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# Principles of Oral Appliance Therapy for the Management of Snoring and Sleep Disordered Breathing

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## KEYWORDS

- Oral appliance (OA) • Mandibular repositioning appliance
- Tongue retaining device • Treatment • Snoring
- Sleep apnea

## OVERVIEW OF ORAL APPLIANCES

Oral appliance (OA) therapy for snoring, obstructive sleep apnea (OSA), or both is simple, reversible, quiet, and cost-effective and may be indicated in patients who are unable to tolerate nasal continuous positive airway pressure (nCPAP) or are poor surgical risks. OAs are effective in varying degrees and seem to work because of an increase in airway space, the provision of a stable anterior position of the mandible, advancement of the tongue or soft palate, and possibly a change in genioglossus muscle activity. The appliances should be used during sleep for life and must be comfortable for the patient. Finally, OAs can only be used in cooperative patients who are motivated to wear the appliance during sleep on a regular basis.

OA therapy falls into two main categories: those that hold the tongue forward and those that reposition the mandible (and the attached tongue) forward during sleep. Before treating either snoring or OSA with any OA, a complete assessment by a physician experienced in the field or by a sleep disorder specialist is important. After concluded that treatment with an OA is indicated, the physician provides

the dentist/orthodontist/oral and maxillofacial surgeon who has skill and experience in OA therapy with a written referral or prescription and a copy of the diagnostic report. Because of the obvious life-threatening implications of several sleep disorders, OA therapy must commence only after a complete medical assessment.

The American Academy of Sleep Medicine (AASM) reviewed the available literature in 2006 and recommended that OAs may be used as first line therapy in adult patients with primary snoring, mild and moderate OSA and in patients with severe OSA who are intolerant of or refuse treatment with nasal nCPAP.<sup>1,2</sup> For some patients, combination therapy with other treatments such as weight loss, surgery and nCPAP may be indicated, and this must be coordinated by the attending sleep physician.

OAs for the treatment of snoring and OSA have proven to be effective in reducing the apnea-hypopnea index (AHI) and increasing minimum oxygen saturation,<sup>3-8</sup> further improving sleep architecture<sup>6</sup> and reducing arousals.<sup>6,8,9</sup> Subjectively and objectively, OAs decrease sleepiness to the same degree as nCPAP,<sup>7,10-13</sup> decrease objectively measured snoring in most patients,<sup>6,7</sup> and improve

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quality of life and neuropsychological function.<sup>14,15</sup> Moreover, OAs have been shown to improve cardiovascular health<sup>9,12,16,17</sup> and driving performance.<sup>13,18</sup>

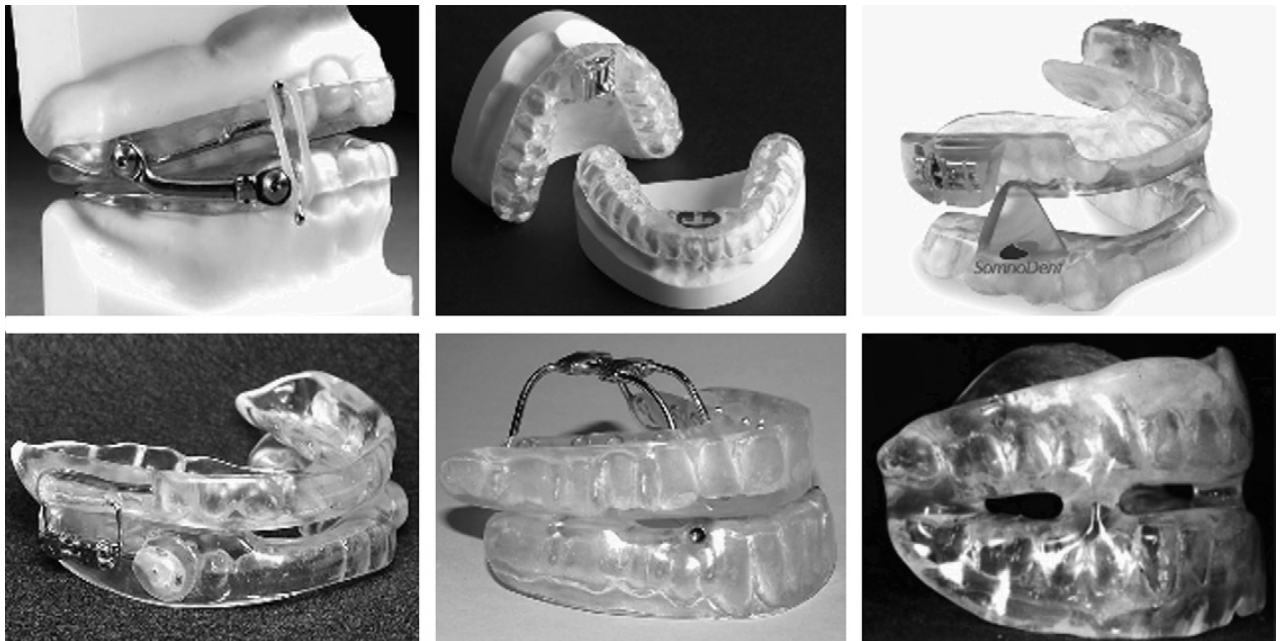
Since the first publication of the AASM position papers,<sup>19,20</sup> two significant advances in this field have occurred: adjustable appliances that allow titration of the mandibular position over time, and the use of materials and designs that significantly improve intraoral retention. Dentists realized early that determining the correct jaw position was the most difficult step when using OA therapy successfully. Patients had considerable variations in the initial comfortable range of the anteroposterior movement of the mandible, and differences in the speed and amount of forward jaw position that could be tolerated. Single jaw position or nonadjustable appliances often must be remade if the initial jaw position proves to be inadequate. Gradual titration forward of the mandible without needing a new appliance to be made each time became the objective, and adjustable appliances were invented and marketed.

A subgroup of patients, particularly those experiencing sleep bruxism,<sup>21</sup> often experience a considerable jaw discomfort in the morning after wearing a rigid hard acrylic single jaw position OA. A need to develop an OA that could allow for lateral jaw movement and some degree of vertical jaw opening was identified. Concurrently, major advances in dental materials significantly

improved the flexibility and strength of thermosensitive acrylic resin materials. Appliances made of temperature-sensitive material that patients could heat in hot water before insertion that would cool and harden somewhat intraorally were found to have considerably more retention than traditionally designed cold-cure acrylic appliances. The combination of adjustability, lateral and vertical jaw movement, increased retention, and better-defined titration protocols have significantly improved the effectiveness of OA since they were first systematically reviewed.

Each OA has a primary effect on either the tongue or the tongue and mandible together. Several appliances move the mandible anteriorly, such as Somnomed (Denton, TX), Klearway (Tonawanda, NY), elastomeric (Tonawanda, NY) single jaw position appliances, Herbst (Tonawanda, NY), TAP III (Dallas, TX), and PM Positioner (Tonawanda, NY), (Fig. 1). The tongue is affected by all appliances, either through direct forward movement of the muscle itself or changes secondary to an altered mandibular rest position. The tongue retaining device is the most commonly used OA that has a direct affect on tongue posture.

Despite the in-depth research in the field of pediatric sleep medicine, little is known about the efficacy and side effects of OAs for children who have no craniofacial abnormalities.<sup>22,23</sup> Orthodontic treatment for children who have OSA and craniofacial anomalies has shown to be effective not only for dentition but also in decreasing



**Fig. 1.** Lateral views of six oral appliances used for the treatment of snoring or obstructive sleep apnea. Herbst (Tonawanda, NY), Tap III (Dallas, TX), Somnomed (Denton, TX), PM Positioner (Tonawanda, NY), Klearway (Tonawanda, NY), and Elastomeric (Tonawanda, NY), single jaw position appliances. (Courtesy of Somnomed Inc, Great Lakes Orthodontics, Dr M. Marklund, Dr J. Parker, Airway Management Inc.)

respiratory disturbances in children.<sup>24,25</sup> This article focuses on the use of OAs in the adult population only.

This article provides a detailed clinical protocol and titration sequence for OAs, because this clinical procedure is often not well understood by practitioners new to the field. Prediction of treatment success is addressed, OA treatment is compared with surgery and nCPAP, OA compliance is described, and the possible adverse effects associated with this type of therapy are discussed.

### CLINICAL PROTOCOL FOR ORAL APPLIANCE THERAPY

The following therapy sequence is suggested for the management of OAs in patients who are being treated for snoring or OSA.

1. Medical assessment is completed by the attending physician or sleep specialist. Before referral to a dentist, the physician should check that the patient has sufficient teeth (at least eight in each of the upper and lower jaws) and that they have no limitations in forward jaw movement (>5 mm) or jaw opening (>25 mm). Totally edentulous patients may not be ideally suited for treatment with mandibular repositioners because they may not have enough intraoral retention to keep the appliance in the mouth during sleep. Patients who have edentulous maxillary arches and adequate teeth in the lower arch may experience favorable response to mandibular repositioners. Full upper and lower dentures may preclude the use of a mandibular repositioner, but some of these patients may experience a good treatment response with a tongue retaining device. Partial dentures that replace four or fewer teeth do not preclude OA use. Evidence of a severe history of temporomandibular joint (TMJ) pathology or chronic joint pain may preclude the use of an OA in some patients. In patients who have mild to moderate TMJ disorders, OAs may be used if the patient is instructed to systematically perform TMJ support therapy exercises.<sup>26</sup> Severe occlusal wear (>20% of the clinical crown) may indicate severe bruxism and complicate OA therapy if the grinding persists. Prediction of OA success is described further in this article.
2. An overnight polysomnogram with a detailed evaluation of the diagnostic criteria for OSA must be completed by the physician or sleep specialist before treatment with an OA is initiated. Written referral or prescription and a diagnostic report are sent to a dentist or dental specialist.
3. An oral examination is completed and includes medical and dental histories. Careful assessments are completed of soft tissue structures, periodontal status, TMJ, occlusion, intraoral habits and the teeth and restorations. Initial dental radiographs, such as panoramic or full mouth survey; cephalometric radiograph (optional); and diagnostic plaster models are important records of the dentist's initial assessment.
4. Appliance determination is made, which includes consideration of mandibular repositioner versus tongue retainer and whether a boil-and-bite type or a custom-made appliance is required.
5. After fabrication, the dentist should fit the appliance and adjust for patient comfort. The patient must then be instructed and trained as how to manage the appliance.
6. If an adjustable OA is used, the dentist should follow up with the patient during the period of titration. Details of a titration protocol are outlined later. Possible need for modification, redesign, or remake of an OA is based on subjective resolution of symptoms, patient compliance, and a follow-up sleep study.
7. The patient should be referred back to attending physician for assessment or repeat overnight sleep study. The objective assessment of OA efficacy is recommended because evidence shows that OAs may have a placebo effect on OSA symptoms.<sup>5,7</sup> During the polysomnogram, further OA titration may be useful.
8. If the OA has been shown to be effective and the patient is comfortable, the attending dentist should schedule recall appointments every 6 months for the first 2 years. At each appointment, the status of the occlusion should be checked. The dentist should also monitor subjective effectiveness, fit, comfort, TMJ, and dental status.
9. Regular follow-up appointments must be scheduled at least once a year to monitor OA wear, efficacy, and possible adverse effects. OAs are known to last approximately 2 to 3 years. If the appliance is showing extensive wear, such as cracks, discoloration, or lost of retention, a new appliance is recommended. The dentist may have to advance the appliance further if symptoms recur. If maximum mandibular advancement is reached and symptoms are still present, the patient must be referred to the sleep specialist for further evaluation. A careful evaluation of the occlusion is necessary and patients must be advised of the probability of occlusal changes.

## TITRATION PROTOCOLS

Once the patient wears the appliance every night and is comfortable for one month, he or she should be instructed to start advancing the appliance. As an example for discussion, we describe the titration of a specific screw mechanism, but the concept is similar for most of the adjustable appliances. When using the Hyrax screw, present in Klearway, PM Positioner, Somnosed appliance, titration is accomplished by turning the screw two times per week until the next appointment. Each turn or activation in the direction of the arrow moves the lower jaw gradually forward in 0.25-mm increments, which has a direct effect on the three-dimensional size of the airway. The patient inserts the tip of the key into the hole on the side of the expansion screw at the base of the arrow and turns or pushes the key toward the direction of the arrow imprinted in the metal expansion screw, which shows the correct movement to advance the lower jaw. Once the key is completely turned from one side to the other it is removed, and a new hole appears for the next turn. If the key is removed before a new hole appears after the completed turn, the patient may be unable to fully place the key in the new hole. The key is always removed after turning. Turning the key opposite to the direction of the arrow closes the expansion screw and retracts the mandible. If significant jaw or joint discomfort occurs, advise the patient to stop turning the screw until their next visit.

Some patients stop snoring and feel more rested shortly after the appliance is inserted, and no further advancement of the mandible is required. Others may require 2 or 3 months of slow and gradual forward repositioning before a significant treatment effect is noted. When the patient or bed partner reports a cessation of snoring and a resolution of symptoms, further advancement of the mandible may not be required and the appliance is considered titrated. The expansion screw should be tied off with stainless steel ligature wire or filled in with cold cure acrylic to prevent any further movement of the screw. The patient should be referred back to his or her physician or sleep specialist for assessment at this time.

The efficacy of titration and timing of a repeat polysomnogram for OA titration are factors in OA therapy that still require further understanding. Krishnan and colleagues<sup>27</sup> showed that although 55% of patients achieve successful self-titration at home, another 32% can reach success with further polysomnography-guided titration. Almeida and colleagues<sup>28</sup> also showed that titration at night can improve results of the usual clinical advancement of the OA by up to 35%. The protocol is

simple to implement in the sleep laboratory, with the technologist asking the patient to advance the appliance in 1-mm increments if the patient continued to snore, showed increased respiratory effort, or had ongoing respiratory events. Patients should not be awakened more than three times to achieve a sufficient sleep time during the titration polysomnogram despite being awakened to make the advancements.

## COMPLIANCE AND ADVERSE EFFECTS

The compliance and side effects of OA treatment might differ depending on the type of the appliance, disease severity, and perhaps patient management. Compliance is often measured subjectively, except in one study in which a compliance monitor indicated that the OA was worn for a mean of 6.8 hours per night.<sup>11</sup> A greater percentage of noncompliant patients is seen in the first 6 months, with approximately 40% of noncompliant patients identified during this period.<sup>29</sup>

The most common reasons to stop using the appliance are discomfort/cumbersome (46%) and no or little effect (36%). Compliance rates vary widely among studies, with a minimum of 4% to a maximum of 82% of compliance after 1 year of treatment.<sup>30,31</sup> In a study involving 630 patients, Marklund and colleagues<sup>32</sup> described compliance among 75% of the patients after 12 months of treatment. After 2 to 5 years of follow-up, studies have shown compliance rates of 48% up to 90%.<sup>12,33-36</sup> One study reported an adherence drop from 82% to 62% from year 1 to 4.<sup>14</sup> Studies with nCPAP have shown that subjective compliance is often higher than objective assessment; therefore, until a compliance monitor is available for OA therapy follow-up, caution should be taken when evaluating OA compliance.

The main reasons for discontinuing treatment are reported to be insufficient reduction of snoring and the presence of side effects.<sup>29</sup> Most side effects caused by OAs are usually described as mild and transient, and most frequently include dry mouth, excessive salivation, mouth or teeth discomfort, muscle tenderness, and jaw stiffness. Significant and persistent TMJ problems are rare.<sup>2</sup> One study used MRI to evaluate the TMJ of seven patients over a mean period of 11 months, concluding that OA in the titrated position seem to be innocuous to the TMJ in patients who have OSA.<sup>10</sup>

Long-term side effects were more recently described in evaluating OA side effects over a period of more than 5 years. Using a titratable appliance (Klearway) Almeida and colleagues<sup>37,38</sup>

showed that OAs used for a mean period of 7.3 years have a significant impact on occlusal and dental structures (eg, a 2.8 mm decrease in overbite and a 2.6 mm decrease in overjet). Changes observed in craniofacial structures were mainly related to significant tooth movements. Marklund<sup>39</sup> observed that the frequent use of a monoblock OA with full occlusal coverage for 5 years resulted in median reductions in overjet and overbite of 0.6 mm in patients who had snoring and OSA. Infrequent users had smaller bite changes. Overjet decreased during the first and second halves of the treatment period, and overbite changes diminished with time.

Although some occlusal changes might be undesirable in certain patients, the effective treatment of a life-threatening disease such as OSA seems to supersede the maintenance of a baseline occlusion. All therapies exhibit side effects, and OAs are no exception.

### PREDICTION OF TREATMENT SUCCESS

The OA treatment protocol varies from nCPAP, especially as it applies to titration. Because patients may not be able to initially tolerate the mandibular advancement required to open the airway during sleep, OAs cannot be easily tried for a single night to predict treatment success and patient compliance. OAs require up to 6 months of gradual titration to be fully adjusted. Previous research has evaluated whether overnight titration of mandibular advancement during polysomnography could be used to initiate OA therapy similar to the titration of nCPAP.<sup>40–43</sup> The first study of overnight titration used an OA that was removed from the patient's mouth and adjusted manually.<sup>40</sup> Other titration studies have used a temporary appliance that can be adjusted either by waking the patient<sup>43</sup> or without waking the patient.<sup>41,42</sup> The temporary appliance was advanced either manually after removal of the temporary appliance,<sup>43</sup> using a hydraulic system,<sup>41</sup> or through remote control of a motorized system.<sup>42</sup> Results of these studies were mixed in terms of predicting the amount of advancement needed for successful OA therapy. Furthermore, overnight titration of an OA remains an experimental approach, and the technology for remote controlled advancement is not widely available.

One study used a prefabricated boil-and-bite appliance as a screening tool for OA therapy.<sup>44</sup> This randomized, controlled, crossover study found that a prefabricated appliance had a compliance failure rate of 31%, whereas a custom-made appliance showed only a 6% rate of compliance failure. The prefabricated appliance showed an

exceptionally high total failure rate of 69%, whereas the failure rate of the custom-made appliance was 40%. This study concluded that custom-made appliances cannot be recommended as a therapeutic option nor can they be used as a screening tool to identify good candidates for OA therapy.

Clinical, physiologic, and polysomnographic variables have been identified as predictors of success in many research studies. Clinically, younger patients<sup>45,46</sup> who have a lower AHI,<sup>5,32,46,47</sup> a smaller neck circumference,<sup>5</sup> a lower body mass index (BMI),<sup>46,48</sup> and positional OSA<sup>32,49</sup> have shown higher success rates with OA therapy. Correlations exist between OA success and the amount of mandibular advancement, with greater advancement exhibiting the highest decrease in AHI and oxygen desaturation index.<sup>10,50</sup> Women have shown a higher success rate than men.<sup>32</sup>

OA success has also been linked to some cephalometric characteristics, such as a shorter palate, a larger retropalatal airway space, a decreased distance between the hyoid and mandibular plane, a narrow anteroposterior position of mandible (SNB) angle, and a higher anteroposterior position of maxilla (SNA) angle.<sup>5,51–53</sup> Using MRI during the Müller maneuver, together with mandibular advancement, one study found a correlation between an improvement in upper airway patency and treatment success.<sup>54</sup> More recently, physiologic assessments of nasal resistance and pulmonary function were shown to have some predictive value.<sup>55–57</sup>

Even with all the variables described, most studies have been underpowered, and no prospective study could define patient characteristics to accurately predict treatment outcome. Therefore, further studies are needed before treatment success or treatment failure can be predicted before the 6 months of OA titration is initiated.

### COMPARATIVE EFFECTIVENESS OF ORAL APPLIANCES, NASAL CONTINUOUS POSITIVE AIRWAY PRESSURE, AND SURGERY

Only one study compares OAs with upper airway surgery (uvulopalatopharyngoplasty [UPPP]), with subsequent reports on the same patient pool.<sup>14,30,58,59</sup> This study<sup>59</sup> was a randomized parallel study that treated 45 patients with an OA and 43 with UPPP. At the 1-year follow-up, OA showed a higher success rate in controlling the AHI than UPPP (78% vs 51%). Both treatments were equally effective in reducing sleepiness, although the surgical group showed greater

contentment. Of the participating patients, 32 treated with OA and 40 treated with UPPP completed the 4-year follow-up.<sup>14</sup> Both groups showed an increase in BMI, and no significant correlation was seen between changes in BMI and AHI from baseline to the 4-year follow-up within the OA and UPPP groups.

According to the criteria for OSA (apnea index  $\geq$  5 or AHI  $\geq$  10), 63% of patients in the dental appliance group attained normalization after 4 years, a proportion that was significantly higher than the 33% among patients in the UPPP group. Three patients in the UPPP group showed a tendency to fibrotic narrowing, but without symptoms. Pronounced complaints of nasopharyngeal regurgitation of fluid and difficulty with swallowing after UPPP were reported by 8% and 10%, respectively. In the OA group, 22 patients did not notice any changes in tooth contacts and 4 noted minor changes. One patient was not able to occlude his teeth in the same way as before treatment and reported TMJ discomfort. OA side effects were described as minor and infrequent.<sup>58</sup> In conclusion, the group treated with an OA showed a significantly higher success and normalization rate than the group treated with UPPP.

Seven randomized controlled trials recently showed the efficacy of OA against nCPAP.<sup>4,8,16,47,60–62</sup> When only AHI is evaluated, nCPAP is consistently superior to OA: in six of seven studies, nCPAP normalized the AHI, whereas OA failed to do so in a third or more of the patients.

Even though the AHI was better controlled with nCPAP, no difference was seen in objective sleepiness or neurobehavioral outcomes between the therapies. One explanation could be the hours of use and acceptance of treatment. Treatment preference is complex and depends on variables such as patient age and lifestyle. In five studies, OAs were preferred over nCPAP treatment, whereas in one no preference was seen<sup>62</sup> and in one the patients preferred nCPAP over an OA.<sup>16</sup> In conclusion, nCPAP is more effective than OA in reducing AHI, but with respect to improvements in symptoms, compliance with and acceptance of OAs are similar to those for nCPAP.

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