Oral Appliance Therapy in Sleep Apnea Syndromes: A Review

Stephen P. Warunek

Obstructive sleep apnea (OSA) can present serious health risks and must be diagnosed by a physician in conjunction with a sleep study. Of nonsurgical treatment alternatives, nasal continuous positive airway pressure (nCPAP) has been shown to be more effective than oral appliance therapy in improving respiratory disturbances. However, many patients initially refuse or cannot tolerate this treatment and randomized trials report patient preference for oral appliances. Since 1980, approximately 150 articles have been published on oral appliance therapy. This article is a review of case studies and randomized trials. Terminology, clinical procedures, and patient communication also are discussed as well as contraindications and complications of this treatment alternative. A 2001 review of 563 patients with different severities of OSA in 30 case studies since 1985 showed a reduction in the apnea-hypopnea index to <10 in 61% of the sample. This report and other studies emphasize that some patients do not improve or become worse despite improvement of some symptoms, eg, snoring. Therefore, physicians must continue progress evaluations. Side effects are usually minor and transient although a small proportion of patients cannot tolerate this approach. It is not yet possible to predict the most advantageous appliance type for a particular patient. Recent randomized trials have shown that devices with a range of vertical openings are effective and adjustability seems to be a desirable feature. Although oral appliance treatment may last for many years, patients must be informed that these devices require periodic replacement, which may be a financial consideration should insurance coverage not be available. (Semin Orthod 2004;10:73-89.)

Sleep apnea is a medical disorder that can be present in any age group.[1,2] It is estimated to affect approximately 2% to 4% of the adult population and is most commonly observed in middle-age overweight males. Strained respiration, decreased blood oxygen levels, and arousals that interrupt a normal sleep pattern characterize this syndrome. Many cases present a significant health risk and can result in excessive daytime sleepiness, early morning headaches, impaired concentration, social impairments, systemic and pulmonary hypertension, traffic and work-related accidents, ischemic heart disease, and cerebrovascular disease.[3,4] Of the 3 types of sleep apnea, obstructive sleep apnea (OSA) is the most prevalent. Also referred to as obstructive sleep apnea/hypopnea syndrome (OSAHS), this condition occurs as the base of the tongue periodically contacts the posterior pharyngeal wall or partially occludes the upper airway during sleep. Relaxation of the genioglossal muscles and reduction of tone of surrounding musculature are contributing factors. Whereas almost all patients with OSA exhibit snoring, not all those who snore have apneic episodes.

From the Department of Orthodontics, School of Dental Medicine, University at Buffalo, Buffalo, NY.

Address correspondence to Stephen P. Warunek, Department of Orthodontics, School of Dental Medicine, Squire Hall, Rm 140, 3435 Main St, Buffalo, NY 14214-3008.

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Treatment modalities for OSA and snoring at the present time most typically include nasal continuous positive airway pressure (nCPAP), oral appliances, and adjunctive measures such as weight loss, medication, avoidance of sedating medication, and body positioning. Surgery options include soft palate surgery such as uvulopalatopharyngoplasty (UPPP) or laser-assisted uvulopalatoplasty (LAUP), radiofrequency (RF) tissue ablation, nasal surgery, genioglossus tongue advancement, and mandibular advancement surgery. Predominant before 1980, tracheotomy has largely been replaced today. Although several randomized, controlled studies with placebos have shown that the first line of nonsurgical treatment is nCPAP in terms of effectiveness,[5-7] less than optimal patient compliance with respect to tolerating the device, inconvenience, and some side effects lowers the overall treatment efficiency.

A literature search indicates that since 1985 approximately 150 articles that describe various oral devices used in the treatment of sleep disorders have been published. The majority of these studies represent case series or case reports and a much smaller number are randomized controlled trials. It is generally accepted that treatment of OSA with oral appliances is a viable option for some patients with varying degrees of short- and long-term improvement and side effects.

Oral appliance treatment includes, in order of decreasing usage, adjustable and nonadjustable mandibular posturing devices, anterior tongue repositioners, and soft palate or uvula-lifting devices. Personal communication with several commercial laboratories (John's Dental Laboratory, Great Lakes Orthodontics, Ltd., and Space Maintainers Laboratory) revealed that the adjustable or titratable advancement devices were the most prescribed over the past several years. An appliance that advances the tongue, or tongue and mandible together with adjacent soft tissue, increases the posterior airway space, increases the activity of the genioglossal and lateral pterygoid muscles,[8] and effects a stretch induction of the pharyngeal motor system.[9] Mandibular advancement devices also alter position of the hyoid and modify the hypopharyngeal airway space. Soft palate or uvula lifters reduce soft tissue vibrations that result in snoring. With respect to the many variations of appliance designs, it is not possible to predict what device will be most effective for a particular patient.

The purpose of this article is to review the sleep medicine literature with special attention to the articles about randomized, controlled studies. It discusses terminology, diagnostic imaging, clinical procedures, patient communication, and contraindications and complications of therapy with different types of adjustable and nonadjustable oral appliances.

Terminology

Apnea is the cessation of airflow for at least 10 seconds.

Apnea index (AI) is the number of apneas per hour of sleep, with 5 or less considered normal.

Apnea-hypopnea index (AHI) is the number of apneas and hypopneas per hour of sleep. Ten or less is usually considered to be normal.

Central sleep apnea is the cessation of airflow from lack of respiratory effort.

Epworth sleepiness scale (ESS) is a reliable and validated subjective assessment of daytime sleepiness. A score greater than 10 on this self-administered questionnaire indicates excessive sleepiness.

FDA 510k is a premarket notification that a medical device manufacturer must submit to the Food and Drug Administration. It allows the FDA to determine whether the device is equivalent to one in commercial distribution before May 28, 1976. New or modified devices must be supported with safety and effectiveness data that may include material composition, biocompatibility, and clinical testing.

Hypopnea is an abnormal reduction of airflow for at least 10 seconds.

Mixed sleep apnea is the cessation of airflow starting as central followed by obstructive.

Multiple sleep latency test (MSLT) is an objective measure of daytime sleepiness. A time greater than 10 minutes is oftentimes defined as normal.

Obstructive sleep apnea (OSA) is the cessation of airflow despite adequate effort to breath.

Polysomnography is the science dealing with the physiology of sleep and the definitive objec-

Figure 1. Noctural Airway-Patency Appliance (NAPA). The NAPA has FDA 510k clearance for OSA. (Color version of figure is available online.)

tive means of diagnosis of sleep apnea and related disorders. Activities monitored during a sleep study are brain waves (EEG), eye movements (EOG), muscle activity (EMG), heartbeat (EKG), blood oxygen levels (SaO_2), and respiration. Polysomnographic markers include total sleep time, sleep efficiency, sleep stage distribution, arousal index (sleep fragmentation), and snoring frequency and intensity.

Respiratory disturbance index (RDI) is another term for AHI. The usual definition of slight OSA is an RDI of 5 to 14, moderate OSA is an RDI of 15 to 30, and severe OSA is an RDI of >30.

Sleep stages are the intervals of non-REM and REM sleep. Non-REM sleep is divided into stages 1 to 4 with stage 1 being the lightest level and stage 4 very deep sleep. After progression through all 4 stages in about 90 minutes, stage REM begins. Dreams most often occur and muscle tone decreases in this stage. The cycle repeats during the night with the length of stage REM increasing until this stage predominates by early morning.

Snoring is breathing through a narrowed upper airway space during sleep with harsh noises, as caused by the vibrating of the soft palate.

Treatment outcomes are the subjective and objective measures of patient responses to a particular mode of therapy. Definitions of complete response, partial response, and failure vary among investigators.

Upper airway resistance syndrome is an incomplete upper airway obstruction without apneas or hypopneas. Snoring, inadequate sleep, and daytime sleepiness characterize this condition.

Literature Review

Case Studies

In 1934, Pierre Robin[10] first described the concept of advancing the mandible with a monoblock functional appliance to treat airway obstruction in infants with micrognathia. His method was not accepted to any extent and it was not until 1985 that Meier-Ewert and coworkers[11] next described an intraoral protraction device for the treatment of sleep apnea. Many articles followed showing therapeutic efficacy in treating OSA with various one-piece, hard acrylic, nonadjustable advancement appliances.[12-21] Soll and George[12] described one of the first devices to receive FDA 510k clearance for commercial distribution (Fig 1). An example of a case series report with comparisons of initial and progress conditions showed 71% of patients

Figure 2. Silicone positioner appliance. The elastomeric sleep appliance has FDA 510k clearance for OSA. (Color version of figure is available online.)

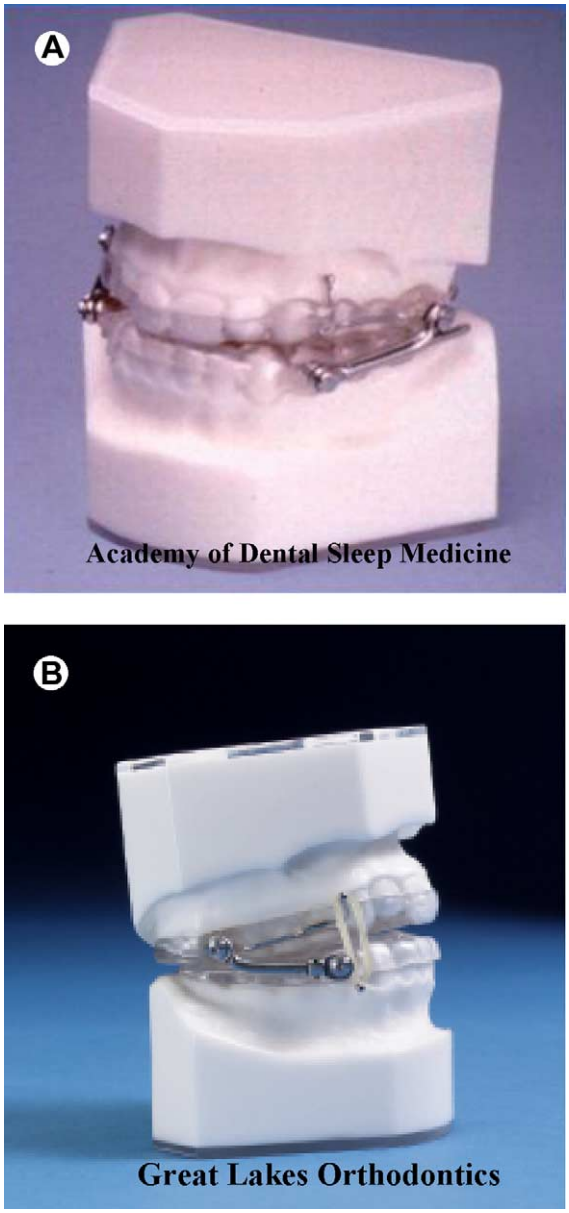

Figure 3. Herbst hardware variations. Standard plunger-tube (A). Telescopic connector (B). The Herbst appliance has FDA 510k clearance for OSA. (Color version of figure is available online.)

(n = 14) experienced normal breathing, defined as AHI <10, after appliance therapy.[18] In 1992, Lyon and coworkers[22] were the first to use a one-piece silicone orthodontic positioner to treat patients with snoring and mild to moderate sleep apnea (Fig 2). This material was used to aid patient comfort, which was sometimes a source of complaint with hard acrylic appliances. Unlike applications in orthodontic finishing positioners, their appliance was designed to be passive and it did not intentionally exert any tooth-moving effects.[23]

Many appliances used to treat OSA are adjustable, the rationale being that single position devices are sometimes uncomfortable or ineffective thereby necessitating refabrication. The first investigator to use a two-piece adjustable advancement device with Herbst hardware was Rider[24] in 1988. His report was largely positive but was based on a relatively subjective symptom improvement questionnaire without support from polysomnographic investigation. In support of the findings of Rider,[24] Clark and coworkers[25] found the Herbst appliance to be effective in reducing the apnea index to a value of <10 in 73% of patients (n = 24), while another like study reported a comparable reduction in 53% of patients.[26] Variations of the Herbst appliance used in the treatment of sleep apnea are illustrated (Fig 3).

Another type of device used to treat OSA causes some clockwise mandibular rotation while holding the tongue in a forward position during sleep.[27-31] Tongue-retaining devices (TRD) are both pre- and custom-fabricated to maintain lingual protrusion with suction derived from a plastic bulb that is held between the lips

Figure 4. Tongue-retaining device (TRD). (Color version of figure is available online.)

and teeth (Fig 4). Tongue protrusion increases the oropharyngeal, velopharyngeal, and hypopharyngeal cross-sectional areas of the upper airway, thereby improving airway patency and function. This type of appliance is said to be of particular benefit in edentulous patients, in individuals who have periodontally compromised dentitions, and in patients suffering from temporomandibular dysfunction (TMD).

Most case studies dealing with OSA use polysomnography, and questionnaires to determine the mean AHI with and without treatment, the mean minimum arterial oxygen saturation, the sleep stage distribution, and the subjective daytime sleepiness. Schmidt-Nowara and coworkers[32] reviewed 19 publications comprising case series and case reports that included a total of 304 patients. Statistical analysis of the data obtained from 271 of the patients included in the 19 publications showed that TRD, and fixed and adjustable mandibular advancement devices, all resulted in an improvement in the average AHI. Similar treatment results were obtained with a variety of appliances used to treat the 271 OSA patients who, on average, experienced a 56% reduction in their AHIs while 51% of patients achieved normal breathing (AHI <10) as a result of their treatment. It should be recorded that not all of the OSA patients reviewed achieved normal breathing and others did not improve or even became worse. Some studies, not all, showed that a statistically significant correlation exists between the levels of treatment success and the value of the initial AHI. From the above studies it is recommended that oral appliances be used as a first treatment option for snoring and mild OSA, and only for moderate to severe OSA if all alternate therapies fail.

Since the review of Schmidt-Nowara and coworkers[32] of 19 publications in 1995, additional case studies have shown that oral appliance therapy has a valuable role to play in the treatment of OSA.[33-44] Thus, in a 2001 review article, Lindman and Bondemark[45] summarized data from 30 case series publications, dating back to 1985, in which 61% of 563 patients experienced a posttreatment AHI <10. This review reemphasized the need for patients to return to their physicians for progress evaluation and polysomnography, since symptoms such as snoring might improve while the degree of apnea actually worsens.

In other notable studies, Lowe and his coworkers[46] were the first to measure patient compliance with a sensor, embedded in the body, of a titratable device of thermo-softening material. In a trial group of 8 patients who wore this appliance for 6.8 hours per night, awake video endoscopy showed that the most significant effect obtained with the appliance in place was at the level of the velopharynx. In a further study of long-term compliance, Pancer and coworkers[41] reported that 86% of patients ($n = 121$) used the appliance every night for about 1 year after delivery and that 87% of these patients were very or moderately satisfied. A further study dealing with patient conformity in OSA patients reported a lesser degree of patient compliance with only 51% of patients ($n = 53$) continuing to wear their advancement devices after 3 years.[9]

Despite their considerable contributions to our understanding of OSA, case studies of patients who suffer from this condition raise questions of validity. Shortcomings in these studies include their retrospective design, the lack of controls, the generally small sample sizes, the variable definitions of treatment success, and the short treatment durations used for progress evaluations. The exclusion of patients with severe apnea and the inclusion of patients who failed to improve with other treatment modalities constitute a major source of bias in these case studies.

Randomized, Controlled Studies

Ferguson and associates[6] conducted a randomized, crossover design study comparing a one-piece, hard acrylic, nonadjustable oral appliance, Snore-Guard™ (SG), to nCPAP in patients with mild to moderate OSA. The amount of advancement of the lower jaw was set at 3 mm posterior to the position of maximal mandibular protrusion and at 7 mm or greater vertical bite opening measured between the upper and lower incisors. The appliances used in both treatment modalities studied were adjusted to maximize patient comfort. In both instances the time period was limited to 4 months, with two 2-week periods during which no treatment was provided. These periods of no treatment comprised an initial period and an intervening 2-week wash-out period. Twenty-one of the 27 patients

completed the treatment protocol, which included home sleep monitoring. Questionnaires designed to evaluate symptoms, treatment efficacy, side effects, and patient satisfaction were administered during the wash-in period and at the end of therapy. The treatment of 48% of the SG and 62% of nCPAP patients was considered successful (AHI <10/hr and with symptom relief), whereas 24% of SG patients and 38% of nCPAP patients were classified as compliance failures (discontinued treatment). In the final analysis, 28% of SG patients and none of the nCPAP patients were classified as treatment failures (AHI > 10/hr and/or no relief of symptoms). While patients preferred the SG treatment to the nCPAP therapy, the former was not as effective as was the CPAP treatment in relieving symptoms of excessive daytime sleepiness. It should be noted that SG currently has FDA 510k clearance for snoring only.

In a recent study Ferguson and coworkers[47] used a randomized, crossover design protocol to compare an adjustable oral advancement mechanism appliance (AMP) to nCPAP for the treatment of mild to moderate OSA. The advancement mechanism consisted of a titanium hinge with 5 adjustment holes that connected full-coverage upper and lower, hard acrylic splints. This design permitted slight lateral movement of the mandible as well as allowing unrestricted airflow for breathing. The advancement was increased until snoring ceased and symptoms improved, or the patient's limit of tolerance was reached but not beyond 70% of maximum mandibular protrusion. Both appliances were adjusted to maximize comfort, and treatment time was 4 months with initial and intervening periods of 2 weeks during which no treatment was provided. Home sleep monitoring and questionnaires, including an Epworth questionnaire, were administered during the intervening 2-week wash-in period and at the end of treatment. Follow-up questions at the end of subsequent posttreatment periods reported symptoms, treatment efficacy, side effects, and patient satisfaction.

Twenty of the 24 patients completed the study, and 55% of AMP patients and 70% of nCPAP patients were assessed to be treatment successes (AHI <10/h with relief of symptoms). Five percent of the 20 patients treated with AMP, and 30% with nCPAP, were compliance failures (discontinued treatment). Forty percent of the AMP patients and none of the nCPAP patients were treatment failures (AHI ≥ 10/hr and/or no relief of symptoms). Two treatment failures with AMP had an increase in AHI with this form of therapy. Both treatments reduced excessive daytime sleepiness to the same degree. There was no significant difference in side effects between the treatments, but patients were more satisfied with the oral appliance.

Bloch and colleagues[48] used a randomized, controlled crossover design study to compare the effectiveness and side effects of a fixed single-piece, mandibular advancement device (Monobloc) with those of an adjustable Herbst appliance with equal advancement. Twenty-four successive patients with a diagnosis of OSA who either refused CPAP, or declined to use it after an initial trial period, participated in this study. This project was one of the first to compare the effectiveness of mandibular advance devices with different designs (Fig 5). Both appliances utilized full coverage splints of hard acrylic, initially set at 75% of maximum protrusion, with the vertical interincisal opening set at 5 to 10 mm for the Monobloc and at 4 to 6 mm for the

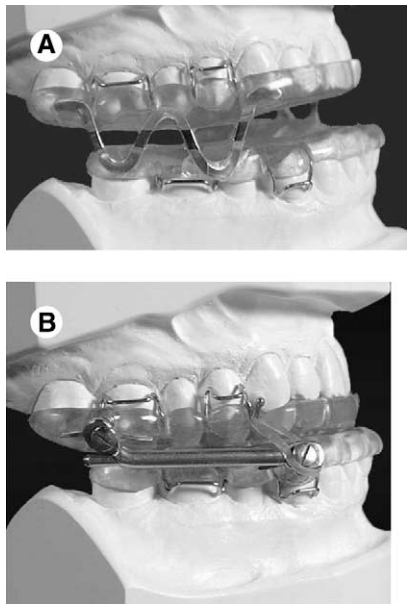

Figure 5. Monobloc (A) and Herbst (B). Reprinted with permission from the American Journal of Respiratory and Critical Care Medicine.[48]

Herbst. The appliances were adjusted to maximize patient comfort and each patient was randomly placed into 1 of 6 possible sequences of treatment with the Herbst, Monobloc, or no treatment. Treatment was evaluated at weekly intervals with a questionnaire and polysomnography.

Patient preference and trends of polysomnographic data showed the Monobloc to have greater patient acceptability and to be more effective than the Herbst appliance in the treatment of OSA. Reasons advanced for appliance preference were greater symptom relief, simplicity, and lack of side effects. The Herbst appliance allows greater jaw opening than does the Monobloc, and this clockwise jaw movement results in a posterior tongue movement that can diminish the effectiveness of this appliance in treating OSA.

In a randomized, controlled, three-period crossover design study of OSA patients Mehta and coworkers[49] compared the treatment effectiveness of a custom-made, adjustable mandibular advancement splint to a lower control plate with no protrusive effect. Protrusion was initially set at the maximum tolerable limit of the patients studied. Two separate, full coverage, hard acrylic splints were fabricated, each 1.5 to 2 mm thick, so as to minimize the vertical bite opening. The upper splints had bilateral flanges extending inferiorly from the palatal aspect of the molar region. These flanges engaged slots in the lingual molar area of the mandibular splint and the system used expansion screws to provide incremental mandibular advancement. The appliance was adjusted to maximize comfort of the patients who were randomly placed into control or treatment groups at weekly intervals. Follow-up polysomnography and an Epworth questionnaire assessed objective and subjective treatment outcomes.

Partial (AHI $\leq$5/hr, or AHI reduced at least 50%, or symptom relief) or complete (AHI $<$5/hr, symptom relief) improvement response was achieved in 62.5% of 24 patients who completed the protocol with the active device. Treatment failure ($<$50% reduction of AHI or no symptom relief) occurred in 37.5% of patients who wore the active device. Two patients discontinued treatment and were deemed to be failures due to lack of compliance. The majority of patients who wore the active appliances reported reduced level of snoring, improved sleep quality, and less daytime sleepiness. In this short-term study, subjective reports of compliance were high as 87.5% of patients who completed the protocol reported nightly use.

A randomized, controlled, two-period crossover study was designed to compare an adjustable mandibular advancement device to an inactive one in a sample drawn from consecutive patients with mild to moderate OSA.[50] Two separate hard acrylic splints were fabricated, each 1.5 to 2 mm thick, so as to minimize the vertical opening. The lower portion, with bilateral buccal flanges, extended in a superior direction in the molar region and abutted against bilateral expansion screws anchored in the upper appliance, which was otherwise similar to the one illustrated (Fig 6). The appliances were adjusted to maximize patient comfort and each subject included in the study was randomly placed into 1 of 2 treatment groups at 4-week intervals. Follow-up polysomnography, Epworth, and symptom questionnaires assessed objective and subjective treatment outcomes. The ESS and MSLT questionnaires assessed subjective and objective treatment outcomes, respectively. Patients experienced significantly improved scores in both measures with the active appliance in comparison with the control device after each treatment

Figure 6. Mandibular advancement device with buccal flanges. (Color version of figure is available online.)

period. This study was the first to report a significant objective reduction in daytime sleepiness with a mandibular advancement appliance. Polysomnography showed that the active device resulted in a 52% reduction in mean RDI and significantly higher mean minimum arterial oxygen saturation compared with the controls. As reported in other studies, a proportion of patients did not respond or only partially responded to treatment with the mandibular advancement device.

A randomized, controlled, two-period crossover design investigated the vertical dimension of opening (VDO) on a mandibular advancement device.[51] Twenty-three patients with a diagnosis of OSA completed this study in which 2 separate hard acrylic splints were fabricated with 4 mm of interincisal opening for the first design at the most comfortable protrusive position. The second design featured an additional 10-mm acrylic overlay to fit between 2-mm-thick splints, for a total of 14 mm of interincisal opening, at the same protrusion as used in the first design. Buccal flanges extending from the lower splint fitted against buccal blocks on the upper portion to prevent posterior movement of the mandible. Following an initial period to maximize comfort, each patient was randomized into 1 of 2 treatment groups at 2-week intervals with intervening wash-out periods. Treatment outcomes were assessed with questionnaires and polysomnography. The investigators concluded that the amount of vertical opening did not have any marked effect on treatment efficacy, as determined by objective and subjective measures, but the patients preferred the device with the reduced vertical opening.

Randerath and coworkers[52] used a randomized, controlled, two-period crossover design study to compare an adjustable mandibular advancement device, adjusted to produce 66% maximum mandibular protrusion, to nCPAP. Twenty patients with a diagnosis of mild to moderate OSA completed this study in which 2 thin thermoplastic splints were connected with a relatively new Herbst hardware design, adjustable by screw-type guide rods (Fig 3B). In contrast to previous studies, the appliance was not adjusted to maximize comfort. Patients were randomized into 1 of 2 treatment groups at 6-week intervals. Each treatment period was evaluated with a questionnaire and polysomnography. After 6 weeks of treatment the AHI recorded with the nCPAP therapy was significantly lower than that noted with the mandibular advancement device. Patients did, however, prefer the oral appliance and 30% of the individuals treated by this means showed a statistically significant reduction in AHI (to <10).

Diagnostic Imaging

Many investigators have used cephalometric analysis in an attempt to diagnose OSA or examine treatment effects with oral appliances. Patients with severe craniofacial anomalies such as the Pierre Robin syndrome, who exhibit micrognathia of the mandible and glossoptosis, tend to develop upper airway obstruction.[53] The majority of OSA patients, however, do not have such obvious anatomical deformities. Despite specific limitations, which include a two-dimensional image taken with the patient in an upright position, lateral cephalometric radiographs have been used extensively to examine the possible relationships that may exist between cranial morphology and OSA. Pae and coworkers[54] discussed some of the shortcomings of radiographic cephalometry, while other workers[55-62] pointed to skeletal and soft tissue morphological features that could be used to diagnose the presence and severity of OSA. Skeletal features thought to be of diagnostic importance in OSA include a retrognathic mandible, a narrow mandibular arch, maxillary and mandibular retrognathia, an increased lower facial height, a downward and forward positioned hyoid bone, a reduced size of the pharynx, and an increased craniocervical angle. Those soft tissue entities that are visible in a sagittal cranial x-ray and that may be important in the diagnosis of OSA include enlarged tonsils and adenoids, increased tongue and soft palate areas, and a reduced distance between the base of the tongue and posterior wall of the pharynx.

In contrast to the findings of others, Rose and coworkers[63] examined the lateral cephalographs of 106 consecutive OSA patients and found no direct correlation existed between cephalometric parameters and the severity of OSA, with the exception of the position of the hyoid bone. The

downward and forward position of the hyoid bone relative to the mandibular plane was reported in a number studies and it is postulated that this movement is an adaptation to altered head and tongue posture.[33,64,65]

A comparison of lateral cephalograms taken for patients with snoring and OSA, before and after 2 years of treatment with a mandibular protruding device, showed pharyngeal volume to increase by about 10% during the period of treatment.[66] One explanation for this relative increase in size is the reduction of soft tissue edema, about one-half in the velum, which occurs as the frequency and intensity of the vibrations, due to the snoring, decreases. Two years of treatment with a mandibular protruding device was associated with a moderate mandibular rotation, a proclination of lower incisors, and no change in mandibular length. The distances between the hyoid bone and 2 reference lines, the nasal and the mandibular line, increased significantly during the period of treatment. Another 2-year study of the effects of OSA treatment on cranial form found a significant decrease in overbite and overjet and, in contrast to the previous study, an increase in mandibular length.[67]

Investigators have also employed 3-dimensional imaging techniques to evaluate the pharyngeal region of OSA patients. Lowe and coworkers[58] used computed tomography (CT) to show the correlation of tongue and soft palate volumes with the body mass index. A magnetic resonance imaging (MRI) study reported on the effects that nCPAP treatment has on cranial morphology. This study published findings that included an increase in pharyngeal volume, a decrease in tongue volume, and a decrease in upper airway edema.[68] Examination of cross-sectional areas of the hypopharynx, oropharynx, and velopharynx, by using video endoscopy with and without a mandibular protruding device appliance, showed that treatment with this device resulted in a significant increase in space at the level of the velopharynx.[46]

Clinical Approach to Obstructive Sleep Apnea

The following treatment guidelines are based on recommendations from the American Sleep Disorders Association.[69] A flowchart illustrating assignment to treatment alternatives is shown in Figure 7.

1. The physician has the responsibility to diagnose OSA and recommend an appropriate course of treatment. Diagnostic criteria include clinical signs, symptoms, and results of polysomnography. The medical provider should be aware of basic dental conditions suitable for oral appliance therapy.
2. The patient is referred to a dentist or dental specialist who practices in this field. A prescription requests further evaluation of the dental status and fabrication of an oral appliance, if appropriate. A diagnostic report is also forwarded.
3. At the initial dental evaluation, medical and dental histories should be taken. The clinician should explain the rationale, advantages, and disadvantages of treatment, together with a review of informed consent.
4. During the initial appointment, a clinical examination notes:
   a. Soft tissue facial features and facial type.
   b. Physiologic activity including abnormal habits.
   c. Temporomandibular joint health, occlusion, range of mandibular movement, and abnormal attrition.
   d. Teeth present and restorations with special attention to full coverage crowns.
   e. Periodontal status assisted by full mouth series or panoramic radiograph no more than 6 months old.
   f. Intraoral soft tissue health and presence of abnormal muscle attachments.

Although records may be included in this appointment, many clinicians and patients prefer to wait until consideration of the advantages and the disadvantages of home treatment are known.

5. A records appointment is scheduled to take impressions for study, and work models, photographs, a mandibular advancement registration, and an optional cephalometric radiograph. A George Gauge™ (Great Lakes Orthodontics; Fig 8) is useful to take a bite registration at or about 75% of the maximum protrusion.
6. The clinician selects an appliance for laboratory fabrication and delivers the completed appliance with home care instructions according to the manufacturer's specifications. Approximately 18 commercially available de-

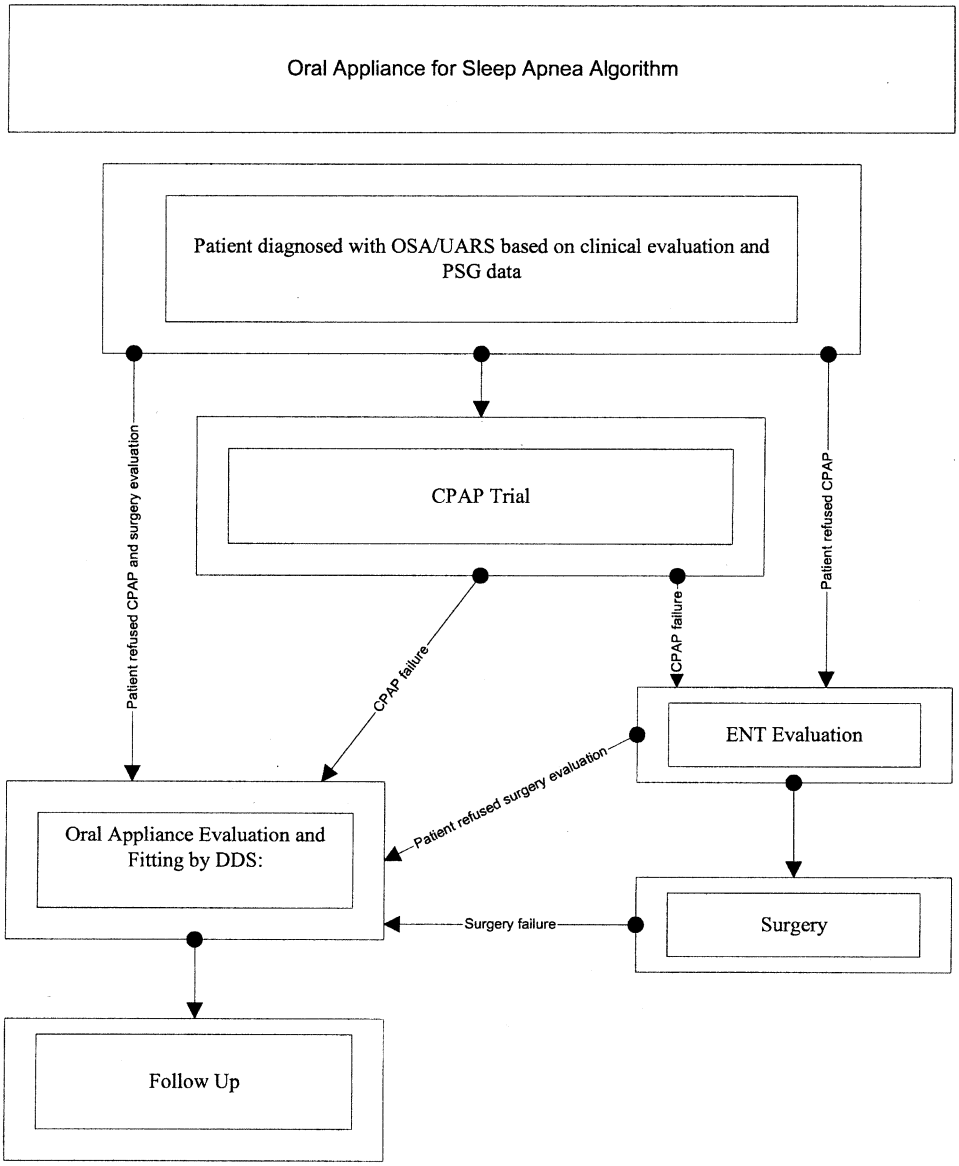

Figure 7. Flowchart of treatment alternatives.

vices have FDA 510k market clearance for OSA. About twice that number have FDA clearance for snoring.

7. Following placement of the chosen appliance patients should be seen after 1 week, after 1 month, and as required for progress evaluations that include notation of symptoms, sore spot adjustments, and modifications of the advancement position. A 1-piece device may need to be sectioned and refabricated at the laboratory at a new advancement registration.
8. The patient should return to the physician for follow-up assessment when the patient and/or bed partner reports a subjective improvement in sleep quality or after no longer than several months. Follow-up polysomnography is not indicated for patients with either primary snoring or mild OSA if symptoms improve. As the degree of improvement varies and some patients show no improvement or worsen, the appliance may need to be modified, refabricated with an alternate design, or discontinued.

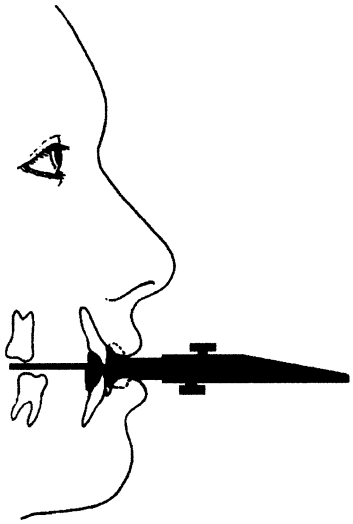

Figure 8. Gauge for registering mandibular anterior advancement.

9. To monitor an effective oral appliance, recall dental appointments are made every 6 months for 2 years and then annually. The occlusion, dental and periodontal condition, temporomandibular joint (TMJ) status, and signs and symptoms of reoccurring OSA are all monitored. Referrals to the physician in charge's office are made as required.

Treatment Considerations

Before placing an appliance to treat OSA clinicians should explain the possible side effects of treatment including the possibility that the appliance may loosen or break dental restorations. Excess salivation, xerostomia, TMJ pain, soreness of the masseter muscle, and tooth discomfort are usually of minor intensity. These symptoms tend to occur at the inception of treatment and they usually ameliorate with time. Patients that are treated with a mandibular protruding device for OSA may find that when they wear the appliance their occlusion feels different for a short while after the appliance is removed. More permanent, but usually relatively minor, occlusal changes have also been reported.[66,67] More significant effects, such as the change in overjet from 2 mm to an edge-to-edge incisor relationship shown in a 5-year-progress cephalometric radiograph, are less commonly seen (Fig 9). The relationship that exists between the degree of unwanted tooth movement and conventional versus heat-softening acrylics is currently being discussed.[70]

Mandibular protrusion devices should only be used when a patient has at least 8 teeth in each arch and is able to demonstrate a mandibular protrusion of at least 5 mm and a bite opening of greater than 25 mm. Appliances may be used in combination with partial dentures that replace no more than 4 teeth. Patients with edentulous maxillary arches and at least 8 teeth in the mandibular arch may be able to wear some mandibular protrusion devices, especially those that are fabricated with heat-softening acrylics. Totally edentulous patients are usually not good candidates for mandibular repositioners, but tongue retaining devices may be used in

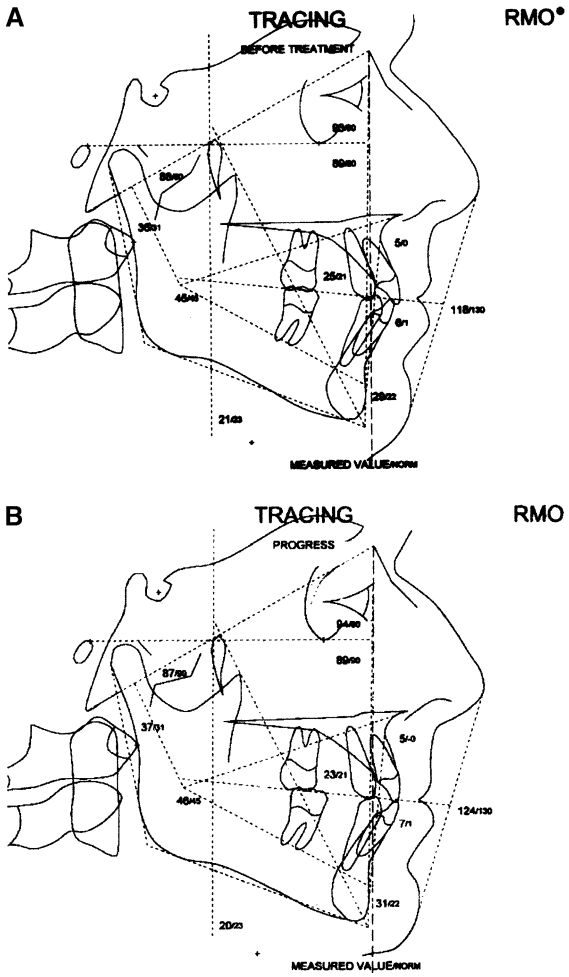

Figure 9. Cephalometric tracings of occlusal changes. Pretreatment (A) and five years progress (B).

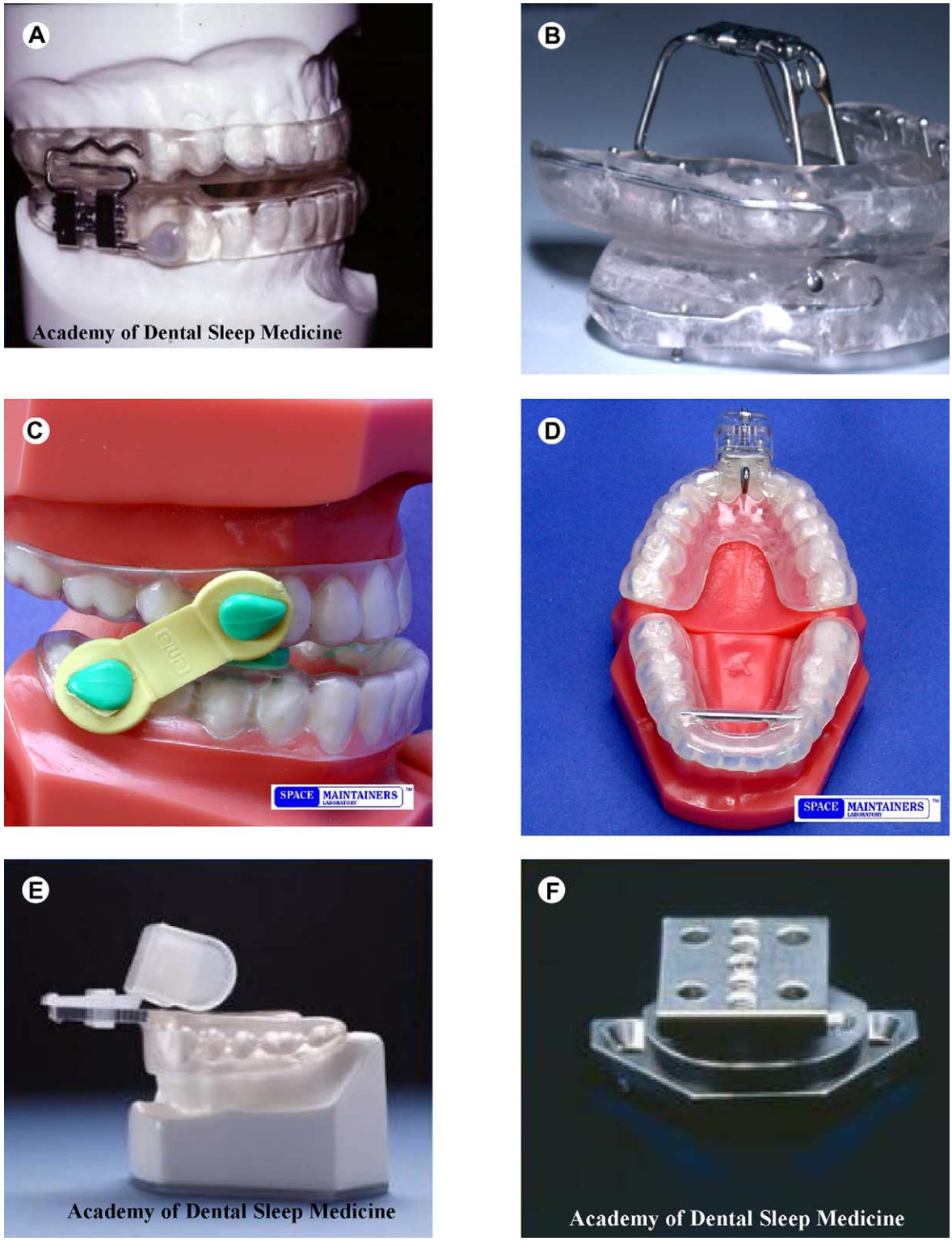

Figure 10. Advancement components. PM Positioner (A). Klearway (B). EMA (C). TAP (D). Snore-Aid (E). Silencer (F). All have FDA 510k clearance for OSA. (Color version of figure is available online.)

edentulous patients, although these appliances only have FDA clearance for snoring, not OSA.

Whereas slight TMJ discomfort can be relieved with forward mandibular positioning, OSA patients who present with more severe TMJ pain probably are not good candidates for treatment with mandibular protrusion appliances. Patients with significant bruxism can frequently damage mandibular protrusion devices and thus make this treatment approach costly and inefficient, while very obese patients, with some exceptions, are best treated by other means than mandibular protrusion.

Appliance Design

Oral appliances that are used to treat OSA can be either fixed, or adjustable sagittally at a vertical opening that ranges from 1 to about 10 mm when measured in the incisor region. L'Estrange and his coworkers[71] recommended minimizing the vertical opening to limit posterior displacement of the tongue and soft palate. In contrast other investigators reporting on the findings of a randomized study concluded that the amount of vertical opening did not have any marked effect on treatment efficacy as determined by objective and subjective measures.[51] Patients, however, preferred devices with reduced vertical opening. In another randomized study, patients preferred a one-piece Monobloc with 5 to 10 mm of vertical opening between the incisors to a Herbst with between 4 and 6 mm of bite opening.[48] Patient preference and results of polysomnographic data indicate that the Monobloc appliance is more effective, in comparison with the Herbst appliance, in treating OSA. George maintains that non-rigid devices that cause mandibular advancement but permit some degree of movement also cause a suppression of the tongue-protruding muscles and that this allows the tongue to retract from the teeth and to be more vulnerable to airway suction.[70]

In addition to Herbst hardware, the advancement mechanisms employed in adjustable mandibular advancement devices include expansion screws, rapid maxillary expansion screws (RME) with connector arms, elastic straps, and other designs (Fig 10). The connector arms that are welded to the body of the RME are designed to support a quasi-static intraarch load mainly parallel to the direction of opening. When used as an interarch connector for mandibular advancement, additional torsional forces that are expressed at the solder joints occasionally cause premature failure of the appliance. Soldering an additional reinforcement wire to the anterior portion of the connector arms at the laboratory minimize this type of failure (Fig 11).

Appliances that are used to treat OSA may be constructed of a variety of materials that include hard methyl methacrylates, soft silicone elastomers, heat-softening acrylics, and hard thermoformed plastics that are lined with soft vinyl rubber. Since replacing vulcanite in the early 1940s, hard methyl methacrylate has been extensively used in many types of dental appliances.[72] While silicones can provide any desired degree of softness, their propensity to tear makes them poor choices when they are used in combination with embedded wires or clasps. Heat-softening acrylics are relatively new on the market and they have not been given a great deal of exposure in the literature other than when they are applied as soft denture reliners.[73,74]

Heat-softening polymers have glass transition temperatures (Tg) that range from 25°C to approximately 40°C, and soften sufficiently in warm water to allow minor undercuts to be engaged, which improves retention. Hard acrylics such as methyl or ethyl methacrylate have Tg values that range from 65°C to over 100°C. A 3-point bending test (ASTM D790-92, standard test methods for flexural properties of unreinforced and reinforced plastics and electrical in-

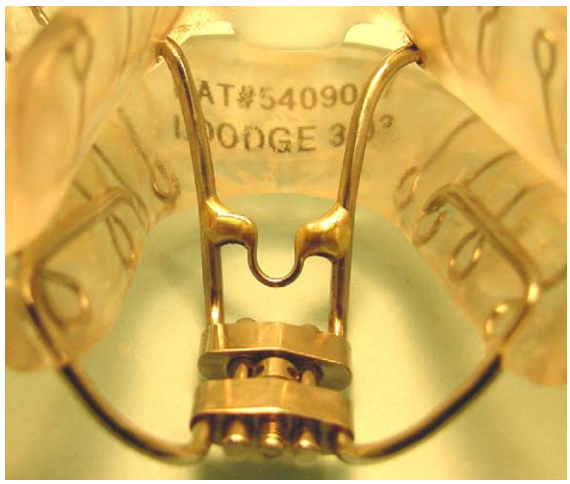

Figure 11. Stabalizing bar in Klearway appliance. (Color version of figure is available online.)

sulating materials) is used to assess material flexibility. Bending experiments are performed in distilled water at different temperatures and, typically, the bending modulus drops by a factor of 2 for every 10°F rise in temperature (Fig 12). A typical heat-softening polymer used to construct dental splints and sleep appliances consists of a liquid/powder system. Water absorption is more significant with heat softening than conventional acrylics; consequently, heat-softening polymers should be stored dry between uses. Patients should be advised that heat softening, and even hard acrylic, devices may need replacement after a period of 1 to 3 years, which may be a concern should insurance coverage not be available. Current research is developing plasticizer-free compositions that, in theory, should improve their long-term durability.

Summary

Oral appliances are a treatment option in the management of sleep apnea syndromes. While many patients experience a complete or partial resolution of their symptoms, some do not improve or may even become worse. It is therefore imperative that physicians conduct progress evaluations while the respective dental care provider continues to make adjustments to optimize the effectiveness of the chosen appliance.

Since the first nonadjustable, hard acrylic appliances were developed to treat OSA, a variety of removable devices have been designed to provide improved patient comfort and hence, hopefully, patient compliance. The trend has been toward adjustable devices, while the materials now being used to construct mandibular protrusion devices include heat-softening acrylics and plastics with soft liners. It should be noted, however, that in a recent randomized trial, patients preferred a single-piece Monobloc appliance to a continuously adjustable Herbst constructed of the same hard acrylic composition. It is not always the case that hard acrylics are necessarily more uncomfortable than heat-softening acrylics and plastics with soft liners.

Future research will help to identify the types of patients who are suitable for a specific kind of OSA treatment.

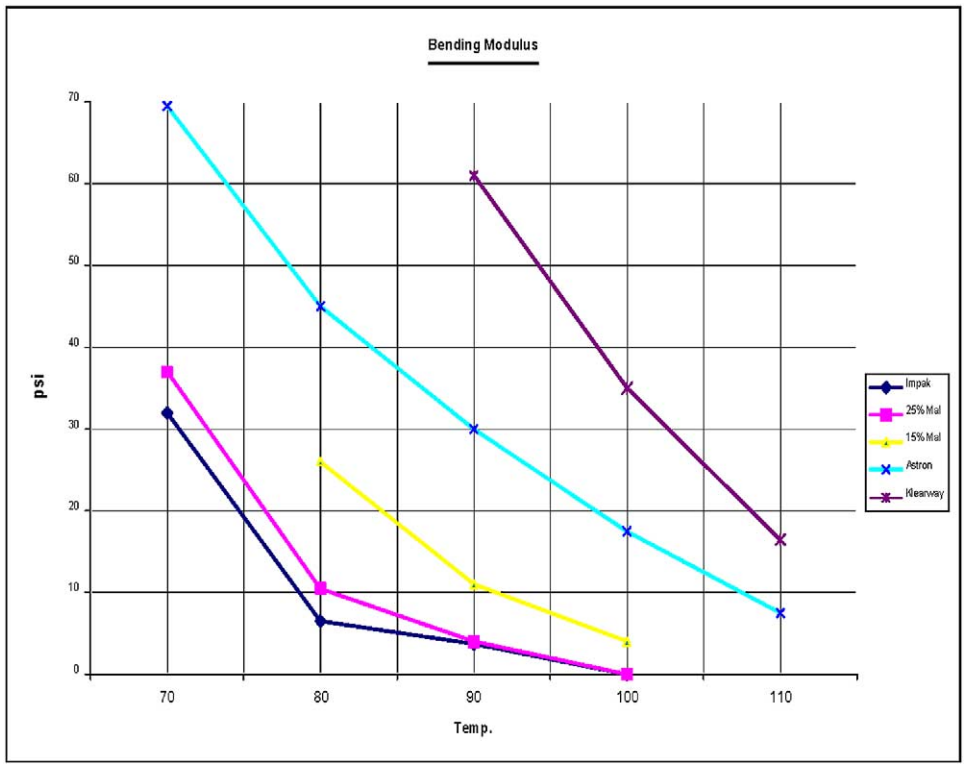

Figure 12. Comparision of heat-softening acrylics. (Color version of figure is available online.)

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References

1. Young T, Palta M, Dempsey J, et al. The occurrence of sleep-disordered breathing among middle-aged adults. N Engl J Med 1993;328:1230-1235.
2. Lynn RC. Obstructive sleep apnea syndrome (OSAS) in children. Diagnostic challenges. Sleep 1996;19:274-277.
3. Martin SE, Engleman HM, Deary IJ, et al. The effect of sleep fragmentation on daytime function. Am J Respir Crit Care Med 1996;153:1328-1332.
4. Laube I, Seeger R, Russi EW, et al. Accidents related to sleepiness: Review of medical causes and prevention with special reference to Switzerland. Schweiz Med Wochenschr 1998;128:1487-1499.
5. Clark GT, Blumenfeld I, Yoffe N, et al. A crossover study comparing the efficacy of continuous positive airway pressure with anterior mandibular positioning devices on patients with obstructive sleep apnea. Chest 1996; 109:1477-1483.
6. Ferguson KA, Ono T, Lowe AA, et al. A randomized crossover study of an oral appliance vs. nasal-continuous positive airway pressure in the treatment of mild-moderate obstructive sleep apnea. Chest 1996;109:1269-1275.
7. Engleman HM, Martin SE, Kingshott RN, et al. Randomized placebo controlled trial of daytime function after continuous positive airway pressure (CPAP) therapy for the sleep apnoea/hypopnoea syndrome. Thorax 1998; 53:341-345.
8. Yoshida K. Effect of a prosthetic appliance for treatment of sleep apnea syndrome on masticatory and tongue muscle activity. J Prosthet Dent 1998;79:537-544.
9. Clark GT, Sohn J-W, Hong CN. Treating obstructive sleep apnea and snoring: Assessment of an anterior mandibular positioning device. J Am Dent Assoc 2000;131: 765-771.
10. Robin P. Glossoptosis due to atresia and hypotrophy of the mandible. Am J Dis Child 1934;48:541-547.
11. Meier-Ewert K, Schafer H, Kloss W. Treatment of sleep apnea by a mandibular protracting device. In: Koella WP, Rüther E, Schulz H (eds). Proceedings of the Seventh European Congress on Sleep Research. Gustav Fischer, Stuttgart, Germany, 1985, p 217.
12. Soll B, George P. Treatment of OSA with a nocturnal airway-patency appliance. N Engl J Med 1985;313:386-387.
13. Kloss W, Meier-Ewert K, Schafer H. Zur therapie des obstruktiven schlaf-apnoe syndromes. Fortschr Neurol Psychiatr 1986;54:267-271.
14. George PT. A modified functional appliance for treatment of obstructive sleep apnea. J Clin Orthod 1987;21: 171-175.
15. Bernstein A, Reidy R. The effects of mandibular repositioning on obstructive sleep apnea. J Craniomandibular Pract 1988;6:179-181.
16. Bonham P, Currier G, Orr W, et al. The effect of a modified functional appliance on obstructive sleep apnea. Am J Orthod Dentofacial Orthop 1988;94:384-392.
17. George PT. Snore therapy in dentistry. Hawaii Dent J 1991;22:6-7:9.
18. Ichioka M, Tojo N, Yoshizawa M, et al. A dental device for the treatment of obstructive sleep apnea: A preliminary study. Otolaryngol Head Neck Surg 1991;104:555-558.
19. Nakazawa Y, Sakamoto T, Yasutake R, et al. Treatment of sleep apnea with prosthetic mandibular advancement (PMA). Sleep 1992;15:499-504.
20. Knudson RC, Meyer JB. Managing obstructive sleep apnea. J Am Dent Assoc 1993;124:75-78.
21. O'Sullivan RA, Hillman DR, Mateljan R, et al. Mandibular advancement splint: An appliance to treat snoring and obstructive sleep apnea. Am J Respir Crit Care Med 1995;151:194-198.
22. Lyon HE, Phillips B, Theiss BL. Treatment of snoring and obstructive sleep apnea. Compend Contin Educ Dent 1990;13:416-420.
23. Warunek SP, Sorensen SE, Cunat JJ, et al. Physical and mechanical properties of elastomers in orthodontic positioners. Am J Orthod 1989;95:388-400.
24. Rider E. Removable Herbst appliance for treatment of obstructive sleep apnea. J Clin Orthod 1988;22:256-257.
25. Clark GT, Arand D, Chung E, et al. Effect of anterior mandibular positioning on obstructive sleep apnea. Am J Respir Crit Care Med 1993;147:624-629.
26. Eveloff SE, Rosenberg CL, Carlisle CC, et al. Efficacy of a Herbst mandibular advancement device in obstructive sleep apnea. Am J Respir Crit Care Med 1994;149:905-909.
27. Cartwright RD, Samelson CF. The effects of a nonsurgical treatment for obstructive sleep apnea: The tongue-retaining device. JAMA 1982;248:705-709.
28. Calderelli DD, Cartwright RD, Lilie JK. Obstructive sleep apnea: Variations in surgical management. Laryngoscope 1985;95:1070-1073.
29. Cartwright RD. Predicting response to the tongue-retaining device for sleep apnea syndrome. Arch Otolaryngol 1985;111:385-388.
30. Cartwright R, Stefoski D, Caldarelli D, et al. Toward a treatment logic for sleep apnea: The place of the tongue-retaining device. Behav Res Ther 1988;26:121-126.
31. Cartwright R, Ristanovic R, Diaz F, et al. A comparative study of treatments for positional sleep apnea. Sleep 1991;14:546-552.
32. Schmidt-Nowara W, Lowe A, Wiegand L, et al. Oral appliances for the treatment of snoring and obstructive sleep apnea: A review. Sleep 1995;18:501-510.
33. Mayer G, Meier-Ewert K. Cephalometric predictors for orthopaedic mandibular advancement in obstructive sleep apnoea. Eur J Orthod 1995;17:35-43.
34. Menn SJ, Louble DI, Morgan TD, et al. The mandibular repositioning device: The role in treatment of obstructive sleep apnea. Sleep 1996;19:794-800.
35. Miles PG, Nimkarn Y, De Leeuw BJ. Dentistry's role in obstructive sleep apnea: Review and a case report. Aust Dent J 1996;41:248-251.
36. Esaki K, Kanegae H, Uchida T, et al. Treatment of sleep apnea with a new separated type of dental appliance

(mandibular advancing positioner). Kurume Med J 1997;44:315-319.
37. Cohen R. Obstructive sleep apnea: Oral appliance therapy and severity of condition. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1998;85:388-392.
38. Millman RP, Rosenberg CL, Carlisle CC, et al. The efficacy of oral appliances in the treatment of persistent sleep apnea after uvulopalatopharyngeoplasty. Chest 1998;113:992-996.
39. Pellanda A, Despland PA, Pasche P. The anterior mandibular positioning device for the treatment of obstructive sleep apnoea syndrome: experience with the Serenox. Clin Otolaryngol 1999;24:134-141.
40. Gao XM, Zeng XL, Fu MK, et al. Magnetic resonance imaging of the upper airway in obstructive sleep apnea before and after oral appliance therapy. Chin J Dent Res 1999;2:27-35.
41. Pancer J, Al-Faifi S, Al-Saifi M, et al. Evaluation of variable mandibular advancement appliance for treatment of snoring and sleep apnea. Chest 1999;116:1511-1518.
42. Ryan CF, Love LL, Peat D, et al. Mandibular advancement oral appliance therapy for obstructive sleep apnoea: Effect on awake caliber of velopharynx. Thorax 1999;54:972-977.
43. Maurer JT, Hirth K, Mattinger C, et al. Use of an intraoral snoring therapy device of thermolabile plastic. HNO 2000;48:302-308.
44. Yoshida K. The relationship between sleep position and therapeutic effect of the Esmarch-Scheine appliance in sleep apnea syndromes. Fortschr Neurol Psychiatr 2000; 68:93-96.
45. Lindman R, Bondemark L. A review of oral devices in the treatment of habitual snoring and obstructive sleep apnoea. Swed Dent J 2001;25:39-51.
46. Lowe AA, Sjoholm TT, Ryan CF, et al. Treatment, airway and compliance effects of a titratable oral appliance. Sleep 2000;23:172-178.
47. Ferguson KA, Ono T, Lowe AA, et al. A short term controlled trial of an adjustable oral appliance for the treatment of mild to moderate obstructive sleep apnoea. Thorax 1997;52:362-368.
48. Bloch KE, Iseli A, Zhang JN, et al. A randomized, controlled crossover trial of two oral appliances for sleep apnea treatment. Am J Respir Crit Care Med 2000;162: 246-251.
49. Mehta A, Qian J, Petocz P, et al. A randomized, controlled study of a mandibular advancement splint for obstructive sleep apnea. Am J Respir Crit Care Med 2001;163:1457-1461.
50. Gotsopoulos H, Chen C, Qian J, et al. Oral appliance therapy improves symptoms in obstructive sleep apnea. Am J Respir Crit Care Med 2002;166:743-748.
51. Pitsis AJ, Darendeliler MA, Gotsopoulos H, et al. Effect of vertical dimension on efficacy of oral appliance therapy in obstructive sleep apnea. Am J Respir Crit Care Med 2002;166:860-864.
52. Randerath WJ, Heise M, Hinz R, et al. An individually adjustable oral appliance vs continuous positive airway pressure in mild-to-moderate obstructive sleep apnea syndrome. Chest 2002;122:569-575.
53. Spier S, Rivlin J, Rowe RD, et al. Sleep in Pierre Robin syndrome. Chest 1986;90:711-715.
54. Pae EK, Lowe AA, Saski K, et al. A cephalometric and electromyographic study of upper airway structure in the upright and supine position. Am J Orthod Dentofacial Orthop 1994;106:52-59.
55. Riley R, Guilleminault C, Herran J, et al. Cephalometric analyses and flow volume loops in obstructive sleep apnea patients. Sleep 1983;6:303-311.
56. Guilleminault C, Riley R, Powell N. Obstructive sleep apnea and cephalometric roentgenograms. Am Rev Respir Dis 1984;130:145-146.
57. Bacon W, Turlot J, Krieger, et al. Cephalometric evaluation of pharyngeal obstructive factors in patients with sleep apnea syndrome. Angle Orthod 1990;60:115-122.
58. Lowe AA, Fleetham JA, Adachi S, et al. Cephalometric and computed tomographic predictors of obstructive sleep apnea severity. Am J Orthod Dentofacial Orthop 1995;107:589-595.
59. Tangugsorn V, Skatvedt O, Krogstad O, et al. Obstructive sleep apnoea: A cephalometric study. Part I. Cervicocraniofacial skeletal morphology. Eur J Orthod 1995;17: 45-56.
60. Tangugsorn V, Skatvedt O, Krogstad O, et al. Obstructive sleep apnoea: A cephalometric study. Part II. Uvulo-glossopharyngeal morphology. Eur J Orthod 1995;17:57-67.
61. Lowe AA, Ono T, Ferguson K, et al. Cephalometric comparison of craniofacial and upper airway structure by skeletal subtype and gender in patients with obstructive apnea. Am J Orthod Dentofacial Orthop 1996;110: 653-654.
62. Battagel JM, Johal A, Kotecha B. A cephalometric comparison of subjects with snoring and obstructive sleep apnea. Eur J Orthod 2000;22:353-365.
63. Rose EC, Staats R, Lehner M, et al. Cephalometric analysis in patients with obstructive sleep apnea. Part I. Diagnostic value. J Orofacial Orthop/Fortschr Kieferorthop 2002;63:143-153.
64. DeBerry-Borowiecki B, Kukwa A, Blanks R. Cephalometric analysis for diagnosis and treatment of obstructive sleep apnea. Laryngoscope 1988;98:226-233.
65. Solow B, Ovesen J, Nielson PW, et al. Head posture in obstructive sleep apnoea. Eur J Orthod 1993;15:107-114.
66. Fransson AMC, Tegelberg A, Svenson BAH, et al. Influence of mandibular protruding device on airway passages and dentofacial characteristics in obstructive sleep apnea and snoring. Am J Orthod Dentofacial Orthop 2002;122:371-379.
67. Bondemark L. Does 2 years' nocturnal treatment with a mandibular advancement splint in adult patients with snoring and OSAS cause a change in the posture of the mandible? Am J Orthod Dentofacial Orthop 1999;116: 621-628.
68. Ryan C, Lowe A, Li D, et al. Magnetic resonance imaging of the upper airway in obstructive sleep apnea before and after chronic nCPAP therapy. Am J Respir Crit Care Med 1991;144:939-944.
69. Standards of Practice Committee of the American Sleep Disorders Association. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. Sleep 1995;18:511-513.
70. George PT. Selecting sleep-disordered-breathing appliances. J Am Dent Assoc 2001;132:339-347.
71. L'Estrange PR, Battagel JM, Harkness B, et al. A method

of studying adaptive changes of the oropharynx to variation in mandibular position in patients with obstructive sleep apnoea. J Oral Rehabil 1996;23:699-711.
72. McIntosh FE. Retention procedures. Am J Orthod Oral Surg 1940;26:37-40.
73. Parker S, Braden M. New soft lining materials. J Dent 1982;10:149-153.
74. Parker S, Martin D, Braden M. Soft acrylic resin materials containing a polymerisable plasticizer. I: Mechanical properties. Biomaterials 1998;19:1695-1701.