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

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As the field of oral appliance therapy (OAT) to manage obstructive sleep apnea has evolved over the past thirty years, side effects of therapy have become increasingly recognized. While the most commonly observed side effect is unwanted tooth movement, a number of other side effects have been reported through anecdotes, case reports, and observational studies.

Members of the American Academy of Dental Sleep Medicine developed a set of consensus recommendations to guide dentists in the management of side effects as a consequence of oral appliance therapy (OAT). Thirteen expert clinicians were appointed to the panel which used the modified RAND/UCLA Appropriateness Method to review the body of evidence on OAT side effects and to establish the recommendations.

Clinicians are encouraged to use these recommendations in conjunction with their clinical expertise to minimize the side effects of OAT. The recommendations are based on knowledge to date and are expected to evolve over time. Future research should aim at timely identification of these side effects for positive treatment outcomes.

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

INTRODUCTION

The American Academy of Dental Sleep Medicine (AADSM) and American Academy of Sleep Medicine (AASM) recently updated the Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy.[1] The Guideline included the following recommendation: **"We suggest that qualified dentists provide oversight – rather than no follow-up - of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence."** The management of side effects is essential to maximize treatment adherence and the clinical effectiveness of oral appliances. The guideline further states that although multiple manuscripts refer to side effects, the overall evidence is limited and of low quality.

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

BACKGROUND

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

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

METHODS

EXPERT PANEL SELECTION

In accordance with the recommendations of the RAND Appropriateness Method (RAM)[3], the Consensus Conference panel comprised 13 voting members. All panel members were dentists who were trained and experienced in the overall care of oral health, the temporomandibular joint, dental occlusion, and associated oral structures with focused emphasis on the proper protocol for diagnosis, treatment, and follow up of patients being managed with oral appliance therapy for sleep disordered breathing. All panelists were required to complete Conflict of Interest disclosures before being officially invited to participate.

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

LITERATURE SEARCH AND REVIEW

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

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

SURVEY OF ABDSM DIPLOMATES AND AADSM COMMITTEE MEMBERS

Concurrent with the literature review, a comprehensive list of the side effects and possible treatment options was developed. Since knowledge about oral appliances varies among providers, an online survey of dentists was

conducted to ensure that common side effects and possible treatment strategies were not overlooked.

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

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

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

MODIFIED RAND APPROPRIATENESS METHOD

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

ROUND 1 VOTING

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

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

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

CONFERENCE PROCEEDINGS: VOTING ROUNDS 2 AND 3

At the conference, panelists reviewed the results of Round 1 voting for each treatment option proposed for each side effect and discussed the available evidence and their clinical experience in treating each side effect. During these discussions, panelists agreed that Cephalometric Changes should be dropped as a category of changes. The two side effects included in this category were "increased facial height" and "altered mandibular position". The results of the online survey conducted prior to the consensus conference suggested to the panel that few

practitioners note these side effects, and panelists speculated that clinicians do not routinely obtain or analyze lateral cephalograms. Furthermore, the cephalometric changes documented are most likely a manifestation of occlusal changes that result from OA use, rather than separate and independent side effects.

At the conclusion of each discussion, panelists completed Round 2 voting for all treatment options proposed for each of the side effects, following the same procedures as Round 1 voting. Only those treatment options for which the panel agreed was appropriate in Round 2 voting were retained in the final recommendations. Panel agreement on treatment options whose median scores fell into the *inappropriate* or *uncertain* categories, were dropped from further consideration.

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

DEVELOPMENT OF RECOMMENDATIONS

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

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

It is expected that these guidelines will be most beneficial to the novice practitioner in the field of dental sleep medicine and will serve not only to highlight the breadth of adverse effects of oral appliance therapy but also to provide strategies for managing them. In developing these recommendations, the panel was careful to consider various clinical scenarios but elected to address the most common, rather than the most esoteric, situations that clinicians would encounter. The panelists stress that this document should be used in conjunction with the clinical expertise of the practicing dentist and that individual patient needs may necessitate deviation from these recommendations.

RECOMMENDATIONS FOR TREATING SIDE EFFECTS OF ORAL APPLIANCE THERAPY FOR OSA

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

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

If the recommendation is made to permanently discontinue oral appliance therapy, this decision should be made in consultation with the local treating physician to ensure that adequate alternative therapy is available to manage the obstructive sleep apnea.

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

Box 1 **- Side effects**

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

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

COMMON MANAGEMENT CONSIDERATIONS:

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

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

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

Morning occlusal guide encompasses many custom made appliances and prefabricated devices used in the effort to reposition the mandible into its habitual pretreatment position. These devices may function by utilizing biting force to re-seat the condyles to help re-establish/maintain the appropriate occlusal relationship in the morning following each night's use of oral appliance therapy. Some of these custom devices may function by reversing changes that may have occurred in tooth position or work to exercise or stretch muscles of mastication as well. They are intended to address the occlusal discrepancy noted after removal of the OA each morning.

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

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

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

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

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

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

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

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

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

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

TEMPOROMANDIBULAR JOINT-RELATED SIDE EFFECTS

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

Transient morning jaw pain

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

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

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

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

Persistent TMJ pain

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

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

use.[9-12]

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

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

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

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

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

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

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

Tenderness in muscles of mastication

"Palliative care, watchful waiting, verifying or correcting midline positions, use of a morning occlusal guide, and isometric contraction and passive jaw stretching exercises are considered first line of treatment to manage tenderness in the muscles of mastication. Decreasing OA advancement, vertical dimension, and

the rate of forward titration, modifying the acrylic, and temporarily discontinuing use of OAT are considered second line treatments. If these treatment options are insufficient or inappropriate, recommending a different OA design, referring to a dental specialist or additional health care provider, and permanently discontinuing OAT may also be appropriate. In very rare instances, increasing OA advancement may be indicated."

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

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

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

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

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

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

Recommendation of a different OA design may be necessary if the clinician judges that muscle tenderness is a

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

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

If none of the above options serve to manage the patient's muscle tenderness sufficiently to continue with OAT, it may be necessary to discontinue OAT permanently.

Joint sounds

"Watchful waiting is considered first line of treatment to manage joint sounds caused as a result of using OAs. If these treatment options are insufficient or inappropriate, temporary or permanent discontinuation of the OAT can also be considered as treatment options."

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

INTRAORAL TISSUE-RELATED SIDE EFFECTS

Soft tissue and tongue irritation

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

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

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

If intraoral soft tissue side effects persist despite the aforementioned measures, consider discontinuing use of the

oral appliance temporarily in order to remove the potential irritant and promote more rapid soft tissue recovery. The patient should be encouraged to use CPAP or consult with their local treating physician about alternative OSA treatment during the oral appliance holiday. Use of the oral appliance is resumed once the offending tissue irritation has resolved.

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

Gingival irritation

"Modification of the appliance and palliative care are considered first line treatment to manage gingival irritation. Discontinuing use of OAT temporarily is considered second line treatment."

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

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

Excessive salivation

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

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

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

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

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

Dry mouth

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

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

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

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

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

OCCLUSAL CHANGES

Altered occlusal contacts/bite changes

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

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

Development of posterior open bites is a common occurrence with OAT.[9, 18, 26-30] In a five-year follow-up study of 45 patients, Ueda noted that the number of occlusal contacts decreased in 67% of patients.[28] The majority of these

changes occurred in the premolar and molar regions. In a study of 51 OA patients, Doff recorded a significant decrease in the number of posterior occlusal contacts after 2 years of OAT.[30] Patients tolerate or are even unaware of such changes and do not discontinue treatment as a consequence. [9, 26, 27, 31, 32]

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

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

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

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

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

Incisor changes

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

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

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

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

Decreased overjet and overbite

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

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

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

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

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

Alterations in position of mandibular canines and molars

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

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

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

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

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

Inter-proximal gaps

"Watchful waiting, use of a morning occlusal guide, adjusting ball clasps and making modifications to the

appliance are considered first line of treatment to manage interproximal gaps. If these treatment options are insufficient or inappropriate, use of a distal wrap-around retainer and restoration of contact areas may be appropriate."

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

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

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

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

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

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

DAMAGE TO TEETH OR RESTORATIONS

Tooth mobility

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

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

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

Temporary discontinuation of OAT may be helpful in alleviating discomfort associated with the mobile teeth. Palliative measures may hasten resolution of symptoms, after which oral appliance use may be resumed. Upon resumption of wear, it may be useful to decrease the amount of mandibular advancement and proceed at a slower

titration rate until therapeutic benefit is achieved. The elimination or modification of anterior ramps, if used on the opposing arch, may also be helpful. Tooth mobility that is detected after the appliance has been advanced to the target protrusion may be addressed by temporarily reducing the protrusive position to allow mobile teeth to adapt to the forces and potentially stabilize before resuming gradual return to the target protrusion.

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

Tooth fractures or damage to dental restorations

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

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

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

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

When damage to teeth is the direct result of stresses from the appliance, the internal surface of the appliance should be modified to eliminate forces that potentially caused the fracture of the tooth and/or dental restoration. Any clasps or tight fitting acrylic adjacent to the damaged tooth or restoration should be adjusted to eliminate stress on that portion of tooth structure or restoration. This area of the appliance should also be modified sufficiently to permit proper restorative treatment and to reduce the possibility of recurrence.

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

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

APPLIANCE ISSUES

Appliance breakage

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

Appliance breakage is a relatively common problem across the field of dental sleep medicine. Some appliances may be more prone to these problems, and it behooves the prescriber to gain experience and knowledge to help

avoid and/or mitigate this treatment complication. Several articles describe appliance breakage or broken components (clasps, acrylic flanges, etc.).[32, 47, 48] In a 2-year follow-up study of patients treated with a Herbst appliance, Battagel reported that 60% had experienced appliance breakage with subsequent repair and 40% required a replacement appliance.[32] Martínez-Gomis noted that most breakages occurred in the telescopic mechanism of the Herbst appliance.[47]

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

Allergies to appliance materials

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

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

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

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

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

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

Gagging

"Modifications to the appliance are considered first line of treatment to manage gagging. Deprogramming the gag reflex is considered second line treatment. If these treatment options are insufficient or

inappropriate, recommendation of a different OA design may also be appropriate."

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

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

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

Anxiety

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

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

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

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

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

SUMMARY OF THE LITERATURE

The recommendations of the consensus panel on the management of oral appliance (OA) side effect are based on their clinical expertise and experience, and a body of literature that included over 140 articles. The manuscripts comprised 29 randomized controlled trials in addition to numerous prospective cohort studies, retrospective studies, reviews, systematic reviews, and meta-analyses. The studies spanned a period of over twenty years of research on oral appliance therapy from 1992[51] to 2016.[52] The findings represent diverse populations: Europe,[12]

North America,[9] New Zealand,[53] Australia,[54] Asia,[55] and South America.[5]

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

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

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

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

DISCUSSION AND FUTURE DIRECTIONS

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

Current evidence supports watchful waiting as the major treatment for OAT-related side effects unless discomfort is present. Most interventions are palliative, involve modification of the OA, or require no active therapy. Many of the side effects were thought to be best addressed prophylactically with use of a morning occlusal guide to help prevent occlusal alterations or to minimize transient muscle contraction. However, it must be noted that despite the widespread use of this technique, no evidence to date has demonstrated its effectiveness.

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

Standardization of both the definition of OAT success as well as clinical and outcome measures in OAT research

would enable meaningful comparison across studies.–Investigation is needed to clarify factors that lead to the onset and progression of side effects such as appliance design features, appliance materials, vertical and sagittal mandibular positioning, and duration of OAT, to name a few. Anthropomorphic and imaging studies may help identify patients at greater risk for the occurrence of side effects.

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

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