SPECIAL ARTICLES

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Identifying the Appropriate Therapeutic Position of an Oral Appliance

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INTRODUCTION

Customized, adjustable oral appliances stabilize and protrude the mandible to effectively treat sleep-related breathing disorders (SRBDs) by reducing respiratory events.[1]

Recognizing that the appropriate therapeutic position of mandibular advancement varies from patient to patient,[2] an American Academy of Dental Sleep Medicine (AADSM) task force evaluated a variety of methods for identifying the therapeutic position of an oral appliance. The task force determined the most clinically useful methods and provided a protocol on how to use each method. These protocols cover the following methods: initial mandibular position, symptom review, pulse oximetry (PO) or home sleep apnea tests (HSATs) administered by qualified dentists, and HSATs or polysomnography (PSG) ordered by physicians. A qualified dentist includes American Board of Dental Sleep Medicine (ABDSM) diplomates, AADSM qualified dentists, and ABDSM international certificants. In order to receive one of the above designations, at a minimum, a dentist must successfully complete all or specific components of the AADSM Mastery Program[3,4]

For the protocols, the appropriate therapeutic position of an oral appliance is defined as:

A position of the mandible that achieves improvement of signs, symptoms, or objective indices of sleep-related breathing disorders. The determination of improvement is agreed upon by the patient, dentist, and medical provider using clinical experience and, when available, evidence-based approaches. At this position, the appliance can be used comfortably, on a nightly basis.

METHODS SUPPORTED BY EVIDENCE

Although each of the methods for therapeutic positioning presented in this article was evaluated separately, they are often used in combination. Figure 1 describes potential combinations of the methods described in the following paragraphs.

Initial Mandibular Positioning

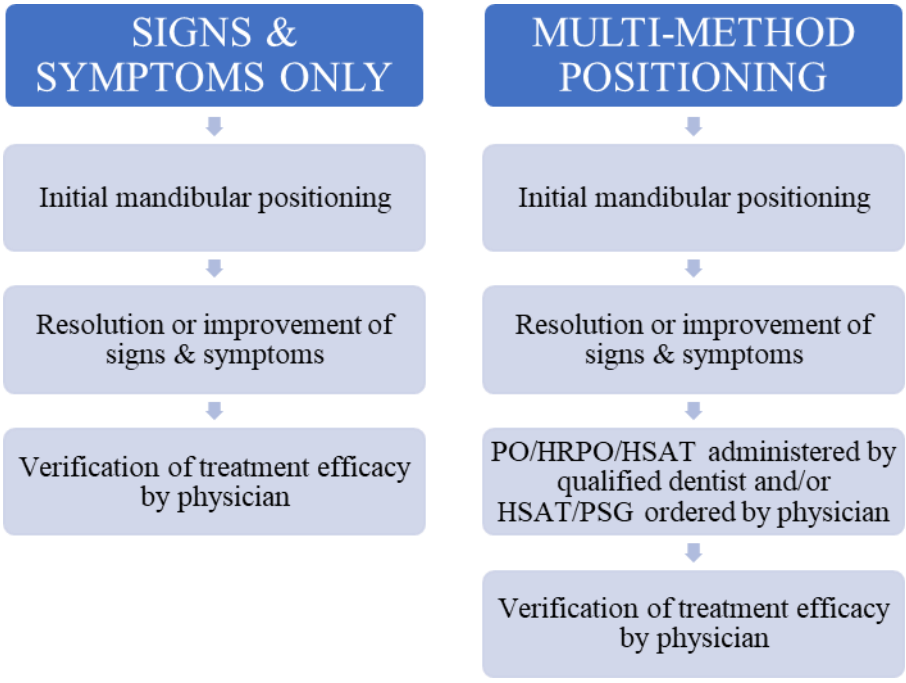
The term initial mandibular position is defined as the starting position of the mandible when an oral appliance is delivered at initiation of therapy. The initial mandibular position may be recorded as a millimeter measurement or as a percentage of maximum mandibular excursion from the posterior reference point to maximal protrusion. The initial mandibular position is recorded with a construction bite by the qualified dentist. It is important to note that the initial mandibular protrusion differs based on which oral appliance is fabricated – the ideal bite gauge varies based on appliance type.

Multiple studies have attempted to determine the most effective initial mandibular position, balancing adverse effects against the time required to reach an appropriate therapeutic position.[5–9] However, past studies do not consistently indicate whether the posterior reference for the construction bite refers to maximal mandibular retrusion or habitual occlusion and other studies have not indicated the posterior reference at all. The task force recommends that the posterior reference point be standardized to the most retruded position.

Studies vary considerably on a recommended initial mandibular position. Starting positions ranged from 25% to 75%.[5,7–9] In a meta-analysis of 13 randomized controlled trials, data analysis suggested that advancements greater than 50% did not influence the success rate.[7] Although most evidence indicates that an initial mandibular position of 50% advancement may both minimize side effects and improve respiratory indices, there are studies indicating that starting treatment at the patient's habitual occlusion without any additional advancement can significantly reduce the apnea-hypopnea index.[6] Clinicians should recognize that 50% advancement may be greater than necessary for any individual patient and may consider decreasing the amount of advancement as long as subjective and/or objective assessments do not worsen.

Data can be derived from motorized systems that are used either at home or in the sleep laboratory while a temporary appliance is in situ. These data are termed

Figure 1. Methods for positioning an oral appliance



PO – Pulse Oximetry
HRPO – High Resolution Pulse Oximetry
HSAT – Home Sleep Apnea Test
PSG - Polysomnogram

theragnostic sleep data. In the case of oral appliance therapy (OAT), these data can be used to both identify the apnea-hypopnea index and suggest an appropriate therapeutic position, thus, expediting the positioning process.[10] One advantage of using such systems in a sleep laboratory is that they enable a sleep technologist to adjust the position of the mandible without removing the appliance from the patient's mouth.[11,12] In one test of such a system, the predicted target protrusion was effective in 87% of patients.[12] In another study, a home version of this technology successfully predicted the appropriate therapeutic position in 85% of cases.[13]

Protocol

The qualified dentist will deliver the appliance with a predetermined initial starting position captured by an interocclusal record that defines the construction bite. The qualified dentist must assess the patient's curve of Spee and include adequate vertical dimension in the construction bite to allow for device advancement.

Different protocols may be used to obtain the construction bite. These may include:

1. A percentage of maximum protrusion, relative to maximum retrusion, determined without theragnostic sleep data.
2. A percentage of maximum protrusion, relative to maximum retrusion, determined by theragnostic sleep data.
3. Other methods as determined by the qualified dentist.

Note that the initial starting position may also be the appropriate therapeutic position. In this instance, no further subsequent advancement is needed.

Review of Signs and Symptoms

Signs and symptoms reported by the patient or the bed partner is a clinically useful method for determining the appropriate therapeutic position of an oral appliance. After the appliance is delivered, the patient uses it nightly for a period of time to acclimatize to the initial mandibular position. Subsequently, the oral appliance may be advanced in small increments by the patient or qualified dentist.[14–16] Within the literature reviewed, there is no consensus regarding the duration of the initial acclimatization period, the increment of advancement or the time between adjustments. However, with few exceptions,[17–19] the studies reported increasing the advancement no more than 1 mm at a time.

Research studies using this method have defined signs and symptoms differently. In some research, the targeted

signs and symptoms include snoring, witnessed apneas and/or excessive daytime sleepiness .[15,17, 19–26,27–30] Snoring can be assessed by informal questioning or the use of the visual analog scale score. Excessive daytime sleepiness can be assessed by informal questioning, use of the visual analog scale score or use of the Epworth Sleepiness Scale or other standardized sleep assessment.

Some studies have considered positioning based on symptomatic improvement alone to be insufficient.[27,28,31] In these studies, the authors demonstrate that better resolution can be obtained by combining reduction of signs and symptoms with results of objective data. Some studies suggest a position that balances the risk of additional advancement, such as temporomandibular joint discomfort, with the benefit of better symptomatic improvement.[14,32–34]

Nevertheless, the task force agreed that the appropriate therapeutic position can be achieved by using signs and symptoms alone in some cases, or by combining this method with other methods.

Protocol

Goal of the therapeutic positioning method: to achieve reduction/elimination of signs and symptoms consistent with untreated SRBDs.

Parameters typical of patient-specific signs and symptoms may include: snoring, witnessed apneas, nocturnal polyuria, gasping, restless sleep, mood disorders, excessive daytime sleepiness, unrefreshed sleep, cognitive impairment, morning headaches, and memory impairment.

1. Prior to delivery of the oral appliance, ensure there has been a recent assessment of signs and symptoms. Use standardized assessments when possible.
2. A period of acclimatization to the appliance at its initial starting position is advisable. Following a 1 to 4 week acclimatization, if signs and symptoms persist and patient comfort permits, the device may now be advanced in 0.25 to 1mm increments.
3. Advancement can be done by the qualified dentist or by the patient at home.
4. Within 30 days post insertion and on regular intervals as needed, the patient should be followed up for evaluation and reassessment of signs and symptoms with the same questionnaires used at initial assessment.
5. Advancement should continue, patient comfort permitting, until signs and symptoms resolve. Frequency of advancements should be determined by the qualified dentist based on the amount of advancement, the patient response, and device features.
6. When signs and symptoms are sufficiently resolved or the maximum comfortable position is reached, the qualified dentist may choose to proceed with another method to further improve the therapeutic position or the patient should return to the referring provider to verify treatment efficacy.

PO, HSATs, or PSG

Pulse Oximetry

The task force determined that PO, including high-resolution pulse oximetry (HRPO), administered by dentists is a supported strategy for identifying the appropriate therapeutic position. PO measures a patient's oxygen levels during sleep and is a type 4 sleep study.[35] The position of the oral appliance is typically adjusted until the frequency of oxygen desaturations (oxygen desaturation index [ODI]) of a given magnitude (often 3% or 4%) is reduced to a target level or further advancement is uncomfortable. Unlike traditional PO, HRPO measures oxygen levels and incorporates a sampling rate at least every second.[36]

Studies have determined that PO may be useful in identifying the appropriate therapeutic position of an appliance.[8,36,37] Adjustment based on reduction in both symptoms and the frequency of oxygen desaturations resulted in better resolution of the patients' SRBD than either method alone.[37] The task force concluded that PO may be relatively easy to use and may be more beneficial than frequent HSATs in certain clinical settings.

Home Sleep Apnea Tests

The task force determined that HSATs are a supported method for identifying the appropriate therapeutic position. HSATs are unattended sleep studies that measure a variety of sleep parameters (for example, respiratory event index [REI], ODI, oxygen nadir, oxygen saturation [SpO_2], body position). Most HSATs are classified as type 3 or type 4 sleep studies. In 2017, the American Dental Association endorsed home sleep apnea testing as a method that dentists may use "to help define the optimal target position of the mandible".[38] It is important for the clinician to recognize that education on use of HSATs is indicated.

HSATs were described as helping to identify the appropriate therapeutic position of an oral appliance.[39,40] HSAT was used in a number of studies in combination with resolution of signs and symptoms to position appliances.[41–44]

Limitations of HSAT include its diminished accuracy in patients with comorbid medical conditions such as moderate to severe pulmonary disease, neuromuscular disease, or congestive heart failure.[35] HSAT is also contraindicated in patients in whom other sleep disorders such as central sleep apnea, periodic limb movement disorder, insomnia, or narcolepsy are suspected or have been diagnosed.[45] It is

also important to understand that because HSAT does not measure electroencephalographic activity, it may underestimate the severity of OSA due to inability to differentiate between total sleep time and time in bed.[45,46]

Polysomnography

The task force determined that PSG is a supported method for identifying the appropriate therapeutic position of an appliance. Adjustment of the oral appliance to achieve the best improvement of signs and symptoms usually precedes the PSG. PSG involves a continuous, simultaneous recording of a number of sleep parameters (electroencephalography, electro-oculography, airflow respiratory effort, oximetry, sleep duration). PSG is performed overnight and is typically attended by a sleep technologist. PSG is useful to clarify whether patients need additional advancement despite symptomatic relief, but the data may also be used by the medical provider to verify treatment efficacy.

In a number of studies, appliances were first positioned using signs and symptoms, and then later, PSG was also used for additional positioning. One study achieved treatment success in almost 74% of patients using this method.[47] Other studies showed an increased number of treatment successes when adding PSG to their positioning method following sign and symptom relief.[48,49] Some studies have initially used PSG to position the appliance. Pételle et al. concluded that single-night PSG is a suitable solution to identify the appropriate therapeutic position or to conclude that OAT is not efficacious.[50]

The qualified dentist should provide the sleep facility with instructions for positioning during the PSG and provide training for the appliances delivered by that dentist. It should be noted that patient preference and lack of access may impede use of this method.

Protocols

PO or HSAT Administered by a Qualified Dentist

The respiratory parameters in this protocol were defined according to the American Academy of Sleep Medicine's scoring manual.[51]

Goal of the therapeutic positioning method: to achieve a reduction in or normalization of PO or HSAT parameters and resolution of SRBD after signs and symptoms have been addressed.

Parameters typically considered with use of PO include: ODI, percentage of time spent at peripheral SpO_2 less than 90% (CT 90), and oxygen nadir (LSAT). Other parameters are available from use of proprietary software and HRPO.

Additional parameters typically considered only with use of HSAT include: respiratory event index [REI], sleep position, and snoring index.

NOTE: This protocol includes positioning with signs and symptoms first.

1. PO or HSAT (unless prohibited by the qualified dentist's state dental board) is administered by the qualified dentist. The qualified dentist should ensure that a written advancement protocol is provided to the patient.
2. Prior to the delivery of an oral appliance, the qualified dentist should obtain baseline parameter values using the same type of monitoring device which will then be used during interim adjustments.
3. The oral appliance device is advanced by the qualified dentist or patient at home to reduce or eliminate signs and symptoms (see previous section on Review of Signs and Symptoms).
4. Once resolution of signs and symptoms has been addressed, PO or HSAT is repeated to determine whether an appropriate therapeutic position has been achieved. If the target parameter values have not been met, oral appliance advancement should continue.
5. Oral appliance advancement should continue until target parameter values are attained, can no longer be improved, or the maximum comfortable position is reached. The patient should return to the referring provider to verify treatment efficacy. The PO /HSAT data should be provided to the referring medical provider; they may use it to verify treatment efficacy.

HSAT or PSG Ordered by the Physician

The respiratory parameters in these protocols were defined according to the American Academy of Sleep Medicine's scoring manual.[51]

Goal of the therapeutic positioning method: to achieve a reduction in or normalization of HSAT parameters or in-laboratory PSG parameters and resolution of SRBDs after signs and symptoms and any home testing (PO or HSAT) administered by the dental office have been addressed.

Parameters typically considered with use of either HSAT and PSG include: ODI, percentage of time spent at peripheral oxygen saturation (SpO_2) less than 90% (CT 90), and oxygen nadir (LSAT), sleep position, and snoring index.

Parameters typically considered with use of HSAT only include: REI.

Parameters typically considered with use of PSG only include: apnea-hypopnea index (AHI) and respiratory disturbance index (RDI).

1. Initially, the oral appliance is advanced by the qualified dentist or patient at home to reduce or

eliminate signs and symptoms (see previous section on Review of Signs and Symptoms).

2. Objective methods may subsequently be used to adjust the oral appliance after resolution of signs and symptoms (see previous section on PO or HSAT).
3. The qualified dentist then refers the patient for a physician-ordered and -monitored multi-night HSAT or single-night PSG to identify the appropriate therapeutic position of the oral appliance.
4. The qualified dentist provides a written advancement protocol to the patient and medical provider.

Instructions for use during multi-night HSAT.

The intent is to allow for assessment of device efficacy at two or three different oral appliance positions as tested on different nights.

Elements of this protocol may include:

- Instructions for how to advance the appliance.
- Amount of additional advancement (the appliance setting) for each night.
- Instructions that following all testing, the patient should re-set the oral appliance to the pre-test setting.

Instructions for use during single-night PSG.

The intent is to allow assessment of device efficacy at several different positions during the single-night PSG.

Elements of this protocol to be sent to the sleep facility may include:

- Name of the oral appliance.
- Current level of advancement.
- The amount of sleep time before the first device advancement and the criteria for advancement.
- Instructions for how to advance the appliance.
- The frequency of advancement, the maximum number of advancements, and the incremental amount of each advancement.
- Instruction to reset the oral appliance to the initial setting before the patient leaves the sleep laboratory.
- Instructions for the sleep technologist to note timing and amount of each advancement during the sleep study and to include in the report.
- The sleep technologist must be provided with the accessories necessary to advance the appliance.

Following HSAT or PSG scoring, the medical provider will determine which setting is the appropriate therapeutic position and relay this information to the qualified dentist. The qualified dentist should be sure to follow up with the patient regarding this information.

When using any of these methods, it is critical to take patient tolerance and comfort into account when identifying the appropriate therapeutic position. It is important not to over advance the appliance in order to avoid potential adverse effects. Although these methods are useful for identifying the appropriate therapeutic position of the appliance, the patient should be referred to a medical provider to verify treatment efficacy. In some cases, the method for final verification of efficacy may differ from the one used for positioning.

METHODS WITH UNCERTAIN EVIDENCE

Nasopharyngoscopy

Nasopharyngoscopy uses a scope to examine the airway and can be performed while the patient is either awake using topical anesthesia (awake endoscopy), or while the patient is asleep using agents such as propofol (drug-induced sleep endoscopy).

Several studies reviewed used nasopharyngoscopy to evaluate anatomic changes in the upper airway during mandibular advancement; however, most studies were focused on identification of potential OAT responders.[8] The task force concluded that no study has demonstrated the usefulness of awake nasopharyngoscopy to determine the appropriate therapeutic position of an oral appliance, and awake nasopharyngoscopy may not accurately mimic the sleeping patient. With the use of sleep nasopharyngoscopy, it is unknown whether anatomic observations made with simulated bite registrations will translate to OAT efficacy or whether additional adjustment with another method (such as HSAT or PSG) will be required to normalize respiratory parameters. Additionally, the task force concluded that although nasopharyngoscopy with neuromuscular block, as used in one study, might prove useful in adjusting an oral appliance, the invasiveness and risk of the procedure precludes its clinical use.

The available evidence led the task force to conclude that the usefulness of nasopharyngoscopy for identifying the appropriate therapeutic position is uncertain at this time, although some studies are promising. For example, preliminary data from a pilot study suggest that drug-induced sleep endoscopy might be used to identify the appropriate therapeutic position for oral appliance success based on anatomic observations of the pharynx and that airway patency may not be optimal at the position of maximum advancement.[52]

METHODS NOT SUPPORTED BY EVIDENCE

The task force found inadequate evidence in support of the following methods for therapeutic positioning.

Maximum Comfortable Protrusion Without Other Information

Some studies advocate either initiating OAT at or advancing to the maximum comfortable protrusion without consideration of improvement of symptoms.[53–57] However, most studies suggest that the maximum comfortable protrusion may result in unwanted dental adverse effects.[58] Studies have demonstrated that some patients respond adequately to a nominal amount of mandibular advancement[6] or that a small mandibular advancement may be more efficacious than a larger one.[59]

Rather than a specific therapeutic positioning method, the task force viewed the maximum comfortable protrusion as the upper limit of advancement for positioning based on other strategies (signs and symptoms, PO, etc.), and therefore did not consider maximum comfortable protrusion to be a method for identifying the appropriate therapeutic position of an oral appliance.

Imaging Techniques

Imaging techniques measure the upper airway while an oral appliance is adjusted either by horizontal advancement or vertical opening of the mandible.[60–62] The imaging techniques in the literature reviewed included magnetic resonance imaging, lateral cephalometry, and pharyngometry. These studies did not assess airway parameters during appliance adjustments and thus did not directly lead to identification of the appropriate therapeutic position of an oral appliance. Furthermore, one study used nonapneic men as study subjects, leading the task force to question its applicability to patients with OSA.[60]

Pharyngometry uses sound waves to classify the site of airway collapse by recording the amplitude of the soundwaves as they reflect off the hypopharynx and oropharynx.[63] It is accomplished in awake patients and thus may not be an accurate assessment of the behavior of the upper airway in sleeping patients. Most articles were either review articles or were focused on the deployment of the technique itself;[64,65] no study reviewed demonstrated the effectiveness of pharyngometry in ascertaining the appropriate therapeutic position of OAT for symptom resolution or normalization/improvement in respiratory parameters.[64-73]

FORTHCOMING TECHNOLOGIES

Consumer sleep technology (CST) is a rapidly evolving field that has been enthusiastically embraced by patients.[74] CST may include commercially available devices and apps that measure sleep parameters (snoring and sleep apps). The task force sought literature on the use of CST to identify the appropriate therapeutic position of oral appliances but did not identify any studies that evaluated the use of CST in this context. Evidence for the use of CST for early screening of sleep-disordered breathing, however,[75] suggests that CST may extend in the future to dental sleep medicine for use in therapeutic positioning of oral appliances.

DEVELOPMENT OF RECOMMENDATIONS

Consensus Conference Process

The AADSM Board of Directors created a task force with seven members, all of whom have extensive experience in dental sleep medicine and reviewing literature. None of the task force members had any conflicts of interest relevant to this topic.

A modified RAND/UCLA Appropriateness Method[76] was used to develop this article Task force members considered scholarly evidence, other clinical literature, their own clinical experience, and patient preferences to determine the most clinically useful methods for identifying the appropriate therapeutic position of an oral appliance. As indicated by RAND/UCLA rules, the inclusion or exclusion of methods did not include consideration of cost or insurance.

Literature Search

A literature search of PubMed and Google Scholar was performed using a combination of terms (see next paragraphs). Additionally, the bibliographies of pertinent review articles and dissertations were searched for relevant articles. Although comprehensive, this literature review was not conducted as a systematic review.

Search Terms

Search terms related to treatment: oral, intraoral, dental, orthodontic(s), mandibular, tongue retaining, tongue stabilizing, occlusal, titratable/titrated, appliance(s), splint(s), device(s).

Search terms related to disease: sleep apnea, sleep apnea syndromes, sleep-related breathing disorder(s), sleep-disordered breathing, snoring.

Search terms related to positioning of the oral appliance: titration, calibration, adjustment.

Literature Review

The final set of 133 articles was divided into categories based on the type of positioning method addressed in the article. An additional 21 articles were reviewed after collecting these 133 original articles, for a total of 154 articles. Task force members performed a detailed review of the literature and presented their evaluations to the full task force at their face-to-face meeting described below.

The task force eliminated literature on strategies used to identify treatment responders. Such methods are based

on phenotyping or on evaluating patterns of airway collapse[77,78] to predict which patients might respond to OAT. However, even after identifying probable or ideal candidates, the appliance must still be adjusted to ascertain the appropriate therapeutic position.

Voting on Strategies

Prior to the face-to-face consensus conference, task force members were sent an exhaustive list of methods for identifying the appropriate therapeutic position of an oral appliance. This list was compiled based on input from members of the AADSM and Diplomates of the American Board of Dental Sleep Medicine. For the first round of voting, task force members were asked to independently rate each method. The rating scale ranged from 1 to 9, with 1 indicating the lowest and 9 indicating the highest level of support by evidence and clinical experience.

Unanimous votes by the task force members are not required by the RAND/UCLA rules. Consensus among the task force members was achieved when at least four members agreed that the particular method was supported by the evidence, unsupported, or that the evidence was uncertain.

During the face-to-face conference on February 21-23, 2020, task force members presented their evaluation of the literature associated with each method. Following each presentation, a second round of voting occurred, using the same scale as the first round. Based on discussion of evidence presented, task force members were free to change their ratings of each method from their first vote. A third round of voting was held after additional discussion of any methods for which consensus was not reached after the second round of voting. After the voting was completed, the most clinically useful methods, supported by both strong levels of evidence and clinical experience, were identified.

LIMITATIONS AND RECOMMENDATIONS

Because no definition of treatment success exists, the task force did not specify the value of respiratory parameters to achieve when adjusting the oral appliance to therapeutic position using the methods described. OAT providers should collaborate with the patient and medical provider to individualize treatment goals for each patient before OAT is initiated.

The literature review for this article was thorough but was not conducted as a systematic review. The task force also acknowledged that the research could have had larger sample sizes, better control groups, and long-term follow-up. Additionally, many articles did not directly test the validity of the method and thus interpretations had to be inferred from indirect data.

The task force recommended that future research focus on how best to identify the appropriate therapeutic position of an oral appliance. Specifically, the following topics merit further investigation:

- Most of the research reviewed for this paper compared end-of-treatment outcome measures to those at baseline, rather than at initiation of treatment. In doing so, the efficacy of OAT is assessed but not the efficacy of the therapeutic positioning method itself. Final outcomes should be compared to those at initiation of therapy in future studies to elucidate the usefulness of the method used to determine the appropriate therapeutic position. Similarly, the posterior reference should be clearly indicated in future studies as well.
- More research should be conducted on whether nasopharyngoscopy can be used to determine the appropriate therapeutic position of an appliance.
- Robust studies should be conducted that compare the value of following symptom resolution with any of several objective methods. Study methodology should ensure that the same equipment and measurement tools are used throughout the study to make meaningful comparisons between treatment assessments. Additionally, therapeutic positioning via symptoms alone should be tested against using symptoms in conjunction with an objective therapeutic positioning method.
- As imaging techniques are refined, studies should test their effectiveness in simplifying the therapeutic positioning process.
- Although the field of CST is expanding, none of these technologies have been evaluated for their efficacy in identifying the appropriate therapeutic position of an oral appliance. As CSTs evolve, their potential should be scientifically tested.

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CITATION

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DISCLOSURE STATEMENT

The authors declare no conflicts of interest.