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Comparison of Adjustable and Fixed Oral Appliances for the Treatment of Obstructive Sleep Apnea

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SCIENTIFIC INVESTIGATIONS

Study Objectives: To compare the efficacy of adjustable and fixed oral appliances for the treatment of OSA.

Methods: Retrospective review of consecutive patients with OSA treated with either adjustable or fixed oral appliances. Polysomnography was conducted before and during therapy. Effective treatment was defined as an apnea-hypopnea index (AHI) < 5 events/h or < 10 events/h with resolution of sleepiness (Epworth < 10). We compared efficacy rates between fixed and adjustable appliances and sought to identify factors associated with greater success.

Results: We included 805 patients, 602 (74.8%) treated with an adjustable and 203 (25.2%) a fixed oral appliances. Among the cohort, 86.4% were men; mean age was 41.3 ± 9.2 years. Mean AHI was 30.7 ± 25.6, with 34.1% having mild (AHI 5-14.9), 29.2% moderate (AHI 15-29.9), and 36.8% severe (AHI ≥ 30) OSA. Successful therapy was significantly more common with adjustable appliances. Obstructive events were reduced to < 5/h in 56.8% with adjustable compared to 47.0% with fixed appliances (p = 0.02). Similarly, a reduction of events to < 10 with resolution of sleepiness occurred in 66.4% with adjustable appliances versus 44.9% with fixed appliances (p < 0.001). For both devices, success was more common in younger patients, with lower BMI and less severe disease.

Conclusions: Adjustable devices produced greater reductions in obstructive events and were more likely to provide successful therapy, especially in moderate-severe OSA. Fixed appliances were effective in mild disease, but were less successful in those with higher AHIs. Given these findings, the baseline AHI should be considered when selecting the type of oral appliance.

Keywords: Oral appliance, mandibular advancement device, obstructive sleep apnea, efficacy

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While continuous positive airway pressure (CPAP) therapy remains the treatment of choice for most patients with obstructive sleep apnea (OSA), its efficacy is often limited by intolerance and poor adherence.[1-3] The need for a reliable source of electricity and inconvenience with travel further limit its use.

A commentary on this article appears in this issue on page 447.

Mandibular advancement devices, or oral appliances (OAs), are an approved, frequently effective alternative to CPAP for the treatment of OSA.[4-7] Numerous studies have established the ability of OAs to ablate obstructive apneas and hypopneas.[8-13] Existing research demonstrates that OA therapy is superior to commonly offered surgical procedures,[8,9] and may be comparable to CPAP when adherence is included in the definition of successful treatment.[12-21] In 2006, the American Academy of Sleep Medicine (AASM) published updated OSA treatment guidelines which state that OAs are a reasonable alternative to CPAP in patients with mild to moderate OSA who prefer these devices or do not tolerate CPAP.[5]

Mandibular advancement devices provide a therapeutic effect by protruding the mandible relative to the maxilla, simultaneously advancing the tongue and reducing the propensity for airway collapse during sleep. Mandibular advancement devices are either fixed (i.e., the degree of mandibular advancement cannot be changed) or adjustable (i.e., mandibular advancement can be increased or decreased). The degree of mandibular advancement sought is a balance between tolerance, side effects, and efficacy.[10]

Both fixed and adjustable oral appliances are custom molded and individually fabricated from models made by impressions of the patient's dentition to fit the upper and lower teeth. Fixed OAs are typically set to advance the mandible between 50% and 80% of its maximal protrusion and fabricated in a permanent position for therapeutic use. Adjustable OAs, on the other hand, can be further titrated (i.e., using a screw-type or similar advancing mechanism) to optimize therapeutic efficacy. Upon

BRIEF SUMMARY

Current Knowledge/Study Rationale: Oral appliances are an approved, frequently effective alternative to CPAP for the treatment of OSA. Both fixed and adjustable devices are available. However, the ability of fixed devices to provide adequate therapy has not been established. The purpose of this study was to compare the efficacy of fixed and adjustable oral appliances in the treatment of OSA.

Study Impact: Among a large cohort of patients with a wide range of OSA severity, we found adjustable appliances provided greater reductions in the AHI and were more likely to provide successful therapy compared with fixed devices, particularly in those with moderate-severe disease. Similar to previous reports, we found that successful therapy was more common in patients who were younger, had lower BMIs and less severe disease.

delivery of the device, patients are instructed to advance the device incrementally to identify the optimal position which improves sleep continuity and reduces snoring and obstructive events. A repeat polysomnogram while using either a fixed or adjustable OA should be obtained to assure that obstructive respiratory events are adequately ablated.[5,7]

While effective, adjustable OAs require consultation and adjustments from providers skilled in sleep dentistry. In addition, adjustable OAs can also be expensive, with fees for fabricating and adjusting these devices potentially exceeding $3000,[22] causing adjustable OAs in some settings to be more expensive than CPAP.[24] In addition to the time required to fabricate adjustable OAs, a period of incremental titration is needed to facilitate patients› tolerance of the mandibular advancement, which further adds to the inherent delay to effective treatment.

Fixed OAs offer the advantages of lower cost, greater ease to obtain and fit, and a decrease in time to therapy compared to adjustable OAs. However, because fixed OAs cannot be titrated, further adjustments cannot be made once the device is set. This may limit the degree of mandibular advancement/protrusion or anterior displacement of the oropharynx, which may lead to inadequate resolution of obstructive events in patients with OSA.

Despite the utilization of fixed OAs, few studies have been conducted establishing the efficacy of these devices in the treatment of OSA. Existing studies are limited by small sample sizes and many do not include repeat polysomnography on therapy. Fixed OAs have been shown to reduce events, but their ability to provide adequate therapy or normalize the AHI has not been established.[24-26]

No large studies directly comparing the performance between fixed and adjustable OAs have been conducted. While fixed OAs offer advantages, they may not provide adequate reduction of obstructive respiratory events and may result in residual disease or inadequate therapy for some patients. We sought to compare the efficacy of fixed OAs and adjustable OAs in their ability to effectively treat patients with OSA.

METHODS

Study Design

We conducted a retrospective review of consecutive adult patients treated with an OA for OSA at our institution between January 2003 and December 2009. Patients who did not undergo repeat polysomnography were excluded from the final analysis. The protocol was approved by our institution›s Department of Clinical Investigation (Scientific Review Committee, Human Use Committee and Institutional Review Board). No external funding was utilized to complete this study.

Patients

All patient records were retrieved from a single, accredited, academic sleep disorders center (Walter Reed Army Medical Center, Washington, DC). All included patients were diagnosed with obstructive sleep apnea syndrome by clinical symptoms and level I polysomnography in accordance with AASM criteria.[27]

All patients prescribed OAs at our institution undergo extensive education regarding the effects of OSA, need for adequate therapy, and the proper use of and care for the device. All patients undergo serial clinical evaluations after initiating OA therapy to optimize the therapeutic response. A repeat level I polysomnography on therapy is performed to optimize the reduction of respiratory events and/or ensure OSA is appropriately treated.

The use of OAs for the treatment of OSA is not standardized at our institution. After confirming the diagnosis of OSA and establishing a need for primary therapy (treatment beyond conservative measures), patients are educated regarding the available therapeutic options (CPAP, OAs, surgery). In conjunction with recommendations made by their sleep physician, patients may elect any treatment modality. Unless contraindicated, OAs may be used as the initial treatment option or subsequently elected by those intolerant of CPAP therapy. As Military Service Members comprise a large proportion of patients seen at our institution, many patients elect to use an OA because CPAP requires a reliable source of electricity, which will limit world-wide deployability.

Oral Appliances

We included patients treated with both adjustable and fixed OAs. All devices used in this analysis were constructed using semi-rigid, thermoplastic material and specifically fabricated for the individual patient. No prefabricated, non-customized devices were utilized in our cohort. The type of OA (fixed or adjustable) prescribed was determined by resource availability at the time of presentation and current duty location, and not by preestablished clinical criteria.

All patients were evaluated for eligibility by a dentist trained in dental sleep medicine prior to initiating OA therapy. To be considered for OA therapy, patients must not have craniofacial abnormalities, active dental disease, mandibular injuries, or preexisting temporomandibular joint (TMJ) dysfunction that would preclude the effective use of or tolerance to the device. In addition, patients must be capable of extending their mandible without pain or discomfort. Those who cannot tolerate wearing the appliance or edentulous patients are not offered OA therapy. When applicable, active sinus disease is adequately treated prior to initiating treatment.

Non-adjustable, fixed devices: Appliances were fabricated in a fixed position that balanced anterior-posterior expansion of the retroglossal space and an acceptable comfort level for the patient, typically 60% to 80% of the maximum possible anterior advancement of the mandible. Fixed devices used in this analysis were constructed from a bilaminate acrylic material (Proform Dual Laminate, Dental resources, Delano, MN). Occlusion registry was obtained at 60% to 75% of the maximal mandibular protrusion with 3-5 mm of vertical clearance. The devices were fabricated using molds from impressions of the patient's dentition. Following final adjustments of the device to optimize fit and comfort, the device was bonded into the final position and the patient underwent a level I polysomnogram to determine if the OA effectively mitigated obstructive events.

Adjustable/Titratable devices: Adjustable OAs used in this analysis were customized, titratable mandibular appliances that consisted of an upper and lower tray that could be adjusted using an embedded hook and screw mechanism to advance the mandibular (lower) tray beyond the fixed maxillary (upper) tray. All adjustable OAs used in this analysis were Thornton Adjustable Positioner (TAP) II devices (Airway Management, Inc, Dallas, TX). Following fabrication and final modifications, patients

treated with adjustable OAs conducted an at-home adjustment protocol prior to their titration polysomnogram. Patients began the at-home adjustment protocol with the OA set in a neutral position, where the device was set to the patient›s normal bite without any mandibular advancement. Once comfortable sleeping with the OA in place, patients were instructed to advance the device 0.5 mm (1 turn) each night as tolerated. In the event of discomfort, the device was regressed 1 mm (2 turns) and subsequent advancement was resumed at a slower pace. Patients maintained a comprehensive sleep diary that recorded subjective assessments of sleep quality (including sleep continuity, snoring, and witnessed apneas) and daytime somnolence. Using the patient›s sleep diary, the degree of mandibular advancement that optimized subjective sleep quality was determined. Each patient then underwent a level I polysomnography with OA titration. By protocol, the OA was initially set to 1 mm of mandibular advancement less than that estimated by the home titration. During the titration polysomnogram, the device was incrementally advanced as needed to ablate snoring and obstructive respiratory events and minimize respiratory effort-related arousals similar to the protocol used during CPAP titration polysomnograms. In response to observed apneas or hypopneas, the polysomnography technologist would briefly awaken the patient and advance the OA by 1 turn. This would continue as needed, up to 3 turns, in order to identify the optimal setting to ablate events, preferably in the supine REM position. Advancement was discontinued if the patient experienced discomfort.

Outcome Measures

Data used in this analysis were obtained from the initial sleep consultation, follow-up evaluations, and polysomnographic studies. Demographic and anthropomorphic variables included age, gender, body mass index (BMI), presence of retrognathia or micrognathia, and Mallampati score. Subjective somnolence both before and after treatment was assessed using the Epworth Sleepiness Scale (ESS).[28] Polysomnographic data included the baseline AHI and the AHI at the prescribed degree of mandibular advancement with the OA. A positional component of the patient›s sleep disordered breathing, defined as a 50% decrease in the AHI in the lateral compared to supine position, was also determined. All polysomnography studies were interpreted by board certified sleep physicians in accordance with established AASM criteria.[27] OSA severity was determined by the observed AHI during polysomnography, with mild, moderate, and severe disease defined as 5-14.9, 15-29.9, and ≥ 30 events/h, respectively.

End Points

The primary endpoint was the degree of successful treatment of OSA. We defined successful treatment as a decrease in the AHI to < 5 events/h. OA failures were defined as intolerance to the device or incomplete resolution of obstructive events. The rate of successful treatment was compared between fixed and adjustable devices. The ability to reduce the AHI to < 10 events/h with resolution of sleepiness (ESS < 10) served as a secondary endpoint.

Statistical Analysis

All data are presented as the mean with standard deviation. Comparisons between categorical variables were performed using χ^2 or Fisher exact tests as appropriate. For continuous variables, differences between means were assessed using 2-sample t-tests. Multivariate modeling was performed using logistic regression. All variables that had a p value ≤ 0.10 in univariate analysis were entered into multivariate models. Data were analyzed using PASW 17 (formerly SPSS 17.0, SPSS Inc, Chicago, IL).

Table 1—Baseline characteristics of individuals treated with oral appliances

	Adjustable Devices	Fixed Devices	p
Age (years)	41.3 ± 9.0	42.9 ± 9.6	0.06
Men (%)	86.4	86.0	0.89
BMI (kg/m^2)	28.7 ± 4.4	29.3 ± 4.7	0.16
ESS	13.2 ± 5.1	14.3 ± 4.5	0.09
Mallampati	2.9 ± 0.9	3.1 ± 0.9	0.24
AHI (events/h)	29.7 ± 24.1	30.1 ± 24.4	0.86
SpO_2 nadir (%)	83.8 ± 7.6	83.3 ± 8.8	0.48
% of sleep time with SpO_2 < 90%	5.0 ± 10.0	5.9 ± 12.3	0.28
Mild OSA (%)	30.9	35.1	0.18
Moderate OSA (%)	28.2	30.2	0.59
Severe OSA (%)	40.9	34.7	0.11

RESULTS

During the inclusive period, 922 patients were treated with an OA. Data were incomplete in 117 individuals; 805 (87.3%) were included in the final analysis. Among the cohort, the mean age was 41.3 ± 9.2 years, the majority (86.7%) were men, and the mean ESS was 13.4 ± 5.0 at baseline. Mean BMI was 28.9 ± 4.4 kg/m^2, and 38.8% were obese (BMI ≥ 30 kg/m^2). The mean AHI for the cohort was 30.7 ± 25.6 events/h; and OSA was categorized as mild in 34.1%, moderate in 29.2%, and severe in 36.8% of subjects. Adjustable OAs were used in 602 (74.8%) patients, and 203 (25.2%) were treated with a fixed OA. Groups were similar at baseline (**Table 1**).

While both devices produced a substantial decrease in the AHI, reduction of obstructive events was significantly greater, and more patients achieved successful therapy, with an adjustable OA (**Tables 2-4**). In comparison to the baseline PSG, those using adjustable OAs experienced a 74.4% reduction in AHI, compared with a 64.9% decrease with fixed devices (p = 0.08). Similarly, the mean change in AHI was −22.6 events/h with adjustable devices versus −18.8 events/h with fixed OAs (p = 0.14). Successful therapy (AHI reduced to < 5 events/h) was achieved in 57.2 % of patients using an adjustable appliance and only 46.9% of those using fixed OAs (p = 0.02). Similarly, 74.3% of patients with an adjustable device achieved an AHI < 10, compared with 63.8% of those using a fixed OA (p = 0.01). Using our alternate definition for successful therapy, a reduction in the AHI to < 10 events/h with normalization of the ESS occurred in 66.4% of patients wearing an adjustable OA and 44.9% of those using a fixed appliance (p < 0.001).

We further compared the rates of successful therapy between the devices based on disease severity. The proportion of

Table 2—Efficacy of adjustable versus fixed oral appliances in the treatment of obstructive sleep apnea

	Adjustable Devices	Fixed Devices	p
AHI on therapy (events/h)	7.6 ± 9.7	10.0 ± 12.4	< 0.01
% Reduction in AHI	74.4	64.9	0.08
SpO_2 nadir on therapy (%)	88.1 ± 7.2	85.7 ± 6.5	0.20
% of sleep time with SpO_2 < 90%	2.8 ± 6.7	4.2 ± 8.9	0.22
ESS on therapy	9.7 ± 4.1	10.6 ± 4.3	0.11
Intolerance of OA (%)	15.4	13.3	0.46
AHI < 5 events/h (%)	57.9	46.9	0.02
AHI < 10 events/h (%)	74.3	63.8	0.01
AHI < 10 and ESS < 10 (%)	66.4	44.9	< 0.01

Table 3—Comparison of rates of successful therapy between fixed and adjustable oral appliances based on OSA severity

	Adjustable	Fixed	p
Mild			
Baseline AHI	9.6 ± 2.8	8.8 ± 3.2	0.07
Baseline ESS	14.4 ± 4.4	14.2 ± 5.6	0.64
ESS on Therapy	9.8 ± 3.9	10.8 ± 4.4	0.08
AHI on OA Therapy	4.4 ± 5.2	4.9 ± 6.8	0.61
AHI on OA Therapy < 5	73.4%	63.8%	0.17
AHI on OA Therapy < 10	86.1%	82.7%	0.68
AHI < 10 and ESS < 10	81.2%	61.7%	< 0.01
Mean AHI Reduction	**5.3** ± 5.6	3.8 ± 7.3	0.11
Moderate			
Baseline AHI	21.0 ± 4.3	22.3 ± 4.9	0.12
Baseline ESS	13.1 ± 3.6	13.3 ± 6.2	0.44
ESS on Therapy	8.4 ± 4.0	8.8 ± 5.4	0.18
AHI on OA Therapy	7.5 ± 8.1	11.0 ± 10.3	0.02
AHI on OA Therapy < 5	52.2%	35.0%	0.05
AHI on OA Therapy < 10	74.3%	62.5%	0.14
AHI < 10 and ESS < 10	64.1%	41.9%	0.02
Mean AHI Reduction	13.9 ± 8.6	11.4 ± 9.3	0.08
Severe			
Baseline AHI	56.3 ± 21.5	54.3 ± 22.6	0.54
Baseline ESS	15.4 ± 6.8	14.9 ± 6.6	0.24
ESS on Therapy	9.8 ± 1.8	10.2 ± 5.4	0.19
AHI on OA Therapy	12.2 ± 15.4	14.2 ± 14.9	0.22
AHI on OA Therapy < 5	44.62%	37.8%	0.35
AHI on OA Therapy < 10	60.1%	46.9%	0.05
AHI < 10 and ESS < 10	53.9%	33.9%	< 0.01
Mean AHI Reduction	44.4 ± 16.1	39.9 ± 12.6	0.07

individuals with mild, moderate, and severe OSA was similar between the 2 groups. For all degrees of severity, adjustable OAs produced a greater mean reduction in AHI and had higher success rates compared to fixed OAs (**Table 3**). Similarly, using progressive cut points for the baseline AHI, the final AHI (**Figure 1**) and probability for successful therapy (**Figure 2**) were superior with adjustable devices.

Figure 1—Apnea-hypopnea index at the prescribed degree of mandibular advancement with fixed versus adjustable oral appliances by baseline apnea-hypopnea index

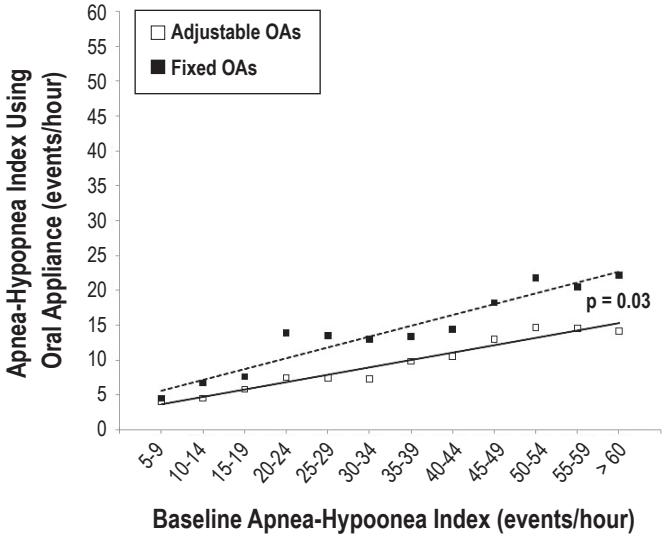
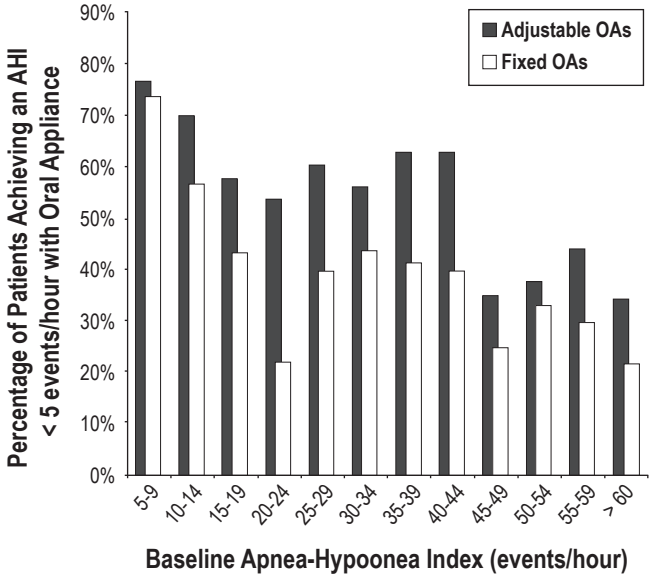


Figure 2—Probability of successful therapy (AHI < 5 events/h) with fixed versus adjustable oral appliances by baseline apnea-hypopnea index



We performed both univariate and multivariate analyses to identify potential predictors of successful treatment with either adjustable or fixed OAs (**Tables 5** and **6**). Variables that achieved statistical significance to $p < 0.10$ were entered into a multivariate logistic regression model. Because AHI, SpO_2 nadir, and percentage of sleep time with $SpO_2 < 90\%$ on baseline polysomnography were all closely correlated, only AHI was entered into the multivariate analysis. Women and those using adjustable devices were significantly more likely to achieve an AHI < 5 with OA therapy. In contrast, patients who were older, had higher BMIs, higher baseline AHIs, or those using fixed devices were less likely to achieve and AHI < 5 with OA therapy.

DISCUSSION

We found that adjustable OAs are superior to fixed OAs in their ability to reduce the AHI among a large cohort of patients with a wide range of OSA severity. Successful treatment and improvements in subjective measures of sleepiness were significantly more likely with adjustable OAs. Although fixed OAs were frequently successful in patients with mild disease, adjustable devices performed better across all severities of OSA. Similar to previous reports, we found that successful therapy with OAs was more common in patients who were younger, had lower BMIs and less severe disease.[4,5,13]

In accordance with the 2005 AASM Practice Parameters for Oral Appliances, these devices are indicated as either primary or alternative therapy for patients with sleep disordered breathing, particularly those with mild to moderate OSA.[5] OAs can be used as either first-line therapy or in those intolerant of CPAP. This recommendation was based on numerous studies establishing their efficacy in ablating obstructive respiratory events, normalizing the AHI, and improving symptoms.[12-21] However, these studies were performed using adjustable devices, and it is important to distinguish between fixed and adjustable OAs, as the former may not be an appropriate choice of therapy or adhere to AASM recommendations. OAs offer advantages over CPAP in that they do not require a source of electricity and are less cumbersome, especially with travel. OAs are well tolerated in most patients, and therapeutic adherence may be better with OAs than CPAP.[14-16,20,21]

The ability to titrate OAs and allow progressive advancements in mandibular protrusion increase the efficacy of OAs. Adjustable devices offer the advantage of being able to produce this advancement without having to recreate or reset the device. In a study of adults with sleep disordered breathing, Kato et al. found that OAs successfully mitigate pharyngeal collapsibility.[29] Their study utilized fixed devices at three different degrees of mandibular advancement, and the authors observed that OAs produced linear, dose-related improvements in both the number and severity of desaturation events. Similarly, Almeida and colleagues found that the AHI reduction produced by OAs was proportionately related to the amount of mandibular protrusion.[26] Patients in this trial received a Klearway adjustable OA, which was incrementally advanced 0.5 mm each week until both clinical and polysomnographic improvements were noted. The authors concluded that progressive advancement of the mandible was associated with a linear reduction in the AHI.

Fixed OAs offer advantages over adjustable OAs. They are typically less expensive, do not require a period of adjustment, and offer treatment sooner than adjustable devices. However, despite these advantageous features, fixed OAs may be less efficacious. The degree of mandibular advancement and resultant expansion of the retroglossal space is a critical design feature of OAs and the premise for how they achieve a successful therapeutic response. When compared with inactive control devices that provided no mandibular advancement, mandibular advancement type OAs have been shown to improve both subjective and objective measures of daytime sleepiness.[30] Inactive control devices versus mandibular advancement OAs have also demonstrated that mandibular advancement was the critical factor for treating sleep disordered breathing events by polysomnography.[24]

There are limited data establishing the efficacy of fixed OAs in the treatment of OSA. In contrast, numerous studies have demonstrated the importance of titrating mandibular advancement to establish the therapeutic setting that optimizes treatment, similar to titration studies used to determine appropriate CPAP pressures.[20,21,31,32] Most comparisons of the efficacy between OA therapy and CPAP therapy have employed titrated CPAP and untitrated OAs. To better determine the comparable effectiveness of these two modalities, Aarab and colleagues compared the efficacy of OAs and CPAP, when both were titrated to the best effect.[21] In 64 subjects with mild to moderate OSA, there was no difference in improvement in AHI between the different therapies.

There are few reports demonstrating that fixed OAs are capable of fully treating OSA to a normal AHI in most patients.[11,34-36] One comparison study showed that a fixed OA was more effective than a tongue retaining device and soft palate lift.[33] While

Table 4—Rates of successful therapy (AHI < 5) between fixed and adjustable oral appliances based on baseline AHI

	Adjustable	Fixed	p
Baseline AHI < 15 events/h	73.4%	63.8%	0.17
Baseline AHI < 30 events/h	64.9%	53.7%	0.04
Baseline AHI < 45 events/h	63.9%	52.3%	0.01
All AHIs	57.9%	46.9%	0.02

Table 5—Univariate analysis: determinants of treatment success with oral appliance therapy

	AHI < 5 on OA Therapy	AHI > 5 on OA Therapy	p
Age	40.5 ± 9.2	43.5 ± 8.9	< 0.001
ESS	12.9 ± 5.0	13.1 ± 5.3	0.78
BMI	28.2 ± 4.7	29.4 ± 4.2	0.004
AHI*	23.7 ± 19.7	35.8 ± 27.3	< 0.001
O_2 nadir*	84.7 ± 7.5	82.8 ± 8.1	0.001
% time SpO_2 < 90%*	3.5 ± 7.7	7.1 ± 12.2	0.004
Men	83.5%	91.6%	0.003
Hypertension	46.5%	43.5%	0.21
Adjustable OA	89.9%	80.5%	0.001
Positional**	66.7%	53.2%	0.07

*Data from baseline diagnostic PSG. **Defined as > 50% decrease in AHI in lateral versus supine position.

Table 6—Multivariate analysis: likelihood of successful treatment (AHI < 5) with oral appliance therapy

	OR (95% CI)	p
Age	0.97 (0.94-0.99)	0.022
Female	2.1 (1.2-3.9)	0.01
Body Mass Index	0.95 (0.90-0.99)	0.02
Apnea-Hypopnea Index	0.98 (0.98-0.99)	< 0.001
Adjustable Oral Appliance	2.1 (1.2-3.9)	0.01

a number of subjects wearing the fixed OA were adequately treated, treatment failures were observed in 40%. This was likely due to the high degree of OSA severity among the cohort (mean AHI 72 events/h). Similarly, Deane and coworkers compared a mandibular advancement splint to a tongue stabilizing device in a randomized crossover trial of patients with OSA. They observed that mandibular advancement performed better than tongue stabilization devices in symptomatic improvement, compliance, and patient preference. Both devices produced similar reductions in the AHI, with mandibular advancement splints performing slightly better. However, neither device achieved an AHI < 10 in the majority of subjects.[36] Vanderveken and colleagues compared a "boil and bite" thermoplastic fixed OA to a custom-made fixed OA. In a cohort of subjects with mild OSA, the custom-made device showed better efficacy (60% vs. 31%) and compliance.[35] While the benefits of fixed devices in the treatment of OSA have been demonstrated, many are compared to non-OAs or show high rates of incomplete resolution of obstructive events, particularly in those with more severe disease. It appears that while fixed OAs may be beneficial in some patients, adjustable devices perform better and are more likely to provide successful treatment of OSA.

In contrast, Marklund et al. evaluated the effects of fixed OAs in a large cohort of subjects with sleep disordered breathing.[13] In this trial, fixed devices were incrementally advanced in response to clinical observations. Among 630 included patients, 263 with OSA and 14 with simple snoring underwent repeat evaluation. The authors found that 72% of those who were re-evaluated achieved an overall AHI < 10, with 54% having successful therapy in both the lateral and supine positions. Similar to our findings, they observed that fixed devices were less likely to be successful in those with higher baseline AHIs. In this study, only 34% of those with moderate or severe OSA achieved an AHI < 5 events/hour. Also similar to our findings, they found that OAs were more likely to be successful in women and those with a greater positional component to their OSA, lower baseline AHIs, and lower weight. This study found that fixed OAs performed better than our observations. This difference is likely the result of their incremental adjustments/advancements of the device to optimize clinical outcomes. However, this is similar to our protocol for incremental advancement of adjustable devices and highlights a clear benefit of adjustable OAs, as they can be titrated to effect without the need for repetitive refitting of the device.

Similar to CPAP, the inability of either fixed or adjustable OA to ablate events during the initial therapeutic period should not be automatically considered a treatment failure. Adjustable devices can be re-titrated over a different range of settings, and fixed devices can be repositioned for greater mandibular advancement. Patients at our center who are not adequately treated with a fixed OA are referred for an adjustable device or CPAP. As such, we may have underestimated the benefits of fixed devices.

Our study has several limitations. We conducted a retrospective study, which limits the validity of our findings. However, we included a relatively large cohort of patients, all of whom underwent level I polysomnography at both baseline and while on therapy. The selection of a fixed versus titratable device was not standardized, mitigating potential selection bias that could occur if an established algorithm based on patient-specific variables was used. Our secondary endpoint used normalization of the ESS as a marker for successful therapy. The duration of therapy prior to repeat polysomnography was not standardized, and it is possible that those using adjustable devices had more time to improve symptoms. However, the primary aim of our study was to determine the ability of each type of OA to ablate obstructive respiratory events and successfully treat OSA, independent of any change in the ESS. Similarly, we did not include long-term data, and while we found that adjustable OAs were superior to fixed devices, it is unknown if this would be influenced by differences in long-term tolerance, acceptance rates, or adverse effects between these two types of devices. Finally, we did not include prefabricated, non-customized OAs in our cohort, as we do not utilize or recommend these devices in our center. While these devices are relatively inexpensive, accessible as an over-the-counter purchase, and do not require sleep dentistry consultation or adjustments, it is unlikely that they would provide adequate treatment of OSA and are not endorsed by the AASM.

Although we found that fixed OAs were less effective than adjustable OAs, there may be a role for these devices in the treatment of patients with mild sleep disordered breathing. Given the rapid increase in the recognized prevalence of sleep disordered breathing, less expensive devices that are easier to fabricate and use may offer treatment options for a greater number of patients. However, these devices still require customized fabrication and repeat polysomnography, which diminish these advantages. In addition, the high failure rate observed in this analysis, particularly in those with an AHI > 15 events/hour, raises significant concerns over the potential use of fixed OAs in the treatment of OSA. In our study, the majority of patients using fixed OAs had inadequately treated disease. Any potential savings with regard to time and money were lost, as the majority of patients in this cohort required the subsequent use an adjustable OA or other form of therapy. In view of the detrimental effects of OSA on quality of life and health, only those treatment options that produce effective therapy should be utilized.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
AHI, apnea hypopnea index
BMI, body mass index
CPAP, continuous positive airway pressure
ESS, Epworth Sleepiness Scale
OA, oral appliance
OSA, obstructive sleep apnea

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