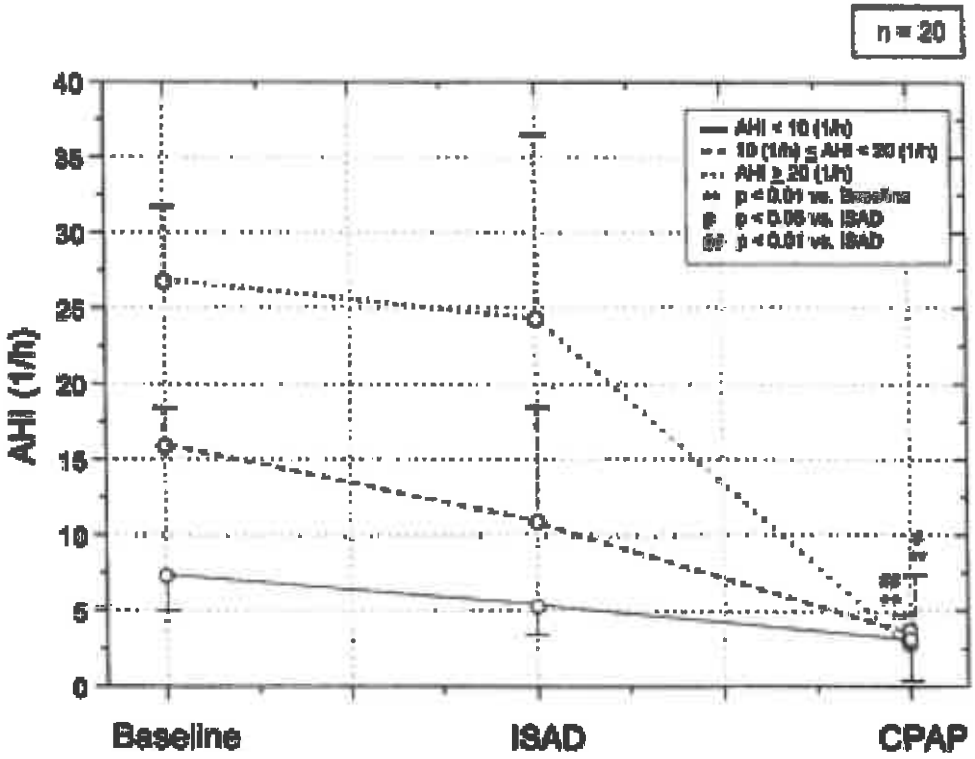

Figure 2. Mean values (SD) of the AHI after 6 weeks of treatment in three subgroups classified according to baseline AHI. In patients with a baseline AHI of 10 to 20/h (n 10, p 0.01) and 20/h (n 6, p 0.01), the AHI decreased significantly with CPAP. In patients with an AHI 10/h, the reduction did not reach the level of significance with either device. There were no significant differences between baseline values and those measured with the ISAD. In comparison with the ISAD, CPAP therapy resulted in significant lower data in the two subgroups with baseline AHI 10 to 20/h (p 0.05) and 20/h (p 0.01).

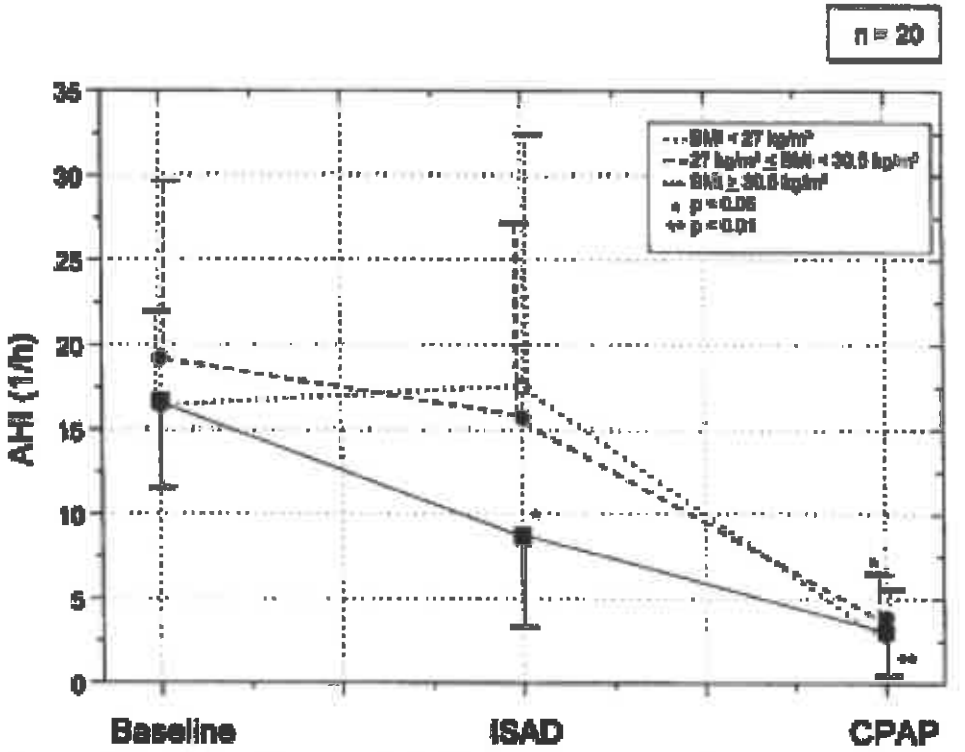

Figure 3. Mean values (SD) of the AHI after 6 weeks of treatment in three subgroups classified according to BMI. There were no significant differences between baseline values and those measured with either treatment modality in the group with BMI 27 (n 6). CPAP significantly reduced the AHI in patients with baseline BMI 27 to 30.5 (n 7, p 0.05) and 30.5 (n 7, p 0.01). With the ISAD, the AHI significantly improved in patients with a baseline BMI 30.5 (p 0.05).

(p 0.01, responders). The patients in whom effec tiveness was demonstrated in the first ISAD appli cation differed from nonresponders by their signifi cantly younger age and heavier weight (mean age, 48.3 10.3 years vs 60.6 6.5 years [p 0.05] and weight, 105.6 23.8 kg vs 82 9.8 kg [p 0.05], respectively). Also, the ISAD responders to long term application were significantly younger than the nonresponders (51.3 5.3 years vs 57.5 11.4 years, respectively; p 0.05). Otherwise, there were no significant differences between responders and nonresponders.

Patient self-assessment revealed no significant dif ferences between the two modalities in terms of improvement in daytime sleepiness, snoring, and concentration. The patients identified the ISAD as being easier to use (score of 1 to 6: ISAD, 1.8 1.1; CPAP, 3.1 1.5 [p 0.05]).

In the questionnaire, the patients reported greater compliance for the ISAD as compared with CPAP. This applied both to the number of nights during which treatment was applied, and also to the hours of use per night (at 8 h/d: CPAP, 9%; ISAD, 33% [NS]; at 6 to 7 h/d: CPAP, 27%; ISAD, 53% [NS]; at 4 to 5 h/d: CPAP, 64%; ISAD, 7% [p 0.01]; and at 2 to 3 h/d: CPAP, 0%; IST, 7% [NS]). All patients used both devices on at least 5 nights per week (7 days: CPAP, 54%; ISAD, 62%; and 5 to 6 days: CPAP, 46%; ISAD, 38% [NS]).

With CPAP treatment, eight patients noted a sensation of pressure on the face (with the ISAD, two patients [p 0.05]). With the ISAD, two pa tients noted a feeling of pressure in the mouth (with CPAP, 0 patients [NS]). With the ISAD, eight patients complained of early morning, nonpersisting discomfort in the mouth and temporomandibular joint (with CPAP, 0 patients [p 0.01]). With regard to other side effects, no relevant differences were found. There were no significant differences be tween the genders in terms of polysomnographic or compliance parameters.

Discussion

The ASDA recognizes intraoral appliances as an alternative to CPAP treatment of nonobstructive snoring and mild OSAS.[21] These ASDA guidelines are grade C recommendations supported by level V evidence.[21] Numerous devices are presently avail

able that differ widely in terms of material, freedom of mandibular movement, amount and rigidity of dental coverage, amount of mandibular advance ment, and bite opening.[6–20,22,29] Despite the pre dominantly positive results, only a few randomized controlled studies have so far been performed to compare MADs with the standard treatment of OSAS applied over the long term.[19,20] Stradling et al[29] presented data on snoring in the absence of OSAS, showing an improvement also in respiratory effort and autonomous parameters. Ferguson et al[19] investigated a nonadjustable device, while our study looked at a device (the ISAD), that is individually adjustable and permits three dimensional move ments of the lower jaw. In the study by Ferguson et al,[19] patients showed a wide range in the severity of their conditions on diagnostic polysomnography (AHI, 5 to 55/h), although the mean value was not substantially higher than that in our own study. On the basis of the ASDA recommendations,[21] our study dealt exclusively with the group of patients with nonsevere OSAS (AHI 30/h), which was con firmed by two diagnostic polysomnographies. This was done both to exclude patients with severe OSAS erroneously diagnosed as mild on the first night in the sleep laboratory due to intraindividual variability, and also to ensure, on the basis of the symptoms and AHI, that the patients investigated really did have OSAS.

The ISAD reduced snoring at both measuring time points (first night and 6 weeks) but significantly improved the AHI only in the early phase of treat ment. In contrast, CPAP normalized AHI, snoring, and arousals throughout the entire treatment period. The remaining number of microphone signals was similar to those of previous studies using the same definition, and may at least partially be artifacts or nonobstructive snores.[26–28]

This superiority of CPAP may be due to the fact that the ISAD might not have resulted in an enlarge ment of the upper airways in all patients. Thus, for example, Rodenstein et al[30] showed that in patients with OSAS, the long axis of the pharyngeal cross section may lie in the sagittal plane rather than in the coronary plane. As a

even diminish the size of the retro glossal space.

Of particular interest would appear to be the fact that the more pronounced effect of the ISAD found initially (first night) subsequently diminished again (6 weeks). Peter et al[31] failed to demonstrate an improvement of the success rate of the uvulopalato pharyngoplasty by localizing the site of the stenosis using endoscopy. This was discussed based on the findings that the site of the collapse changes after uvulopalatopharyngoplasty, but an obstruction per

sists.[31] Therefore, our results may also be due to a shift in the location of the obstruction of the upper airways during the course of treatment. In contrast, the effect of CPAP therapy is not influenced by the plane of the long axis of the pharyngeal space, or any shift in the location of the functional narrowing.

Although CPAP therapy is generally more advan tageous, adequate treatment (AHI 10/h) persist ing over the longer term was nevertheless also observed in 30% of the patients treated with the ISAD. Responders to treatment with the ISAD were significantly younger than nonresponders. While the mean age of our own patients was 56.5 10.2 years, the patients investigated by Ferguson et al[20] had a mean age of 44.0 10.6 years. This might be the explanation for the different percentage of respond ers found in the two studies. When the group of 20 patients was classified according to BMI, those with the highest BMI showed a significant improve ment in AHI with the ISAD (Fig 3). There were no other differences in the anthropometric or polysom nographic findings between these groups. However, as we did not record body position, the question whether posture might have influenced these results must for the time being remain unanswered.

Another limitation of our study has to be dis cussed. It is possible that the number of responders might be increased by adjusting the ISAD more specifically. The initial adjustment of the ISAD to 66% of the maximum protrusion was not changed during the treatment period so as to allow the patients to adapt to this form of therapy.

With regard to side effects, mask-related

discom fort on the face was frequently observed with CPAP, and morning stiffness in the temporomandibular joint with the ISAD. Evidence of damage in the region of the jaws has not so far been reported,[32] although recently published data[33] suggest that the use of MADs over 6 to 30 months can cause dental and skeletal changes. The higher percentage of use of the ISAD vs CPAP is in agreement with the results reported by Ferguson et al.[20] Moreover, the patients indicated that they found the ISAD easier to use. This might well be the reason why patients applied the ISAD on more days than CPAP. The greater utilization of the ISAD per day might be due to the fact that after waking in the morning, patients no longer reapplied CPAP. The compliance data are largely in accord with the results reported by Weaver et al,[34] who found consistent CPAP use (7 d/wk) in 53% of the patients. However, in that study, inter mittent users objectively applied their devices be tween 2% and 79% of the days, whereas all our patients claimed to use CPAP on at least 5 nights per week. This difference may be due to unreliable self-assessment, in particular by irregular users.

On the basis of the results of effectiveness and compliance taken together, the ISAD cannot be recommended for general use in patients with mild to-moderate OSAS. An advantage of this modality is its greater acceptance. However, especially the most seriously affected subgroup of our population (AHI 20/h) failed to show any relevant improvement in AHI. Therefore, also in patients with mild-to moderate OSAS, CPAP is superior to treatment with MADs. As one third of the patients respond suffi ciently to treatment with the ISAD, in patients who refuse CPAP, the use of mandibular advancement should be considered. The true effectiveness of the ISAD, however, must be assessed on the basis of long-term treatment.

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Comparison of Adjustable and Fixed Oral Appliances for the Treatment of Obstructive Sleep Apnea

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Study Objectives: To compare the effi cacy of adjustable and fi xed oral appliances for the treatment of OSA.

Methods: Retrospective review of consecutive patients with OSA treated with either adjustable or fi xed oral appliances. Polysomnography was conducted before and during therapy. Effective treatment was defi ned as an apnea-hypopnea index (AHI) < 5 events/h or < 10 events/h with resolution of sleepi ness (Epworth < 10). We compared effi cacy rates between fi xed and adjustable appliances and sought to identify factors associated with greater success.

Results: We included 805 patients, 602 (74.8%) treated with an adjustable and 203 (25.2%) a fi xed oral appliances. Among the cohort, 86.4% were men; mean age was 41.3 ± 9.2 years. Mean AHI was 30.7 ± 25.6, with 34.1% having mild (AHI 5-14.9), 29.2% moderate (AHI 15-29.9), and 36.8% se vere (AHI ≥ 30) OSA. Successful therapy was signifi cantly more common with adjustable appliances. Obstructive events were reduced to < 5/h in 56.8% with adjustable compared to 47.0% with fi xed appliances (p = 0.02). Similarly, a reduction of events to < 10 with resolution of sleepiness occurred in 66.4% with adjustable appliances versus 44.9% with fi xed appliances (p < 0.001). For both devices, success was more common in younger patients, with lower BMI and less severe disease.

Conclusions: Adjustable devices produced greater reduc tions in obstructive events and were more likely to provide successful therapy, especially in moderate-severe OSA. Fixed appliances were effective in mild disease, but were less suc cessful in those with higher AHIs. Given these fi ndings, the baseline AHI should be considered when selecting the type of oral appliance.

Keywords: Oral appliance, mandibular advancement device, obstructive sleep apnea, effi cacy

Citation: Lettieri CJ; Paolino N; Eliasson AH; Shah AA; Hol ley AB. Comparison of adjustable and fi xed oral appliances

While continuous positive airway pressure (CPAP) therapy remains the treatment of choice for most patients with obstructive sleep apnea (OSA), its effi cacy is often limited by intolerance and poor adherence.[1-3] The need for a reliable source of electricity and inconvenience with travel further limit its use.

A commentary on this article appears in this issue on page 447.

Mandibular advancement devices, or oral appliances (OAs), are an approved, frequently effective alternative to CPAP for the treatment of OSA.[4-7] Numerous studies have established the ability of OAs to ablate obstructive apneas and hypopneas.[8-13] Existing research demonstrates that OA therapy is superior to commonly offered surgical procedures,[8,9] and may be compa rable to CPAP when adherence is included in the defi nition of successful treatment.[12-21] In 2006, the American Academy of Sleep Medicine (AASM) published updated OSA treatment guidelines which state that OAs are a reasonable alternative to CPAP in patients with mild to moderate OSA who prefer these devices or do not tolerate CPAP.[5]

Mandibular advancement devices provide a therapeutic effect by protruding the mandible relative to the maxilla, simultane ously advancing the tongue and reducing the propensity for air way collapse during sleep. Mandibular advancement devices are either fi xed (i.e., the degree of mandibular advancement cannot

bRIEF SUMMARY

Current Knowledge/Study Rationale: Oral appliances are an ap proved, frequently effective alternative to CPAP for the treatment of OSA. Both fi xed and adjustable devices are available. However, the ability of fi xed devices to provide adequate therapy has not been established. The purpose of this study was to compare the effi cacy of fi xed and adjustable oral appliances in the treatment of OSA.

Study Impact: Among a large cohort of patients with a wide range of OSA severity, we found adjustable appliances provided greater reduc tions in the AHI and were more likely to provide successful therapy compared with fi xed devices, particularly in those with moderate-severe disease. Similar to previous reports, we found that successful therapy was more common in patients who were younger, had lower BMIs and less severe disease.

be changed) or adjustable (i.e., mandibular advancement can be increased or decreased). The degree of mandibular advancement sought is a balance between tolerance, side effects, and effi cacy.[10]

Both fi xed and adjustable oral appliances are custom molded and individually fabricated from models made by impressions of the patient's dentition to fi t the upper and lower teeth. Fixed OAs are typically set to advance the mandible between 50% and 80% of its maximal protrusion and fabricated in a perma
nent position for therapeutic use. Adjustable OAs, on the other hand, can be further titrated (i.e., using a screw-type or similar advancing mechanism) to optimize therapeutic effi cacy. Upon

delivery of the device, patients are instructed to advance the device incrementally to identify the optimal position which improves sleep continuity and reduces snoring and obstructive events. A repeat polysomnogram while using either a fixed or adjustable OA should be obtained to assure that obstructive re spiratory events are adequately ablated.[5,7]

While effective, adjustable OAs require consultation and ad justments from providers skilled in sleep dentistry. In addition, adjustable OAs can also be expensive, with fees for fabricat ing and adjusting these devices potentially exceeding $3000,[22] causing adjustable OAs in some settings to be more expensive than CPAP.[24] In addition to the time required to fabricate adjust able OAs, a period of incremental titration is needed to facili tate patients› tolerance of the mandibular advancement, which further adds to the inherent delay to effective treatment.

Fixed OAs offer the advantages of lower cost, greater ease to obtain and fit, and a decrease in time to therapy compared to ad justable OAs. However, because fixed OAs cannot be titrated, further adjustments cannot be made once the device is set. This may limit the degree of mandibular advancement/protrusion or anterior displacement of the oropharynx, which may lead to in adequate resolution of obstructive events in patients with OSA.

Despite the utilization of fixed OAs, few studies have been conducted establishing the efficacy of these devices in the treat ment of OSA. Existing studies are limited by small sample sizes and many do not include repeat polysomnography on therapy. Fixed OAs have been shown to reduce events, but their ability to provide adequate therapy or normalize the AHI has not been established.[24-26]

No large studies directly comparing the performance be tween fixed and adjustable OAs have been conducted. While fixed OAs offer advantages, they may not provide adequate reduction of obstructive respiratory events and may result in residual disease or inadequate therapy for some patients. We sought to compare the efficacy of fixed OAs and adjustable OAs in their ability to effectively treat patients with OSA.

Methods

Study Design

We conducted a retrospective review of consecutive adult patients treated with an OA for OSA at our institution between January 2003 and December 2009. Patients who did not un dergo repeat polysomnography were excluded from the final analysis. The protocol was approved by our institutions De partment of Clinical Investigation (Scientific Review Commit tee, Human Use Committee and Institutional Review Board). No external funding was utilized to complete this study.

Patients

All patient records were retrieved from a single, accredited, academic sleep disorders center (Walter Reed Army Medical Center, Washington, DC). All included patients were diagnosed with obstructive sleep apnea syndrome by clinical symptoms and level I polysomnography in accordance with AASM criteria.[27]

All patients prescribed OAs at our institution undergo exten sive education regarding the effects of OSA, need for adequate therapy, and the proper use of and care for the device. All patients undergo serial clinical evaluations after initiating OA therapy to optimize the therapeutic response. A repeat level I polysom nography on therapy is performed to optimize the reduction of respiratory events and/or ensure OSA is appropriately treated. The use of OAs for the treatment of OSA is not standardized at our institution. After confirming the diagnosis of OSA and estab lishing a need for primary therapy (treatment beyond conservative measures), patients are educated regarding the available therapeu tic options (CPAP, OAs, surgery). In conjunction with recom mendations made by their sleep physician, patients may elect any treatment modality. Unless contraindicated, OAs may be used as the initial treatment option or subsequently elected by those intol erant of CPAP therapy. As Military Service Members comprise a large proportion of patients seen at our institution, many patients elect to use an OA because CPAP requires a reliable source of electricity, which will limit world-wide deployability.

Oral Appliances

We included patients treated with both adjustable and fixed OAs. All devices used in this analysis were constructed using semi-rigid, thermoplastic material and specifically fabricated for the individual patient. No prefabricated, non-customized devices were utilized in our cohort. The type of OA (fixed or adjustable) prescribed was determined by resource availability at the time of presentation and current duty location, and not by preestablished clinical criteria.

All patients were evaluated for eligibility by a dentist trained in dental sleep medicine prior to initiating OA therapy. To be considered for OA therapy, patients must not have craniofacial abnormalities, active dental disease, mandibular injuries, or preexisting temporomandibular joint (TMJ) dysfunction that would preclude the effective use of or tolerance to the device. In addition, patients must be capable of extending their mandible without pain or discomfort. Those who cannot tolerate wearing the appliance or edentulous patients are not offered OA therapy. When applicable, active sinus disease is adequately treated pri or to initiating treatment.

Non-adjustable, fixed devices: Appliances were fabricated in a fixed position that balanced anterior-posterior expansion of the retroglossal space and an acceptable comfort level for the patient, typically 60% to 80% of the maximum possible anterior advancement of the mandible. Fixed devices used in this analysis were constructed from a bilaminate acrylic mate rial (Proform Dual Laminate, Dental resources, Delano, MN). Occlusion registry was obtained at 60% to 75% of the maximal mandibular protrusion with 3-5 mm of vertical clearance. The devices were fabricated using molds from impressions of the patient's dentition. Following final adjustments of the device to optimize fit and comfort, the device was bonded into the final position and the patient underwent a level I polysomnogram to determine if the OA effectively mitigated obstructive events.

Adjustable/Titratable devices: Adjustable OAs used in this analysis were customized, titratable mandibular appliances that consisted of an upper and lower tray that could be adjusted using an embedded hook and screw mechanism to advance the man
dibular (lower) tray beyond the fixed maxillary (upper) tray. All adjustable OAs used in this analysis were Thornton Adjustable Positioner (TAP) II devices (Airway Management, Inc, Dallas, TX). Following fabrication and final modifications, patients

treated with adjustable OAs conducted an at-home adjustment protocol prior to their titration polysomnogram. Patients began the at-home adjustment protocol with the OA set in a neutral position, where the device was set to the comfortable sleep patient›s normal bite without any mandibular advancement. Once ing with the OA in place, patients were instructed to advance the device 0.5 mm (1 turn) each night as tolerated. In the event of discomfort, the device was regressed 1 mm (2 turns) and sub sequent advancement was resumed at a slower pace. Patients maintained a comprehensive sleep diary that recorded subjective assessments of sleep quality (including sleep continuity, snor ing, and witnessed apneas) and daytime somnolence. Using the patient›s sleep diary, the degree of mandibular advancement that optimized subjective sleep quality was determined. Each patient then underwent a level I polysomnography with OA titration. By protocol, the OA was initially set to 1 mm of mandibular advancement less than that estimated by the home titration. Dur ing the titration polysomnogram, the device was incrementally advanced as needed to ablate snoring and obstructive respiratory events and minimize respiratory effort-related arousals similar to the protocol used during CPAP titration polysomnograms. In response to observed apneas or hypopneas, the polysomnogra phy technologist would briefly awaken the patient and advance the OA by 1 turn. This would continue as needed, up to 3 turns, in order to identify the optimal setting to ablate events, prefer ably in the supine REM position. Advancement was discontin ued if the patient experienced discomfort.

Adjustable Devices

Outcome Measures

Data used in this analysis were obtained from the initial sleep consultation, follow-up evaluations, and polysomnographic stud ies. Demographic and anthropomorphic variables included age, gender, body mass index (BMI), presence of retrognathia or mi crognathia, and Mallampati score. Subjective somnolence both before and after treatment was assessed using the Epworth Sleep iness Scale (ESS).[28] Polysomnographic data included the baseline AHI and the AHI at the prescribed degree of mandibular ad vancement with the OA. A positional component of the patient›s sleep disordered breathing, defined as a 50% decrease in the AHI in the lateral compared to supine position, was also determined. All polysomnography studies were interpreted by board certified sleep physicians in accordance with established AASM criteria.[27] OSA severity was determined by the observed AHI during poly somnography, with mild, moderate, and severe disease defined as 5-14.9, 15-29.9, and ≥ 30 events/h, respectively.

Table 1—Baseline characteristics of individuals treated with oral appliances

	Fixed Devices	p
Age (years)	41.3 ± 9.0	42.9 ± 9.6	0.06
Men (%)	86.4	86.0	0.89
BMI (kg/m^2)	28.7 ± 4.4	29.3 ± 4.7	0.16
ESS	13.2 ± 5.1	14.3 ± 4.5	0.09
Mallampati	2.9 ± 0.9	3.1 ± 0.9	0.24
AHI (events/h)	29.7 ± 24.1	30.1 ± 24.4	0.86
SpO_2 nadir (%)	83.8 ± 7.6	83.3 ± 8.8	0.48
% of sleep time with SpO_2 < 90%	5.0 ± 10.0	5.9 ± 12.3	0.28
Mild OSA (%)	30.9	35.1	0.18
Moderate OSA (%)	28.2	30.2	0.59
Severe OSA (%)	40.9	34.7	0.11

End Points

The primary endpoint was the degree of successful treatment of OSA. We defined successful treatment as a decrease in the AHI to < 5 events/h. OA failures were defined as intolerance to the device or incomplete resolution of obstructive events. The rate of successful treatment was compared between fixed and adjustable devices. The ability to reduce the AHI to < 10 events/h with resolution of sleepiness (ESS < 10) served as a secondary endpoint.

Statistical Analysis

All data are presented as the mean with standard deviation. Comparisons between categorical variables were performed using χ^2 or Fisher exact tests as appropriate. For continuous variables, differences between means were assessed using 2-sample t-tests. Multivariate modeling was performed us ing logistic regression. All variables that had a p value ≤ 0.10 in univariate analysis were entered into multivariate models. Data were analyzed using PASW 17 (formerly SPSS 17.0, SPSS Inc, Chicago, IL).

During the inclusive period, 922 patients were treated with an OA. Data were incomplete in 117 individuals; 805 (87.3%)

were included in the final analysis. Among the cohort, the mean age was 41.3 ± 9.2 years, the majority (86.7%) were men, and the mean ESS was 13.4 ± 5.0 at baseline. Mean BMI was 28.9 ± 4.4 kg/m^2, and 38.8% were obese (BMI ≥ 30 kg/m^2). The mean AHI for the cohort was 30.7 ± 25.6 events/h; and OSA was categorized as mild in 34.1%, moderate in 29.2%, and severe in 36.8% of subjects. Adjustable OAs were used in 602 (74.8%) patients, and 203 (25.2%) were treated with a fixed OA. Groups were similar at baseline (**Table 1**).

While both devices produced a substantial decrease in the AHI, reduction of obstructive events was significantly greater, and more patients achieved successful therapy, with an adjustable OA (**Tables 2-4**). In comparison to the baseline PSG, those using adjustable OAs experienced a 74.4% reduction in AHI, compared with a 64.9% decrease with fixed devices (p = 0.08). Similarly, the mean change in AHI was −22.6 events/h with adjustable devices versus −18.8 events/h with fixed OAs (p = 0.14). Successful therapy (AHI reduced to < 5 events/h) was achieved in 57.2 % of patients using an adjustable appliance and only 46.9% of those using fixed OAs (p = 0.02). Similarly, 74.3% of patients with an adjustable device achieved an AHI < 10, compared with 63.8% of those using a fixed OA (p = 0.01). Using our alternate definition for successful therapy, a reduction in the AHI to < 10 events/h with normalization of the ESS occurred in 66.4% of patients wearing an adjustable OA and 44.9% of those using a fixed appliance (p < 0.001). We further compared the rates of successful therapy between the devices based on disease severity. The proportion of

Table 2—Efficacy of adjustable versus fixed oral appliances in the treatment of obstructive sleep apnea

	Adjustable Devices	Fixed	p
AHI on therapy (events/h)	7.6 ± 9.7	10.0 ± 12.4	< 0.01
% Reduction in AHI	74.4	64.9	0.08
SpO_2 nadir on therapy (%)	88.1 ± 7.2	85.7 ± 6.5	0.20
% of sleep time with SpO_2 < 90%	2.8 ± 6.7	4.2 ± 8.9	0.22
ESS on therapy	9.7 ± 4.1	10.6 ± 4.3	0.11
Intolerance of OA (%)	15.4	13.3	0.46
AHI < 5 events/h (%)	57.9	46.9	0.02
AHI < 10 events/h (%)	74.3	63.8	0.01
AHI < 10 and ESS < 10 (%)	66.4	44.9	< 0.01

Figure 1—Apnea-hypopnea index at the prescribed degree of mandibular advancement with fixed versus adjustable oral appliances by baseline

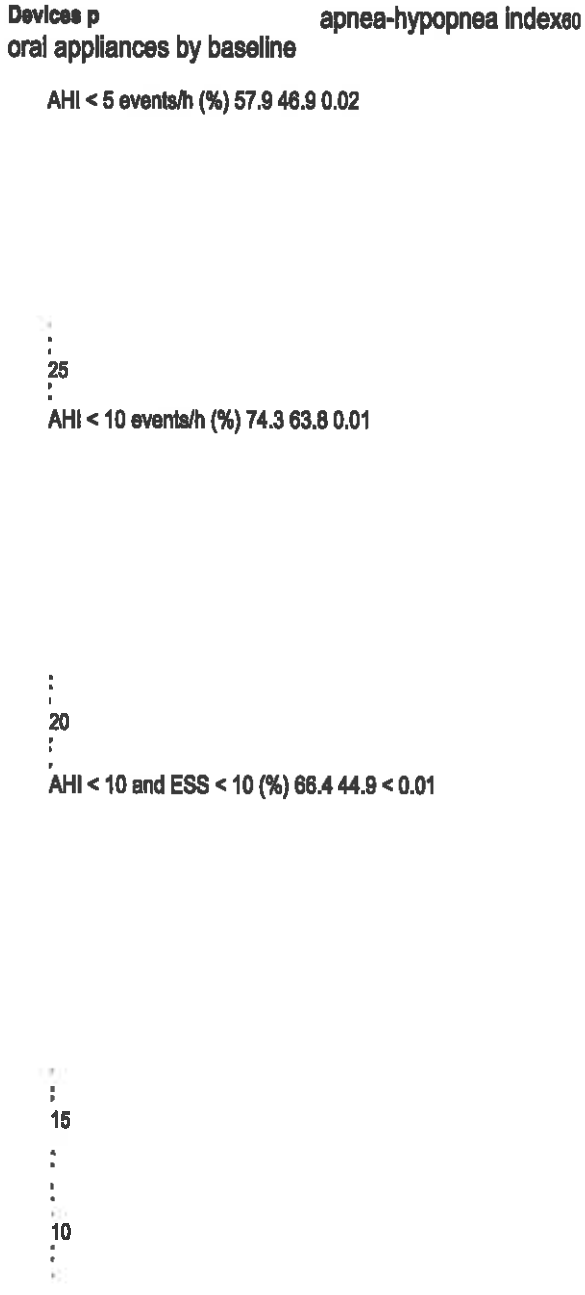


Table 3—Comparison of rates of successful therapy

p = 0.03

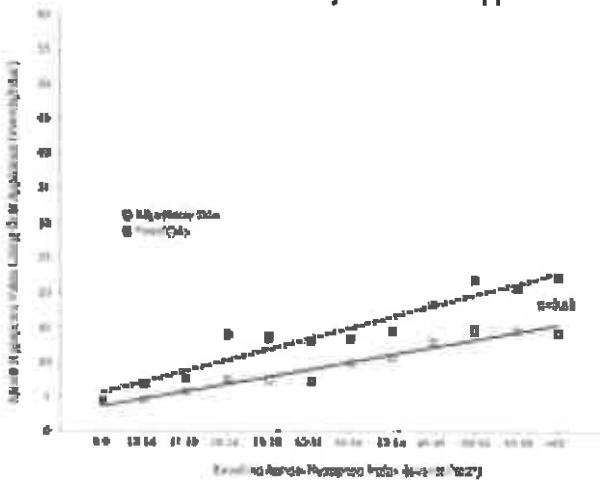
5

between fixed and adjustable oral appliances based on OSA 0

Adjustable OAs

Fixed OAs

≤0 >0



severity

4 8 4 8 4 8 4 8 4 8 4
10-1 15-1 20-2 25-2 30-3 35-3 40-4 45-4 50-5 55-6

Adjustable Fixed p

Mild

Baseline AHI 9.6 ± 2.8 8.8 ± 3.2 0.07 Baseline ESS 14.4 ± 4.4 14.2 ± 5.6 0.64 ESS on Therapy 9.8 ± 3.9 10.8 ± 4.4 0.08 AHI on OA Therapy 4.4 ± 5.2 4.9 ± 6.8 0.61 AHI on OA Therapy < 5 73.4% 63.8% 0.17

Baseline Apnea-Hypoonea Index (events/hour)

Baseline AHI 21.0 ± 4.3 22.3 ± 4.9 0.12

Figure 2—Probability of successful therapy (AHI < 5 events/h) with fixed versus adjustable oral appliances by baseline apnea-hypopnea index

90%

AHI on OA Therapy < 10 86.1% 82.7% 0.68
AHI < 10 and ESS < 10 81.2% 61.7% < 0.01

80%

Mean AHI Reduction 5.3 ± 5.6 3.8 ± 7.3 0.11

70%

Moderate

60%

Baseline ESS 13.1 ± 3.6 13.3 ± 6.2 0.44

50%

ESS on Therapy 8.4 ± 4.0 8.8 ± 5.4 0.18

20%

Mean AHI Reduction 13.9 ± 8.6 11.4 ± 9.3 0.08

AHI on OA Therapy 7.5 ± 8.1 11.0 ± 10.3 0.02

10%
Severe

40%

AHI on OA Therapy < 5 52.2% 35.0% 0.05

30%

AHI on OA Therapy < 10 74.3% 62.5% 0.14

Baseline AHI 56.3 ± 21.5 54.3 ± 22.6 0.54

AHI < 10 and ESS < 10 64.1% 41.9% 0.02

0%
Adjustable OAs Fixed OAs

5-9
ESS on Therapy 9.8 ± 1.8 10.2 ± 5.4 0.19
4 9 4 9 4 9 4 9 4
10-1 15-1 20-2 25-2 30-3 35-3 40-4 45-4 50-5 55-5[9]
>6[0]

Baseline ESS 15.4 ± 6.8 14.9 ± 6.6 0.24

AHI on OA Therapy 12.2 ± 15.4 14.2 ± 14.9 0.22 AHI on OA Therapy < 5 44.62% 37.8% 0.35 AHI on OA Therapy < 10 60.1% 46.9% 0.05 AHI < 10 and ESS < 10 53.9% 33.9% < 0.01 Mean AHI Reduction 44.4 ± 16.1 39.9 ± 12.6 0.07

individuals with mild, moderate, and severe OSA was similar between the 2 groups. For all degrees of severity, adjustable OAs produced a greater mean reduction in AHI and had higher success rates compared to fixed OAs (**Table 3**). Similarly, us ing progressive cut points for the baseline AHI, the final AHI (**Figure 1**) and probability for successful therapy (**Figure 2**) were superior with adjustable devices.

Baseline Apnea-Hypoonea Index (events/hour)

Discussion

We found that adjustable OAs are superior to fixed OAs in their ability to reduce the AHI among a large cohort of patients with a wide range of OSA severity. Successful treatment and improvements in subjective measures of sleepiness were sig nificantly more likely with adjustable OAs. Although fixed OAs were frequently successful in patients with mild disease, ad justable devices performed better across all severities of OSA. Similar to previous reports, we found that successful therapy with OAs was more common in patients who were younger, had lower BMIs and less severe disease.[4,5,13]

In accordance with the 2005 AASM primary Practice Parameters for Oral Appliances, these devices are indicated as either **AHI < 5 on OA Therapy** or alternative therapy for patients with sleep disordered breath ing, particularly those with mild to moderate OSA.[5] OAs can be used as either first-line therapy or in those intolerant of CPAP. This recommendation was based on numerous studies estab lishing their efficacy in ablating obstructive respiratory events, normalizing the AHI, and improving symptoms.[12-21] However, these studies were performed using adjustable devices, and it is important to distinguish between fixed and adjustable OAs, as the former may not be an appropriate choice of therapy or adhere to AASM recommendations. OAs offer advantages over CPAP in that they do not require a source of electricity and are less cumbersome, especially with travel. OAs are well tolerated in most patients, and therapeutic adherence may be better with OAs than CPAP.[14-16,20,21]

We performed both univariate and multivariate analyses to identify potential predictors of successful treatment with ei ther adjustable or fixed OAs (**Tables 5** and **6**). Variables that achieved statistical significance to $p < 0.10$ were entered into a multivariate logistic regression model. Because AHI, SpO_2 [na] dir, and percentage of sleep time with $SpO_2 < 90\%$ on baseline polysomnography were all closely correlated, only AHI was entered into the multivariate analysis. Women and those using adjustable devices were significantly more likely to achieve an AHI < 5 with OA therapy. In contrast, patients who were older, had higher BMIs, higher baseline AHIs, or those using fixed de vices were less likely to achieve and AHI < 5 with OA therapy.

Table 4—Rates of successful therapy (AHI < 5) between fixed and adjustable oral appliances based on baseline AHI

Adjustable Fixed p

Baseline AHI < 15 events/h 73.4% 63.8% 0.17 Baseline AHI < 30 events/h 64.9% 53.7% 0.04 Baseline AHI < 45 events/h 63.9% 52.3% 0.01 All AHIs 57.9% 46.9% 0.02

Table 5—Univariate analysis: determinants of treatment success with oral appliance therapy

AHI > 5 on OA Therapy p

The ability to titrate OAs and allow progressive advance ments in mandibular protrusion increase the efficacy of OAs. Adjustable devices offer the advantage of being able to pro duce this advancement without having to recreate or reset the device. In a study of adults with sleep disordered breathing, Kato et al. found that OAs successfully mitigate pharyngeal collapsibility.[29] Their study utilized fixed devices at three dif ferent degrees of mandibular advancement, and the authors observed that OAs produced linear, dose-related improve ments in both the number and severity of desaturation events. Similarly, Almeida and colleagues found that the AHI re duction produced by OAs was proportionately related to the amount of mandibular protrusion.[26] Patients in this trial re ceived a Klearway adjustable OA, which was incrementally

advanced 0.5 mm each week until both clinical and polysomnographic improvements were noted. The authors concluded that progressive advancement of the mandible was associated with a linear reduction in the AHI.

Fixed OAs offer advantages over adjustable OAs. They are typically less expensive, do not require a period of adjustment, and offer treatment sooner than adjustable devices. However, despite these advantageous features, fixed OAs may be less efficacious. The degree of mandibular advancement and resultant expansion of the retroglossal space is a critical design feature of OAs and the premise for how they achieve a successful therapeutic response. When compared with inactive control devices that provided no mandibular advancement, mandibular advancement type OAs have been shown to improve both subjective and objective measures of daytime sleepiness.[30] In active control devices versus mandibular advancement OAs have also demonstrated that mandibular advancement was the critical factor for treating sleep disordered breathing events by polysomnography.[24]

There are limited data establishing the efficacy of fixed OAs in the treatment of OSA. In contrast, numerous studies have demonstrated the importance of titrating mandibular advancement to establish the therapeutic setting that optimizes treatment, similar to titration studies used to determine appropriate CPAP pressures.[20,21,31,32] Most comparisons of the efficacy between OA therapy and CPAP therapy have employed titrated CPAP and untitrated OAs. To better determine the comparable effectiveness of these two modalities, Aarab and colleagues compared the efficacy of OAs and CPAP, when both were titrated to the best effect.[21] In 64 subjects with mild to moderate OSA, there was no difference in improvement in AHI between the different therapies.

There are few reports demonstrating that fixed OAs are capable of fully treating OSA to a normal AHI in most patients.[11,34-36] One comparison study showed that a fixed OA was more effective than a tongue retaining device and soft palate lift.[33] While

				OR (95% CI) p
Age 40.5 ± 9.2	43.5 ± 8.9	< 0.001	ESS 12.9 ± 5.0	13.1 ± 5.3 0.78
BMI 28.2 ± 4.7	29.4 ± 4.2	0.004	AHI* 23.7 ± 19.7	35.8 ± 27.3 < 0.001
O_2 nadir* 84.7 ± 7.5	82.8 ± 8.1	0.001	% time SpO_2 < 90%* 3.5 ± 7.7	7.1 ± 12.2 0.004
Men 83.5%	91.6%	0.003	Hypertension 46.5%	43.5% 0.21
Adjustable OA 89.9%	80.5%	0.001	Positional** 66.7%	53.2% 0.07
Age 0.97 (0.94-0.99) 0.022			Female 2.1 (1.2-3.9) 0.01	
Body Mass Index 0.95 (0.90-0.99) 0.02			Apnea-Hypopnea Index 0.98 (0.98-0.99) < 0.001	
Adjustable Oral Appliance 2.1 (1.2-3.9) 0.01				

*Data from baseline diagnostic PSG. **Defined as > 50% decrease in AHI in lateral versus supine position.

Table 6—Multivariate analysis: likelihood of successful treatment (AHI < 5) with oral appliance therapy

a number of subjects wearing the fixed OA were adequately treated, treatment failures were observed in 40%. This was likely due to the high degree of OSA severity among the cohort (mean AHI 72 events/h). Similarly, Deane and coworkers compared a mandibular advancement splint to a tongue stabilizing device in a randomized crossover trial of patients with OSA. They observed that mandibular advancement performed better than tongue stabilization devices in symptomatic improvement, compliance, and patient preference. Both devices produced similar reductions in the AHI, with mandibular advancement splints performing slightly better. However, neither device achieved an AHI < 10 in the majority of subjects.[36] Vanderveken and colleagues compared a "boil and bite" thermoplastic fixed OA to a custom-made fixed OA. In a cohort of subjects with mild OSA, the custom-made device showed better efficacy (60% vs. 31%) and compliance.[35] While the benefits of fixed devices in the treatment of OSA have been demonstrated, many are compared to non-OAs or show high rates of incomplete resolution of obstructive events, particularly in those with more severe disease. It appears that while fixed OAs may be beneficial in some patients, adjustable devices perform better and are more likely to provide successful treatment of OSA.

In contrast, Marklund et al. evaluated the effects of fixed OAs in a large cohort of subjects with sleep disordered breathing.[13] In this trial, fixed devices were incrementally advanced in response to clinical observations. Among 630 included patients, 263 with OSA and 14 with simple snoring underwent repeat evaluation. The authors found that 72% of those who were re evaluated achieved an overall AHI < 10, with 54% having successful therapy in both the lateral and supine positions. Similar to our findings, they observed that fixed devices were less likely to be successful in those with higher baseline AHIs. In this study, only 34% of those with moderate or severe OSA achieved an AHI < 5 events/hour. Also similar to our findings, they found that OAs were more likely to be successful in women and those with a greater positional component to their OSA, lower baseline AHIs, and lower weight. This study found that fixed OAs performed better than our observations. This difference is likely the result of their incremental adjustments/advancements of the device to optimize clinical outcomes. However, this is similar to our protocol for incremental advancement of adjustable devices and highlights a clear benefit of adjustable OAs, as they can be titrated to effect without the need for repetitive refitting of the device.

Similar to CPAP, the inability of either fixed or adjustable OA to ablate events during the initial therapeutic period should not be automatically considered a treatment failure. Adjustable devices can be re-titrated over a different range of settings, and fixed devices can be repositioned for greater mandibular advancement. Patients at our center who are not adequately treated with a fixed OA are referred for an adjustable device or CPAP. As such, we may have underestimated the benefits of fixed devices.

Our study has several limitations. We conducted a retrospective study, which limits the validity of our findings. However, we included a relatively large cohort of patients, all of whom underwent level I polysomnography at both baseline and while

on therapy. The selection of a fixed versus titratable device was not standardized, mitigating potential selection bias that could occur if an established algorithm based on patient-specific variables was used. Our secondary endpoint used normalization of the ESS as a marker for successful therapy. The duration of therapy prior to repeat polysomnography was not standardized, and it is possible that those using adjustable devices had more time to improve symptoms. However, the primary aim of our study was to determine the ability of each type of OA to ablate obstructive respiratory events and successfully treat OSA, independent of any change in the ESS. Similarly, we did not include long-term data, and while we found that adjustable OAs were superior to fixed devices, it is unknown if this would be influenced by differences in long-term tolerance, acceptance rates, or adverse effects between these two types of devices. Finally, we did not include prefabricated, non-customized OAs in our cohort, as we do not utilize or recommend these devices in our center. While these devices are relatively inexpensive, accessible as an over-the-counter purchase, and do not require sleep dentistry consultation or adjustments, it is unlikely that they would provide adequate treatment of OSA and are not endorsed by the AASM.

Although we found that fixed OAs were less effective than adjustable OAs, there may be a role for these devices in the treatment of patients with mild sleep disordered breathing. Given the rapid increase in the recognized prevalence of sleep disordered breathing, less expensive devices that are easier to fabricate and use may offer treatment options for a greater number of patients. However, these devices still require customized fabrication and repeat polysomnography, which diminish these advantages. In addition, the high failure rate observed in this analysis, particularly in those with an AHI > 15 events/hour, raises significant concerns over the potential use of fixed OAs in the treatment of OSA. In our study, the majority of patients using fixed OAs had inadequately treated disease. Any potential savings with regard to time and money were lost, as the major ity of patients in this cohort required the subsequent use an adjustable OA or other form of therapy. In view of the detrimental effects of OSA on quality of life and health, only those treatment options that produce effective therapy should be utilized.

Abbreviations Did Not Print

AASM, American Academy of Sleep Medicine
AHI, apnea hypopnea index
BMI, body mass index
CPAP, continuous positive airway pressure
ESS, Epworth Sleepiness Scale
OA, oral appliance
OSA, obstructive sleep apnea

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Dental Sleep Medicine Recommendations:

Bare Minimum Requirements:

Education:

- The Dental Sleep Medicine provider should go through some ACCREDITED training to receive certification to perform dental sleep medicine. That training should cover:
  - Proper identification of a patient through qualified screening.
  - The correct way to obtain a Sleep Test
  - Obtaining Letters of Medical Necessity and Rx for Oral Appliance
  - Proper Records Collecting and Documentation for Legal and Insurance Billing
  - Appliance Selection and Design
  - Delivery of the Device and Bite Recapturing
  - Titration
  - Efficacy Testing
  - Recall
- If the Doctor is going to bill through Medical – training should also cover how to do this properly to not aggravate the Insurance world and close off dentists from accessing payments in the future.

Screening:

- Every patient in the chair should receive a basic screening for Sleep Apnea (STOP BANG and EPWORTH).
- This should be done annually as health continues to change over time.

Testing for OSA:

- A dentist is not allowed to order or administer a Home Sleep Test. Involvement of the PCP or a Telemedicine call to allow a qualified Physician to ascertain the risk factor and determine if a HST is called for. The qualified physician is preferably a board certified sleep physician.
- The dentist may deliver the device to the patient, but not to administer or read the test. This MUST be done by a Board Certified Sleep MD. All diagnosis and prescriptions for appliances MUST come from the MD.

Treatment:

- OSA treatment with Oral Appliance Therapy (OAT) is approved as a first-line treatment for Mild (AHI 5-15) or Moderate (AHI 16-30).
- If a patient is Severe (AHI >30) – Dentist should refer to qualified Board Certified Sleep MD for initial trial with CPAP, APAP, or BiPAP.
- OAT can be used for Severe patient as combo therapy CPAP and OAT if recommended by Sleep Physician
- OAT can also be used for Severe patient if they try and fail or refuse CPAP therapy – should be documented (CPAP Intolerance Affidavit)

- Oral Appliance Design should consider and maintain retention of teeth in current position
- Patient should be free of TMJ Pain and Dysfunction, Caries, or Active Periodontal Disease
- Patient should have requisite number of teeth to support an appliance (depends on appliance type and design)
- Bite Recapturing Appliance (AM Aligner) should be made, delivered, and patient instructed on use.

Informed Consent:

- Must have document in place that covers risks and limitations to Oral Appliance Therapy.

Efficacy Testing and Titration

- How a patient is doing with a device is partially how they feel but can also be measured by follow up Efficacy Testing. Dialing in the device settings and re-testing to see if device is efficacious should be performed and documented

Communication with PCP and Long Term Follow Up

- Obtaining the patient's PCP and sending correspondence to the Physician is recommended. Should include:
    - Chief Complaint
    - Review of Systems
    - Screening Results
    - Review of Dental Health
    - Any Diagnosis from HST
    - Treatment Rendered
    - Follow Up Test Results
    - Plan going forward

MINUTES
NC STATE BOARD OF DENTAL EXAMINERS
BOARD MEETING
Morrisville, North Carolina
June 7-10, 2018

THURSDAY, JUNE 7, 2018

The North Carolina State Board of Dental Examiners convened at 6:00 p.m., Thursday, June 7, 2018 at the Board's offices in Morrisville for the purposes of conducting a public Rule Making Hearing involving proposed rule changes to 21 NCAC 16P .0105 and 21 NCAC 16R .0201. Dr. Merlin Young presided over the hearing and Mr. Douglas Brocker appeared on behalf of the Board as legal counsel. All members of the Board were present with the exception of Dr. Litaker. The public hearing concluded at 6:45 p.m., at which time Dr. Young called the business meeting to order.

I. CALL TO ORDER & ESTABLISHMENT OF QUORUM — Dr. Young

A. Call to Order

Dr. Merlin Young, President of the Board, called the business meeting to order at 6:45 p.m., Thursday, June 7, 2018, at the Board's offices in Morrisville, North Carolina. Dr. Young read the following statement regarding conflicts of interest as a reminder to all Board members:

In accordance with General Statute 138A-15(e), it is the duty of every Board member to avoid both conflicts of interest and appearances of conflict.

Does any Board member have any known conflict of interest or appearance of conflict with respect to any matters coming before the Board this weekend?

If so, please identify the conflict or appearance of conflict and refrain from any undue participation in the particular matter involved.

If, as agenda items are discussed, any Board member learns of a conflict or appearance of a conflict, he or she should notify the Chair and take appropriate action to recuse him or herself.

B. Roll Call

All members of the Board were present except Dr. William Litaker, Jr.. The members included Dr. Merlin W. Young, Dr. Millard Wester, III, Dr. Clifford O. Feingold, Dr. Catherine Watkins, Dr. Kenneth M. Sadler, Ms. Nancy St. Onge, R.D.H. and Mr. Dominic Totman, Esq. Mr. Bobby D. White, Chief Executive Officer, Ms. Casie S. Goode, Deputy Operations Officer, and Mr. Douglas Brocker Legal Counsel for the Board, was also present.

C. Declaration of Quorum

With seven members of the Board present, Dr. Young declared a quorum for the purposes of conducting the business of the Board.

At 6:45 p.m., Mr. Sean Murphy, JD and Dr. James Martin requested permission to address the Board regarding take home orthodontics. The presentation concluded at 7:00 p.m. at which time the Board remained in open session to discuss Board business.

II. APPROVAL & ORDER OF AGENDA — Dr. Young

Dr. Wester moved, which was seconded by Ms. St. Onge, to accept the agenda as presented and to allow the President of the Board to determine the order of business. The motion passed by general consent.

III. APPROVAL OF MINUTES

A. Minutes of May 16-17, 2018 [Item #1] — Dr. Young

Following a review of the May 16-17, 2018 Minutes, Ms. St. Onge moved to approve the Minutes as amended. Dr. Watkins seconded the motion, which passed by general consent.

IV. REPORT FROM PRESIDENT — Dr. Young

[No Report]

V. REPORT FROM CHIEF EXECUTIVE OFFICER — Mr. White

A. Financial Report (May) [Item #2]

Following a review of the February Financial Report, Dr. Wester moved to accept the report for informational purposes. Dr. Sadler seconded the motion, which passed by general consent.

B. Personnel Matters

[None]

C. Miscellaneous

- Legislative Update

HB 689 – An Act Directing the Program Evaluation Division to Study the Average Time Between Application for Licensure and Granting of Licensure for Each Occupational Licensing Board of North Carolina. This Bill, in part, requires the Program Evaluation Division to report the results of the study to the chairs of the Joint Legislative Program Evaluation Oversight Committee on or before May 1, 2018.

HB 998 – Representative Bert Jones, DDS requested the Board's opinion regarding new legislation that he would like to introduce which proposes to improve access to dental care in North Carolina rural areas by amending N.C.G.S. §90-36. Dr. Sadler made a motion for Mr. White to contact Representative Jones to relay the Board's opinion that the statute could accomplish what he proposes if amended to allow those licensed by credentials to practice in North Carolina and their home state,

which would require amending the Dental Practice Act. Dr. Feingold seconded the motion which passed by general consent.

- Ballot Counting
  Mr. White reported that this year's ballot to elect the upcoming two open Dental Board Member seats was disseminated with the incorrect return address. The accounting firm contracted to receive and monitor the election process merged with another firm and moved locations without informing the Board of their new address. However, the firm's mail is being forwarded to its current address. Mr. White contacted each candidate to inform him about the situation and request permission to canvass ballots on a later date to allow for additional time for the United States Postal Service to forward mail. All three candidates agreed and ballot counting will commence on Wednesday, June 13, 2018, at 12:00 noon, which comports with the statutory requirements.

VI. REPORTS OF STANDING COMMITTEES

A. Executive Committee
[No Report]

B. Finance Committee
[No Report]

C. Sedation/General Anesthesia Committee
Dr. Sadler reported that the sedation advisory committee will meet, on Friday, July 27, 2018 at the Grandover Resort in Greensboro beginning at 8:00 am. The committee will work to generate back-up questions for the purposes of creating alternative versions of the written examinations.

VII. OLD BUSINESS

A. Prudential Account **[Item #3] Mr. White**
When an employee leaves employment at the Dental Board and has unvested funds in the defined contribution retirement plan, the employee forfeits those funds thereby creating a forfeiture account. Mr. White informed the Board that a forfeiture account in the amount of $43,000 currently exists. This amount has accrued since the inception of the Board's current retirement plan, approximately 30 years ago. Dr. Wester made a motion to apply the current forfeiture amount toward the amount of Board contributions matched by the staff employees until the account balance is zero. Dr. Feingold seconded the motion which passed by general consent.

B. Bylaws **[Item #4] Dr. Feingold**
Mr. Totman made a motion to approve the revised bylaws after correcting typographical errors. Dr. Wester seconded the motion, which passed by general consent.

C. Informed Consent **[Item #5] Mr. Brocker**

Dr. Wester made a motion to approve rules pertaining to informed consent for publication and to approve the interpretive statement with amendments. Dr. Sadler seconded the motion. The motion passed.

The Board recessed its meeting for dinner at 7:30 p.m. and resumed to continue with business at 8:00 p.m.

VIII. NEW BUSINESS

A. Approve Radiology Course **[Item #6]** **Ms. Goode**

Ms. Akilah Baptist submitted a radiology course on behalf of Dental Assistant Solutions, LLC for approval. Following a review of the course, the Board instructed staff to request additional information to include the following: a revised course content correcting typographical errors, the submission of sample radiograph requirements, the submission of the complete post-test and more detailed information about the Charlotte Dental Assistant School where Ms. Baptist is an instructor.

B. Approve Radiology Course **[Item #7]** **Ms. Goode**

Brightwood College submitted a dental radiology course and radiology course instructors for approval. Upon review of the documentation submitted, Dr. Wester made a motion to approve the course and to approve Shannon Cogen-Knowles and Genise Kelley as the course instructors. Dr. Feingold seconded the motion. The motion passed by general consent.

C. Dental Sleep Therapy **[Item #8]** **Mr. White**

Dr. Ashley Collins requested clarification from the Board regarding its position regarding dental sleep therapy. Specifically, Dr. Collins asked if the use of home sleep tests by dentists to determine the efficacy of dental appliances after a proper medical diagnosis of sleep apnea is permitted. Dr. Feingold made a motion to allow dentists to utilize this testing as a mechanism to follow up with a patient regarding the success of the sleep appliance. Dr. Watkins seconded the motion, which passed by general consent.

IX. LICENSURE MATTERS

A. Approval of Licenses/Permits/Reinstatements **[Item #9]** **Ms. Goode**

Dr. Wester moved to approve all provisional licenses, licenses issued by credentials, intern permits, sedation permits, CE waivers and reinstatements issued since the last meeting. The motion was seconded by Dr. Feingold and passed by general consent.

B. Examinations

[No Report]

X. REPORT FROM LEGAL COUNSEL **Mr. Brocker**

[No Report]

XI. INVESTIGATIVE MATTERS

A. Investigative Statistics (May) **[Item #10]** **Dr. Wester**

The Board reviewed investigative statistics for the month of May. The statistics were accepted for informational purposes.

B. Hearing Panel Decisions
[None]

C. Settlement Conferences
[None]

The Board recessed its meeting for the evening at 9:50 p.m.

FRIDAY, JUNE 8, 2018

The North Carolina State Board of Dental Examiners reconvened at 8:00 a.m., Friday, June 8, 2018, at the Board's offices in Morrisville, North Carolina in order to complete its consideration of Board business and to conduct a formal hearing. Dr. Young, President of the Board, called the meeting to order. All members of the Board were present except for Dr. Litaker. Also present were Mr. Bobby D. White, Chief Executive Officer, Ms. Casie Goode, Deputy Operations Officer, Betty Sines, Investigations Coordinator, Mr. Line Dempsey, Senior Investigator.

At 8:00 a.m., the Board met with Ms. Jennilee Richardson and Ms. Sandy Newall of Bernard Robinson & Company, L.L.P. Ms. Richardson and Ms. Newall presented the results of the Board's financial audit for the year ending December 31, 2017. It was the auditor's opinion that the financial statements of the Board fairly and accurately presented the Board's financial position and cash flow for 2017. Ms. Richardson and Ms. Newall left the meeting at 8:30 a.m. at which time the Board remained in open session to conduct a formal hearing involving Dr. Carlos J. Privette. Mr. Douglas Brocker and Ms. Whitney Waldenberg served as legal counsel for the Investigative Panel and Mr. Fred Morelock served as legal counsel for the Hearing Panel. Ms. Carrie Meigs and Mr. Justin May served as legal counsel for Dr. Privette. A court reporter was present to transcribe the proceedings. The hearing recessed for the day at 6:30 p.m..

SATURDAY, JUNE 9, 2018

The North Carolina State Board of Dental Examiners reconvened at 8:00 a.m., Saturday, June 9, 2018, at the Board's offices in Morrisville, North Carolina in order to continue the formal hearing involving Dr. Carlos Privette. Dr. Young, President of the Board, called the meeting to order. All members of the Board were present. Also present were Mr. Bobby D. White, Chief Executive Officer, Ms. Casie Goode, Deputy Operations Officer, Betty Sines, Investigations Coordinator, Mr. Line Dempsey, Senior Investigator. Douglas Brocker and Ms. Whitney Waldenberg served as legal counsel for the Investigative Panel and Mr. Fred Morelock served as legal counsel for the Hearing Panel. Ms. Carrie Meigs and Mr. Justin May served as legal counsel for Dr. Privette. A court reporter was present to transcribe the proceedings. The hearing recessed for the day at 7:45 p.m.

XII. NEXT MEETING

The Board's next regularly scheduled meeting will begin on Thursday, July 12, 2018, and will be held at the Board's offices in Morrisville, North Carolina, for the purposes of conducting a public Rule Making Hearing, to consider routine business and to reconvene the formal hearing involving Dr. Carlos Privette.

XIII. ADJOURNMENT

There being no further business, Dr. Wester made a motion to adjourn the meeting. Dr. Litaker seconded the motion, which passed by general consent. The meeting adjourned at 7:50 p.m.

Reported by: Casie S. Goode

Casie S. Goode
Deputy Operations Officer

Date of Approval: 9-7/7/18

March 5, 2021

Dear Dental Board:

On behalf of the undersigned organizations, we are writing to express our concerns regarding a recently published position issued by the American Academy of Dental Sleep Medicine (AADSM). This statement encourages the use of home sleep apnea tests by dentists for the diagnosis of obstructive sleep apnea (OSA). We argue that ordering, administering, and interpreting home sleep apnea tests is outside the scope of practice for dentists, and herein are requesting that your board protect both patients and dentists in your state by adopting a policy to clarify this fact.

The AADSM position states that it is within the scope of practice for dentists to identify patients who are at risk for OSA and then order or administer diagnostic home sleep apnea tests. Furthermore, since most state dental boards have no policy addressing this issue, the AADSM position indicates that this "silence" gives dentists tacit permission to provide this medical service, which is a dangerous interpretation. This position statement is in direct conflict with that of the American Academy of Sleep Medicine (AASM) and a policy of the American Medical Association (AMA), both of which emphasize that a home sleep apnea test is a medical assessment that must be ordered by a medical provider and, moreover, must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician. The AADSM position also is not supported by the policy statement of the American Dental Association (ADA) or by a white paper from the American Association of Orthodontists (AAO).

An evidence-based AASM clinical practice guideline indicates that the decision to order a home sleep apnea test should be made by a medical provider only after reviewing the patient's medical history and conducting a face-to-face examination. The medical evaluation should include a thorough sleep history and a physical examination of the respiratory, cardiovascular, and neurologic systems. The sleep history is important because many patients have more than one sleep disorder or present with atypical sleep apnea symptoms. The medical provider also should identify chronic diseases and conditions that are associated with increased risk for OSA, such as obesity, hypertension, stroke, and congestive heart failure. An evaluation by a medical provider also is necessary to rule out conditions that place the patient at increased risk of central sleep apnea and other forms of non-obstructive sleep-disordered breathing, which typical home sleep apnea tests are insufficient to detect. While dentists can use questionnaires and examine the oral structures to screen patients for symptoms of OSA, they are untrained in conducting the comprehensive medical evaluation needed to assess OSA risk.

Based on this medical evaluation, the medical provider can determine if diagnostic testing is indicated to confirm a clinical suspicion of OSA. The selection of the appropriate diagnostic test — either in-lab polysomnography or a home sleep apnea test — is critical. Because a home sleep apnea test is less sensitive than polysomnography, it is more likely to produce false negative results when ordered inappropriately. The resulting misdiagnosis can lead to significant harm for the patient. Because dentists lack the required medical education and training needed to order, administer, and interpret diagnostic tests for OSA, implementing the AADSM position could jeopardize the quality of patient care.

In addition, the AADSM position does not align with the current national and local coverage determination policies of the Centers for Medicare & Medicaid Services (CMS) and the policies of private insurers for reimbursement of home sleep apnea tests and oral appliances for OSA.

These medical insurance policies also require a comprehensive clinical evaluation by a medical provider to determine that the test or treatment is reasonable and necessary. Patients will have to pay full price for the uncovered services provided by a dentist, dramatically increasing their out-of-pocket costs.

It is for the aforementioned reasons that our organizations urge your board to adopt a policy clarifying that ordering and administering a home sleep apnea test is outside the scope of practice for dentists in your state. We encourage you to use as a model the policy adopted by the Georgia Board of Dentistry, "Prescribing and Fabrication of Sleep Apnea Appliances":

> *Depending upon the diagnosis of the type and severity, one possible treatment option for obstructive apnea is the use of oral appliances. The design, fitting and use of oral appliances and the maintenance of oral health related to the appliance falls within the scope of practice of dentistry. The continuing evaluation of a person's sleep apnea, the effect of the oral appliance on the apnea, and the need for, and type of, alternative treatment do not fall within the scope of dentistry. Therefore, the prescribing of sleep apnea appliance does not fall within the scope of the practice of dentistry. It is the position of the Board that a dentist may not order a sleep study. Home sleep studies should only be ordered and interpreted by a licensed physician. Therefore, only under the orders of a physician should a dentist fabricate a sleep apnea appliance for the designated patient and conduct only those tasks permitted under O.C.G.A. Title 43, Chapter 11. (adopted 04/01/16)*

We thank you for your consideration of our concerns. For any additional information or to discuss this issue, please contact AASM Executive Director Steve Van Hout at (630) 737-9700.

Sincerely,

Kannan Ramar, MD, FAASM
American Academy of Sleep Medicine
President

James C. Stevens, MD, FAAN
American Academy of Neurology
President

Carol R. Bradford, MD, MS
American Academy of Otolaryngology-Head and Neck Surgery
President

Juan C. Celedón, MD, DrPH, ATSF
American Thoracic Society
President

NORTH CAROLINA STATE BOARD OF DENTAL EXAMINERS

RECEIVED
APR 08 2021
By AMA

March 25, 2021

emailed TO Dr. Hardesty

Dr. Stan Hardesty
President
North Carolina Dental Society
1600 Evans Road
Cary, NC 27513

Dr. Hardesty:

The North Carolina Dental Society (NCDS) requested that the North Carolina State Board of Dental Examiners (NCSBDE) review the Board's policy statement on the prescribing of Home Sleep Apnea Tests (HSATs) in light of certain modifications the NCDS has made to its statement on "The Role of North Carolina Dentists in Managing Sleep Related Breathing Disorders." Previously, the NCSBDE issued an opinion stating that NC dentists should not prescribe HSATs for patients as these devices were primarily for diagnostic purposes and sleep related breathing disorders required a medical rather than a dental diagnosis. However, the NCSBDE went on to say that once a sleep related breathing disorder (SRBD), such as sleep apnea, was diagnosed by a medical doctor and a dentist had constructed an oral appliance to treat the SRBD pursuant to the physician's order, the dentist could prescribe and utilize a HSAT to determine if the appliance was working properly and effectively.

Considering the modifications to the NCDS policy, the new issue put before the NCSBDE is more specific: May a dentist prescribe an HSAT when the result of such a test is used only for screening and not for diagnostic purposes? To answer this question the Board appointed a subcommittee that interviewed practicing dentists, consulted with dental sleep medicine experts, and reviewed hundreds of pages of pertinent scholarly articles. At the outset it must be said that there appears to be broad agreement among various medical and dental groups interested in sleep apnea that the diagnosis of such a condition should only be made by a qualified medical doctor. Likewise, there seems to be broad agreement that dentists are quite capable of screening patients for sleep apnea if such screening does not include diagnosis of the disease. However, there does not appear to be a consensus on the use of HSAT's as a screening tool.

The lack of consensus and the evolving nature of the field of dental sleep medicine engendered vigorous discussion by the Board on this issue. In the end, however, the Board decided not to change its previous opinion and concluded that North Carolina dentists should not prescribe or utilize HSATs as screening

devices prior to the diagnosis of a SRBD by a physician. The Board reached this conclusion based on its belief that current examination methods and screening procedures available to dentists provide sufficient data for dentists to make recommendations for patients who may need to seek a medical diagnosis of sleep apnea.

Please note this is an opinion of the Board. As such it is not enforceable as either a statute or rule and should serve only to provide guidance as to how the Board likely would rule should a case based on similar facts and issues come before it. The NCSBDE reserves the right to modify, change, or revise this opinion based on additional information that becomes available.

Thank you for the opportunity to review this issue and for all that you continue to do for the dental community in our state.

Best regards,

Millard "Buddy" Wester
President

cc: Dr. Alec Parker
Executive Director, NCDS

North Carolina State Board of Dental Examiners

E-Forum

Volume 5, Issue 1 January-March 2018

Filing Period Now Open

Those interested in running for Board positions may do so by filing an appropriate petition with the Board. There is no standard petition form, but for dentists the petition must be signed by no less than 10 dentists who are licensed to practice in North Carolina and who are residing or practicing in this state. Since signatures are often difficult to read and the identity of those signing the petition must be verified, candidates should ask signatories to include their license number and print their names as well. To be eligible to run for office, at the time of nomination and election, a dentist must be licensed and actually engaged in the practice of dentistry in North Carolina. Petitions must be received in the Board's office no later than midnight May 20, 2018. Two dentist positions will be eligible for election this year.

Free Continuing Education

The Dental Board is providing two **free** continuing education opportunities during 2018. The first will be offered at Kingston Plantation in Myrtle Beach, SC on May 17th from 5:30 to 6:30 p.m. in conjunction with the annual meeting of the North Carolina Dental Society. Topics to be covered include patient records, informed consent, and a review of the investigation and disciplinary process.

On December 7th at 10 a.m. at its meeting in Asheville, NC, the Board will offer a one-hour opioid prescribing course that will fulfill the CE requirements as mandated by state law for those who have a DEA license and prescribe opioids. The place where the course will be offered has not yet been determined, but will be posted under the "What's New" tab on the Board's website as soon as arrangements are finalized.

Minutes and Agendas

The Minutes and Agendas of Board meetings have always been available to the public by making a simple inquiry. Now, even a simple inquiry is not required for the most recent Minutes and Agendas of the Board. These are now posted under the "Meeting Announcements" tab on the Board's website: http://www.ncdentalboard.org/meeting_announcements.htm.

Inside this issue:

Upcoming Board Meetings

Unless otherwise noted, all meetings begin at 8:30 a.m. and occur at the Board's Office, 2000 Perimeter Park Dr., Suite 160, Morrisville, NC 27560. All meetings are open to the public. However, certain portions of the meetings may be closed when necessary and in compliance with North Carolina's Open Meetings law.

May 16-17	Sunset Beach, NC Sea Trail Conv.Ctr.
June 8-9	Morrisville, NC Board Office
July 13-14	Morrisville, NC Board Office
August 10-11	Morrisville, NC Board Office
September 7-8	Morrisville, NC Board Office
October 12-13	Morrisville, NC Board Office
November 9-10	Morrisville, NC Board Office
December 7-8	Asheville, NC

Board Responds to Inquiries about ADA CDT Code D0411 and Screening Patients for Sleep Apnea

ADA CDT Code D0411

The new American Dental Association CDT Code D0411 became effective on January 1, 2018. The code concerns a finger stick capillary HbA1c glucose test procedure. The test is a measure of the amount of glucose attached to red blood cells and directly relates to the average blood glucose levels over a certain time frame. The test can be utilized by physicians as part of a potential diagnosis of diabetes. Because only a physician can diagnose diabetes, dentists should not administer an HbA1c test to diagnose or pre-screen for diabetes. Consequently, ADA CDT Code D0411 cannot be billed in North Carolina for an HbA1c test administered to pre-screen or diagnose diabetes.

It is within the proper scope of the practice of dentistry, however, for a dentist with appropriate training, knowledge, and experience to administer the HbA1c test and use the test results to make decisions about potential dental treatment. As noted in the ADA guide on CDT Code D0411, a dentist also would need to comply with all applicable federal and state regulatory requirements to offer such tests, including the federal regulation – Clinical Laboratory Improvement Amendments of 1988 (CLIA). ADA CDT Code D0411 may be billed if a dentist properly administers the HbA1c test to determine appropriate dental treatment. If a dentist receives the results of an HbA1c test properly administered to determine dental treatment, which results along with other known risk factors also raise concerns about potential diabetes or pre-diabetes, it is appropriate for the dentist to make a referral to a physician for a potential diagnosis and treatment.

Sleep Apnea

The Board responded to an inquiry about whether a dentist in North Carolina should be allowed to screen patients for Obstructive Sleep Apnea (OSA) and to facilitate a diagnosis through the dispensing of an acceptable home sleep test unit to a dental patient. In the Dental Board's opinion, being involved in diagnosing OSA, including dispensing home sleep tests, would fall outside the scope of the practice of dentistry and would violate the Board's statutes and regulations.

However, a dentist can perform initial or preliminary screening for OSA, including identifying certain risk factors, and make referrals to other appropriate medical providers to diagnose and treat this potential medical condition. Determining whether to utilize home sleep tests as part of a potential diagnosis should be done by appropriate medical provider to whom the patient is referred. If a physician diagnoses a patient with OSA, a properly trained dentist may work with the physician to fabricate a dental appliance for the patient to treat the condition.

NOTE: The Board is providing the answers to these inquiries for guidance only and has reached these conclusions based only on the facts supplied. Answers to inquiries are not part of the Dental Practice Act and its attendant rules.

New Requirements for Health Information Exchange (HIE)

Contained within the 2017 Appropriations Act (SB257, S.L. 2017-57. pp.147-151) you will find new requirements to provide patient data to the HIE for services rendered. The law applies to those who provide services to Medicaid recipients and "other State-funded health care program beneficiaries and paid for with Medicaid or other State-funded health care funds." This means, in addition to Medicaid recipients, you must report all treatment rendered by you to any person who is insured through HealthChoice, or any division of the state health care system. If you treat any patient who is covered by any of these entities you will be required to establish a computer connection with the HIE network and share patient data with the HIE at least twice per day. This reporting requirement goes into effect for dentists on June 1, 2019.

The law also outlines how practitioners are to deal with HIPPA regulations, provides for an extension of time to establish the computer connection beyond the June 1, 2019 deadline (not to exceed June 1, 2020), and provides a means for individuals to opt out of sharing their protected health information. Below is a link to the Bill. Pertinent information starts on p. 147.

https://www.ncga.state.nc.us/Sessions/2017/Bills/Senate/PDF/S257v9.pdf

Employee Classification

While we are on the subject of new requirements, you may have noticed one on your renewal application. Senate Bill 407 (S.L. 2017-203) went into full effect December 31, 2017 and mandates that all occupational licensing agencies require all applicants and licensees to certify that they have read and understand the following statement:

Public Notice Statement required by N.C. Gen. Stat. § 143-764(a)(5), Effective December 31, 2017

Any worker who is defined as an employee by N.C. Gen. Stat. §§ 95-25.2(4)(NC Department Of Labor), 143-762(a)(3) (Employee Fair Classification Act), 96-1(b)(10)(Employment Security Act), 97-2(2)(Workers' Compensation Act), or 105 -163.1(4)(Withholding; Estimated Income Tax for Individuals) shall be treated as an employee unless the individual is an independent contractor. Any employee who believes that the employee has been misclassified as an independent contractor by the employee's employer may report the suspected misclassification to the Employee Classification Section within the North Carolina Industrial Commission. Employee Classification Section North Carolina Industrial Commission 1233 Mail Service Center Raleigh, NC 27699-1233 Telephone: (919) 807-2582 Fax: (919)715-0282 Email: emp.classification@ic.nc.gov

Employee misclassification is defined as avoiding tax liabilities and other obligations imposed by Chapter 95, 96, 97, 105, or 143 of the North Carolina General Statutes by misclassifying an employee as an independent contractor. [N.C. Gen. Stat. § 143-762(5)]

In addition, applicants and licensees must disclose if they have been investigated for employee misclassification anytime during the past three years. Failure to comply with the certification and disclosure requirements means the licensing board shall deny the license, permit, or application.

The public policy behind this new law is to serve notice to all licensed professionals that the Department of Revenue is serious about catching those who avoid tax liabilities by misclassifying employees as independent contractors.

New Rules

Adopted Rules

New rules were recently approved by the NC Rules Review Commission dealing with delegable duties for Dental Hygienists [21 NCAC 16G .0101 et seq.] and Dental Assistants [21 NCAC 16H .0101 et seq.] Please note two important points as you review these rules.

First, a new change in format may give the appearance that more duties were added to Dental Assistants while others were eliminated for Dental Hygienists. This is not true. The change in format simply lists all delegable duties for Dental Assistants in one place [21 NCAC 16H. 0203]. The new hygiene rule then states that hygienists can perform all functions of a Dental Assistant PLUS the duties specifically listed in 21 NCAC 16G .0101.

Second, the application of Silver Diamine Fluoride is specifically listed as a delegable function for a dental hygienist.

Click here for a copy of the new rules on delegable duties:
[M:Rules\Delegable Duties Revision 2018]

*The Board has approved, but not yet published, a proposed amendment to 21 NCAC 16H .0203(a)(1) that would allow the making of digital images by a dental assistant to be a delegable function. As with any delegable function, making digital images by a dental assistant or hygienist requires the direct on-site supervision of a dentist when digital images are made. Currently, the rule addresses the making of impressions, but does not speak to digital images.

Proposed Rules

Proposed amendments to the sedation rules would create an "Itinerant Moderate Sedation Permit" and an "Itinerant Moderate Pediatric Conscious Sedation Permit" for those holding these permits who would like to travel to other offices and provide sedation services. These new itinerant permits are intended to parallel the "Itinerant General Anesthesia Permit" which is currently available for those holding a general anesthesia permit. Comments on these proposed rule changes may be submitted through April 16, 2018.

Click here for a copy of the proposed rules on Itinerant Moderate and Pediatric Permits:
[M:Rules\Itinerant Mod and Ped Permits 2018]

By the Numbers

Sedation and General Anesthesia Permits

General anesthesia	190
Moderate pediatric	107
Moderate	220
Minimal	169

Dentists

Licensed by NC	6,183
Licensed and Living in NC	5,497
Licensed and Active in NC	5,156
Licensed and Active in any state	5,783

Dental Hygienists

Licensed by NC	8,075
Licensed and Living in NC	7,087
Licensed and Active	6,027
Licensed and Active in any State	6,985

Top 15 Counties for Dentists (*includes retired working part-time*)

Wake	906
Mecklenburg	806
Guilford	325
Orange	245
Durham	243
Buncombe	221
Forsyth	219
New Hanover	201
Cumberland	167
Pitt	130
Iredell	100
Cabarrus	98
Moore	97
Union	94
Catawba	90
	3,942

North Carolina State Board of Dental Examiners

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The purpose of the North Carolina State Board of Dental Examiners is to ensure that the dental profession merit and receive the confidence of the public and that only qualified persons be permitted to practice dentistry and dental hygiene in the state of North Carolina.

Disciplinary Actions

Recent disciplinary actions are reported on the Board's website under the "Disciplinary Action" tab. Actions involving revoked or suspended licenses remain posted until the revocation or suspension is lifted. **All** past disciplinary actions can be accessed by searching by name or license number under the "License Verification" tab.

http://www.ncdentalboard.org/license_verification.htm

Current Board Members (as of August 1, 2017)

Current Board Members	Term Expires	Hometown
Merlin W. Young, DDS (President)	2020	Wendell, NC
William M. Litaker, Jr. DDS (Past Pres.)	2019	Hickory, NC
Millard "Buddy" Wester, III (Sec/Treas.)*	2018	Henderson, NC
Clifford O. Feingold, DDS	2018	Asheville, NC
Kenneth M. Sadler, DDS*	2019	Winston-Salem, NC
Catherine Watkins, DDS *	2020	Winston-Salem, NC
Nancy St. Onge, RDH*	2020	Apex, NC
Dominic Totman, Esq. (Consumer)*	2018	Raleigh, NC

*Eligible for a second term

AASM American Academy of SLEEP MEDICINE™

Previous Next

AASM releases position statement on home sleep apnea testing

DARIEN, IL – A new position statement published by the American Academy of Sleep Medicine (AASM) describes the appropriate clinical use of a home sleep apnea test (HSAT).

An HSAT is a medical assessment that can be ordered by a physician for the diagnosis of obstructive sleep apnea (OSA) in select adults. In the position statement the term "physician" refers to a medical provider who is licensed to practice medicine.

Properly diagnosing and treating OSA in adults is of crucial health importance. When left untreated, OSA is a potentially lethal disease that can increase the risk of serious health complications such as hypertension, heart failure, type 2 diabetes, and stroke.

"A home sleep apnea test provides valuable information for the diagnostic assessment of certain patients with suspected obstructive sleep apnea," said AASM President Dr. Ilene Rosen. "However, the at-home sleep apnea test is only one component of a comprehensive sleep evaluation, and it is important for a board-certified sleep medicine physician to be involved in reviewing and interpreting the raw data from the device."

The statement, which is published in the Oct. 15 issue of the Journal of Clinical Sleep Medicine, comprises the following positions:

- Only a physician can diagnose medical conditions such as OSA and primary snoring.

- The need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a physician, either in person or via telemedicine.
- An HSAT is a medical assessment that must be ordered by a physician to diagnose OSA or evaluate treatment efficacy.
- A sleep apnea home test should not be used for general screening of asymptomatic populations.
- Diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety.
- The raw data from the home sleep apnea test device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

Common symptoms of OSA include loud snoring, choking or gasping during sleep, and daytime sleepiness. According to a clinical practice guideline published earlier in the year by the AASM, polysomnography is the standard diagnostic test for the diagnosis of OSA in adult patients in whom there is a concern for OSA based on a comprehensive sleep evaluation. However, a home sleep apnea test with a technically adequate device can be used for the diagnosis of OSA in uncomplicated adult patients presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.

Also published in the Oct. 15 issue of the Journal of Clinical Sleep Medicine is an AASM position paper stating that the use of an HSAT is not recommended for the diagnosis of OSA in children. An objective evaluation of the available literature found that an HSAT may be technically feasible in carefully controlled conditions when electrodes are placed on a child by a trained clinician. However, there is insufficient evidence to support the efficacy of an HSAT when used at home to assess a child's breathing during sleep.

For a copy of the statement, "Clinical Use of a Home Sleep Apnea Test: An American Academy of Sleep Medicine Position Statement," or the paper, "American Academy of Sleep Medicine Position Paper for the Use of a Home Sleep Apnea Test for the Diagnosis of OSA in Children," or to arrange an interview with an AASM spokesperson, please contact AASM Communications Coordinator Corinne Lederhouse at 630-737-9700, ext. 9366, or clederhouse@aasm.org.

The monthly, peer-reviewed Journal of Clinical Sleep Medicine is the official publication of the American Academy of Sleep Medicine, a professional membership society that improves sleep health and promotes high quality, patient-centered care through advocacy, education, strategic research, and practice standards. The AASM encourages patients to talk to their doctor about sleep problems and visit www.sleepeducation.org for more information about sleep, including a searchable directory of AASM-accredited sleep centers.

October 13th, 2017 | Press Releases

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January 18th, 2022

AASM announces new Specialty Practice Accreditation program

January 10th, 2022

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December 28th, 2021

Privacy Details

pii: jc-17-00478 http://dx.doi.org/10.5664/jcsm.6774

JCSM
Journal of Clinical
Sleep Medicine

SPECIAL ARTICLES

Clinical Use of a Home Sleep Apnea Test: An American Academy of Sleep Medicine Position Statement

Ilene M. Rosen, MD, MS[1]; Douglas B. Kirsch, MD[2]; Ronald D. Chervin, MD, MS[3]; Kelly A. Carden, MD[4]; Kannan Ramar, MD[5]; R. Nisha Aurora, MD[6]; David A. Kristo, MD[7]; Raman K. Malhotra, MD[8,9]; Jennifer L. Martin, PhD[10]; Eric J. Olson, MD[5]; Carol L. Rosen, MD[11]; James A. Rowley, MD[12]; American Academy of Sleep Medicine Board of Directors

[1]Division of Sleep Medicine, Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania; [2]Carolinas Healthcare Medical Group Sleep Services, Charlotte, North Carolina; [3]University of Michigan Sleep Disorders Center, University of Michigan, Ann Arbor, Michigan; [4]Saint Thomas Medical Partners - Sleep Specialists, Nashville, Tennessee; [5]Division of Pulmonary/Sleep/Critical Care, Mayo Clinic, Rochester, Minnesota; [6]Johns Hopkins University, School of Medicine, Baltimore, Maryland; [7]University of Pittsburgh, Pittsburgh, Pennsylvania; [8]SLUCare Sleep Disorders Center; [9]Department of Neurology, Saint Louis University, St. Louis, Missouri; [10]Veteran Affairs Greater Los Angeles Health System, North Hills, California and David Geffen School of Medicine at the University of California, Los Angeles, Los Angeles, California; [11]Department of Pediatrics, Case Western Reserve University, University Hospitals - Cleveland Medical Center, Cleveland, Ohio; [12]Wayne State University, Detroit, Michigan

The diagnosis and effective treatment of obstructive sleep apnea (OSA) in adults is an urgent health priority. It is the position of the American Academy of Sleep Medicine (AASM) that only a physician can diagnose medical conditions such as OSA and primary snoring. Throughout this statement, the term "physician" refers to a medical provider who is licensed to practice medicine. A home sleep apnea test (HSAT) is an alternative to polysomnography for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA. It is also the position of the AASM that: the need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a physician, either in person or via telemedicine; an HSAT is a medical assessment that must be ordered by a physician to diagnose OSA or evaluate treatment efficacy; an HSAT should not be used for general screening of asymptomatic populations; diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety; and the raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

Keywords: home sleep apnea test, HSAT, obstructive sleep apnea, OSA

Citation: Rosen IM, Kirsch DB, Chervin RD, Carden KA, Ramar K, Aurora RN, Kristo DA, Malhotra RK, Martin JL, Olson EJ, Rosen CL, Rowley JA, American Academy of Sleep Medicine Board of Directors. Clinical use of a home sleep apnea test: an American Academy of Sleep Medicine position statement. *J Clin Sleep Med.* 2017;13(10):1205–1207.

INTRODUCTION

The American Academy of Sleep Medicine (AASM) is the leading professional society dedicated to promotion of sleep health. The AASM improves sleep health and fosters high-quality, patient-centered care through advocacy, education, strategic research, and practice standards. The AASM endeavors to advance sleep health policy that improves the health and well-being of the general public.

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder that is characterized by repetitive episodes of complete or partial upper airway obstruction during sleep.[1] Untreated, OSA is a potentially lethal disease that increases the risk of numerous health complications, including hypertension, congestive heart failure, atrial fibrillation, coronary artery disease, stroke and type 2 diabetes.[2] Data also suggest that untreated OSA is associated with an increased risk of all-cause and cardiovascular mortality, and this risk can be reduced with effective treatment.[3,4] Therefore, the diagnosis and effective treatment of OSA in adults is an urgent health priority.

As snoring is a cardinal symptom of OSA, primary snoring and OSA are distinguishable only after evaluation by a physician and objective testing. (Throughout this statement, the term "physician" refers to a medical provider who is licensed to practice medicine.) Polysomnography is the standard medical test for the diagnosis of OSA in adult patients when concern arises for OSA, and a home sleep apnea test (HSAT) is an alternative medical test for the diagnosis of OSA in uncomplicated adults presenting with signs and symptoms that indicate an increased risk of moderate to severe OSA.

HSAT devices (ie, cardiorespiratory portable monitors) are classified by the United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) as Class II medical devices, which have moderate risk associated with them and are subject to increased regulatory controls to provide reasonable assurance of safety and effectiveness.[5,6] Most HSAT studies, including randomized controlled trials that are most generalizable to clinical practice, have involved accredited sleep centers and the clinical expertise of board-certified sleep medicine physicians. Data suggest that sleep

medicine accreditation and certification are associated with higher quality care for patients with OSA.[7]

POSITION

It is the position of the AASM that:

- Only a physician can diagnose medical conditions such as OSA and primary snoring.
- The need for, and appropriateness of, an HSAT must be based on the patient's medical history and a face-to-face examination by a physician, either in person or via telemedicine.
- An HSAT is a medical assessment that must be ordered by a physician to diagnose OSA or evaluate treatment efficacy.
- An HSAT should not be used for general screening of asymptomatic populations.
- Diagnosis, assessment of treatment efficacy, and treatment decisions must not be based solely on automatically scored HSAT data, which could lead to sub-optimal care that jeopardizes patient health and safety.
- The raw data from the HSAT device must be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.

DISCUSSION

Historically, HSAT devices have been classified (eg, Type III or Type IV) according to the number and type of sensors that are utilized. In contrast to polysomnography, HSAT devices typically do not include electroencephalography (EEG), electrooculography (EOG) or electromyography (EMG) sensors, all of which are required to define sleep versus wake. While polysomnography identifies the severity of sleep-disordered breathing (ie, apnea-hypopnea index or AHI) based on actual sleep time, an HSAT produces an estimate of severity (ie, respiratory event index or REI) based on monitoring time. The conventional sensors used in HSAT devices also are unable to detect hypopneas that are only associated with cortical arousals. Due to these limitations, an HSAT may underestimate the severity of OSA.[8]

Although it is less sensitive than polysomnography in the detection of OSA, an HSAT can be ordered by a physician for the diagnosis of OSA when the physician has determined that the patient does not have other medical conditions or risk for other sleep disorders that would preclude the use of an HSAT and has identified signs and symptoms that indicate an increased risk of moderate to severe OSA, rather than mild OSA.[8] The management of OSA also may include a follow-up HSAT ordered by a physician to collect objective data that can help improve or confirm treatment efficacy.[9] Data are insufficient to support the use of HSAT devices for general screening of asymptomatic populations.[10]

The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications includes scoring criteria for HSAT data and recommends that HSAT devices have the ability to display raw tracings in detail for review, manual scoring or editing of events.[11] The limitations of current automatic scoring algorithms restrict their diagnostic accuracy, and these algorithms are not set up to detect other abnormal findings (eg, sleep-related hypoxia) that may be indicative of underlying pulmonary disease. Therefore, it is essential for the raw HSAT data to be reviewed and interpreted by a physician who is either board-certified in sleep medicine or overseen by a board-certified sleep medicine physician.[12,13] These data should be interpreted by the physician in the context of the patient's medical history.

CONCLUSIONS

HSAT devices are diagnostic medical tools that help physicians to provide high quality, patient-centered care for select adult patients who are suspected to have OSA. A physician's diagnosis of OSA is based on a patient's medical history, symptoms from a medical evaluation, and findings from either polysomnography or an HSAT. Decisions to treat OSA, and assessment of treatment efficacy, require the medical judgment of a physician and must take into consideration the patient's symptoms, other medical conditions, and the severity of OSA determined by objective medical testing. The accurate diagnosis and effective treatment of OSA can improve individual health, promote public safety, and reduce overall health care expenses.

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DISCLOSURE STATEMENT

This position statement was developed by the board of directors of the AASM to help physicians and other health care providers make decisions about the appropriate evaluation of patients with suspected OSA. It is published by the AASM as an advisory that is to be used for educational and informational purposes only.

VIRGINIA TOTAL SLEEP

February 4, 2022

I appreciate and am honored by the opportunity to be a member of this workgroup related to dentistry's role in the evaluation and treatment of sleep disordered breathing. I also appreciate the opportunity to provide this brief primer on sleep apnea testing as well as various thoughts/items I feel are important to consider as the Board evaluates how best to protect the public.

This primer is by no means exhaustive. My goal is to provide the minimum amount of information necessary to have a thoughtful discussion of these issues and from the perspective of an orofacial pain specialist.

Within the scope of dentistry, sleep apnea is often managed by orofacial pain specialists, oral medicine specialists, oral surgeons, orthodontists, and general dentists. The American Board of Orofacial Pain specifically devotes a portion of the exam toward sleep apnea. Additionally, the American Board of Dental Sleep Medicine serves as a non-advanced specialty board to attest to the knowledge/proficiency of a dental provider in the evaluation and treatment of sleep apnea. While there are additional boards/organizations that certify aptitude in treatment of apnea, the ABDSM is the largest and most common among general dentists.

Diagnosis

Sleep apnea is a sleep disorder in which a patient's natural respiration during sleep is disordered. The extent of the disorder determines the overall diagnosis and severity. Apnea specifically is diagnosed based off the number and cause of apnea and hypopnea events per hour that a patient experiences. The measurement of the number of apnea and hypopnea events per hour of sleep is known as the Apnea Hypopnea Index (AHI). The types of events (hypopnea and apnea) are categorized in a scoring manual published by the American Academy of Sleep Medicine and are generally considered the gold standard of how to "score" a sleep study.

Sleep Testing Modalities

There are generally two main modalities of "sleep testing". The most well known modality is an attended polysomnogram (PSG). As the name implies, this testing is comprised of recording multiple variables during sleep to provide a comprehensive analysis of a patient's functions during sleep. A PSG is typically completed in a sleep lab where a patient is monitored throughout the test by a Licensed Polysomnographic Technologist. The technologist's function is to apply the various electrodes and apparatus necessary for the PSG, analyze and score the study, and intervene during the study as necessary for the safety of the patient or for accuracy of the test (e.g. replace a sensor the fell off during the study).

A PSG is used to diagnose a large variety of sleep disorders including insomnia, sleep-related breathing disorders, movement disorders, disorders of excessive somnolence, and parasomnias.

A PSG will typically utilize the following "channels" for monitoring and scoring: electroencephalography, electrooculography, chin and leg electromyography, airflow, thoracoabdominal bands, snoring sensor, body position, electrocardiography, and oxygen saturation.

The second, and now much more common, modality of "sleep testing" is the home sleep apnea test (HSAT). While there are multiple defined "types" of HSATs, the general idea is that an HSAT is designed to simply evaluate a patient's breathing and effect of breathing during sleep to allow for the positive diagnosis of sleep apnea rather than evaluate the entirety of a patient's sleep.

An HSAT is approved by the FDA for at home use in which the patient is the "technologist". The patient applies the sensors and apparatus necessary for the HSAT and there is no live monitoring of the data. The other name of this test is an unattended polysomnogram.

An HSAT will typically utilize the following "channels" for monitoring and scoring: airflow, thoracoabdominal bands, body position, and oxygen saturation. However, the FDA has approved many sleep tests that utilize seemingly unrelated "channels" along with a computer algorithm to correlate with the patients AHI

Scope of Medicine vs Dentistry

During the Business Meeting there was a comment made that Polysomnographic Technologists are regulated by the Board of Medicine. I wish to quickly highlight that Chapter 29 of Title 54.1 of the Code of Virginia, "Medicine and Other Healing Arts", § 54.1-2901 states:

A. The provisions of this chapter shall not prevent or prohibit:
    5. Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities

A plain text reading is clear that while the Board of Medicine may regulate Polysomnographic Technologists, that the existence of such license and regulation has no bearing on the practice of dentistry.

As the committee is aware, dentistry is defined in Chapter 27 of Title 54.1 of the Code of Virginia as:

> "'Dentistry' means the evaluation, diagnosis, prevention, and treatment, through surgical, nonsurgical, or related procedures, of diseases, disorders, and conditions of the oral cavity and the maxillofacial, adjacent, and associated structures and their impact on the human body."

Obstructive sleep apnea is typically managed through one of 4 main modalities. Positive airway pressure devices (CPAP, APAP, BiPAP), oral appliance therapy (mandibular advancement device, tongue retainer device), maxillomandibular advancement surgery (MMA), and/or hypoglossal nerve stimulation (HNS). Of those modalities, 3 clearly target intra-oral structures (oral appliance therapy, MMA, and HNS) with the remaining modality, PAP devices, targeting the oropharynx.

These modalities target the oral cavity as well as adjacent and associated structures specifically because the etiology of obstructive sleep apnea is so often related to these structures and their associated collapse during sleep.

There is clearly no question that the treatment of obstructive sleep apnea falls within the scope of dentistry. As dentistry is currently defined, our license includes not only the treatment but the evaluation of these conditions as well.

Ordering vs Diagnosing

At the heart of this discussion is an important distinction between ordering vs interpreting/diagnosing. Specifically, the American Dental Association (ADA and the American Academy of Dental Sleep Medicine (AADSM) have published positions that state that ordering an HSAT is within the scope of dentistry and that only a sleep physician can render the diagnosis.

The American Academy of Sleep Medicine's (AASM) letter improperly implied that the AADSM was advocating that both ordering and interpreting were within the scope of dentistry. At this time, there was no such recommendation from the AADSM to include diagnosing sleep apnea.

As the AASM and AADSM both highlight, obstructive sleep apnea is only one of many different sleep disorders and as such, a sleep physician in an important factor in accurate diagnosis. This is why the AADSM is not advocating that dentists provide the diagnosis of apnea.

Like other diagnostic testing such as radiology, pathology, and serology, home sleep testing is comprised of ordering, rendering, and interpreting. These stages can be completed by the same provider or multiple providers. Within dentistry, for example, we often order, expose, and interpret our own radiographs; whereas in medicine, the ordering, rendering, and interpreting provider are often 3 separate providers with the physician providing an order to an imaging center. The imaging center then exposes/produces the radiograph. The exposed radiograph is then sent to a radiologist who interprets and reports on the findings.

The AADSM position is that the ordering and dispensing of home sleep apnea testing is within the scope of dentistry as evaluation of a patient's oral structures is clearly within the scope of dentistry.

As a home sleep apnea test is approved by the FDA for at-home use, many HSATs are dispensed through mail-order services. In these cases the study is ordered by a provider and the study is then sent to the patient directly with no contact with a provider. If a mail order service is appropriate for dispensing a test, it seems clear that a dentist dispensing a sleep test based on a valid order is not in dispute. As such, this seems to boil down to the question of whether or not it is appropriate for a dentist to order a sleep study.

Considerations

Home sleep apnea tests typically measures respiratory volume, respiratory effort, pulse rate, and blood oxygenation while a patient sleeps. If we consider these metrics as something only a physician is qualified to measure, would that not imply that dentists should no longer perform sedation? Afterall, the standards for sedation require monitoring of those exact same values.

This seems to be a similar situation to that of hypertension. Dentists have played an extremely key role in the early detection and treatment of hypertension through ordering testing of a patient's blood pressure via sphygmomanometry with referral to physicians for interpretation of these test values when appropriate. As we know, many of our healthy patients see their dentists more often than their physicians and we are a key component of the early detection of many diseases.

At the workgroup meeting I will bring 2 examples of FDA approved home sleep apnea tests to provide a better understanding of what a patient will undergo. You will see that this equipment is non-invasive and designed for home use by a lay individual.

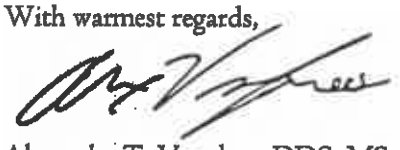
It seems then, that the highest risk to the public is of failure to diagnose if the dentist who dispensed the home sleep apnea test does not have it interpreted by a sleep physician.

According to the most recent findings of the American Academy of Sleep Medicine in 2016, approximately 29.4 million adults (12%) in the United States have sleep apnea. Of those 29.4 million adults, 23.5 million (80%) are undiagnosed.

Dentist can and do play an absolutely vital role in the detection and eventual diagnosis of sleep apnea through the use of home sleep apnea testing and partnering with sleep physicians for interpretation of these studies.

It stands to reason that restricting dentists from ordering and/or administering home sleep apnea testing would constitute a greater harm to the public than the potential risk of a missed diagnosis. Additionally, dentists who do fail to refer the study to a sleep physician for diagnosis would remain liable and subject to review by the board of dentistry due to this failure to diagnose.

With warmest regards,



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