

An American Sleep Disorders Association Review

Oral Appliances for the Treatment of Snoring and Obstructive Sleep Apnea: A Review

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Summary: This paper, which has been reviewed and approved by the Board of Directors of the American Sleep Disorders Association, provides the background for the Standards of Practice Committee's parameters for the practice of sleep medicine in North America. The 21 publications selected for this review describe 320 patients treated with oral appliances for snoring and obstructive sleep apnea. The appliances modify the upper airway by changing the posture of the mandible and tongue. Despite considerable variation in the design of these appliances, the clinical effects are remarkably consistent. Snoring is improved and often eliminated in almost all patients who use oral appliances. Obstructive sleep apnea improves in the majority of patients; the mean apnea-hypopnea index (AHI) in this group of patients was reduced from 47 to 19. Approximately half of treated patients achieved an AHI of <10; however, as many as 40% of those treated were left with significantly elevated AHIs. Improvement in sleep quality and sleepiness reflects the effect on breathing. Limited follow-up data indicate that oral discomfort is a common but tolerable side effect, that dental and mandibular complications appear to be uncommon and that long-term compliance varies from 50% to 100% of patients. Comparison of the risk and benefit of oral appliance therapy with the other available treatments suggests that oral appliances present a useful alternative to continuous positive airway pressure (CPAP), especially for patients with simple snoring and patients with obstructive sleep apnea who cannot tolerate CPAP therapy. **Key Words:** Sleep apnea syndromes—Snoring—Orthodontic appliances—Diagnosis—Therapy.

1.0 INTRODUCTION

An oral appliance was considered as treatment for mandibular deficiency and upper airway obstruction as early as 1902 (1). With the recent interest in sleep apnea, oral appliances of various designs have been proposed and studied, and are used increasingly to treat snoring and sleep apnea. The purpose of this review is to evaluate evidence regarding the effectiveness of these

devices. The term "oral appliance" is used as a generic term for devices inserted into the mouth in order to modify the position of the mandible, the tongue, and other structures in the upper airway for the purpose of relieving snoring or sleep apnea. Although many of these devices attach to the teeth and use conventional dental technology, we use the more general term to include devices that are used intraorally but are not necessarily retained directly by the teeth.

2.0 METHODS

2.1 Selection of papers

The data for this review were derived from computer searches of the clinical literature (MEDLINE, July 1994;

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search terms: orthodontic appliances, activator appliances or related subjects; sleep apnea syndromes, snoring; search period 1966–1994) and from consultation with experts. We selected articles, principally from peer-reviewed publications, that describe the patients, the treatments and the measurements in sufficient detail to allow reproduction of the study. Abstracts and review papers were not considered.

2.2 Validity of published data

Our search strategy identified 21 papers suitable for this review (Table 1). Each paper was evaluated according to recommended validity criteria (2). None of the studies used a randomized control design. Instead, this literature consists entirely of case series (Sackett's Level V, reference 2) with comparisons of conditions before and with treatment. Although this design allows for confounding by other time-related changes, the interval between studies is usually brief, and other interventions have been excluded. In two studies, polysomnography was performed with and without the appliance during the same night, a study design that strengthens the identification of a treatment effect (18,19). Furthermore, the average effect on the apnea-hypopnea index (AHI), the main outcome variable for obstructive sleep apnea (OSA), is greater than what might be attributed to random variability (23). All the patients were adults who appeared to be similar to OSA patients in other case series: predominantly male, middle-aged and overweight. However, selection bias based on the clinician's judgment and the patient's preference may limit the ability to generalize to other populations of sleep apnea patients. The diagnosis of OSA was validated with polysomnography in all but one study (14). Outcomes were assessed with subjective reports (4,10,14,17–21) and objective measurements (3–22,24) that are widely used in clinical practice and research.

3.0 BACKGROUND

3.1 Snoring

Snoring is a common affliction, affecting persons of all ages, but particularly middle-aged and elderly men and women who are overweight (25–27). Snoring has been identified as a risk indicator of and possible risk factor for hypertension, ischemic heart disease and stroke, although its etiologic role in these conditions is controversial (28). Although not all snorers have sleep apnea, snoring is a cardinal symptom of OSA and may by this mechanism be associated with increased morbidity. Furthermore, snoring in some patients without apnea has been associated with significant sleep disturbance and sleepiness. This so-called

“upper airway resistance syndrome” is characterized by repeated arousals related to increased upper airway resistance without recognizable hypopneas or apneas; treatment of the upper airway obstruction improves sleepiness in these patients (29). Thus, snoring is now recognized as a symptom that may be related to clinical conditions with significant morbidity. In addition, the social embarrassment and distress of loud snoring often motivate individuals to request professional help.

3.2 OSA

Obstructive sleep apnea syndrome is a common, chronic disorder of sleep and breathing that causes disability from pathologic sleepiness and respiratory and cardiovascular complications (30,31). OSA is related to upper airway obstruction that develops during sleep with manifestations that include snoring, apneas and hypopneas.

3.3 Pathophysiology of OSA

The pathophysiology of OSA includes factors related to upper airway anatomy, upper airway resistance and upper airway muscle function during sleep (32). Upper airway anatomy varies considerably among patients, so that no single finding is pathognomonic of obstructive apnea. However, narrowing of the upper airway is commonly observed, especially at the level of the soft palate and the base of the tongue (33,34). Cephalometric variants of the facial skeleton have been described, including a relative retrognathia and a low position of the hyoid bone (35,36). Soft tissue changes include a decrease in the posterior airway space (35,36), an increase in tongue volume (37) and, in some cases, pathologic enlargement of the palatine or adenoidal tonsils (38).

Upper airway resistance is relatively increased in sleep apnea patients (39,40). The resulting more negative inspiratory pressure is thought to be an important factor in airway collapse and obstruction (41). Increased airway compliance may also contribute to airway collapse in apnea patients (42). Inspiratory excitation of upper airway muscles maintains patency when awake (43). Excessive relaxation or loss of compensatory excitation of upper airway muscles explains the propensity to collapse during sleep (41,43).

3.4 Treatments of snoring and OSA

Treatments of snoring and OSA are directed at the upper airway and have included tracheostomy, surgery of the soft palate and oropharynx [uvulopalatopharyngoplasty (UPPP)], reconstructive surgery of the facial skeleton, nasal continuous positive airway pressure

TABLE 1. Papers meeting the selection criteria for this review of oral appliances: effects on obstructive sleep apnea, sleep and sleepiness

First author (reference)	Number of patients	Study design	Device	Mean AHI without/with appliance	SaO ₂ minimum with appliance	AHI with treatment			Sleep	Sleepiness
						<50% initial AHI ^a	<10 ^a	>20 ^b		
Peer reviewed										
Bernstein (3)	1	Case re- port	MAD	35/9	88/86	100	100	0	No change in stage distri- bution	—
Bonham (4)	12	Case series	MAD	54/34	75/80	58	—	—	—	9/12 improved, patient report
Calderelli (5)	16	Case series	TRD	—	—	56	—	—	—	—
Cartwright (6)	14	Case series	TRD	56/27	—	71	36	43	Less stage 1, more stage 3 and REM	14/14 improved, patient report
Cartwright (7)	16	Case series	TRD	54/33	73/79	50	25	73	Less stage 1	—
Cartwright (8)	12	Case series	TRD	37/17	—	75	58	17	—	—
Cartwright (9)	15	Case series	TRD	27/11	—	73	73	57	—	—
Clark (10)	24	Case series	Herbst	48/12	Improved	87	46	20	Less stage 1, more REM	Improved, subjec- tive scale
Eveloff (11)	19	Case series	Herbst	35/13	84/88	—	53	33	—	—
George (12, 13)	9	Case series	NAPA	45/11	72/82	78	68	29	Decreased arousals	—
Ichioka (14)	14	Case series	MAD	32/9	Improved	100	71	9	—	Improved, symp- tom score
Kloss (15)	7	Case series	Esmarch	37/12	83/87	71	57	40	—	Improved, patient report
Knudson (16)	2	Case series	MAD	30/7	—	100	50	0	—	—
Nakazawa (17)	12	Case series	MAD	50/19	—	—	—	—	Significantly more delta and REM and less mid-sleep wake time	10/12 improved, patient report
O'Sullivan (18)	51	Case series	MAD	32/18	—	—	—	—	Decreased mean arousals from 31 to 19 per hour	—
Schmidt-Nowara (19)	20	Case series	Snore- Guard	47/20	75/80	75	40	31	Significantly less sleep fragmenta- tion	18/35 improved, subjective scale
Not peer reviewed										
Lowe (20)	1	Case re- port	MAD	57/2	—	100	100	0	—	Improved, patient report
Lyon (21)	15	Case series	MAD	47% decrease	—	—	—	—	—	—
Meier-Ewert (22)	44	Case series	Esmarch	50/23	—	59	—	—	—	Improved, vigi- lance test
Total	304	Case series				70	51	39	—	—

Abbreviations used: AHI, apnea-hypopnea index; MAD, mandibular advancement device; TRD, tongue-retaining device; NAPA, nocturnal airway patency device.

^a Percent of all patients.

^b Percent of patients with initial AHI > 20.

(CPAP) and medications (44,45). Weight reduction is an important adjunct in obese patients. These treatments are limited by a low and unpredictable success rate (UPPP, medication, weight reduction), inconvenience (tracheostomy, CPAP), cost (reconstructive surgery) and/or patient noncompliance (CPAP).

3.5 Central sleep apnea

Infrequently a clinically significant sleep disorder occurs due to periodic breathing and central apneas caused by intermittent reductions in respiratory effort. The pathophysiology of this central sleep apnea syndrome

is not well understood, although upper airway obstruction may be a factor in some cases (46). Oral appliances have been used almost exclusively for snoring and OSA, but one report of successful treatment of 2 patients with central sleep apnea with the tongue-retaining device (TRD) has appeared in the literature (47). The subsequent discussion of oral appliances will be restricted to their use for the treatment of snoring and OSA.

4.0 ORAL APPLIANCES

4.1 Background

Oral appliances are used by dentists for many purposes, including correction of various types of occlusal disorders. The techniques often modify the position of the mandible within the restricted mobility defined by the temporomandibular joint (TMJ) and the pterygoid muscles. In the last decade, a variety of dental devices have been developed for treatment of snoring and OSA. A recent review summarizes design features and claims and/or proofs of efficacy of 13 devices (48). Oral appliances offer an alternative that may be attractive for OSA patients dissatisfied with other therapies or unwilling to accept more complex interventions.

4.2 Types of oral appliances used for snoring and OSA

The appliances evaluated in this review include predominantly devices that are designed to advance the mandible. Because of this shared design feature, these appliances are treated in the following discussion as one class, although individual design differences may have important effects on their clinical utility. Also included in the review is one well-studied appliance that modifies tongue position (6). We have not found studies of other devices that modify tongue position that meet our selection criteria, nor have we found such studies of the several devices with posterior extension to the soft palate or the base of the tongue. For all appliances, proper fitting and alignment is important. A professional society of dentists interested in sleep disorders has issued recommendations for the implementation of oral appliance therapy (48). However, we have not found information that allows us to critically evaluate this element of the treatment. The potential for worsening upper airway function should be recognized: patients with worse apnea-hypopnea frequencies with treatment than before are described in several of the selected reports (4,7-11,19). For all these reasons, conclusions regarding clinical effects should be limited to the devices specified by citation.

4.2.1 Mandibular advancing devices

Of the many oral appliances that have been proposed for the treatment of snoring or sleep apnea, most have designs that use traditional dental techniques to attach the device to one or both dental arches and to modify the mandibular posture. Construction requires dental impressions, bite registration and fabrication by a dental laboratory. However, at least one device is now available in a prefabricated form with a thermolabile material that can be molded to the patient's teeth in the clinician's office (19). Several appliances allow readjustment of the mandibular position after initial construction, but for others this requires refabrication of the entire device. All oral appliances produce downward rotation of the mandible to varying extents; many also advance the mandible by design. Of the appliances that attach to both dental arches, some restrict mouth opening by means of clasps and elastic bands, whereas others allow relatively unhindered mouth opening. Some designs include tubes or openings for oral breathing or pressure relief. Several appliances feature a posterior extension of the maxillary component that is designed to modify the position of the soft palate or tongue. Illustrations of 13 oral appliances, including mandibular advancing devices and tongue-positioning devices, have been published (48).

4.2.2 Tongue retainers

A second class of oral appliance is designed to keep the tongue in an anterior position during sleep. These devices secure the tongue by means of negative pressure in a soft plastic bulb; a flange, which fits between the lips and teeth, holds the device and tongue anteriorly in the oral cavity. It should be noted that these devices also modify mandibular posture, at least by downward rotation. The TRD has been fabricated from dental impressions, but a prefabricated version, suitable for molding to the patient's teeth in the clinic, is now available (6).

5.0 MECHANISM OF ACTION OF ORAL APPLIANCES

The goal of therapy with an oral appliance is to modify the position of upper airway structures so as to enlarge the airway or otherwise reduce its collapsibility. In addition to airway size, the effects on muscle function or airway compliance may also be important. Mandible-advancing oral appliances have been shown, via cephalometric radiographs, to increase various upper airway dimensions in patients when they are awake. In 12 patients, the consistent change caused by an oral appliance that produced advancement and downward

TABLE 2. Reviewed publications reporting the effect of oral appliances on snoring

First author (reference)	Number of patients	Device	Snoring improved (%)	Comment
Bonham (4)	12	MAD	73	Spouse report
Clark (10)	24	Herbst	Yes	Subjective score
Ichioka (14)	14	MAD	100	Subjective score
Kloss (15)	7	Esmarch	100	Patient report
Nakazawa (17)	12	MAD	100	Patient report
O'Sullivan (18)	51	MAD	100	Patient report and laboratory measurement
Schmidt-Nowara (19)	68	SnoreGuard	98	Patient report
Lowe (20)	1	MAD	100	Laboratory measurement
Lyon (21)	15	Elastomeric	100	Method not specified
Total	204			

Abbreviation used: MAD, mandibular advancement device, not otherwise specified.

rotation of the mandible was an increase in the superior airway space, i.e. the space between the soft palate and the posterior nasopharynx (4). The posterior airway space, i.e. the space between the base of the tongue and the posterior oropharynx, was significantly increased with one oral appliance (19), but was not increased with two others (4,11). Another cephalometric study of 10 patients with OSA showed a 56% mean increase in posterior airway space when maximal mandibular protrusion was compared to the rest position (49). Hyoid bone position was important in one series both as a pretreatment predictor and as a posttreatment indicator of a successful reduction of AHI (11). This same study also associated shortening of the soft palate length with a good treatment response. Each study revealed considerable variation between patients. In a complex computerized tomographic study of one patient, an oral appliance increased the airway space but also changed the shape of the tongue and soft palate (20).

Each of these studies has a bias to external validity because the observations were made in the awake state and oral appliances are intended to be used for sleeping patients. The studies indicate that dental devices produce complex changes in the shape and function of the upper airway that may positively influence airway patency during sleep.

6.0 EFFICACY OF ORAL APPLIANCES

6.1 Evaluation of clinical utility

The clinical utility of a treatment consists of its benefit, including efficacy and patient compliance, and its cost, including side effects, complications and the financial cost of treatment and related diagnostic procedures. Efficacy for these oral appliances includes their effects on snoring and sleep apnea as well as their secondary consequences, including sleep disturbance, sleepiness and any putative long-term sequelae. The

subsequent discussion reviews the evidence regarding oral appliances in each of these dimensions.

6.2 Snoring

All published clinical studies in which snoring was assessed, representing a variety of devices, show improvement in a high proportion of patients (Table 2). For example, a follow-up study of 68 patients reported reduced snoring in all but one patient, and 50% of patients reported elimination of snoring (19). In another study of 48 patients, 17% of bed partners reported snoring to be eliminated, 75% reported snoring to be much improved, and 8% reported improvement of a lesser extent (18). The effect of the TRD on snoring has not been reported in the several publications describing this device. However, in a retrospective telephone survey of 36 patients who had successfully adapted to chronic use (duration 1 month to 12 years), all but one patient reported a decrease in their snoring; 19 patients reported that their snoring was "eliminated" (Rosalind Cartwright, personal communication, 1994).

In the majority of studies, improved snoring has generally been inferred from the reports of patients or bed partners. However, laboratory recording documented improved snoring with an appliance in one case report (20). Additionally, a recent report documented a significant reduction of laboratory-recorded snore frequency and sound intensity in 51 patients after treatment with a "mandibular advancement splint"; each of these patients with a bed partner reported improved snoring (18). Although limited in number, these objective observations support the consistent improvement reported by patients and bed partners.

Patients with snoring and without apnea or hypopnea may have sleep pathology due to the upper airway resistance syndrome. Oral appliances may be effective in this condition, because they improve snoring in a

high proportion of patients. However, the studies necessary to identify this condition and the effect of oral appliance therapy have not been performed.

6.3 Sleep apnea

This review includes 20 publications reporting the effects of oral appliances on OSA in 304 patients (Table 1). All reports showed improvement with an appliance in the average AHI. Inspection of this table shows similar treatment effects in the peer-reviewed and other papers and shows no consistent differences among the various devices. When statistics were provided, the decrease in AHI was always significant ($p < 0.05$). Of the 271 cases with data reported in a form suitable for calculation, the mean AHIs before and with treatment were 42.6 and 18.8, respectively, an average reduction of 56%. The degree of improvement varied: although 70% of the patients in these studies had at least a 50% reduction in AHI, many did not correct to normal levels, and some patients did not improve or became worse. Fifty-one percent of patients achieved normal breathing, defined as an AHI of < 10 , with treatment. Conversely, 39% of patients with an initial AHI of > 20 remained above that level with treatment. In the 14 papers presenting data for individual patients, 20 patients (13%) had a greater AHI with treatment with the device than before treatment (4,7-11,19).

With oral appliance treatment, eight of nine studies reported an improvement in oxygenation assessed by the minimum oxygen saturation, although the changes were modest (Table 1). In one study, the median oxygen saturation during sleep remained unchanged, but the time in sleep with oxygen saturation of $< 90\%$ was reduced from 4.4% to 3.1% (18).

Treatment success was related to the initial AHI in three studies (11,18,19), but not in a fourth (13). Two studies suggested success would be unlikely with an AHI of > 50 or > 60 , respectively (18,19), but substantial improvement has been reported in other patients with AHIs of > 60 (10-12,20). In another study, consideration of several cephalographic parameters in addition to the initial AHI significantly improved the ability to predict posttreatment AHI (11). These observations represent attempts to predict treatment success with oral appliances, but the data are too limited to formulate any general recommendations.

The effect of the TRD on apnea and "low" oxygen saturation is similar to that achieved with other oral appliances (Table 1). Two studies noted that a reduction in AHI of at least 50% was associated with a significant positional effect before treatment, i.e. a greater apnea frequency in the supine than the side position (7,8). Predictors of treatment success were body weight less than 125% of ideal and an AHI at

least twice the frequency in the supine position of that in the lateral position. Additional reports suggest that the TRD is a useful adjunct to failed UPPP surgery (5) and to position training (to avoid sleep in the supine position) (9).

6.4 Sleep and sleepiness

Polygraphic assessments of sleep before and during oral appliance treatment have shown a reduction in stage 1 sleep, an increase in slow wave and stage REM sleep and a reduction in sleep fragmentation, mid-sleep wake time and arousals (Table 1). Most, but not all, patients reported an improvement in daytime sleepiness. One study showed improvement in 2 vigilance tests associated with improvement of AHI (21). Multiple sleep latency testing with oral appliance use has not been reported.

7.0 SIDE EFFECTS, COMPLICATIONS, AND COST

7.1 Side effects and complications

Nine reports on oral appliances mention side effects and complications, although the methods for their investigation are not always described (Table 3). Excessive salivation and transient discomfort for a brief time after awakening are commonly reported with initial use and may prevent early acceptance of oral appliances (18,19). With regular use and adjustment of fit, these symptoms subside. Later complications may include TMJ discomfort and changes in occlusive alignment. In one study, 3 of 20 patients reported TMJ pain as a reason for discontinuing treatment; the symptoms remitted after treatment was stopped (10). In another study, 3 of 14 surveyed patients reported a sense of altered occlusion, but the severity was not specified (17). Other reports examined but did not find these problems (11,19,21,22,49). Thus, published reports suggest that TMJ pain and occlusal changes are relatively uncommon occurrences, but the long-term risk of these complications is not well defined. With the TRD, 8 of 12 respondents to a 6-month survey admitted some discomfort with this therapy (6). The potential for an adverse effect on breathing exists, but the frequency of this complication is not known. Other side effects or complications for this device have not been reported.

7.2 Cost

A formal survey of the costs of devices and service has not been performed for oral appliances. The production cost of the device varies depending on whether

TABLE 3. *Reviewed publications reporting the side effects, complications, and patient compliance with oral appliances*

First author (reference number)	Number of patients	Device	Side effect or complication	Rate of occurrence	Compliance	Length of follow-up (years)
Cartwright (6)	14	TRD	Discomfort	8/12	11/13	0.5
Clark (10)	24	Herbst	TMJ pain	3/20	50%	3
Eveloff (11)	19	Herbst	No pain		13/14	1-3.5 (mean, 2)
Ichioka (14)	14	MAD	Discomfort	2/14	100%	0.4-1.75
Nakazawa (17)	12	MAD	Discomfort	2/21	14/21	Mean, 0.6
			Occlusal changes	3/14		
			"TMJ dullness"	1/14		
O'Sullivan (18)	51	MAD	"Jaw discomfort"	67%	79%	—
Schmidt-Nowara (19)	68	SnoreGuard	Discomfort	48%	75%	Mean, 0.6
Lyon (21)	15	MAD		0/15	—	—
Rider (24)	16	Herbst	"No problems"	—	—	0.83
Total	233					

Abbreviations used: MAD, mandibular advancement device; TRD, tongue-retaining device; TMJ, temporomandibular joint.

a dental laboratory is required for custom fitting or a prefabricated unit can be adapted in the clinician's office. The TRD is provided in one clinical laboratory for \$200. The lowest cost of dental services known to the task force is \$300 for fitting and adjustment of a prefabricated appliance. More typical costs for custom-fitted appliances and service range from \$400 to \$900 (Great Lakes Orthodontics, Tonawanda, NY, personal communication, October 1993). When cephalometric radiographs or other airway studies are performed as part of the procedure, the cost increases accordingly.

8.0 COMPLIANCE

Data on long-term compliance are limited in number and are all based on patient reports (Table 3). The experience with nasal CPAP, however, indicates that self reports may significantly overestimate objectively determined actual use (50,51). Patients need instruction regarding the proper use of all oral appliances. Some patients do not initially use the device for the whole night (6). One study reported that, after adaptation, patients used an oral appliance "the entire night and almost every night" (19). Overall compliance rates vary in different studies and may be related to the length of follow-up. Compliance with oral appliance use ranged from 100% in 14 patients followed for 3 to 21 months (14), to 75% in 68 patients queried after a median of 7 months (19), to 52% in 24 patients queried after 3 years (10). The reasons for discontinuing appliance use include the side effects and complications noted above and lack of efficacy.

9.0 COMPARISON WITH OTHER THERAPIES

A direct comparison of oral appliance therapy to other treatments has not been published. In the absence of a controlled trial, selection bias could produce important differences between groups of patients receiv-

ing different treatments, and these differences could bias any comparison between treatments. With this important caveat, it may be useful to compare oral appliances to the major treatments of snoring and OSA in terms of efficacy, compliance, complications and cost. It is beyond the scope of this paper to critically review all these other therapies for snoring and OSA. Readers are referred to illustrative citations and two recent reviews (44,45).

For primary snoring, oral appliances and soft palate surgery (presently UPPP) are the principal considerations. Treatment of rhinitis and nasal obstruction, weight loss and alcohol restriction are important adjuncts, but patients who request medical relief from snoring have usually tried these remedies. Laser surgery of the soft palate, a new procedure attracting considerable public attention, cannot be evaluated because of insufficient data (52). UPPP reduces snoring intensity in 90% of patients and eliminates it in a smaller proportion (53,54), a success rate similar to that of oral appliances (Table 2). Compliance is a problem with oral appliance treatment. Relapse of snoring after surgery has not been examined in published reports, but probably does occur since relapse of OSA is well documented (55). Complications are relatively infrequent with both treatments but appear to be less severe with the oral appliances (54) (Table 3). Cost is substantially less for oral appliances. Thus, oral appliance therapy and palatal surgery offer a similar rate of treatment success for primary snoring, but they differ significantly in terms of cost and compliance.

For OSA, no currently available treatment provides the ideal combination of a high rate of success and patient acceptance without complications. Nasal CPAP has become the consensus first choice because of its efficacy (44,45), but patient acceptance and compliance are significant problems. On average, 10% of patients offered CPAP choose not to try the treatment (56). At follow-up 2-48 months after starting CPAP, 50-90%

of patients are still using this form of treatment (56). Of those using CPAP, many do not use it all night or every night (50,51). Tracheostomy is the only other treatment with an efficacy comparable to CPAP (57), but given today's alternatives, few patients select a treatment requiring a permanent prosthesis in the neck. Oral appliances and all the other alternatives to nasal CPAP and tracheostomy, either medical or surgical, are effective in a lower proportion of patients. The widely applied UPPP surgery is effective, depending on the criterion for success, in 50–80% of patients (53–55,58), which is no better than the oral appliances reviewed here (Table 1). Compared with UPPP or the more complex facial reconstruction pioneered by Riley and Powell (59), oral appliance therapy costs less and has the advantage of being easily terminated without sequelae. Compared to protriptyline, the principal medication used for OSA (60), the efficacy of oral appliance therapy is better and side effects appear to be more tolerable. Compared to weight loss, the effect of oral appliances is realized more quickly and the rate of success is higher (61). Thus, oral appliances, though providing a lower rate of AHI reduction, offer an alternative to nasal CPAP; the combination of side effects, complications, reversibility and cost compares favorably to the non-CPAP treatments of moderate to severe OSA.

10.0 LIMITATIONS IN THE DATA

The critical reader of this literature may be dismayed by the relatively small size of most case series, the lack of randomized controlled studies, the often sparse description of the patients and the study methods. Nevertheless, the consistency of the findings among the many studies suggests that larger studies would come to the same conclusions. The absence of controls has been noted but was no different in the studies that established nasal CPAP and the other treatments of OSA. The problem of publication bias should always be considered. How many negative experiences have gone unreported? Furthermore, to what extent are the results in this literature dependent on the special expertise of the authors and can they be reproduced in regular clinical practice?

Clearly there is a great need for more information. Most studies have focused on the acute effect of oral appliance treatment on sleep apnea. Future studies must better define the effect on oxygenation in various types of patients and the effect on sleep per se and sleepiness. Patients with well-defined upper airway resistance syndrome should be studied with oral appliance treatment. More follow-up data are needed to define the rate of compliance, the risk of complications and the need for adjustment of the appliance. Follow-up stud-

ies should also address the long-term efficacy of oral appliances for snoring and OSA. Studies on the mechanism of the treatment effect may help the development of more effective devices. Outcome studies that directly compare oral appliances to other sleep apnea therapies are needed to more precisely define the indications within the spectrum of sleep apnea disorders.

11.0 SUMMARY

The 21 publications selected for this review describe 320 patients treated with oral appliances for snoring and OSA. Despite considerable variation in the designs of these appliances, the clinical effects are remarkably consistent. Snoring is improved in almost all patients and is often eliminated. Mean results of studies show that OSA improves in the majority of patients. Approximately half of those patients who improve achieve an AHI of <20, but as many as 40% are left with notably elevated AHIs. Sleep is generally improved, although significant sleep disturbance persists in the patients with residual apnea. Limited follow-up data indicate that oral discomfort is a common but tolerable side effect, that dental and mandibular complications appear to be uncommon and that long-term compliance varies from 50% to 100% of patients. Comparison of the risks and benefits of oral appliance therapy with those of other available treatments suggests that oral appliances present a useful alternative, especially for patients with simple snoring and others with moderate OSA who cannot tolerate nasal CPAP. More studies are needed to define the therapeutic role of oral appliances in the spectrum of sleep disorders related to upper airway obstruction.

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