Oral Appliances for Sleep-Disordered Breathing
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ABSTRACT
Oral appliances (OAs) are an established treatment option for snoring and mild obstructive sleep apnea (OSA). OA therapy is a simple, reversible approach to treatment. OAs appear to work as a result 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 upper airway muscle activity. Recent randomized, controlled trials of OA therapy have shown a good level of effectiveness in patients with mild to moderate OSA and effectiveness in some patients with more severe OSA. In most of the studies comparing OAs with continuous positive airway pressure (CPAP), patients exhibited a preference for the OA even though CPAP lowered the apnea-hypopnea index more effectively. With evidence of effectiveness from randomized, controlled trials, it is now reasonable to expand the indications for first-line therapy with an OA to the treatment of patients with moderate OSA.

Current evidence suggests that the pathogenesis of OSA involves a combination of reduced upper airway size and altered upper airway muscle activity. OAs may improve upper airway patency during sleep by enlarging the upper airway or by decreasing upper airway collapsibility (e.g., improving upper airway muscle tone). The effects of OAs on upper airway size vary between studies, and these differences are likely due to the different imaging techniques used, the study methods (i.e., evaluation during wakefulness versus during sleep), differences with regard to the subject’s body position (i.e., supine versus upright), and different types of appliances and degrees of protrusion. Most imaging studies suggest that OAs have a direct effect on mandibular posture and thereby increase airway size. The effects on upper airway size are summarized in Table 91-1. Effects on upper airway muscles have been less well studied.

Mandibular repositioning appliances (MRA) cover the upper and lower teeth and hold the mandible in a forward position. An example of the effect of an MRA on airway size is illustrated in Figure 91-1. Tongue-advancing appliances hold the tongue in a forward position without mandibular advancement. Some tongue-advancing appliances like the tongue-retaining device (TRD) hold the tongue forward in a bulb using suction (Fig. 91-2).

Simple anterior movement of the tongue or mandible during wakefulness can increase cross-sectional airway size at all levels in subjects with and without OSA. Passive mandibular advancement during general anesthesia (done by a jaw thrust maneuver) stabilizes the upper airway by increasing airway size in both the retropalatal and retroglossal area and by reducing upper airway closing pressure (the level of intraluminal pressure at which closure occurs). Mandibular advancement with an MRA reduces closing pressure (e.g., makes it more negative) and therefore decreases upper airway collapsibility.

Effects of Mandibular and Tongue Advancement on Upper Airway Muscle Tone
TRDs affect genioglossus muscle activity in patients with OSA (awake or asleep), but effects of the TRD on other upper
Table 91-1. Effect of Mandibular Repositioning Appliances on Upper Airway Size

<table>
<thead>
<tr>
<th>Imaging Modality</th>
<th>Image Obtained</th>
<th>Body Position</th>
<th>Dimension</th>
<th>Effect</th>
<th>References</th>
</tr>
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<tbody>
<tr>
<td>Lateral cephalometry</td>
<td>Awake</td>
<td>Upright</td>
<td>Posterior airway space</td>
<td>Increased</td>
<td>29, 67</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Posterior airway space</td>
<td>Unchanged</td>
<td>68</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Retropalatal airway space</td>
<td>Increased</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Tongue posture</td>
<td>Flattened</td>
<td>69, 70</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Oropharynx size</td>
<td>Increased</td>
<td>70</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Hypopharynx size</td>
<td>Increased</td>
<td>71</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Velopharynx size</td>
<td>Increased</td>
<td>72</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Supine</td>
<td>Oropharynx size</td>
<td>Unchanged</td>
<td>60</td>
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<tr>
<td></td>
<td>Awake</td>
<td>Supine</td>
<td>Sagittal cross-sectional area of</td>
<td>Increased</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Supine</td>
<td>Oropharynx size</td>
<td>Increased</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Upright</td>
<td>Mandibular plane to hyoid distance</td>
<td>Decreased</td>
<td>67, 69, 70</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Supine</td>
<td>Mandibular plane to hyoid distance</td>
<td>Increased</td>
<td>73</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Supine</td>
<td>Pharyngeal cross-sectional airway</td>
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<td>67</td>
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<tr>
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<td>Supine</td>
<td>Oropharynx size</td>
<td>Increased</td>
<td>74</td>
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<tr>
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<td>Awake</td>
<td>Supine</td>
<td>Hypopharynx size</td>
<td>Increased</td>
<td>75</td>
</tr>
<tr>
<td></td>
<td>Awake</td>
<td>Supine</td>
<td>Velopharynx size</td>
<td>Increased</td>
<td>75</td>
</tr>
</tbody>
</table>

Airway muscles have not been evaluated. A TRD worn during sleep reduced the apnea-hypopnea index (AHI), and when the TRD was worn without tongue advancement (no bulb), the AHI decreased and peak genioglossus activity, measured just before airway opening, increased. The mechanism for this effect and its significance is not certain, but increased genioglossus tone may contribute to upper airway reopening.

A study using an MRA found that upper airway muscle tone increased with an MRA except in the post-apnea period, when genioglossus tone was lower. Another study also found augmentation of genioglossus tone with mandibular advancement. These studies suggest that activation of the upper airway muscles by an MRA may contribute to airway patency. In a more recent, placebo-controlled trial the presence

Figure 91-1. Lateral cephalograms of a patient pretreatment (left) and while wearing a Klearway mandibular repositioning appliance (right).
patients may respond to a TRD. Dental records are obtained and may include dental radiographs and a panoramic or full-mouth survey. Some practitioners obtain a cephalogram. The dentist obtains informed consent about the risks and benefits of OA therapy. A discussion about potential long-term side effects and complications should take place as part of the informed consent process.

Moderate to severe TMJ problems, bruxism, an inadequate protrusive range, and advanced periodontal disease are all relative contraindications to MRA use. Thirty-four of 100 patients consecutively assessed by oral and maxillofacial surgeons were found to have contraindications to therapy and 16% to have dental issues that would require close follow-up. Not all TMJ problems are contraindications to MRA therapy—mild problems may be lessened by a forward jaw position. TRDs do not necessarily require teeth and do not require mandibular protrusion. Patients who are claustrophobic with CPAP may also be claustrophobic with an appliance.

### Appliance Selection and Management

#### Types of Oral Appliances

The dentist determines the most appropriate type of appliance to use. There are two main appliance groups in common clinical use—tongue-repositioning devices and MRAs (see Figs. 91–2 through 91–6). The dentist chooses which type of appliance to use. Tongue-repositioning devices, such as the TRD, are often used in patients with large tongues, an inadequate protrusive range, or insufficient teeth to use an MRA. Information about OAs that have received 510k market clearance from the U.S. Food and Drug Administration for the treatment of snoring or OSA is available at the Academy of Dental Sleep Medicine website (http://www.dentalsleepmed.org/fda.htm). Soft palate lifters are used rarely for snoring or OSA. Because this device is poorly tolerated and is ineffective in the treatment of snoring and OSA, it is not discussed.

#### Appliance Selection, Fabrication, Insertion, and Management

An appliance may be “off the shelf” or be custom. May provide partial or full occlusal coverage, may be made of soft or hard materials, and may be rigid or allow jaw movement. Some appliances are made of temperature-sensitive acrylic (Fig. 91–3). These appliances become pliable in hot water and when they cool to mouth temperature they firmly grip the teeth and are very retentive. Bruxism is common in patients with OSA and may be a contraindication to MRA therapy. Patients who experience jaw discomfort after wearing a rigid MRA may benefit from using an appliance that allows lateral and vertical jaw movement. A small amount of movement may improve comfort for patients with bruxism who use an MRA. Plaster models are obtained as appropriate for the specific OA. Boil-and-bite appliances are fit to the patient in the office. Custom appliances may be fabricated by the dentist or by the dental laboratory.

Appliances may be nonadjustable and worn in one position or be partly adjustable (more than one possible preset position). Newer appliances tend to be fully adjustable. This allows the mandible to be incrementally advanced to obtain the therapeutic position. The initial position is usually set between 50% and 75% of maximum mandibular protrusion.
taken place, the patient is referred back to the attending physician for a clinical assessment or repeat overnight assessment. Medical follow-up is necessary to evaluate treatment response and to assess for recurrence of OSA. It is recommended that follow-up overnight studies be performed to verify the improvement in apnea, oxygenation, and sleep fragmentation by the OA.¹ This recommendation is supported by the evidence that some patients have an increase in AHI with OA treatment.³⁴⁻²⁸⁻³⁰ Regular follow-up visits are continued as long as the patient is using OA therapy. The dentist monitors device usage, symptoms, side effects, complications, and the degree of advancement at follow-up visits. The dentist monitors effectiveness, fit, and comfort, as well as TMJ, occlusal, and dental status at all follow-up visits.

OVERVIEW OF ORAL APPLIANCE EFFECTIVENESS

A comprehensive review of OA therapy was published in 1995,³¹ along with practice parameters for their use.¹ The literature at that time consisted of case reports and retrospective and prospective case series. The authors pooled the results for the TRDs and MRAs of different designs. Seventy percent of the 304 subjects had a reduction in AHI by at least 50% from baseline. Fifty-one percent had a post-treatment AHI of less than 10, but as much as 40% of subjects had a post-treatment AHI of greater than 20. Snoring was reported improved in most patients. Since 1995, many prospective studies have been published, including randomized and controlled trials. In the more recent prospective case series of OA therapy, 54% to 84% of patients had a reduction in AHI by at least 50%,³²⁻³⁵ and 51% to 82% of patients had a post-treatment AHI of less than 10.³³⁻³⁷

Mandibular Repositioning Appliances

Seventeen controlled clinical studies have been published on OA therapy and OSA or snoring. There are six crossover studies comparing MRAs with CPAP (five randomized,²³⁻¹⁰⁻¹²⁻¹³ one nonrandomized¹⁹); five randomized studies comparing two different MRAs or appliance designs;⁴⁻⁶⁻⁸⁻¹¹⁻¹⁵ and three randomized, placebo-controlled trials.⁷⁻⁹⁻¹⁴ There is one randomized study comparing an MRA with uvulopalatopharyngoplasty (UPPP),³ with additional data in three subsequent manuscripts.⁹⁻¹⁴ Two randomized studies in snoring have been published—one comparing three appliances¹⁶ and one comparing an MRA with placebo.¹⁷

Randomized, Crossover Studies of Oral Appliances with Continuous Positive Airway Pressure

The first randomized, controlled, crossover study of OA therapy was published in 1996.² The investigators compared the efficacy, side effects, compliance, and preference between an MRA (fixed position, boil-and-bite [SureGuard]) and CPAP in patients with mild to moderate OSA (AHI 15 to 40). Treatment success for the MRA was 48% (reduction in AHI to 10 or less with relief of symptoms) and for CPAP was 62%. The AHI was lower with CPAP than with the MRA. The MRA was well tolerated, with fewer side effects than CPAP, but some patients (24%) were unable or unwilling to use the MRA because of poor retention (ability to keep the OA in place in

Figure 91-3. The Klearway adjustable oral appliance. (Courtesy of Great Lakes Orthodontics, Ltd., Tonawanda, NY.)

Patients tolerate the initial amount of protrusion differently and sometimes need to start at less than 50% of maximum. Appliances with a single jaw position can usually be remade if the initial position is too far forward and uncomfortable or if it is not forward enough to provide benefit.

A typical titration protocol would consist of gradual forward adjustments of the MRA to a position associated with relief of snoring and other symptoms but without significant side effects. Patients vary considerably in the speed of advancement during titration of an MRA and in how far forward they can comfortably go in terms of the amount of protrusion achieved. Gradual forward titration of the mandible by the patient without remaking the MRA each time is an advantage of adjustable MRAs. If an optimal position is not obtained (e.g., persistent snoring), the MRA is set at the maximum forward position that does not produce significant side effects.

TRDs are custom made for the patient. The patient advances the tongue into the bulb while squeezing the bulb to create negative suction. The patient experiments with the amount of forward positioning of the tongue that is required to decrease snoring and symptoms. Denture adhesive powder may be placed into the bulb to enhance retention of the tongue during sleep.

The dentist teaches the patient how to use the appliance, to care for it, to adjust it (if that is a feature of the design), and what side effects and complications to look for. The appliance may need repairs, modification, further advancement, or even redesign or replacement with a different device if side effects develop or if there is an inadequate subjective or objective improvement. Patient compliance should be monitored at each visit. Once a satisfactory improvement in symptoms has
the oral cavity) or discomfort. The MRA was effective in reducing snoring in most patients and in reducing daytime sleepiness. Side effects were more common and the patients were less satisfied with CPAP. The authors concluded that a simple fixed-position appliance was an effective treatment in some patients with mild to moderate OSA and was associated with fewer side-effects and greater patient satisfaction than CPAP. A second randomized, crossover study evaluated a partly adjustable custom appliance. This MRA was successful (AHI of 10 or less and relief of symptoms) in treating 55% of patients. Sleep quality was improved more by CPAP and CPAP was more effective at reducing the AHI. Daytime sleepiness was equally improved by the two treatments.

Another randomized, crossover study of an intraoral sleep apnea device (a type of MRA) versus CPAP was conducted in patients with mild to moderate OSA (AHI between 5 and 30). The MRA was arbitrarily set at two thirds of maximum mandibular protrusion and was not further adjusted during the study. After 6 weeks of therapy, CPAP was more effective at improving snoring, the AHI, and oxygenation. This MRA was not particularly effective at reducing the AHI (baseline AHI 17.5 ± 7.7 to 13.8 ± 11.1 at 6 weeks, P = not significant), although patients reported greater ease of use and higher compliance with the MRA. Subjective sleepiness was improved equally with both treatments. Overall, only 30% of patients (6 of 20) had an AHI of less than 10 with the MRA. The relatively low level of efficacy of this MRA may be related to the lack of titration of the appliance during the study.

Another randomized, crossover study of CPAP and OA in patients with OSA (AHI 11 to 43) and at least two OSA symptoms was published. The patients were selected for the presence of sleepiness. The study included objective measures of sleepiness and assessments of quality of life and performance. The appliance was set at roughly 80% of maximum mandibular protrusion. The two appliances chosen for the study were fixed-position appliances. CPAP was more effective than the MRA for improving AHI and subjective ratings of daytime function even in the patients with milder OSA. There were no differences between the treatments in the effect on objective measures of sleepiness or cognition, or patient preference. Patients who preferred CPAP therapy had a higher body mass index and greater daytime impairment. The researchers concluded that CPAP would be the preferred first-line therapy in patients with OSA who have significant functional impairment and sleepiness even if they had mild OSA (defined by a lower AHI). The lower level of effectiveness of OA therapy in this study may be related to the selected appliance (single position, not state of the art) being compared with state-of-the-art CPAP therapy and the lack of titration of the MRA during the study.

A randomized, crossover trial of an MRA and CPAP therapy in 24 patients with mild to moderate OSA was published in 2002. Two types of appliances were used—a single-piece device and a two-part appliance. Both appliances were set at approximately 75% of maximal protrusion but could be advanced further if needed. The AHI decreased from 22.2 to 8 with the MRA and to 3.1 with CPAP. Sleepiness as measured by the Epworth Sleepiness Scale (ESS) score was improved by both treatments (P < .001). Sixteen of the 23 patients (70%) who completed MRA therapy (22 completed CPAP therapy) had an AHI of less than 10.

**Summary**

In these five published randomized, crossover studies of MRA therapy compared with CPAP in the treatment of OSA, CPAP was more effective in reducing snoring, improving oxygenation, and decreasing the AHI. In three of the five studies, they were equally effective in relieving excessive daytime sleepiness.

**Randomized, Controlled Studies of Two Appliances or Two Designs**

Five studies have compared different MRAs or MRA designs. One study evaluated a fixed-position appliance (SnoreGuard) and a modified device in 24 patients with mild OSA. The device that protruded the mandible (device A) was more effective in reducing the AHI than the device that minimally opened the vertical dimension without mandibular protrusion (device B). Some patients had an increase in AHI using device A or device B. A randomized, controlled, crossover study of the Herbst (Fig. 91-4) and the Monobloc appliance (Fig. 91–5) has been published. The AHI was less than 10 in 75% of patients with the Monobloc and in 67% of patients with the Herbst. Both devices reduced sleepiness and snoring, but patients preferred the Monobloc.

One randomized, crossover study specifically evaluated the effect of vertical opening on the efficacy of an MRA. The splint was constructed with 4 mm of interincisal opening or 14 mm of opening. Twenty-three patients wore each MRA for 2 weeks in random order. Both MRAs had similar efficacy...

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**Figure 91-4.** An adjustable Herbst appliance. (Courtesy of Great Lakes Orthodontics, Ltd., Tonawanda, NY.)
in reducing the AHI. Both MRAs improved snoring and sleepiness, but there was a trend to more jaw discomfort with the greater incisal opening. Overall, the patients preferred the appliance with less incisal opening for treatment. In this short-term study, increasing the vertical opening did not have an impact on efficacy, but there is concern that with long-term use it could increase side effects.

Another randomized, crossover study of two distinct MRAs for the treatment of mild OSA in 26 patients was published in 2002. The appliances differed in materials, the amount of vertical opening, and the type of retention. Both were set at approximately 75% of maximum protrusion. Both MRAs improved symptoms like snoring, sleepiness, and sleep quality. The MRA made of hard material with more vertical opening had more side effects and was less effective at improving OSA. Another study evaluated two different amounts of mandibular protrusion, 75% or 50%, with an MRA in 86 men with severe OSA. There were no more side effects with further protrusion. The MRA set at 75% reduced the AHI to less than 10 in 52% of patients, whereas the MRA set at 50% reduced the AHI to less than 10 in 31% of patients (P = .04).

SUMMARY
Different MRAs have different levels of effectiveness at reducing the AHI. There may be differences in terms of side effects, comfort, and preference. These differences may be related to design features of the appliance such as amount of vertical opening and the amount of protrusion.

**Randomized, Placebo-Controlled Studies**

The first randomized, placebo-controlled, crossover trial of an MRA (Fig. 91–6) for the treatment of OSA was published in 2001. The authors studied 28 patients who wore an MRA that was incrementally advanced until symptoms resolved or maximum tolerated protrusion was obtained. Patients were randomly assigned to treatment with the placebo (lower plate of the appliance only) or with the MRA. A partial response was defined as symptomatic improvement with an AHI reduced by at least 50% but greater than 5 at outcome, and a complete response was defined as a resolution of symptoms and an AHI of less than 5. The MRA resulted in a partial response in 15 patients (62.5%) and a complete response in 9 (37.5%). Seventy-one percent had an AHI of less than 10 with the MRA. The placebo device had no impact on AHI or on oxygen saturation. The MRA improved snoring, sleep structure, oxygenation, and daytime symptoms. There were few important side effects and no complications.

Another randomized, placebo-controlled, crossover study evaluated the effect of an MRA on subjective and objective sleepiness in 73 subjects. Sixty-two subjects (85%) had moderate to severe OSA (AHI of 15 or more) and 38 (52%) reported sleepiness (ESS score greater than 10). The MRA was set at roughly 80% of maximum protrusion. The MRA improved snoring and reduced the AHI by 52%, with 63% having a complete or partial response (as defined for the study discussed previously). The MRA reduced the ESS score and increased the mean sleep latency compared with placebo.

A further randomized, crossover study compared an MRA set at 75% maximum protrusion with a placebo maxillary splint. The MRA decreased the AHI, but there was a small increase in AHI with the placebo. Six of the 18 patients had a reduction in AHI to less than 10 with the MRA. Subjects reported a high level of compliance.

**SUMMARY**

Placebo-controlled trials of OA therapy consistently demonstrate that devices that advance the mandible are effective at lowering the AHI. In general, the active devices improve symptoms better than the placebo, but not always. Most of these studies are small, and larger placebo-controlled trials might find more improvement in subjective outcomes.
Randomized Study Comparing a Mandibular Repositioning Appliance with Uvulopalatopharyngoplasty

There is one randomized study of UPPP versus an MRA in patients with mild to moderate OSA. The MRA was set at 50% of maximum protrusion and the surgical group had a conventional UPPP. Similar numbers of patients withdrew before treatment from both groups, but additional patients withdrew from the MRA group during the 1-year treatment period. The MRA was more effective at lowering the AHI (AH1 of less than 10 in 78% with the MRA versus 51% with UPPP). The treatments were equally effective at improving subjective sleepiness. MRA side effects were described as minor and infrequent in a later publication, with no significant occlusal changes. After 4 years, 10% of patients with UPPP had persistent swallowing complaints. Quality-of-life scores improved in both treatment groups at 1 year. Although the MRA reduced the AH1 by more than UPPP, there was no difference in vitality and sleep scores between the treatments. Contentment scores were higher in the UPPP group. After 4 years of treatment, five patients in the MRA group had stopped using the device. Some patients in the UPPP group had begun using an MRA because of persisting OSA.

Randomized, Prospective Studies of Snoring

There have been two randomized studies of OA for snoring. One study evaluated three different appliances in a crossover design. The appliance that advanced the mandible improved snoring in four of five patients. Another study found that an MRA was effective at reducing the frequency and loudness of snoring compared with the placebo (upper plate of the appliance).

Summary of Randomized, Prospective Studies

In summary, MRAs are an effective treatment option for many patients with OSA, including some patients with more severe OSA (higher AH1). They improve snoring and daytime symptoms, reduce the AH1, and improve oxygenation during sleep. They are not as effective as CPAP in reducing the AH1 or snoring or at improving oxygenation. In some studies they are not as effective in reducing symptoms of sleepiness as CPAP, but in other studies they were. Overall, CPAP is more effective than an MRA and is considered first-line therapy in patients with more severe symptoms and in patients with more severe OSA, particularly if there is significant impairment of oxygenation.

Tongue-Advancing Appliances

Tongue-repositioning devices include the TRD, which is the best studied of these devices (see Fig. 91-2). The TRD is a custom-made, soft acrylic appliance that covers the upper and lower teeth and has an anterior bulge. It uses negative suction pressure to hold the tongue in a forward position inside the bulb. For those patients with limited nasal breathing, the TRD may be modified by the addition of lateral airway tubes that permit mouth breathing. The TRD appliance may be particularly useful in patients who have a relatively large tongue, poor dentition, or a poor protrusive range. Side effects include tongue soreness and excessive salivation, and some patients have difficulty using the TRD for the entire night.

In 1982, Cartwright and Samelson reported their initial experience with the TRD in 20 patients. Fourteen of the 20 patients had undergone polysomnography before and with the TRD. There was a reduction in AH1 of approximately 50% even though patients wore the TRD only half the night. Cartwright reported a second uncontrolled study of the TRD in 16 patients. Treatment success in this study was defined as a reduction in apnea index (AI) to the normal range (0 to 6) or a 50% reduction in AI. Sixty-nine percent were successfully treated by the TRD by these criteria. The TRD was more effective in patients who were less severely overweight and in patients with a positional apnea (apnea that is more severe in the supine position). Sleep architecture was improved with the TRD. When obesity, age, and the position ratio were used in a discriminant function analysis, these three variables predicted TRD success (as defined by an AI of less than 6 or a 50% reduction in AI) correctly for 13 (81%) of the patients. In a subsequent case series comparing treatments for positional OSA, the success rate with the TRD was reported as 80% for the reduction of the AH1 to less than 10.

Other tongue-advancing appliances have also been developed. A tongue-stabilizing device was assessed in a pilot study of six patients. This device is based on the bulb component of the TRD and because it does not cover the dentition, it is an "off-the-shelf" product. The tongue-stabilizing device reduced snoring significantly, but the reduction in AH1 from 26 ± 17 to 15 ± 13, P = .06 was not significant.

SIDE EFFECTS AND COMPLICATIONS

Several studies have been published that have evaluated long-term side effects and complications from OA therapy. Pantin and others assessed 132 of 191 (69%) patients consecutively treated with an MRA during a 5-year period and performed a dental examination on 106 patients. Ten patients had stopped using the MRA because of minor dental side effects. Occlusal changes were seen in 14%, and in two cases they recommended the patient stop treatment. Marklund and colleagues investigated side effects of a soft and a hard acrylic MMA in 75 patients who reported using the device more than 50% of nights for approximately 2.5 years. Overbite and overjet decreased and three patients reported a permanent occlusal change. Hard acrylic appliances and larger amounts of protrusion were associated with more occlusal changes. Fritsch and colleagues evaluated 22 patients who had used either a Monobloc or a Herbst MRA for the treatment of OSA. Common side effects included mucosal dryness (86%), tooth discomfort (59%), excessive salivation (55%), and jaw pain (41%), but they were described as minor. Long-term appliance use was associated with small orthodontic changes—decreased overjet and overbite, retroclined maxillary incisors, and slight anterior movement of the first mandibular molars. Patients reported that symptoms due to these changes usually resolved after a few minutes in the morning. Other long-term studies that have carefully evaluated the patient's dental status have confirmed the presence of small orthodontic changes and indicate that the changes may be progressive with time.

Overall, there is a degree of occlusal change in patients with long-term MRA use and these changes need to be monitored and addressed when they arise. Usually, the changes are minor and reversible when treatment is discontinued. Rarely, the occlusal changes are permanent. Patients need to be
informed of the potential for occlusal change when they embark on OA therapy. TMJ problems in patients without pre-existing joint problems are very uncommon, and long-term use does not seem to predispose to joint dysfunction.32,53

Occasionally, an OA can worsen apnea severity.2,3,4,28,30 In one recent trial, 4 of 28 subjects (14%) had an increase in AHI with the appliance.30 The reason for this increase could not be determined from a review of the patient data.

**PREDICTORS OF TREATMENT OUTCOME**

Although many studies have examined variables that may be associated with treatment outcome, most studies have been underpowered to find relationships between outcome and these variables. Clinical variables and upper airway characteristics associated with good treatment outcome are summarized in Box 91–1. In general, a younger, thinner patient with positional OSA (AHI higher when supine) and an overall lower AHI is the preferred candidate for OA therapy. One study found that heavier patients responded better to MRA treatment than thinner patients.10 Marklund and colleagues reviewed 630 patients treated with MRAs and found that women had greater success with the device than men.71 They also found that weight gain in treated male patients and nasal obstruction symptoms in female patients decreased treatment success. Some studies have demonstrated reasonably good success rates in patients with more severe OSA.7,26,30,34,53,56

Published studies have used a variety of imaging techniques to assess the upper airway and the factors associated with treatment response. Upper airway features associated with a good response are summarized in Box 91–1. It has been suggested that a more micrognathic or retrognathic mandible is associated with improved treatment response,37 but other studies have suggested that a normal mandibular length and less overjet is associated with a better outcome.58 A hypopharyngeal site of obstruction may be associated with improved treatment outcome,59 but many patients with velopharyngeal closure still get a good result.30 Increased hypopharyngeal size and middle airway space (airway width at the tip of the soft palate) with the MRA were associated with a good response in one study of 16 patients using supine cephalography.60

**TREATMENT COMPLIANCE**

In recent studies, 76% to 90% of patients have reported regular use of the MRA.25,61 In two of the studies comparing OAs with CPAP, compliance was measured by patient reports.2,3 There was no difference in reported nightly use between the treatments (roughly 60% for all treatment arms). Until objective compliance monitors are available for OAs, compliance rates will be uncertain given the unreliability of self-report. One preliminary study using a built-in compliance monitor embedded in the device32 found that patients were using the MRA an average of 6.8 hours per night (range, 5.6 to 7.5).

**INDICATIONS FOR ORAL APPLIANCE THERAPY**

Prospective, controlled trials of OA therapy have shown a good level of effectiveness in patients with mild to moderate OSA and effectiveness in some patients with more severe OSA. In most of the studies comparing OAs with CPAP, patients exhibited a strong preference for the OA even though CPAP lowered the AHI more effectively. There may be difficulties implementing CPAP therapy in patients who have previously had UPPP,50 but OAs may be effective in this group.35 There are case reports detailing the successful use of an OA in the treatment of upper airway resistance syndrome,93,60 with improvements in objective daytime sleepiness.65

OAs are usually not indicated as first-line therapy for severe OSA or severe sleepiness, or in patients who have very abnormal oxygen levels during sleep. CPAP therapy can be titrated in 1 night, but it can take weeks to months to optimize protrusion of an MRA. Two published studies have assessed overnight titration of an MRA to determine the therapeutic position and efficacy.26,66 This is a promising approach that may allow identification of patients in whom an OA might be effective. Overnight titration might allow patients with more severe OSA to be treated without delay.

**SUMMARY**

OA therapy is a simple, reversible approach to treatment. Patients require alternatives to surgery and CPAP and the usefulness of OA therapy is no longer in question. Randomized, controlled clinical trials have shown them to be an effective treatment option for many patients, particularly in patients with less severe OSA. They are indicated in patients who have failed other treatments even if they have severe OSA. OAs appear to work as a result 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 by a change in upper airway muscle activity.

Although MRAs are not as effective as CPAP therapy, they work in most patients to relieve symptoms and apnea and are well tolerated by most patients. Most patients report improvements in sleep quality and excessive daytime sleepiness. Short-term side effects are usually minor and are related to excessive salivation, jaw and tooth discomfort, and occasionally joint discomfort. These symptoms usually improve over time.
Significant TMJ complications are rare, but occlusal changes are more common than previously thought.

OA therapy is a unique opportunity for dentists and physicians to work together to select the ideal patients for this form of treatment. Each plays a crucial role in providing the patient with optimal care. With collaboration and good communication between the dentist and the sleep clinician, many patients with snoring or OSA can be treated effectively with OAs.

FUTURE DIRECTIONS

Future studies are needed to compare the effectiveness of different types of appliances and different design features (e.g., the amount of vertical opening). The precise indications, complication rates, and reasons for treatment failure need to be determined for each OA if it is going to be used in clinical practice. Ongoing refinements of appliance design may eventually lead to improved outcomes. Only when the mechanisms of action are fully understood can more effective appliances be developed. On the horizon for the field of OA therapy are the introduction of a compliance monitor that will allow an objective determination of appliance use, and more rapid overnight titration approaches for implementing OA therapy quickly.

Clinical Pearls

OAs are not as effective as CPAP for the treatment of patients with OSA. In particular, they work less well in patients with significant hypoxemia or morbid obesity. They are most effective in younger, thinner patients with milder OSA. Randomized, controlled clinical trials have indicated that OAs may be used as first-line therapy for the treatment of mild to moderate OSA. However, OAs are not the preferred treatment for patients with severe sleepiness because of the time it may take to achieve the final therapeutic position.

REFERENCES


