

ORIGINAL RESEARCH—SLEEP MEDICINE

Otolaryngology office-based treatment of obstructive sleep apnea-hypopnea syndrome with titratable and nontitratable thermoplastic mandibular advancement devices

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ABSTRACT

OBJECTIVE: 1) Share our experiences treating patients with obstructive sleep apnea-hypopnea syndrome (OSAHS) with titratable and nontitratable thermoplastic mandibular advancement devices (MADs) fitted in our otolaryngology clinic. 2) Compare these devices in terms of objective response (OR), as defined by a ≥ 50 percent decrease in baseline apnea-hypopnea index (AHI) and an AHI < 20 , and subjective parameters, including adherence. 3) Determine overall success, as defined by OR plus adherence at two months follow-up.

STUDY DESIGN: Cohort study.

SETTING: Tertiary care center.

SUBJECTS AND METHODS: Patients with OSAHS who tried and failed or refused both continuous positive airway pressure (CPAP) and surgical therapy were fitted with a nontitratable Snore Guard ($n = 38$), nontitratable SomnoGuard 2.0 ($n = 8$), or titratable SomnoGuard AP ($n = 41$). Pre- and post-treatment assessment included: 1) Epworth Sleepiness Scale, 2) snoring level, 3) polysomnogram. Patients were contacted at two months follow-up to assess adherence and subjective parameters.

RESULTS: OR was achieved in 62.1 percent of patients. Overall mean reduction in AHI was from 39.96 ± 23.70 to 14.86 ± 13.46 ($P = 0.000$). Adherence at two months was 58.5 percent. No significant differences were observed in OR or adherence according to MAD type, though improvements in AHI and minimum oxygen saturation were significantly better for the SomnoGuard AP than for the nontitratable devices. Overall success was 38.6 percent.

CONCLUSION: Thermoplastic MADs are a relatively inexpensive treatment alternative for patients with OSAHS who fail/refuse CPAP and upper airway surgery. They can be easily fitted in the otolaryngology clinic. Long-term compliance, efficacy, and safety are unknown at this time.

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Comprehensive care of any disease requires expertise in all aspects of diagnosis and treatment. Practice parameters issued by the American Academy of Sleep Medicine (AASM) identify two treatments for mild to moderate obstructive sleep apnea-hypopnea syndrome (OSAHS): continuous positive airway pressure (CPAP) and mandibular advancement devices (MADs),¹ also known as oral appliances. While CPAP has been widely accepted as the gold standard for nonsurgical treatment of mild to severe OSAHS, it often suffers from poor patient compliance.

Due largely to their smaller size and intraoral application, MADs offer several advantages over CPAP, including noiselessness and superior portability. The efficacy of MADs for the treatment of mild/moderate OSAHS has been demonstrated in many published reports.^{1–4} The vast majority of these reports have studied custom-made devices created by dentists. Thermoplastic MADs are designed for simplified, on-site office-based molding and can easily be incorporated into an otolaryngology practice with an interest in sleep medicine.

Until recently, thermoplastic devices were not adjustable, unlike many custom-made devices that can be titrated during polysomnography (PSG) to achieve maximum effectiveness. The SomnoGuard AP (Tomed Dr. Toussaint GmbH, Bensheim, Germany) is a titratable thermoplastic MAD that recently became available for the treatment of OSAHS. The main purpose of this study is to report the experiences of our Otolaryngology Department fitting and treating OSAHS patients with three types of thermoplastic MADs, including the titratable SomnoGuard AP. Specific aims include comparing PSG parameters with and without the MADs, assessing changes in subjective parameters after two months of use, and determining rates of adherence and adverse effects. This is the first published

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Figure 1 Snore Guard, Salida, CA.

report on a titratable thermoplastic device for the treatment of OSAHS.

Materials and Methods

This was a prospective study of three nonrandomized, non-controlled cohorts at a tertiary care center. Approval from the Institutional Review Board at Advocate Health Care in Chicago, IL, was obtained prior to commencing the study. Subjects were recruited from among OSAHS patients fitted with a MAD at our otolaryngology clinic between January 2008 and August 2009. Inclusion criteria were: 1) age \geq 18 years, 2) apnea-hypopnea index (AHI) \geq 5, 3) refusal or failure of CPAP and surgical therapy, 4) Friedman tonsil size 0-2, and 5) acceptable dentition. The latter criterion was defined by the absence of periodontal disease, loose teeth, missing teeth besides the second or third molars, bridge-work, brackets, or other structural impediments to fitting the device directly and securely to the upper and lower dental arches. For patients with a history of upper airway surgery, a postoperative PSG test displaying evidence of persistent disease (AHI \geq 5) was an additional requirement. Patients with temporomandibular joint disorders or severe nasal ob-



Figure 2 SomnoGuard 2.0.

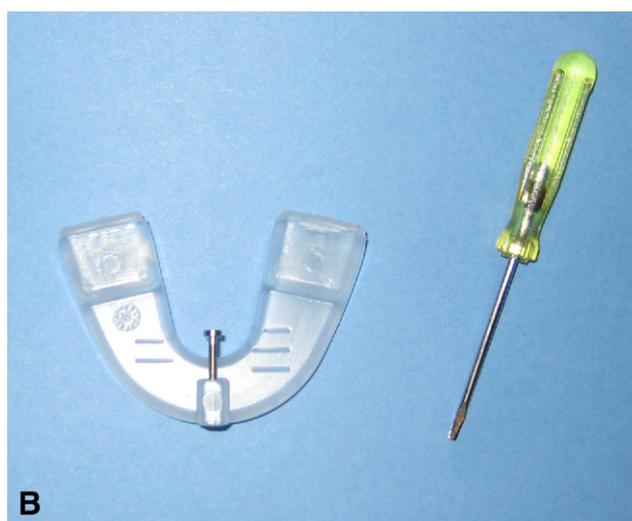


Figure 3 (A) SomnoGuard AP (Tomed Dr. Toussaint GmbH, Bensheim, Germany). (B) SomnoGuard AP (Tomed Dr. Toussaint GmbH).

struction were excluded. Friedman tonsil size was assessed as follows: size 0 = surgically absent tonsils, size 1 = tonsils hidden within pillars, size 2 = tonsils extending to pillars but not beyond, size 3 = tonsils extending beyond pillars but not to midline, and 4 = tonsils extending to midline.

Study participants completed the Epworth Sleepiness Scale (ESS) prior to device fitting. Their bed partner was asked to rate snoring intensity on a visual analog scale (VAS) ranging from 0 to 10, with 0 indicating no appreciable snoring and 10 snoring loud enough to require leaving the room. When the bed partner was unavailable, snoring intensity was assessed according to the same scale by the sleep technician overseeing the PSG.

Three MADs were reviewed with patients. Devices were selected according to patient preference, which often de-

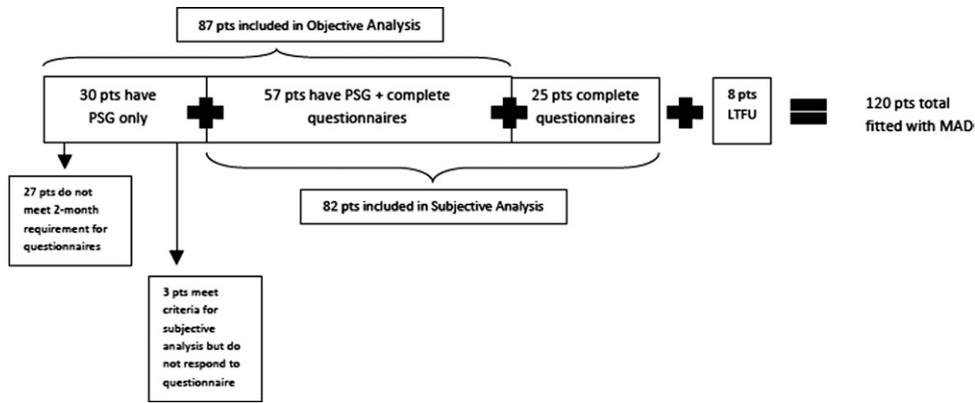


Figure 4 Patient distribution schema. *PSG*, polysomnogram; *pts*, patients; *LTFU*, lost to follow-up.

pendent on financial considerations. The Snore Guard (Snore Guard, Salida, CA) is a nontitratable one-piece MAD that fits securely to the upper teeth and has a lower ramp to hold the mandible forward (Fig 1). The cost to patients is \$100.00. The SomnoGuard 2.0 (Tomed Dr. Toussaint GmbH) is another nontitratable one-piece MAD that features full trays for the maxillary and mandibular dental arches (Fig 2). The cost to patients is \$150.00. The SomnoGuard AP is a titratable two-piece device joined by a screw that allows for adjustment of the degree of mandibular protrusion (Fig 3). The cost to patients is \$200.00.

Patients were fitted with the MAD in the office and scheduled for a repeat PSG with the device in place. Patients with the SomnoGuard AP underwent titration of the device during repeat PSG; parameters at the optimum degree of mandibular protrusion were used for data analysis. Charts of patients were reviewed for gender, age, history of upper

airway surgery, body mass index (BMI), and PSG results. Patients were contacted by phone two months after MAD fitting to complete questionnaires regarding adherence, ESS, VAS for snoring, and adverse effects.

MAD Fitting

All three devices are made of thermoplastic material that softens when heated above 45°C. Devices were fitted according to manufacturer instructions and were remolded at any point during the study for improved fit or comfort upon patient request.

Polysomnogram

An all-night, attended, comprehensive sleep study was performed using a computerized polygraph to monitor electroencephalogram (C3-A2, C4-A1, O1-A2, O2-A1), left and

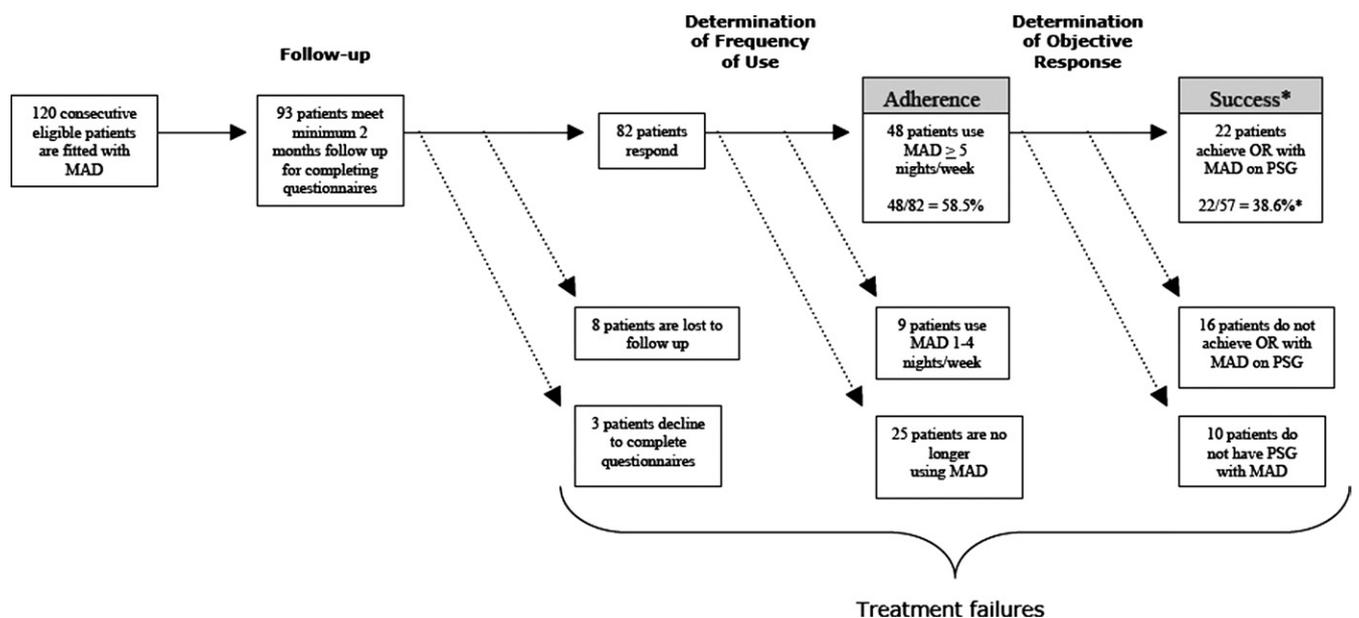


Figure 5 Algorithm for determining treatment success. *MAD*, mandibular advancement device; *PSG*, polysomnogram; *OR*, objective response. *Success calculated as number of patients with OR using the device five or more nights a week divided by the total number of patients who completed both the follow-up PSG and questionnaires.

Table 1
Demographic characteristics of patients included in the objective analysis

	Overall (n = 87)	Snore Guard (n = 38)	SomnoGuard (n = 8)	SomnoGuard AP (n = 41)	P value
Mean age (yrs)	45.70 ± 11.47 (range: 19-65)	46.42 ± 11.58 (range: 22-65)	46.88 ± 11.79 (range: 30-60)	44.80 ± 11.53 (range: 19-63)	0.789
Gender					0.003
Male	67 (77.0%)	25 (65.8%)	4 (50.0%)	38 (92.7%)	
Female	20 (23.0%)	13 (34.2%)	4 (50.0%)	3 (7.3%)	
Mean BMI (kg/m ²)	29.20 ± 4.44	28.11 ± 4.41	30.48 ± 4.58	29.98 ± 4.32	0.123
BMI classification (kg/m ²)					0.717
Normal (18.45-24.9)	11 (12.8%)	7 (18.4%)	1 (12.5%)	3 (7.5%)	
Overweight (25.0-29.9)	40 (46.5%)	18 (47.4%)	3 (37.5%)	19 (47.5%)	
Obese (30.0-39.9)	34 (39.5%)	13 (34.2%)	4 (50.0%)	17 (42.5%)	
Extremely obese (≥40.0)	1 (1.2%)	0	0	1 (2.5%)	
OSAHS severity					0.120
Mild (AHI ≥5 and <15)	6 (6.9%)	3 (7.9%)	1 (12.5%)	2 (4.9%)	
Moderate (AHI ≥15 and <30)	25 (28.7%)	14 (36.8%)	4 (50.0%)	7 (17.1%)	
Severe (AHI ≥30)	56 (64.4.0%)	21 (55.3%)	3 (37.5%)	32 (78.0%)	
History of upper airway surgery					0.288
Yes	58 (66.7%)	23 (60.5%)	6 (75.0%)	29 (70.7%)	
No	29 (33.3%)	15 (39.5%)	2 (25.0%)	12 (29.3%)	

BMI, body mass index; OSAHS, obstructive sleep apnea-hypopnea syndrome; AHI, apnea-hypopnea index.

right electro-oculogram, electrocardiogram, chin and anterior tibialis electromyogram, abdominal and thoracic movement by inductive plethysmography, nasal and oral airflow, arterial oxygen saturation by pulse oximetry (SpO₂), and throat sonogram. Apnea was defined as cessation of breathing for ≥ 10 seconds. Hypopnea was defined as a decrease in airflow ≥ 50 percent from baseline with minimum four percent decrease in SpO₂. AHI was calculated as the sum of apneas and hypopneas per hour. All reports were scored by a certified technician according to the same criteria. OSAHS severity was classified as mild (AHI ≥ 5 and < 15), moderate (AHI ≥ 15 and < 30), or severe (AHI ≥ 30).

During the follow-up study, patients wore the MAD for the duration of the study. Patients with the SomnoGuard AP were tested initially at the default setting (0-mm mandibular advancement). In the absence of apneas or hypopneas, no further adjustments were made. If apneas or hypopneas were detected, the device was adjusted to achieve increasing

degrees of mandibular advancement until the apneas and hypopneas were eliminated (up to three additional settings). Adjusting the setting required awakening the patient and removing the device. Patients were tested at each setting for a minimum of 60 minutes sleep time.

Data Analysis

Two separate analyses were conducted (Fig 4). The first was based on objective data obtained from all patients who completed a follow-up PSG with the MAD, regardless of the length of time they had the device. Data were analyzed to determine objective response (OR), defined by a minimum 50 percent reduction in AHI and an AHI < 20, and differences in outcome associated with device type, prior history of upper airway surgery, OSAHS severity, and BMI. The definition of OR was based on the commonly accepted cutoff for defining surgical success.

Table 2
Polysomnogram results of patients included in the objective analysis

	Objective response*	Mean AHI			P value
		Without MAD	With MAD	Mean % Δ	
Overall (n = 87)	54 (62.1%)	39.96 ± 23.70	14.86 ± 13.46	25.10 ± 22.92	0.000
Snore Guard (n = 38)	22 (57.9%)	37.23 ± 26.07	17.51 ± 13.80	19.71 ± 26.89	0.000
SomnoGuard 2.0 (n = 8)	5 (62.5%)	26.65 ± 12.02	13.09 ± 12.21	13.56 ± 19.02	0.084
SomnoGuard AP (n = 41)	27 (65.9%)	45.09 ± 21.99	12.75 ± 13.23	32.33 ± 17.00	0.000

AHI, apnea-hypopnea index; SpO₂, oxygen saturation by pulse oximetry; MAD, mandibular advancement device.

*As defined by a 50 percent or greater reduction in AHI and an AHI < 20.

The second analysis was based on subjective information gathered via telephone questionnaires from patients who had the device for at least two months. Completion of a repeat PSG with the MAD was not a requirement for this analysis. The rate of patient adherence, incidence of adverse effects, and changes in ESS and snoring intensity were determined. Adherence was defined as use of the device at least five nights a week.

The overall rate of success was calculated as the number of patients who achieved OR and were adherent to treatment divided by the number of patients who had data for both OR and adherence. Figure 5 depicts the algorithm for determining success.

Statistical Analysis

Statistical analysis was performed using SPSS for Macintosh 16.0 (SPSS Inc., Chicago, IL). Continuous data are displayed as mean \pm standard deviation. Statistical significance was accepted when $P < 0.05$. The one-way analysis of variance (ANOVA) and the independent Student's t -test were used to determine statistically significant differences in continuous variables between groups. The paired t -test was employed to determine statistical difference between continuous variables. The χ^2 test was used to determine significant differences in categorical variables between groups.

Results

Objective Analysis

OR, based on 87 patients who completed a repeat PSG test with the MAD, was achieved in 62.1 percent of subjects overall. The demographic characteristics and PSG results of these patients are detailed in Tables 1 and 2, respectively. No significant difference was found with regard to OR as a function of MAD type ($P = 0.767$), history of upper airway surgery ($P = 0.450$), OSAHS severity ($P = 0.139$), or BMI classification ($P = 0.168$). OR was achieved in six of six (100%) mild, 15 of 25 (60%) moderate, and 33 of 56 (58.9%) severe OSAHS patients. The overall mean AHI decreased from 39.96 ± 23.70 to 14.86 ± 13.46 ($P = 0.000$), while the mean minimum percent SpO₂ improved

from 83.18 ± 7.40 to 88.71 ± 5.18 ($P = 0.000$). Approximately two thirds of patients had a history of minimally invasive multilevel single-stage surgery (nasal surgery, palatal stiffening using pillar implants, uvular shortening to 1 cm if > 1 cm in length, and/or tongue base reduction). When patients were grouped according to device type, no significant differences were identified on one-way ANOVA with regard to mean age, BMI, or baseline AHI. However, significantly greater improvements in mean AHI and mean minimum percent SpO₂ were seen with the SomnoGuard AP than with the other two devices ($P = 0.003$ and 0.000 , respectively).

Subjective Analysis

Eight of the 93 patients who met the minimum two-month follow-up time for the subjective analysis were lost to follow-up, while three declined to respond. Of the 82 respondents to questionnaires, seven (8.5%) were using the device one to three nights a week, two (2.4%) were using it four nights a week, three (3.7%) were using it five nights a week, three (3.7%) were using it six nights a week, and 42 (51.2%) were using it seven nights a week. Twenty-five of the respondents (30.5%) were no longer using the device. Of these, one patient chose to undergo upper airway surgery despite achieving OR with the device and not experiencing any adverse effects, while three discontinued use due to lack of symptomatic relief. The remaining 21 patients stopped using the device due to intolerable adverse effects. Adherence, as defined by use five or more nights a week, was 58.5 percent. The rate of adherence did not differ significantly according to device type.

Thirty-eight (46.3%) of the 82 respondents reported adverse effects. Temporary effects occurring with treatment onset included general discomfort (5 patients), suboptimal fit (5), jaw pain (4), tooth pain (3), excessive salivation (1), cough (1), localized mucosal reaction to the thermoplastic material (1), and headache (1). Ongoing effects occurred in 20.7 percent of respondents and included general discomfort (10 patients), excessive salivation (3), jaw pain (3), and dry mouth (1). The overall incidence of adverse effects did not differ significantly according to MAD type. None of the patients who stopped using the device reported persistence of the adverse effect after discontinuation. For the 17 pa-

Table 2
(Continued)

Mean Minimum SpO ₂			
Without MAD	With MAD	Mean % Δ	<i>P</i> value
83.13 \pm 7.42	88.67 \pm 5.1	-5.53 \pm 7.95	0.000
84.77 \pm 6.87	86.73 \pm 4.89	-1.96 \pm 6.97	0.092
86.46 \pm 5.98	89.00 \pm 3.46	-2.54 \pm 7.68	0.381
81.07 \pm 7.66	90.50 \pm 5.14	-9.42 \pm 7.15	0.000

Table 3
Changes in Epworth Sleepiness Scale and snoring intensity

	Without MAD	With MAD	Mean % Δ	P value
ESS				
Overall (n = 57)	12.09 \pm 6.94	7.04 \pm 5.45	-5.04 \pm 6.45	0.000
Snore Guard (n = 31)	10.81 \pm 6.71	6.56 \pm 5.18	-4.24 \pm 6.26	0.001
SomnoGuard (n = 10)	15.60 \pm 4.35	8.90 \pm 3.67	-6.70 \pm 1.16	0.000
SomnoGuard AP (n = 16)	11.36 \pm 8.22	7.00 \pm 7.08	-4.36 \pm 2.08	0.056
Snoring intensity				
Overall (n = 83)	7.06 \pm 2.03	2.24 \pm 2.24	-4.82 \pm 2.83	0.000
Snore Guard (n = 45)	6.56 \pm 2.26	2.42 \pm 2.18	-4.13 \pm .46	0.000
SomnoGuard (n = 10)	7.00 \pm 1.70	1.70 \pm 1.89	-5.30 \pm .63	0.000
SomnoGuard AP (n = 28)	7.85 \pm 1.41	2.23 \pm 2.54	-5.62 \pm .46	0.000

MAD, mandibular advancement device; ESS, Epworth Sleepiness Scale.

tients reporting adverse effects who were still using the device at two months follow-up, the effects either gradually resolved over time or were mild enough to permit continued use. Changes in ESS and snoring intensity are listed in Table 3.

Success of Treatment

Treatment was successful in 22 (38.6%) of the 57 patients who underwent combined assessment for OR and adherence (Fig 5).

Discussion

Interest in MADs for treating OSAHS has grown substantially among otolaryngologists as recognition of the devices as a viable alternative to CPAP has increased in recent years. Since the AASM's 2006 update of practice parameters for oral appliances¹ and the Cochrane review on MADs in 2008,² the number of studies led by ENTs and published in otolaryngology journals has risen. Nevertheless, the vast majority of the literature to date has focused on custom devices fitted by dentists. The purpose of the present study was to address the relative dearth of information regarding otolaryngologist-fitted devices by sharing our experiences fitting and treating patients with three thermoplastic MADs, including a recently introduced titratable device.

The main advantage of offering thermoplastic MADs in the otolaryngology clinic is convenience to patients. Custom-made MADs require taking impressions, which must then be sent to an outside laboratory for device fabrication. In contrast, thermoplastic devices are premanufactured with moldable material and can be fitted in the otolaryngology clinic in approximately 15 to 20 minutes. The only necessary supplies are boiling water and scissors to trim any excess thermoplastic material after fitting. In our experience, patients have been more apt to try a MAD when it can be made immediately, on-site, for use as early as the same night, as opposed to being referred to a dentist who specializes in sleep medicine. The latter option often entails a delay due to scheduling and insurance issues and can require

additional visits for fitting and adjustments. Thermoplastic devices can be readily remolded in the otolaryngology clinic should patients experience problems with fit or discomfort. Frequently, these issues are recognizable at the time of initial fitting and can be addressed immediately.

Cost is another advantage of thermoplastic devices over custom-made ones. Thermoplastic devices range from approximately \$100 to \$300, whereas custom devices may cost as much as \$1500 to \$4000. When the additional investment of time and money spent on multiple visits is considered, the relative savings of thermoplastic MADs can be significant. Thermoplastic MADs can also serve as an inexpensive screening tool for subsequent custom device elaboration for patients whose respiratory parameters do not fully normalize with a thermoplastic MAD.

Although several studies^{1,2} have shown CPAP to be superior to MADs in reducing PSG-detected respiratory disturbances, it is important to remember that the success of any treatment is not contingent upon objective response alone. Treatment acceptance and adherence are critical. Rates of adherence reported in the 2006 systematic review of oral appliances by Ferguson et al³ often surpassed 75 percent. Although our rate of adherence was not quite as good, we expect it to improve as our experience working with the devices grows. Counseling patients on potential adverse effects, the possible need for refitting and troubleshooting, and the existence of an acclimation period is important.

MADs have demonstrated promising outcomes when compared to upper airway surgery. Wilhelmsson et al^{5,6} compared treatment with a MAD to uvulopalatopharyngoplasty at one and four years follow-up. In both cases, the rate of success for the MAD group was higher than that of the surgical group, though not to a statistically significant degree when compliance with the MAD was taken into account.⁷ Millman et al⁸ studied the Herbst appliance, a type of custom-made device, as salvage therapy following failed surgery in 24 patients with OSAHS. Of the 18 patients who adhered to treatment with the appliance in this study, 56 percent were successfully treated, showing a 50 percent drop in AHI to a value < 10.

The overall rate of OR in our study compares favorably with other published reports that have focused mainly on custom devices.^{1,2} Notably, our patients with severe OSAHS achieved a higher rate of OR than patients in other studies. One possible explanation for this is the high percentage of patients in our study with a history of upper airway surgery. Theoretically, surgical correction of sites of obstruction besides those addressed by the MAD should have had a synergistic effect. Nevertheless, patients in our study with prior surgery did not fare better than those naïve to surgery. In addition, although the rate of OR was not higher for the titratable SomnoGuard AP, patients with this device experienced significantly greater improvements in AHI and minimum SpO₂ than users of the other devices. Furthermore, because adjusting the SomnoGuard AP setting required awakening patients and thereby disrupting their sleep, the true rate of OR for this device and degree of improvement in PSG parameters may have been even higher.

At 38.6 percent, our rate of success, as defined by OR plus adherence at two months, is somewhat lower than expected. Loss to follow-up and failure of a number of patients to obtain a repeat PSG test are factors that may have adversely affected the overall success of treatment. It should also be noted that several patients who were satisfied with the device in terms of symptomatic relief but did not achieve complete normalization of respiratory parameters on PSG were counted as failures.

One main limitation of this study was the short follow-up period. As more serious and intransigent adverse effects such as occlusal change may not become apparent until after extended periods of use, we may have failed to detect problems that could arise later in the course of treatment. In addition, several studies have suggested that adherence to treatment with MADs diminishes over time.⁶ Our ability to accurately assess adherence and, in turn, success of treatment was thus hindered. Further research is necessary to determine efficacy, long-term adherence, and adverse effects.

Conclusions

Thermoplastic MADs are a relatively inexpensive treatment option for patients with OSAHS who refuse or fail CPAP and surgical therapy. These devices can be easily fitted in the otolaryngology clinic. Short-term success was only 38.6 percent, and long-term compliance, efficacy, and safety are unknown at this time.

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Author Contributions

Michael Friedman, study design and conception, literature review, data analysis and interpretation, manuscript preparation; **Tanya Pulver**, data collection, analysis, and interpretation; manuscript preparation; **Meghan N. Wilson**, study design, data collection, manuscript preparation; **Dina Golbin**, data collection; **Christopher Leesman**, data collection; **George Lee**, data collection; **Ninos J. Joseph**, statistical analysis.

Disclosures

Competing interests: **Michael Friedman**, recipient of a grant for a study on nasal irrigation as treatment for sinonasal symptoms: TriCord Pharmaceuticals; member of the speakers' bureau: Glaxo-Smith-Kline.

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