Oral Appliance Therapy for the Treatment of Obstructive Sleep Apnea

J. A. Fleetham, K. A. Ferguson, A. A. Lowe and C. F. Ryan

Division of Respiratory Medicine and Department of Clinical Dental Sciences, University of British Columbia, Vancouver, British Columbia, Canada

Summary: A variety of oral appliances (OA) are now available for the treatment of obstructive sleep apnea (OSA). OA therapy is effective in some patients with mild to moderate OSA and is associated with greater patient satisfaction than nasal CPAP. Adjustable OA are associated with improved treatment success and fewer compliance failures compared to non-adjustable OA. Large randomized clinical trials are necessary to further determine the precise indications, benefits, and risks of each OA in the treatment of OSA. Key Words: Obstructive sleep apnea—Nasal CPAP—Oral appliance—Sleep.

Nasal continuous positive airway pressure therapy (nCPAP) is a highly effective and safe treatment for obstructive sleep apnea (OSA) and is generally considered to be the current primary treatment for OSA. However, only 50–80% of patients use this treatment on a long-term basis, and in these patients, covert monitoring has shown that the average usage is <50% of the night. Consequently, there is a need for an alternative treatment for OSA that is safe, effective, and acceptable. The development of oral appliances (OA) represents an interesting new approach for the management of OSA, and this has recently been the subject of a detailed review (1). This review identified 13 different OA, and this number has at least doubled over the last two years. There are major design differences in the OA available that may have an impact on their success and compliance rates.

The majority of OA advance the mandible, utilizing traditional dental techniques to attach the appliance to one or both dental arches. Construction usually requires dental impressions, bite registration, and fabrication by a dental laboratory. However, at least one appliance is available in a pre-fabricated form that can be molded to the patient's teeth in an office setting. Some appliances restrict mouth opening by means of clasps, whereas others allow relatively unhindered movement. Appliances sometimes include tubes or openings for oral breathing or pressure relief. Several appliances feature a posterior extension of the maxillary component to modify the position of the soft palate or tongue. More recently, OA have been developed with an adjustable hinge that allows progressive advancement of the mandible after initial construction until an optimal mandibular position is achieved. Mandibular advancement OA require at least 10 teeth in each of the maxillary and mandibular arches. In addition to advancing the mandible, they also produce downward rotation of the mandible.

The other type of OA available is a tongue retainer that keeps the tongue in an anterior position during sleep by means of negative pressure in a soft plastic bulb. This type of appliance is available in both a fabricated and prefabricated version and can be used in edentulous patients.

The American Sleep Disorders Association has issued practice guidelines (2) that state that OA therapy is indicated for simple snoring and mild OSA, and for moderate–severe OSA if nCPAP is not accepted. We have recently completed two prospective randomized crossover studies comparing the efficacy, side effects, patient compliance, and preference of both a non-adjustable (3) and adjustable (4) mandibular advancement OA (Fig. 1) to nCPAP in 51 patients with mild to moderate OSA. Efficacy, side effects, patient compliance, and preference were evaluated by questionnaire and home-sleep monitoring. Treatment success was defined as a reduction in apnea/hypopnea index (AHI) to <10/hour and relief of symptoms, treatment failure as failure to reduce AHI to <10/hour and/or failure to relieve symptoms, and compliance failure as...
FIG. 1. A prefabricated non-adjustable (a) and fabricated adjustable (b) mandibular advancement oral appliance.
TABLE 1. Treatment outcome

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<tr>
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<th>Non-adjustable oral appliance (%)</th>
<th>Adjustable oral appliance (%)</th>
<th>nCPAP (%)</th>
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<tbody>
<tr>
<td>Treatment success</td>
<td>48</td>
<td>61</td>
<td>66</td>
</tr>
<tr>
<td>Treatment failure</td>
<td>28</td>
<td>35</td>
<td>0</td>
</tr>
<tr>
<td>Compliance failure</td>
<td>24</td>
<td>4</td>
<td>34</td>
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* Resolution of symptoms and reduction in AHI <10/hour.
* Ongoing clinical symptoms and/or AHI >10/hour.
* Inability or unwillingness of patient to continue to use the treatment.

inability or unwillingness to use the treatment. Forty-eight percent of patients treated with the non-adjustable OA were treatment successes compared to 61% for the adjustable OA and 66% for nCPAP (Table 1). Both OA and nCPAP were effective in reducing symptoms, but OA was less effective improving sleep oxygenation. Side-effects were more common and the patients less satisfied with nCPAP. The long-term preference was overwhelmingly in favor of OA therapy. Fourteen patients were treatment successes with both treatments; 12 of these patients preferred OA and two preferred nCPAP as a long-term treatment. This study confirmed previous observations that nCPAP works but cannot always be used, and OA therapy can be effective but does not always work (5).

Larger, randomized, clinical trials are necessary to further determine the precise indications, benefits, and risks of each OA in the treatment of OSA. These studies should include objective assessment of daytime sleepiness and performance, covert compliance monitoring, and long-term followup. In 1994, Inspiraplex, the Respiratory Health Network of Centres of Excellence in Canada, initiated a randomized prospective parallel multicenter study to compare the efficacy, compliance, and side-effects between a new adjustable mandibular advancement OA (Klearway®) and nCPAP in patients with OSA for a two-year treatment period. Efficacy is assessed by symptom and quality of life questionnaire, a subjective and objective measurement of daytime vigilance, and overnight polysomnography. Treatment compliance is determined by subjective and objective monitoring, and a covert compliance monitor that senses body heat has been developed for the OA. The mechanism of action of the appliance is being determined by lateral cephalometry and awake and asleep videoendoscopy. Patient recruitment is ongoing and the study is due to conclude in 1998.

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REFERENCES