Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
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MEETING NOTICE

LICENSING, STANDARDS, AND COMPETENCY COMMITTEE MEETING

Oregon Board of Dentistry
1500 SW 1st Ave.,
Portland, Oregon 97201

ZOOM MEETING INFORMATION
https://zoom.us/j/93135429635?pwd=T2lpcGc0Nnkzc3BUMEM1SUprWUVEZz09
Dial-In Phone #: 1-253-215-8782 • Meeting ID: 931 3542 9635 • Passcode: 544304

October 7, 2020
5:00 – 7:30 p.m.

Committee Members:
Yadira Martinez, R.D.H., Chair
Jose Javier, D.D.S.
Hai Pham, D.M.D.
Chip Dunn
Daren L. Goin, D.M.D. - ODA Rep.
Susan Kramer, R.D.H. - ODHA Rep.
Ginny Jorgensen, CDA, EFDA, EFODA, AAS - ODAA Rep.

AGENDA

Call to Order Yadira Martinez, R.D.H., Chair

1. Review and approve Minutes of May 24, 2019 Committee Meeting
   - May 24, 2019 Minutes - **Attachment #1**

2. Review and discuss ODA's request for name change from "Well Being Committee" to "Wellness Committee". Referred to discussion from the Board on October 25, 2019.
   - ORS 679.310 – **Attachment #2**

3. Review, discuss and make possible recommendations to the Board regarding OAR 818-001-0000 – Notice of Proposed Rule Making. (Update language to reflect current practices).
   - OAR 818-001-0000 – Notice of Proposed Rule Making – **Attachment #3**

4. Review, discuss and make possible recommendations to the Board regarding OAR 818-001-0002 – Definitions. (Staff recommendation – clarification).
   - OAR 818-002-0002 – Definitions – **Attachment #4**

5. Review, discuss and make possible recommendations to the Board regarding OAR 818-001-0082 – Access to Public Records. (Update language to reflect current practices).
   - OAR 818-001-0082 – Access to Public Records – **Attachment #5**

6. Review, discuss and make possible recommendations to the Board regarding OAR 818-012-0005 – Scope of Practice.
   - Correspondence – Stephen Bush – **Attachment #6**
   - Correspondence – Dr. Akshay Govind – **Attachment #7**
   - Memo **–** Dental Implants Proposed Rules and Informed Consent – **Attachment #8**

This meeting is being held remotely via Zoom. A request for accommodations for persons with disabilities should be made at least 48 hours before the meeting to Haley Robinson at (971) 673-3200.

- OAR 818-012-0005 – Scope of Practice – **Attachment #9**

7. Review and discuss correspondence regarding a proposed rule that was referred back from the Board on October 25, 2019 for further consideration - OAR 818-012-0030 – Unprofessional Conduct.
   - Correspondence – Ann Ossinger, R.D.H., E.P.D.H. – **Attachment #10**
   - OAR 818-012-0030 – **Attachment #11**

8. Review, discuss and make possible recommendations to the Board regarding OAR 818-012-0070 – Patient Records. (Staff recommendation).
   - OAR 818-012-0070 – Patient Records – **Attachment #12**

9. Review, discuss and make possible recommendations to the Board regarding OAR 818-021-0080 – Renewal of License. (Update language to reflect current practices).
   - OAR 818-021-0080 Renewal of License – **Attachment #13**

10. Review, discuss and make possible recommendations to the Board regarding OAR 818-026-0040 – Qualification, Standards Applicable, and Continuing Education Requirements for Anesthesia Permits: Nitrous Oxide Permit. (Housekeeping – staff recommendations).
    - OAR 818-026-0040 – Qualification, Standards Applicable, and Continuing Education Requirements for Anesthesia Permits: Nitrous Oxide Permit – **Attachment #14**

11. Review, discuss and make possible recommendations to the Board regarding OAR 818-026-0050 – Minimal Sedation. (Housekeeping – make consistent with other sedation rules).
    - OAR 818-026-0050 – Minimal Sedation – **Attachment #15**

12. Review and discuss public comments from the October 2019 Public Rulemaking Hearing regarding OAR 818-026-0065 Deep Sedation Permit and OAR 818-026-0070 General Anesthesia Permit – Anesthesia Monitors.
    - Oregon Society of Anesthesiologists – Public Comment – **Attachment #16**
    - American Society of Anesthesiologists – Public Comment- **Attachment #17**
    - Certified Anesthesia Monitor Federal Guidelines – **Attachment #18**
    - OAR 818-026-0065 – Deep Sedation Permit – **Attachment #19**
    - OAR 818-026-0070 – General Anesthesia Permit – **Attachment #20**

13. Review, discuss and make possible recommendations to the Board regarding OAR 818-035-0020 – Authorization to Practice.
    - Correspondence – Lisa Rowley - **Attachment #21**
    - OAR 818-035-0020 – Authorization to Practice - **Attachment #22**

14. Review, discuss and make possible recommendations to the Board regarding OAR 818-035-0025 – Prohibitions. (Housekeeping – staff recommendations).
    - OAR 818-035-0025 – Prohibitions – **Attachment #23**

15. Review, discuss and make possible recommendations to the Board regarding OAR 818-042-0040 – Prohibited Acts. (Housekeeping – staff recommendations).
    - OAR 818-042-0040 – Prohibited Acts – **Attachment #24**

16. Review, discuss and make possible recommendations to the Board regarding OAR 818-042-0080 Certification – Expanded Function Dental Assistant (EFDA), OAR 818-042-0110 – Certification – Expanded Function Orthodontic Assistant (EFODA) and OAR 818-042-0113 – Certification – Expanded Function Preventive Dental Assistants (EFPDA). Referred from Board for discussion on August 23, 2019.
    - OAR 818-042-0080 - Certification – Expanded Function Dental Assistant (EFDA) – **Attachment #25**
    - OAR 818-042-0110 - Certification – Expanded Function Orthodontic Assistant (EFODA) - **Attachment #26**
    - OAR 818-042-0113 - Certification – Expanded Function Preventive Dental Assistants (EFPDA) – **Attachment #27**

17. Review and discuss correspondence from the Academy of Sleep Medicine. Referred for discussion from the Board on February 21, 2020.
    - Correspondence - Academy of Sleep Medicine – **Attachment #28**
        - AADSM Policy Statement on a Dentist's Role for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy – **Attachment #29**
        - AADSM Collaborative Care Model - **Attachment #30**
        - AADSM Dental Sleep Medicine Standards for Screening, Treating, and Managing Adults with Sleep-Related Breathing Disorders - **Attachment #31**
        - AADSM Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy - **Attachment #32**

18. Review, discuss and make possible recommendations to the Board regarding OAR 818-021-0088 Volunteer License. (Housekeeping – staff recommendations).
    - OAR 818-021-0088 – Volunteer License – **Attachment #33**

19. Discuss rule due to COVID-19 and infection control concerns.
    - OAR 818-012-0040 – Infection Control Guidelines – **Attachment #34**

20. Review, discuss, and make possible recommendations to the Board regarding recognizing orofacial pain and oral medicine as dental specialties.
    - OAR 818-015-0007 – Specialty Advertising – **Attachment #35**
    - OAR 818-021-0012 – Specialties Recognized – **Attachment #36**

21. Review, discuss and make possible recommendations to the Board regarding the proposed temporary licensure rules requiring that the clinical licensure examinations include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient.
    - Temporary Rules the Board approved at 8.21.2020 Board Meeting, to be effective 2021 **- Attachment #37**

22. Review, discuss and make possible recommendations to the Board regarding OAR 818-012-0006 – Administration of Vaccines.
    - OAR 818-012-0006 – Administration of Vaccines – **Attachment #38**

23. Review, discuss and make recommendation to fix language referencing the "Oregon Board of Medical Examiners." That Board is officially named the "Oregon Medical Board.".
    - OAR 818-026-0080 – **Attachment #39**

24. Review, discuss and make possible recommendations to the Board regarding creating a new OAR 818-012-XXXX – Compliance with Governor's Executive Orders.
    - OAR 818-012-XXXX – **Attachment #40**

25. Review, discuss and make possible recommendations when the 180-day limit begins to the Board regarding OAR 818-021-0120 – Application Valid for 180 Days. (Staff recommendation).
    - OAR 818-021-0120 – Application Valid for 180 Days – **Attachment #41**

Any Other Business

Adjourn

This meeting is being held remotely via Zoom. A request for accommodations for persons with disabilities should be made at least 48 hours before the meeting to Haley Robinson at (971) 673-3200.

LICENSING, STANDARDS AND COMPETENCY COMMITTEE

Minutes
May 24, 2019

MEMBERS PRESENT: Amy B. Fine, D.M.D., Chair
Alicia Riedman, R.D.H., E.P.P.
Todd Beck, D.M.D.
Hai Pham, D.M.D.
Chip Dunn
Daren L. Goin, D.M.D. - ODA Representative
Susan Kramer, R.D.H. - ODHA Representative
Ginny Jorgensen, CDA, EFDA, EFODA - ODAA Representative

STAFF PRESENT: Stephen Prisby, Executive Director
Daniel Blickenstaff, D.D.S., Dental Director/Chief Investigator
Teresa Haynes, Office Manager
Ingrid Nye, Examination & Licensing Manager

ALSO PRESENT: Lori Lindley, Sr. Assistant Attorney General

VISITORS PRESENT:
Julie Ann Smith, D.D.S., M.D., M.C.R.; Katie Simonsen; Jen Lewis-Goff, ODA; Dean Philip Marucha, OHSU Dental School; Abigail Rollins, D.M.D., Chemeketa Community College; Jill Lomax, Chemeketa Community College; Michael Christie, Resuscitation Group; Mary Harrison, ODAA; Dayna Steringer, Willamette Dental Group; Cassie Leone, ODA; Despoina Bompolaki, Prosthodontist, OHSU; Magda C. D'Angelis-Morris, Portland Community College; Lisa Rowley, R.D.H., ODHA; Heather Mobus, R.D.H., ODHA; Leslie Greer, Lane Community College

Call to Order: The meeting was called to order by Dr. Fine, at 12:00 p.m.

MINUTES

Dr. Beck moved and Dr. Pham seconded that the minutes of the December 15, 2017 Licensing, Standards and Competency Committee meeting be approved as presented. The motion passed unanimously.

Dr. Beck moved and Ms. Riedman seconded that the Committee recommend that the Board move OAR 818-001-0002(a)-(j) as presented to the Rules Oversight Committee. The motion passed unanimously.

818-001-0002
Definitions
As used in OAR Chapter 818:
(1) "Board" means the Oregon Board of Dentistry, the members of the Board, its

employees, its agents, and its consultants.
(2) "Dental Practice Act" means ORS Chapter 679 and 680.010 to 680.170 and the rules adopted pursuant thereto.
(3) "Dentist" means a person licensed pursuant to ORS Chapter 679 to practice dentistry.
(4) "Direct Supervision" means supervision requiring that a dentist diagnose the condition to be treated, that a dentist authorize the procedure to be performed, and that a dentist remain in the dental treatment room while the procedures are performed.
(5) "General Supervision" means supervision requiring that a dentist authorize the procedures, but not requiring that a dentist be present when the authorized procedures are performed. The authorized procedures may also be performed at a place other than the usual place of practice of the dentist.
(6) "Hygienist" means a person licensed pursuant to ORS 680.010 to 680.170 to practice dental hygiene.
(7) "Indirect Supervision" means supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed.
(8) "Informed Consent" means the consent obtained following a thorough and easily understood explanation to the patient, or patient's guardian, of the proposed procedures, any available alternative procedures and any risks associated with the procedures. Following the explanation, the licensee shall ask the patient, or the patient's guardian, if there are any questions. The licensee shall provide thorough and easily understood answers to all questions asked.
(9) "Licensee" means a dentist or hygienist.
(a) “Volunteer Licensee” is a dentist or dental hygienist licensed according to rule to provide dental health care without receiving or expecting to receive compensation.
(10) "Limited Access Patient" means a patient who, due to age, infirmity, or handicap is unable to receive regular dental hygiene treatment in a dental office.
(11) "Specialty." The specialty definitions are added to more clearly define the scope of the practice as it pertains to the specialty areas of dentistry.

(a) “Dental Anesthesiology” is the specialty of dentistry that deals with the management of pain through the use of advanced local and general anesthesia techniques.

~~(a)~~ **(b)** "Dental Public Health" is the science and art of preventing and controlling dental diseases and promoting dental health through organized community efforts. It is that form of dental practice which serves the community as a patient rather than the individual. It is concerned with the dental health education of the public, with applied dental research, and with the administration of group dental care programs as well as the prevention and control of dental diseases on a community basis.
~~(b)~~ **(c)** "Endodontics" is the branch of dentistry which is concerned with the morphology, physiology and pathology of the human dental pulp and periradicular tissues. Its study and practice encompass the basic and clinical sciences including biology of the normal pulp, the etiology, diagnosis, prevention and treatment of diseases and injuries of the pulp and associated periradicular conditions.
~~(c)~~ **(d)** "Oral and Maxillofacial Pathology" is the specialty of dentistry and discipline of pathology that deals with the nature, identification, and management of diseases affecting the oral and maxillofacial regions. It is a science that investigates the causes, processes, and effects of these diseases. The practice of oral pathology includes research and diagnosis of diseases using clinical, radiographic, microscopic,

biochemical, or other examinations.
~~(d)~~ **(e)** “Oral and Maxillofacial Radiology” is the specialty of dentistry and discipline of radiology concerned with the production and interpretation of images and data produced by all modalities of radiant energy that are used for the diagnosis and management of diseases, disorders and conditions of the oral and maxillofacial region.
~~(e)~~ **(f)** "Oral and Maxillofacial Surgery" is the specialty of dentistry which includes the diagnosis, surgical and adjunctive treatment of diseases, injuries and defects involving both the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial region.
~~(f)~~ **(g)** "Orthodontics and Dentofacial Orthopedics" is the area of dentistry concerned with the supervision, guidance and correction of the growing or mature dentofacial structures, including those conditions that require movement of teeth or correction of malrelationships and malformations of their related structures and the adjustment of relationships between and among teeth and facial bones by the application of forces and/or the stimulation and redirection of functional forces within the craniofacial complex. Major responsibilities of orthodontic practice include the diagnosis, prevention, interception and treatment of all forms of malocclusion of the teeth and associated alterations in their surrounding structures; the design, application and control of functional and corrective appliances; and the guidance of the dentition and its supporting structures to attain and maintain optimum occlusal relations in physiologic and esthetic harmony among facial and cranial structures.
~~(g)~~**(h)** "Pediatric Dentistry" is an age defined specialty that provides both primary and comprehensive preventive and therapeutic oral health care for infants and children through adolescence, including those with special health care needs.
~~(h)~~**(i)** "Periodontics" is the specialty of dentistry which encompasses the prevention, diagnosis and treatment of diseases of the supporting and surrounding tissues of the teeth or their substitutes and the maintenance of the health, function and esthetics of these structures and tissues.
~~(i)~~ **(j)** "Prosthodontics" is the branch of dentistry pertaining to the restoration and maintenance of oral functions, comfort, appearance and health of the patient by the restoration of natural teeth and/or the replacement of missing teeth and contiguous oral and maxillofacial tissues with artificial substitutes.
(12) “Full-time” as used in ORS 679.025 and 680.020 is defined by the Board as any student who is enrolled in an institution accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency in a course of study for dentistry or dental hygiene.
(13) For purposes of ORS 679.020(4)(h) the term “dentist of record” means a dentist that either authorized treatment for, supervised treatment of or provided treatment for the patient in clinical settings of the institution described in 679.020(3).
(14) “Dental Study Group” as used in ORS 679.050, OAR 818-021-0060 and OAR 818-021-0070 is defined as a group of licensees who come together for clinical and non-clinical educational study for the purpose of maintaining or increasing their competence. This is not meant to be a replacement for residency requirements.
(15) “Physical Harm” as used in OAR 818-001-0083(2) is defined as any physical injury that caused, partial or total physical disability, incapacity or disfigurement. In no event shall physical harm include mental pain, anguish, or suffering, or fear of injury.
(16) “Teledentistry” is defined as the use of information technology and telecommunications to facilitate the providing of dental primary care, consultation, education, and public awareness in the same manner as telehealth and telemedicine.

(17) "BLS for Healthcare Providers or its Equivalent" The CPR certification standard is the American Heart Association's BLS Healthcare Providers Course or its equivalent, as determined by the Board. This initial CPR course must be a hands-on course; online CPR courses will not be approved by the Board for initial CPR certification:
After the initial CPR certification, the Board will accept a Board-approved BLS for Healthcare Providers or its equivalent Online Renewal course for license renewal. A CPR certification card with an expiration date must be received from the CPR provider as documentation of CPR certification. The Board considers the CPR expiration date to be the last day of the month that the CPR instructor indicates that the certification expires.

Dr. Beck moved and Ms. Kramer seconded that the Committee recommend that the Board move OAR 818-001-0002(17) as presented to the Rules Oversight Committee. The motion passed unanimously.

818-001-0002
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After the initial CPR certification, the Board will accept a Board-approved BLS for Healthcare Providers or its equivalent Online Renewal course for license renewal. A CPR certification card with an expiration date must be received from the CPR provider as documentation of CPR certification. The Board considers the CPR expiration date to be the last day of the month that the CPR instructor indicates that the certification expires.

Dr. Beck left the meeting at 12:20 p.m. and rejoined at 12:28 p.m.

The Committee deferred to later in the meeting reviewing and discussing OAR 818-012-0005.

Dr. Goin moved and Dr. Pham seconded that the Committee recommend that the Board move OAR 818-012-0006 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-012-0006 – Qualifications – Administration of Vaccines
(1) A dentist may administer vaccines to a patient of record.
(2) A dentist may administer vaccines under Section (1) of this rule only if:
(a) The dentist has completed a course of training approved by the Board;
(b) The vaccines are administered in accordance with the “Model Standing Orders” approved by the Oregon Health Authority (OHA); and
(c) The dentist has a current copy of the CDC reference, “Epidemiology and Prevention of Vaccine-Preventable Diseases.”

~~(d) The dentist has an emergency kit that contains at a minimum;~~
~~(i) Epinephrine auto injector – Adult 0.3mg~~
~~(ii) Epinephrine auto injector – Pediatric 0.15mg~~
~~(i) 1 multi-dose vial of 1:1000 epinephrine with appropriate syringes, or 3 adult-dose epinephrine auto-injectors and 3 pediatric-dose auto-injectors.~~
~~(iii) (ii) Diphenhydramine 50mg/mL~~
~~(iv) (iii) Ammonia Inhalants~~
~~(v) (iv) Appropriate syringes with needles~~
~~(vi) (v) CPR shield~~
(3) The dentist may not delegate the administration of vaccines to another person.
~~(4) The dentist may not self-administer a vaccine to themselves.~~

Dr. Pham moved and Ms. Riedman seconded that the Committee recommend that the Board move OAR 818-012-0007 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-012-0007 – Procedures, Record Keeping and Reporting
(1) Prior to administering a vaccine to a patient of record, the dentist must follow the "Model Standing Orders" approved by the Oregon Health Authority (OHA) for administration of vaccines and the treatment of severe adverse events following administration of a vaccine.
(2) The dentist must maintain written policies and procedures for handling and disposal of used or contaminated equipment and supplies.
(3) The dentist or designated staff must give the appropriate Vaccine Information Statement (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The dentist or designated must ensure that the patient or legal representative is available and has read, or has had read to them, the information provided and has had their questions answered prior to the dentist administering the vaccine. The VIS given to the patient must be the most current statement.
(4) The dentist or designated staff must document in the patient record:
(a) The date and site of the administration of the vaccine;
(b) The brand name, or NDC number, or other acceptable standardized vaccine code set, dose, manufacturer, lot number, and expiration date of the vaccine;
(c) The name or identifiable initials of the administering dentist;
(d) The address of the office where the vaccine(s) was administered unless automatically embedded in the electronic report provided to the OHA ALERT Immunization System;
(e) The date of publication of the VIS; and
(f) The date the VIS was provided and the date when the VIS was published.
(5) If providing state or federal vaccines, the vaccine eligibility code as specified by the OHA must be reported to the ALERT system.
(6) A dentist who administers any vaccine must report, the elements of Section (3), and Section (4) of this rule if applicable, to the OHA ALERT Immunization System within 14 days of administration.
(7) The dentist must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS), to the Oregon Board of Dentistry within 10 business days and to the primary care provider as identified by the patient.
(8) A dentist who administers any vaccine will follow storage and handling

guidance from the vaccine manufacturer and the Centers for Disease Control and Prevention (CDC).
(9) Dentists who do not follow this rule can be subject to discipline for failure to adhere to these requirements.

Dr. Beck moved and Ms. Riedman seconded that the Committee recommend that the Board move OAR 818-012-0030 as amended to the Rules Oversight Committee. The motion passed unanimously

818-012-0030
Unprofessional Conduct
The Board finds that in addition to the conduct set forth in ORS 679.140(2), unprofessional conduct includes, but is not limited to, the following in which a licensee does or knowingly permits any person to:
(1) Attempt to obtain a fee by fraud, or misrepresentation.
(2) Obtain a fee by fraud, or misrepresentation.
(a) A licensee obtains a fee by fraud if the licensee knowingly makes, or permits any person to make, a material, false statement intending that a recipient, who is unaware of the truth, rely upon the statement.
(b) A licensee obtains a fee by misrepresentation if the licensee obtains a fee through making or permitting any person to make a material, false statement.
(c) Giving cash discounts and not disclosing them to third party payers is not fraud or misrepresentation.
(3) Offer rebates, split fees, or commissions for services rendered to a patient to any person other than a partner, employee, or employer.
(4) Accept rebates, split fees, or commissions for services rendered to a patient from any person other than a partner, employee, or employer.
(5) Initiate, or engage in, with a patient, any behavior with sexual connotations. The behavior can include but is not limited to, inappropriate physical touching; kissing of a sexual nature; gestures or expressions, any of which are sexualized or sexually demeaning to a patient; inappropriate procedures, including, but not limited to, disrobing and draping practices that reflect a lack of respect for the patient's privacy; or initiating inappropriate communication, verbal or written, including, but not limited to, references to a patient's body or clothing that are sexualized or sexually demeaning to a patient; and inappropriate comments or queries about the professional's or patient's sexual orientation, sexual performance, sexual fantasies, sexual problems, or sexual preferences.
(6) Engage in an unlawful trade practice as defined in ORS 646.605 to 646.608.
(7) Fail to present a treatment plan with estimated costs to a patient upon request of the patient or to a patient's guardian upon request of the patient's guardian.
(8) Misrepresent any facts to a patient concerning treatment or fees.
(9)(a) Fail to provide a patient or patient's guardian within 14 days of written request:
(A) Legible copies of records; and
(B) Duplicates of study models, radiographs of the same quality as the originals, and photographs if they have been paid for.
(b) The licensee may require the patient or guardian to pay in advance a fee reasonably calculated to cover the costs of making the copies or duplicates. The licensee may charge a fee not to exceed $30 for copying 10 or fewer pages of written material and no more than $0.50 per page for pages 11 through 50 and no more than $0.25 for each

additional page (including records copied from microfilm), plus any postage costs to mail copies requested and actual costs of preparing an explanation or summary of information, if requested. The actual cost of duplicating radiographs may also be charged to the patient. Patient records or summaries may not be withheld from the patient because of any prior unpaid bills, except as provided in (9)(a)(B) of this rule.
(10) Fail to identify to a patient, patient's guardian, or the Board the name of an employee, employer, contractor, or agent who renders services.
(11) Use prescription forms pre-printed with any Drug Enforcement Administration number, name of controlled substances, or facsimile of a signature.
(12) Use a rubber stamp or like device to reproduce a signature on a prescription form or sign a blank prescription form.
(13) Order drugs listed on Schedule II of the Drug Abuse Prevention and Control Act, 21 U.S.C. Sec. 812, for office use on a prescription form.
(14) Violate any Federal or State law regarding controlled substances.
(15) Becomes addicted to, or dependent upon, or abuses alcohol, illegal or controlled drugs, or mind altering substances, or practice with an untreated substance use disorder diagnosis that renders the licensee unable to safely conduct the practice of dentistry or dental hygiene.
(16) Practice dentistry or dental hygiene in a dental office or clinic not owned by an Oregon licensed dentist(s), except for an entity described under ORS 679.020(3) and dental hygienists practicing pursuant to ORS 680.205(1)(2).
(17) Make an agreement with a patient or person, or any person or entity representing patients or persons, or provide any form of consideration that would prohibit, restrict, discourage or otherwise limit a person's ability to file a complaint with the Oregon Board of Dentistry; to truthfully and fully answer any questions posed by an agent or representative of the Board; or to participate as a witness in a Board proceeding.
(18) Fail to maintain at a minimum a current BLS for Healthcare Providers certificate or its equivalent. (Effective January 2015).
(19) Conduct unbecoming a licensee or detrimental to the best interests of the public, including conduct contrary to the recognized standards of ethics of the licensee's profession or conduct that endangers the health, safety or welfare of a patient or the public.
(20) Knowingly deceiving or attempting to deceive the Board, an employee of the Board, or an agent of the Board in any application or renewal, or in reference to any matter under investigation by the Board. This includes but is not limited to the omission, alteration or destruction of any record in order to obstruct or delay an investigation by the Board, or to omit, alter or falsify any information in patient or business records.
(21) Knowingly practicing with a physical or mental impairment that renders the Licensee unable to safely conduct the practice of dentistry or dental hygiene.
(22) Take any action which could reasonably be interpreted to constitute harassment or retaliation towards a person whom the licensee believes to be a complainant or witness.
(23) Fail to register with the Prescription Drug Monitoring Program (PDMP) in order to have access to the Program's electronic system if the Licensee holds an Oregon DEA registration.
(24) Every dental office, facility or location providing dental or dental hygiene services in the state of Oregon must have a properly functioning automated external defibrillator (AED) or defibrillator.
(a) An expanded practice dental hygienist must have access to a properly functioning automated external defibrillator(AED) or defibrillator. The AED or

defibrillator must be available and within reach within sixty seconds.
(b) A dental office or facility may share a single AED or defibrillator with adjacent businesses if it meets the requirements of this section. (Effective January 1, 2021).

Dr. Pham moved and Dr. Goin seconded that the Committee recommend that the Board move OAR 818-012-0070 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-012-0070
Patient Records
(1) Each licensee shall have prepared and maintained an accurate **and legible** record for each person receiving dental services, regardless of whether any fee is charged. The record shall contain the name of the licensee rendering the service and include:
(a) Name and address and, if a minor, name of guardian;
(b) Date description of examination and diagnosis;
(c) An entry that informed consent has been obtained and the date the informed consent was obtained. Documentation may be in the form of an acronym such as "PARQ" (Procedure, Alternatives, Risks and Questions) or "SOAP" (Subjective Objective Assessment Plan) or their equivalent.
(d) Date and description of treatment or services rendered;
(e) Date, description and documentation of informing the patient of any recognized treatment complications;
(f) Date and description of all radiographs, study models, and periodontal charting;
(g) Health history; and
(h) Date, name of, quantity of, and strength of all drugs dispensed, administered, or prescribed.
(2) Each licensee shall have prepared and maintained an accurate record of all charges and payments for services including source of payments.
(3) Each licensee shall maintain patient records and radiographs for at least seven years from the date of last entry unless:
(a) The patient requests the records, radiographs, and models be transferred to another licensee who shall maintain the records and radiographs;
(b) The licensee gives the records, radiographs, or models to the patient; or
(c) The licensee transfers the licensee's practice to another licensee who shall maintain the records and radiographs.
(4) When a dental implant is placed the following information must be given to the patient in writing and maintained in the patient record:
(a) Manufacture brand;
(b) Design name of implant;
(c) Diameter and, length;
(d) Lot number;
(e) Reference number;
(f) Expiration date;
(g) Product labeling containing the above information may be used in satisfying this requirement.
~~(4)~~**(5)** When changing practice locations, closing a practice location or retiring, each licensee must retain patient records for the required amount of time or transfer the custody of patient records to another licensee licensed and practicing dentistry in Oregon. Transfer of patient records pursuant to this section of this rule must be reported

to the Board in writing within 14 days of transfer, but not later than the effective date of the change in practice location, closure of the practice location or retirement. Failure to transfer the custody of patient records as required in this rule is unprofessional conduct. ~~(5)~~**(6)** Upon the death or permanent disability of a licensee, the administrator, executor, personal representative, guardian, conservator or receiver of the former licensee must notify the Board in writing of the management arrangement for the custody and transfer of patient records. This individual must ensure the security of and access to patient records by the patient or other authorized party, and must report arrangements for permanent custody of patient records to the Board in writing within 90 days of the death of the licensee.

The Committee reviewed and discussed OAR 818-015-0007 and decided not to take any action on OAR 818-015-0007, OAR 818-021-0012, OAR 818-021-0015 and OAR 818-021-0017 pending potential legislation. It was determined that after the legislative session is complete, there is time for the Rules Oversight Committee to review any rule changes based on the legislation.

818-015-0007
Specialty Advertising

~~(1) A dentist may only advertise as a specialist in an area of dentistry which is recognized by the Board and in which the dentist is licensed or certified by the Board.~~
~~(2) The Board recognizes the following specialties:~~
~~(a) Endodontics;~~
~~(b) Oral and Maxillofacial Surgery;~~
~~(c) Oral and Maxillofacial Radiology;~~
~~(d) Oral and Maxillofacial Pathology;~~
~~(e) Orthodontics and Dentofacial Orthopedics;~~
~~(f) Pediatric Dentistry;~~
~~(g) Periodontics;~~
~~(h) Prosthodontics;~~
~~(i) Dental Public Health~~
~~(3) A dentist whose license is not limited to the practice of a specialty under OAR 818-021-0017 may advertise that the dentist performs or limits practice to specialty services even if the dentist is not a specialist in the advertised area of practice so long as the dentist clearly discloses that the dentist is a general dentist or a specialist in a different specialty. For example, the following disclosures would be in compliance with this rule for dentists except those licensed pursuant to 818-021-0017: "Jane Doe, DDS, General Dentist, practice limited to pediatric dentistry." "John Doe, DMD, Endodontist, practice includes prosthodontics."~~

(1) A dentist shall not advertise or hold themselves out to the public as a specialist or use any variation of the term, in the area of practice, if the communication is false, deceptive or misleading under OAR 818-015-0005.
(2) It shall not be false, deceptive or misleading for a dentist to hold themselves out to the public as a specialist in a practice area provided the dentist has completed a qualifying postdoctoral education program in that area. A qualifying postdoctoral education program is a postdoctoral advanced dental educational program accredited by an agency recognized by the United States Department of Education.

(3) A dentist who has not completed a qualifying postdoctoral educational program shall not advertise or otherwise hold themselves out to the public as a specialist, certified specialist, or board-certified specialist, or use any variation of those terms, unless they hold current certification by a qualifying specialty board or organization and are licensed by the laws of Oregon to practice a dental specialty.
The Board shall consider the following criteria in determining a qualifying specialty board or organization:
(a) The organization requires completion of a training program with training, documentation, and clinical requirements similar in scope and complexity to a qualifying postdoctoral education program in the specialty or subspecialty field of dentistry in which the dentist seeks certification. Programs that require solely experiential training, continuing education classes, on-the-job training, or payment to the specialty board shall not constitute an equivalent specialty board;
(b) The organization requires all dentists seeking certification to pass a written or oral examination, or both, that tests the applicant's knowledge and skill in the specialty or subspecialty area of dentistry and includes a psychometric evaluation for validation;
(c) The organization has written rules on maintenance of certification and requires periodic recertification;
(d) The organization has written bylaws and a code of ethics to guide the practice of its members;
(e) The organization has staff to respond to consumer and regulatory inquiries; and
(f) The organization is recognized by another entity whose primary purpose is to evaluate and assess dental specialty boards and organizations.
(4) A dentist qualifying under Subsection (3) and advertising or otherwise holding themselves out to the public as a "specialist," "certified specialist," or "board-certified specialist" shall disclose in the advertisement or communication the specialty board by which the dentist was certified and provide information about the certification criteria or where the certification criteria may be located.
(5) A dentist shall maintain documentation of either completion of a qualifying postdoctoral educational program or of his or her current specialty certification and provide the documentation to the Board upon request. Dentists shall maintain documentation demonstrating that the certifying board qualifies under the criteria in Subsection (3)(a)-(f) of this rule and provide the documentation to the Board upon request.
(6) Nothing in this section shall be construed to prohibit a dentist who does not qualify as a "specialist," "certified specialist," or "board-certified specialist" under paragraphs (2) and (3) of this rule from restricting their practice to one or more specific areas of dentistry or from advertising the availability of their services, provided that such advertisements do not include the terms "specialist," "certified specialist," or "board-certified specialist" or any variation of those terms, and must state that the services advertised are being provided by a general dentist.

818-021-0012
Specialties Recognized

(1) A dentist may advertise that the dentist is an ~~endodontist, oral and maxillofacial pathologist, oral and maxillofacial surgeon, oral and maxillofacial radiologist, orthodontist and dentofacial orthopedist, pediatric dentist, periodontist, prosthodontist or dental public health dentist, only if the dentist is licensed or certified by the Board in the specialty in accordance with Board rules. a~~ **specialist in a practice area provided the dentist has completed a qualifying postdoctoral education program in that area. A qualifying postdoctoral education program is a postdoctoral advanced dental educational program accredited by an agency recognized by the United States Department of Education.**

(2) ~~A dentist may advertise that the dentist specializes in or is a specialist in endodontics, oral and maxillofacial pathology, oral and maxillofacial surgery, oral and maxillofacial radiology, orthodontics and dentofacial orthopedics, pediatric dentistry, periodontics, prosthodontics or dental public health only if the dentist is licensed or certified by the Board in the specialty in accordance with Board rules.~~ **The Board shall consider the following criteria in determining a qualifying specialty board or organization:**

a) The organization requires completion of a training program with training, documentation, and clinical requirements similar in scope and complexity to a qualifying postdoctoral education program in the specialty or subspecialty field of dentistry in which the dentist seeks certification. Programs that require solely experiential training, continuing education classes, on-the-job training, or payment to the specialty board shall not constitute an equivalent specialty board;

b) The organization requires all dentists seeking certification to pass a written or oral examination, or both, that tests the applicant's knowledge and skill in the specialty or subspecialty area of dentistry and includes a psychometric evaluation for validation;

c) The organization has written rules on maintenance of certification and requires periodic recertification;

d) The organization has written bylaws and a code of ethics to guide the practice of its members;

e) The organization has staff to respond to consumer and regulatory inquiries; and

f) The organization is recognized by another entity whose primary purpose is to evaluate and assess dental specialty boards and organizations.

(3) A dentist shall maintain documentation of either completion of a qualifying postdoctoral educational program or of his or her current specialty certification and provide the documentation to the Board upon request. Dentists shall maintain documentation demonstrating that the certifying board qualifies under the criteria in Subsection (2)(a)-(f) of this rule and provide the documentation to the Board upon request.

818-021-0015
Certification as a Specialist

The Board may certify a dentist as a specialist if the dentist:

(1) Holds a current Oregon dental license;

(2) ~~Is a diplomate of or a fellow in a specialty board accredited or recognized by the American Dental Association; or~~ **Has completed a qualifying postdoctoral education program in the area of specialty. A qualifying postdoctoral education program is**

a postdoctoral advanced dental educational program accredited by an agency recognized by the United States Department of Education.
~~(3) Has completed a post-graduate program approved by the Commission on Dental Accreditation of the American Dental Association; or~~
(~~4~~**3**) ~~Was qualified to~~ **A**~~a~~dvertise**ment** as a specialist **is required to comply with** ~~under former~~ OAR 818-01~~0~~5-00~~61~~**07**.

818-021-0017
Application to Practice as a Specialist
(1) A dentist who wishes to practice as a specialist in Oregon, who does not have a current Oregon license, in addition to meeting the requirements set forth in ORS 679.060 and 679.065, shall submit to the Board satisfactory evidence of:
(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association and active licensure as a general dentist in another state. Licensure as a general dentist must have been obtained as a result of the passage of any clinical Board examination administered by any state or regional testing agency;
(b) Certification of having passed the dental examination administered by the Joint Commission on National Dental Examinations or Canadian National Dental Examining Board Examination; and
(c) Proof of satisfactory completion of a ~~post-graduate specialty program accredited by the Commission on Dental Accreditation of the American Dental Association~~ **postdoctoral education program in the area of specialty. A qualifying postdoctoral education program is a postdoctoral advanced dental educational program accredited by an agency recognized by the United States Department of Education.**
(2) A dentist who graduated from a dental school located outside the United States or Canada who wishes to practice as a specialist in Oregon, who does not have a current Oregon license, in addition to meeting the requirements set forth in ORS 679.060 and 679.065, shall submit to the Board satisfactory evidence of:
(a) Completion of a ~~post-graduate specialty program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association~~ **postdoctoral education program in the area of specialty. A qualifying postdoctoral education program is a postdoctoral advanced dental educational program of not less than two years accredited by an agency recognized by the United States Department of Education**, proficiency in the English language, and evidence of active licensure as a general dentist in another state obtained as a result of the passage of any clinical Board examination administered by any state or regional testing agency; or
(b) Completion of a ~~post-graduate specialty program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association~~ **postdoctoral education program in the area of specialty. A qualifying postdoctoral education program is a postdoctoral advanced dental educational program of not less than two years accredited by an agency recognized by the United States Department of Education**, proficiency in the English language and certification of having successfully passed the clinical examination administered by any state or regional testing agency within the five years immediately preceding application; and
(c) Certification of having passed the dental examination administered by the Joint

Commission on National Dental Examinations or Canadian National Dental Examining Board Examination; and
(3) An applicant who meets the above requirements shall be issued a specialty license upon:
(a) Passing a specialty examination approved by the Board **within the five years immediately preceding application, or;** ~~.~~
(b) Passing a specialty examination approved by the Board greater than five years prior to application, and;
(A) Having conducted licensed clinical practice in the applicant's postdoctoral dental specialty in Oregon, other states or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately preceding application. Licensed clinical practice could include hours devoted to teaching the applicant's dental specialty by dentists employed by a dental education program in a CODA-accredited dental school, with verification from the dean or appropriate administration of the institution documenting the length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching clinical dentistry in the specialty applicant is applying for, and any adverse actions or restrictions; and;
(B) Having completed 40 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application, and;
(~~b~~**c**) Passing the Board's jurisprudence examination.
(4) Any applicant who does not pass the first examination for a specialty license may apply for a second and third regularly scheduled specialty examination. ~~The applicable fee and application for the reexamination shall be submitted to the Board at least 45 days before the scheduled examination.~~ If the applicant fails to pass the third examination for the practice of a recognized specialty, the applicant will not be permitted to retake the particular specialty examination until he/she has attended and successfully passed a remedial program prescribed by a dental school accredited by the Commission on Dental Accreditation of the American Dental Association and approved by the Board.
(5) Licenses issued under this rule shall be limited to the practice of the specialty only.

The Committee reviewed and discussed splitting the hours so Licensees who wish to perform Botulinum Toxin Type A or dermal fillers are only required to take a course in the area they wish to perform. The Committee took no action.

A spelling error was noted in OAR 818-012-0005 by Dr. Julie Ann Smith and should be corrected in the rule.

818-012-0005
Scope of Practice
(1) No dentist may perform any of the procedures listed below:
(a) Rhinoplasty;
(b) Blepharoplasty;
(c) ~~Rhydidectomy~~ **Rhytidectomy**;
(d) Submental liposuction;
(e) Laser resurfacing;
(f) Browlift, either open or endoscopic technique;

(g) Platysmal muscle plication;
(h) Otoplasty;
(i) Dermabrasion;
(j) Hair transplantation, not as an isolated procedure for male pattern baldness; and
(k) Harvesting bone extra orally for dental procedures, including oral and maxillofacial procedures.
(2) Unless the dentist:
(a) Has successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association, Commission on Dental Accreditation (CODA), or
(b) Holds privileges either:
(A) Issued by a credentialing committee of a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to perform these procedures in a hospital setting; or
(B) Issued by a credentialing committee for an ambulatory surgical center licensed by the State of Oregon and accredited by either the JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC).
(3) A dentist may utilize Botulinum Toxin Type A and dermal fillers to treat a condition that is within the scope of the practice of dentistry after completing a minimum of 20 hours in a hands on clinical course(s), which includes both Botulinum Toxin Type A and dermal fillers, and the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP).

Dr. Beck moved and Dr. Goin seconded that the Committee recommend that the Board move OAR 818-021-0010 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-021-0010
Application for License to Practice Dentistry
(1) An applicant to practice general dentistry, in addition to the requirements set forth in ORS 679.060 and 679.065, shall submit to the Board satisfactory evidence of:
(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and
(c) Certification of having passed the dental examination administered by the Joint Commission on National Dental Examinations or Canadian National Dental Examining Board Examination.
(2) An applicant who has not met the educational requirements for licensure may apply for examination if the Dean of an accredited school certifies the applicant will graduate.
(3) An applicant must pass a Board examination consisting of a clinical portion administered by the Board, or any clinical Board examination administered by any state**,** ~~or~~ regional testing agency**, national testing agency or other Board-recognized testing agency** and a jurisprudence portion administered by the Board. Clinical examination results will be recognized by the Board for five years.
~~(4) An applicant who passes the clinical portion but not the jurisprudence portion of the examination may retake the jurisprudence examination without limit on the number of~~

~~times. The applicant must pass the jurisprudence portion within five years of passing the clinical portion or must retake the clinical examination.~~
(~~5~~4) A person who fails any Board approved clinical examination three times must successfully complete the remedial training recommended by the testing agency. Such remedial training must be conducted by a dental school accredited by the Commission on Dental Accreditation of the American Dental Association.

Ms. Riedman moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-021-0011 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-021-0011
Application for License to Practice Dentistry Without Further Examination
(1) The Oregon Board of Dentistry may grant a license without further examination to a dentist who holds a license to practice dentistry in another state or states if the dentist meets the requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory evidence of:
(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or completion of a postdoctoral General Dentistry Residency program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and
(c) Having passed the dental clinical examination conducted by a regional testing agency**,** ~~or~~ by a state dental licensing authority**, by a national testing agency or other Board-recognized testing agency**; and
(d) Holding an active license to practice dentistry, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and
(e) Having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately preceding application. Licensed clinical practice could include hours devoted to teaching by dentists employed by a dental education program in a CODA accredited dental school, with verification from the dean or appropriate administration of the institution documenting the length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching clinical dentistry, and any adverse actions or restrictions; and
(f) Having completed 40 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.
(2) Applicants must pass the Board's Jurisprudence Examination.
(3) A dental license granted under this rule will be the same as the license held in another state; i.e., if the dentist holds a general dentistry license, the Oregon Board will

issue a general (unlimited) dentistry license. If the dentist holds a license limited to the practice of a specialty, the Oregon Board will issue a license limited to the practice of that specialty. If the dentist holds more than one license, the Oregon Board will issue a dental license which is least restrictive.

The Committee reviewed and discussed correspondence from Dr. Bryan Williams who requests that the Board accept clinical residency hours count towards the 3,500 hours of licensed clinical practice to obtain Licensure Without Further Examination. Dr. Goin moved and Dr. Pham seconded the Committee's recommendation that the Board accept clinical residency hours towards the 3,500 hours of licensed clinical practice for Licensure Without Further Examination.

The Committee reviewed and discussed correspondence from the American Board of Prosthodontics requesting that the Board accept their Board examination in addition to The Commission on Dental Competency Assessments (CDCA) for specialists who meet all other requirements for licensure in Oregon to obtain an Oregon license. Dr. Pham moved and Dr. Beck seconded the Committee's recommendation that the Board accept all American Board recognized specialty examinations in addition to the CDCA's examination for specialty licensure.

Dr. Beck moved and Dr. Goin seconded that the Committee recommend that the Board move OAR 818-021-0020 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-021-0020
Application for License to Practice Dental Hygiene
(1) An applicant to practice dental hygiene, in addition to the requirements set forth in ORS 680.040 and 680.050, shall submit to the Board satisfactory evidence of:
(a) Having graduated from a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and
(c) Certification of having passed the dental hygiene examination administered by the Joint Commission on National Dental Examinations or the Canadian National Dental Hygiene Certificate Examination.
(2) An applicant who has not met the educational requirements for licensure may apply if the Director of an accredited program certifies the applicant will graduate.
(3) An applicant must pass a Board examination consisting of a clinical portion administered by the Board, or any clinical Board examination administered by any state**,** ~~or~~ regional testing agency**, national testing agency or other Board-recognized testing agency** and a jurisprudence portion administered by the Board. Clinical examination results will be recognized by the Board for five years.
~~(4) An applicant who passes the clinical portion but not the jurisprudence portion of the examination may retake the jurisprudence examination without limit on the number of times. The applicant must pass the jurisprudence portion within five years of passing the clinical portion or must retake the clinical examination.~~
(~~5~~**4**) A person who fails any Board approved clinical examination three times must successfully complete the remedial training recommended by the testing agency. Such remedial training must be conducted by a dental hygiene program accredited by the

Commission on Dental Accreditation of the American Dental Association.

Ms. Riedman moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-021-0025 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-021-0025
Application for License to Practice Dental Hygiene Without Further Examination
(1) The Oregon Board of Dentistry may grant a license without further examination to a dental hygienist who holds a license to practice dental hygiene in another state or states if the dental hygienist meets the requirements set forth in ORS 680.040 and 680.050 and submits to the Board satisfactory evidence of:
(a) Having graduated from a dental hygiene program accredited by the Commission on Dental
Accreditation of the American Dental Association; or
(b) Having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and
(c) Having passed the clinical dental hygiene examination conducted by a regional testing agency or by a state dental or dental hygiene licensing authority**, by a national testing agency or other Board-recognized testing agency**; and
(d) Holding an active license to practice dental hygiene, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dental hygiene, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and
(e) Having conducted licensed clinical practice in Oregon, in other states or in the Armed Forces of the United States, the United States Public Health Service, the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately preceding application. Licensed clinical practice could include hours devoted to teaching by dental hygienists employed by a CODA accredited dental hygiene program with verification from the dean or appropriate administration of the institution documenting the length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching clinical dental hygiene, and any adverse actions or restrictions; and
(f) Having completed 24 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.
(2) Applicants must pass the Board's Jurisprudence Examination.

Dr. Pham moved and Ms. Riedman seconded that the Committee recommend that the Board move OAR 818-021-0060 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-021-0060
Continuing Education — Dentists

(1) Each dentist must complete 40 hours of continuing education every two years. Continuing education (C.E.) must be directly related to clinical patient care or the practice of dental public health.
(2) Dentists must maintain records of successful completion of continuing education for at least four licensure years consistent with the licensee's licensure cycle. (A licensure year for dentists is April 1 through March 31.) The licensee, upon request by the Board, shall provide proof of successful completion of continuing education courses.
(3) Continuing education includes:
(a) Attendance at lectures, dental study groups, college post-graduate courses, or scientific sessions at conventions.
(b) Research, graduate study, teaching or preparation and presentation of scientific sessions. No more than 12 hours may be in teaching or scientific sessions. (Scientific sessions are defined as scientific presentations, table clinics, poster sessions and lectures.)
(c) Correspondence courses, videotapes, distance learning courses or similar self-study course, provided that the course includes an examination and the dentist passes the examination.
(d) Continuing education credit can be given for volunteer pro bono dental services provided in the state of Oregon; community oral health instruction at a public health facility located in the state of Oregon; authorship of a publication, book, chapter of a book, article or paper published in a professional journal; participation on a state dental board, peer review, or quality of care review procedures; successful completion of the National Board Dental Examinations taken after initial licensure; a recognized specialty examination taken after initial licensure; or test development for clinical dental, dental hygiene or specialty examinations. No more than 6 hours of credit may be in these areas.
(4) At least three hours of continuing education must be related to medical emergencies in a dental office. No more than four hours of Practice Management and Patient Relations may be counted toward the C.E. requirement in any renewal period.
(5) All dentists licensed by the Oregon Board of Dentistry will complete a one-hour pain management course specific to Oregon provided by the Pain Management Commission of the Oregon Health Authority. All applicants or licensees shall complete this requirement by January 1, 2010 or within 24 months of the first renewal of the dentist's license.
(6) At least ~~2~~ **one (1)** hour~~s~~ of continuing education must be related to infection control. ~~(Effective January 1, 2015.)~~
(7) At least one (1) hour of continuing education must be related to cultural competency.

Ms. Riedman moved and Dr. Goin seconded that the Committee recommend that the Board move OAR 818-021-0070 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-021-0070
Continuing Education — Dental Hygienists
(1) Each dental hygienist must complete 24 hours of continuing education every two years. An Expanded Practice Permit Dental Hygienist shall complete a total of 36 hours of continuing education every two years. Continuing education (C.E.) must be directly related to clinical patient care or the practice of dental public health.

(2) Dental hygienists must maintain records of successful completion of continuing education for at least four licensure years consistent with the licensee's licensure cycle. (A licensure year for dental hygienists is October 1 through September 30.) The licensee, upon request by the Board, shall provide proof of successful completion of continuing education courses.
(3) Continuing education includes:
(a) Attendance at lectures, dental study groups, college post-graduate courses, or scientific sessions at conventions.
(b) Research, graduate study, teaching or preparation and presentation of scientific sessions. No more than six hours may be in teaching or scientific sessions. (Scientific sessions are defined as scientific presentations, table clinics, poster sessions and lectures.)
(c) Correspondence courses, videotapes, distance learning courses or similar self-study course, provided that the course includes an examination and the dental hygienist passes the examination.
(d) Continuing education credit can be given for volunteer pro bono dental hygiene services provided in the state of Oregon; community oral health instruction at a public health facility located in the state of Oregon; authorship of a publication, book, chapter of a book, article or paper published in a professional journal; participation on a state dental board, peer review, or quality of care review procedures; successful completion of the National Board Dental Hygiene Examination, taken after initial licensure; or test development for clinical dental hygiene examinations. No more than 6 hours of credit may be in these areas.
(4) At least three hours of continuing education must be related to medical emergencies in a dental office. No more than two hours of Practice Management and Patient Relations may be counted toward the C.E. requirement in any renewal period.
(5) Dental hygienists who hold a Nitrous Oxide Permit must meet the requirements contained in OAR 818-026-0040(~~10~~**11**) for renewal of the Nitrous Oxide Permit.
(6) At least ~~2~~ **one (1)** hour~~s~~ of continuing education must be related to infection control. ~~(Effective January 1, 2015.)~~
(7) At least one (1) hour of continuing education must be related to cultural competency.

Dr. Beck moved and Dr. Pham seconded that the Committee recommend that the Board move OAR 818-021-0088 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-021-0088 - Volunteer License
(1) An Oregon licensed dentist or dental hygienist who will be practicing for a supervised volunteer dental clinic, as defined in ORS 679.020(3)(f) and (g), may be granted a volunteer license provided licensee completes the following:
(a) Licensee must register with the Board as a health care professional and provide a statement as required by ORS 676.345.
(b) Licensee will be responsible to meet all the requirements set forth in ORS 676.345.
(c) Licensee must provide the health care service without compensation.
(d) Licensee shall not practice dentistry or dental hygiene for remuneration in any capacity under the volunteer license.
(e) Licensee must comply with all continuing education requirements for active licensed dentist or dental hygienist.

(f) Licensee must agree to volunteer for a minimum of ~~40 hours per calendar year~~ **80 hours per renewal cycle.**
(2) Licensee may surrender the volunteer license designation at any time and request a return to an active license. The Board will grant an active license as long as all active license requirements have been met.

Dr. Beck moved and Mr. Dunn seconded that the Committee recommend that the Board move OAR 818-026-0030 as proposed to the Rules Oversight Committee. The motion passed unanimously.

Division 26 – Anesthesia
818-026-0030 – Requirement for Anesthesia Permit~~, Standards and Qualifications of an Anesthesia Monitor~~
(1) A permit holder who administers sedation shall assure that drugs, drug dosages, and/or techniques used to produce sedation shall carry a margin of safety wide enough to prevent unintended deeper levels of sedation.
(2) No licensee shall induce central nervous system sedation or general anesthesia without first having obtained a permit under these rules for the level of anesthesia being induced.
(3) A licensee may be granted a permit to administer sedation or general anesthesia with documentation of training/education and/or competency in the permit category for which the licensee is applying by any one the following:
(a) Initial training/education in the permit category for which the applicant is applying shall be completed no more than two years immediately prior to application for sedation or general anesthesia permit; or
(b) If greater than two years but less than five years since completion of initial training/education, an applicant must document completion of all continuing education that would have been required for that anesthesia/permit category during that five year period following initial training; or
(c) If greater than two years but less than five years since completion of initial training/education, immediately prior to application for sedation or general anesthesia permit, current competency or experience must be documented by completion of a comprehensive review course approved by the Board in the permit category to which the applicant is applying and must consist of at least one-half (50%) of the hours required by rule for Nitrous Oxide, Minimal Sedation, Moderate Sedation and General Anesthesia Permits. Deep Sedation and General Anesthesia Permits will require at least 120 hours of general anesthesia training.
(d) An applicant for sedation or general anesthesia permit whose completion of initial training/education is greater than five years immediately prior to application, may be granted a sedation or general anesthesia permit by submitting documentation of the requested permit level from another state or jurisdiction where the applicant is also licensed to practice dentistry or dental hygiene, and provides documentation of the completion of at least 25 cases in the requested level of sedation or general anesthesia in the 12 months immediately preceding application; or
(e) Demonstration of current competency to the satisfaction of the Board that the applicant possesses adequate sedation or general anesthesia skill to safely deliver sedation or general anesthesia services to the public.
~~(4) Persons serving as anesthesia monitors in a dental office shall maintain current certification in Health Care Provider Basic Life Support (BLS)/Cardio Pulmonary~~

~~Resuscitation (CPR) training, or its equivalent, shall be trained in monitoring patient vital signs, and be competent in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. (The term "competent" as used in these rules means displaying special skill or knowledge derived from training and experience.)~~
(4)~~(5)~~ A licensee holding a nitrous or minimal sedation permit, shall at all times maintain a current BLS for Health**care** Care Providers certificate or its equivalent.
(5)~~(6)~~ A licensee holding an anesthesia permit for moderate sedation, deep sedation or general anesthesia at all times maintains a current BLS for Health**care** ~~Care~~ Providers certificate or its equivalent, and a current Advanced Cardiac Life Support (ACLS) Certificate or Pediatric Advanced Life Support (PALS) Certificate, whichever is appropriate for the patient being sedated. If a licensee permit holder sedates only patients under the age of 12, only PALS is required. If a licensee permit holder sedates only patients age 12 and older, only ACLS is required. If a licensee permit holder sedates patients younger than 12 years of age as well as older than 12 years of age, both ACLS and PALS are required. For licensees with a moderate sedation permit only, successful completion of the American Dental Association's course "Recognition and Management of Complications during Minimal and Moderate Sedation" at least every two years may be substituted for ACLS, but not for PALS.
(6)~~(7)~~ Advanced Cardiac Life Support (ACLS) and or Pediatric Advanced Life Support (PALS) do not serve as a substitute for Health ~~C~~**care** Provider Basic Life Support (BLS).
(7) ~~(8)~~ When a dentist utilizes a single oral agent to achieve anxiolysis only, no anesthesia permit is required.
(8) ~~(9)~~ The applicant for an anesthesia permit must pay the appropriate permit fee, submit a completed Board-approved application and consent to an office evaluation.
(9) ~~(10)~~ Permits shall be issued to coincide with the applicant's licensing period.

Ms. Riedman moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-026-0040 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-026-0040 - Qualifications, Standards Applicable, and Continuing Education Requirements for Anesthesia Permits: Nitrous Oxide Permit
Qualifications, Standards Applicable, and Continuing Education Requirements for Anesthesia Permits: Nitrous Oxide Permit
Nitrous Oxide Sedation.
(1) The Board shall issue a Nitrous Oxide Permit to an applicant who:
(a) Is either a licensed dentist or licensed hygienist in the State of Oregon;
(b) Maintains a current BLS for Healthcare Providers certificate or its equivalent; and
(c) Has completed a training course of at least 14 hours of instruction in the use of nitrous oxide from a dental school or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association, or as a postgraduate.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedure and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow delivery of appropriate care in an emergency situation;
(b) An operating table or chair which permits the patient to be positioned so that the patient's airway can be maintained, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;

(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full face masks and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system; and
(g) Sphygmomanometer and stethoscope and/or automatic blood pressure cuff.
(3) Before inducing nitrous oxide sedation, a permit holder shall:
(a) Evaluate the patient;
(b) Give instruction to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian;
(c) Certify that the patient is an appropriate candidate for nitrous oxide sedation; and
(d) Obtain informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(4) If a patient chronically takes a medication which can have sedative side effects, including, but not limited to, a narcotic or benzodiazepine, the practitioner shall determine if the additive sedative effect of nitrous oxide would put the patient into a level of sedation deeper than nitrous oxide. If the practitioner determines it is possible that providing nitrous oxide to such a patient would result in minimal sedation, a minimal sedation permit would be required.
(5) A patient under nitrous oxide sedation shall be visually monitored by the permit holder or by an anesthesia monitor at all times. The patient shall be monitored as to response to verbal stimulation, oral mucosal color and preoperative and postoperative vital signs.
(6) The permit holder or anesthesia monitor shall record the patient's condition. The record must include documentation of all medications administered with dosages, time intervals and route of administration.
(7) Persons serving as anesthesia monitors for nitrous oxide in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)
(8)~~(7)~~ The person administering the nitrous oxide sedation may leave the immediate area after initiating the administration of nitrous oxide sedation only if a qualified anesthesia monitor is continuously observing the patient.
(9)~~(8)~~ The permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(b) The patient can talk and respond coherently to verbal questioning;
(c) The patient can sit up unaided or without assistance;
(d) The patient can ambulate with minimal assistance; and
(e) The patient does not have nausea, vomiting or dizziness.

(10)~~(9)~~ The permit holder shall make a discharge entry in the patient's record indicating the patient's condition upon discharge.
(11)~~(10)~~ Permit renewal. In order to renew a Nitrous Oxide Permit, the permit holder must provide proof of a current BLS for Healthcare Providers certificate or its equivalent. In addition, Nitrous Oxide Permit holders must also complete four (4) hours of continuing education in one or more of the following areas every two years: sedation, nitrous oxide, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current BLS for Healthcare Providers certificate or its equivalent, may not be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060 and 818-021-0070.

Dr. Goin moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-026-0050 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-026-0050
Minimal Sedation Permit
Minimal sedation and nitrous oxide sedation.
(1) The Board shall issue a Minimal Sedation Permit to an applicant who:
(a) Is a licensed dentist in Oregon;
(b) Maintains a current BLS for Healthcare Providers certificate or its equivalent; and
(c) Completion of a comprehensive training program consisting of at least 16 hours of training and satisfies the requirements of the current ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced or postgraduate instruction was completed, or the equivalent of that required in graduate training programs, in sedation, recognition and management of complications and emergency care; or
(d) In lieu of these requirements, the Board may accept equivalent training or experience in minimal sedation anesthesia.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedures and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least two individuals to freely move about the patient;
(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full facemask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;

(g) Sphygmomanometer, stethoscope, pulse oximeter, and/or automatic blood pressure cuff; and
(h) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, antihistamines, antihypertensives and anticonvulsants.
(3) Before inducing minimal sedation, a dentist permit holder who induces minimal sedation shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for minimal sedation;
(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian;
(c) Certify that the patient is an appropriate candidate for minimal sedation; and
(d) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(4) No permit holder shall have more than one person under minimal sedation at the same time.
(5) While the patient is being treated under minimal sedation, an anesthesia monitor shall be present in the room in addition to the treatment provider. The anesthesia monitor may be the dental assistant. After training, a dental assistant, when directed by a dentist permit holder, may administer oral sedative agents or anxiolysis agents calculated and dispensed by a dentist permit holder under the direct supervision of a dentist permit holder.
(6) A patient under minimal sedation shall be visually monitored at all times, including recovery phase. **The record must include documentation of all medications administered with dosages, time intervals and route of administration.** The dentist permit holder or anesthesia monitor shall monitor and record the patient's condition.
(7) Persons serving as anesthesia monitors for minimal sedation in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)
(8)~~(7)~~ The patient shall be monitored as follows:
(a) Color of mucosa, skin or blood must be evaluated continually. Patients must have continuous monitoring using pulse oximetry. The patient's response to verbal stimuli, blood pressure, heart rate, **pulse oximetry** and respiration shall be monitored and documented **every fifteen minutes,** if they can reasonably be obtained.
(b) A discharge entry shall be made by the dentist permit holder in the patient's record indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.
(9)~~(8)~~ The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;
(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(c) The patient can talk and respond coherently to verbal questioning;

(d) The patient can sit up unaided;
(e) The patient can ambulate with minimal assistance; and
(f) The patient does not have uncontrollable nausea or vomiting and has minimal dizziness.
(g) A dentist permit holder shall not release a patient who has undergone minimal sedation except to the care of a responsible third party.
(10)~~(9)~~ Permit renewal. In order to renew a Minimal Sedation Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent. In addition, Minimal Sedation Permit holders must also complete four (4) hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current BLS for Healthcare Providers certificate, or its equivalent, may not be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

Dr. Pham moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-026-0055 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-026-0055
Dental Hygiene and Dental Assistant Procedures Performed Under Nitrous Oxide or Minimal Sedation
1) Under indirect supervision, dental hygiene procedures may be performed for a patient who
is under nitrous oxide or minimal sedation under the following conditions:
(a) A licensee holding a Nitrous Oxide, Minimal, Moderate, Deep Sedation or General Anesthesia Permit administers the sedative agents;
(b) The permit holder, or an anesthesia monitor, monitors the patient; or
(c) if a dental hygienist with a nitrous oxide permit administers nitrous oxide sedation to a patient and then performs authorized procedures on the patient, an anesthesia monitor is not required to be present during the time the patient is sedated unless the permit holder leaves the patient.
(d) The permit holder performs the appropriate pre- and post-operative evaluation and discharges the patient in accordance with 818-026-0050(7) and (8).
(2) Under **in**direct supervision, a dental assistant may perform those procedures for which the
dental assistant holds the appropriate certification for a patient who is under nitrous oxide or minimal sedation under the following conditions:
(a) A licensee holding the Nitrous Oxide, Minimal, Moderate, Deep Sedation or General Anesthesia Permit administers the sedative agents;
(b) The permit holder, or an anesthesia monitor, monitors the patient; and
(c) The permit holder performs the appropriate pre- and post-operative evaluation and discharges the patient in accordance with 818-026-0050(7) and (8).

Dr. Pham moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-026-0060 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-026-0060
Moderate Sedation Permit
Moderate sedation, minimal sedation, and nitrous oxide sedation.
(1) The Board shall issue or renew a Moderate Sedation Permit to an applicant who:
(a) Is a licensed dentist in Oregon;
(b) In addition to a current BLS for Healthcare Providers certificate or its equivalent, either maintains a current Advanced Cardiac Life Support (ACLS) certificate and/or a Pediatric Advanced Life Support (PALS) certificate, whichever is appropriate for the patient being sedated; and
(c) Satisfies one of the following criteria:
(A) Completion of a comprehensive training program in enteral and/or parenteral sedation that satisfies the requirements described in Part V of the current ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced.
(i) Enteral Moderate Sedation requires a minimum of 24 hours of instruction plus management of at least 10 dental patient experiences by the enteral and/or enteral-nitrous oxide/oxygen route.
(ii) Parenteral Moderate Sedation requires a minimum of 60 hours of instruction plus management of at least 20 dental patients by the intravenous route.
(B) Completion of an ADA accredited postdoctoral training program (e.g., general practice residency) which affords comprehensive and appropriate training necessary to administer and manage parenteral sedation, commensurate with these Guidelines.
(C) In lieu of these requirements, the Board may accept equivalent training or experience in moderate sedation anesthesia.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedures and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least two individuals to freely move about the patient;
(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full face mask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;
(g) A recovery area that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area can be the operating room;
(h) Sphygmomanometer, precordial/pretracheal stethoscope, capnograph, pulse oximeter, oral and nasopharyngeal airways, larynageal mask airways, intravenous fluid administration equipment, automated external defibrillator (AED); and

(i) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, antihistamines, antihypertensives and anticonvulsants.
(3) No permit holder shall have more than one person under moderate sedation, minimal sedation, or nitrous oxide sedation at the same time.
(4) During the administration of moderate sedation, and at all times while the patient is under moderate sedation, an anesthesia monitor, and one other person holding a current BLS for Healthcare Providers certificate or its equivalent, shall be present in the operatory, in addition to the dentist permit holder performing the dental procedures.
(5) Before inducing moderate sedation, a dentist permit holder who induces moderate sedation shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for moderate sedation;
(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian; and
(c) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(6) A patient under moderate sedation shall be visually monitored at all times, including the recovery phase. The dentist permit holder or anesthesia monitor shall monitor and record the patient's condition.
(7) Persons serving as anesthesia monitors for moderate sedation in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)
(8)(7) The patient shall be monitored as follows:
(a) Patients must have continuous monitoring using pulse oximetry, and End-tidal CO2 monitors. Patients with cardiovascular disease shall have continuous electrocardiograph (ECG) monitoring. The patient's blood pressure, heart rate, and respiration shall be recorded at regular intervals but at least every 15 minutes, and these recordings shall be documented in the patient record. The record must also include documentation of preoperative and postoperative vital signs, all medications administered with dosages, time intervals and route of administration. If this information cannot be obtained, the reasons shall be documented in the patient's record. A patient under moderate sedation shall be continuously monitored and shall not be left alone while under sedation;
(b) During the recovery phase, the patient must be monitored by an individual trained to monitor patients recovering from moderate sedation.
(9)~~(8)~~ A dentist permit holder shall not release a patient who has undergone moderate sedation except to the care of a responsible third party.
(a) When a reversal agent is administered, the dentist permit holder shall document justification for its use and how the recovery plan was altered.
(10)~~(9)~~ The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;

(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(c) The patient can talk and respond coherently to verbal questioning;
(d) The patient can sit up unaided;
(e) The patient can ambulate with minimal assistance; and
(f) The patient does not have uncontrollable nausea or vomiting and has minimal dizziness.
(11)~~(10)~~ A discharge entry shall be made by the dentist permit holder in the patient's record indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.
(12)~~(11)~~ After adequate training, an assistant, when directed by a dentist permit holder, may dispense oral medications that have been prepared by the dentist permit holder for oral administration to a patient under direct supervision. Pursuant to OAR 818-042-0115 a Certified Anesthesia Dental Assistant, when directed by a dentist permit holder, may introduce additional anesthetic agents into an infusion line under the direct supervision of a dentist permit holder.
(13)~~(12)~~ Permit renewal. In order to renew a Moderate Sedation Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent; a current Advanced Cardiac Life Support (ACLS) certificate and/or a current Pediatric Advanced Life Support (PALS) certificate; Successful completion of a board approved course on minimal/moderate sedation at least every two years may be substituted for ACLS, but not for PALS; and must complete 14 hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current ACLS or PALS certification or successful completion of the American Dental Association's course "Recognition and Management of Complications during Minimal and Moderate Sedation" may be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

Dr. Pham moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-026-0065 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-026-0065
Deep Sedation Permit
Deep sedation, moderate sedation, minimal sedation, and nitrous oxide sedation.
(1) The Board shall issue a Deep Sedation Permit to a licensee who holds a Class 3 Permit on or before July 1, 2010 who:
(a) Is a licensed dentist in Oregon; and
(b) In addition to a current BLS for Healthcare Providers certificate or its equivalent, maintains a current Advanced Cardiac Life Support (ACLS) certificate and/or a Pediatric Advanced Life Support (PALS) certificate, whichever is appropriate for the patient being sedated.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedures and during recovery:

(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least two individuals to freely move about the patient;
(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full face mask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;
(g) A recovery area that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area can be the operating room;
(h) Sphygmomanometer, precordial/pretracheal stethoscope, capnograph, pulse oximeter, electrocardiograph monitor (ECG), automated external defibrillator (AED), oral and nasopharyngeal airways, laryngeal mask airways, intravenous fluid administration equipment; and
(i) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, antihistamines, antihypertensives and anticonvulsants.
(3) No permit holder shall have more than one person under deep sedation, moderate sedation, minimal sedation, or nitrous oxide sedation at the same time.
(4) During the administration of deep sedation, and at all times while the patient is under deep sedation, an anesthesia monitor, and one other person holding a current BLS for Healthcare Providers certificate or its equivalent, shall be present in the operatory, in addition to the dentist permit holder performing the dental procedures.
(5) Before inducing deep sedation, a dentist permit holder who induces deep sedation shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for deep sedation;
(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian; and
(c) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(6) A patient under deep sedation shall be visually monitored at all times, including the recovery phase. The dentist permit holder or anesthesia monitor shall monitor and record the patient's condition.
(7 Persons serving as anesthesia monitors for deep sedation in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized.

("competent" means displaying special skill or knowledge derived from training and experience.)

(8)(7) The patient shall be monitored as follows:

(a) Patients must have continuous monitoring using pulse oximetry, electrocardiograph monitors (ECG) and End-tidal CO2 monitors. The patient's heart rhythm shall be continuously monitored and the patient's blood pressure, heart rate, and respiration shall be recorded at regular intervals but at least every 5 minutes, and these recordings shall be documented in the patient record. The record must also include documentation of preoperative and postoperative vital signs, all medications administered with dosages, time intervals and route of administration. If this information cannot be obtained, the reasons shall be documented in the patient's record. A patient under deep sedation shall be continuously monitored;

(b) Once sedated, a patient shall remain in the operatory for the duration of treatment until criteria for transportation to recovery have been met.

(c) During the recovery phase, the patient must be monitored by an individual trained to monitor patients recovering from deep sedation.

(9)~~(8)~~ A dentist permit holder shall not release a patient who has undergone deep sedation except to the care of a responsible third party. When a reversal agent is administered, the dentist permit holder shall document justification for its use and how the recovery plan was altered.

(10)~~(9)~~ The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:

(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;

(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;

(c) The patient can talk and respond coherently to verbal questioning;

(d) The patient can sit up unaided;

(e) The patient can ambulate with minimal assistance; and

(f) The patient does not have uncontrollable nausea or vomiting and has minimal dizziness.

(11)~~(10)~~ A discharge entry shall be made by the dentist permit holder in the patient's record indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.

(12)~~(11)~~ Pursuant to OAR 818-042-0115 a Certified Anesthesia Dental Assistant, when directed by a dentist permit holder, may administer oral sedative agents calculated by a dentist permit holder or introduce additional anesthetic agents into an infusion line under the direct visual supervision of a dentist

(13)~~(12)~~ Permit renewal. In order to renew a Deep Sedation Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent; a current Advanced Cardiac Life Support (ACLS) certificate and/or a current Pediatric Advanced Life Support (PALS) certificate; and must complete 14 hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current ACLS and/or PALS certificates may be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

Dr. Pham moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-026-0070 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-026-0070
General Anesthesia Permit

General anesthesia, deep sedation, moderate sedation, minimal sedation and nitrous oxide sedation.

(1) The Board shall issue a General Anesthesia Permit to an applicant who:

(a) Is a licensed dentist in Oregon;

(b) In addition to a current BLS for Healthcare Providers certificate or its equivalent, maintains a current Advanced Cardiac Life Support (ACLS) certificate and/or a Pediatric Advanced Life Support (PALS) certificate, whichever is appropriate for the patient being sedated, and

(c) Satisfies one of the following criteria:

(A) Completion of an advanced training program in anesthesia and related subjects beyond the undergraduate dental curriculum that satisfies the requirements described in the current ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students consisting of a minimum of 2 years of a postgraduate anesthesia residency at the time training was commenced.

(B) Completion of any ADA accredited postdoctoral training program, including but not limited to Oral and Maxillofacial Surgery, which affords comprehensive and appropriate training necessary to administer and manage general anesthesia, commensurate with these Guidelines.

(C) In lieu of these requirements, the Board may accept equivalent training or experience in general anesthesia.

(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedure and during recovery:

(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least three individuals to freely move about the patient;

(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;

(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;

(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;

(e) An oxygen delivery system with adequate full face mask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;

(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;

(g) A recovery area that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area can be the operating room;

(h) Sphygmomanometer, precordial/pretracheal stethoscope, capnograph, pulse oximeter, electrocardiograph monitor (ECG), automated external defibrillator (AED), oral

and nasopharyngeal airways, laryngeal mask airways, intravenous fluid administration equipment; and
(i) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, intravenous medications for treatment of cardiac arrest, narcotic antagonist, antihistaminic, antiarrhythmics, antihypertensives and anticonvulsants.
(3) No permit holder shall have more than one person under general anesthesia, deep sedation, moderate sedation, minimal sedation or nitrous oxide sedation at the same time.
(4) During the administration of deep sedation or general anesthesia, and at all times while the patient is under deep sedation or general anesthesia, an anesthesia monitor, and one other person holding a current BLS for Healthcare Providers certificate or its equivalent, shall be present in the operatory in addition to the dentist permit holder performing the dental procedures.
(5) Before inducing deep sedation or general anesthesia the dentist permit holder who induces deep sedation or general anesthesia shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for general anesthesia or deep sedation;
(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian; and
(c) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(6) A patient under deep sedation or general anesthesia shall be visually monitored at all times, including recovery phase. A dentist permit holder who induces deep sedation or general anesthesia or anesthesia monitor trained in monitoring patients under deep sedation or general anesthesia shall monitor and record the patient's condition on a contemporaneous record.
(7) Persons serving as anesthesia monitors for general anesthesia in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)
(8)(7) The patient shall be monitored as follows:
(a) Patients must have continuous monitoring of their heart rate, heart rhythm, oxygen saturation levels and respiration using pulse oximetry, electrocardiograph monitors (ECG) and End-tidal CO2 monitors. The patient's blood pressure, heart rate and oxygen saturation shall be assessed every five minutes, and shall be contemporaneously documented in the patient record. The record must also include documentation of preoperative and postoperative vital signs, all medications administered with dosages, time intervals and route of administration. The person administering the anesthesia and the person monitoring the patient may not leave the patient while the patient is under deep sedation or general anesthesia;
(b) Once sedated, a patient shall remain in the operatory for the duration of treatment until criteria for transportation to recovery have been met.
(c) During the recovery phase, the patient must be monitored, including the use of pulse oximetry, by an individual trained to monitor patients recovering from general anesthesia.

(9)~~(8)~~ A dentist permit holder shall not release a patient who has undergone deep sedation or general anesthesia except to the care of a responsible third party. When a reversal agent is administered, the dentist permit holder shall document justification for its use and how the recovery plan was altered.
(10)~~(9)~~ The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;
(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(c) The patient can talk and respond coherently to verbal questioning;
(d) The patient can sit up unaided;
(e) The patient can ambulate with minimal assistance; and
(f) The patient does not have nausea or vomiting and has minimal dizziness.
(11)~~(10)~~ A discharge entry shall be made in the patient's record by the dentist permit holder indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.
(12)~~(11)~~ Pursuant to OAR 818-042-0115 a Certified Anesthesia Dental Assistant, when directed by a dentist permit holder, may introduce additional anesthetic agents to an infusion line under the direct visual supervision of a dentist permit holder.
(13)~~(12)~~ Permit renewal. In order to renew a General Anesthesia Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent; a current Advanced Cardiac Life Support (ACLS) certificate and/or a current Pediatric Advanced Life Support (PALS) certificate; and must complete 14 hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current ACLS and/or PALS certificates may be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

The Committee recommends the Board refer back to the Anesthesia Committee for further clarification on defining anesthesia monitors for OAR 818-026-0060, OAR 818-026-0065 and OAR 818-026-0070.

Dr. Pham moved and Dr. Goin seconded that the Committee recommend that the Board move OAR 818-026-0080 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-026-0080
Standards Applicable When a Dentist Performs Dental Procedures and a Qualified Provider Induces Anesthesia
(1) A dentist who does not hold an anesthesia permit may perform dental procedures on a patient who receives anesthesia induced by a physician anesthesiologist licensed by the Oregon Board of Medical Examiners, another Oregon licensed dentist holding an appropriate anesthesia permit, or a Certified Registered Nurse Anesthetist (CRNA) licensed by the Oregon Board of Nursing.

(2) A dentist who does not hold a Nitrous Oxide Permit for nitrous oxide sedation may perform dental procedures on a patient who receives nitrous oxide induced by an Oregon licensed dental hygienist holding a Nitrous Oxide Permit.
(3) A dentist who performs dental procedures on a patient who receives anesthesia induced by a physician anesthesiologist, another dentist holding an anesthesia permit, a CRNA, or a dental hygienist who induces nitrous oxide sedation, shall maintain a current BLS for Healthcare Providers certificate, or its equivalent, and have the same personnel, facilities, equipment and drugs available during the procedure and during recovery as required of a dentist who has a permit for the level of anesthesia being provided.
(4) A dentist, a dental hygienist or an Expanded Function Dental Assistant (EFDA) who performs procedures on a patient who is receiving anesthesia induced by a physician anesthesiologist, another dentist holding an anesthesia permit or a CRNA shall not schedule or treat patients for non emergent care during the period of time of the sedation procedure.
(5) Once anesthetized, a patient shall remain in the operatory for the duration of treatment until criteria for transportation to recovery have been met.
(6) The qualified anesthesia provider who induces moderate sedation, deep sedation or general anesthesia shall monitor the patient~~'s condition the patient is discharged~~ **until easily arousable and can independently and continuously maintain their airway with stable vital signs. Once this has occurred the patient may be monitored by a qualified anesthesia monitor until discharge criteria is met. The patient's dental record shall document** the patient's condition at discharge ~~in the patient's dental record~~ as required by the rules applicable to the level of anesthesia being induced. ~~The~~ **A copy of the** anesthesia record shall be maintained in the patient's dental record and is the responsibility of the dentist who is performing the dental procedures.
(7) No qualified provider shall have more than one person under any form of sedation or general anesthesia at the same time exclusive of recovery.
(8)~~(7)~~ A dentist who intends to use the services of a qualified anesthesia provider as described in section 1 above, shall notify the Board in writing of his/her intent. Such notification need only be submitted once every licensing period.

The Committee reviewed and discussed correspondence from Ms. Gonzales regarding if it was permissible for dental hygienist to administer silver nitrate as an antimicrobial. The Committee reviewed OAR 818-035-0025 Prohibitions and OAR 818-035-0030 Additional Functions of Dental Hygienists and determined under current rules dental hygienists can prescribe, administer and dispense antimicrobials. No action was taken.

The Committee reviewed and discussed correspondence from Ms. DeMallie regarding if it was permissible for dental hygienist to take final impressions for supplying artificial teeth as substitutes for natural teeth. The Committee reviewed 818-035-0025 Prohibitions and determined under current rules dental hygienists can take final impressions. No action was taken

818-035-0025
Prohibitions
A dental hygienist may not:
(1) Diagnose and treatment plan other than for dental hygiene services;
(2) Cut hard or soft tissue with the exception of root planing;

(3) Extract any tooth;
(4) Fit or adjust any correctional or prosthetic appliance except as provided by OAR 818-035-0030(1)(h);
(5) Prescribe, administer or dispense any drugs except as provided by OAR 818-035-0030, 818-035- 0040, 818-026-0060(11) and 818-026-0070(11);
(6) Place, condense, carve or cement permanent restorations except as provided in OAR 818-035-0072, or operatively prepare teeth;
(7) Irrigate or medicate canals; try in cones, or ream, file or fill canals;
(8) Use the behavior management techniques of Hand Over Mouth (HOM) or Hand Over Mouth Airway Restriction (HOMAR) on any patient.
(9) Place or remove healing caps or healing abutments, except under direct supervision.
(10) Place implant impression copings, except under direct supervision.

818-035-0030
Additional Functions of Dental Hygienists
(1) In addition to functions set forth in ORS 679.010, a dental hygienist may perform the following functions under the general supervision of a licensed dentist:
(a) Make preliminary intra-oral and extra-oral examinations and record findings;
(b) Place periodontal dressings;
(c) Remove periodontal dressings or direct a dental assistant to remove periodontal dressings;
(d) Perform all functions delegable to dental assistants and expanded function dental assistants providing that the dental hygienist is appropriately trained;
(e) Administer and dispense antimicrobial solutions or other antimicrobial agents in the performance of dental hygiene functions.
(f) Prescribe, administer and dispense fluoride, fluoride varnish, antimicrobial solutions for mouth rinsing or other non-systemic antimicrobial agents.
(g) Use high-speed handpieces to polish restorations and to remove cement and adhesive material.
(h) Apply temporary soft relines to complete dentures for the purpose of tissue conditioning.
(i) Perform all aspects of teeth whitening procedures.
(2) A dental hygienist may perform the following functions at the locations and for the persons described in ORS 680.205(1) and (2) without the supervision of a dentist:
(a) Determine the need for and appropriateness of sealants or fluoride; and
(b) Apply sealants or fluoride.

Dr. Beck moved and Dr. Pham seconded that the Committee recommend that the Board move OAR 818-042-0040 as amended to the Rules Oversight Committee. The motion passed unanimously.

818-042-0040
Prohibited Acts
No licensee may authorize any dental assistant to perform the following acts:
(1) Diagnose or plan treatment.
(2) Cut hard or soft tissue.
(3) Any Expanded Function duty (**OAR** 818-042-0070 and **OAR** 818-042-0090) or

Expanded Orthodontic Function duty (OAR 818-042-0100) **or Restorative Functions (OAR 818-042-0095 or Expanded Preventive Duty OAR 818-042-0113 and OAR 818-042-0114 or Expanded Function Anesthesia (OAR 818-042-0115)** without holding the appropriate certification.
(4) Correct or attempt to correct the malposition or malocclusion of teeth except as provided by OAR 818-042-0100.
(5) Adjust or attempt to adjust any orthodontic wire, fixed or removable appliance or other structure while it is in the patient's mouth.
(6) Administer any drug except fluoride, topical anesthetic, desensitizing agents, over the counter medications per package instructions or drugs administered pursuant to ~~OAR 818-026-0030(6),~~ OAR 818-026-0050(5)(a)**,** OAR 818-026-0060(11), **OAR** 818-026-0065(11), **OAR** 818-026-0070(11) and as provided in **OAR** 818-042-0070, **OAR** 818-042-0090 and **OAR** 818-042-0115.
(7) Prescribe any drug.
(8) Place periodontal packs.
(9) Start nitrous oxide.
(10) Remove stains or deposits except as provided in OAR 818-042-0070.
(11) Use ultrasonic equipment intra-orally except as provided in OAR 818-042-0100.
(12) Use a high-speed handpiece or any device that is operated by a high-speed handpiece intra-orally except as provided in OAR 818-042-0095, and only for the purpose of adjusting occlusion, contouring, and polishing restorations on the tooth or teeth that are being restored.
(13) Use lasers, except laser-curing lights.
(14) Use air abrasion or air polishing.
(15) Remove teeth or parts of tooth structure.
(16) Cement or bond any fixed ~~prosthetic~~ **prosthesis** or orthodontic appliance including bands, brackets, retainers, tooth moving devices, or orthopedic appliances except as provided in **OAR** 818-042-0100.
(17) Condense and carve permanent restorative material except as provided in OAR 818-042-0095.
(18) Place any type of retraction material subgingivally except as provided in OAR 818-042-0090.
~~(19) Take jaw registrations or oral impressions for supplying artificial teeth as substitutes for natural teeth, except diagnostic or opposing models or for the fabrication of temporary or provisional restorations or appliances.~~
(~~20~~**19**)Apply denture relines except as provided in OAR 818-042-0090(2).
(~~21~~**20**) Expose radiographs without holding a current Certificate of Radiologic Proficiency issued by the Board (**OAR** 818-042-0050 and **OAR** 818-042-0060) except while taking a course of instruction approved by the Oregon Health Authority, Oregon Public Health Division, Office of Environmental Public Health, Radiation Protection Services, or the Oregon Board of Dentistry.
(~~22~~**21**) Use the behavior management techniques known as Hand Over Mouth (HOM) or Hand Over Mouth Airway Restriction (HOMAR) on any patient.
(~~23~~**22**) Perform periodontal probing.
(~~24~~**23**) Place or remove healing caps or healing abutments, except under direct supervision.
(~~25~~**24**) Place implant impression copings, except under direct supervision.
(~~26~~**25**) Any act in violation of Board statute or rules. ~~No licensee may authorize any dental assistant to perform the following acts:~~

Dr. Pham moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-042-0050 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-042-0050
Taking of X-Rays — Exposing of Radiographs
(1) A dentist may authorize the following persons to place films**/sensors**, adjust equipment preparatory to exposing films**/sensors**, and expose the films **and create the images** under general supervision:
(a) A dental assistant certified by the Board in radiologic proficiency; or
(b) A radiologic technologist licensed by the Oregon Board of Medical Imaging and certified by the Oregon Board of Dentistry (OBD) who has completed ten (10) clock hours in a Board approved dental radiology course.
(2) A dentist or dental hygienist may authorize a dental assistant who has completed a course of
instruction approved by the Oregon Board of Dentistry, and who has passed the written Dental
Radiation Health and Safety Examination administered by the Dental Assisting National Board, or comparable exam administered by any other testing entity authorized by the Board, or other
comparable requirements approved by the Oregon Board of Dentistry to place films**/sensors**, adjust equipment preparatory to exposing films**/sensors**, and expose the films **and create the images** under the indirect supervision of a dentist, dental hygienist, or dental assistant who holds an Oregon Radiologic Proficiency Certificate. The dental assistant must submit within six months, certification by an Oregon licensed dentist or dental hygienist that the assistant is proficient to take radiograph**ic**~~s~~ **images**.

Ms. Riedman moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-042-0095 as proposed to the Rules Oversight Committee. The motion passed unanimously.

818-042-0095
Restorative Functions of Dental Assistants
~~**Restorative Functions of Dental Assistants**~~
(1) The Board shall issue a Restorative Functions Certificate (RFC) to a dental assistant who holds an Oregon EFDA Certificate, and has successfully completed:
(a) A Board approved curriculum from a program accredited by the Commission on Dental Accreditation of the American Dental Association or other course of instruction approved by the Board, and successfully passed the Western Regional Examining Board's Restorative Examination or other equivalent examinations approved by the Board within the last five years, or
(b) If successful passage of the Western Regional Examining Board's Restorative Examination or other equivalent examinations approved by the Board occurred over five years from the date of application, the applicant must submit verification from another state or jurisdiction where the applicant is legally authorized to perform restorative functions and certification from the supervising dentist of successful completion of at

least 25 restorative procedures within the immediate five years from the date of application.
(2) A dental assistant may perform the placement and finishing of direct restorations, except gold foil, under the indirect supervision of a licensed dentist, after the supervising dentist has prepared the tooth (teeth) for restoration(s):
(a) These functions can only be performed after the patient has given informed consent for the procedure and informed consent for the placement of the restoration by a Restorative Functions dental assistant.
(b) Before the patient is released, the final restoration(s) shall be checked by a dentist and documented in the chart.

The Committee reviewed and discussed correspondence from Ms. Harrison, Ms. Jorgensen and the Dental Assisting Consortiums regarding amending Division 42. The Committee asked that the Consortium and Ms. Harrison and Ms. Jorgensen to form a workgroup and asked that they work together to come with proposed language for possible changes to Division 42. Dr. Beck agreed to represent the Board at this workgroup.

Dr. Pham moved and Dr. Beck seconded that the Committee recommend that the Board move OAR 818-042-0113 as amended to the Rules Oversight Committee. The motion passed unanimously

818-042-0113
Certification — Expanded Function Preventive Dental Assistants (EFPDA)
The Board may certify a dental assistant as an expanded function preventive dental assistant:
(1) By credential in accordance with OAR 818-042-0120, or
(2) If the assistant submits a completed application, pays the fee and provides evidence of;
(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the Oregon Basic or Certified Preventive Functions Dental Assistant (CPFDA) examination, ~~and~~ **or** the Expanded Function Dental Assistant examination, or **the Coronal Polish (CP) examination, or** equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by an Oregon licensed dentist that the applicant has successfully polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains on six patients

Dr. Beck moved and Dr. Pham seconded that the Committee recommend that the Board move OAR 818-042-0116 as proposed to the Rules Oversight Committee. The motion passed unanimously

818-042-0116
Certification — Anesthesia Dental Assistant
The Board may certify a person as an Anesthesia Dental Assistant if the applicant submits a completed application, pays the certification fee and shows satisfactory

evidence of:
(1) Successful completion of:
(a) The "Oral and Maxillofacial Surgery Anesthesia Assistants Program" or successor program, conducted by the American Association of Oral and Maxillofacial Surgeons; or
(b) The "Oral and Maxillofacial Surgery Assistants Course" or successor course, conducted by the California Association of Oral and Maxillofacial Surgeons (CALAOMS), or a successor entity; or
(c) The "Certified Oral and Maxillofacial Surgery Assistant" examination, or successor examination, conducted by the Dental Assisting National Board or other Board approved examination; ~~and~~ **or**
(d) The Resuscitation Group – Anesthesia Dental Assistant course; or
(e) Other course approved by the Board; and
(2) Holding valid and current documentation showing successful completion of a Health**care** ~~Care~~ Provider BLS/CPR course, or its equivalent.

The Committee reviewed and discussed the Implant Safety Workgroup recommendations:

- Require a written informed consent form for dental implant placement. The level of detail that should be included in such a form was not yet agreed upon.
- Develop the educational requirements/prerequisites for dentists who wish to place implants.
- Develop a plan for "grandfathering in" licensees with a great deal of experience and success placing and restoring dental implants.
- Require a certain amount of CE pertaining to dental implants be required of licensees practicing implant dentistry for each renewal cycle.
- Determine whether all licensed dentists will be required to complete a certain amount of CE pertaining to dental implants each renewal cycle.
- Communicate with the Oregon Dental Association regarding developing a set of specific "guidelines" for Oregon licensed dentists practicing implant dentistry.
- Develop a requirement for how important information related to the implant (such as type/ manufacturer) is properly documented and provided to the patient.

The Committee directed Board staff to draft language to present to the full Board at their August 23, 2019 meeting for action on the following:

- Minimal requirements for a written informed consent form for dental implant placement.
- Continuing education requirements pertaining to dental implants for licensees practicing implant dentistry.

Dr. Fine noted that the recommendation regarding information related to implants being properly documented and provided to the patient in writing was added to the proposed rule change previously voted on to go to the Board to refer to the Rules Oversight Committee.

The Committee reviewed and discussed the Anesthesia Office Evaluation Safety Workgroup recommendations:

- Add an Attestation Form to renewal forms for those that have any level of anesthesia permit, with the form also indicating that the drugs kept for emergency management have not expired.
- A reminder at the time of renewal that every office should hold quarterly emergency drills and the Board would give a brief outline of what should be covered in those drills.
- A quiz be added to renewal forms for those that have a moderate, deep and general anesthesia permit.
- That those that utilize a qualified provider per OAR 818-026-0080, attest that they hold emergency drills annually with that provider.
- A recommendation that OAR 818-026-0080 be reviewed closer to highlight that no two patients can be sedated at any time, and that there be proper protocol and hand off to a qualified anesthesia monitor, if the qualified provider will no longer be required to monitor the patient until criteria for discharge met.
- Review and update lists of drugs an office should have relevant to the anesthesia permit they hold and also of those the qualified provider has.

The Committee determined the items dealing with the renewal process could be implemented when the OBD gets a new database as the existing database would not support it.

Dr. Fine noted that the recommendation regarding OAR 818-026-0080 highlighting no two patients can be sedated at the same time, and when a patient who was sedated can be released to a qualified anesthesia monitor was added to the proposed rule change previously voted on to go to the Board to refer to the Rules Oversight Committee.

The meeting adjourned at 3:30 p.m.

679.310 Duty to report violations; exceptions; liability. (1)(a) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, any dentist or dental hygienist, or any person licensed by the Oregon Board of Dentistry, shall report to the board any suspected violation of this chapter or ORS 680.010 to 680.205 or any rule adopted by the board.

(b) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a dentist or dental hygienist, or any person licensed by the board, shall report any prohibited conduct as defined in ORS 676.150 in the manner provided in ORS 676.150.

(c) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, the Oregon Dental Association or any other organization representing dentists or dental hygienists shall report to the board any suspected violation of this chapter or ORS 680.010 to 680.205 or any rule adopted by the board.

(d) Any person may report to the board any suspected violation of this chapter or ORS 680.010 to 680.205 or any rule adopted by the board, association or other organization representing dentists or dental hygienists.

(2) This section is not intended to require any person working on or with the Oregon Dental Association's Dentist Well Being Committee or Peer Review Committee or the Quality Assurance or Peer Review Committee of the Oregon Dental Hygienists' Association to report to the board any confidential information received within the scope of duties with that committee.

(3) No person who has made a complaint as to the conduct of a licensee of the board or who has given information or testimony relative to a proposed or pending proceeding for misconduct against the licensee of the board, shall be answerable for any such act in any proceeding except for perjury. [1985 c.323 §11; 1999 c.578 §4; 2009 c.536 §7]

818-001-0000
Notice of Proposed Rule Making
Prior to the adoption, amendment, or repeal of any permanent rule, the Oregon Board of Dentistry shall give notice of the proposed adoption, amendment, or repeal:
(1) By publishing a notice in the Secretary of State's Bulletin referred to in ORS 183.370 at least 21 days prior to the effective date.
(2) By mailing **or emailing** a copy of the notice to persons on the mailing list established pursuant to ORS 183.335(8) at least 28 days before the effective date of the adoption, amendment, or repeal.
(3) By mailing **or emailing** a copy of the notice to the following persons and publications:
(a) Oregon Dental Hygienists' Association;
(b) Oregon Dental Assistants Association;
(c) Oregon Association of Dental Laboratories;
(d) Oregon Dental Association;
(e) The Oregonian;
(f) Oregon Health & Science University, School of Dentistry;
(g) The United Press International;
(h) The Associated Press;
(i) The Capitol Building Press Room.

818-001-0002
Definitions
As used in OAR chapter 818:
(1) "Board" means the Oregon Board of Dentistry, the members of the Board, its employees, its agents, and its consultants.
(2) "Dental Practice Act" means ORS Chapter 679 and 680.010 to 680.170 and the rules adopted pursuant thereto.
(3) "Dentist" means a person licensed pursuant to ORS Chapter 679 to practice dentistry.
(4) "Direct Supervision" means supervision requiring that a dentist diagnose the condition to be treated, that a dentist authorize the procedure to be performed, and that a dentist remain in the dental treatment room while the procedures are performed.
(5) "General Supervision" means supervision requiring that a dentist authorize the procedures, but not requiring that a dentist be present when the authorized procedures are performed. The authorized procedures may also be performed at a place other than the usual place of practice of the dentist.
(6) "Hygienist" means a person licensed pursuant to ORS 680.010 to 680.170 to practice dental hygiene.
(7) "Indirect Supervision" means supervision requiring that a dentist authorize the procedures and that a dentist be on the premises while the procedures are performed.
(8) "Informed Consent" means the consent obtained following a thorough and easily understood explanation to the patient, or patient's guardian, of the proposed procedures, any available alternative procedures and any risks associated with the procedures. Following the explanation, the licensee shall ask the patient, or the patient's guardian, if there are any questions. The licensee shall provide thorough and easily understood answers to all questions asked.
(9) "Licensee" means a dentist or hygienist.
(10) “Volunteer Licensee” is a dentist or dental hygienist licensed according to rule to provide dental health care without receiving or expecting to receive compensation.
(11) "Limited Access Patient" means a patient who, due to age, infirmity, or handicap is unable to receive regular dental hygiene treatment in a dental office.
(12) "Specialty." The specialty definitions are added to more clearly define the scope of the practice as it pertains to the specialty areas of dentistry.
(a) “Dental Anesthesiology” is the specialty of dentistry that deals with the management of pain through the use of advanced local and general anesthesia techniques.
(b) "Dental Public Health" is the science and art of preventing and controlling dental diseases and promoting dental health through organized community efforts. It is that form of dental practice which serves the community as a patient rather than the individual. It is concerned with the dental health education of the public, with applied dental research, and with the administration of group dental care programs as well as the prevention and control of dental diseases on a community basis.
(c) "Endodontics" is the branch of dentistry which is concerned with the morphology, physiology and pathology of the human dental pulp and periradicular tissues. Its study and practice encompass the basic and clinical sciences including biology of the normal pulp, the etiology, diagnosis, prevention and treatment of diseases and injuries of the pulp and associated periradicular conditions.
(d) "Oral and Maxillofacial Pathology" is the specialty of dentistry and discipline of pathology that deals with the nature, identification, and management of diseases affecting the oral and maxillofacial regions. It is a science that investigates the causes, processes, and effects of these diseases. The practice of oral pathology includes research and diagnosis of diseases using clinical, radiographic, microscopic, biochemical, or other examinations.
(e) “Oral and Maxillofacial Radiology” is the specialty of dentistry and discipline of radiology concerned with the production and interpretation of images and data produced by all modalities of radiant energy that are used for the diagnosis and management of diseases, disorders and conditions of the oral and maxillofacial region.
(f) "Oral and Maxillofacial Surgery" is the specialty of dentistry which includes the diagnosis, surgical and adjunctive treatment of diseases, injuries and defects involving both the functional and esthetic aspects of the hard and soft tissues of the oral and maxillofacial region.
(g) "Orthodontics and Dentofacial Orthopedics" is the area of dentistry concerned with the supervision, guidance and correction of the growing or mature dentofacial structures, including those conditions that require movement of teeth or correction of malrelationships and malformations of their related structures and the adjustment of relationships between and among teeth and facial bones by the application of

forces and/or the stimulation and redirection of functional forces within the craniofacial complex. Major responsibilities of orthodontic practice include the diagnosis, prevention, interception and treatment of all forms of malocclusion of the teeth and associated alterations in their surrounding structures; the design, application and control of functional and corrective appliances; and the guidance of the dentition and its supporting structures to attain and maintain optimum occlusal relations in physiologic and esthetic harmony among facial and cranial structures.
(h) "Pediatric Dentistry" is an age defined specialty that provides both primary and comprehensive preventive and therapeutic oral health care for infants and children through adolescence, including those with special health care needs.
(i) "Periodontics" is the specialty of dentistry which encompasses the prevention, diagnosis and treatment of diseases of the supporting and surrounding tissues of the teeth or their substitutes and the maintenance of the health, function and esthetics of these structures and tissues.
(j) "Prosthodontics" is the branch of dentistry pertaining to the restoration and maintenance of oral functions, comfort, appearance and health of the patient by the restoration of natural teeth and/or the replacement of missing teeth and contiguous oral and maxillofacial tissues with artificial substitutes.
(13) “Full-time” as used in ORS 679.025 and 680.020 is defined by the Board as any student who is enrolled in an institution accredited by the Commission on Dental Accreditation of the American Dental Association or its successor agency in a course of study for dentistry or dental hygiene.
(14) For purposes of ORS 679.020(4)(h) the term “dentist of record” means a dentist that either authorized treatment for, supervised treatment of or provided treatment for the patient in clinical settings of the institution described in 679.020(3).
(15) “Dental Study Group” as used in ORS 679.050, OAR 818-021-0060 and OAR 818-021-0070 is defined as a group of licensees who come together for clinical and non-clinical educational study for the purpose of maintaining or increasing their competence. This is not meant to be a replacement for residency requirements.
(16) “Physical Harm” as used in OAR 818-001-0083(2) is defined as any physical injury that caused, partial or total physical disability, incapacity or disfigurement. In no event shall physical harm include mental pain, anguish, or suffering, or fear of injury.

(17) “Teledentistry” is defined as the use of information technology and telecommunications to facilitate the providing of dental primary care, consultation, education, and public awareness in the same manner as telehealth and telemedicine.
(18) “BLS for Healthcare Providers or its Equivalent” the **BLS/**CPR certification standard is the American Heart Association’s BLS Healthcare Providers Course or its equivalent, as determined by the Board. This initial **BLS/**CPR course must be a hands-on course; online **BLS/**CPR courses will not be approved by the Board for initial **BLS/**CPR certification: After the initial **BLS/**CPR certification, the Board will accept a Board-approved BLS for Healthcare Providers or its equivalent Online Renewal course for license renewal. A **BLS/**CPR certification card with an expiration date must be received from the **BLS/**CPR provider as documentation of **BLS/**CPR certification. The Board considers the CPR expiration date to be the last day of the month that the **BLS/**CPR instructor indicates that the certification expires.

818-001-0082
Access to Public Records

(1) Public records not exempt from disclosure may be inspected during office hours at the Board office upon reasonable notice.

(2) Copies of public records not exempt from disclosure may be purchased upon receipt of a written request. The Board may withhold copies of public records until the requestor pays for the copies.

(3) The Board follows the Department of Administrative Service's statewide policy (107-001-030) for fees in regards to public records request; in addition, the Board establishes the following fees:

(a) $0.10 per name and address for computer-generated lists on paper or ~~labels~~; $0.20 per name and address for computer-generated lists on paper ~~or labels~~ sorted by specific zip code;

(b) Data files ~~on diskette~~ **submitted electronically** or **on a device** ~~CD~~:

(A) All Licensed Dentists — $50;

(B) All Licensed Dental Hygienists — $50;

(C) All Licensees — $100.

(c) Written verification of licensure — $2.50 per name; and

(d) Certificate of Standing — $20.

Statutory/Other Authority: ORS 183, 192, 670 & 679
Statutes/Other Implemented: ORS 192.420, 192.430 & 192.440

From: Stephen Prisby
Sent: Monday, October 7, 2019 12:11 PM
To: Teresa Haynes <Teresa.Haynes@state.or.us>
Subject: FW: OAR 818-012-0005 - proposed amendment

Please add to Lic Stds and Comp Meeting agenda along with OAR 818-012-0005. Thank you!

From: Stephen Bush [mailto:Stephen.C.Bush@kp.org]
Sent: Monday, October 7, 2019 10:43 AM
To: Stephen Prisby <Stephen.Prisby@state.or.us>
Cc: Daniel Blickenstaff <Daniel.Blickenstaff@state.or.us>
Subject: OAR 818-012-0005 - proposed amendment

Dear Stephen,

I spoke with Dr. Blickenstaff this morning regarding an ambiguity in OAR 818-012-0005. In his view, the requirements to administer Botox under subsection (3) would already be met by a dentist who has completed an OMFS residency. But the way the rule is written, successful completion of an OMFS residency would still require 20 hours of CE and approval by AGD PACE or ADA CERP, which I don't believe is the Board's intent.

Dr. Blickenstaff invited me to propose to you an amendment for the OBD's next round of rule-making, and I have done so in red underscore below. Please let me know your thoughts.

818-012-0005
Scope of Practice

(1) No dentist may perform any of the procedures listed below:

(a) Rhinoplasty;

(b) Blepharoplasty;

(c) Rhydidectomy;

(d) Submental liposuction;

(e) Laser resurfacing;

(f) Browlift, either open or endoscopic technique;

(g) Platysmal muscle plication;

(h) Otoplasty;

(i) Dermabrasion;

(j) Hair transplantation, not as an isolated procedure for male pattern baldness; and

(k) Harvesting bone extra orally for dental procedures, including oral and maxillofacial procedures.

(2) Unless the dentist:

(a) Has successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association, Commission on Dental Accreditation (CODA), or

(b) Holds privileges either:

(A) Issued by a credentialing committee of a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to perform these procedures in a hospital setting; or

(B) Issued by a credentialing committee for an ambulatory surgical center licensed by the State of Oregon and accredited by either the JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC).

(3) A dentist may utilize Botulinum Toxin Type A and dermal fillers to treat a condition that is within the scope of the practice of dentistry after completing a minimum of 20 hours in a hands on clinical course(s), which includes both Botulinum Toxin Type A and dermal fillers, and the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP). Alternatively, a dentist may meet the requirements of this subsection (3) by successfully completing a residency in Oral and Maxillofacial Surgery accredited by CODA.

Thank you in advance for your consideration.

Steve

Stephen Bush, JD (he, him, his)
Vice-President, Legal Services & Government Relations
Compliance, Privacy & Security Official
Permanente Dental Associates, PC | PDA MSO, LLC

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Stephen.C.Bush@kp.org
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For Litigation or Board Licensing Matters –-
Cynthia Tarvin, Cynthia.L.Tarvin@kp.org, 503-813-3060 (49-3060)
Bret Morrow, Bret.T.Morrow@kp.org, 503-813-2231 (49-2231)

Office Hours (most weeks):
M 8:30-1:30
T 8:30-5
W 10-3
Th 8:30 – 1:30
F 8:30-1:30

Upcoming PTO: September 25

Teresa Haynes

From: Akshay Govind <govind@ohsu.edu>
Sent: Tuesday, February 18, 2020 2:29 PM
To: Teresa Haynes
Subject: Re: Botox Course

Dear Teresa,

This is a follow-up note from our conversation last month formally requesting that the board consider a separate certification for use of botulinum toxin for temporomandibular disorders. The current wording combines use of botulinum toxin and dermal fillers, which is appropriate for cosmetic use, but doesn't quite capture the indications for TMD. My long-term idea is to devise a training course which would include both didactic and hands-on training on the topic. For me, 12 hours seems like the appropriate amount of time to get through all the relevant material, but I am open to discussion on how best to create this rubric.

Please let me know what the appropriate next steps are in the process.

Thank you,
Akshay Govind

From: Teresa Haynes <Teresa.Haynes@state.or.us>
Sent: Tuesday, January 14, 2020 10:49:56 AM
To: Phillip Marucha; Akshay Govind
Subject: Botox Course

Hi Dr. Marucha and Dr. Govind,

It was nice speaking with you both this morning.

Dr. Govind when you submit your request to the Board, if you could mention that you are looking more for the use of Botox for TMD etc., instead of esthetics. This will give the Board information of why you would like to see the rule changed, if you also could give them an Idea of how many hours you think it should be in comparison to what the existing rule is, that also may be helpful.

When you're ready to propose language for a possible rule revision if you would like to run it by Stephen or I, we would be glad to look at it and assist in any way possible.

Please let me know if you either of you have questions.

Sincerely,
Teresa

Teresa Haynes
Office Manager
Oregon Board of Dentistry
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Portland, OR 97201
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FAX: 971-673-3202

www.oregon.gov/dentistry

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"The Mission of the Oregon Board of Dentistry is to promote high quality oral health care in the State of Oregon by equitably regulating dental professionals."

Oregon
Kate Brown, Governor

Board of Dentistry
1500 SW 1st Ave. Ste 770
Portland, OR 97201-5837
(971) 673-3200
Fax: (971) 673-3202

TO: OBD Board Members, Licensees and Interested Parties

FROM: Stephen Prisby, Executive Director

DATE: June 11, 2019

SUBJECT: Proposed Dental Implant Continuing Education and Informed Consent Forms

At the Licensing, Standards and Competency Committee Meeting on May 24, 2019 the Committee directed OBD Staff to:

- Develop proposed continuing education rules regarding placement of dental implants
- Develop proposed informed consent form language that would be required prior to placing dental implants

The Committee directed the staff to have the information ready by the August 23, 2019 Board meeting. Staff were able to develop ideas in time for this June Meeting, so that the Board and other interested parties can digest these proposals.

I attached sample informed consent forms to review and for your discussion at the meeting. OBD staff believe a form should be similar to the one that the OHSU School of Dentistry uses, which has the patient acknowledge with initials each piece of important information relating to the procedure and possible outcomes.

Since these proposals were not reviewed by the Licensing, Standards and Competency Committee, they should not be referred to the Rules Committee for action yet.

818-021-0060 – Continuing Education-Dentists

(8) A dentist may place endosseous implants to replace natural teeth after completing a minimum of 56 hours of hands on clinical course(s), which includes treatment planning, appropriate case selection, potential complications and the surgical placement of the implants under direct supervision, and the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP).
(9) A dentist placing endosseous implants must complete at least seven (7) hours of continuing education related to the placement and or restoration of dental implants every licensure renewal period.

OHSU School of Dentistry Advanced Education Program in Periodontics
CONSENT: TWO-STAGE, ONE-STAGE, &/or IMMEDIATE
OSSEOINTEGRATED IMPLANT SURGERY

Patient Name: _____Patient Chart # _____

Today's date: _____

Surgery date: _____

You have the right to be given pertinent information about your proposed implant placement so that you have sufficient information to make the decision as to whether or not to proceed with surgery. What you are being asked to sign is a confirmation that we have discussed the nature of the proposed treatment, the known risks associated with it and the feasible alternate treatments.

PLEASE INITIAL EACH PARAGRAPH AFTER READING. IF YOU HAVE ANY QUESTIONS, PLEASE ASK YOUR DOCTOR BEFORE INITIALING.

____1. I hereby authorize Dr(s). _____, and any other agents, assistants, or employees selected by him / her to treat the condition described as:

_____
_____

____2. The procedure necessary to treat the condition has been explained to me, and I understand the nature of the procedure to be:

_____
_____

____3. I understand incisions will be made inside my mouth for the purpose of placing one or more root form structures (implants) in my jaw to serve as anchors for a missing tooth or teeth or to stabilize a crown (cap), bridge or denture. I acknowledge that the doctor has explained the procedure, including the number and location of the incisions and the type of implant to be used. I understand that the crown, bridge or denture that will later be attached to this implant will be made and attached by Dr. _____ and that a separate charge will be made for that work.

____4. I understand that the implant must remain covered by gum tissue for a minimum of three to six months before it can be used and that a second surgery is required to uncover the top of the implant if a two stage implant. If the implant is placed with the top exposed this is a one stage implant with no second surgery required to uncover the implant. If a tooth is being extracted with an implant placed at the same surgery appointment, that implant is an immediate implant.

____5. No guarantee can be or has been given that the implant(s) will last for a specific time period. It has also been explained to me that once the implant is inserted, the entire treatment plan must be followed and completed on schedule. If this schedule is not carried out, the implant(s) may fail.

____6. It has been explained to me that during the course of the procedure, unforeseen conditions may be revealed which will necessitate extension of the original procedure or a different procedure from those described in paragraph 2 above. I authorize my doctor and his/her staff to perform such different procedure(s) as necessary and desirable in the exercise of his/her professional judgment.

OHSU School of Dentistry Advanced Education Program in Periodontics
CONSENT: TWO-STAGE, ONE-STAGE, &/or IMMEDIATE
OSSEOINTEGRATED IMPLANT SURGERY

____7. I have been informed of possible alternative methods of treatment (if any), including
_____ no treatment
_____ removable partial denture
_____ fixed partial denture (bridge)
_____ full conventional denture
_____ other: _____

I understand that other forms of treatment or no treatment at all are choices that I have and the risks of those choices have been presented to me.

____8. My doctor has explained to me that there are certain inherent and potential risks, side effects in any surgical procedure. In this specific instance such risks include, but are not limited to the following:

____a. Postoperative discomfort and swelling that may require several days of at-home recouperation.
____b. Prolonged or heavy bleeding that may require additional treatment.
____c. Injury or damage to adjacent teeth or roots of adjacent teeth.
____d. Postoperative infection that may require additional treatment.
____e. Stretching of the corners of the mouth that may cause cracking and bruising, and may heal slowly.
____f. Restricted mouth opening for several days; sometimes related to swelling and muscle soreness and sometimes related to stress on the jaw joints (TMJ). Pre-existing TMJ symptoms get worse.
____g. Injury to the nerve branches in the lower jaw resulting in numbness or tingling of the chin, lips, cheek, gums or tongue on the operated side. This may persist for several weeks, months or, in rare instances, permanently. In some cases the implant may need to be removed.
____h. Opening into the sinus (a normal chamber above the upper back teeth) requiring additional treatment.
____i. If the sinus is intentionally entered (sinus lift procedure with grafting), there will usually be several weeks of sinusitis symptoms requiring certain medications and additional recovery time.
____j. If an indirect sinus lift with use of a mallet is necessary to place the implants, dizziness & inability to be balanced when standing or walking (Benign Paroxysmal Positional Vertigo, JP 01/10 p.158) can result.
____k. The removal of grafted bone from any donor site has its own potential risks and complications, which have been explained to me.
_____l. Fracture of the jaw.
____m. Other: _____
_____

____9. I have been made aware that certain medications, drugs, anesthetics and prescriptions which I may be given can cause drowsiness, incoordination, and lack of awareness which also may be increased by the use of alcohol and other drugs. I have been advised not to operate any vehicle or hazardous machinery and not to return to work while taking such medications, or until fully recovered from the effects of same. I understand this recovery may take up to 24 hours or more after I have taken the last dose of medication. If I am to be given sedative medication during my surgery, I agree not to drive myself home and will have a responsible adult drive me home and accompany me until I am fully recovered from the effects of the sedation.

OHSU School of Dentistry Advanced Education Program in Periodontics
CONSENT: TWO-STAGE, ONE-STAGE, &/or IMMEDIATE
OSSEOINTEGRATED IMPLANT SURGERY

____10. I consent to the administration of _____ _____ anesthesia in connection with the procedure referred to above. If intravenous sedation anesthesia is used, there may be soreness at the injection site or along the vein, as well as bruising around the injection site. In rare instances, the vein irritation may cause restricted mobility of the arm or hand and may require additional treatment.

____11. I understand that I am not to have anything (or have not had anything) by mouth for at least six hours before my surgery if intravenous sedation is to be used. **To do otherwise may be life-threatening.**

____12. It has been explained to me, and I understand, that a perfect result is not, and cannot be guaranteed or warranted. I understand that implant placement is an elective procedure.

____13. I agree to follow all pre-operative and post-operative instructions. I will use proper oral hygiene measures and will return for all post treatment follow-up appointments.

I certify that I have read all of the previous information and consent prior to my surgery, I have been fully informed of the nature of root form implant surgery, and acknowledge that any and all questions have been answered to my satisfaction regarding the proposed treatment, routine post surgical course, and possible complications. The procedure(s), alternatives, and risks have been explained to me in substantial detail, and I am satisfied with my surgeon's explanations. I have no additional questions about the procedure(s), other alternative procedures, or risks.

I also consent to the use of an alternative implant system or method if clinical conditions are found to be unfavorable for the use of the implant system that has been described to me. If clinical conditions prevent the placement of implants, I defer to my surgeon's judgment on the surgical management of that situation. I also give my permission to receive supplemental bone grafts or other types of grafts to build up the ridge of my jaw and thereby to assist in placement, closure and security of my implants.

I authorize photos, slides, x-rays or any other viewing of my care and treatment during or after its completion to be used for the advancement of dentistry and for reimbursement purposes. However, my identity will not be revealed to the general public without my permission.

I also certify that I speak, read, and write English, or, have used a translator to explain all of the previous information to me and I understand all of the information translated to me. I give my permission and consent to the procedure(s) proposed.

I CERTIFY THAT I HAVE READ AND FULLY UNDERSTAND THIS DOCUMENT

Patient/parent or Guardian	Time	Date
Witness/Staff	Time	Date
Surgeon	Time	Date

INFORMED CONSENT FORM
FOR ORAL AND MAXILLOFACIAL SURGERY
AND ANESTHESIA

Dear Patient:

You have a right to be informed about your diagnosis and planned surgery so that you may make a decision whether to undergo a procedure after knowing the risks and hazards. The disclosure is not meant to frighten or alarm you. It is simply an effort to make you better informed so we may give an informed consent to the procedure. Please be assured that we will do our best at all times to make healing as rapid and trouble-free as possible.

POSSIBLE COMPLICATIONS *(may be variable in occurrence):*

Please initial each paragraph after reading. If you have any questions, please ask your doctor before initialing.

_____ ALL SURGERIES:

1. Soreness, pain, swelling, bruising, and restricted mouth opening during healing sometimes related to swelling and muscle soreness and sometimes related to stress on the jaw joints (TMJ), especially when TMJ problems already exists.
2. Bleeding, usually controllable, but may be prolonged and required additional care.
3. Drug reactions or allergies.
4. Infection; possibly requiring additional care, including hospitalization and additional surgery.
5. Stretching or cracking at the corners of the mouth.

_____ ALL TOOTH EXTRACTIONS:

1. Dry socket (delayed healing) causing discomfort a few days after extraction requiring further care.
2. Damage to adjacent teeth or fillings.
3. Sharp ridges or bone splinters; may require additional surgery to smooth area.
4. Portions of tooth remaining - sometimes fine root tips break off and may be deliberately left in place to avoid damage to nearby vital structures such as nerves or the sinus cavity.

_____ UPPER TEETH:

1. SINUS INVOLVEMENT: Due to closeness of the roots of upper back teeth to the sinus or from a root teeth being displaced into the sinus, a possible sinus infection and/or sinus opening may result, which may require medication and/or later surgery to correct.

_____ LOWER TEETH:

2. NUMBNESS: Due to proximity of tooth roots (especially wisdom teeth) and other surgical sites to the nerves, it is possible to loose function of nerves following the removal of the tooth or surgery in the area. The lip, chin, teeth, gums, or tongue could thus feel numb (resembling local anesthetic injection). There may also be pain, loss of taste, and change in speech. This could remain for days, weeks, or possibly, permanently.
3. JAW FRACTURE: While quite rare, it is possible in difficult or deeply impacted teeth and usually requires additional treatment, including surgery and hospitalization.

_____ ANESTHESIA:

1. LOCAL ANESTHESIA: Certain possible risks exists that, although rare, could include pain, swelling, bruising, infection, nerve damage, and unexpected reactions which could result in heart attacks, stroke, brain damage, and/or death.
2. INTRAVENOUS OR GENERAL ANESTHESIA: Certain possible risk exists that, although uncommon, may include nausea, pain, swelling, inflammation, and/or bruising at the injection site.

Rare complications include nerve or blood vessel injury (phlebitis) in the arm or hand and allergic or unexpected drug reactions, pneumonia, heart attack, stroke, brain damage, and/or death.

If I am having intravenous sedation or general anesthesia, I understand that I have NOT HAD ANY FOOD OR DRINK FOR SIX HOURS before my appointment. To do otherwise MAY BE LIFE-THREATENING! I agree not to drive myself home for the next 24 hours and will have a responsible adult accompany me.

ALTERNATIVE TREATMENT OPTIONS:_____

PATIENT NAME:_____

I hereby authorize Dr. _____ and staff to perform the following procedures:

_____

_____ and to administer an anesthetic. I understand the doctor may discover other or different conditions that may require additional or different procedures than those planned. I authorize him/her to perform such other procedures as he/she deems necessary in his/her professional judgment in order to complete my surgery.

I have discussed my past medical history with my doctor and disclosed all diseases and medications and drug use. I agree not to operate vehicles or hazardous machinery while taking prescription narcotic pain medications.

I have received written postoperative instructions regarding home care, including emergency after hour phone numbers.

I understand that individual reactions to treatment cannot be predicted, and that if I experience any unanticipated reactions during or following treatment, I agree to report them to the doctor or his/her designated agent as soon as possible.

I have read and discussed the preceding with the doctor and believe I have been given sufficient information to give my consent to the planned surgery. No warrantee or guarantee has been made as to the results or cure. I certify that I speak, read, and write English and have read and fully understand this consent form for surgery; or if do not, I have had someone translate so that I can understand the consent form. All blanks were filled in prior to my initials and signature.

_____

Patient's (or legal guardian's) signature Date

_____

Witness signature Date

_____

Doctor's signature Date

Oral Surgery Consent Form

Patient Name_____ Date_____

I hearby authorize **Dr._____** to perform the following procedures:_____

The doctor and or staff have explained to me the proposed treatment and the anticipated results of such treatment. I understand this is an elective procedure and that there are other forms of treatment available, including the option of no treatment.
The doctor has explained to me that there are certain potential risks in the treatment plan or procedure. These include:

1. Injury to a nerve resulting in numbness or tingling of the chin, lip, cheek, gums, and or tongue to the operated side. This may persist for several weeks, months, or in remote instances, permanently._____
2. Postoperative infection requiring additional treatment._____
3. Opening of the sinus (a normal cavity situated above the upper teeth) requiring additional surgery._____
4. Restricted mouth opening for several days or weeks, with possible dislocation of the tempromandibular (jaw) joint._____
5. Injury to adjacent teeth and fillings._____
6. In rare circumstances, cardiac arrest or breakage of the jaw._____
7. Postoperative discomfort, swelling, and bleeding that may necessitate several days of recuperation._____
8. Decision to leave a small piece of root in the jaw when its removal requires extensive surgery._____
9. Stretching of the corners of the mouth with resultant cracking and bruising. _____

Unforeseen conditions may arise during the procedure that requires a different procedure than as set forth above. I therefore authorize the doctor and any associates to perform such procedures when, in their professional judgment, they are necessary.
I understand that the medications, drugs, anesthetic, and prescriptions taken for this procedure may cause drowsiness and lack of awareness and coordination. I also understand that I should not consume alcohol or other drugs because they can increase these effects. I have been advised not to work and no to operated any vehicle, automobile, or hazardous devices while taking such medications and until fully recovered from their effects**. I have also been advised not to smoke for two weeks after the surgery._____**

It has been explained to me and I understand that a perfect result is not guaranteed or warranted.

Patient signature_____Date_____

Doctor's signature_____Date_____

Dental Implant Consent Form/Oral Surgery Consent Form

All patients receiving dental implants and other oral surgery will be asked to sign consent forms. We've included the text of our consent forms so you can review their contents before coming in to the office.

Dental Implant Consent Form

1. ACKNOWLEDGEMENT OF RECEIPT OF INFORMATION

State law requires that you be given certain information and that we obtain your consent prior to beginning any treatment. What you are being asked to sign is a confirmation that we have discussed the nature and purpose of the treatment, the known risks associated with the treatment, and the feasible treatment alternatives; that you have been given an opportunity to ask questions; that all your questions have been answered in a satisfactory manner. Please read this form carefully before signing it and ask about anything that you do not understand. We will be pleased to explain.

2. CONSENT FOR DENTAL IMPLANT

I hereby authorize and direct the oral and maxillofacial surgeon whose name appears above with associates or assistants of his or her choice to perform surgery upon me (or upon any person identified above as the patient, for whom I am empowered to consent) to insert dental implant(s) in my upper and/or lower jaw and/or placement of bone graft (etc.) as needed.

3. NATURE AND PURPOSE OF THE PROCEDURE

I understand incision(s) will be made inside my mouth for the purpose of placing one or more metal structures in my jaw(s) to serve a anchor(s) for a missing tooth or teeth or to stabilize a crown (cap), denture or bridge. I acknowledge that the oral and maxillofacial surgeon whose name appears above has explained the pocedure, including the number and location of the incisions to be made, in detail. I understand that the crown (cap) , denture or bridge, will later be attached to this implant by a general dentist or prosthodontist and that the cost for that work is not included in the charge for this procedure. I have been informed that the implant must remain covered under the gum tissue for at least three months before it can be used and that a second surgical procedure is required to uncover the top of the implant. Finally, I understand that this is a relatively new procedure. I have received literature, anesthesia information,pre and post surgical instructions and diet information and have read and understand the information.

4. ALTERNATIVES TO A DENTAL IMPLANT

The alternatives to the use of a dental implant, including no treatment at all; construction of a new standard dental prosthesis; augmentation of the upper or lower jaw by means of a vestibuloplasty, skin and bone grafting, or with synthetic materials; and implantation of another type of device have been explained to me as have the advantages and disadvantages of each procedure and I choose to procede with insertation of the dental implant.

5. AUTHORIZATION OF ANCILLARY TREATMENT

I also authorize and direct the oral and maxillofacial surgeon whose name appears

above with the associate or assistants of his or her choice to provide such additional services as he or they may deem reasonable and necessary, including, but not limited to , the administration of anesthetic agents; the performance of necessary laboratory, radiological (X-ray), and other diagnostic procedures; the administration of medications orally, by injection, by infusion, or by other medically accepted route of administration; and the removal of bone, tissue and fluids for diagnostic and therapeutic purposes and the retention or disposal of same in accordance with usual practices.

6. AUTHORIZATION FOR SUPPLEMENTAL TREATMENT

If any unforeseen condition arises in the course of treatment which calls for the performance of procedures in addition to or different from that now contemplated and I am under general anesthesia or sedation, I further authorize and direct the oral and maxillofacial surgeon whose name appears above with associates or assistants of his choice to do whatever he deems necessary and advisable under the circumstances.

7. NO GUARANTEE OF TREATMENT RESULTS

I understand that there is no way to accurately predict the healing capabilities of any particular patient following the placement of the implant and that complications do occur; and I confirm that I have been given no guarantee or assurance by the oral and maxillofacial surgeon whose name appears above, or by anyone else, as to the results that may be obtained from treatment. In the event of implant failure, there will be no refund of fees.

8. RISKS AND COMPLICATIONS ASSOCIATED WITH DENTAL IMPLANTS

I have been informed and understand that there are risks and complications from surgery, drugs, and/or anesthetics.

9. SURGICAL COMPLICATIONS

Such possibilities include but are not limited to, infection, tissue discoloration (bruising), alteration in taste and/or numbness, tingling, increased sensitivity of the lips, tongue, chin, cheek or teeth which may last for an indefinite period and may be permanent. Also possible are injury to teeth if present, loss of bone, bone fractures, nasal or sinus penetration (for implants placed in the upper jaw), chronic pain, bleeding and decreased ability to open the mouth. I have also been informed that any procedure which is outside the mouth will leave a scar on the skin, and that although a good cosmetic result is hoped for, it cannot be guaranteed.

I also understand that any of these treatment complications may necessitate medical, dental, or surgical treatment; may necessitate wiring of my teeth or jaws, and may require an additional period of recuperation at home or even in the hospital. Finally, I have been told that this treatment may not be successful, that problems may arise during the procedure which may prevent placement of the implant, and that rejection of this implant is possible which would necessitate its removal at any time after placement. Should this happen, I understand that it may possible to insert another implant after a suitable healing period and that charge will be made for this procedure.

10. DRUG AND ANESTHETIC COMPLICATIONS

If intravenous medications are used, there may be irritation of, or damage to the

vein in which anesthetic medications are injected. I understand there are certain drugs and anesthetic risks, which could involve serious bodily injury, and are inherent of any procedure requiring their use.

11. RISKS ASSOCIATED WITH NO TREATMENT

I understand that should I **not** have this implant procedure, one or more of the following may occur: faster dissolving of the jaw bone structure, increased difficulty wearing conventional dentures, increased loss of bony support of the face, lips and cheeks, increased difficulty chewing, pain and numbness, and fracture of a very thin jawbone.

12. IMPORTANCE OF PATIENT COMPLIANCE

I agree and understand that the degree of success of any dental treatment is directly related to my cooperation and that, if I fail to cooperate as requested and instructed, I may suffer temporary or permanent injury to my dental and general health and to the dental work performed by my dentist.

I understand that the success of dental implants depends to a great extent on my maintenance and meticulous hygiene throughout my mouth and especially around the implant posts where they come through the gum tissue.

I understand that smoking, alcohol, improper dietary practices may affect gum and bone healing and will limit the success of the implant. I agree to follow home care and dietary instructions as prescribed. I will not wear my dentures for 2 weeks.

I agree to return at regular intervals as specified by the doctor for inspection of my mouth and implant cleansings by the doctor or the hygienist and to have performed such dental services as may be needed to maintain my oral health. This will involve regular and long-term follow –up care for the life of the implant.

I agree to report immediately any evidence of pain, swelling, or inflammation around my implant(s) and agree to attend the office/hospital if necessary. A reasonable fee will be charged for these visits commencing one year after placement of my implant (s).

I agree not to eat or drink anything for 6 hours prior to my surgery/anesthesia. Medications, drugs, anesthetics and prescriptions may cause drowsiness and lack of awareness and coordination, which can be increased by the use of alcohol or other drugs. Thus, I have been advised not to operate any vehicle, automobile, hazardous devices, or work while taking such medications and/or drugs; or until fully recovered from their effects. I understand and agree not to operate any vehicle or hazardous device for at least twenty-four hours after my release from surgery or until further recovered from the effects of anesthetic medication and drugs that may have been given to me in the office or the hospital for my care. I agree not to drive myself home after surgery and will have a responsible adult drive me or accompany me home after my discharge from surgery. Failure to follow these instructions may be life threatening.

13. AUTHORIZATION OF USE OF DENTAL RECORDS

I authorize photographs, X-rays, or other viewing of my care and treatment during its progress may be used for educational purposes and research.

I hereby state that I have read and I fully understand this consent form, that I have

been given an opportunity to ask any questions I might have had, that those questions have been answered in a satisfactory manner.

Date_____

Time_____

Signature_____

Signature of relative or Representative (where required)
_____

Witness_____

INFORMED CONSENT FOR DENTAL IMPLANTS

Diagnosis. After careful oral examination and study of my dental condition, my doctor has advised me that my missing tooth or teeth may be replaced with artificial teeth supported by an implant.

Recommended Treatment. In order to treat my condition, my doctor has recommended the use of root form dental implants. I understand that the procedure for root form implants involves placing implants into the jawbone. This procedure has a surgical phase followed by a prosthetic phase.

Surgical Phase of Procedures. I understand that sedation may be utilized and that a local anesthetic will be administered to me as part of the treatment. My gum tissues will be opened to expose the bone. Implants will be placed by tapping or threading them in to holes that have been drilled into my jawbone. The implants will have to be snugly fitted and held tightly in place during the healing phase.

The gum and soft tissues will be stitched closed over or around the implants. A periodontal bandage or dressing may be placed. Healing will be allowed to proceed for a period of four to six months. I understand the dentures usually cannot be worn during the first one to two weeks of the healing phase.

I further understand that if clinical conditions turn out to be unfavorable for the use of this implant system or prevent the placement of implants, my doctor will make a professional judgment on the management of the situation. The procedure also may involve supplemental bone grafts or other types of grafts to build up the ridge of my jaw and thereby to assist in placement, closure, and security of my implants.

For implants requiring a second surgical procedure, the overlying tissues will be opened at the appropriate time, and the stability of the implant will be verified. If the implant appears satisfactory, an attachment will be connected to the implant. Plans and procedures to create an implant prosthetic appliance can then begin.

Prosthetic Phase of Procedure. This phase is just as important as the surgical phase for the long-term success of the oral reconstruction. During this phase, an implant prosthetic device will be attached to the implant.

Expected Benefits. The purpose of dental implants is to allow me to have more functional artificial teeth. The implants provide support, anchorage, and retention for these teeth.

Principal Risks and Complications. I understand that some patients do not respond successfully to dental implants, and in such cases, the implant may be lost. Implant surgery may not be successful in providing artificial teeth. Because each patient's condition is unique, long-term success may not occur.

I understand that complications may result from the implant surgery, drugs, and anesthetics. These complications include, but are not limited to:

- Post surgical infection
- Bleeding
- Swelling
- Pain
- Facial discoloration
- Transient but on occasion permanent numbness of the lip, tongue, teeth, chin, or gum
- Jaw joint injuries or associated muscle spasm
- Transient but on occasion permanent increased tooth looseness
- Tooth sensitivity to hot, cold, sweet, or acidic foods
- Shrinkage of the gum upon healing resulting in elongation of some teeth and greater spaces between some teeth
- Cracking or bruising of the corners of the mouth
- Restricted ability to open the mouth for several days or weeks
- Impact on speech
- Allergic reactions
- Injury to teeth
- Bone fractures
- Nasal sinus penetrations
- Delayed healing
- Accidental swallowing of foreign matter

The exact duration of any complications cannot be determined, and they may be irreversible.

I understand that the design and structure of the prosthetic appliance can be a substantial factor in the success or failure of the implant. I further understand that alterations made on the artificial appliance or the implant can lead to loss of the appliance or implant. This loss would be the sole responsibility of the person making such alterations. I am advised that the connection between the implant and the tissue may fail and that it may become necessary to remove the implant. This can happen in the preliminary phase, during the initial integration of the implant to the bone, or at any time thereafter.

Alternative to Suggested Treatment. Alternative treatments for missing teeth include no treatment, new removable appliances, and other procedures—depending on the circumstances. However, continued wearing of ill-fitting and loose removable appliances can result in further damage to the bone and soft tissue of my mouth.

Necessary Follow-up Care and Self-Care. I understand that it is important for me to continue to see my dentist. Implants, natural teeth, and appliances have to be maintained daily in a clean, hygienic manner. Implants and appliances must also be examined periodically and may need to b e adjusted. I understand that it is important for me to abide by the specific prescriptions and instructions given by my doctor.

No Warranty or Guarantee. I hereby acknowledge that no guarantee, warranty, or assurance has been given to me that the proposed treatment will be successful. Due to individual patient differences, a doctor cannot

predict certainty of success. There exists the risk of failure, relapse, additional treatment, or worsening of my present condition, including the possible loss of certain teeth, despite the best of care.

Publication of Records. I authorize photos, slides, x-rays, or any other viewings of my care and treatment during or after its completion to be used for the advancement of dentistry and for reimbursement purposes. My identity will not be revealed to the general public, however, without my permission.

PATIENT CONSENT

I have been fully informed of the nature of root form implant surgery, the procedure to be utilized, the risks and benefits of the surgery, the alternative treatments available, and the necessity for follow-up care and self care. I have had an opportunity to ask any questions I may have in connection with the treatment and to discuss my concerns with my doctor. After thorough deliberation, I hereby consent to the performance of dental implant surgery as presented to me during consultation and in the treatment plan presentation as described in this document.

I also consent to use of an alternative implant system or method if clinical conditions are found to be unfavorable for the use of the implant systems that has been described to me. If clinical conditions prevent the placement of implants, I defer to my doctor's judgment on the surgical management of that situation. I also give my permission to receive supplemental bone grafts or other types of grafts to build up the ridge of my jaw and thereby to assist in placement, closure, and security of my implants.

I CERTIFY THAT I HAVE READ AND FULLY UNDERSTAND THIS DOCUMENT.

Date	Patient, Parent or Guardian Name (Print)	Signature
_____	_____	_____
_____	_____	_____
Date	Witness Name (Print)	Signature

818-012-0005
Scope of Practice

(1) No dentist may perform any of the procedures listed below:

(a) Rhinoplasty;

(b) Blepharoplasty;

(c) Rhytidectomy;

(d) Submental liposuction;

(e) Laser resurfacing;

(f) Browlift, either open or endoscopic technique;

(g) Platysmal muscle plication;

(h) Otoplasty;

(i) Dermabrasion;

(j) Hair transplantation, not as an isolated procedure for male pattern baldness; and

(k) Harvesting bone extra orally for dental procedures, including oral and maxillofacial procedures.

(2) Unless the dentist:

(a) Has successfully completed a residency in Oral and Maxillofacial Surgery accredited by the American Dental Association, Commission on Dental Accreditation (CODA), or

(b) Holds privileges either:

(A) Issued by a credentialing committee of a hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to perform these procedures in a hospital setting; or

(B) Issued by a credentialing committee for an ambulatory surgical center licensed by the State of Oregon and accredited by either the JCAHO or the Accreditation Association for Ambulatory Health Care (AAAHC).

(3) A dentist may utilize Botulinum Toxin Type A ~~and dermal fillers~~ to treat ~~a~~ condition**s** that ~~is~~ **are** within the **oral and maxillofacial region** ~~scope of the practice of dentistry~~ after completing a minimum of **10** ~~20~~ hours in a hands on clinical course(s), ~~which includes both~~ **in** Botulinum Toxin Type A ~~and dermal fillers~~, and the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP). **Alternatively, a dentist may meet the requirements of subsection (3) by successfully completing training in Botulinum Toxin Type A and/or dermal fillers as part of a CODA accredited program.**

(4) A dentist may utilize dermal fillers to treat conditions that are within the oral and maxillofacial region after completing a minimum of 10 hours in a hands on clinical course(s), in dermal fillers, and the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP). Alternatively, a dentist may meet the requirements of subsection (4) by successfully completing training in dermal fillers as part of a CODA accredited program.

(5) A dentist may place endosseous implants to replace natural teeth after completing a minimum of 56 hours of hands on clinical course(s), which includes treatment planning, appropriate case selection, potential complications and the surgical placement of the implants under direct supervision, and the provider is approved by the Academy of General Dentistry Program Approval for Continuing Education (AGD PACE) or by the American Dental Association Continuing Education Recognition Program (ADA CERP).

(6) A dentist placing endosseous implants must complete at least seven (7) hours of continuing education related to the placement and or restoration of dental implants every licensure renewal period. (Effective January 1, 2022.)

Dear Dr. Todd Beck, DMD, and the Oregon Board of Dentistry.

Re: Rulemaking proposed AED for EPDH's.

I am writing this, per your request, from the Oregon Board of Dentistry meeting of October 25th, 2019, where I provided oral testimony as an EPDH. This is a written summary of that testimony.

Most of my patients have a "DNR" (do not resuscitate). If I were to visit a private home or an adult foster home, do I still need to have an AED with me, even if the patient I am seeing has a DNR?

About half the nursing homes I called and surveyed have an AED and about half do not. Given that most patients in a nursing home have a DNR, the practical reality is that the AED's are more for staff and visitors, and not so much for the actual residents. For those facilities where there is an AED available, would I be responsible for the maintenance of that AED?

I called DHS (Dept. of Human Services) regarding AED's and Adult Foster Homes. There are three classifications for AFH, depending on the level of care required for their residents. The State of Oregon does NOT require AFH's, of any classification, to have an AED on site.

I have a friend who is a Registered Nurse and a Certified Emergency Nurse. She owns and operates her own "RN on Call" practice that caters to coordinating post-hospital stays as the patient transitions to their home environment—and she has been doing this for over a dozen years. When I asked her if she carries an AED, she replied "NO! That's crazy! And you can quote me on that!". Home health nurses are NOT required to carry an AED for home health visits in the State of Oregon.

CPR/AED is a controversial subject for patients 85 years and older, with corresponding comorbidities. Only 10% of observable cardiac events are "shockable" (as older, sicker patients tend to have different types of arrhythmias). Of those, only 1-5% survive the immediate cardiac event, with "survivability" being a mean average of 30 days, often with broken ribs, bruised lungs, damaged airways, punctured spleens and lacerated livers. Some cardiac and geriatric experts have stated that CPR/AED on older, sicker patients (i.e. nursing home patients) can lead to a prolonged and painful death.

Unsurprisingly, when surveyed for themselves, 90% of doctors and nurses choose DNR as they age and become infirm.

As a point of reference, younger, healthier patients who have an observable cardiac event with CPR/AED, (20% of which have a "shockable" event) have a 45% of surviving (and living considerably longer and healthier) after their post-cardiac event.

Thank you for listening to my testimony.

Ann Ossinger, RDH, BSDH, EPP

818-012-0030
Unprofessional Conduct
The Board finds that in addition to the conduct set forth in ORS 679.140(2), unprofessional conduct includes, but is not limited to, the following in which a licensee does or knowingly permits any person to:
(1) Attempt to obtain a fee by fraud, or misrepresentation.
(2) Obtain a fee by fraud, or misrepresentation.
(a) A licensee obtains a fee by fraud if the licensee knowingly makes, or permits any person to make, a material, false statement intending that a recipient, who is unaware of the truth, rely upon the statement.
(b) A licensee obtains a fee by misrepresentation if the licensee obtains a fee through making or permitting any person to make a material, false statement.
(c) Giving cash discounts and not disclosing them to third party payers is not fraud or misrepresentation.
(3) Offer rebates, split fees, or commissions for services rendered to a patient to any person other than a partner, employee, or employer.
(4) Accept rebates, split fees, or commissions for services rendered to a patient from any person other than a partner, employee, or employer.
(5) Initiate, or engage in, with a patient, any behavior with sexual connotations. The behavior can include but is not limited to, inappropriate physical touching; kissing of a sexual nature; gestures or expressions, any of which are sexualized or sexually demeaning to a patient; inappropriate procedures, including, but not limited to, disrobing and draping practices that reflect a lack of respect for the patient's privacy; or initiating inappropriate communication, verbal or written, including, but not limited to, references to a patient's body or clothing that are sexualized or sexually demeaning to a patient; and inappropriate comments or queries about the professional's or patient's sexual orientation, sexual performance, sexual fantasies, sexual problems, or sexual preferences.
(6) Engage in an unlawful trade practice as defined in ORS 646.605 to 646.608.
(7) Fail to present a treatment plan with estimated costs to a patient upon request of the patient or to a patient's guardian upon request of the patient's guardian.
(8) Misrepresent any facts to a patient concerning treatment or fees.
(9)(a) Fail to provide a patient or patient's guardian within 14 days of written request:
(A) Legible copies of records; and
(B) Duplicates of study models, radiographs of the same quality as the originals, and photographs if they have been paid for.
(b) The licensee may require the patient or guardian to pay in advance a fee reasonably calculated to cover the costs of making the copies or duplicates. The licensee may charge a fee not to exceed $30 for copying 10 or fewer pages of written material and no more than $0.50 per page for pages 11 through 50 and no more than $0.25 for each additional page (including records copied from microfilm), plus any postage costs to mail copies requested and actual costs of preparing an explanation or summary of information, if requested. The actual cost of duplicating radiographs may also be charged to the patient. Patient records or summaries may not be withheld from the patient because of any prior unpaid bills, except as provided in (9)(a)(B) of this rule.
(10) Fail to identify to a patient, patient's guardian, or the Board the name of an employee, employer, contractor, or agent who renders services.
(11) Use prescription forms pre-printed with any Drug Enforcement Administration number, name of controlled substances, or facsimile of a signature.
(12) Use a rubber stamp or like device to reproduce a signature on a prescription form or sign a blank prescription form.
(13) Order drugs listed on Schedule II of the Drug Abuse Prevention and Control Act, 21 U.S.C. Sec. 812, for office use on a prescription form.
(14) Violate any Federal or State law regarding controlled substances.
(15) Becomes addicted to, or dependent upon, or abuses alcohol, illegal or controlled drugs, or mind altering substances, or practice with an untreated substance use disorder diagnosis that renders the licensee unable to safely conduct the practice of dentistry or dental hygiene.
(16) Practice dentistry or dental hygiene in a dental office or clinic not owned by an Oregon licensed dentist(s), except for an entity described under ORS 679.020(3) and dental hygienists practicing pursuant to ORS 680.205(1)(2).

(17) Make an agreement with a patient or person, or any person or entity representing patients or persons, or provide any form of consideration that would prohibit, restrict, discourage or otherwise limit a person's ability to file a complaint with the Oregon Board of Dentistry; to truthfully and fully answer any questions posed by an agent or representative of the Board; or to participate as a witness in a Board proceeding.
(18) Fail to maintain at a minimum a current BLS for Healthcare Providers certificate or its equivalent. (Effective January 2015).
(19) Conduct unbecoming a licensee or detrimental to the best interests of the public, including conduct contrary to the recognized standards of ethics of the licensee's profession or conduct that endangers the health, safety or welfare of a patient or the public.
(20) Knowingly deceiving or attempting to deceive the Board, an employee of the Board, or an agent of the Board in any application or renewal, or in reference to any matter under investigation by the Board. This includes but is not limited to the omission, alteration or destruction of any record in order to obstruct or delay an investigation by the Board, or to omit, alter or falsify any information in patient or business records.
(21) Knowingly practicing with a physical or mental impairment that renders the Licensee unable to safely conduct the practice of dentistry or dental hygiene.
(22) Take any action which could reasonably be interpreted to constitute harassment or retaliation towards a person whom the licensee believes to be a complainant or witness.
(23) Fail to register with the Prescription Drug Monitoring Program (PDMP) in accordance with OAR 888-023-0820(8) in order to have access to the Program's electronic system if the Licensee holds an Oregon DEA registration.
(24) Fail to maintain in a dental office or an expanded practice dental hygienist practice, an Automated External Defibrillator (AED). Each AED, or equivalent defibrillator, shall be maintained in a properly functioning capacity at all times. Proof of the availability of a properly functioning AED, or equivalent defibrillator shall be retained by the licensee for the current calendar year and the two preceding calendar years. (Effective January 1, 2021)

818-012-0070
Patient Records
(1) Each licensee shall have prepared and maintained an accurate and legible record for each person receiving dental services, regardless of whether any fee is charged. The record shall contain the name of the licensee rendering the service and include:
(a) Name and address and, if a minor, name of guardian;
(b) Date description of examination and diagnosis;
(c) An entry that informed consent has been obtained and the date the informed consent was obtained. Documentation may be in the form of an acronym such as "PARQ" (Procedure, Alternatives, Risks and Questions) or ~~"SOAP" (Subjective Objective Assessment Plan) or~~ ~~their~~ **its** equivalent.
(d) Date and description of treatment or services rendered;
(e) Date, description and documentation of informing the patient of any recognized treatment complications;
(f) Date and description of all radiographs, study models, and periodontal charting;
(g) **Current** ~~H~~**h**ealth history; and
(h) Date, name of, quantity of, and strength of all drugs dispensed, administered, or prescribed.
(2) Each licensee shall have prepared and maintained an accurate record of all charges and payments for services including source of payments.
(3) Each licensee shall maintain patient records and radiographs for at least seven years from the date of last entry unless:
(a) The patient requests the records, radiographs, and models be transferred to another licensee who shall maintain the records and radiographs;
(b) The licensee gives the records, radiographs, or models to the patient; or
(c) The licensee transfers the licensee's practice to another licensee who shall maintain the records and radiographs.
(4) When a dental implant is placed the following information must be given to the patient in writing and maintained in the patient record:
(a) Manufacture brand;
(b) Design name of implant;
(c) Diameter and length;
(d) Lot number;
(e) Reference number;
(f) Expiration date;
(g) Product labeling containing the above information may be used in satisfying this requirement.
(5) When changing practice locations, closing a practice location or retiring, each licensee must retain patient records for the required amount of time or transfer the custody of patient records to another licensee licensed and practicing dentistry in Oregon. Transfer of patient records pursuant to this section of this rule must be reported to the Board in writing within 14 days of transfer, but not later than the effective date of the change in practice location, closure of the practice location or retirement. Failure to transfer the custody of patient records as required in this rule is unprofessional conduct.
(6) Upon the death or permanent disability of a licensee, the administrator, executor, personal representative, guardian, conservator or receiver of the former licensee must notify the Board in writing of the management arrangement for the custody and transfer of patient records. This individual must ensure the security of and access to patient records by the patient or other authorized party, and must report arrangements for permanent custody of patient records to the Board in writing within 90 days of the death of the licensee.

818-021-0080
Renewal of License
Before the expiration date of a license, the Board will, as a courtesy, mail notice for renewal of license to the last mailing address on file in the Board's records to every ~~person~~ **licensee** holding a current license. The licensee must ~~return the~~ complete~~d~~ **the online** renewal application **and pay the** ~~along with~~ current renewal fees prior to the expiration of said license. Licensees who fail to renew their license prior to the expiration date may not practice dentistry or dental hygiene until the license is reinstated and are subject to the provisions of OAR 818-021-0085, "Reinstatement of Expired Licenses."
(1) Each dentist shall submit the renewal fee and completed ~~and signed~~ **online** renewal application ~~form~~ by March 31 every other year. Dentists licensed in odd numbered years shall apply for renewal in odd numbered years and dentists licensed in even numbered years shall apply for renewal in even numbered years.
(2) Each **dental** hygienist must submit the renewal fee and completed ~~and signed~~ **online** renewal application ~~form~~ by September 30 every other year. **Dental** ~~H~~**h**ygienists licensed in odd numbered years shall apply for renewal in odd numbered years and **dental** hygienists licensed in even numbered years shall apply for renewal in even numbered years.
(3) The renewal application shall contain:
(a) Licensee's full name;
(b) Licensee's mailing address;
(c) Licensees business address including street and number or if the licensee has no business address, licensee's home address including street and number;
(d) Licensee's business telephone number or if the licensee has no business telephone number, licensee's home telephone number;
(e) Licensee's employer or person with whom the licensee is on contract;
(f) Licensee's assumed business name;
(g) Licensee's type of practice or employment;
(h) A statement that the licensee has met the **continuing** educational requirements for renewal set forth in OAR 818-021-0060 or 818-021-0070;
(i) Identity of all jurisdictions in which the licensee has practiced during the two past years; ~~and~~
(j) A statement that the licensee has not been disciplined by the licensing board of any other jurisdiction ~~or convicted of a crime.~~**;**
(k) A statement disclosing if the licensee has been arrested and or convicted of a misdemeanor or felony;
(l) A statement disclosing if the licensee or licensees malpractice insurance company or risk retention group has had any request for an alleged injury; and
(m) A statement disclosing any physical or mental condition that would inhibit Licensee's ability to practice safely.

818-026-0040
Qualifications, Standards Applicable, and Continuing Education Requirements for Anesthesia Permits: Nitrous Oxide Permit
Nitrous Oxide Sedation.
(1) The Board shall issue a Nitrous Oxide Permit to an applicant who:
(a) Is either a licensed dentist or licensed hygienist in the State of Oregon;
(b) Maintains a current BLS for Healthcare Providers certificate or its equivalent; and
(c) Has completed a training course of at least 14 hours of instruction in the use of nitrous oxide from a dental school or dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association, or as a postgraduate.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedure and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow delivery of appropriate care in an emergency situation;
(b) An operating table or chair which permits the patient to be positioned so that the patient's airway can be maintained, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full face masks and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system; and
(g) Sphygmomanometer and stethoscope and/or automatic blood pressure cuff.
(3) Before inducing nitrous oxide sedation, a permit holder shall:
(a) Evaluate the patient **and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for nitrous oxide sedation**;
(b) Give instruction to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian;
(c) Certify that the patient is an appropriate candidate for nitrous oxide sedation; and
(d) Obtain informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(4) If a patient chronically takes a medication which can have sedative side effects, including, but not limited to, a narcotic or benzodiazepine, the practitioner shall determine if the additive sedative effect of nitrous oxide would put the patient into a level of sedation deeper than nitrous oxide. If the practitioner determines it is possible that providing nitrous oxide to such a patient would result in minimal sedation, a minimal sedation permit would be required.
(5) A patient under nitrous oxide sedation shall be visually monitored by the permit holder or by an anesthesia monitor at all times. The patient shall be monitored as to response to verbal stimulation, oral mucosal color and preoperative and postoperative vital signs.
(6) The permit holder or anesthesia monitor shall record the patient's condition. The record must include documentation of **preoperative and postoperative vital signs, and** all medications administered with dosages, time intervals and route of administration.
(7) Persons serving as anesthesia monitors in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)

(8) The person administering the nitrous oxide sedation may leave the immediate area after initiating the administration of nitrous oxide sedation only if a qualified anesthesia monitor is continuously observing the patient.
(9) The permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(b) The patient can talk and respond coherently to verbal questioning;
(c) The patient can sit up unaided or without assistance;
(d) The patient can ambulate with minimal assistance; and
(e) The patient does not have nausea, vomiting or dizziness.
(10) The permit holder shall make a discharge entry in the patient's record indicating the patient's condition upon discharge.
(11) Permit renewal. In order to renew a Nitrous Oxide Permit, the permit holder must provide proof of a current BLS for Healthcare Providers certificate or its equivalent. In addition, Nitrous Oxide Permit holders must also complete four (4) hours of continuing education in one or more of the following areas every two years: sedation, nitrous oxide, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current BLS for Healthcare Providers certificate or its equivalent, may not be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060 and 818-021-0070.

818-026-0050
Minimal Sedation Permit
Minimal sedation and nitrous oxide sedation.
(1) The Board shall issue a Minimal Sedation Permit to an applicant who:
(a) Is a licensed dentist in Oregon;
(b) Maintains a current BLS for Healthcare Providers certificate or its equivalent; and
(c) Completion of a comprehensive training program consisting of at least 16 hours of training and satisfies the requirements of the current ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students at the time training was commenced or postgraduate instruction was completed, or the equivalent of that required in graduate training programs, in sedation, recognition and management of complications and emergency care; or
(d) In lieu of these requirements, the Board may accept equivalent training or experience in minimal sedation anesthesia.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedures and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least two individuals to freely move about the patient;
(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full facemask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;
(g) Sphygmomanometer, stethoscope, pulse oximeter, and/or automatic blood pressure cuff; and
(h) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, antihistamines, antihypertensives and anticonvulsants.
(3) Before inducing minimal sedation, a dentist permit holder who induces minimal sedation shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for minimal sedation;
(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian;
(c) Certify that the patient is an appropriate candidate for minimal sedation; and
(d) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(4) No permit holder shall have more than one person under minimal sedation at the same time.
(5) While the patient is being treated under minimal sedation, an anesthesia monitor shall be present in the room in addition to the treatment provider. The anesthesia monitor may be the dental assistant. After training, a dental assistant, when directed by a dentist permit holder, may administer oral sedative agents or anxiolysis agents calculated and dispensed by a dentist permit holder under the direct supervision of a dentist permit holder.
(6) A patient under minimal sedation shall be visually monitored at all times, including recovery phase. The record must include documentation of all medications administered with dosages, time intervals and route of administration. The dentist permit holder or anesthesia monitor shall monitor and record the patient's condition.
(7) Persons serving as anesthesia monitors for minimal sedation in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the

use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)
(8) The patient shall be monitored as follows:
(a) Color of mucosa, skin or blood must be evaluated continually. Patients must have continuous monitoring using pulse oximetry. The patient's response to verbal stimuli, blood pressure, heart rate, pulse oximetry and respiration shall be monitored and documented every fifteen minutes, if they can reasonably be obtained.
(b) A discharge entry shall be made by the dentist permit holder in the patient's record indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.
(9) The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;
(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(c) The patient can talk and respond coherently to verbal questioning;
(d) The patient can sit up unaided;
(e) The patient can ambulate with minimal assistance; and
(f) The patient does not have uncontrollable nausea or vomiting and has minimal dizziness.
(g) A dentist permit holder shall not release a patient who has undergone minimal sedation except to the care of a responsible third party.
(10) The permit holder shall make a discharge entry in the patient's record indicating the patient's condition upon discharge.
(~~10~~**11**) Permit renewal. In order to renew a Minimal Sedation Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent. In addition, Minimal Sedation Permit holders must also complete four (4) hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current BLS for Healthcare Providers certificate, or its equivalent, may not be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

Oregon Society of Anesthesiologists

October 2nd, 2019

Dr. Fine and members of the Oregon Board of Dentistry-

On behalf of the Oregon Society of Anesthesiologists (OSA), I would like would like to express our society's concern about proposed changes to 818-026-0065 (Deep Sedation Permit) and 818-026-0070 (General Anesthesia).

As physician anesthesiologists, we truly appreciate your efforts to enhance minimal requirements for anesthesia monitors involved with deep sedation and general anesthesia cases. Along with our national society, the American Society of Anesthesiologists (ASA, asahq.com), I encourage the Board of Dentistry to further amend the proposed language within 818-026-0065 and 818-026-0070 to reflect the 2019 American Academy of Pediatric Dentistry (AAPD) and American Academy of Pediatrics (AAP) "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures." At a minimum, the proposed language defining an anesthesia monitor should be amended to mean a qualified anesthesia provider as defined in the CMS Conditions of Participation at 42 C.F.R. § 482.52(a).

Briefly, the ASA, American Society of Dentist Anesthesiologists, the Society for Pediatric Anesthesia, and the Society for Pediatric Sedation endorse the AAP/AAPD guidelines. These guidelines recommend that at least two individuals with specific training and credentials should be present with a pediatric patient undergoing deep sedation/general anesthesia for dental treatment in a dental facility or hospital/surgicenter. Specifically, the guidelines clarify that a separate qualified anesthesia professional (a physician anesthesiologist, a certified registered nurse anesthetist, a dentist anesthesiologist or a second oral surgeon) must administer the anesthesia and/or sedation and monitor the patient.

We appreciate the time you have taken to consider our concerns.

Sincerely,
Seth Palesch, MD

President, Oregon Society of Anesthesiologists

American Society of Anesthesiologists™

1061 American Lane | Schaumburg, IL 60173-4973 | (847) 825-5586
905 16th Street N.W. | Washington, D.C. 20006 | (202) 289-2222

October 11, 2019

Amy B. Fine, DMD, President
Oregon Board of Dentistry
1500 SW 1st Avenue, Suite 770
Portland, OR 97201

[Submitted via Email: stephen.prisby@state.org.us]

Re: Notice of Proposed Rulemaking

Dear Dr. Fine,

The American Society of Anesthesiologists (ASA) appreciates the opportunity to comment on the Oregon Board of Dentistry's proposed amendments to the Oregon Administrative Rules. On behalf of ASA, I am writing to express concern regarding proposed changes to 818-026-0065 (Deep Sedation Permit) and 818-026-0070 (General Anesthesia).

ASA is a more than 53,000 member educational, research, and advocacy organization dedicated to improving the medical care of patients and raising standards in the science and art of anesthesiology. Since its founding in 1905, the ASA's achievements have made it the leading voice and the foremost expert in American medicine on matters of patient safety in the perioperative environment and pain medicine.

On behalf of ASA, I encourage the Board of Dentistry to further amend the proposed language[1] within 818-026-0065 and 818-026-0070 to reflect the 2019 American Academy of Pediatric Dentistry (AAPD) and American Academy of Pediatrics (AAP) "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures". [2]

ASA appreciates the Board of Dentistry's efforts to enhance minimal requirements for anesthesia monitors involved with deep sedation and general anesthesia cases. In recent years, a number of pediatric deaths have been reported in dental offices. Subsequently, numerous states and dental organizations have enhanced their sedation and anesthesia requirements/guidelines. Most recently the AAP, in conjunction with the AAPD, released a clinical report on their updated "Guidelines for Monitoring and Management of Pediatric Patients Before, During and After Sedation for Diagnostic and Therapeutic

[1] (7) Persons serving as anesthesia monitors for general anesthesia in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)

[2] Coté CJ, Wilson S. American Academy of Pediatric Dentistry, American Academy of Pediatrics. Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures. Pediatr Dent 2019;41(4):E26-E52.

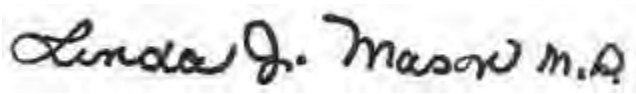
Procedures." In a joint statement,[3] ASA, the Society for Pediatric Anesthesia, the American Society of Dentist Anesthesiologists, and the Society for Pediatric Sedation endorsed the AAP/AAPD guidelines.

The guidelines – updated from 2016 – recommend that at least two individuals with specific training and credentials should be present with a pediatric patient undergoing deep sedation/general anesthesia for dental treatment in a dental facility or hospital/surgicenter. Further, the guidelines clarify that a separate qualified anesthesia professional who is one of the following: a physician anesthesiologist, a certified registered nurse anesthetist, a dentist anesthesiologist or a second oral surgeon – must administer the anesthesia and/or sedation and monitor the patient in a dental facility. Additional providers with advanced training in perioperative care and airway management skills may fill this vital role in preventing sedation-related morbidity and mortality in a hospital or surgicenter setting.

ASA policy offers a wealth of guidance for anesthesia administration in a variety of settings.[4,5,6,7] A common recommendation within our policy is that a designated individual, other than the individual performing the procedure, should be present to monitor the patient throughout procedures performed with sedation. During deep sedation and/or general anesthesia, this individual should have no other responsibilities – thus ensuring singular focus on the anesthetized patient's safety. Critically important for the patient's safety is that the individual monitoring the anesthetized patient be competent to fully understand and apply the clinical information they are receiving.

On behalf of ASA, I thank you for your consideration of this very important issue. Should you have any questions, please feel free to contact Jason Hansen, M.S., J.D., Director of State Affairs, at j.hansen@asahq.org.

Sincerely,



Linda J. Mason, M.D., FASA
President

[3] Anesthesia Health Care Groups Join American Academy of Pediatrics in Endorsement of Guidelines for Deep Sedation and Anesthesia During Dental Procedures. Available at: https://www.asahq.org/advocacy-and-asapac/advocacy-topics/ofØce-based-anesthesiaand-dental-anesthesia/joint-statement-pediatric-dental-sedation

[4] ASA Statement on Nonoperating Room Anesthetizing Locations. *Available at*: https://www.asahq.org/standards-and-guidelines/statement-on-nonoperating-room-anesthetizing-locations

[5] ASA Statement on Sedation & Anesthesia Administration in Dental Office-Based Settings. *Available at*: https://www.asahq.org/standards-and-guidelines/statement-on-sedation--anesthesia-administration-in-dental-officebased-settings

[6] ASA Guidelines for Office-Based Anesthesia. *Available at*: https://www.asahq.org/standards-and-guidelines/guidelines-for-office-based-anesthesia

[7] ASA Standards for Basic Anesthetic Monitoring. *Available at*: https://www.asahq.org/standards-and-guidelines/standards-for-basic-anesthetic-monitoring

42 CFR § 410.69 - Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

CFR

§ 410.69 Services of a certified registered nurse anesthetist or an anesthesiologist's assistant: Basic rule and definitions.

(a) ***Basic rule.*** Medicare Part B pays for anesthesia services and related care furnished by a certified registered nurse anesthetist or an anesthesiologist's assistant who is legally authorized to perform the services by the State in which the services are furnished.

(b) ***Definitions.*** For purposes of this part -

Anesthesia and related care means those services that a certified registered nurse anesthetist is legally authorized to perform in the state in which the services are furnished.

Anesthesiologist's assistant means a person who -

(1) Works under the direction of an anesthesiologist;

(2) Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and

(3) Is a graduate of a medical school-based anesthesiologist's assistant educational program that -

(A) Is accredited by the Committee on Allied Health Education and Accreditation; and

(B) Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background.

Anesthetist includes both an anesthesiologist's assistant and a certified registered nurse anesthetist.

Certified registered nurse anesthetist means a registered nurse who:

Is licensed as a registered professional nurse by the State in which the nurse practices;

Meets any licensure requirements the State imposes with respect to non-physician anesthetists;

Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and

(4) Meets the following criteria:

(i) Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or

(ii) Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of paragraph (4)(i) of this definition.

[57 FR 33896, July 31, 1992, as amended at 77 FR 69363, Nov. 16, 2012]

42 CFR § 482.52 - Condition of participation: Anesthesia services.

CFR

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) ***Standard: Organization and staffing.*** The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by -

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in § 410.69 (b) of this chapter, who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) ***Standard: Delivery of services.*** Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, performed within 48 hours prior to surgery or a procedure requiring anesthesia services.

(2) An intraoperative anesthesia record.

(3) A postanesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of this section, no later than 48 hours after surgery or a procedure requiring anesthesia services. The postanesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.

(c) ***Standard: State exemption.***

(1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986, as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001; 71 FR 68694, Nov. 27, 2006; 72 FR 66934, Nov. 27, 2007]

818-026-0065
Deep Sedation Permit
Deep sedation, moderate sedation, minimal sedation, and nitrous oxide sedation.
(1) The Board shall issue a Deep Sedation Permit to a licensee who holds a Class 3 Permit on or before July 1, 2010 who:
(a) Is a licensed dentist in Oregon; and
(b) In addition to a current BLS for Healthcare Providers certificate or its equivalent, maintains a current Advanced Cardiac Life Support (ACLS) certificate and/or a Pediatric Advanced Life Support (PALS) certificate, whichever is appropriate for the patient being sedated.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedures and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least two individuals to freely move about the patient;
(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full face mask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;
(g) A recovery area that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area can be the operating room;
(h) Sphygmomanometer, precordial/pretracheal stethoscope, capnograph, pulse oximeter, electrocardiograph monitor (ECG), automated external defibrillator (AED), oral and nasopharyngeal airways, laryngeal mask airways, intravenous fluid administration equipment; and
(i) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, antihistamines, antihypertensives and anticonvulsants.
(3) No permit holder shall have more than one person under deep sedation, moderate sedation, minimal sedation, or nitrous oxide sedation at the same time.
(4) During the administration of deep sedation, and at all times while the patient is under deep sedation, an anesthesia monitor, and one other person holding a current BLS for Healthcare Providers certificate or its equivalent, shall be present in the operatory, in addition to the dentist permit holder performing the dental procedures.
(5) Before inducing deep sedation, a dentist permit holder who induces deep sedation shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for deep sedation;
(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian; and
(c) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient’s record.
(6) A patient under deep sedation shall be visually monitored at all times, including the recovery phase. The dentist permit holder or anesthesia monitor shall monitor and record the patient's condition.
(7) Persons serving as anesthesia monitors for deep sedation in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)

(8) The patient shall be monitored as follows:
(a) Patients must have continuous monitoring using pulse oximetry, electrocardiograph monitors (ECG) and End-tidal CO2 monitors. The patient's heart rhythm shall be continuously monitored and the patient's blood pressure, heart rate, and respiration shall be recorded at regular intervals but at least every 5 minutes, and these recordings shall be documented in the patient record. The record must also include documentation of preoperative and postoperative vital signs, all medications administered with dosages, time intervals and route of administration. If this information cannot be obtained, the reasons shall be documented in the patient's record. A patient under deep sedation shall be continuously monitored;
(b) Once sedated, a patient shall remain in the operatory for the duration of treatment until criteria for transportation to recovery have been met.
(c) During the recovery phase, the patient must be monitored by an individual trained to monitor patients recovering from deep sedation.
(9) A dentist permit holder shall not release a patient who has undergone deep sedation except to the care of a responsible third party. When a reversal agent is administered, the dentist permit holder shall document justification for its use and how the recovery plan was altered.
(10) The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;
(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(c) The patient can talk and respond coherently to verbal questioning;
(d) The patient can sit up unaided;
(e) The patient can ambulate with minimal assistance; and
(f) The patient does not have uncontrollable nausea or vomiting and has minimal dizziness.
(11) A discharge entry shall be made by the dentist permit holder in the patient's record indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.
(12) Pursuant to OAR 818-042-0115 a Certified Anesthesia Dental Assistant, when directed by a dentist permit holder, may administer oral sedative agents calculated by a dentist permit holder or introduce additional anesthetic agents into an infusion line under the direct visual supervision of a dentist.
(13) Permit renewal. In order to renew a Deep Sedation Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent; a current Advanced Cardiac Life Support (ACLS) certificate and/or a current Pediatric Advanced Life Support (PALS) certificate; and must complete 14 hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current ACLS and/or PALS certificates may be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

818-026-0070
General Anesthesia Permit
General anesthesia, deep sedation, moderate sedation, minimal sedation and nitrous oxide sedation.
(1) The Board shall issue a General Anesthesia Permit to an applicant who:
(a) Is a licensed dentist in Oregon;
(b) In addition to a current BLS for Healthcare Providers certificate or its equivalent, maintains a current Advanced Cardiac Life Support (ACLS) certificate and/or a Pediatric Advanced Life Support (PALS) certificate, whichever is appropriate for the patient being sedated, and
(c) Satisfies one of the following criteria:
(A) Completion of an advanced training program in anesthesia and related subjects beyond the undergraduate dental curriculum that satisfies the requirements described in the current ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students consisting of a minimum of 2 years of a postgraduate anesthesia residency at the time training was commenced.
(B) Completion of any ADA accredited postdoctoral training program, including but not limited to Oral and Maxillofacial Surgery, which affords comprehensive and appropriate training necessary to administer and manage general anesthesia, commensurate with these Guidelines.
(C) In lieu of these requirements, the Board may accept equivalent training or experience in general anesthesia.
(2) The following facilities, equipment and drugs shall be on site and available for immediate use during the procedure and during recovery:
(a) An operating room large enough to adequately accommodate the patient on an operating table or in an operating chair and to allow an operating team of at least three individuals to freely move about the patient;
(b) An operating table or chair which permits the patient to be positioned so the operating team can maintain the patient's airway, quickly alter the patient's position in an emergency, and provide a firm platform for the administration of basic life support;
(c) A lighting system which permits evaluation of the patient's skin and mucosal color and a backup lighting system of sufficient intensity to permit completion of any operation underway in the event of a general power failure;
(d) Suction equipment which permits aspiration of the oral and pharyngeal cavities and a backup suction device which will function in the event of a general power failure;
(e) An oxygen delivery system with adequate full face mask and appropriate connectors that is capable of delivering high flow oxygen to the patient under positive pressure, together with an adequate backup system;
(f) A nitrous oxide delivery system with a fail-safe mechanism that will insure appropriate continuous oxygen delivery and a scavenger system;
(g) A recovery area that has available oxygen, adequate lighting, suction and electrical outlets. The recovery area can be the operating room;
(h) Sphygmomanometer, precordial/pretracheal stethoscope, capnograph, pulse oximeter, electrocardiograph monitor (ECG), automated external defibrillator (AED), oral and nasopharyngeal airways, laryngeal mask airways, intravenous fluid administration equipment; and
(i) Emergency drugs including, but not limited to: pharmacologic antagonists appropriate to the drugs used, vasopressors, corticosteroids, bronchodilators, intravenous medications for treatment of cardiac arrest, narcotic antagonist, antihistaminic, antiarrhythmics, antihypertensives and anticonvulsants.
(3) No permit holder shall have more than one person under general anesthesia, deep sedation, moderate sedation, minimal sedation or nitrous oxide sedation at the same time.
(4) During the administration of deep sedation or general anesthesia, and at all times while the patient is under deep sedation or general anesthesia, an anesthesia monitor, and one other person holding a current BLS for Healthcare Providers certificate or its equivalent, shall be present in the operatory in addition to the dentist permit holder performing the dental procedures.
(5) Before inducing deep sedation or general anesthesia the dentist permit holder who induces deep sedation or general anesthesia shall:
(a) Evaluate the patient and document, using the American Society of Anesthesiologists (ASA) Patient Physical Status Classifications, that the patient is an appropriate candidate for general anesthesia or deep sedation;

(b) Give written preoperative and postoperative instructions to the patient or, when appropriate due to age or psychological status of the patient, the patient's guardian; and
(c) Obtain written informed consent from the patient or patient's guardian for the anesthesia. The obtaining of the informed consent shall be documented in the patient's record.
(6) A patient under deep sedation or general anesthesia shall be visually monitored at all times, including recovery phase. A dentist permit holder who induces deep sedation or general anesthesia or anesthesia monitor trained in monitoring patients under deep sedation or general anesthesia shall monitor and record the patient's condition on a contemporaneous record.
(7) Persons serving as anesthesia monitors for general anesthesia in a dental office shall maintain current certification in BLS for Healthcare Providers Basic Life Support (BLS)/Cardio Pulmonary Resuscitation (CPR) training, or its equivalent, shall be trained and competent in monitoring patient vital signs, in the use of monitoring and emergency equipment appropriate for the level of sedation utilized. ("competent" means displaying special skill or knowledge derived from training and experience.)
(8) The patient shall be monitored as follows:
(a) Patients must have continuous monitoring of their heart rate, heart rhythm, oxygen saturation levels and respiration using pulse oximetry, electrocardiograph monitors (ECG) and End-tidal CO2 monitors. The patient's blood pressure, heart rate and oxygen saturation shall be assessed every five minutes, and shall be contemporaneously documented in the patient record. The record must also include documentation of preoperative and postoperative vital signs, all medications administered with dosages, time intervals and route of administration. The person administering the anesthesia and the person monitoring the patient may not leave the patient while the patient is under deep sedation or general anesthesia;
(b) Once sedated, a patient shall remain in the operatory for the duration of treatment until criteria for transportation to recovery have been met.
(c) During the recovery phase, the patient must be monitored, including the use of pulse oximetry, by an individual trained to monitor patients recovering from general anesthesia.
(9) A dentist permit holder shall not release a patient who has undergone deep sedation or general anesthesia except to the care of a responsible third party. When a reversal agent is administered, the dentist permit holder shall document justification for its use and how the recovery plan was altered.
(10) The dentist permit holder shall assess the patient's responsiveness using preoperative values as normal guidelines and discharge the patient only when the following criteria are met:
(a) Vital signs including blood pressure, pulse rate and respiratory rate are stable;
(b) The patient is alert and oriented to person, place and time as appropriate to age and preoperative psychological status;
(c) The patient can talk and respond coherently to verbal questioning;
(d) The patient can sit up unaided;
(e) The patient can ambulate with minimal assistance; and
(f) The patient does not have nausea or vomiting and has minimal dizziness.
(11) A discharge entry shall be made in the patient's record by the dentist permit holder indicating the patient's condition upon discharge and the name of the responsible party to whom the patient was discharged.
(12) Pursuant to OAR 818-042-0115 a Certified Anesthesia Dental Assistant, when directed by a dentist permit holder, may introduce additional anesthetic agents to an infusion line under the direct visual supervision of a dentist permit holder.
(13) Permit renewal. In order to renew a General Anesthesia Permit, the permit holder must provide documentation of a current BLS for Healthcare Providers certificate or its equivalent; a current Advanced Cardiac Life Support (ACLS) certificate and/or a current Pediatric Advanced Life Support (PALS) certificate; and must complete 14 hours of continuing education in one or more of the following areas every two years: sedation, physical evaluation, medical emergencies, monitoring and the use of monitoring equipment, or pharmacology of drugs and agents used in sedation. Training taken to maintain current ACLS and/or PALS certificates may be counted toward this requirement. Continuing education hours may be counted toward fulfilling the continuing education requirement set forth in OAR 818-021-0060.

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From: Rowley, Lisa J. [mailto:lisajrowley@pacificu.edu]
Sent: Monday, July 15, 2019 3:52 PM
To: Teresa Haynes <Teresa.Haynes@state.or.us>
Subject: OAR 818-035-0020

Hi Teresa-

I was reviewing the rules for dental hygiene and I wanted to get your thoughts on the highlighted portions of 818-035-0020.

818-035-0020 Authorization to Practice
(1) A dental hygienist may practice dental hygiene in the places specified by ORS 680.150 under general supervision upon authorization of a supervising dentist.
(2) A dentist who authorizes a dental hygienist to practice dental hygiene on a limited access patient must review the hygienist's findings.
(3) A supervising dentist, without first examining a new patient, may authorize a dental hygienist: (a) To take a health history from a patient; (b) To take dental radiographs; (c) To perform periodontal probings and record findings; (d) To gather data regarding the patient; and (e) To diagnose, treatment plan and provide dental hygiene services.
(4) When hygiene services are provided pursuant to subsection (3), the supervising dentist need not be on the premises when the services are provided.
(5) When hygiene services are provided pursuant to subsection (3), the patient must be scheduled to be examined by the supervising dentist within fifteen business days following the day the hygiene services are provided.
(6) If a new patient has not been examined by the supervising dentist subsequent to receiving dental hygiene services pursuant to subsection (3), no further dental hygiene services may be provided until an examination is done by the supervising dentist.

In referring back to ORS 680.150 it looks like a dental hygienist does not need to have an expanded practice permit to work in any place where limited access patients are located as long as they are working under the general supervision of a dentist.

Sections 4, 5 & 6 refer back to Section 3 but not to Sections 1 & 2. So if a dental hygienist works under the general supervision of a dentist in any place where limited access patients are located, Sections 4, 5 & 6 do not apply? So the patient does not need to be scheduled to be examined by the supervising dentist within 15 business days?

Do you think that I am interpreting this correctly? If so, perhaps ODHA could offer a rule change just to re-format this a bit to make it a bit easier to understand?

Thanks for your help!

-Lisa

From:	Rowley, Lisa J.
To:	Teresa Haynes
Subject:	RE: OAR 818-035-0020
Date:	Monday, July 22, 2019 1:41:57 PM
Attachments:	2019 Rule Amendment 2 - Authorization.docx

Hi Teresa-

So I'm thinking that it may be more clear if (1) & (2) were moved to the end and then they were referred back to (3), (4), (5) & (6). And of course everything would be re-numbered.

Please let me know if you think the attachment makes sense.

-Lisa

From: Teresa Haynes <Teresa.Haynes@state.or.us>
Sent: Monday, July 22, 2019 12:58 PM
To: Rowley, Lisa J. <lisajrowley@pacificu.edu>
Subject: RE: OAR 818-035-0020

Hi Lisa,

It has always been the interruption of the OBD that a dentist would have to see the patient since the hygienist is working under the general supervision. Otherwise the hygienist could get their expanded practice permit and of course treat patients without supervision.

Hope that helps.

Sincerely,

Teresa

Teresa Haynes
Office Manager
Oregon Board of Dentistry
1500 SW 1st Avenue, Suite 770
Portland, OR 97201
Telephone: 971-673-3200
FAX: 971-673-3202
www.oregon.gov/dentistry

Your opinion matters. Please complete our Customer Satisfaction Survey at https://www.surveymonkey.com/r/OBDSurveyLink

"The Mission of the Oregon Board of Dentistry is to promote high quality oral health care in the State of Oregon by equitably regulating dental professionals."

Proposed Amendment to the Rules
Authorization to Practice

818-035-0020
Authorization to Practice
(1) A supervising dentist, without first examining a new patient, may authorize a dental hygienist:
(a) To take a health history from a patient;
(b) To take dental radiographs;
(c) To perform periodontal probings and record findings;
(d) To gather data regarding the patient; and
(e) To diagnose, treatment plan and provide dental hygiene services.
(2) When **dental** hygiene services are provided pursuant to subsection **(1)**, the supervising dentist need not be on the premises when the services are provided.
(3) When **dental** hygiene services are provided pursuant to subsection **(1)**, the patient must be scheduled to be examined by the supervising dentist within fifteen business days following the day the **dental** hygiene services are provided.
(4) If a new patient has not been examined by the supervising dentist subsequent to receiving dental hygiene services pursuant to subsection **(1)**, no further dental hygiene services may be provided until an examination is done by the supervising dentist.
(5) A dental hygienist may practice dental hygiene in the places specified by ORS 680.150 under general supervision upon authorization of a supervising dentist.
(6) A dentist who authorizes a dental hygienist to practice dental hygiene on a limited access patient must review the **dental** hygienist's findings.
(7) When dental hygiene services are provided pursuant to subsection (5), subsections (2), (3) and (4) also apply.

NOTE:
Language in **blue bold underline** is new to be added.
Language in ~~red strikethrough~~ is existing to be omitted.

818-035-0020
Authorization to Practice
(1) A dental hygienist may practice dental hygiene in the places specified by ORS 680.150 under general supervision upon authorization of a supervising dentist.
(2) A dentist who authorizes a dental hygienist to practice dental hygiene on a limited access patient must review the hygienist's findings.
(3) A supervising dentist, without first examining a new patient, may authorize a dental hygienist:
(a) To take a health history from a patient;
(b) To take dental radiographs;
(c) To perform periodontal probings and record findings;
(d) To gather data regarding the patient; and
(e) To diagnose, treatment plan and provide dental hygiene services.
(4) When hygiene services are provided pursuant to subsection (3), the supervising dentist need not be on the premises when the services are provided.
(5) When hygiene services are provided pursuant to subsection (3), the patient must be scheduled to be examined by the supervising dentist within fifteen business days following the day the hygiene services are provided.
(6) If a new patient has not been examined by the supervising dentist subsequent to receiving dental hygiene services pursuant to subsection (3), no further dental hygiene services may be provided until an examination is done by the supervising dentist.

818-035-0025
Prohibitions
A dental hygienist may not:
(1) Diagnose and treatment plan other than for dental hygiene services;
(2) Cut hard or soft tissue with the exception of root planing;
(3) Extract any tooth;
(4) Fit or adjust any correctional or prosthetic appliance except as provided by OAR 818-035-0030(1)(h);
(5) Prescribe, administer or dispense any drugs except as provided by OAR 818-035-0030, **OAR** 818-035-0040, **OAR** 818-026-0060(~~11~~ **12**)**, OAR 818-026-0065(12)** and 818-026-0070(~~11~~ **12**);
(6) Place, condense, carve or cement permanent restorations except as provided in OAR 818-035-0072, or operatively prepare teeth;
(7) Irrigate or medicate canals; try in cones, or ream, file or fill canals;
(8) Use the behavior management techniques of Hand Over Mouth (HOM) or Hand Over Mouth Airway Restriction (HOMAR) on any patient.
(9) Place or remove healing caps or healing abutments, except under direct supervision.
(10) Place implant impression copings, except under direct supervision.

818-042-0040
Prohibited Acts
No licensee may authorize any dental assistant to perform the following acts:
(1) Diagnose or plan treatment.
(2) Cut hard or soft tissue.
(3) Any Expanded Function duty (OAR 818-042-0070 and OAR 818-042-0090) or Expanded Orthodontic Function duty (OAR 818-042-0100) or Restorative Functions (OAR 818-042-0095 or Expanded Preventive Duty **(**OAR 818-042-0113 and OAR 818-042-0114**)** or Expanded Function Anesthesia (OAR 818-042-0115) without holding the appropriate certification.
(4) Correct or attempt to correct the malposition or malocclusion of teeth except as provided by OAR 818-042-0100.
(5) Adjust or attempt to adjust any orthodontic wire, fixed or removable appliance or other structure while it is in the patient's mouth.
(6) Administer any drug except fluoride, topical anesthetic, desensitizing agents, over the counter medications per package instructions or drugs administered pursuant to OAR 818-026-0050(5)(a), OAR 818-026-0060(~~11~~**12**), OAR 818-026-0065(~~11~~**12**), OAR 818-026-0070(~~11~~**12**) and as provided in OAR 818-042-0070, OAR 818-042-0090 and OAR 818-042-0115.
(7) Prescribe any drug.
(8) Place periodontal packs.
(9) Start nitrous oxide.
(10) Remove stains or deposits except as provided in OAR 818-042-0070.
(11) Use ultrasonic equipment intra-orally except as provided in OAR 818-042-0100.
(12) Use a high-speed handpiece or any device that is operated by a high-speed handpiece intra-orally except as provided in OAR 818-042-0095, and only for the purpose of adjusting occlusion, contouring, and polishing restorations on the tooth or teeth that are being restored.
(13) Use lasers, except laser-curing lights.
(14) Use air abrasion or air polishing.
(15) Remove teeth or parts of tooth structure.
(16) Cement or bond any fixed prosthesis or orthodontic appliance including bands, brackets, retainers, tooth moving devices, or orthopedic appliances except as provided in OAR 818-042-0100.
(17) Condense and carve permanent restorative material except as provided in OAR 818-042-0095.
(18) Place any type of retraction material subgingivally except as provided in OAR 818-042-0090.
(19) Apply denture relines except as provided in OAR 818-042-0090(2).
(20) Expose radiographs without holding a current Certificate of Radiologic Proficiency issued by the Board (OAR 818-042-0050 and OAR 818-042-0060) except while taking a course of instruction approved by the Oregon Health Authority, Oregon Public Health Division, Office of Environmental Public Health, Radiation Protection Services, or the Oregon Board of Dentistry.
(21) Use the behavior management techniques known as Hand Over Mouth (HOM) or Hand Over Mouth Airway Restriction (HOMAR) on any patient.
(22) Perform periodontal probing.
(23) Place or remove healing caps or healing abutments, except under direct supervision.
(24) Place implant impression copings, except under direct supervision.
(25) Any act in violation of Board statute or rules.

818-042-0080
Certification — Expanded Function Dental Assistant (EFDA)
The Board may certify a dental assistant as an expanded function assistant:
(1) By credential in accordance with OAR 818-042-0120, or
(2) If the assistant submits a completed application, pays the fee and provides evidence of;
(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the Oregon Basic, Infection Control or Certified Dental Assisting (CDA) examination, and the Expanded Function Dental Assistant examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by a**n Oregon** licensed dentist that the applicant has successfully polished six (6) amalgam or composite surfaces, removed supra-gingival excess cement from four (4) crowns and/or fixed partial dentures (bridges) with hand instruments; placed temporary restorative material in three (3) teeth; preliminarily fitted four (4) crowns to check contacts or to adjust occlusion outside the mouth; removed four (4) temporary crowns for final cementation and cleaned teeth for final cementation; fabricated four (4) temporary crowns and/or fixed partial dentures (bridges) and temporarily cemented the crowns and/or fixed partial dentures (bridges); polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis in six (6) patients; placed matrix bands on four (4) teeth prepared for Class II restorations. **The dental assistant must submit within six months' certification by a licensed dentist that the dental assistant is proficient to perform all the expanded function duties in subsection (b). If no expanded function certificate is issued within the six months, the dental assistant is no longer able to continue to perform expanded function duties until EFDA certification is achieved.**

818-042-0110
Certification — Expanded Function Orthodontic Dental Assistant (EFODA)
The Board may certify a dental assistant as an expanded function orthodontic assistant:
(1) By credential in accordance with OAR 818-042-0120, or
(2) Completion of an application, payment of fee and satisfactory evidence of;
(a) Completion of a course of instruction in a program in dental assisting accredited by the American Dental Association Commission on Dental Accreditation; or
(b) Passage of the Oregon Basic, Infection Control, Certified Dental Assistant (CDA) or Certified Orthodontic Assistant (COA) examination, and Expanded Function Orthodontic Assistant examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by a licensed dentist that the applicant has successfully placed and ligated orthodontic wires on ten (10) patients and removed bands/brackets and remaining adhesive using an ultrasonic, hand scaler or a slow speed handpiece from teeth on four (4) patients. **The dental assistant must submit within six months' certification by a licensed dentist that the dental assistant is proficient to perform all the expanded function orthodontic duties in subsection (b). If no expanded function certificate is issued within the six months, the dental assistant is no longer able to continue to perform expanded function orthodontic duties until EFODA certification is achieved.**

818-042-0113
Certification — Expanded Function Preventive Dental Assistants (EFPDA)
The Board may certify a dental assistant as an expanded function preventive dental assistant:
(1) By credential in accordance with OAR 818-042-0120, or
(2) If the assistant submits a completed application, pays the fee and provides evidence of;
(a) Certification of Radiologic Proficiency (OAR 818-042-0060); and satisfactory completion of a course of instruction in a program accredited by the Commission on Dental Accreditation of the American Dental Association; or
(b) Certification of Radiologic Proficiency (OAR 818-042-0060); and passage of the Oregon Basic or Infection Control examination, and Certified Preventive Functions Dental Assistant (CPFDA) examination, or the Expanded Function Dental Assistant (EFDA) examination, or the Coronal Polish (CP) examination, or equivalent successor examinations, administered by the Dental Assisting National Board, Inc. (DANB), or any other testing entity authorized by the Board; and certification by an Oregon licensed dentist that the applicant has successfully polished the coronal surfaces of teeth with a brush or rubber cup as part of oral prophylaxis to remove stains on six **(6)** patients. **The dental assistant must submit within six months' certification by a licensed dentist that the dental assistant is proficient to perform all the expanded function preventive duties in subsection (b). If no expanded function preventive certificate is issued within the six months, the dental assistant is no longer able to continue to perform expanded function preventive duties until EFPDA certification is achieved.**

AMERICAN ACADEMY OF DENTAL SLEEP MEDICINE®

January 10, 2020

Amy Fine, DMD
President, Oregon Board of Dentistry
1500 SW 1st Ave., Ste. # 770
Portland, OR 97201

Dear Dr. Fine:

On behalf of the American Academy of Dental Sleep Medicine, I am requesting clarification on the scope of practice in Oregon 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: Stephen Prisby - Executive Director, Oregon Board of Dentistry

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

SPECIAL ARTICLES

http://dx.doi.org/10.15331/jdsm.6920

Policy Statement on a Dentist's Role in Treating Sleep-Related Breathing Disorders

Nancy Addy, DDS[1]; Kathleen Bennett, DDS[2]; Alan Blanton, DDS[3]; Leslie Dort, DDS[4]; Mitchell Levine, DMD[5]; Kevin Postol, DDS[6]; Thomas Schell, DMD[7]; David Schwartz, DDS[8]; Rose Sheats, DMD[9]; Harold Smith, DDS[10]; for the American Academy of Dental Sleep Medicine Board of Directors

[1]Snoring and Sleep Apnea Dental Treatment Center, Leawood, Kansas; [2]Associated with UC Health Sleep Medicine Fellowship Program, Cincinnati, Ohio; [3]Center for Dental Sleep Medicine and Orofacial Pain, University of Tennessee Health Science Center, Memphis, Tennessee; [4]University of Calgary, Calgary, Alberta, Canada; [5]Jacksonville Center for Snoring and Sleep Apnea, Jacksonville, Florida; [6]Family and Cosmetic Dentistry, Ballwin, Missouri; [7]Schellnoble Dentistry, Lebanon, New Hampshire; [8]The Center for Sleep Medicine, Skokie, Illinois; [9]Chapel Hill, North Carolina; [10]Dental Sleep Medicine of Indiana, Indianapolis, Indiana

The American Academy of Dental Sleep Medicine (AADSM) is the only non-profit national professional society dedicated exclusively to the practice of dental sleep medicine and firmly believes that by screening and providing oral appliance therapy, dentists, with appropriate training and in collaboration with physicians, help reduce the number of undiagnosed and untreated patients with sleep-disordered breathing, which includes snoring and obstructive sleep apnea.

It is the position of the AADSM that:

- Dentists play an integral role in reducing the public health burden of undiagnosed and untreated sleep-related breathing disorders.
- Dentists should screen patients for sleep-disordered breathing with questionnaires and by evaluating the airway.
- Physicians are responsible for diagnosing sleep-disordered breathing and primary snoring, as well as prescribing the most appropriate or acceptable treatment options.
- Education in dental sleep medicine is required in order for dentists to provide safe, quality care to patients using oral appliance therapy for sleep-related breathing disorders. At minimum, dentists should meet the educational requirements defined by the AADSM to be a "Qualified Dentist"in dental sleep medicine.[1]
- 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.
- Following the fitting and initial titration of an oral appliance by a "Qualified Dentist," the patient should always be referred back to the physician. Physicians should confirm the treatment efficacy of oral appliance therapy in a timely manner.
- Dentists need to provide timely, appropriate and ongoing follow-up care to manage dental-related side effects of oral appliance therapy.
- Dentists, in close collaboration with physicians, are an integral component to successfully managing sleep-related breathing disorders with oral appliance therapy.

Sleep-related breathing disorders impact a significant portion of the population. It is estimated that 23.5 million of United States adults have undiagnosed or untreated obstructive sleep apnea—costing billions[2]; increasing the risk of health complications such as hypertension, congestive heart failure, atrial fibrillation, coronary artery disease, stroke and type 2 diabetes[3]; in addition to reducing the quality of life for a significant portion of the population.

It is imperative that dentists receive postgraduate training to be able to provide and manage oral appliance therapy and its side effects. Inappropriately chosen and monitored oral appliance therapy by an inadequately trained dentist exposes patients to potentially life-threatening outcomes and dentists to potentially serious medicolegal liability. The AADSM recommends that dentists have at minimum: a valid state dental license, proof of liability coverage, and at least 25 hours of recognized continuing education in dental sleep medicine provided by a non-profit organization focused on dental sleep medicine or accredited dental school within the last two years in order to provide oral appliance therapy to patients with sleep-disordered breathing.[1] The AADSM encourages all dentists providing oral appliance therapy to become "Qualified Dentists" and subsequently Diplomates of the American Board of Dental Sleep Medicine.

Dentists play an integral role in screening patients for sleep-related breathing disorders and referring patients to a physician for diagnosis. When oral appliance therapy is prescribed by a physician, qualified dentists provide custom-made, adjustable oral appliances, in addition to providing diligent ongoing follow-up. Dentists who are not properly trained in oral appliance therapy may provide ineffective treatment and follow-up care, potentially reducing referrals from physicians to dentists and the potential role that dentistry plays in lessening the burden of snoring and sleep apnea on public health.

CITATION

Addy N, Bennett K, Blanton A, Dort L, Levine M, Postol K, Schell T, Schwartz D, Sheats R, Smith H. Policy statement on a dentist's role in treating sleep-related breathing disorders. *Journal of Dental Sleep Medicine*. 2018;5(1):25–26.

REFERENCES

1. Ramar K, Dort LC, Katz SG, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. *J Clin Sleep Med*. 2015;11(7):773–827.
2. Frost & Sullivan; American Academy of Sleep Medicine. Hidden health crisis costing America billions: underdiagnosing and undertreating obstructive sleep apnea draining health care system. American Academy of Sleep Medicine website. https://aasm.org/advocacy/initiatives/economic-impact-obstructive-sleep-apnea/. Published August 8, 2016. Accessed December 11, 2017.
3. Punjabi NM. The epidemiology of adult obstructive sleep apnea. *Proc Am Thorac Soc*. 2008;5(2):136–143.

SUBMISSION & CORRESPONDENCE INFORMATION

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Submitted in final revised form December 11, 2017
Accepted for publication December 11, 2017
Address correspondence to: American Academy of Dental Sleep Medicine National Office, 2510 North Frontage Road, Darien, IL 60561; Tel: (630) 737-9705; Email: info@aadsm.org

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.

(This model is not intended for Medicare patients. Prior to implementing this model, verify that the state dental practice act allows dentists to order HSATs.)

Physician Responsibility

Dentist Responsibility

Does the patient have signs and symptoms that indicate a risk for OSA?

Yes

No

Both physician and dentist continue to screen at future visits.

Based upon mutually agreed upon criteria, is the patient a candidate for HSAT?

Yes

No

Order HSAT for patient and refer to sleep physician for diagnosis.

Refer to sleep physician to determine appropriate testing for diagnosing OSA. Does the patient have OSA?

No

Yes

Physician = Family Physician
Dentist = Qualified Dentist

HSAT = Home sleep apnea test
OAT = Oral appliance therapy
OSA = Obstructive sleep apnea

Provide physician with pertinent patient information and interpreted HSAT data to aide in the treatment. Data or results should not be provided to patients prior to physician approval. Dentist must document transfer of pertinent patient information and interpreted HSAT data to physician in patient record. Does the patient have OSA?

No

Yes

OSA diagnosed and appropriate therapy prescribed. If OAT is prescribed, dentist must document OAT prescription from physician in patient record.

Dentist provides OAT.

Dentist determines optimal position for oral appliance, based upon mutually agreed upon criteria.

Patient referred back to physician to determine treatment efficacy.

Dentist manages long-term follow-up of patient and provides updates to physician.

Page 101 of 183

Attachment #30

SPECIAL ARTICLE

http://dx.doi.org/10.15331/jdsm.7030

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]

[1]University of Tennessee, College of Dentistry, Memphis, TN; Division of Dental Sleep Medicine and Orofacial Pain, College of Dentistry, University of Tennessee, Memphis, TN [2]Associated with UC Health Sleep Medicine Fellowship Program, Cincinnati, OH; [3]Center for Dental Sleep Medicine, Lancaster, PA; [4]Sleep Disordered Dentistry, Ballwin, Missouri; [5]The Center for Sleep Medicine, Skokie, Illinois

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 p in the treatment and ongoing management of OSA and snoring. The guideline stipulates that a dentist should have at least one of the following: (1) diplomate certification in dental sleep medicine by a non-profit organization; (2) designation as the dental director of a dental sleep medicine facility accredited by a nonprofit organization; or (3) obtain the designation of "qualified dentist." The qualified dentist is encouraged to continue their education in dental sleep medicine and seek either diplomate and/or dental director status. Throughout this paper, our use of the designation "qualified" includes the diplomate certified dentist, the dental director of an accredited facility, as well as the dentist who has completed the qualified dentist requirements established in the 2015 clinical practice guideline.

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

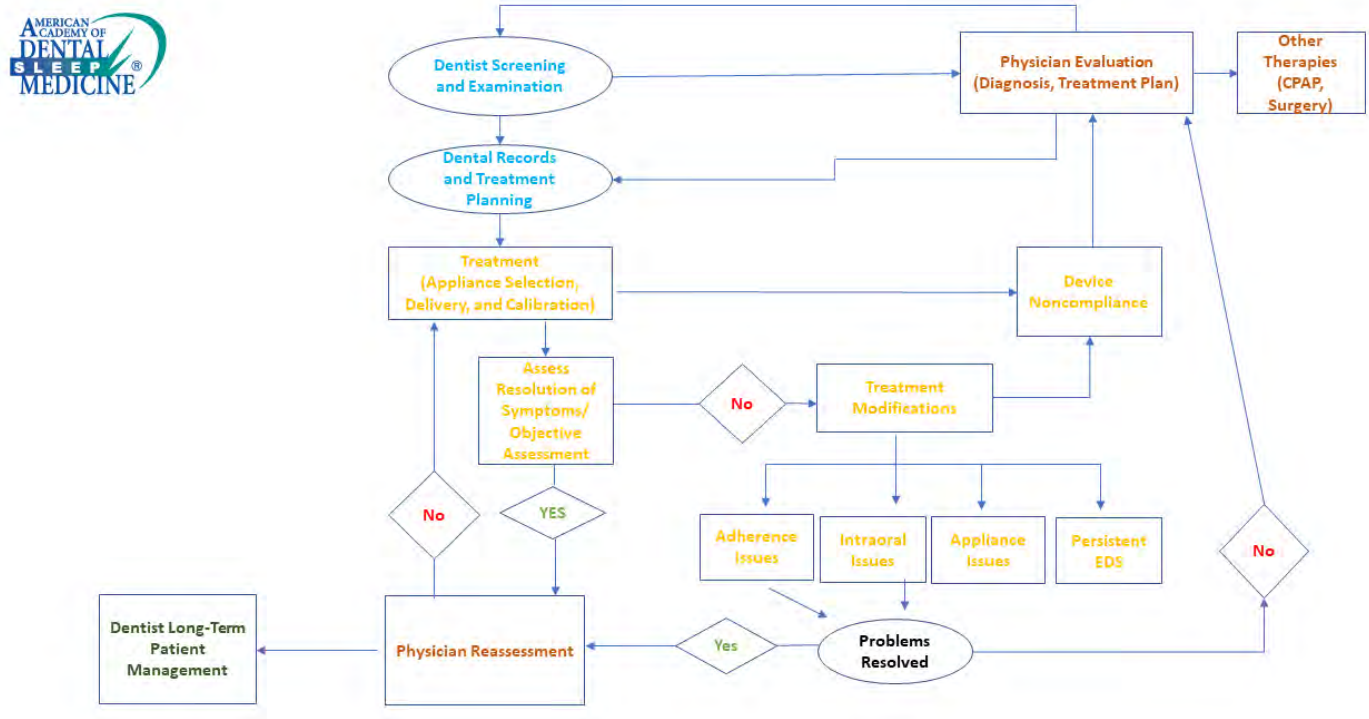
manage the SRBD through evidence-based practices.[8]

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

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

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

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



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

SCREENING

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

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

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

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

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

PHYSICAL EXAMINATION

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

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

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

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

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

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

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

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

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

PATIENT EDUCATION

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

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

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

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

DIAGNOSIS

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

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

TREATMENT OPTIONS

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

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

An oral appliance is prescribed by the physician to

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

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

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

OAT INITIATION

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

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

OA SELECTION

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

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

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

OA FABRICATION

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

OA DELIVERY

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

The qualified dentist should provide appropriate

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

OA CALIBRATION

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

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

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

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

LONG-TERM FOLLOW-UP/MANAGEMENT

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

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

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

OA REPLACEMENT

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

For a patient in whom there was a previous diagnosis

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

SIDE EFFECTS

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

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

DISCUSSION

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

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

SPECIAL ARTICLES

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

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

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

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

Recommendations:

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

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

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

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SUMMARY

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

Methods

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

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

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

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

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

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

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

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

Results

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

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

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

Summary of Recommendations

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

Quality of Evidence: High

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

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

Quality of Evidence: Low

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

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

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

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

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

Quality of Evidence: Moderate

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

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

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

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

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

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

Quality of Evidence: Low

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

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

Quality of Evidence: Low

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

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

Quality of Evidence: Low

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

1.0 INTRODUCTION

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

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

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

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

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

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

2.0 BACKGROUND

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

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

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

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

Table 1—PICO Questions.

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

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

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

3.0 METHODS

3.1 Expert Task Force

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

3.2 PICO Questions

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

3.3 Literature Search

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

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

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

3.4 Meta-Analysis

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

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

3.5 Quality of Evidence

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

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

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

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

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

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

Table 4—AASM strengths of recommendations.

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

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

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

3.6 Strength of Recommendations

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

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

Table 5—Summary of recommendation statements.

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

3.7 Approval and Interpretation of Recommendations

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

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

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

4.0 RECOMMENDATIONS

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

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

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

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

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

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

4.1 Primary Snoring

4.1.1 Snoring Indices

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

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

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

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

4.1.2 Quality of Life

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

4.1.3 OAs vs. CPAP

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

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

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

4.2 OSA

4.2.1 Physiologic Sleep Parameters

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

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

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

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

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

4.2.1.1.1 All Appliance Types

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

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

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

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

4.2.1.1.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

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

4.2.1.1.4 OAs vs. CPAP

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

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

4.2.1.2 Oxygen Saturation

4.2.1.2.1 All Appliance Types

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

4.2.1.2.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

4.2.1.2.4 OAs vs. CPAP

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

4.2.1.3 Arousal Index

4.2.1.3.1 All Appliance Types

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

4.2.1.3.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

4.2.1.3.4 OAs vs. CPAP

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

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

4.2.1.4 Oxygen Desaturation Index (ODI)

4.2.1.4.1 All Appliance Types

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

4.2.1.4.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

4.2.1.4.4 OAs vs. CPAP

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

4.2.1.5 Sleep Architecture

4.2.1.5.1 All Appliance Types

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

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

4.2.1.5.2 Custom vs. Non-Custom OAs

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

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

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

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

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

4.2.1.5.4 OAs vs. CPAP

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

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

4.2.1.6 Sleep Efficiency

4.2.1.6.1 All Appliance Types

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

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

4.2.1.6.2 Custom vs. Non-Custom OAs

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

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

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

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

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

4.2.1.6.4 OAs vs. CPAP

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

4.2.2 Daytime sleepiness

4.2.2.1 All Appliance Types

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

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

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

4.2.2.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

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

4.2.2.4 OAs vs. CPAP

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

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

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

4.2.3 Quality of Life

4.2.3.1 All Appliance Types

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

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

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

4.2.3.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

4.2.3.4 OAs vs. CPAP

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

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

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

4.2.4 Hypertension

4.2.4.1 All Appliance Types

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

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

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

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

4.2.4.2 Custom vs. Non-Custom OAs

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

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

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

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

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

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

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

4.2.4.4 OAs vs. CPAP

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

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

4.2.5 Adherence

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

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

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

4.2.6 Assessment of Side Effects

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4.2.7 Long-term Management

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

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

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

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

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

5.0 FUTURE DIRECTIONS

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

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

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

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

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

NOTES

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APPENDIX

Meta-Analyses and GRADE Summary of Findings Reports

Figure 1—Custom, Non-Titratable (C-NT) OAs for Mild to Moderate Adult OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Randerath 2002	10.5	7.5	20	17.5	7.7	20	34.8%	-7.00 [-11.71, -2.29]
Rose 2002	5.5	3.3	20	16.2	4.6	20	65.2%	-10.70 [-13.18, -8.22]
Total (95% CI)			**40**			**40**	**100.0%**	**-9.41 [-12.87, -5.96]**

Heterogeneity: Tau² = 3.16; Chi² = 1.86, df = 1 (P = 0.17); I² = 46%
Test for overall effect: Z = 5.34 (P < 0.00001)

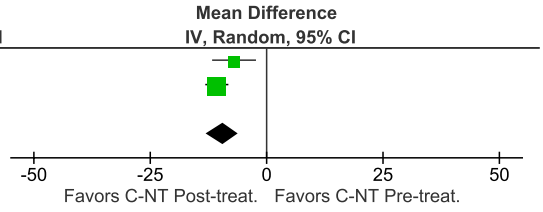


Figure 2—Custom, Non-Titratable OAs for Moderate to Severe Adult OSA (AHI/RDI/REI).

Study or Subgroup	C-NT post-treatment Mean	SD	Total	C-NT pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Bloch 2000	7.9	1.6	24	22.6	3.1	24	51.7%	-14.70 [-16.10, -13.30]
Zhou 2012	6.6	2.3	16	26.4	4.1	16	48.3%	-19.80 [-22.10, -17.50]
Total (95% CI)			**40**			**40**	**100.0%**	**-17.16 [-22.16, -12.17]**

Heterogeneity: Tau² = 12.06; Chi² = 13.77, df = 1 (P = 0.0002); I² = 93%
Test for overall effect: Z = 6.73 (P < 0.00001)

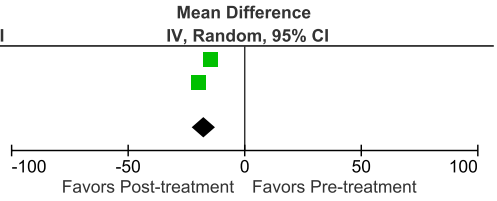


Figure 3—Custom, Titratable (C-T) OAs for Mild to Moderate Adult OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Gauthier 2009	6.5	1.3	16	10	1.2	16	28.8%	-3.50 [-4.37, -2.63]
Gauthier 2009	4.7	0.9	16	10	1.2	16	29.8%	-5.30 [-6.03, -4.57]
Gauthier 2011	4.5	0.7	14	10.4	1.3	14	29.5%	-5.90 [-6.67, -5.13]
Rose 2002	7.4	5.3	18	16	4.4	18	11.8%	-8.60 [-11.78, -5.42]
Total (95% CI)			**64**			**64**	**100.0%**	**-5.35 [-6.71, -3.98]**

Heterogeneity: Tau² = 1.49; Chi² = 22.12, df = 3 (P < 0.0001); I² = 86%
Test for overall effect: Z = 7.66 (P < 0.00001)

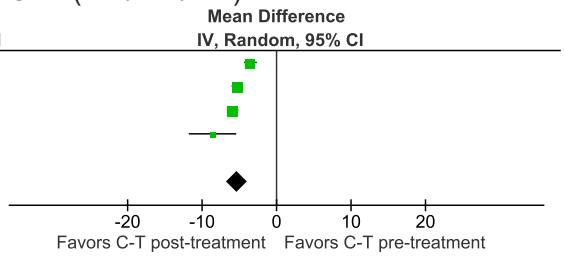


Figure 4—Custom, Titratable OAs for Moderate to Severe Adult OSA (AHI/RDI/REI).

Study or Subgroup	C-T post-treatment Mean	SD	Total	C-T pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Bloch 2000	8.7	1.5	24	22.6	3.1	24	37.4%	-13.90 [-15.28, -12.52]
Ghazal 2009	8.7	11.6	47	23	18.2	47	10.6%	-14.30 [-20.47, -8.13]
Ghazal 2009	7	13.6	48	22	21.3	48	8.4%	-15.00 [-22.15, -7.85]
Lawton 2005	34	13.5	15	45.5	9.8	15	6.4%	-11.50 [-19.94, -3.06]
Lawton 2005	24.5	11.2	16	45.5	9.8	16	8.2%	-21.00 [-28.29, -13.71]
Zhou 2012	8.9	2.9	16	26.4	4.1	16	29.0%	-17.50 [-19.96, -15.04]
Total (95% CI)			**166**			**166**	**100.0%**	**-15.51 [-17.82, -13.19]**

Heterogeneity: Tau² = 3.25; Chi² = 9.65, df = 5 (P = 0.09); I² = 48%
Test for overall effect: Z = 13.12 (P < 0.00001)

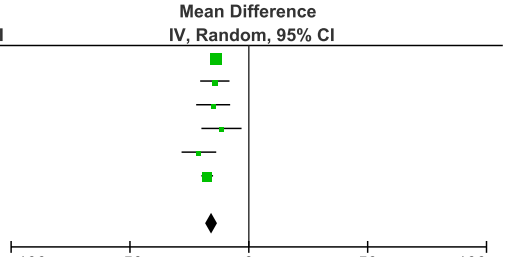


Figure 5—CPAP for Mild to Moderate Adult OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Lam 2007	2.8	1.1	34	23.8	1.9	34	53.6%	-21.00 [-21.74, -20.26]
Randerath 2002	3.2	2.9	20	17.5	7.7	20	46.4%	-14.30 [-17.91, -10.69]
Total (95% CI)			**54**			**54**	**100.0%**	**-17.89 [-24.44, -11.34]**

Heterogeneity: Tau² = 20.68; Chi² = 12.73, df = 1 (P = 0.0004); I² = 92%
Test for overall effect: Z = 5.35 (P < 0.00001)

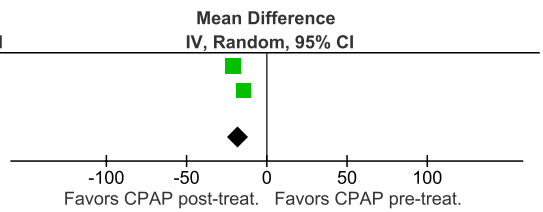


Figure 6—CPAP for Severe Adult OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Trzepizur 2009	2	5.2	12	40	13.3	12	100.0%	-38.00 [-46.08, -29.92]
Total (95% CI)			**12**			**12**	**100.0%**	**-38.00 [-46.08, -29.92]**

Heterogeneity: Not applicable
Test for overall effect: Z = 9.22 (P < 0.00001)

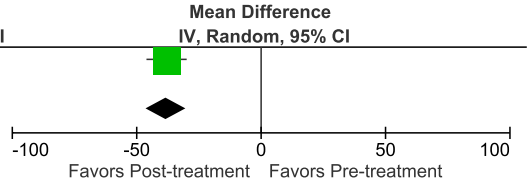


Figure 7—OAs for Primary Snoring (Snoring Loudness).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Cooke 2006	6	2	22	8.5	1	22	46.1%	-2.50 [-3.43, -1.57]
Johnston 2001	2.5	0.97	25	6.5	0.59	25	53.9%	-4.00 [-4.45, -3.55]
Total (95% CI)			**47**			**47**	**100.0%**	**-3.31 [-4.77, -1.84]**

Heterogeneity: Tau² = 0.99; Chi² = 8.07, df = 1 (P = 0.005); I² = 88%
Test for overall effect: Z = 4.42 (P < 0.00001)

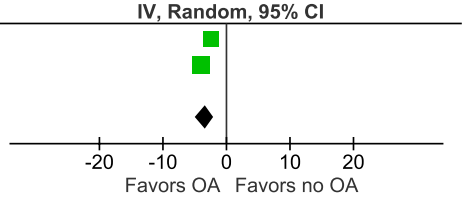


Figure 8—Summary of Findings (Primary Snoring, Snoring Indices).

Oral Appliances (OAs) for Primary Snoring

Patient or population: Patients with Primary Snoring
Intervention: OAs

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk	Corresponding risk	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Control	**OAs**				
Snoring (snores/h)		The mean snoring (snores/h) in the intervention groups was **278 lower** (375.3 to 180.7 lower)		11 (1 study)	⊕⊕⊕⊕ **high**	
Snoring (nights/wk)		The mean snoring (nights/wk) in the intervention groups was **1.9 lower** (1.32 to 2.48 lower)		25 (1 study)	⊕⊕⊕⊕ **high**	
Snoring loudness (1-10 VAS)		The mean snoring loudness (1-10 VAS) in the intervention groups was **3.31 lower** (4.77 to 1.84 lower)		47 (2 studies)	⊕⊕⊕⊕ **high**	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

Figure 9—OAs for OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	5.8	14.9	20	22.1	10.8	20	1.9%	-16.30 [-24.37, -8.23]
Aarab 2011b	6.4	15.2	15	21.4	11	21	1.7%	-15.00 [-24.02, -5.98]
Barnes 2004	14	1.1	85	21.3	1.3	85	3.3%	-7.30 [-7.66, -6.94]
Blanco 2005	9.6	12.1	8	33.8	14.7	8	1.1%	-24.20 [-37.39, -11.01]
Bloch 2000	8.7	1.5	24	22.6	3.1	24	3.2%	-13.90 [-15.28, -12.52]
Bloch 2000	7.9	1.6	24	22.6	3.1	24	3.2%	-14.70 [-16.10, -13.30]
Campbell 2009	14.3	9.8	16	25.4	7.4	16	2.3%	-11.10 [-17.12, -5.08]
Campbell 2009	11.7	10	12	26.5	12	12	1.7%	-14.80 [-23.64, -5.96]
Cunali 2011	9	7	29	16	8	29	2.8%	-7.00 [-10.87, -3.13]
Deane 2009	12	9	22	27	17.2	22	1.8%	-15.00 [-23.11, -6.89]
Engleman 2002	15	16	48	31	26	48	1.7%	-16.00 [-24.64, -7.36]
Ferguson 1996	9.7	7.3	19	19.7	13.8	19	2.1%	-10.00 [-17.02, -2.98]
Ferguson 1997	14.2	14.7	20	25.3	15	20	1.6%	-11.10 [-20.30, -1.90]
Gagnadoux 2009	6	8.2	56	34.2	13	56	2.8%	-28.20 [-32.23, -24.17]
Gauthier 2009	4.7	0.9	16	10	1.2	16	3.3%	-5.30 [-6.03, -4.57]
Gauthier 2009	6.5	1.3	16	10	1.2	16	3.3%	-3.50 [-4.37, -2.63]
Gauthier 2011	4.5	0.7	14	10.4	1.3	14	3.3%	-5.90 [-6.67, -5.13]
Ghazal 2009	5.3	15.6	48	21	24.4	48	1.8%	-15.70 [-23.89, -7.51]
Ghazal 2009	8.7	11.6	47	23	18.2	47	2.3%	-14.30 [-20.47, -8.13]
Gotsopoulos 2002	12	2	73	27	2	73	3.3%	-15.00 [-15.65, -14.35]
Gotsopoulos 2004	12	2	67	27	15	67	2.9%	-15.00 [-18.62, -11.38]
Hoekema 2007a	3.2	6.5	20	20.4	16	20	2.0%	-17.20 [-24.77, -9.63]
Hoekema 2007b	5.2	7.2	9	50	59.7	9	0.2%	-44.80 [-84.09, -5.51]
Hoekema 2008a	4	6.9	12	31	9.3	12	2.2%	-27.00 [-33.55, -20.45]
Hoekema 2008b	7.8	14.4	51	39.4	30.8	51	1.6%	-31.60 [-40.93, -22.27]
Johnston 2002	22.9	22.8	20	31.9	21.2	20	1.0%	-9.00 [-22.64, 4.64]
Lawton 2005	34	13.5	15	45.5	9.8	15	1.8%	-11.50 [-19.94, -3.06]
Lawton 2005	24.5	11.2	16	45.5	9.8	16	2.0%	-21.00 [-28.29, -13.71]
Mehta 2001	14	2	28	30	2	28	3.3%	-16.00 [-17.05, -14.95]
Naismith 2005	12.2	12.3	73	26.9	15.4	73	2.7%	-14.70 [-19.22, -10.18]
Phillips 2013	11.1	12.1	126	25.6	12.3	126	3.0%	-14.50 [-17.51, -11.49]
Randerath 2002	13.8	11.1	20	17.5	7.7	20	2.3%	-3.70 [-9.62, 2.22]
Rose 2002	5.5	3.3	20	16.2	4.6	20	3.1%	-10.70 [-13.18, -8.22]
Rose 2002	7.4	5.3	18	16	4.4	18	3.0%	-8.60 [-11.78, -5.42]
Sutherland 2011	12	12.6	39	26.9	17.1	39	2.2%	-14.90 [-21.57, -8.23]
Tan 2002	8	10.9	24	22.2	9.6	24	2.4%	-14.20 [-20.01, -8.39]
Tzepizur 2009	14	8.2	12	40	13.3	12	1.7%	-26.00 [-34.84, -17.16]
Vanderveken 2008	11	9	23	14	12	23	2.3%	-3.00 [-9.13, 3.13]
Vanderveken 2008	6	8	23	14	12	23	2.3%	-8.00 [-13.89, -2.11]
Wilhelmsson 1999	6	1.5	41	18.2	1.2	41	3.3%	-12.20 [-12.79, -11.61]
Zhou 2012	6.6	2.3	16	26.4	4.1	16	3.1%	-19.80 [-22.10, -17.50]
Zhou 2012	9.9	2.9	16	26.4	4.1	16	3.1%	-16.50 [-18.96, -14.04]
Total (95% CI)			**1301**			**1307**	**100.0%**	**-13.59 [-15.25, -11.94]**

Heterogeneity: Tau² = 21.47; Chi² = 1461.67, df = 41 (P < 0.00001); I² = 97%
Test for overall effect: Z = 16.09 (P < 0.00001)

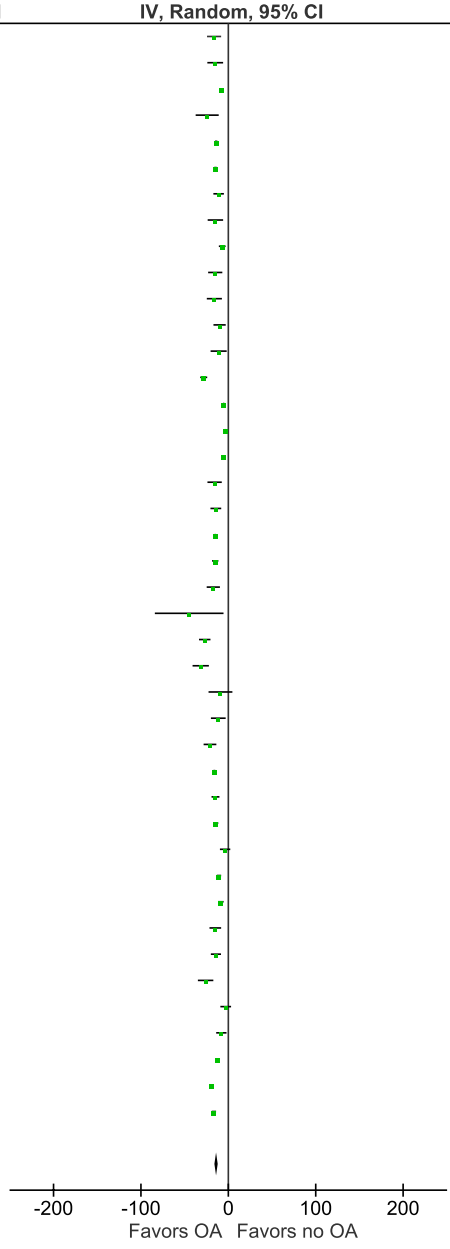


Figure 10—Custom OAs for OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	5.8	14.9	20	22.1	10.8	20	1.9%	-16.30 [-24.37, -8.23]
Aarab 2011b	6.4	15.2	15	21.4	11	21	1.7%	-15.00 [-24.02, -5.98]
Barnes 2004	14	1.1	85	21.3	1.3	85	3.5%	-7.30 [-7.66, -6.94]
Blanco 2005	9.6	12.1	8	33.8	14.7	8	1.1%	-24.20 [-37.39, -11.01]
Bloch 2000	7.9	1.6	24	22.6	3.1	24	3.4%	-14.70 [-16.10, -13.30]
Bloch 2000	8.7	1.5	24	22.6	3.1	24	3.4%	-13.90 [-15.28, -12.52]
Campbell 2009	11.7	10	12	26.5	12	12	1.8%	-14.80 [-23.64, -5.96]
Campbell 2009	14.3	9.8	16	25.4	7.4	16	2.4%	-11.10 [-17.12, -5.08]
Cunali 2011	9	7	29	16	8	29	2.9%	-7.00 [-10.87, -3.13]
Deane 2009	12	9	22	27	17.2	22	1.9%	-15.00 [-23.11, -6.89]
Engleman 2002	15	16	48	31	26	48	1.8%	-16.00 [-24.64, -7.36]
Ferguson 1997	14.2	14.7	20	25.3	15	20	1.7%	-11.10 [-20.30, -1.90]
Gagnadoux 2009	6	8.2	56	34.2	13	56	2.9%	-28.20 [-32.23, -24.17]
Gauthier 2009	4.7	0.9	16	10	1.2	16	3.4%	-5.30 [-6.03, -4.57]
Gauthier 2009	6.5	1.3	16	10	1.2	16	3.4%	-3.50 [-4.37, -2.63]
Gauthier 2011	4.5	0.7	14	10.4	1.3	14	3.4%	-5.90 [-6.67, -5.13]
Ghazal 2009	8.7	11.6	47	23	18.2	47	2.4%	-14.30 [-20.47, -8.13]
Ghazal 2009	5.3	15.6	48	21	24.4	48	1.9%	-15.70 [-23.89, -7.51]
Gotsopoulos 2002	12	2	73	27	2	73	3.4%	-15.00 [-15.65, -14.35]
Gotsopoulos 2004	12	2	67	27	15	67	3.0%	-15.00 [-18.62, -11.38]
Hoekema 2007a	3.2	6.5	20	20.4	16	20	2.0%	-17.20 [-24.77, -9.63]
Hoekema 2007b	5.2	7.2	9	50	59.7	9	0.2%	-44.80 [-84.09, -5.51]
Hoekema 2008a	4	6.9	12	31	9.3	12	2.3%	-27.00 [-33.55, -20.45]
Hoekema 2008b	7.8	14.4	51	39.4	30.8	51	1.7%	-31.60 [-40.93, -22.27]
Johnston 2002	22.9	22.8	20	31.9	21.2	20	1.1%	-9.00 [-22.64, 4.64]
Lawton 2005	34	13.5	15	45.5	9.8	15	1.9%	-11.50 [-19.94, -3.06]
Lawton 2005	24.5	11.2	16	45.5	9.8	16	2.1%	-21.00 [-28.29, -13.71]
Mehta 2001	14	2	28	30	2	28	3.4%	-16.00 [-17.05, -14.95]
Naismith 2005	12.2	12.3	73	26.9	15.4	73	2.8%	-14.70 [-19.22, -10.18]
Phillips 2013	11.1	12.1	126	25.6	12.3	126	3.1%	-14.50 [-17.51, -11.49]
Randerath 2002	13.8	11.1	20	17.5	7.7	20	2.4%	-3.70 [-9.62, 2.22]
Rose 2002	5.5	3.3	20	16.2	4.6	20	3.2%	-10.70 [-13.18, -8.22]
Rose 2002	7.4	5.3	18	16	4.4	18	3.1%	-8.60 [-11.78, -5.42]
Sutherland 2011	12	12.6	39	26.9	17.1	39	2.2%	-14.90 [-21.57, -8.23]
Tan 2002	8	10.9	24	22.2	9.6	24	2.5%	-14.20 [-20.01, -8.39]
Tzepizur 2009	14	8.2	12	40	13.3	12	1.8%	-26.00 [-34.84, -17.16]
Vanderveken 2008	6	8	23	14	1.2	23	3.1%	-8.00 [-11.31, -4.69]
Wilhelmsson 1999	6	1.5	41	18.2	1.2	41	3.4%	-12.20 [-12.79, -11.61]
Zhou 2012	6.6	2.3	16	26.4	4.1	16	3.2%	-19.80 [-22.10, -17.50]
Zhou 2012	9.9	2.9	16	26.4	4.1	16	3.2%	-16.50 [-18.96, -14.04]
Total (95% CI)			**1259**			**1265**	**100.0%**	**-13.89 [-15.57, -12.20]**

Heterogeneity: Tau² = 21.42; Chi² = 1457.86, df = 39 (P < 0.00001); I² = 97%
Test for overall effect: Z = 16.14 (P < 0.00001)

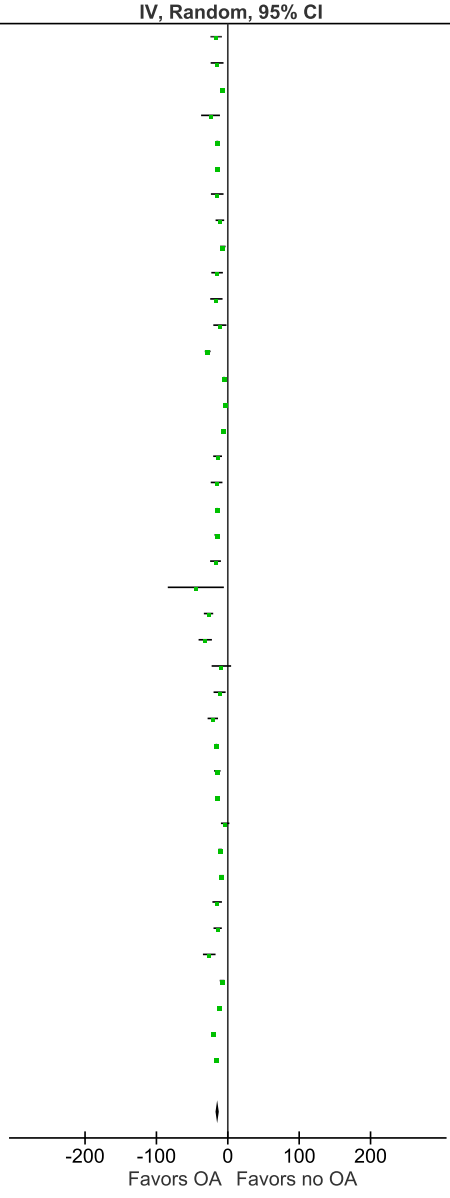


Figure 11—Non-Custom OAs for OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Ferguson 1996	9.7	7.3	19	19.7	13.8	19	46.9%	-10.00 [-17.02, -2.98]
Vanderveken 2008	11	9	23	14	12	23	53.1%	-3.00 [-9.13, 3.13]
Total (95% CI)			**42**			**42**	**100.0%**	**-6.28 [-13.13, 0.56]**

Heterogeneity: Tau² = 13.19; Chi² = 2.17, df = 1 (P = 0.14); I² = 54%
Test for overall effect: Z = 1.80 (P = 0.07)

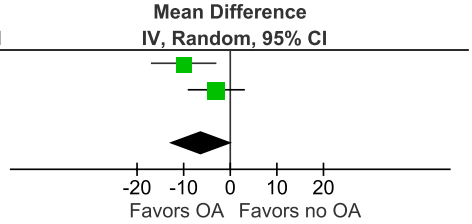


Figure 12—Custom, Titratable OAs for OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	5.8	14.9	20	22.1	10.8	20	2.4%	-16.30 [-24.37, -8.23]
Aarab 2011b	6.4	15.2	15	21.4	11	21	2.2%	-15.00 [-24.02, -5.98]
Barnes 2004	14	1.1	85	21.3	1.3	85	4.2%	-7.30 [-7.66, -6.94]
Bloch 2000	8.7	1.5	24	22.6	3.1	24	4.1%	-13.90 [-15.28, -12.52]
Campbell 2009	14.3	9.8	16	25.4	7.4	16	3.0%	-11.10 [-17.12, -5.08]
Campbell 2009	11.7	10	12	26.5	12	12	2.2%	-14.80 [-23.64, -5.96]
Cunali 2011	9	7	29	16	8	29	3.6%	-7.00 [-10.87, -3.13]
Deane 2009	12	9	22	27	17.2	22	2.4%	-15.00 [-23.11, -6.89]
Ferguson 1997	14.2	14.7	20	25.3	15	20	2.2%	-11.10 [-20.30, -1.90]
Gagnadoux 2009	7.2	8.1	59	34.2	13	59	3.6%	-27.00 [-30.91, -23.09]
Gauthier 2009	6.5	1.3	16	10	1.2	16	4.2%	-3.50 [-4.37, -2.63]
Gauthier 2009	4.7	0.9	16	10	1.2	16	4.2%	-5.30 [-6.03, -4.57]
Gauthier 2011	4.5	0.7	14	10.4	1.3	14	4.2%	-5.90 [-6.67, -5.13]
Ghazal 2009	7.9	15.6	48	22.2	24.4	48	2.4%	-14.30 [-22.49, -6.11]
Ghazal 2009	8.4	11.6	47	21.4	18.2	47	2.9%	-13.00 [-19.17, -6.83]
Gotsopoulos 2002	12	2	73	27	2	73	4.2%	-15.00 [-15.65, -14.35]
Gotsopoulos 2004	12	2	67	27	15	67	3.7%	-15.00 [-18.62, -11.38]
Hoekema 2007a	3.2	6.5	20	20.4	16	20	2.6%	-17.20 [-24.77, -9.63]
Hoekema 2007b	5.2	7.2	9	50	62.4	9	0.2%	-44.80 [-85.84, -3.76]
Hoekema 2008a	4	6.9	12	31	9.3	12	2.8%	-27.00 [-33.55, -20.45]
Hoekema 2008b	7.8	14.4	47	39.4	30.8	51	2.1%	-31.60 [-41.00, -22.20]
Lawton 2005	35	10	15	47	9.6	16	2.7%	-12.00 [-18.91, -5.09]
Lawton 2005	23.5	8.3	16	47	9.6	16	2.9%	-23.50 [-29.72, -17.28]
Mehta 2001	14	2	28	30	2	28	4.1%	-16.00 [-17.05, -14.95]
Naismith 2005	12.2	12.3	73	26.9	15.4	73	3.4%	-14.70 [-19.22, -10.18]
Phillips 2013	11.1	12.1	126	25.6	12.3	126	3.8%	-14.50 [-17.51, -11.49]
Randerath 2002	13.8	11.1	20	17.5	7.7	20	3.0%	-3.70 [-9.62, 2.22]
Rose 2002	5.5	3.3	20	16.2	4.6	20	3.9%	-10.70 [-13.18, -8.22]
Rose 2002	7.4	5.3	18	16	4.4	18	3.8%	-8.60 [-11.78, -5.42]
Sutherland 2011	12	12.6	39	26.9	17.1	39	2.8%	-14.90 [-21.57, -8.23]
Trzepizur 2009	14	8.2	12	40	13.3	12	2.2%	-26.00 [-34.84, -17.16]
Zhou 2012	9.9	2.9	16	26.4	4.1	16	3.9%	-16.50 [-18.96, -14.04]
Total (95% CI)			**1054**			**1065**	**100.0%**	**-13.80 [-15.74, -11.87]**

Heterogeneity: Tau² = 23.22; Chi² = 1207.31, df = 31 (P < 0.00001); I² = 97%
Test for overall effect: Z = 13.98 (P < 0.00001)

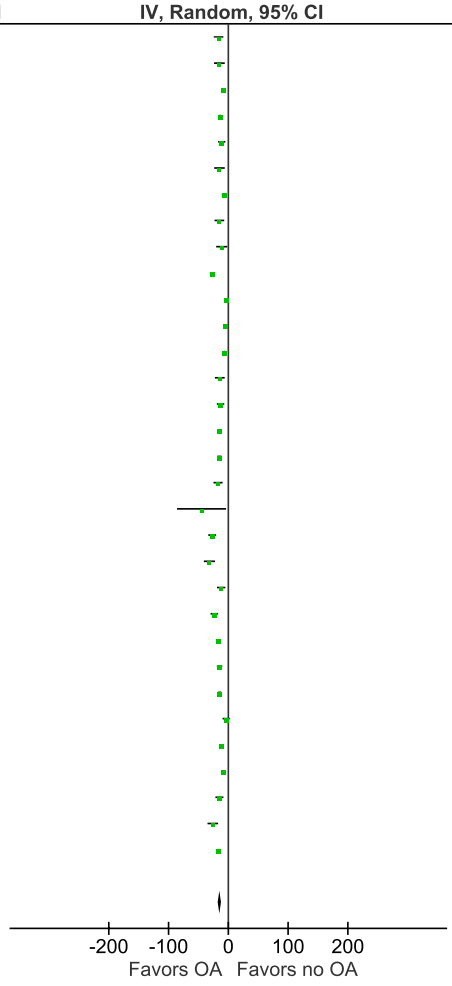


Figure 13—Custom, Non-Titratable OAs for OSA (AHI/RDI/REI).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Blanco 2005	9.6	12.1	8	33.8	14.7	8	3.8%	-24.20 [-37.39, -11.01]
Bloch 2000	7.9	1.6	24	22.6	3.1	24	34.5%	-14.70 [-16.10, -13.30]
Engleman 2002	15	16	48	31	26	48	7.8%	-16.00 [-24.64, -7.36]
Johnston 2002	22.9	22.8	20	31.9	21.2	20	3.6%	-9.00 [-22.64, 4.64]
Vanderveken 2008	11	9	23	14	12	23	12.9%	-3.00 [-9.13, 3.13]
Wilhelmsson 1999	6	1.5	41	18.2	1.2	41	37.3%	-12.20 [-12.79, -11.61]
Total (95% CI)			**164**			**164**	**100.0%**	**-12.51 [-15.23, -9.80]**

Heterogeneity: Tau² = 5.06; Chi² = 23.66, df = 5 (P = 0.0003); I² = 79%
Test for overall effect: Z = 9.03 (P < 0.00001)

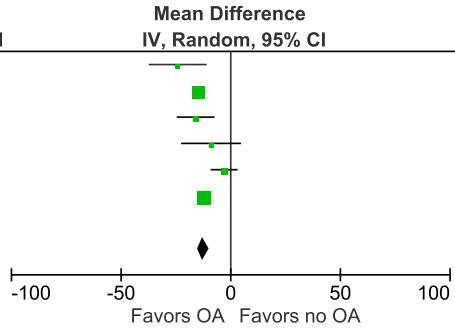


Figure 14—OAs vs. CPAP for OSA (AHI/RDI/REI).

Study or Subgroup	OA Mean	OA SD	OA Total	CPAP Mean	CPAP SD	CPAP Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	5.8	14.9	20	1.4	13.1	18	3.2%	4.40 [-4.50, 13.30]
Aarab 2011b	6.4	15.2	15	0	12.4	13	2.6%	6.40 [-3.83, 16.63]
Barnes 2004	14	1.1	85	4.8	0.5	85	11.0%	9.20 [8.94, 9.46]
Engleman 2002	15	16	48	8	6	48	6.4%	7.00 [2.17, 11.83]
Ferguson 1996	14.2	14.7	20	4	2.2	20	4.8%	10.20 [3.69, 16.71]
Ferguson 1997	9.7	7.3	19	3.6	1.7	20	8.2%	6.10 [2.73, 9.47]
Gagnadoux 2009	6	8.2	28	2	5.2	29	7.9%	4.00 [0.42, 7.58]
Hoekema 2007a	3.2	6.5	27	1.6	3.1	20	8.9%	1.60 [-1.20, 4.40]
Hoekema 2007b	5.2	7.2	9	0	3.6	10	6.0%	5.20 [-0.01, 10.41]
Hoekema 2008a	4	6.9	12	2.6	4.7	13	6.6%	1.40 [-3.27, 6.07]
Hoekema 2008b	7.8	14.4	47	2.4	4.2	47	7.1%	5.40 [1.11, 9.69]
Phillips 2013	11.1	12.1	108	4.5	6.6	108	9.1%	6.60 [4.00, 9.20]
Randerath 2002	13.8	11.1	20	3.2	2.9	20	6.2%	10.60 [5.57, 15.63]
Tan 2002	8	10.9	21	3.1	2.8	21	6.5%	4.90 [0.09, 9.71]
Tzepizur 2009	14	8.2	12	2	5.2	9	5.5%	12.00 [6.25, 17.75]
Total (95% CI)			**491**			**481**	**100.0%**	**6.24 [4.34, 8.14]**

Heterogeneity: Tau² = 8.56; Chi² = 63.94, df = 14 (P < 0.00001); I² = 78%
Test for overall effect: Z = 6.43 (P < 0.00001)

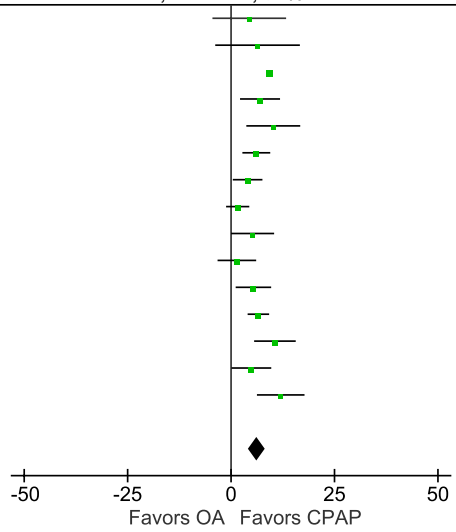


Figure 15—OAs for OSA (Minimum Oxygen Saturation).

Study or Subgroup	Post-treatment Mean	Post-treatment SD	Post-treatment Total	Pre-treatment Mean	Pre-treatment SD	Pre-treatment Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	87.8	0.4	85	86.7	0.6	85	6.8%	1.10 [0.95, 1.25]
Cunali 2011	87	5	29	86	4	29	3.7%	1.00 [-1.33, 3.33]
Deane 2009	87	5	22	84	7	22	2.3%	3.00 [-0.59, 6.59]
Ferguson 1996	83.8	7.3	19	83	7.4	19	1.6%	0.80 [-3.87, 5.47]
Ferguson 1997	75.8	11.6	20	78.7	8.6	20	0.9%	-2.90 [-9.23, 3.43]
Gauthier 2009	95.6	0.3	19	95.2	0.3	19	6.8%	0.40 [0.21, 0.59]
Gauthier 2009	95.4	0.2	19	95.2	0.3	19	6.8%	0.20 [0.04, 0.36]
Gauthier 2011	87.4	1.4	16	83.7	2.1	16	5.5%	3.70 [2.46, 4.94]
Ghazal 2009	86	2.2	48	82	8.2	48	3.6%	4.00 [1.60, 6.40]
Ghazal 2009	85.5	2.2	47	82	9.6	47	3.1%	3.50 [0.68, 6.32]
Gotsopoulos 2002	89	1	73	86	1	73	6.8%	3.00 [2.68, 3.32]
Gotsopoulos 2004	89	1	67	85	6	67	5.2%	4.00 [2.54, 5.46]
Hoekema 2007a	89.8	3.8	20	82	5.2	20	3.1%	7.80 [4.98, 10.62]
Hoekema 2007b	91	7.8	9	78	4.8	9	1.0%	13.00 [7.02, 18.98]
Hoekema 2008a	89.3	4.9	12	77.2	7.8	12	1.3%	12.10 [6.89, 17.31]
Hoekema 2008b	87.7	6.3	47	78	8.5	51	2.9%	9.70 [6.75, 12.65]
Lawton 2005	88	8.1	15	87.5	7.4	15	1.2%	0.50 [-5.05, 6.05]
Lawton 2005	89	7.4	16	87.5	7.4	16	1.3%	1.50 [-3.63, 6.63]
Mehta 2001	91	1	28	87	1	28	6.6%	4.00 [3.48, 4.52]
Naismith 2005	88.7	5.3	73	85.7	5.6	73	4.6%	3.00 [1.23, 4.77]
Phillips 2013	87.2	5.9	126	82.7	7.6	126	4.8%	4.50 [2.82, 6.18]
Randerath 2002	85.3	3.1	20	83.6	4.6	20	3.6%	1.70 [-0.73, 4.13]
Rose 2002	92.2	2.1	20	88.7	1.2	20	5.8%	3.50 [2.44, 4.56]
Rose 2002	90.1	4.8	18	89.1	3.2	18	3.3%	1.00 [-1.67, 3.67]
Vanderveken 2008	82	6	23	83	7	23	2.1%	-1.00 [-4.77, 2.77]
Vanderveken 2008	82	8	23	83	7	23	1.7%	-1.00 [-5.34, 3.34]
Zhou 2012	78.4	5.8	16	75.3	6.9	16	1.7%	3.10 [-1.32, 7.52]
Zhou 2012	89.6	5.6	16	75.3	6.9	16	1.7%	14.30 [9.95, 18.65]
Total (95% CI)			**946**			**950**	**100.0%**	**3.09 [2.43, 3.76]**

Heterogeneity: Tau² = 1.67; Chi² = 622.00, df = 27 (P < 0.00001); I² = 96%
Test for overall effect: Z = 9.13 (P < 0.00001)

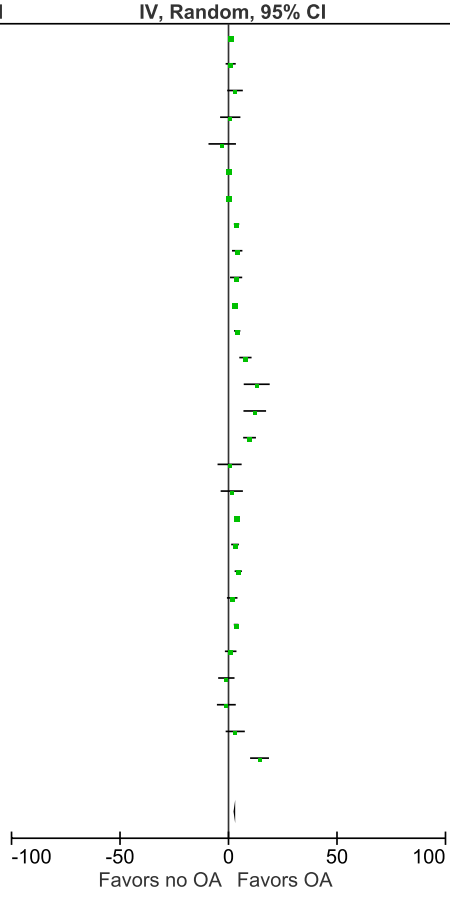


Figure 16—Custom OAs for OSA (Minimum Oxygen Saturation).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	87.8	0.4	85	86.7	0.6	85	7.1%	1.10 [0.95, 1.25]
Cunali 2011	87	5	29	86	4	29	3.9%	1.00 [-1.33, 3.33]
Deane 2009	87	5	22	84	7	22	2.4%	3.00 [-0.59, 6.59]
Ferguson 1997	75.8	11.6	20	78.7	8.6	20	1.0%	-2.90 [-9.23, 3.43]
Gauthier 2009	95.4	0.2	19	95.2	0.3	19	7.1%	0.20 [0.04, 0.36]
Gauthier 2009	95.6	0.3	19	95.2	0.3	19	7.1%	0.40 [0.21, 0.59]
Gauthier 2011	87.4	1.4	16	83.7	2.1	16	5.8%	3.70 [2.46, 4.94]
Ghazal 2009	85.5	2.2	47	82	9.6	47	3.2%	3.50 [0.68, 6.32]
Ghazal 2009	86	2.2	48	82	8.2	48	3.8%	4.00 [1.60, 6.40]
Gotsopoulos 2002	89	1	73	86	1	73	7.0%	3.00 [2.68, 3.32]
Gotsopoulos 2004	89	1	67	85	6	67	5.4%	4.00 [2.54, 5.46]
Hoekema 2007a	89.8	3.8	20	82	5.2	20	3.2%	7.80 [4.98, 10.62]
Hoekema 2007b	91	7.8	9	78	4.8	9	1.1%	13.00 [7.02, 18.98]
Hoekema 2008a	89.3	4.9	12	77.2	7.8	12	1.4%	12.10 [6.89, 17.31]
Hoekema 2008b	87.7	6.3	47	78	8.5	51	3.0%	9.70 [6.75, 12.65]
Lawton 2005	89	7.4	16	87.5	7.4	16	1.4%	1.50 [-3.63, 6.63]
Lawton 2005	88	8.1	15	87.5	7.4	15	1.2%	0.50 [-5.05, 6.05]
Mehta 2001	91	1	28	87	1	28	6.8%	4.00 [3.48, 4.52]
Naismith 2005	88.7	5.3	73	85.7	5.6	73	4.8%	3.00 [1.23, 4.77]
Phillips 2013	87.2	5.9	126	82.7	7.6	126	5.0%	4.50 [2.82, 6.18]
Randerath 2002	85.3	3.1	20	83.6	4.6	20	3.7%	1.70 [-0.73, 4.13]
Rose 2002	92.2	2.1	20	88.7	1.2	20	6.1%	3.50 [2.44, 4.56]
Rose 2002	90.1	4.8	18	89.1	3.2	18	3.4%	1.00 [-1.67, 3.67]
Vanderveken 2008	82	8	23	83	7	23	1.8%	-1.00 [-5.34, 3.34]
Zhou 2012	89.6	5.6	16	75.3	6.9	16	1.8%	14.30 [9.95, 18.65]
Zhou 2012	78.4	5.8	16	75.3	6.9	16	1.8%	3.10 [-1.32, 7.52]
Total (95% CI)			**904**			**908**	**100.0%**	**3.22 [2.54, 3.90]**

Heterogeneity: Tau² = 1.68; Chi² = 620.92, df = 25 (P < 0.00001); I² = 96%
Test for overall effect: Z = 9.32 (P < 0.00001)

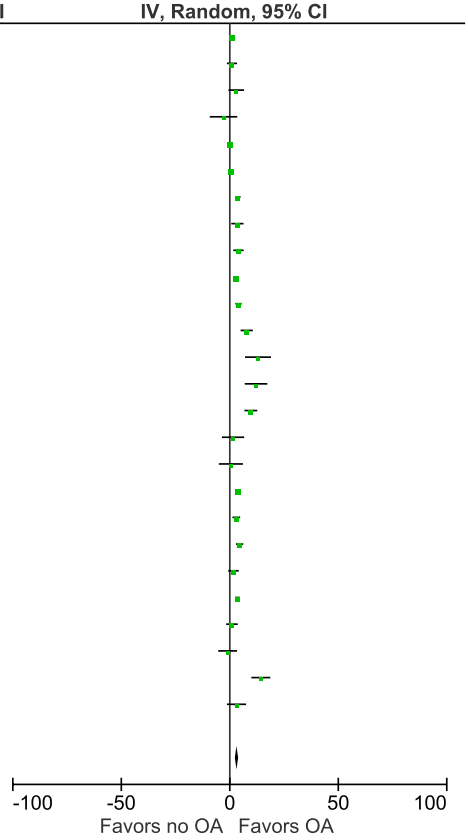


Figure 17—Non-Custom OAs for OSA (Minimum Oxygen Saturation).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Ferguson 1996	83.8	7.3	19	83	7.4	19	39.4%	0.80 [-3.87, 5.47]
Vanderveken 2008	82	6	23	83	7	23	60.6%	-1.00 [-4.77, 2.77]
Total (95% CI)			**42**			**42**	**100.0%**	**-0.29 [-3.22, 2.64]**

Heterogeneity: Tau² = 0.00; Chi² = 0.35, df = 1 (P = 0.56); I² = 0%
Test for overall effect: Z = 0.19 (P = 0.85)

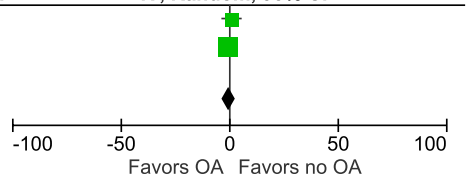


Figure 18—Custom, Titratable OAs for OSA (Minimum Oxygen Saturation).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	87.8	0.4	85	86.7	0.6	85	7.7%	1.10 [0.95, 1.25]
Cunali 2011	87	5	29	86	4	29	4.1%	1.00 [-1.33, 3.33]
Deane 2009	87	5	22	84	7	22	2.5%	3.00 [-0.59, 6.59]
Ferguson 1997	75.8	11.6	20	78.7	8.6	20	1.0%	-2.90 [-9.23, 3.43]
Gauthier 2009	95.4	0.2	19	95.2	0.3	19	7.7%	0.20 [0.04, 0.36]
Gauthier 2009	95.6	0.3	19	95.2	0.3	19	7.7%	0.40 [0.21, 0.59]
Gauthier 2011	87.4	1.4	16	83.7	2.1	16	6.2%	3.70 [2.46, 4.94]
Ghazal 2009	85.5	2.2	47	82	9.6	47	3.4%	3.50 [0.68, 6.32]
Ghazal 2009	86	2.2	48	82	8.2	48	4.0%	4.00 [1.60, 6.40]
Gotsopoulos 2002	89	1	73	86	1	73	7.6%	3.00 [2.68, 3.32]
Gotsopoulos 2004	89	1	67	85	6	67	5.8%	4.00 [2.54, 5.46]
Hoekema 2007a	89.8	3.8	20	82	5.2	20	3.4%	7.80 [4.98, 10.62]
Hoekema 2007b	91	7.8	9	78	4.8	9	1.1%	13.00 [7.02, 18.98]
Hoekema 2008a	89.3	4.9	12	77.2	7.8	12	1.4%	12.10 [6.89, 17.31]
Hoekema 2008b	87.7	6.3	47	78	8.5	51	3.2%	9.70 [6.75, 12.65]
Lawton 2005	88	8.1	15	87.5	7.4	15	1.3%	0.50 [-5.05, 6.05]
Lawton 2005	89	7.4	16	87.5	7.4	16	1.5%	1.50 [-3.63, 6.63]
Mehta 2001	91	1	28	87	1	28	7.4%	4.00 [3.48, 4.52]
Naismith 2005	88.7	5.3	73	85.7	5.6	73	5.1%	3.00 [1.23, 4.77]
Phillips 2013	87.2	5.9	126	82.7	7.6	126	5.3%	4.50 [2.82, 6.18]
Randerath 2002	85.3	3.1	20	83.6	4.6	20	3.9%	1.70 [-0.73, 4.13]
Rose 2002	92.2	2.1	20	88.7	1.2	20	6.6%	3.50 [2.44, 4.56]
Zhou 2012	78.4	5.8	16	75.3	6.9	16	1.9%	3.10 [-1.32, 7.52]
Total (95% CI)			**847**			**851**	**100.0%**	**3.15 [2.46, 3.84]**

Heterogeneity: Tau² = 1.59; Chi² = 584.21, df = 22 (P < 0.00001); I² = 96%
Test for overall effect: Z = 8.97 (P < 0.00001)

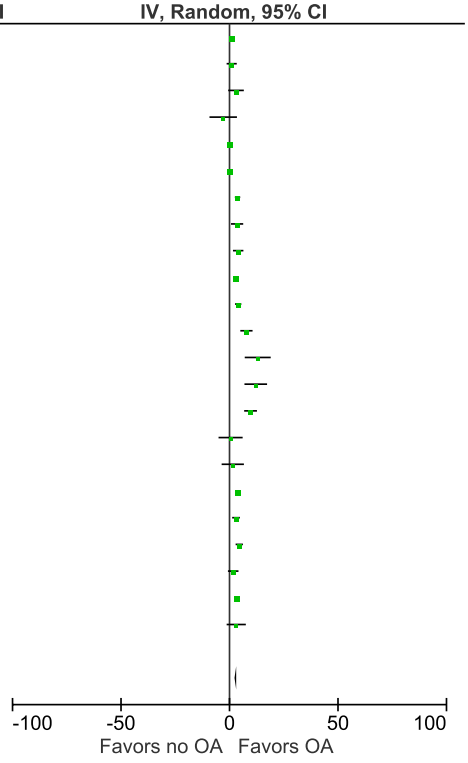


Figure 19—Custom, Non-Titratable OAs for OSA (Minimum Oxygen Saturation).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Rose 2002	90.1	4.8	18	89.1	3.2	18	34.6%	1.00 [-1.67, 3.67]
Vanderveken 2008	82	8	23	83	7	23	32.7%	-1.00 [-5.34, 3.34]
Zhou 2012	89.6	5.6	16	75.3	6.9	16	32.7%	14.30 [9.95, 18.65]
Total (95% CI)			**57**			**57**	**100.0%**	**4.70 [-3.83, 13.22]**

Heterogeneity: Tau² = 52.86; Chi² = 31.13, df = 2 (P < 0.00001); I² = 94%
Test for overall effect: Z = 1.08 (P = 0.28)

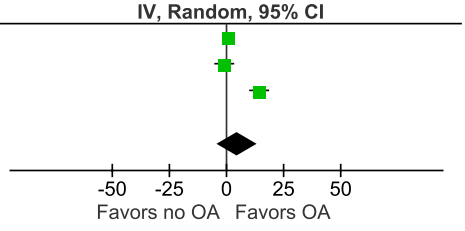


Figure 20—OAs vs. CPAP for OSA (Minimum Oxygen Saturation).

Study or Subgroup	CPAP Mean	SD	Total	OA Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	91.9	0.3	89	87.8	0.4	89	20.0%	4.10 [4.00, 4.20]
Ferguson 1996	88.7	2.5	20	83.8	7.3	19	8.8%	4.90 [1.44, 8.36]
Ferguson 1997	87.7	2.4	20	75.8	11.6	20	5.2%	11.90 [6.71, 17.09]
Hoekema 2007a	88.7	6.5	27	89.8	3.8	20	10.3%	-1.10 [-4.06, 1.86]
Hoekema 2007b	92	4.4	10	91	7.8	10	4.7%	1.00 [-4.55, 6.55]
Hoekema 2008a	89.3	4.2	13	89.3	4.9	13	8.6%	0.00 [-3.51, 3.51]
Hoekema 2008b	89.7	5.8	47	87.7	6.3	47	12.2%	2.00 [-0.45, 4.45]
Phillips 2013	90.6	5	108	87.2	5.9	108	16.3%	3.40 [1.94, 4.86]
Randerath 2002	89	3.4	20	85.3	3.1	20	13.9%	3.70 [1.68, 5.72]
Total (95% CI)			**354**			**346**	**100.0%**	**3.11 [1.74, 4.48]**

Heterogeneity: Tau² = 2.44; Chi² = 30.92, df = 8 (P = 0.0001); I² = 74%
Test for overall effect: Z = 4.45 (P < 0.00001)

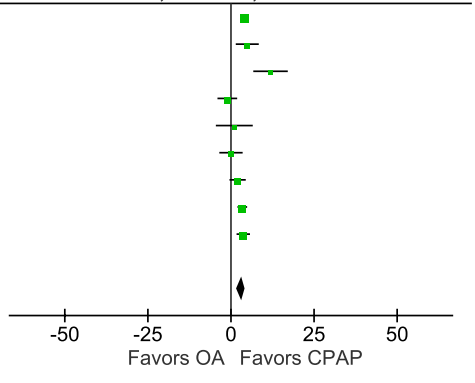


Figure 21—OAs for OSA (Arousal Index).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	4	13.2	20	17	9.6	20	5.0%	-13.00 [-20.15, -5.85]
Aarab 2011b	4.4	14.8	15	17.5	10.4	15	4.1%	-13.10 [-22.25, -3.95]
Barnes 2004	22	1.2	85	23.8	1.2	85	7.5%	-1.80 [-2.16, -1.44]
Blanco 2005	16	11.5	8	33.8	13.9	8	3.0%	-17.80 [-30.30, -5.30]
Bloch 2000	26.5	3.9	24	41	3.7	24	7.1%	-14.50 [-16.65, -12.35]
Bloch 2000	30.9	3.6	24	41	3.7	24	7.2%	-10.10 [-12.17, -8.03]
Deane 2009	21	9	22	33	16	22	4.7%	-12.00 [-19.67, -4.33]
Ghazal 2009	6	3.7	48	18	11.1	48	6.7%	-12.00 [-15.31, -8.69]
Ghazal 2009	9	11.1	47	24	14.1	47	5.9%	-15.00 [-20.13, -9.87]
Gotsopoulos 2002	25	2	73	35	2	73	7.4%	-10.00 [-10.65, -9.35]
Gotsopoulos 2004	25	2	67	33	2	67	7.4%	-8.00 [-8.68, -7.32]
Mehta 2001	27	2	28	41	2	28	7.4%	-14.00 [-15.05, -12.95]
Naismith 2005	25	2	73	35	2	73	7.4%	-10.00 [-10.65, -9.35]
Phillips 2013	19.2	11.6	126	34.3	15.3	126	6.7%	-15.10 [-18.45, -11.75]
Randerath 2002	17	5.1	20	21.8	9.9	20	6.1%	-4.80 [-9.68, 0.08]
Tan 2002	11.6	5.6	24	19.3	9.6	24	6.3%	-7.70 [-12.15, -3.25]
Total (95% CI)			**704**			**704**	**100.0%**	**-10.78 [-13.54, -8.02]**

Heterogeneity: Tau² = 26.57; Chi² = 1207.98, df = 15 (P < 0.00001); I² = 99%
Test for overall effect: Z = 7.65 (P < 0.00001)

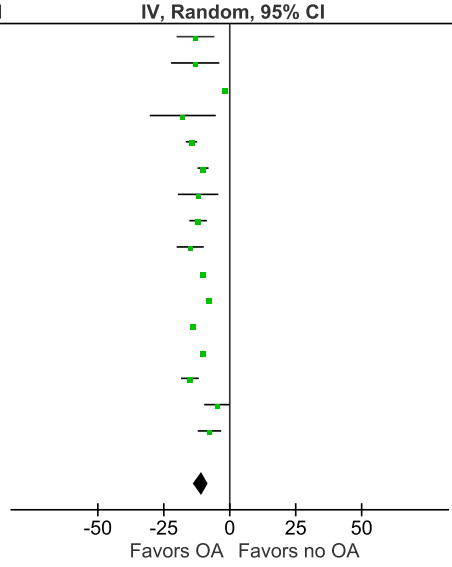


Figure 22—Custom, Titratable OAs for OSA (Arousal Index).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	4	13.2	20	17	9.6	20	5.9%	-13.00 [-20.15, -5.85]
Aarab 2011b	4.4	14.8	15	17.5	10.4	15	4.9%	-13.10 [-22.25, -3.95]
Barnes 2004	22	1.2	85	23.8	1.2	85	8.9%	-1.80 [-2.16, -1.44]
Bloch 2000	30.9	3.6	24	41	3.7	24	8.6%	-10.10 [-12.17, -8.03]
Deane 2009	21	9	22	33	16	22	5.6%	-12.00 [-19.67, -4.33]
Ghazal 2009	9	11.1	47	24	14.1	47	7.1%	-15.00 [-20.13, -9.87]
Ghazal 2009	6	3.7	48	18	11.1	48	8.1%	-12.00 [-15.31, -8.69]
Gotsopoulos 2002	25	2	73	35	2	73	8.9%	-10.00 [-10.65, -9.35]
Gotsopoulos 2004	25	2	67	33	2	67	8.9%	-8.00 [-8.68, -7.32]
Mehta 2001	27	2	28	41	2	28	8.9%	-14.00 [-15.05, -12.95]
Naismith 2005	25	2	73	35	2	73	8.9%	-10.00 [-10.65, -9.35]
Phillips 2013	19.2	11.6	126	34.3	15.3	126	8.0%	-15.10 [-18.45, -11.75]
Randerath 2002	17	5.1	20	21.8	9.9	20	7.2%	-4.80 [-9.68, 0.08]
Total (95% CI)			**648**			**648**	**100.0%**	**-10.44 [-13.44, -7.45]**

Heterogeneity: Tau² = 26.04; Chi² = 1146.17, df = 12 (P < 0.00001); I² = 99%
Test for overall effect: Z = 6.84 (P < 0.00001)

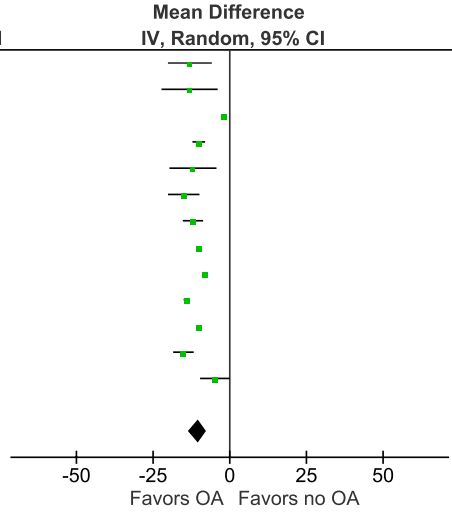


Figure 23—Custom, Non-Titratable OAs for OSA (Arousal Index).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Blanco 2005	16	11.5	8	33.8	13.9	8	2.9%	-17.80 [-30.30, -5.30]
Bloch 2000	26.5	3.9	24	41	3.7	24	97.1%	-14.50 [-16.65, -12.35]
Total (95% CI)			**32**			**32**	**100.0%**	**-14.59 [-16.71, -12.48]**

Heterogeneity: Tau² = 0.00; Chi² = 0.26, df = 1 (P = 0.61); I² = 0%
Test for overall effect: Z = 13.50 (P < 0.00001)

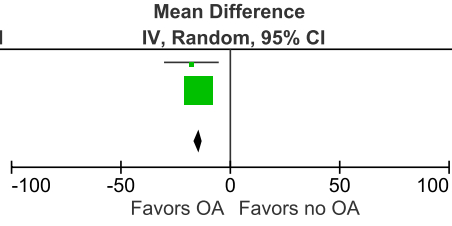


Figure 24—OAs vs. CPAP for OSA (Arousal Index).

Study or Subgroup	OA Mean	OA SD	OA Total	CPAP Mean	CPAP SD	CPAP Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	4	13.2	20	2.5	14.8	18	4.2%	1.50 [-7.46, 10.46]
Aarab 2011b	4.4	14.8	15	1	15.5	13	2.7%	3.40 [-7.87, 14.67]
Barnes 2004	23.8	1.2	85	18.3	0.9	89	37.2%	5.50 [5.18, 5.82]
Phillips 2013	19.2	11.6	110	16.6	10.6	108	20.1%	2.60 [-0.35, 5.55]
Randerath 2002	17	5.1	20	14.1	5.1	20	18.8%	2.90 [-0.26, 6.06]
Tan 2002	11.6	5.6	24	9.8	6.6	24	17.1%	1.80 [-1.66, 5.26]
Total (95% CI)			**274**			**272**	**100.0%**	**3.57 [1.64, 5.51]**

Heterogeneity: Tau² = 2.60; Chi² = 11.25, df = 5 (P = 0.05); I² = 56%
Test for overall effect: Z = 3.61 (P = 0.0003)

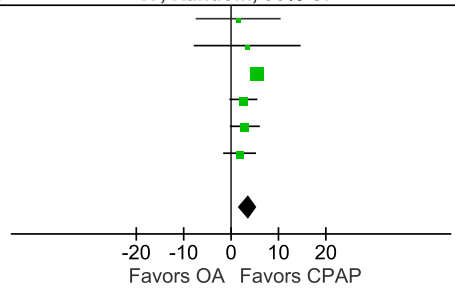


Figure 25—OAs for OSA (Oxygen Desaturation Index; ODI).

Study or Subgroup	Post-treatment Mean	Post-treatment SD	Post-treatment Total	Pre-treatment Mean	Pre-treatment SD	Pre-treatment Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	8.1	1.3	85	12.4	1.5	85	14.7%	-4.30 [-4.72, -3.88]
Ghazal 2009	4	13.5	48	14	10.4	48	12.2%	-10.00 [-14.82, -5.18]
Ghazal 2009	8	8.2	47	16	13.3	47	12.5%	-8.00 [-12.47, -3.53]
Johnston 2002	21.1	19.8	20	30.7	18.8	20	6.5%	-9.60 [-21.57, 2.37]
Phillips 2013	9	11.6	126	20.8	12.5	126	13.6%	-11.80 [-14.78, -8.82]
Wilhelmsson 1999	6.1	1.6	41	17	1.4	41	14.6%	-10.90 [-11.55, -10.25]
Zhou 2012	15	4.8	16	37	6.4	16	12.9%	-22.00 [-25.92, -18.08]
Zhou 2012	12	4.4	16	37	6.4	16	13.0%	-25.00 [-28.81, -21.19]
Total (95% CI)			**399**			**399**	**100.0%**	**-12.77 [-16.85, -8.69]**

Heterogeneity: Tau² = 29.53; Chi² = 445.13, df = 7 (P < 0.00001); I² = 98%
Test for overall effect: Z = 6.13 (P < 0.00001)

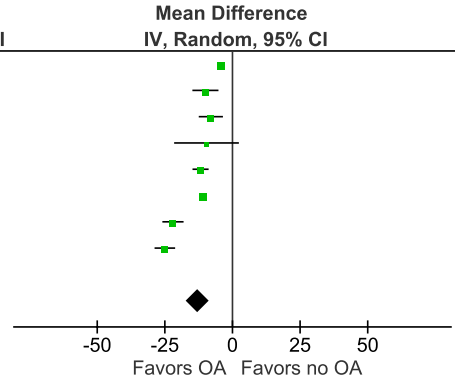


Figure 26—Custom, Titratable OAs for OSA (ODI).

Study or Subgroup	Post-treatment Mean	Post-treatment SD	Post-treatment Total	Pre-treatment Mean	Pre-treatment SD	Pre-treatment Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	8.1	1.3	85	12.4	1.5	85	21.4%	-4.30 [-4.72, -3.88]
Ghazal 2009	7	13.5	48	11.5	10.4	48	19.0%	-4.50 [-9.32, 0.32]
Ghazal 2009	7.2	8.1	47	14.5	13.3	47	19.3%	-7.30 [-11.75, -2.85]
Phillips 2013	9	11.6	126	20.8	12.5	126	20.4%	-11.80 [-14.78, -8.82]
Zhou 2012	15	4.8	16	37	6.4	16	19.8%	-22.00 [-25.92, -18.08]
Total (95% CI)			**322**			**322**	**100.0%**	**-9.95 [-16.25, -3.66]**

Heterogeneity: Tau² = 48.16; Chi² = 101.41, df = 4 (P < 0.00001); I² = 96%
Test for overall effect: Z = 3.10 (P = 0.002)

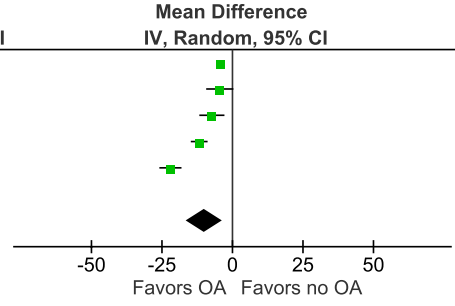


Figure 27—Custom, Non-Titratable OA for OSA (ODI).

Study or Subgroup	Post-treatment Mean	Post-treatment SD	Post-treatment Total	Pre-treatment Mean	Pre-treatment SD	Pre-treatment Total	Weight	Mean Difference IV, Random, 95% CI
Johnston 2002	21.1	19.8	20	30.7	18.8	20	26.4%	-9.60 [-21.57, 2.37]
Wilhelmsson 1999	6.1	3.2	41	17	2.9	41	37.5%	-10.90 [-12.22, -9.58]
Zhou 2012	12	4.4	16	37	6.4	16	36.1%	-25.00 [-28.81, -21.19]
Total (95% CI)			**77**			**77**	**100.0%**	**-15.65 [-26.86, -4.44]**

Heterogeneity: Tau² = 86.83; Chi² = 47.27, df = 2 (P < 0.00001); I² = 96%
Test for overall effect: Z = 2.74 (P = 0.006)

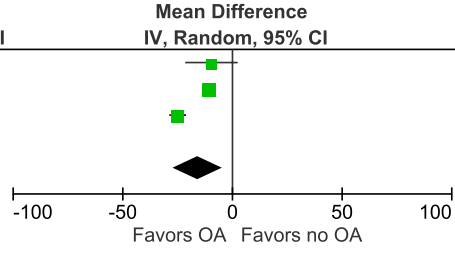


Figure 28—OAs vs. CPAP for OSA (ODI).

Study or Subgroup	OA Mean	OA SD	OA Total	CPAP Mean	CPAP SD	CPAP Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	8.1	1.3	80	1.6	0.2	80	41.5%	6.50 [6.21, 6.79]
Gagnadoux 2009	6.3	5	28	2.3	3.2	28	30.9%	4.00 [1.80, 6.20]
Phillips 2013	9	11.6	126	6	9.7	126	27.7%	3.00 [0.36, 5.64]
Total (95% CI)			**234**			**234**	**100.0%**	**4.76 [2.37, 7.15]**

Heterogeneity: Tau² = 3.57; Chi² = 11.39, df = 2 (P = 0.003); I² = 82%
Test for overall effect: Z = 3.90 (P < 0.0001)

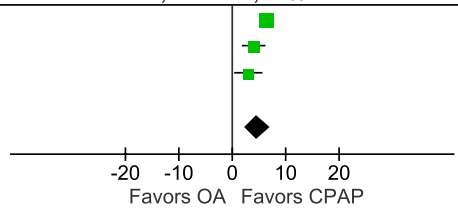


Figure 29—OAs for OSA (% Rapid Eye Movement; %REM).

Study or Subgroup	Post-treatment Mean	Post-treatment SD	Post-treatment Total	Pre-treatment Mean	Pre-treatment SD	Pre-treatment Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	20.2	6.4	20	18.3	6.4	20	3.9%	1.90 [-2.07, 5.87]
Aarab 2011b	22.6	7.6	15	18.6	6.4	21	3.3%	4.00 [-0.72, 8.72]
Barnes 2004	19.8	0.6	80	18.8	0.7	80	7.2%	1.00 [0.80, 1.20]
Blanco 2005	15.5	5.9	8	16.8	4.3	8	3.0%	-1.30 [-6.36, 3.76]
Bloch 2000	15	1	24	14	1	24	7.1%	1.00 [0.43, 1.57]
Bloch 2000	16	1	24	14	1	24	7.1%	2.00 [1.43, 2.57]
Deane 2009	18.2	0.5	22	13.2	0.4	22	7.2%	5.00 [4.73, 5.27]
Ferguson 1996	20	12.3	19	14.3	6.5	19	2.3%	5.70 [-0.56, 11.96]
Ferguson 1997	13.1	6	19	16.1	13.6	19	2.1%	-3.00 [-9.68, 3.68]
Gauthier 2009	22.8	1.2	16	20.2	0.9	16	7.0%	2.60 [1.87, 3.33]
Gauthier 2009	22	1.5	16	20.2	0.9	16	6.9%	1.80 [0.94, 2.66]
Gauthier 2011	18.3	1.8	14	20	1	14	6.8%	-1.70 [-2.78, -0.62]
Ghazal 2009	14	26.4	48	19	29.6	48	0.9%	-5.00 [-16.22, 6.22]
Ghazal 2009	13	4.1	46	14	30.4	46	1.4%	-1.00 [-9.86, 7.86]
Gotsopoulos 2002	18	1	73	18	1	73	7.1%	0.00 [-0.32, 0.32]
Gotsopoulos 2004	18	1	67	18	7	67	6.2%	0.00 [-1.69, 1.69]
Hoekema 2008b	26.5	6.7	47	21	7.8	51	5.0%	5.50 [2.63, 8.37]
Mehta 2001	21	1	24	16	1	24	7.1%	5.00 [4.43, 5.57]
Randerath 2002	14.8	7.3	20	15.1	5.9	20	3.8%	-0.30 [-4.41, 3.81]
Tan 2002	13.8	5.6	24	12.7	5.8	24	4.6%	1.10 [-2.13, 4.33]
Total (95% CI)			**626**			**636**	**100.0%**	**1.67 [0.51, 2.84]**

Heterogeneity: Tau² = 4.89; Chi² = 911.17, df = 19 (P < 0.00001); I² = 98%
Test for overall effect: Z = 2.82 (P = 0.005)

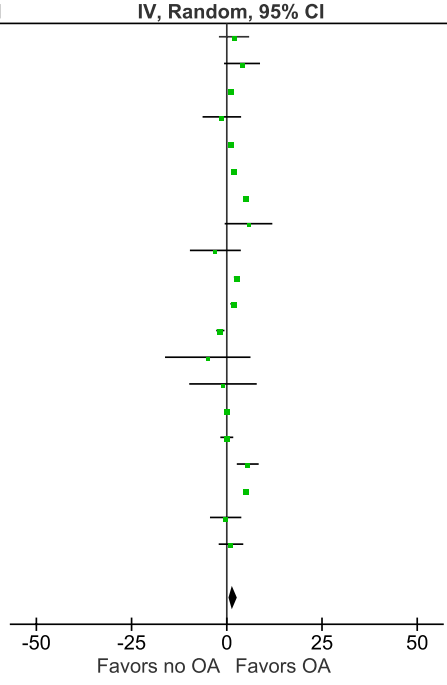


Figure 30—Custom OAs (%REM).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	20.2	6.4	20	18.3	6.4	20	3.3%	1.90 [-2.07, 5.87]
Aarab 2011b	22.6	7.6	15	18.6	6.4	21	2.7%	4.00 [-0.72, 8.72]
Barnes 2004	19.8	0.6	80	18.8	0.7	80	8.0%	1.00 [0.80, 1.20]
Blanco 2005	15.5	5.9	8	16.8	4.3	8	2.4%	-1.30 [-6.36, 3.76]
Bloch 2000	15	1	24	14	1	24	7.8%	1.00 [0.43, 1.57]
Bloch 2000	16	1	24	14	1	24	7.8%	2.00 [1.43, 2.57]
Deane 2009	18.2	0.5	22	14	1	24	7.9%	4.20 [3.75, 4.65]
Ferguson 1997	13.1	6	20	16.1	13.6	20	1.7%	-3.00 [-9.51, 3.51]
Gauthier 2009	22.8	1.2	16	20.2	0.9	16	7.7%	2.60 [1.87, 3.33]
Gauthier 2009	22	1.5	16	20.2	0.9	16	7.5%	1.80 [0.94, 2.66]
Gauthier 2011	18.3	1.8	14	20	1	14	7.3%	-1.70 [-2.78, -0.62]
Ghazal 2009	14	26.4	48	19	29.6	48	0.7%	-5.00 [-16.22, 6.22]
Ghazal 2009	13	4.1	46	14	30.4	46	1.0%	-1.00 [-9.86, 7.86]
Gotsopoulos 2002	18	1	73	18	1	73	8.0%	0.00 [-0.32, 0.32]
Gotsopoulos 2004	18	1	67	18	7	67	6.4%	0.00 [-1.69, 1.69]
Hoekema 2008b	26.5	6.7	47	21	7.8	51	4.6%	5.50 [2.63, 8.37]
Mehta 2001	21	1	24	16	1	24	7.8%	5.00 [4.43, 5.57]
Randerath 2002	14.8	7.3	20	15.1	5.9	20	3.2%	-0.30 [-4.41, 3.81]
Tan 2002	13.8	5.6	24	12.7	5.8	24	4.2%	1.10 [-2.13, 4.33]
Total (95% CI)			**608**			**620**	**100.0%**	**1.58 [0.64, 2.53]**

Heterogeneity: Tau² = 2.91; Chi² = 455.35, df = 18 (P < 0.00001); I² = 96%
Test for overall effect: Z = 3.27 (P = 0.001)

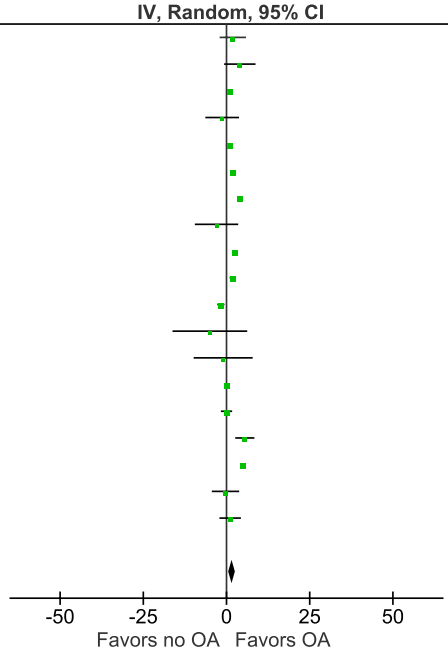


Figure 31—Custom, Titratable OAs for OSA (%REM).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	16.4	6.4	20	18.3	6.4	20	4.8%	-1.90 [-5.87, 2.07]
Aarab 2011b	14.6	7.6	15	18.6	6.4	21	4.1%	-4.00 [-8.72, 0.72]
Barnes 2004	19.8	0.6	80	18.8	0.7	80	8.5%	1.00 [0.80, 1.20]
Bloch 2000	16	1	24	14	1	24	8.4%	2.00 [1.43, 2.57]
Deane 2009	18.2	0.5	22	13.2	0.4	22	8.5%	5.00 [4.73, 5.27]
Ferguson 1997	13.1	6	19	16.1	13.6	19	2.7%	-3.00 [-9.68, 3.68]
Gauthier 2009	22.8	1.2	16	20.2	0.9	16	8.3%	2.60 [1.87, 3.33]
Gauthier 2009	22	1.5	16	20.2	0.9	16	8.3%	1.80 [0.94, 2.66]
Gauthier 2011	18.3	1.8	14	20	1	14	8.1%	-1.70 [-2.78, -0.62]
Ghazal 2009	14	26.4	48	19	29.6	48	1.2%	-5.00 [-16.22, 6.22]
Ghazal 2009	13	4.1	46	14	30.4	46	1.8%	-1.00 [-9.86, 7.86]
Gotsopoulos 2002	18	1	73	18	1	73	8.5%	0.00 [-0.32, 0.32]
Gotsopoulos 2004	18	1	67	18	7	67	7.5%	0.00 [-1.69, 1.69]
Hoekema 2008b	26.5	6.7	47	21	7.8	51	6.1%	5.50 [2.63, 8.37]
Mehta 2001	21	1	24	16	1	24	8.4%	5.00 [4.43, 5.57]
Randerath 2002	14.8	7.3	20	15.1	5.9	20	4.7%	-0.30 [-4.41, 3.81]
Total (95% CI)			**551**			**561**	**100.0%**	**1.24 [-0.09, 2.56]**

Heterogeneity: Tau² = 5.32; Chi² = 904.08, df = 15 (P < 0.00001); I² = 98%
Test for overall effect: Z = 1.83 (P = 0.07)

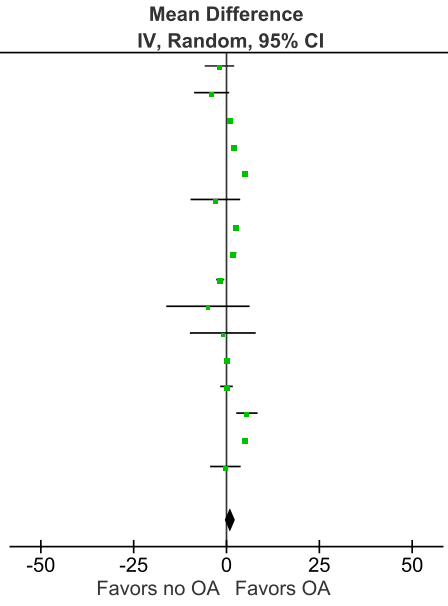


Figure 32—Custom, Non-Titratable OA for OSA (%REM).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Blanco 2005	15.5	5.9	8	16.8	4.3	8	1.2%	-1.30 [-6.36, 3.76]
Bloch 2000	15	1	24	14	1	24	98.8%	1.00 [0.43, 1.57]
Total (95% CI)			**32**			**32**	**100.0%**	**0.97 [0.41, 1.53]**

Heterogeneity: Tau² = 0.00; Chi² = 0.78, df = 1 (P = 0.38); I² = 0%
Test for overall effect: Z = 3.39 (P = 0.0007)

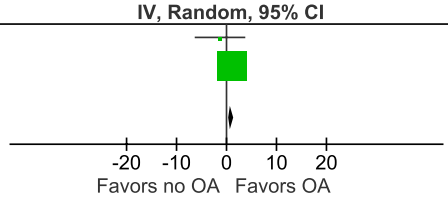


Figure 33—OAs vs. CPAP for OSA (%REM).

Study or Subgroup	CPAP Mean	CPAP SD	CPAP Total	OA Mean	OA SD	OA Total	Weight	Mean Difference IV, Random, 95% CI
Aarab 2011a	20.6	10.4	20	16.4	6.4	20	7.7%	4.20 [-1.15, 9.55]
Aarab 2011b	19.3	10.6	13	14.6	7.6	15	5.3%	4.70 [-2.23, 11.63]
Barnes 2004	18.9	0.5	80	19.8	0.6	80	23.9%	-0.90 [-1.07, -0.73]
Ferguson 1996	16.1	6.1	20	14.3	6.5	19	11.1%	1.80 [-2.16, 5.76]
Ferguson 1997	12.1	5.4	20	13.1	6	19	12.3%	-1.00 [-4.59, 2.59]
Hoekema 2008b	24.1	5.7	47	26.5	6.7	47	16.4%	-2.40 [-4.91, 0.11]
Randerath 2002	15.3	6.8	20	14.8	7.3	20	10.0%	0.50 [-3.87, 4.87]
Tan 2002	18.5	6.1	24	13.8	5.6	24	13.3%	4.70 [1.39, 8.01]
Total (95% CI)			**244**			**244**	**100.0%**	**0.72 [-1.09, 2.52]**

Heterogeneity: Tau² = 3.54; Chi² = 20.45, df = 7 (P = 0.005); I² = 66%
Test for overall effect: Z = 0.78 (P = 0.44)

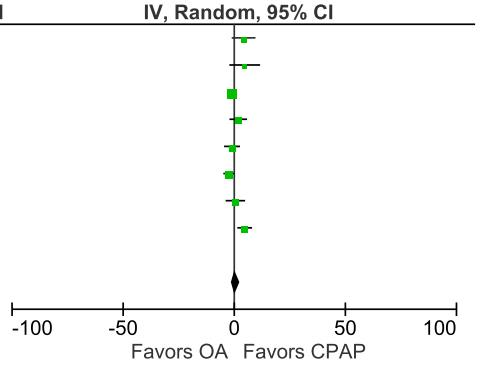


Figure 34—OAs for OSA (Sleep Efficiency).

Study or Subgroup	Post-treatment Mean	Post-treatment SD	Post-treatment Total	Pre-treatment Mean	Pre-treatment SD	Pre-treatment Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	82	1	80	79.5	1.1	80	7.8%	2.50 [2.17, 2.83]
Blanco 2005	71.3	12	8	65.8	15.2	8	0.7%	5.50 [-7.92, 18.92]
Bloch 2000	88	2	24	89	2	24	7.3%	-1.00 [-2.13, 0.13]
Bloch 2000	89	1	24	89	2	24	7.5%	0.00 [-0.89, 0.89]
Deane 2009	78	17	22	80	11	22	1.5%	-2.00 [-10.46, 6.46]
Ferguson 1996	86.5	10.6	19	88	5.4	19	3.0%	-1.50 [-6.85, 3.85]
Ferguson 1997	87.9	5.5	19	85.9	5.7	19	4.5%	2.00 [-1.56, 5.56]
Gauthier 2009	85.6	2.1	16	83.1	2	16	7.0%	2.50 [1.08, 3.92]
Gauthier 2009	83.9	2.1	16	83.1	2	16	7.0%	0.80 [-0.62, 2.22]
Gauthier 2011	80.9	2.1	14	83.6	2.2	14	6.9%	-2.70 [-4.29, -1.11]
Ghazal 2009	89	14.1	48	81	14.1	48	2.8%	8.00 [2.36, 13.64]
Ghazal 2009	82	11.8	47	89	16.8	47	2.6%	-7.00 [-12.87, -1.13]
Gotsopoulos 2002	84	1	73	81	1	73	7.8%	3.00 [2.68, 3.32]
Gotsopoulos 2004	83	1	61	80	12	61	5.1%	3.00 [-0.02, 6.02]
Hoekema 2008b	86.1	8.1	47	88.3	9.7	51	4.6%	-2.20 [-5.73, 1.33]
Mehta 2001	85	1	24	87	1	24	7.7%	-2.00 [-2.57, -1.43]
Naismith 2005	83.6	10.7	73	80.6	12	73	4.4%	3.00 [-0.69, 6.69]
Tan 2002	83.2	8.1	24	81.6	10.4	24	3.0%	1.60 [-3.67, 6.87]
Vanderveken 2008	81	12	23	78	11	23	2.2%	3.00 [-3.65, 9.65]
Vanderveken 2008	80	11	23	78	11	23	2.4%	2.00 [-4.36, 8.36]
Zhou 2012	84.9	7.8	16	80.7	12.5	16	2.0%	4.20 [-3.02, 11.42]
Zhou 2012	89.4	6.4	16	80.7	12.5	16	2.1%	8.70 [1.82, 15.58]
Total (95% CI)			**717**			**721**	**100.0%**	**0.95 [-0.21, 2.12]**

Heterogeneity: Tau² = 4.48; Chi² = 342.31, df = 21 (P < 0.00001); I² = 94%
Test for overall effect: Z = 1.60 (P = 0.11)

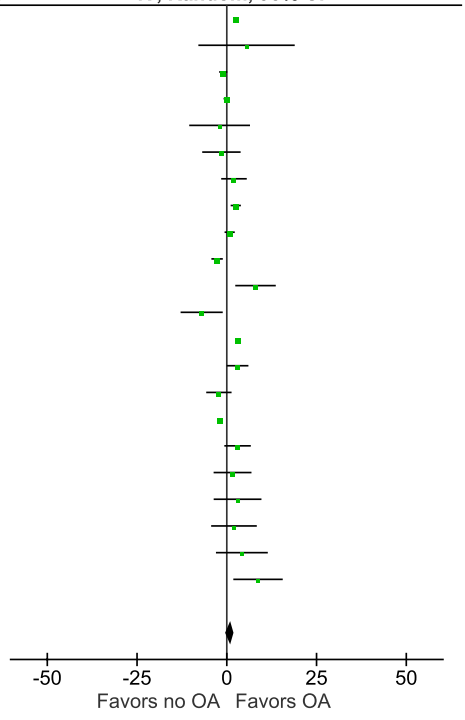


Figure 35—Custom OAs for OSA (Sleep Efficiency).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	82	1	80	79.5	1.1	80	8.2%	2.50 [2.17, 2.83]
Blanco 2005	71.3	12	8	65.8	15.2	8	0.7%	5.50 [-7.92, 18.92]
Bloch 2000	88	2	24	89	2	24	7.7%	-1.00 [-2.13, 0.13]
Bloch 2000	89	1	24	89	2	24	7.9%	0.00 [-0.89, 0.89]
Deane 2009	78	17	22	80	11	22	1.6%	-2.00 [-10.46, 6.46]
Ferguson 1997	87.9	5.5	19	85.9	5.7	19	4.8%	2.00 [-1.56, 5.56]
Gauthier 2009	85.6	2.1	16	83.1	2	16	7.4%	2.50 [1.08, 3.92]
Gauthier 2009	83.9	2.1	16	83.1	2	16	7.4%	0.80 [-0.62, 2.22]
Gauthier 2011	80.9	2.1	14	83.6	2.2	14	7.2%	-2.70 [-4.29, -1.11]
Ghazal 2009	82	11.8	47	89	16.8	47	2.8%	-7.00 [-12.87, -1.13]
Ghazal 2009	89	14.1	48	81	14.1	48	2.9%	8.00 [2.36, 13.64]
Gotsopoulos 2002	84	1	73	81	1	73	8.2%	3.00 [2.68, 3.32]
Gotsopoulos 2004	83	1	61	80	12	61	5.4%	3.00 [-0.02, 6.02]
Hoekema 2008b	86.1	8.1	47	88.3	9.7	51	4.8%	-2.20 [-5.73, 1.33]
Mehta 2001	85	1	24	87	1	24	8.1%	-2.00 [-2.57, -1.43]
Naismith 2005	83.6	10.7	73	80.6	12	73	4.6%	3.00 [-0.69, 6.69]
Tan 2002	83.2	8.1	24	81.6	10.4	24	3.2%	1.60 [-3.67, 6.87]
Vanderveken 2008	80	11	23	78	11	23	2.5%	2.00 [-4.36, 8.36]
Zhou 2012	84.9	7.8	16	80.7	12.5	16	2.1%	4.20 [-3.02, 11.42]
Zhou 2012	89.4	6.4	16	80.7	12.5	16	2.2%	8.70 [1.82, 15.58]
Total (95% CI)			**675**			**679**	**100.0%**	**0.98 [-0.22, 2.18]**

Heterogeneity: Tau² = 4.50; Chi² = 340.73, df = 19 (P < 0.00001); I² = 94%
Test for overall effect: Z = 1.61 (P = 0.11)

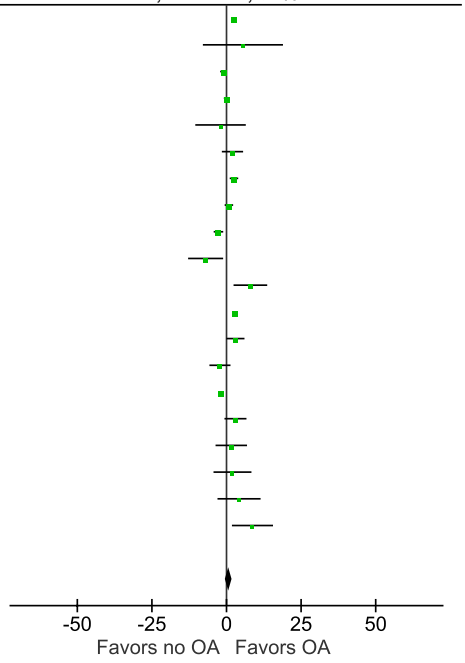


Figure 36—Non-Custom OAs for OSA (Sleep Efficiency).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Ferguson 1996	86.5	10.6	19	88	5.4	19	60.1%	-1.50 [-6.85, 3.85]
Vanderveken 2008	81	12	23	78	11	23	39.9%	3.00 [-3.65, 9.65]
Total (95% CI)			**42**			**42**	**100.0%**	**0.30 [-4.02, 4.62]**

Heterogeneity: Tau² = 0.64; Chi² = 1.07, df = 1 (P = 0.30); I² = 6%
Test for overall effect: Z = 0.13 (P = 0.89)

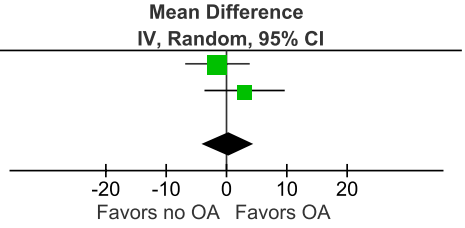


Figure 37—Custom, Titratable OA for OSA (Sleep Efficiency).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	82	1	80	79.5	1.1	80	9.9%	2.50 [2.17, 2.83]
Bloch 2000	89	1	24	89	2	24	9.5%	0.00 [-0.89, 0.89]
Deane 2009	78	17	22	80	11	22	1.9%	-2.00 [-10.46, 6.46]
Ferguson 1997	87.9	5.5	19	85.9	5.7	19	5.7%	2.00 [-1.56, 5.56]
Gauthier 2009	83.9	2.1	16	83.1	2	16	8.9%	0.80 [-0.62, 2.22]
Gauthier 2009	85.6	2.1	16	83.1	2	16	8.9%	2.50 [1.08, 3.92]
Gauthier 2011	80.9	2.1	14	83.6	2.2	14	8.7%	-2.70 [-4.29, -1.11]
Ghazal 2009	89	14.1	48	81	14.1	48	3.5%	8.00 [2.36, 13.64]
Ghazal 2009	82	11.8	47	89	16.8	47	3.3%	-7.00 [-12.87, -1.13]
Gotsopoulos 2002	84	1	73	81	1	73	9.9%	3.00 [2.68, 3.32]
Gotsopoulos 2004	83	1	61	80	12	61	6.5%	3.00 [-0.02, 6.02]
Hoekema 2008b	86.1	8.1	47	88.3	9.7	51	5.7%	-2.20 [-5.73, 1.33]
Mehta 2001	85	1	24	87	1	24	9.8%	-2.00 [-2.57, -1.43]
Naismith 2005	83.6	10.7	73	80.6	12	73	5.5%	3.00 [-0.69, 6.69]
Zhou 2012	84.9	7.8	16	80.7	12.5	16	2.4%	4.20 [-3.02, 11.42]
Total (95% CI)			**580**			**584**	**100.0%**	**0.87 [-0.43, 2.17]**

Heterogeneity: Tau² = 4.44; Chi² = 312.55, df = 14 (P < 0.00001); I² = 96%
Test for overall effect: Z = 1.31 (P = 0.19)

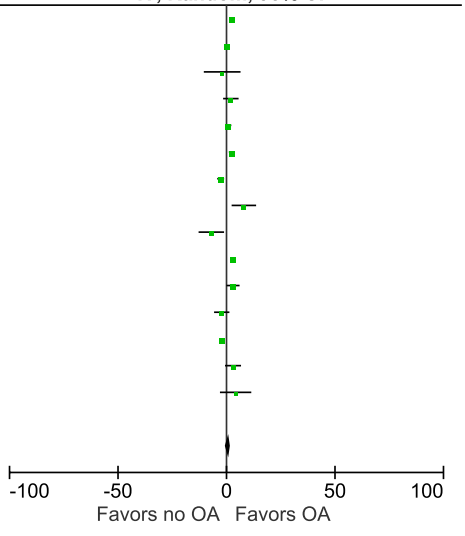


Figure 38—Custom, Non-Titratable OA for OSA (Sleep Efficiency).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Blanco 2005	71.3	12	8	65.8	15.2	8	10.5%	5.50 [-7.92, 18.92]
Bloch 2000	88	2	24	89	2	24	41.0%	-1.00 [-2.13, 0.13]
Vanderveken 2008	80	11	23	78	11	23	25.1%	2.00 [-4.36, 8.36]
Zhou 2012	89.4	6.4	16	80.7	12.5	16	23.4%	8.70 [1.82, 15.58]
Total (95% CI)			**71**			**71**	**100.0%**	**2.71 [-2.32, 7.73]**

Heterogeneity: Tau² = 15.70; Chi² = 8.93, df = 3 (P = 0.03); I² = 66%
Test for overall effect: Z = 1.06 (P = 0.29)

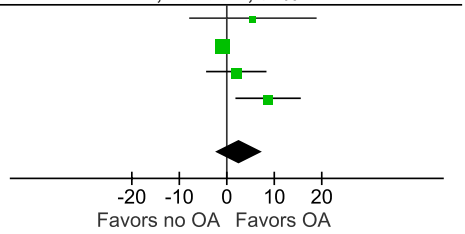


Figure 39—OAs vs. CPAP (Sleep Efficiency).

Study or Subgroup	CPAP Mean	SD	Total	OA Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	82.1	0.8	80	82	1	80	80.0%	0.10 [-0.18, 0.38]
Ferguson 1996	87.8	7.7	20	88	5.4	19	3.9%	-0.20 [-4.36, 3.96]
Ferguson 1997	89.9	3.4	20	87.9	5.5	20	8.0%	2.00 [-0.83, 4.83]
Hoekema 2008b	86.2	10	47	86.1	8.1	47	4.9%	0.10 [-3.58, 3.78]
Tan 2002	87.2	8.1	24	83.2	8.1	24	3.2%	4.00 [-0.58, 8.58]
Total (95% CI)			**191**			**190**	**100.0%**	**0.37 [-0.47, 1.21]**

Heterogeneity: Tau² = 0.21; Chi² = 4.48, df = 4 (P = 0.34); I² = 11%
Test for overall effect: Z = 0.85 (P = 0.39)

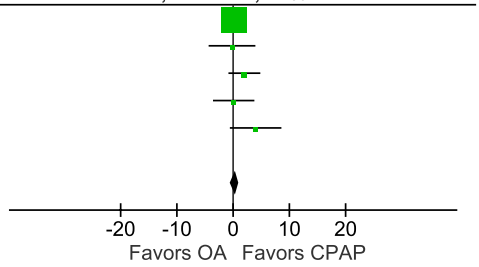


Figure 40—Summary of Findings: OA Pre- vs. Post-Treatment of OSA (All Physiologic Sleep Outcome Measures).

OAs for OSA

Patient or population: Patients with OSA
Intervention: OAs

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk	Corresponding risk	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Control	OAs				
AHI/RDI/REI		The mean AHI/RDI in the intervention groups was **13.59 lower** (15.25 to 11.94 lower)		1301 (34 studies)	⊕⊕⊕⊖ **moderate**[1]	
Minimum Oxygen Saturation		The mean min oxygen saturation in the intervention groups was **3.09 higher** (2.43 to 3.76 higher)		946 (22 studies)	⊕⊕⊕⊖ **moderate**[1]	
Arousal Index		The mean arousal index in the intervention groups was **10.78 lower** (13.54 to 8.02 lower)		704 (14 studies)	⊕⊕⊕⊖ **moderate**[1]	
ODI		The mean ODI in the intervention groups was **12.77 lower** (16.85 to 8.69 lower)		399 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	
%REM		The mean %REM in the intervention groups was **1.67 higher** (0.51 to 0 higher)		626 (17 studies)	⊕⊕⊖⊖ **low**[1,2]	
Sleep Efficiency		The mean sleep efficiency in the intervention groups was **0.95 higher** (0.21 lower to 2.12 higher)		717 (17 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 41—Summary of Findings: Custom OAs Pre- vs. Post-Treatment of OSA (All Physiologic Sleep Outcome Measures).

Custom OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom OAs				
AHI/RDI/REI		The mean AHI/RDI in the intervention groups was **13.89 lower** (15.57 to 12.20 lower)		1259 (33 studies)	⊕⊕⊕⊖ **moderate**[1]	
Minimum Oxygen Saturation		The mean min oxygen sat. in the intervention groups was **3.22 higher** (2.54 to 3.90 higher)		904 (21 studies)	⊕⊕⊕⊖ **moderate**[1]	
Arousal Index		The mean arousal index in the intervention groups was **10.78 lower** (13.54 to 8.02 lower)		704 (14 studies)	⊕⊕⊕⊖ **moderate**[1]	
ODI		The mean ODI in the intervention groups was **12.77 lower** (16.85 to 8.69 lower)		399 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	
%REM		The mean %REM in the intervention groups was **1.58 higher** (0.64 to 2.53 higher)		608 (16 studies)	⊕⊕⊖⊖ **low**[1,2]	
Sleep Efficiency		The mean sleep efficiency in the intervention groups was **0.95 higher** (0.22 lower to 2.18 higher)		675 (16 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI crosses the decision making threshold

Figure 42—Summary of Findings: Non-Custom OAs Pre- vs. Post-Treatment of OSA (All Physiologic Sleep Outcome Measures).

Non-Custom OAs for OSA

Patient or population: Patients with OSA
Intervention: Non-Custom OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Non-Custom OAs				
AHI/RDI/REI		The mean AHI/RDI in the intervention groups was **6.28 lower** (13.13 to 0.56 lower)		42 (2 studies)	⊕⊖⊖⊖ **low**[1,2]	
Minimum Oxygen Saturation		The mean min oxygen sat. in the intervention groups was **0.29 lower** (3.22 lower to 2.64 higher)		42 (2 studies)	⊕⊕⊕⊖ **moderate**[2]	
Arousal Index				(0 studies)	N/A	
ODI				(0 studies)	N/A	
%REM		The mean %REM in the intervention groups was **5.70 higher** (0.56 lower to 11.96 higher)		19 (1 study)	⊕⊕⊕⊖ **moderate**[2]	
Sleep Efficiency		The mean sleep efficiency in the intervention groups was **0.3 higher** (4.02 lower to 4.62 higher)		42 (2 studies)	⊕⊕⊕⊖ **moderate**[2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 43—Summary of Findings: Custom, Titratable OAs Pre- vs. Post-Treatment of OSA (All Physiologic Sleep Outcome Measures).

Custom, titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom, titratable OAs				
AHI/RDI/REI		The mean AHI/RDI in the intervention groups was **13.80 lower** (15.74 to 11.87 lower)		1054 (27 studies)	⊕⊕⊕⊖ **moderate**[1]	
Minimum Oxygen Saturation		The mean oxygen saturation in the intervention groups was **3.15 higher** (2.46 to 3.84 higher)		847 (20 studies)	⊕⊕⊕⊖ **moderate**[1,2]	
Arousal Index		The mean arousal index in the intervention groups was **10.44 lower** (13.44 to 7.45 lower)		648 (12 studies)	⊕⊕⊕⊖ **moderate**[1]	
ODI		The mean ODI in the intervention groups was **9.95 lower** (16.25 to 3.66 lower)		322 (4 studies)	⊕⊕⊕⊖ **moderate**[1]	
%REM		The mean %REM in the intervention groups was **1.24 higher** (0.09 to 2.56 higher)		551 (14 studies)	⊕⊕⊖⊖ **low**[1,2]	
Sleep Efficiency		The mean sleep efficiency in the intervention groups was **0.87 higher** (0.43 lower to 2.17 higher)		580 (13 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 44—Summary of Findings: Custom, Non-Titratable OAs Pre- vs. Post-Treatment of OSA (All Physiologic Sleep Outcome Measures).

Custom, non-titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, non-titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom, non-titratable OAs				
AHI/RDI/REI		The mean AHI in the intervention groups was **12.51 lower** (15.23 to 9.8 lower)		164 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	
Minimum Oxygen Saturation		The mean min oxygen sat. in the intervention groups was **4.70 higher** (3.83 to 13.22 higher)		57 (3 studies)	⊕⊕⊖⊖ **low**[1,2]	
Arousal Index		The mean arousal index in the intervention groups was **14.59 lower** (12.48 to 16.71 lower)		272 (2 studies)	⊕⊕⊖⊖ **low**[1,2]	
ODI		The mean ODI in the intervention groups was **15.65 lower** (28.86 to 4.44 lower)		77 (3 studies)	⊕⊕⊕⊖ **moderate**[1]	
%REM		The mean %REM in the intervention groups was **0.97 lower** (0.41 to 1.53 lower)		32 (2 studies)	⊕⊕⊕⊖ **moderate**[2]	
Sleep Efficiency		The mean sleep efficiency in the intervention groups was **2.71 higher** (2.32 lower to 7.73 higher)		71 (4 studies)	⊕⊕⊕⊖ **moderate**[2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses the clinical decision threshold

Figure 45—Summary of Findings: OAs vs. CPAP for OSA (All Physiologic Sleep Outcome Measures).

OAs compared to CPAP for OSA

Patient or population: patients with OSA
Intervention: OAs
Comparison: CPAP

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	CPAP	OAs				
AHI/RDI/REI		The mean AHI/RDI in the intervention groups was **6.24 higher** (8.14 to 4.34 higher)		481 (15 studies)	⊕⊕⊕⊖ **moderate**[1]	
Oxygen Saturation		The mean oxygen saturation in the intervention groups was **3.11 lower** (1.74 to 4.48 lower)		354 (9 studies)	⊕⊕⊕⊖ **moderate**[1]	
Arousal Index		The mean arousal index in the intervention groups was **3.57 higher** (5.51 to 1.64 higher)		274 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	
Sleep Efficiency		The mean sleep efficiency in the intervention groups was **0.37 lower** (0.47 higher to 1.21 lower)		191 (5 studies)	⊕⊕⊕⊖ **moderate**[2]	
%REM		The mean %REM in the intervention groups was **0.72 lower** (1.09 higher to 2.52 lower)		244 (8 studies)	⊕⊕⊖⊖ **low**[1,2]	
ODI		The mean ODI in the intervention groups was **4.76 higher** (7.15 to 2.37 higher)		234 (3 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval;

GRADE Working Group quality of evidence.
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 46—OAs for OSA (Epworth Sleepiness Scale; ESS).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Andren 2012	6.7	5.4	36	11	5.4	36	2.9%	-4.30 [-6.79, -1.81]
Barnes 2004	9.2	0.4	85	10.7	0.4	85	6.2%	-1.50 [-1.62, -1.38]
Blanco 2005	5.1	1.9	8	14.7	5.1	8	1.7%	-9.60 [-13.37, -5.83]
Bloch 2000	8.6	2.6	24	13.1	4.8	24	3.3%	-4.50 [-6.68, -2.32]
Bloch 2000	8.9	3.3	24	13.1	4.8	24	3.1%	-4.20 [-6.53, -1.87]
Campbell 2009	9.5	5.1	12	11	5.3	12	1.5%	-1.50 [-5.66, 2.66]
Campbell 2009	7.8	4.5	16	11	5.3	16	2.0%	-3.20 [-6.61, 0.21]
Cunali 2011	11	6	14	12	6	14	1.3%	-1.00 [-5.44, 3.44]
Engleman 2002	12	5	19	13	4	19	2.5%	-1.00 [-3.88, 1.88]
Gagnadoux 2009	7.7	4	59	10.6	4.5	59	4.3%	-2.90 [-4.44, -1.36]
Gauthier 2009	9.9	1.3	16	13.9	1.3	16	5.4%	-4.00 [-4.90, -3.10]
Gauthier 2009	9.3	1.2	16	13.9	1.3	16	5.4%	-4.60 [-5.47, -3.73]
Gauthier 2011	7.7	1	14	13.5	1.5	14	5.3%	-5.80 [-6.74, -4.86]
Ghazal 2009	6.5	5.9	47	7.5	7.4	47	2.6%	-1.00 [-3.71, 1.71]
Ghazal 2009	4.5	3	48	10	5.9	48	3.8%	-5.50 [-7.37, -3.63]
Gotsopoulos 2002	7	1	73	11	5	73	4.9%	-4.00 [-5.17, -2.83]
Hoekema 2007a	5	4.1	20	11	8.2	20	1.6%	-6.00 [-10.02, -1.98]
Hoekema 2007b	6.7	6	9	11.3	7.9	9	0.7%	-4.60 [-11.08, 1.88]
Hoekema 2008a	4.5	5.4	12	12.5	5.9	12	1.3%	-8.00 [-12.53, -3.47]
Hoekema 2008b	6.9	5.5	51	12.9	5.6	51	3.3%	-6.00 [-8.15, -3.85]
Johnston 2002	11.6	6.7	18	13.9	6.4	18	1.4%	-2.30 [-6.58, 1.98]
Lawton 2005	8.5	10.4	15	10	11.8	15	0.5%	-1.50 [-9.46, 6.46]
Lawton 2005	8	10.4	16	10	11.8	16	0.5%	-2.00 [-9.71, 5.71]
Mehta 2001	3.9	0.6	24	10.1	1.1	24	5.9%	-6.20 [-6.70, -5.70]
Naismith 2005	7.1	4.5	73	10.9	4.8	73	4.4%	-3.80 [-5.31, -2.29]
Phillips 2013	7.2	0.4	108	9.1	0.4	108	6.2%	-1.90 [-2.01, -1.79]
Tan 2002	9	5.1	24	13.4	4.6	24	2.6%	-4.40 [-7.15, -1.65]
Tzepizur 2009	8.2	3.7	12	11	4.4	12	2.1%	-2.80 [-6.05, 0.45]
Vanderveken 2008	6	4	23	7	5	23	2.7%	-1.00 [-3.62, 1.62]
Vanderveken 2008	5	4	23	7	5	23	2.7%	-2.00 [-4.62, 0.62]
Zhou 2012	8	2.5	16	11.88	2.68	16	3.9%	-3.88 [-5.68, -2.08]
Zhou 2012	7.88	2.3	16	11.88	2.68	16	4.0%	-4.00 [-5.73, -2.27]
Total (95% CI)			**971**			**971**	**100.0%**	**-3.81 [-4.39, -3.23]**

Heterogeneity: Tau² = 1.42; Chi² = 551.58, df = 31 (P < 0.00001); I² = 94%
Test for overall effect: Z = 12.84 (P < 0.00001)

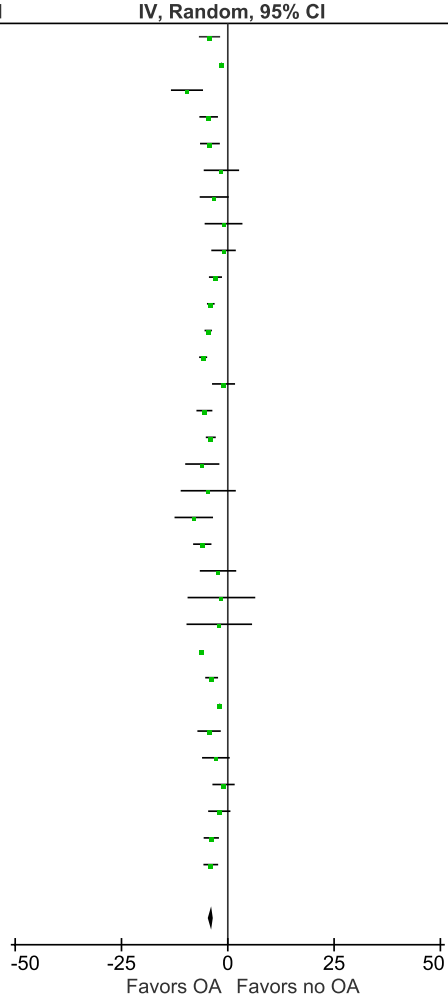


Figure 47—Custom OAs for OSA (ESS).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Andren 2012	6.7	5.4	36	11	5.4	36	0.1%	-4.30 [-6.79, -1.81]
Barnes 2004	9.2	0.4	85	10.7	0.4	85	40.9%	-1.50 [-1.62, -1.38]
Blanco 2005	5.1	1.9	8	14.7	5.1	8	0.0%	-9.60 [-13.37, -5.83]
Bloch 2000	8.9	3.3	24	13.1	4.8	24	0.1%	-4.20 [-6.53, -1.87]
Bloch 2000	8.6	2.6	24	13.1	4.8	24	0.1%	-4.50 [-6.68, -2.32]
Campbell 2009	9.5	5.1	12	11	5.3	12	0.0%	-1.50 [-5.66, 2.66]
Campbell 2009	7.8	4.5	16	11	5.3	16	0.1%	-3.20 [-6.61, 0.21]
Cunali 2011	11	6	14	12	6	14	0.0%	-1.00 [-5.44, 3.44]
Engleman 2002	12	5	19	13	4	19	0.1%	-1.00 [-3.88, 1.88]
Gagnadoux 2009	7.7	4	59	10.6	4.5	59	0.3%	-2.90 [-4.44, -1.36]
Gauthier 2009	9.9	1.3	16	13.9	1.3	16	0.7%	-4.00 [-4.90, -3.10]
Gauthier 2009	9.3	1.2	16	13.9	1.3	16	0.8%	-4.60 [-5.47, -3.73]
Gauthier 2011	7.7	1	14	13.5	1.5	14	0.7%	-5.80 [-6.74, -4.86]
Ghazal 2009	6.5	5.9	47	7.5	7.4	47	0.1%	-1.00 [-3.71, 1.71]
Ghazal 2009	4.5	3	48	10	5.9	48	0.2%	-5.50 [-7.37, -3.63]
Gotsopoulos 2002	7	1	73	11	5	73	0.4%	-4.00 [-5.17, -2.83]
Hoekema 2007a	5	4.1	20	11	8.2	20	0.0%	-6.00 [-10.02, -1.98]
Hoekema 2007b	6.7	6	9	11.3	7.9	9	0.0%	-4.60 [-11.08, 1.88]
Hoekema 2008a	4.5	5.4	12	12.5	5.9	12	0.0%	-8.00 [-12.53, -3.47]
Hoekema 2008b	6.9	5.5	51	12.9	5.6	51	0.1%	-6.00 [-8.15, -3.85]
Johnston 2002	11.6	6.7	18	13.9	6.4	18	0.0%	-2.30 [-6.58, 1.98]
Lawton 2005	8.5	10.4	15	10	11.8	15	0.0%	-1.50 [-9.46, 6.46]
Lawton 2005	8	10.4	16	10	11.8	16	0.0%	-2.00 [-9.71, 5.71]
Mehta 2001	3.9	0.6	24	10.1	1.1	24	2.4%	-6.20 [-6.70, -5.70]
Naismith 2005	7.1	4.5	73	10.9	4.8	73	0.3%	-3.80 [-5.31, -2.29]
Phillips 2013	7.2	0.4	108	9.1	0.4	108	52.0%	-1.90 [-2.01, -1.79]
Tan 2002	9	5.1	24	13.4	4.6	24	0.1%	-4.40 [-7.15, -1.65]
Tzepizur 2009	8.2	3.7	12	11	4.4	12	0.1%	-2.80 [-6.05, 0.45]
Vanderveken 2008	5	4	23	7	5	23	0.1%	-2.00 [-4.62, 0.62]
Zhou 2012	7.88	2.3	16	11.88	2.68	16	0.2%	-4.00 [-5.73, -2.27]
Zhou 2012	8	2.5	16	11.88	2.68	16	0.2%	-3.88 [-5.68, -2.08]
Total (95% CI)			**948**			**948**	**100.0%**	**-1.95 [-2.03, -1.88]**

Heterogeneity: Chi² = 551.07, df = 30 (P < 0.00001); I² = 95%
Test for overall effect: Z = 49.75 (P < 0.00001)

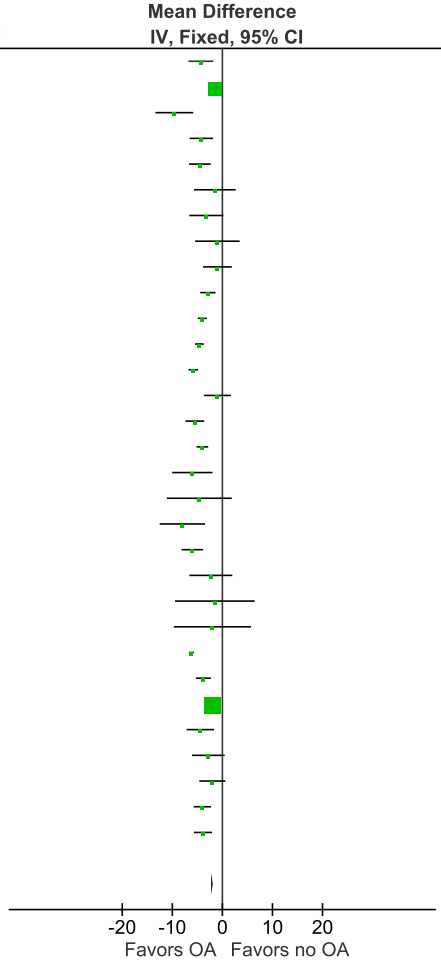
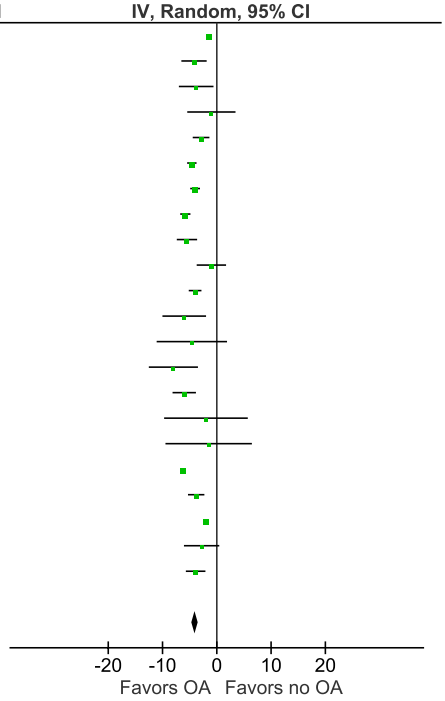


Figure 48—Custom, Titratable OAs for OSA (ESS).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	9.2	0.4	85	10.7	0.4	85	8.3%	-1.50 [-1.62, -1.38]
Bloch 2000	8.9	3.3	24	13.1	4.8	24	4.1%	-4.20 [-6.53, -1.87]
Campbell 2009	7.8	4.5	16	11.6	4.7	16	2.9%	-3.80 [-6.99, -0.61]
Cunali 2011	11	6	14	12	6	14	1.8%	-1.00 [-5.44, 3.44]
Gagnadoux 2009	7.7	4	59	10.6	4.5	59	5.8%	-2.90 [-4.44, -1.36]
Gauthier 2009	9.3	1.2	16	13.9	1.3	16	7.3%	-4.60 [-5.47, -3.73]
Gauthier 2009	9.9	1.3	16	13.9	1.3	16	7.2%	-4.00 [-4.90, -3.10]
Gauthier 2011	7.7	1	14	13.5	1.5	14	7.1%	-5.80 [-6.74, -4.86]
Ghazal 2009	4.5	3	48	10	5.9	48	5.0%	-5.50 [-7.37, -3.63]
Ghazal 2009	6.5	5.9	47	7.5	7.4	47	3.5%	-1.00 [-3.71, 1.71]
Gotsopoulos 2002	7	1	73	11	5	73	6.6%	-4.00 [-5.17, -2.83]
Hoekema 2007a	5	4.1	20	11	8.2	20	2.1%	-6.00 [-10.02, -1.98]
Hoekema 2007b	6.7	6	9	11.3	7.9	9	0.9%	-4.60 [-11.08, 1.88]
Hoekema 2008a	4.5	5.4	12	12.5	5.9	12	1.7%	-8.00 [-12.53, -3.47]
Hoekema 2008b	6.9	5.5	51	12.9	5.6	51	4.4%	-6.00 [-8.15, -3.85]
Lawton 2005	8	10.4	16	10	11.8	16	0.7%	-2.00 [-9.71, 5.71]
Lawton 2005	8.5	10.4	15	10	11.8	15	0.6%	-1.50 [-9.46, 6.46]
Mehta 2001	3.9	0.6	24	10.1	1.1	24	7.9%	-6.20 [-6.70, -5.70]
Naismith 2005	7.1	4.5	73	10.9	4.8	73	5.8%	-3.80 [-5.31, -2.29]
Phillips 2013	7.2	0.4	108	9.1	0.4	108	8.3%	-1.90 [-2.01, -1.79]
Trzepizur 2009	8.2	3.7	12	11	4.4	12	2.8%	-2.80 [-6.05, 0.45]
Zhou 2012	8	2.5	16	11.9	2.7	16	5.2%	-3.90 [-5.70, -2.10]
Total (95% CI)			**768**			**768**	**100.0%**	**-3.95 [-4.61, -3.28]**

Heterogeneity: Tau² = 1.39; Chi² = 518.43, df = 21 (P < 0.00001); I² = 96%
Test for overall effect: Z = 11.61 (P < 0.00001)



Attachment #32

Figure 49—Custom, Non-Titratable OAs for OSA (ESS).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Andren 2012	6.7	5.4	36	11	5.4	36	23.0%	-4.30 [-6.79, -1.81]
Johnston 2002	11.6	6.7	18	13.9	6.4	45	11.0%	-2.30 [-5.92, 1.32]
Tegelberg 2012	6.8	4.5	45	11.2	4.1	45	45.1%	-4.40 [-6.18, -2.62]
Vanderveken 2008	5	4	23	7	5	23	20.9%	-2.00 [-4.62, 0.62]
Total (95% CI)			**122**			**149**	**100.0%**	**-3.65 [-4.84, -2.45]**

Heterogeneity: Tau² = 0.00; Chi² = 3.01, df = 3 (P = 0.39); I² = 0%
Test for overall effect: Z = 5.97 (P < 0.00001)

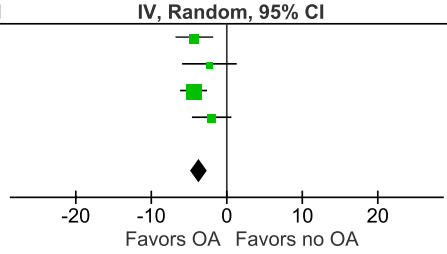


Figure 50—OAs vs. CPAP for OSA (ESS).

Study or Subgroup	OA Mean	SD	Total	CPAP Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	9.2	0.4	85	9.2	0.4	89	44.1%	0.00 [-0.12, 0.12]
Engleman 2002	12	5	19	8	5	29	1.0%	4.00 [1.11, 6.89]
Gagnadoux 2009	7.7	4	59	8.2	3.9	59	4.0%	-0.50 [-1.93, 0.93]
Hoekema 2007a	5	4.1	20	5	6.7	27	0.9%	0.00 [-3.10, 3.10]
Hoekema 2007b	6.7	6	9	5.5	4.1	10	0.4%	1.20 [-3.47, 5.87]
Hoekema 2008a	4.5	5.4	12	5	5.2	13	0.5%	-0.50 [-4.66, 3.66]
Hoekema 2008b	6.9	5.5	49	5.9	4.8	50	2.1%	1.00 [-1.04, 3.04]
Phillips 2013	7.2	0.4	108	7.5	0.4	108	44.7%	-0.30 [-0.41, -0.19]
Tan 2002	9	5.1	24	8.1	4.1	24	1.3%	0.90 [-1.72, 3.52]
Tzepizur 2009	8.2	3.7	12	8.8	3.7	12	1.0%	-0.60 [-3.56, 2.36]
Total (95% CI)			**397**			**421**	**100.0%**	**-0.08 [-0.38, 0.21]**

Heterogeneity: Tau² = 0.05; Chi² = 24.06, df = 9 (P = 0.004); I² = 63%
Test for overall effect: Z = 0.55 (P = 0.58)

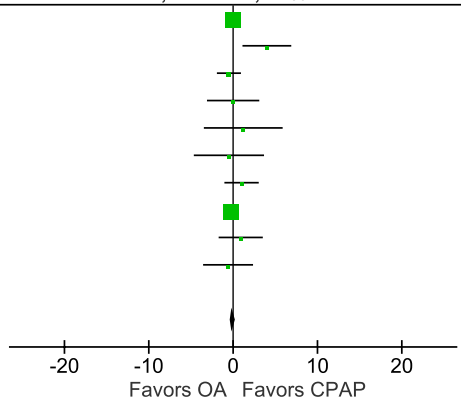


Figure 51—Summary of Findings: OAs Pre- vs. Post-Treatment for OSA (ESS).

OAs for OSA

Patient or population: Patients with OSA
Intervention: OAs

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk	Corresponding risk	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Control	**OAs**				
ESS (Daytime sleepiness)		The mean ESS in the intervention groups was **3.81 lower** (4.39 to 3.23 lower)		971 (25 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 52—Summary of Findings: Custom OAs for OSA (ESS).

Custom OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom OAs				
ESS (Daytime sleepiness)		The mean ESS in the intervention groups was **1.95 lower** (2.03 to 1.88 lower)		948 (25 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 53—Summary of Findings: Non-Custom OAs for OSA (ESS).

Non-custom OAs for OSA

Patient or population: Patients with OSA
Intervention: Non-custom OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Non-custom OAs				
ESS (Daytime sleepiness)		The mean ESS in the intervention groups was **1.00 lower** (3.62 lower to 1.62 higher)		23 (1 study)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] CI of absolute effect crosses clinical decision threshold

Figure 54—Summary of Findings: Custom, Titratable OAs for OSA (ESS).

Custom, titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom, titratable OAs				
ESS (Daytime sleepiness)		The mean ESS in the intervention groups was **3.95 lower** (4.61 to 3.28 lower)		768 (19 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 55—Summary of Findings: Custom, Non-Titratable OAs for OSA (ESS).

Custom, non-titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, non-titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**Custom, non-titratable OAs**				
ESS (Daytime sleepiness)		The mean ESS in the intervention groups was **3.65 lower** (5.18 to 2.13 lower)		156 (8 studies)	⊕⊕⊕⊕ **high**	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

Figure 56—Summary of Findings: OAs vs. CPAP for OSA (ESS).

OAs compared to CPAP for OSA

Patient or population: patients with OSA
Intervention: OAs
Comparison: CPAP

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	CPAP	**OAs**				
ESS (Daytime sleepiness)		The mean ESS in the intervention groups was **0.08 lower** (0.21 higher to 0.38 lower)		397 (10 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval;

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses the clinical decision threshold

Figure 57—OAs for OSA (Quality of Life, QOL; Short Form-36, SF-36).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	73.7	1.2	85	69.4	1.3	85	4.2%	4.30 [3.92, 4.68]
Blanco 2005	67	21.3	8	70.3	38.7	8	0.2%	-3.30 [-33.91, 27.31]
Blanco 2005	78.2	12.4	8	78.3	13.6	8	0.9%	-0.10 [-12.85, 12.65]
Blanco 2005	74.1	18.4	8	70.7	16.4	8	0.5%	3.40 [-13.68, 20.48]
Blanco 2005	61	20.7	8	60.7	22	8	0.4%	0.30 [-20.63, 21.23]
Blanco 2005	87.5	30.6	8	83.4	30.2	8	0.2%	4.10 [-25.69, 33.89]
Blanco 2005	77.7	46.6	8	81	37.7	8	0.1%	-3.30 [-44.84, 38.24]
Blanco 2005	50.7	8.4	8	49.3	18.8	8	0.7%	1.40 [-12.87, 15.67]
Blanco 2005	59.4	19.2	8	60.1	19.3	8	0.4%	-0.70 [-19.56, 18.16]
Cunali 2011	66	28	29	66	28	29	0.7%	0.00 [-14.41, 14.41]
Cunali 2011	54	40	29	32	34	29	0.4%	22.00 [2.89, 41.11]
Cunali 2011	51	26	29	44	21	29	0.9%	7.00 [-5.16, 19.16]
Cunali 2011	59	20	29	54	24	29	1.0%	5.00 [-6.37, 16.37]
Cunali 2011	44	19	29	31	15	29	1.5%	13.00 [4.19, 21.81]
Cunali 2011	76	28	29	58	29	29	0.7%	18.00 [3.33, 32.67]
Cunali 2011	59	44	29	40	40	29	0.3%	19.00 [-2.64, 40.64]
Cunali 2011	57	22	29	48	48	29	0.4%	9.00 [-10.22, 28.22]
Engleman 2002	45	10	19	49	6	19	2.5%	-4.00 [-9.24, 1.24]
Engleman 2002	48	11	19	45	12	19	1.9%	3.00 [-4.32, 10.32]
Ghazal 2009	73.2	8.6	47	69.4	14.1	47	2.8%	3.80 [-0.92, 8.52]
Ghazal 2009	80	6.6	48	73.5	13.2	48	3.0%	6.50 [2.33, 10.67]
Hoekema 2008b	67.3	42.5	49	40.7	40.3	51	0.6%	26.60 [10.35, 42.85]
Hoekema 2008b	78.8	21.5	49	71.8	23.3	51	1.5%	7.00 [-1.78, 15.78]
Hoekema 2008b	74	27.5	49	39.7	24.6	51	1.2%	34.30 [24.06, 44.54]
Hoekema 2008b	79.9	26.5	49	75.4	26.6	51	1.2%	4.50 [-5.91, 14.91]
Hoekema 2008b	63.8	21.2	49	39	18.6	51	1.7%	24.80 [16.97, 32.63]
Hoekema 2008b	78.9	37.1	49	70.6	41.5	51	0.6%	8.30 [-7.12, 23.72]
Hoekema 2008b	65.5	20.6	49	57.6	21.3	51	1.6%	7.90 [-0.31, 16.11]
Hoekema 2008b	77.5	16.5	49	70.9	17.8	51	2.0%	6.60 [-0.12, 13.32]
Hoekema 2008b	79.7	21.4	49	66.4	22.9	51	1.5%	13.30 [4.62, 21.98]
Lawton 2005	47.5	12.3	16	47	11.1	16	1.6%	0.50 [-7.62, 8.62]
Lawton 2005	45	9.9	16	47	11.1	16	1.9%	-2.00 [-9.29, 5.29]
Lawton 2005	68.9	18.7	16	74.4	21.5	16	0.7%	-5.50 [-19.46, 8.46]
Lawton 2005	66	11.8	16	68	10.9	16	1.7%	-2.00 [-9.87, 5.87]
Lawton 2005	70	18.8	16	68	10.9	16	1.1%	2.00 [-8.65, 12.65]
Lawton 2005	80.6	1.8	16	71.5	2.2	16	4.0%	9.10 [7.71, 10.49]
Lawton 2005	62	12.8	16	59.5	15.2	16	1.3%	2.50 [-7.24, 12.24]
Lawton 2005	187.5	18.5	16	175	24.7	16	0.7%	12.50 [-2.62, 27.62]
Lawton 2005	50	18.5	16	50	12.3	16	1.1%	0.00 [-10.89, 10.89]
Lawton 2005	68.9	12.1	16	66.7	14.8	16	1.4%	2.20 [-7.17, 11.57]
Lawton 2005	72.5	19.8	16	70	19.8	16	0.8%	2.50 [-11.22, 16.22]
Lawton 2005	200	8.2	16	200	24.7	16	0.9%	0.00 [-12.75, 12.75]
Lawton 2005	66.7	14.8	16	66.7	14.8	16	1.2%	0.00 [-10.26, 10.26]
Lawton 2005	50	12.3	16	50	12.3	16	1.5%	0.00 [-8.52, 8.52]
Lawton 2005	200	24.7	16	175	24.7	16	0.5%	25.00 [7.88, 42.12]
Lawton 2005	200	24.7	16	200	24.7	16	0.5%	0.00 [-17.12, 17.12]
Lawton 2005	65	19.8	16	70	19.8	16	0.8%	-5.00 [-18.72, 8.72]
Lawton 2005	75.5	19.2	16	74.4	21.5	16	0.7%	1.10 [-13.02, 15.22]
Phillips 2013	74.4	1.6	108	68.1	1.8	108	4.2%	6.30 [5.85, 6.75]
Phillips 2013	81.6	2.9	108	65.1	4	108	4.1%	16.50 [15.57, 17.43]
Phillips 2013	60.1	2	108	48.9	2.1	108	4.2%	11.20 [10.65, 11.75]
Phillips 2013	84.7	1.9	108	82.3	1.8	108	4.2%	2.40 [1.91, 2.89]
Phillips 2013	80.6	1.8	108	71.5	2.2	108	4.2%	9.10 [8.56, 9.64]
Phillips 2013	81	1.9	108	76.5	2.2	108	4.2%	4.50 [3.95, 5.05]
Phillips 2013	67.4	2	108	63.1	2	108	4.2%	4.30 [3.77, 4.83]
Phillips 2013	84.8	1.8	108	77.6	2.3	108	4.2%	7.20 [6.65, 7.75]
Phillips 2013	79.9	2.9	108	70.4	3.4	108	4.1%	9.50 [8.66, 10.34]
Phillips 2013	75.3	1.5	108	71.7	1.5	108	4.2%	3.60 [3.20, 4.00]
Total (95% CI)			**2323**			**2341**	**100.0%**	**6.41 [5.08, 7.75]**

Heterogeneity: Tau² = 10.99; Chi² = 1675.31, df = 57 (P < 0.00001); I² = 97%
Test for overall effect: Z = 9.43 (P < 0.00001)

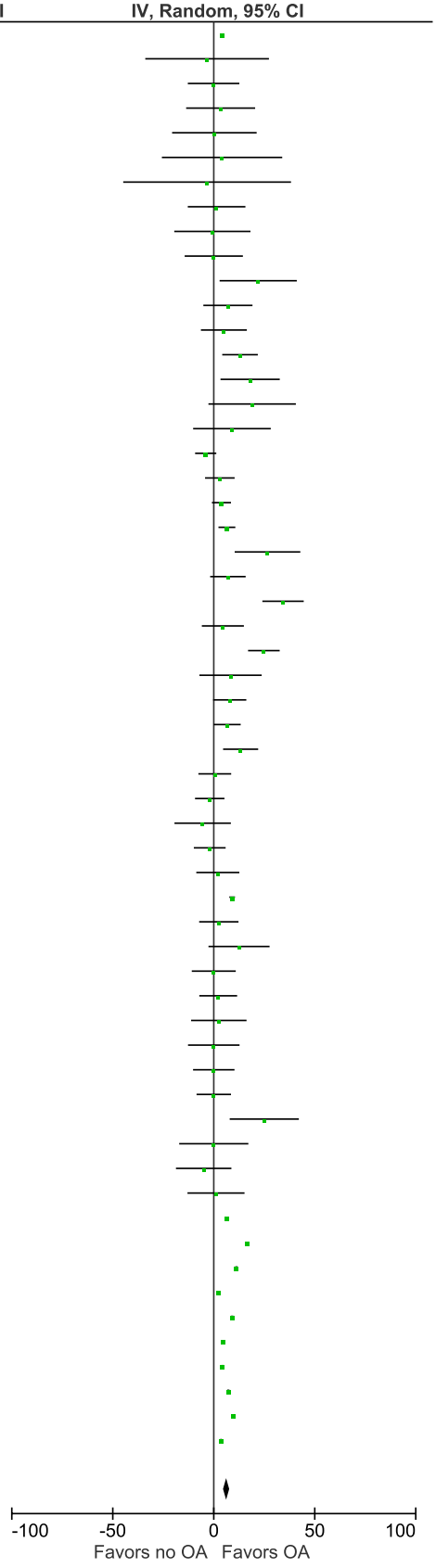


Figure 58—Custom, Titratable OAs for OSA (QOL; SF-36).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	73.7	1.2	85	69.4	1.3	85	4.8%	4.30 [3.92, 4.68]
Cunali 2011	54	40	29	32	34	29	0.5%	22.00 [2.89, 41.11]
Cunali 2011	66	28	29	66	28	29	0.8%	0.00 [-14.41, 14.41]
Cunali 2011	59	20	29	54	24	29	1.2%	5.00 [-6.37, 16.37]
Cunali 2011	51	26	29	44	21	29	1.1%	7.00 [-5.16, 19.16]
Cunali 2011	76	28	29	58	29	29	0.8%	18.00 [3.33, 32.67]
Cunali 2011	44	19	29	31	15	29	1.7%	13.00 [4.19, 21.81]
Cunali 2011	59	44	29	40	40	29	0.4%	19.00 [-2.64, 40.64]
Cunali 2011	57	22	29	48	48	29	0.5%	9.00 [-10.22, 28.22]
Ghazal 2009	80	6.6	48	73.5	13.2	48	3.4%	6.50 [2.33, 10.67]
Ghazal 2009	73.2	8.6	47	69.4	14.1	47	3.1%	3.80 [-0.92, 8.52]
Hoekema 2008b	63.8	21.2	49	39	18.6	51	2.0%	24.80 [16.97, 32.63]
Hoekema 2008b	78.9	37.1	49	70.6	41.5	51	0.7%	8.30 [-7.12, 23.72]
Hoekema 2008b	79.7	21.4	49	66.4	22.9	51	1.7%	13.30 [4.62, 21.98]
Hoekema 2008b	78.8	21.5	49	71.8	23.3	51	1.7%	7.00 [-1.78, 15.78]
Hoekema 2008b	77.5	16.5	49	70.9	17.8	51	2.3%	6.60 [-0.12, 13.32]
Hoekema 2008b	79.9	26.5	49	75.4	26.6	51	1.3%	4.50 [-5.91, 14.91]
Hoekema 2008b	74	27.5	49	39.7	24.6	51	1.4%	34.30 [24.06, 44.54]
Hoekema 2008b	65.5	20.6	49	57.6	21.3	51	1.8%	7.90 [-0.31, 16.11]
Hoekema 2008b	67.3	42.5	49	40.7	40.3	51	0.7%	26.60 [10.35, 42.85]
Lawton 2005	72.5	19.8	16	70	19.8	16	0.9%	2.50 [-11.22, 16.22]
Lawton 2005	75.5	19.2	16	74.4	21.5	16	0.8%	1.10 [-13.02, 15.22]
Lawton 2005	70	18.8	16	68	10.9	16	1.3%	2.00 [-8.65, 12.65]
Lawton 2005	200	24.7	16	175	24.7	16	0.6%	25.00 [7.88, 42.12]
Lawton 2005	187.5	18.5	16	175	24.7	16	0.7%	12.50 [-2.62, 27.62]
Lawton 2005	68.9	12.1	16	66.7	14.8	16	1.6%	2.20 [-7.17, 11.57]
Lawton 2005	47.5	12.3	16	47	11.1	16	1.9%	0.50 [-7.62, 8.62]
Lawton 2005	62	12.8	16	59.5	15.2	16	1.5%	2.50 [-7.24, 12.24]
Lawton 2005	65	19.8	16	70	19.8	16	0.9%	-5.00 [-18.72, 8.72]
Lawton 2005	200	8.2	16	200	24.7	16	1.0%	0.00 [-12.75, 12.75]
Lawton 2005	67.8	10.4	16	66.7	14.8	16	1.7%	1.10 [-7.76, 9.96]
Lawton 2005	68.9	18.7	16	74.4	21.5	16	0.9%	-5.50 [-19.46, 8.46]
Lawton 2005	200	24.7	16	200	24.7	16	0.6%	0.00 [-17.12, 17.12]
Lawton 2005	53.5	16.4	16	59.5	15.2	16	1.2%	-6.00 [-16.96, 4.96]
Lawton 2005	66	11.5	16	68	10.9	16	2.0%	-2.00 [-9.76, 5.76]
Lawton 2005	45	9.9	16	47	11.1	16	2.1%	-2.00 [-9.29, 5.29]
Lawton 2005	50	12.3	16	50	18.5	16	1.3%	0.00 [-10.89, 10.89]
Phillips 2013	81.6	2.9	108	65.1	4	108	4.7%	16.50 [15.57, 17.43]
Phillips 2013	74.4	1.6	108	68.1	1.8	108	4.8%	6.30 [5.85, 6.75]
Phillips 2013	75.3	1.5	108	71.7	1.5	108	4.8%	3.60 [3.20, 4.00]
Phillips 2013	81	1.9	108	76.5	2.2	108	4.7%	4.50 [3.95, 5.05]
Phillips 2013	79.9	2.9	108	70.4	3.4	108	4.7%	9.50 [8.66, 10.34]
Phillips 2013	60.1	2	108	48.9	2.1	108	4.7%	11.20 [10.65, 11.75]
Phillips 2013	67.4	2	108	63.1	2	108	4.7%	4.30 [3.77, 4.83]
Phillips 2013	84.7	1.9	108	82.3	1.8	108	4.7%	2.40 [1.91, 2.89]
Phillips 2013	84.8	1.8	108	77.6	2.3	108	4.7%	7.20 [6.65, 7.75]
Phillips 2013	80.6	1.8	108	71.5	2.2	108	4.7%	9.10 [8.56, 9.64]
Total (95% CI)			**2205**			**2223**	**100.0%**	**6.84 [5.42, 8.26]**

Heterogeneity: Tau² = 11.02; Chi² = 1641.34, df = 46 (P < 0.00001); I² = 97%
Test for overall effect: Z = 9.43 (P < 0.00001)

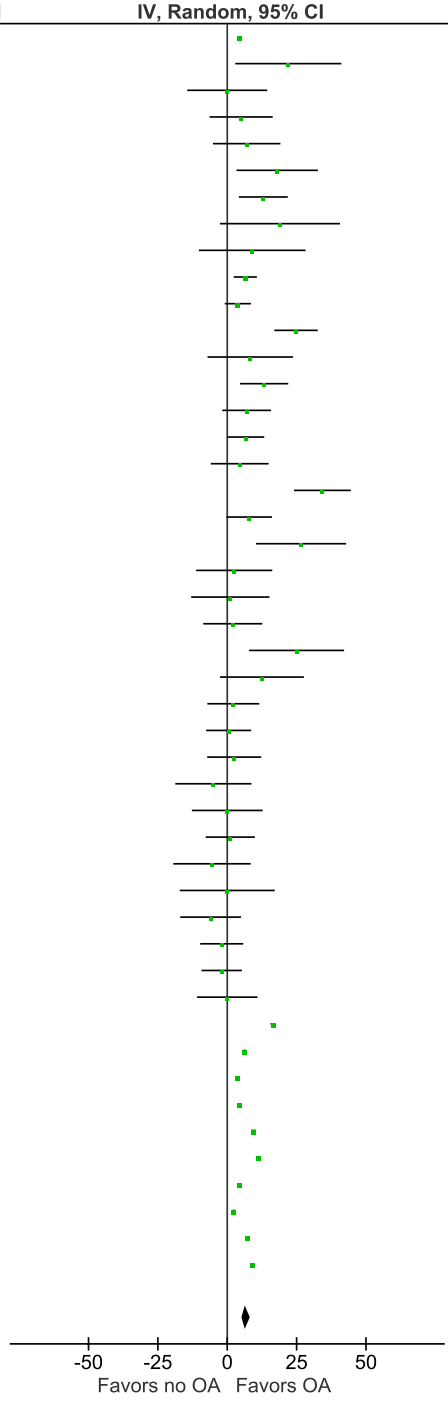


Figure 59—Custom, Non-Titratable OAs for OSA (QOL; SF-36).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Blanco 2005	50.7	8.4	8	49.3	18.8	8	6.3%	1.40 [-12.87, 15.67]
Blanco 2005	78.2	12.4	8	78.3	13.6	8	7.9%	-0.10 [-12.85, 12.65]
Blanco 2005	59.4	19.2	8	60.1	19.3	8	3.6%	-0.70 [-19.56, 18.16]
Blanco 2005	74.1	18.4	8	70.7	16.4	8	4.4%	3.40 [-13.68, 20.48]
Blanco 2005	67	21.3	8	70.3	38.7	8	1.4%	-3.30 [-33.91, 27.31]
Blanco 2005	61	20.7	8	60.7	22	8	2.9%	0.30 [-20.63, 21.23]
Blanco 2005	77.7	46.6	8	81	37.7	8	0.7%	-3.30 [-44.84, 38.24]
Blanco 2005	87.5	30.6	8	83.4	30.2	8	1.5%	4.10 [-25.69, 33.89]
Engleman 2002	45	10	19	49	6	19	47.0%	-4.00 [-9.24, 1.24]
Engleman 2002	48	11	19	45	12	19	24.1%	3.00 [-4.32, 10.32]
Total (95% CI)			**102**			**102**	**100.0%**	**-0.95 [-4.55, 2.64]**

Heterogeneity: Tau² = 0.00; Chi² = 2.95, df = 9 (P = 0.97); I² = 0%
Test for overall effect: Z = 0.52 (P = 0.60)

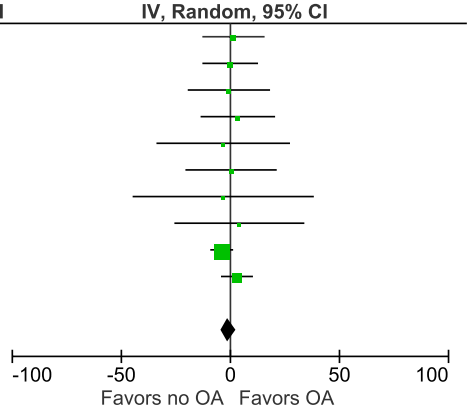


Figure 60—OAs vs. CPAP for OSA (QOL; SF-36).

Study or Subgroup	CPAP Mean	SD	Total	OA Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	73.7	1.2	85	74.1	1.2	89	7.8%	-0.40 [-0.76, -0.04]
Engleman 2002	47	10	29	45	10	19	2.4%	2.00 [-3.78, 7.78]
Engleman 2002	52	10	29	48	11	19	2.2%	4.00 [-2.14, 10.14]
Hoekema 2008b	67.3	42.5	49	71.5	40.4	50	0.4%	-4.20 [-20.54, 12.14]
Hoekema 2008b	78.9	37.1	49	77.2	38	50	0.5%	1.70 [-13.09, 16.49]
Hoekema 2008b	79.9	26.5	49	82.3	23.9	50	1.0%	-2.40 [-12.35, 7.55]
Hoekema 2008b	63.8	21.2	49	61.3	19.9	50	1.4%	2.50 [-5.60, 10.60]
Hoekema 2008b	77.5	16.5	49	75	16.2	50	2.1%	2.50 [-3.94, 8.94]
Hoekema 2008b	78.8	21.5	49	80.6	18.5	50	1.5%	-1.80 [-9.71, 6.11]
Hoekema 2008b	79.7	21.4	49	78.6	21.1	50	1.4%	1.10 [-7.27, 9.47]
Hoekema 2008b	65.5	20.6	49	60.9	23.4	50	1.3%	4.60 [-4.08, 13.28]
Hoekema 2008b	74	27.5	49	73.5	26.4	50	0.9%	0.50 [-10.12, 11.12]
Phillips 2013	67.4	2	108	65.7	1.9	108	7.7%	1.70 [1.18, 2.22]
Phillips 2013	81.6	2.9	108	78.8	3.3	108	7.5%	2.80 [1.97, 3.63]
Phillips 2013	81	1.9	108	76.2	2.1	108	7.7%	4.80 [4.27, 5.33]
Phillips 2013	79.9	2.9	108	81.7	3.2	108	7.5%	-1.80 [-2.61, -0.99]
Phillips 2013	60.1	2	108	56.3	2.2	108	7.7%	3.80 [3.24, 4.36]
Phillips 2013	84.8	1.8	108	79.7	2.2	108	7.7%	5.10 [4.56, 5.64]
Phillips 2013	74.4	1.6	108	72.6	1.7	108	7.8%	1.80 [1.36, 2.24]
Phillips 2013	80.6	1.8	108	77.1	2	108	7.7%	3.50 [2.99, 4.01]
Phillips 2013	84.7	1.9	108	83.7	1.9	108	7.7%	1.00 [0.49, 1.51]
Phillips 2013	75.3	1.5	108	72.6	1.6	108	7.8%	2.70 [2.29, 3.11]
Total (95% CI)			**1664**			**1657**	**100.0%**	**2.18 [1.10, 3.25]**

Heterogeneity: Tau² = 3.84; Chi² = 595.43, df = 21 (P < 0.00001); I² = 96%
Test for overall effect: Z = 3.95 (P < 0.0001)

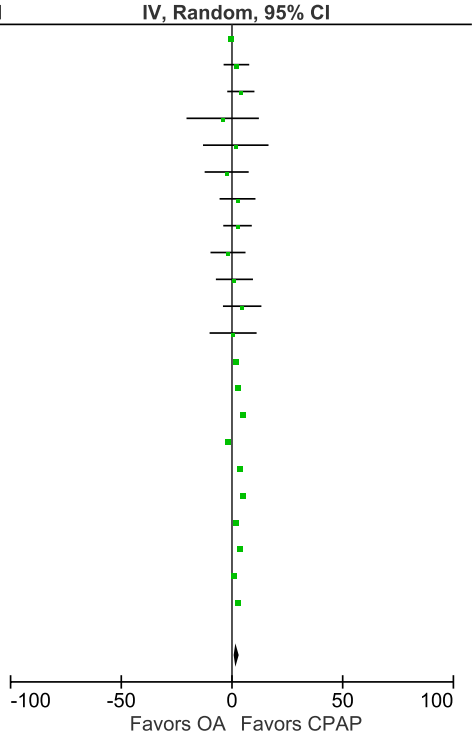


Figure 61—Summary of Findings: OAs Pre- vs. Post-Treatment for OSA (Quality of Life; QOL).

OAs for OSA

Patient or population: Patients with OSA
Intervention: OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**OAs**				
QOL		The mean QOL in the intervention groups was **6.41 higher** (5.08 to 7.75 higher)		2323 (8 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 62—Summary of Findings: Custom, Titratable OAs for OSA (QOL).

Custom, titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**Custom, titratable OAs**				
QOL		The mean QOL in the intervention groups was **6.84 higher** (5.42 to 8.26 higher)		2205 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 63—Summary of Findings: Custom, Non-Titratable OAs for OSA (QOL).

Custom, non-titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, non-titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	**Custom, non-titratable OAs**				
QOL		The mean QOL in the intervention groups was **0.95 lower** (4.55 lower to 2.64 higher)		102 (2 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 64—Summary of Findings: OAs vs. CPAP for OSA (QOL).

OAs compared to CPAP for OSA

Patient or population: patients with OSA
Intervention: OAs
Comparison: CPAP

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	CPAP	OAs				
QOL		The mean QOL in the intervention groups was 2.18 lower (1.1 to 3.25 lower)		1664 (4 studies)	⊕⊕⊖⊖ low[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval;

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 65—OAs for OSA (Systolic blood pressure).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Andren 2012	134.6	10.4	36	136.9	10.8	36	4.2%	-2.30 [-7.20, 2.60]
Barnes 2004	126.7	1	80	126.5	1	80	19.0%	0.20 [-0.11, 0.51]
Gauthier 2009	123.6	1.7	16	127.3	2.8	16	13.9%	-3.70 [-5.31, -2.09]
Gauthier 2009	123	2.2	16	127.3	2.8	16	13.2%	-4.30 [-6.04, -2.56]
Gauthier 2011	123.7	2.4	14	128	3.2	14	11.6%	-4.30 [-6.40, -2.20]
Gotsopoulos 2004	125.2	1.3	61	127.3	1.3	61	18.6%	-2.10 [-2.56, -1.64]
Phillips 2013	123.9	1.1	108	123.9	1.2	108	19.0%	0.00 [-0.31, 0.31]
Trzepizur 2009	140	22.2	12	150	11.1	12	0.6%	-10.00 [-24.04, 4.04]
Total (95% CI)			**343**			**343**	**100.0%**	**-2.09 [-3.22, -0.96]**

Heterogeneity: Tau² = 1.73; Chi² = 124.02, df = 7 (P < 0.00001); I² = 94%
Test for overall effect: Z = 3.62 (P = 0.0003)

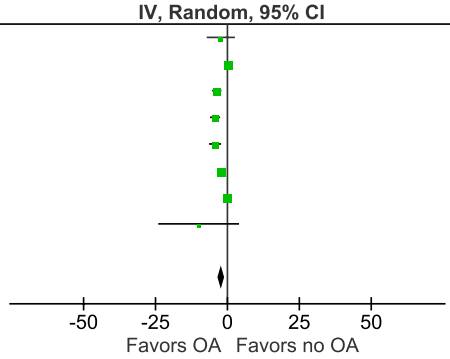


Figure 66—OAs for OSA (Diastolic blood pressure).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Andren 2012	81.6	8.7	36	83.8	8.7	36	5.4%	-2.20 [-6.22, 1.82]
Barnes 2004	76.3	0.7	80	76.3	0.8	80	18.1%	0.00 [-0.23, 0.23]
Gauthier 2009	84.6	2.3	16	91	2.7	16	12.7%	-6.40 [-8.14, -4.66]
Gauthier 2009	85	1.9	16	91	2.7	16	13.2%	-6.00 [-7.62, -4.38]
Gauthier 2011	81.9	2.3	14	92	3	14	11.6%	-10.10 [-12.08, -8.12]
Gotsopoulos 2004	76.2	0.9	61	77.7	0.9	61	18.0%	-1.50 [-1.82, -1.18]
Phillips 2013	77.1	0.7	108	77.3	0.8	108	18.2%	-0.20 [-0.40, 0.00]
Trzepizur 2009	63	5.2	12	61	9.6	12	2.8%	2.00 [-4.18, 8.18]
Total (95% CI)			**343**			**343**	**100.0%**	**-3.15 [-4.26, -2.03]**

Heterogeneity: Tau² = 1.78; Chi² = 244.23, df = 7 (P < 0.00001); I² = 97%
Test for overall effect: Z = 5.52 (P < 0.00001)

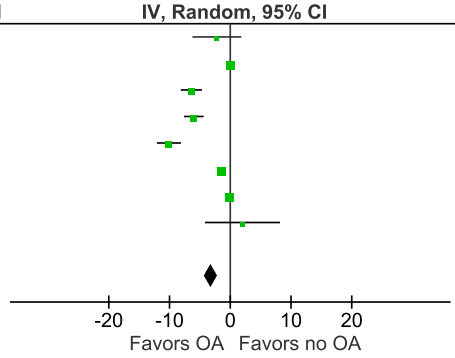


Figure 67—Custom, Titratable OAs for OSA (Systolic blood pressure).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	126.7	1	80	126.5	1	80	18.8%	0.20 [-0.11, 0.51]
Gauthier 2009	123	2.2	16	127.3	2.8	16	13.4%	-4.30 [-6.04, -2.56]
Gauthier 2009	123.6	1.7	16	127.3	2.8	16	14.0%	-3.70 [-5.31, -2.09]
Gauthier 2011	123.7	2.4	14	128	3.2	14	11.8%	-4.30 [-6.40, -2.20]
Gotsopolous 2004	125.2	1.3	61	127.3	1.3	61	18.5%	-2.10 [-2.56, -1.64]
Phillips 2013	123.9	1.1	108	123.9	1.2	108	18.8%	0.00 [-0.31, 0.31]
Trzepizur 2009	140.5	7.4	12	149.3	3.7	12	4.7%	-8.80 [-13.48, -4.12]
Total (95% CI)			**307**			**307**	**100.0%**	**-2.37 [-3.55, -1.20]**

Heterogeneity: Tau² = 1.89; Chi² = 133.93, df = 6 (P < 0.00001); I² = 96%
Test for overall effect: Z = 3.95 (P < 0.0001)

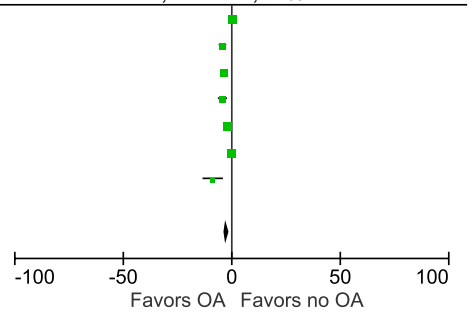


Figure 68—Custom, Titratable OAs for OSA (Diastolic blood pressure).

Study or Subgroup	Post-treatment Mean	SD	Total	Pre-treatment Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	76.3	0.7	80	76.3	0.8	80	17.6%	0.00 [-0.23, 0.23]
Gauthier 2009	84.6	2.3	16	92	3	16	11.9%	-7.40 [-9.25, -5.55]
Gauthier 2009	85	1.9	16	91	2.7	16	12.9%	-6.00 [-7.62, -4.38]
Gauthier 2011	81.9	2.3	14	92	3	14	11.3%	-10.10 [-12.08, -8.12]
Gotsopolous 2004	76.4	0.9	61	77.7	0.9	61	17.5%	-1.30 [-1.62, -0.98]
Phillips 2013	77.1	0.7	108	77.3	0.8	108	17.7%	-0.20 [-0.40, 0.00]
Trzepizur 2009	62.8	1.7	12	60.2	3.2	12	11.1%	2.60 [0.55, 4.65]
Total (95% CI)			**307**			**307**	**100.0%**	**-2.77 [-3.88, -1.67]**

Heterogeneity: Tau² = 1.80; Chi² = 246.54, df = 6 (P < 0.00001); I² = 98%
Test for overall effect: Z = 4.91 (P < 0.00001)

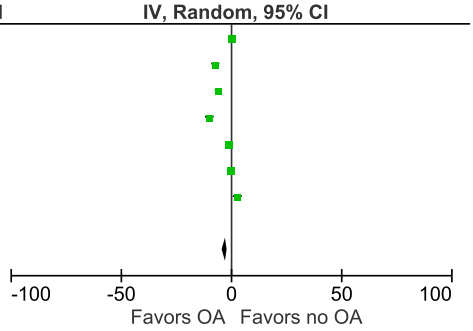


Figure 69—OAs vs. CPAP for OSA (Systolic blood pressure).

Study or Subgroup	OA Mean	SD	Total	CPAP Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	126.7	1	80	127.3	1.2	80	40.1%	-0.60 [-0.94, -0.26]
Phillips 2013	123.9	1.1	108	124.4	1	108	59.8%	-0.50 [-0.78, -0.22]
Trzepizur 2009	140	22.2	12	142	14.8	14	0.0%	-2.00 [-16.76, 12.76]
Total (95% CI)			**200**			**202**	**100.0%**	**-0.54 [-0.76, -0.32]**

Heterogeneity: Tau² = 0.00; Chi² = 0.23, df = 2 (P = 0.89); I² = 0%
Test for overall effect: Z = 4.88 (P < 0.00001)

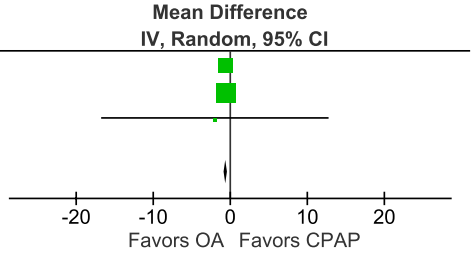


Figure 70—OAs vs. CPAP for OSA (Diastolic blood pressure).

Study or Subgroup	OA Mean	SD	Total	CPAP Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	76.3	0.7	80	76.7	0.8	80	46.2%	-0.40 [-0.63, -0.17]
Phillips 2013	77.1	0.7	108	77.2	0.7	108	53.5%	-0.10 [-0.29, 0.09]
Trzepizur 2009	63	5.2	12	64	7.4	14	0.3%	-1.00 [-5.87, 3.87]
Total (95% CI)			**200**			**202**	**100.0%**	**-0.24 [-0.50, 0.02]**

Heterogeneity: Tau² = 0.02; Chi² = 3.98, df = 2 (P = 0.14); I² = 50%
Test for overall effect: Z = 1.84 (P = 0.07)

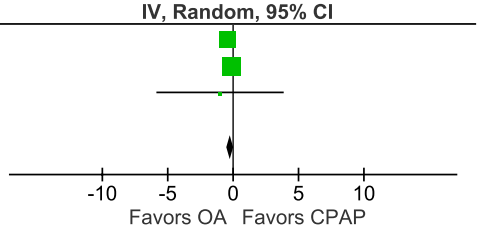


Figure 71—Summary of Findings: OAs for OSA (Hypertension).

OAs for OSA

Patient or population: Patients with OSA
Intervention: OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	OAs				
Systolic blood pressure		The mean systolic blood pressure in the intervention groups was **2.09 lower** (3.22 to 0.96 lower)		343 (7 studies)	⊕⊕⊕⊖ **moderate**[1]	
Diastolic blood pressure		The mean diastolic blood pressure in the intervention groups was **3.15 lower** (4.26 to 2.03 lower)		343 (7 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 72—Summary of Findings: Custom, Titratable OAs for OSA (Hypertension).

Custom, titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom, titratable OAs				
Systolic blood pressure		The mean systolic blood pressure in the intervention groups was **2.37 lower** (1.20 to 3.55 lower)		307 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	
Diastolic blood pressure		The mean diastolic blood pressure in the intervention groups was **2.77 lower** (1.67 to 3.88 lower)		307 (6 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high

Figure 73—Summary of Findings: Custom, Non-Titratable OAs for OSA (Hypertension).

Custom, non-titratable OAs for OSA

Patient or population: Patients with OSA
Intervention: Custom, non-titratable OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Custom, non-titratable OAs				
Systolic blood pressure		The mean systolic blood pressure in the intervention groups was **2.30 lower** (7.2 to 2.6 lower)		36 (1 study)	⊕⊕⊕⊕ **high**	
Diastolic blood pressure		The mean diastolic blood pressure in the intervention groups was **2.2 lower** (6.22 to 1.82 lower)		36 (1 study)	⊕⊕⊕⊕ **high**	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

Figure 74—Summary of Findings: OAs vs. CPAP for OSA (Hypertension).

OAs compared to CPAP for OSA

Patient or population: Patients with OSA
Intervention: OAs
Comparison: CPAP

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	CPAP	OAs				
Systolic blood pressure		The mean systolic blood pressure in the intervention groups was **0.54 lower** (0.76 to 0.32 lower)		202 (3 studies)	⊕⊕⊖⊖ **low**[1,2]	
Diastolic blood pressure		The mean diastolic blood pressure in the intervention groups was **0.24 lower** (0.5 lower to 0.02 higher)		202 (3 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 75—OAs vs. CPAP for OSA (Adherence).

Study or Subgroup	CPAP Mean	CPAP SD	CPAP Total	OA Mean	OA SD	OA Total	Weight	Mean Difference IV, Random, 95% CI
Barnes 2004	3.6	0.3	89	5.5	0.3	85	11.1%	-1.90 [-1.99, -1.81]
Doff 2012	6.9	1.3	39	7.2	0.8	36	10.3%	-0.30 [-0.78, 0.18]
Doff 2013	6.7	1.3	34	7.1	0.8	29	10.2%	-0.40 [-0.93, 0.13]
Engleman 2002	4.9	2.4	29	5	2.3	19	7.0%	-0.10 [-1.45, 1.25]
Gagnadoux 2009	6	2.2	29	7	5.2	28	4.7%	-1.00 [-3.09, 1.09]
Hoekema 2007a	6.3	1.3	27	7.1	1.1	20	9.7%	-0.80 [-1.49, -0.11]
Hoekema 2007b	6.7	1.4	10	7	0.9	9	8.2%	-0.30 [-1.35, 0.75]
Hoekema 2008a	7	0.7	13	6.8	1.3	12	9.1%	0.20 [-0.63, 1.03]
Hoekema 2008b	6.5	1.6	50	6.9	1	49	10.2%	-0.40 [-0.92, 0.12]
Phillips 2013	5.2	2	108	6.5	1.3	108	10.4%	-1.30 [-1.75, -0.85]
Trzepizur 2009	5.6	1.2	14	6.8	1	12	9.0%	-1.20 [-2.05, -0.35]
Total (95% CI)			**442**			**407**	**100.0%**	**-0.70 [-1.30, -0.11]**

Heterogeneity: Tau² = 0.82; Chi² = 142.38, df = 10 (P < 0.00001); I² = 93%
Test for overall effect: Z = 2.34 (P = 0.02)

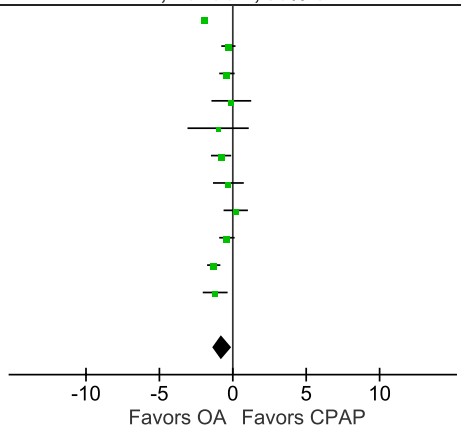


Figure 76—Summary of Findings: OAs vs. CPAP for OSA (Adherence).

OAs compared to CPAP for OSA

Patient or population: Patients with OSA
Intervention: OAs
Comparison: CPAP

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	CPAP	OAs				
Adherence (hrs./night)		The mean adherence (h/night) in the intervention groups was **0.70 higher** (0.11 to 1.30 higher)		442 (11 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval

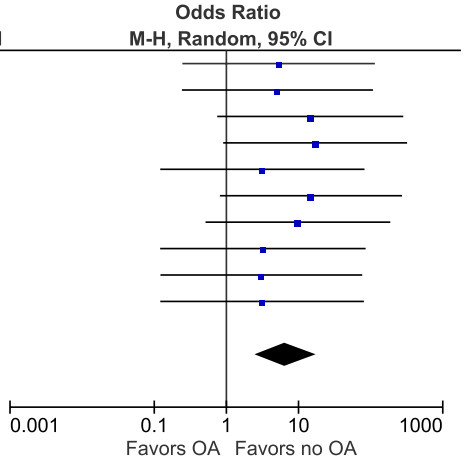
GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] I squared is high
[2] CI of absolute effect crosses clinical decision threshold

Figure 77—OAs for OSA (Side Effects).

Study or Subgroup	Post-treatment Events	Post-treatment Total	Pre-treatment Events	Pre-treatment Total	Weight	Odds Ratio M-H, Random, 95% CI
Aarab 2011b	2	35	0	35	10.0%	5.30 [0.25, 114.47]
Barnes 2004	2	99	0	99	10.2%	5.10 [0.24, 107.65]
Blanco 2005	5	20	0	20	10.8%	14.55 [0.75, 283.37]
Ferguson 1996	6	25	0	25	11.0%	17.00 [0.90, 320.37]
Ferguson 1997	1	20	0	20	8.9%	3.15 [0.12, 82.16]
Ghazal 2009	6	47	0	47	11.2%	14.88 [0.81, 272.17]
Ghazal 2009	4	48	0	48	10.9%	9.81 [0.51, 187.40]
Hoekema 2008b	1	15	0	15	8.8%	3.21 [0.12, 85.20]
Phillips 2013	1	60	0	60	9.1%	3.05 [0.12, 76.39]
Tan 2002	1	24	0	24	9.0%	3.13 [0.12, 80.68]
Total (95% CI)		**393**		**393**	**100.0%**	**6.65 [2.51, 17.62]**
Total events	29		0			

Heterogeneity: Tau² = 0.00; Chi² = 1.95, df = 9 (P = 0.99); I² = 0%
Test for overall effect: Z = 3.81 (P = 0.0001)



Attachment #32

Figure 78—OAs vs. CPAP for OSA (Side Effects).

Study or Subgroup	OA Events	OA Total	CPAP Events	CPAP Total	Weight	Odds Ratio M-H, Random, 95% CI
Aarab 2011a	0	21	3	22	5.8%	0.13 [0.01, 2.67]
Aarab 2011b	2	35	6	35	18.8%	0.29 [0.05, 1.57]
Barnes 2004	2	99	1	97	9.1%	1.98 [0.18, 22.19]
Ferguson 1996	6	25	8	25	34.2%	0.67 [0.19, 2.33]
Ferguson 1997	1	20	3	20	9.5%	0.30 [0.03, 3.15]
Hoekema 2008b	1	15	0	13	4.9%	2.79 [0.10, 74.63]
Phillips 2013	1	60	2	62	9.0%	0.51 [0.04, 5.76]
Tan 2002	1	24	2	24	8.7%	0.48 [0.04, 5.66]
Total (95% CI)		**299**		**298**	**100.0%**	**0.54 [0.26, 1.12]**
Total events	14		25			

Heterogeneity: Tau² = 0.00; Chi² = 3.82, df = 7 (P = 0.80); I² = 0%
Test for overall effect: Z = 1.65 (P = 0.10)

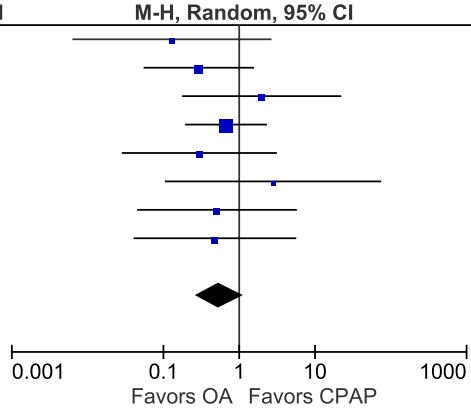


Figure 79—Summary of Findings: OAs for OSA (Side Effects).

OAs for OSA

Patient or population: Patients with OSA
Intervention: OAs

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	OAs				
Discontinuation of therapy from side effects			**RR 6.65** (2.51 to 17.62)	786 (9 studies)	⊕⊕⊕⊕ **high**	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

Figure 80—Summary of Findings: OAs vs. CPAP for OSA (Side Effects).

OAs compared to CPAP for OSA

Patient or population: Patients with OSA
Intervention: OAs
Comparison: CPAP

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	CPAP	**OAs**				
Discontinuation of therapy from side effects	**84 per 1000**	**45 per 1000** (22 to 94)	**RR 0.54** (0.26 to 1.12)	597 (8 studies)	⊕⊕⊕⊖ **moderate**[1]	

*The basis for the **assumed risk** (e.g., the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group quality of evidence:
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] CI of absolute effect crosses the clinical decision threshold

818-021-0088
Volunteer License

(1) An Oregon licensed dentist or dental hygienist who will be practicing **in Oregon** for a supervised volunteer dental clinic, as defined in ORS 679.020(3)(f) and (g), may be granted a volunteer license provided licensee completes the following:
(a) Licensee must register with the Board as a health care professional and provide a statement as required by ORS 676.345.
(b) Licensee will be responsible to meet all the requirements set forth in ORS 676.345.
(c) Licensee must provide the health care service without compensation.
(d) Licensee shall not practice dentistry or dental hygiene for remuneration in any capacity under the volunteer license.
(e) Licensee must comply with all continuing education requirements for active licensed dentist or dental hygienist.
(f) Licensee must agree to volunteer for a minimum of 80 hours per renewal cycle.
(2) Licensee may surrender the volunteer license designation at anytime and request a return to an active license. The Board will grant an active license as long as all active license requirements have been met.

818-012-0040
Infection Control Guidelines

In determining what constitutes unacceptable patient care with respect to infection control, the Board may consider current infection control guidelines such as those of the Centers for Disease Control and Prevention and the American Dental Association.

(1) Additionally, licensees must comply with the following requirements:

(a) Disposable gloves shall be worn whenever placing fingers into the mouth of a patient or when handling blood or saliva contaminated instruments or equipment. Appropriate hand hygiene shall be performed prior to gloving.

(b) Masks and protective eyewear or chin-length shields shall be worn by licensees and other dental care workers when spattering of blood or other body fluids is likely.

(c) Between each patient use, instruments or other equipment that come in contact with body fluids shall be sterilized.

(d) Environmental surfaces that are contaminated by blood or saliva shall be disinfected with a chemical germicide which is mycobactericidal at use.

(e) Impervious backed paper, aluminum foil, or plastic wrap may be used to cover surfaces that may be contaminated by blood or saliva and are difficult or impossible to disinfect. The cover shall be replaced between patients.

(f) All contaminated wastes and sharps shall be disposed of according to any governmental requirements.

(2) Licensees must comply with the requirement that heat sterilizing devices shall be tested for proper function by means of a biological monitoring system that indicates micro-organisms kill each calendar week in which scheduled patients are treated. Testing results shall be retained by the licensee for the current calendar year and the two preceding calendar years.

818-015-0007
Specialty Advertising

(1) A dentist may only advertise as a specialist in an area of dentistry which is recognized by the Board and in which the dentist is licensed or certified by the Board.

(2) The Board recognizes the following specialties:

(a) Endodontics;

(b) Oral and Maxillofacial Surgery;

(c) Oral and Maxillofacial Radiology;

(d) Oral and Maxillofacial Pathology;

(e) Orthodontics and Dentofacial Orthopedics;

(f) Pediatric Dentistry;

(g) Periodontics;

(h) Prosthodontics;

(i) Dental Public Health;

(j) Dental Anesthesiology**;**

(k) Oral Medicine;

(l) Orofacial Pain.

(3) A dentist whose license is not limited to the practice of a specialty under OAR 818-021-0017 may advertise that the dentist performs or limits practice to specialty services even if the dentist is not a specialist in the advertised area of practice so long as the dentist clearly discloses that the dentist is a general dentist or a specialist in a different specialty. For example, the following disclosures would be in compliance with this rule for dentists except those licensed pursuant to 818-021-0017: "Jane Doe, DDS, General Dentist, practice limited to pediatric dentistry." "John Doe, DMD, Endodontist, practice includes prosthodontics."

818-021-0012
Specialties Recognized

(1) A dentist may advertise that the dentist is a dentist anesthesiologist, endodontist, oral and maxillofacial pathologist, oral and maxillofacial surgeon, oral and maxillofacial radiologist, **oral medicine dentist, orofacial pain dentist,** orthodontist and dentofacial orthopedist, pediatric dentist, periodontist, prosthodontist or dental public health dentist, only if the dentist is licensed or certified by the Board in the specialty in accordance with Board rules.

(2) A dentist may advertise that the dentist specializes in or is a specialist in dental anesthesiology, endodontics, oral and maxillofacial pathology, oral and maxillofacial surgery, oral and maxillofacial radiology, **oral medicine, orofacial pain,** orthodontics and dentofacial orthopedics, pediatric dentistry, periodontics, prosthodontics or dental public health only if the dentist is licensed or certified by the Board in the specialty in accordance with Board rules.

818-021-0010
Application for License to Practice Dentistry

(1) An applicant to practice general dentistry, in addition to the requirements set forth in ORS
679.060 and 679.065, shall submit to the Board satisfactory evidence of:

(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) Certification of having passed the dental examination administered by the Joint Commission on National Dental Examinations or Canadian National Dental Examining Board Examination.

(2) An applicant who has not met the educational requirements for licensure may apply for examination if the Dean of an accredited school certifies the applicant will graduate.

(3) An applicant must pass a Board examination consisting of a clinical portion administered by the Board, or any clinical Board examination administered by any state, or regional testing agency, national testing agency or other Board-recognized testing agency and a jurisprudence portion administered by the Board. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative and endodontics.** Clinical examination results will be recognized by the Board for five years.

(4) A person who fails any Board approved clinical examination three times must successfully complete the remedial training recommended by the testing agency. Such remedial training must be conducted by a dental school accredited by the Commission on Dental Accreditation of the American Dental Association.

818-021-0011

Application for License to Practice Dentistry Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dentist who holds a license to practice dentistry in another state or states if the dentist meets the requirements set forth in ORS 679.060 and 679.065 and submits to the Board satisfactory evidence of:

(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association or completion of a postdoctoral General Dentistry Residency program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) Having passed the dental clinical examination conducted by a regional testing agency, by a state dental licensing authority, by a national testing agency or other Board-recognized testing agency. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative and endodontics**; and

(d) Holding an active license to practice dentistry, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dentistry, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and

(e) Having conducted licensed clinical practice in Oregon, other states or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately preceding application. Licensed clinical practice could include hours devoted to teaching by dentists employed by a dental education program in a CODA accredited dental school, with verification from the dean or appropriate administration of the institution documenting the length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching clinical dentistry, and any adverse actions or restrictions; and

(f) Having completed 40 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(2) Applicants must pass the Board's Jurisprudence Examination.

(3) A dental license granted under this rule will be the same as the license held in another state; i.e., if the dentist holds a general dentistry license, the Oregon Board will issue a general (unlimited) dentistry license. If the dentist holds a license limited to the practice of a specialty, the Oregon Board will issue a license limited to the practice of that specialty. If the dentist holds more than one license, the Oregon Board will issue a dental license which is least restrictive.

818-021-0017
Application to Practice as a Specialist

(1) A dentist who wishes to practice as a specialist in Oregon, who does not have a current Oregon license, in addition to meeting the requirements set forth in ORS 679.060 and 679.065, shall submit to the Board satisfactory evidence of:

(a) Having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association and active licensure as a general dentist in another state. Licensure as a general dentist must have been obtained as a result of the passage of any clinical Board examination administered by any state or regional testing agency, national testing agency or other Board recognized testing agency. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative and endodontics;**

(b) Certification of having passed the dental examination administered by the Joint Commission on National Dental Examinations or Canadian National Dental Examining Board Examination; and

(c) Proof of satisfactory completion of a post-graduate specialty program accredited by the Commission on Dental Accreditation of the American Dental Association.

(d) Passing the Board's jurisprudence examination.

(2) A dentist who graduated from a dental school located outside the United States or Canada who wishes to practice as a specialist in Oregon, who does not have a current Oregon license, in addition to meeting the requirements set forth in ORS 679.060 and 679.065, shall submit to the Board satisfactory evidence of:

(a) Completion of a post-graduate specialty program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, proficiency in the English language, and evidence of active licensure as a general dentist in another state obtained as a result of the passage of any clinical Board examination administered by any state or regional testing agency; or

(b) Completion of a post-graduate specialty program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, proficiency in the English language and certification of having successfully passed the clinical examination administered by any state or regional testing a ional testing agency or other Board recognized testing agency within the five

years immediately preceding application. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative and endodontics**; and

(c) Certification of having passed the dental examination administered by the Joint Commission on National Dental Examinations or Canadian National Dental Examining Board Examination;

(d) Passing the Board's jurisprudence examination; and

(3) An applicant who meets the above requirements shall be issued a specialty license upon:

(a) Passing a specialty examination approved by the Board within the five years immediately preceding application; or

(b) Passing a specialty examination approved by the Board greater than five years prior to application; and

(A) Having conducted licensed clinical practice in the applicant's postdoctoral dental specialty in Oregon, other states or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately preceding application. Licensed clinical practice could include hours devoted to teaching the applicant's dental specialty by dentists employed by a dental education program in a CODA-accredited dental school, with verification from the dean or appropriate administration of the institution documenting the length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching clinical dentistry in the specialty applicant is applying for, and any adverse actions or restrictions; and;

(B) Having completed 40 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(4) Any applicant who does not pass the first examination for a specialty license may apply for a second and third regularly scheduled specialty examination. If the applicant fails to pass the third examination for the practice of a recognized specialty, the applicant will not be permitted to retake the particular specialty examination until he/she has attended and successfully passed a remedial program prescribed by a dental school accredited by the Commission on Dental Accreditation of the American Dental Association and approved by the Board.

(5) Licenses issued under this rule shall be limited to the practice of the specialty only.

818-021-0018

Temporary Dental License for Spouses or Domestic Partners of Active Duty Armed Forces of the United States Stationed in Oregon

(1) A temporary license to practice dentistry shall be issued to the spouse or domestic partner of an active duty armed forces personnel when the following requirements are met:

(a) completed application and payment of fee is received by the Board; and

(b)Satisfactory evidence of having graduated from a school of dentistry accredited by the Commission on Dental Accreditation of the American Dental Association; or

(c) Satisfactory evidence of having graduated from a dental school located outside the United States or Canada, completion of a predoctoral dental education program of not less than two years at a dental school accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(d) Submission of a copy of the military orders assigning the active duty member to an assignment in Oregon; and

(e) The spouse holds a current license in another state to practice dentistry at the level of application; and

(f) The license is unencumbered and verified as active and current through processes defined by the Board; and

(g) Satisfactory evidence of successfully passing a clinical examination administered by any state, national testing agency or other Board-recognized testing agency. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative and endodontics.**

(2) The temporary license shall expire on the following date, whichever occurs first:

(a)Oregon is no longer the duty station of the active armed forces member; or

(b) The license in the state used to obtain a temporary license expires; or

(c) Two years after the issuance of the temporary license.

(3) This temporary license is not renewable. If the dates in section two of this rule are exceeded and the spouse continues to practice in Oregon, the spouse must apply for an active Oregon license. This license must be obtained using the processes and fees established for permanent licensure. Continuing to work in Oregon when the temporary license has expired will be considered practicing without a valid license and is subject to Board action.

818-021-0019

Temporary Dental Hygiene License for Spouses or Domestic Partners of Active Duty Armed Forces of the United States Stationed in Oregon

(1) A temporary license to practice dental hygiene shall be issued to the spouse or domestic partner of active duty armed forces personnel when the following requirements are met:

(a) A completed application and payment of fee is received by the Board; and

(b) Satisfactory evidence of having graduated from a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(c) Satisfactory evidence of having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(d) Submission of a copy of the military orders assigning the active duty member to an assignment in Oregon; and

(e) The spouse holds a current license in another state to practice dentistry at the level of application; and

(f) The license is unencumbered and verified as active and current through processes defined by the Board; and

(g) Satisfactory evidence of successfully passing a clinical examination administered by any state, national testing agency or other Board-recognized testing agency. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative, if applicable and periodontics.**

(2) The temporary license shall expire on the following date, whichever occurs first:

(a) Oregon is no longer the duty station of the active armed forces member; or

(b) The license in the state used to obtain a temporary license expires; or

(c) Two years after the issuance of the temporary license.

(3) This temporary license is not renewable. If the dates in section two of this rule are exceeded and the spouse continues to practice in Oregon, the spouse must apply for an active Oregon license. This license must be obtained using the processes and fees established for permanent licensure. Continuing to work in Oregon when the temporary license has expired will be considered practicing without a valid license and is subject to Board action.

818-021-0020
Application for License to Practice Dental Hygiene

(1) An applicant to practice dental hygiene, in addition to the requirements set forth in ORS
680.040 and 680.050, shall submit to the Board satisfactory evidence of:

(a) Having graduated from a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) Certification of having passed the dental hygiene examination administered by the Joint Commission on National Dental Examinations or the Canadian National Dental Hygiene Certificate Examination.

(2) An applicant who has not met the educational requirements for licensure may apply if the Director of an accredited program certifies the applicant will graduate.

(3) An applicant must pass a Board examination consisting of a clinical portion administered by the Board, or any clinical Board examination administered by any state, regional testing agency, national testing agency or other Board-recognized testing agency and a jurisprudence portion administered by the Board. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative, if applicable and periodontics.** Clinical examination results will be recognized by the Board for five years.

(4) A person who fails any Board approved clinical examination three times must successfully complete the remedial training recommended by the testing agency. Such remedial training must be conducted by a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association.

818-021-0025
Application for License to Practice Dental Hygiene Without Further Examination

(1) The Oregon Board of Dentistry may grant a license without further examination to a dental hygienist who holds a license to practice dental hygiene in another state or states if the dental hygienist meets the requirements set forth in ORS 680.040 and 680.050 and submits to the Board satisfactory evidence of:

(a) Having graduated from a dental hygiene program accredited by the Commission on Dental Accreditation of the American Dental Association; or

(b) Having graduated from a dental hygiene program located outside the United States or Canada, completion of not less than one year in a program accredited by the Commission on Dental Accreditation of the American Dental Association, and proficiency in the English language; and

(c) Having passed the clinical dental hygiene examination conducted by a regional testing agency, by a state dental or dental hygiene licensing authority, by a national testing or other Board-recognized testing agency. **All acceptable exams must include at a minimum a clinical portion demonstrating psychomotor competency utilizing a typodont mounted in a manikin or live patient to test the areas of restorative, if applicable and periodontics.**; and

(d) Holding an active license to practice dental hygiene, without restrictions, in any state; including documentation from the state dental board(s) or equivalent authority, that the applicant was issued a license to practice dental hygiene, without restrictions, and whether or not the licensee is, or has been, the subject of any final or pending disciplinary action; and

(e) Having conducted licensed clinical practice in Oregon, in other states or in the Armed Forces of the United States, the United States Public Health Service, the United States Department of Veterans Affairs for a minimum of 3,500 hours in the five years immediately preceding application. Licensed clinical practice could include hours devoted to teaching by dental hygienists employed by a CODA accredited dental hygiene program with verification from the dean or appropriate administration of the institution documenting the length and terms of employment, the applicant's duties and responsibilities, the actual hours involved in teaching clinical dental hygiene, and any adverse actions or restrictions; and

(f) Having completed 24 hours of continuing education in accordance with the Board's continuing education requirements contained in these rules within the two years immediately preceding application.

(2) Applicants must pass the Board's Jurisprudence Examination.

Enrolled
Senate Bill 824

Sponsored by Senator GIROD; Representatives HAYDEN, KENY-GUYER (at the request of Oregon Dental Association)

CHAPTER .....

AN ACT

Relating to dental licensure examinations; creating new provisions; amending ORS 679.070 and 680.060; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 679.070 is amended to read:

679.070. (1) The Oregon Board of Dentistry may administer written, laboratory or clinical examinations to test professional knowledge and skills.

(2) The examination [*shall*] **must** be elementary and practical in character but sufficiently thorough to test the fitness of the applicant to practice dentistry. It [*shall*] **must** include, written in the English language, questions on any subjects pertaining to dental science. [*The written examination may be supplemented by oral examination. Demonstrations of the applicant's skill in operative and prosthetic dentistry also may be required.*]

[*(3) The board may accept the results of national standardized examinations in satisfaction of the written examination as authorized by this section, and shall accept the results of regional testing agencies or of clinical board examinations administered by other states in satisfaction of the laboratory or clinical examination authorized under this section, provided:*]

[*(a) The test or examination was taken within five years of the date of application; and*]

[*(b) The applicant received a passing score on the test or examination as established by the board by rule.*]

[*(4) The board shall accept the results of regional testing agencies or of clinical board examinations administered by other states in satisfaction of the examinations authorized under this section for applicants who have engaged in the active practice of dentistry in other states, in Oregon or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for at least 3,500 hours in the five years immediately preceding application and who meet all other requirements for licensure.*]

(3) If a test or examination was taken within five years of the date of application and the applicant received a passing score on the test or examination, as established by the board by rule, the board:

(a) To satisfy the written examination authorized under this section, may accept the results of national standardized examinations.

(b) To satisfy the laboratory or clinical examination authorized under this section:

(A) Shall accept the results of regional and national testing agencies or clinical board examinations administered by other states; and

(B) May accept the results of board-recognized testing agencies.

(4) The board shall accept the results of regional and national testing agencies or of clinical board examinations administered by other states, and may accept results of board-recognized testing agencies, in satisfaction of the examinations authorized under this section for applicants who have engaged in the active practice of dentistry in other states, in Oregon or in the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for at least 3,500 hours in the five years immediately preceding application and who meet all other requirements for licensure.

SECTION 2. ORS 680.060 is amended to read:

680.060. (1) The Oregon Board of Dentistry may administer written, laboratory or clinical examinations to test professional knowledge and skills.

(2) The examination [*shall*] **must** be sufficiently thorough to test the fitness of the applicant to practice dental hygiene. [*It shall*] **The examination must** include, written in the English language, questions on any subjects pertaining to dental hygiene. [*The written examination may be supplemented by oral examination. Demonstrations of the applicant's skill in clinical dental hygiene also may be required.*]

[*(3) The board may accept the results of national standardized examinations in satisfaction of the written examination as authorized by this section, and shall accept the results of regional testing agencies or of clinical board examinations administered by other states in satisfaction of the clinical examination authorized under this section, provided:*]

[*(a) The test or examination was taken within five years of the date of application; and*]

[*(b) The applicant received a passing score on the test or examination as established by the board by rule.*]

(3) If a test or examination was taken within five years of the date of application and the applicant received a passing score on the test or examination, as established by the board by rule, the board:

(a) To satisfy the written examination authorized under this section, may accept the results of national standardized examinations.

(b) To satisfy the clinical or laboratory examination authorized under this section:

(A) Shall accept the results of regional and national testing agencies or clinical board examinations administered by other states; and

(B) May accept the results of board-recognized testing agencies.

(4) The board **may accept results of board-recognized testing agencies and** shall accept the results of regional **and national** testing agencies or of clinical board examinations administered by other states in satisfaction of the examinations authorized under this section for applicants who have engaged in the active practice of dental hygiene in Oregon, other states, the Armed Forces of the United States, the United States Public Health Service or the United States Department of Veterans Affairs for a period of at least 3,500 hours in the five years immediately preceding application and who meet all other requirements for licensure.

SECTION 3. The amendments to ORS 679.070 and 680.060 by sections 1 and 2 of this 2019 Act apply to applications for licensure submitted on or after the operative date specified in section 4 of this 2019 Act.

SECTION 4. (1) The amendments to ORS 679.070 and 680.060 by sections 1 and 2 of this 2019 Act become operative on January 1, 2020.

(2) The Oregon Board of Dentistry may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by the amendments to ORS 679.070 and 680.060 by sections 1 and 2 of this 2019 Act.

SECTION 5. This 2019 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2019 Act takes effect on its passage.

Passed by Senate April 11, 2019

Repassed by Senate June 10, 2019

.....
Lori L. Brocker, Secretary of Senate

.....
Peter Courtney, President of Senate

Passed by House June 4, 2019

.....
Tina Kotek, Speaker of House

Received by Governor:

.....M.,....., 2019

Approved:

.....M.,....., 2019

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M.,....., 2019

.....
Bev Clarno, Secretary of State

818-012-0006 – Qualifications – Administration of Vaccines

(1) A dentist may administer vaccines to a patient of record.
(2) A dentist may administer vaccines under Section (1) of this rule only if:
(a) The dentist has completed a course of training approved by the Board;
(b) The vaccines are administered in accordance with the “Model Standing Orders” approved by the Oregon Health Authority (OHA); and
(3) The dentist may not delegate the administration of vaccines to another person.

818-026-0080
Standards Applicable When a Dentist Performs Dental Procedures and a Qualified Provider Induces Anesthesia

(1) A dentist who does not hold an anesthesia permit may perform dental procedures on a patient who receives anesthesia induced by a physician anesthesiologist licensed by the Oregon ~~Board of~~ Medical ~~Examiners~~ **Board**, another Oregon licensed dentist holding an appropriate anesthesia permit, or a Certified Registered Nurse Anesthetist (CRNA) licensed by the Oregon Board of Nursing.

(2) A dentist who does not hold a Nitrous Oxide Permit for nitrous oxide sedation may perform dental procedures on a patient who receives nitrous oxide induced by an Oregon licensed dental hygienist holding a Nitrous Oxide Permit.

(3) A dentist who performs dental procedures on a patient who receives anesthesia induced by a physician anesthesiologist, another dentist holding an anesthesia permit, a CRNA, or a dental hygienist who induces nitrous oxide sedation, shall maintain a current BLS for Healthcare Providers certificate, or its equivalent, and have the same personnel, facilities, equipment and drugs available during the procedure and during recovery as required of a dentist who has a permit for the level of anesthesia being provided.

(4) A dentist, a dental hygienist or an Expanded Function Dental Assistant (EFDA) who performs procedures on a patient who is receiving anesthesia induced by a physician anesthesiologist, another dentist holding an anesthesia permit or a CRNA shall not schedule or treat patients for non emergent care during the period of time of the sedation procedure.

(5) Once anesthetized, a patient shall remain in the operatory for the duration of treatment until criteria for transportation to recovery have been met.

(6) The qualified anesthesia provider who induces moderate sedation, deep sedation or general anesthesia shall monitor the patient until easily arousable and can independently and continuously maintain their airway with stable vital signs. Once this has occurred the patient may be monitored by a qualified anesthesia monitor until discharge criteria is met. The patient’s dental record shall document the patient's condition at discharge as required by the rules applicable to the level of anesthesia being induced. A copy of the anesthesia record shall be maintained in the patient's dental record and is the responsibility of the dentist who is performing the dental procedures.

(7) No qualified provider shall have more than one person under any form of sedation or general anesthesia at the same time exclusive of recovery.

(8) A dentist who intends to use the services of a qualified anesthesia provider as described in section 1 above, shall notify the Board in writing of his/her intent. Such notification need only be submitted once every licensing period.

818-012-XXXX - Compliance with Governor's Executive Orders

(1) During a declared emergency, unprofessional conduct includes failing to comply with any applicable provision of a Governor's Executive Order or any provision of this rule.
(2) Failing to comply as described in subsection (1) includes, but is not limited to:
(a) Operating a business required by an Executive Order to be closed under any current
Executive Order.
(b) Providing services at a business required by an Executive Order to be closed under any current Executive Order.
(c) Failing to comply with Oregon Health Authority (OHA) guidance implementing an Executive Order, including but not limited to:
(A) Failing to satisfy required criteria in OHA guidance prior to resuming elective and non-emergent procedures;
(B) Failing to implement a measured approach when resuming elective and nonemergent
procedures in accordance with OHA guidance;
(d) Failing to comply with any Board of Dentistry guidance implementing an Executive Order;
(3) No disciplinary action or penalty action shall be taken under this rule if the Executive Order alleged to have been violated is not in effect at the time of the alleged violation.
(4) Penalties for violating this rule include: up to $5,000 per violation pursuant to ORS 679.140(10). Any such penalties shall be
imposed in accordance with ORS 679.140.

818-021-0120
Application Valid for 180 Days

(1) If all information and documentation necessary for the Board to act on an application is not provided to the Board by the applicant within 180 days from the date the application is received by the Board, the Board shall reject the application as incomplete.

(2) An applicant whose application has been rejected as incomplete must file a new application and must pay a new application fee.

(3) An applicant who fails the examination or who does not take the examination during the 180-day period following the date the Board receives the application, must file a new application and must pay a new application fee.