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ORIGINAL RESEARCH

Does an oral appliance reduce palatal flutter and tongue base snoring?

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OBJECTIVES: Oral appliances are designed to treat snoring and sleep apnea by advancing the mandible and tongue. We test the hypothesis that an oral appliance affects palatal snoring as well as tongue base obstruction.

METHODS: Prospective observational cohort study. Sixty patients with a chief complaint of snoring with or without apnea were enrolled. Each patient underwent a home sleep test followed by 3 weeks sleeping with an oral appliance. Each patient then underwent a repeat home sleep test while using the device.

RESULTS: There was a statistically significant improvement in the snores per hour ($P = 0.0005$), the maximum snoring loudness ($P = 0.0001$), average snoring loudness ($P = 0.00001$), and the percentage of palatal snoring ($P = 0.0007$). There was also a significant decrease in oxygen desaturation events ($P = 0.003$).

CONCLUSIONS: This study suggests oral appliances may be effective treatment for both palatal and tongue base snoring.

Snoring and obstructive sleep apnea (OSA) are part of a continuum of sleep-related breathing disorders treated with a wide variety of modalities. The gold standard of therapy has been continuous positive airway pressure (CPAP), which has been shown to be effective for both snoring and OSA.[1,2] Many quality studies have also demonstrated the efficacy of oral appliances for both snoring and obstructive sleep apnea while indicating that CPAP is somewhat more effective than oral appliances.[3-9] Studies investigating compliance for both oral appliances and CPAP have generally found compliance to be in the range of 50% to 75%.[10-12] Neither method is a perfect treatment for all patients with OSA. Each modality is able to provide very effective and well-tolerated treatment options to patients with sleep-disordered breathing symptoms.

Most studies indicate that snoring is treated more effectively by oral appliances than is OSA.[12] However, no study to date has investigated the relative effect of an oral appliance on snoring originating from the tongue base vs snoring originating from the soft palate. Additionally, the exact mechanism of action of oral appliances is not fully understood. The mechanism of action of oral appliances is presumed to be expansion of the airway by advancing the tongue base via its attachment to the mandible. If this hypothesized mechanism of action is the true mechanism of action, then oral appliances should be much more effective for tongue base snoring than for palatal snoring. Several studies have demonstrated that oral appliances may exert influence on areas of the upper airway other than the tongue base. Kyung et al studied cross-sectional pharyngeal dimensions using CT scan in patients with OSA treated with oral appliances. They found, as expected, that the pharyngeal dimensions decreased most at the retroglossal and retropalatal levels during apneic events. They also found that the oral appliance used resulted in a larger increase in the lateral dimension of the pharynx at both levels than in the anteroposterior dimension.[13] Ryan et al actually found a larger increase in the velopharyngeal cross-sectional area than in that of the hypopharynx during oral appliance use.[14] This study indicates that oral appliances may exert influence at the palatal as well as at the tongue base level via a more complex anatomic in-

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teraction than simple advancement of the tongue base, as might be presumed.

These studies demonstrate an increase in the anatomic dimensions of the airway at both velopharyngeal and hypopharyngeal levels; however, the functional effect of these anatomic changes at different levels is not known. The primary purpose of this investigation is to determine if use of an oral appliance is effective at reducing snoring caused at both the velopharyngeal and hypopharyngeal levels.

METHODS

This study is a prospective clinical trial and received approval from our Institutional Review Board prior to beginning. Patients with a complaint of primary snoring and/or sleep apnea were recruited from the otolaryngology and multidisciplinary sleep disorders clinics of a tertiary referral medical center. A pre-enrollment polysomnogram was not a requirement. Patients with simple habitual snoring as well as those with sleep apnea were enrolled. After informed consent was obtained the patients underwent a complete head and neck physical exam. Each patient then underwent a baseline home sleep study. The home sleep study device used was the SNAP test (SNAP Laboratories, Wheeling, IL). This device consists of a small case enclosing a removable disk drive that measures and continuously records oximetry. It also records the sounds from a microphone attached to a strap worn on the upper lip. The acoustic recording provides information on snoring sounds as well as airflow. The data on the disk is then analyzed via proprietary software and reviewed by a sleep physician at SNAP Laboratories to provide data on apneas, hypopneas, snoring loudness, frequency, and type (palatal vs lingual), as well as standard oximetry. The SNAP test has been shown to have good correlation with standard attended polysomnography[15] and was chosen for the study because of its ability to provide information on the anatomical site from which the snoring is coming. SNAP uses a proprietary algorithm to analyze acoustical data for the prediction of the anatomic level of snoring; therefore, the details of sensitivity and specificity of such predictions are not available. Clinically, Brietzke and Mair found a strong correlation between people with predominantly palatal snoring on SNAP and improvement in snoring after palatal stiffening procedures.[16,17] After the initial home sleep study each patient received a dental examination performed by one prosthodontist. The examination assessed the following exclusion criteria: 1) insufficient number of teeth to support the device; 2) carious teeth; 3) periodontal disease inducing tooth mobility; 4) active temporomandibular joint (TMJ) disorder; 5) limited maximum protrusive distance (<6 mm). Maxillary and mandibular impressions were made and poured in a Type V dental stone. The casts were duplicated to fabricate a two-piece oral device called the Thornton Adjustable Positioner II (TAP II) (see Fig 1A and B). This device consists of custom maxillary and mandibular components that seat snugly over the teeth. The maxillary component has a stainless steel ball-headed hook that bisects the edge of the central incisors. The ball of this hook mates with a socket in the mandibular component, thus providing an assembly to protrude the mandible. The degree of advancement was progressively adjusted by the patient until symptoms were reduced or alleviated. One 180-degree turn of the key ad-

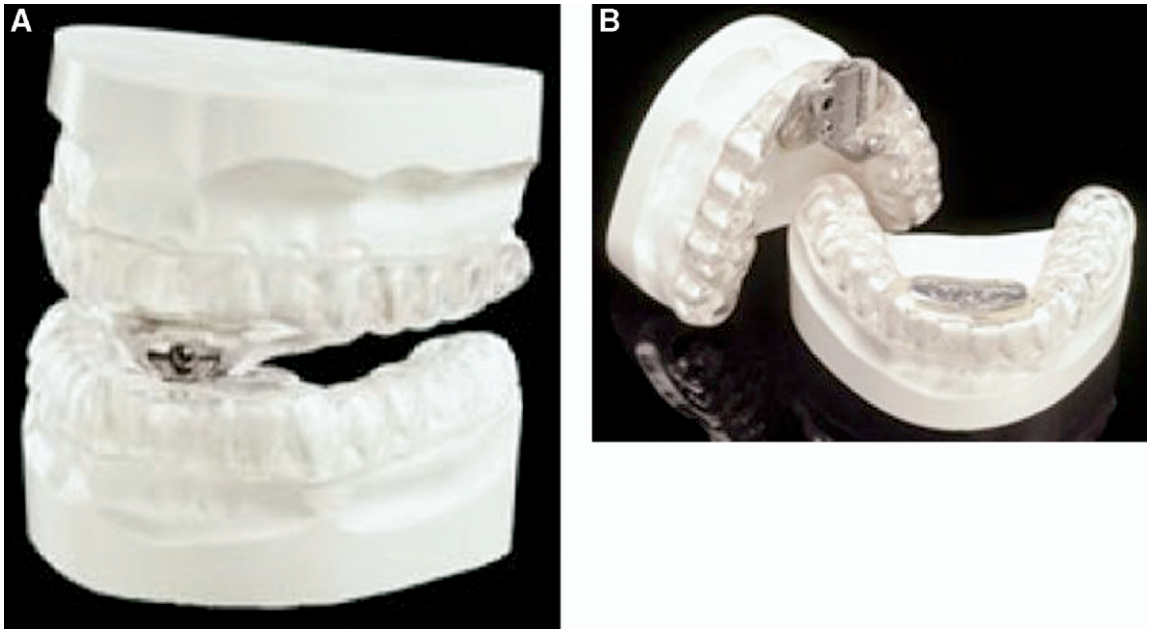

Figure 1 **(A)** Image shows the device with the maxilla separate from the mandible and demonstrates the hook on the maxillary component which attaches to the mandible and provides adjustable mandibular advancement. **(B)** Image shows the device in situ as it would be worn.

vanced the mandible one-quarter millimeter. The gradual advancement of the mandible allows the patient to become comfortable with the device. Most patients will advance the mandible approximately 6 millimeters from their individualized starting position to notice a change of the airway. Each patient used the oral appliance for 3 weeks after receiving it. During these 3 weeks the degree of advancement was adjusted by the patient to subjective symptom resolution. The endpoint of this titration was based only on the subjective symptom (snoring, daytime somnolence, witnessed apneas) assessment of the patient and/or his or her bed partner. The actual degree of advancement at which each patient stopped titration was not recorded for analysis. Two to 8 weeks after completion of the 3-week titration period, each patient underwent a repeat home sleep test and filled out a questionnaire to provide information on compliance, side effects such as jaw or tooth pain, and overall happiness with the device.

Forty patients completed the entire study. Sixty-seven patients were initially recruited. Fifty-eight received a TAP II device. The 9 patients who did not receive a device either moved from the region due to military orders, had dental problems that precluded device use, or removed themselves from the study. Eighteen patients who received a TAP II did not complete the study. Reasons for removal among these 18 patients included exacerbations of TMJ in 2 patients and military transfer or deployment in 3 patients; the final 13 patients were lost to follow-up or did not desire to continue in the study mainly due to an extended length of time from enrolling in the study to its completion. Characteristics of these 40 patients included mean age of 44.8 years. There were 15 female and 25 male patients.

All patients who enrolled in the study and were not pleased with the oral appliance were offered other standard surgical and/or nonsurgical treatments in our multidisciplinary sleep clinic as warranted.

Objective outcome measures included improvement in snoring (snores per hour, average and peak loudness of snores, and anatomic site of snoring as indicated by SNAP testing) and sleep apnea (apnea index, hypopnea index, respiratory disturbance index). Particularly the data was analyzed to determine the size of effect of the oral appliance on palatal vs lingual types of snoring. Subjective findings including patient satisfaction with TAP II device, comfort, and results with regard to both snoring and sleep apnea were also measured via a questionnaire.

RESULTS

Statistically significant improvements were observed in several snoring parameters as measured by SNAP home sleep test. The number of snoring events per hour (snore index) decreased from 363.7 to 216.2 ($P = 0.0005$). The loudness of snoring was also decreased. Maximal loudness of snoring sounds (measured as the number of decibels above ambient background and quiet breathing noises) decreased from 18.0 db to 13.3 db ($P = 0.0001$). The average loudness of snoring sounds decreased from 9.7 db to 5.4 db ($P = 0.00001$). A decrease of 6 db represents a 50% decrease in the acoustic pressure and approximately a 50% decrease in the perceived loudness of a sound. There was also a reduction in the percentage of snoring sounds classified as palatal flutter sounds by SNAP from 78.6% to 58.1% ($P = 0.0016$). The percentage of snoring sounds analyzed by SNAP as originating from the tongue base showed a trend toward increasing (10.95% pre to 16.55% post) without reaching statistical significance. This trend toward an increased percentage of tongue base snoring does not indicate an increase in the absolute amount of tongue base snoring, rather a shift in the relative proportion due to a greater decrease in palatal snoring. The average total number of snores per hour attributed to the tongue base by SNAP decreased from 39.75 per hour to 35.75 per hour. Improvement was also observed in some but not all sleep apnea parameters. The total hypopneas and the hypopnea index both decreased. Total hypopneas went from 45.7 to 32.1 ($P = 0.0021$) and the hypopnea index decreased from 10.2 to 7.6 ($P = 0.0217$). The number of pulse-oximetry desaturation events decreased from 41.9 to 24.1 ($P = 0.0421$). The respiratory disturbance index (RDI) did not have a statistically significant decrease but did trend toward improvement. The RDI decreased from 14.4 to

Table 1
Results of SNAP analysis

Parameter	Pretreatment	Posttreatment	*P* value
Snores per hour	363.7	216.2	0.0005
Max snoring loudness	18.0 db	13.3 db	0.0001
Average snoring loudness	9.7 db	5.4 db	0.00001
Palatal snoring %	78.6	58.1	0.0016
Tongue snoring %	10.95	16.55	NS
Tongue snoring number	39.75 snores/hr	35.75 snores/hr	NS
Total hypopneas	45.7	32.1	0.0021
Hypopnea index	10.2 hyp/hr	7.6 hyp/hr	0.0217
Desaturation events	41.9	24.1	0.0421
Resp dist index	14.4 events/hr	10.4 events/hr	0.0618
Apnea index	3.07 apnea/hr	3.21 apnea/hr	NS

Table 2
Results of subjective questionnaire

Statement	Mean score: 0 = strongly disagree, 5 = strongly agree
Appliance was used each night during study	4.40
Appliance was used the entire night during the study nights	4.73
There was jaw pain in the morning when the device was removed	1.57
There was tooth pain in the morning when device was removed	1.18
Snoring significantly improved (patient rating)	3.16
Snoring significantly improved (partner's impression)	3.71
OSA symptoms improved	3.11
Used device continuously since study ended	2.40

10.4 ($P = 0.0618$). The apnea index did not improve (pre = 3.07, post = 3.21, $P = 0.1992$). See Table 1 for a summary of the SNAP data. The SNAP test does not provide any data on arousals or other sleep architecture information.

The patients also responded to a series of questions regarding their level of compliance in use of the device, the prevalence and severity of side effects, and overall happiness with the device. All questions were answered with a 0 to 5 scale (strongly disagree to strongly agree). The data is shown in Table 2. Epworth sleepiness scales were also completed pre- and post-treatment by patients. There was not a statistically significant difference between the pretreatment (8.96) and posttreatment (7.65) Epworth sleepiness score. At the time of the poststudy questionnaire (2-8 weeks after the titration period), 55% of patients indicated they continued to use the TAP II at least half of the time.

DISCUSSION

The results of this study demonstrate that an oral appliance designed to advance the mandible and improve snoring and sleep apnea symptoms does exert an effect on palatal snoring as determined by the SNAP home sleep test. This result has not been previously documented and may not be intuitively obvious based on the presumed mechanism of action of oral appliances (ie, advancement of the mandible and thus the tongue base). This result may be expected based on the outcomes of several studies which demonstrated an increase in airway dimensions at the level of the velum as well as at the tongue base level.[13,14] This outcome adds credence to the possibility that oral appliances (TAP II in this study) can have an effect on obstructive events at all levels of the pharyngeal airway. This further emphasizes the fact that more investigation into the mechanisms of oral appliances, and indeed investigation into the dynamic relationships within the pharyngeal airway in OSA and snoring patients, is needed.

The improvements in snoring and the decreases in the percentage of snoring coming from palatal flutter were significant; however, most OSA indices failed to improve significantly. This may be due to several factors such as the inclusion of patients without OSA in the study. Only 10 of the 40 patients who completed the study had an RDI of 20 or greater upon enrollment. This small total number of patients diagnosed with significant OSA resulted in a dramatic decrease in the power of this study to detect effects of this oral appliance on sleep apnea.

The poststudy questionnaire revealed that the device caused little actual pain in the jaw or teeth of most patients, and that patients and partners were moderately to quite satisfied with the device. In spite of these findings, the patients' use of the TAP II after the study was completed is less frequent than might be expected. Patients with snoring with or without mild OSA were aware that office-based procedures such as palatal radiofrequency ablation or palatal sclerosant injection were available as a treatment alternative. This knowledge may have influenced some to abandon the TAP II in the hope for a treatment that would not require the continuous use of any device or machine.

This study has several shortcomings. Although it is a prospective clinical trial it is neither controlled nor randomized. There was a significant dropout rate and this may result in a form of selection bias. Finally the outcome measures did not include validated measures of quality of life or other OSA-related surveys.

CONCLUSION

This study demonstrates that the TAP II oral appliance is effective at reducing snoring originating from the palatal and glossal levels. The study lacked power to determine if these effects extended to the improvement of OSA; however, further study with a larger patient population may demonstrate such effects, as have previous studies of oral appliances for OSA.[3-9] Overall, the TAP II oral appliance is an effective treatment of snoring from all airway levels for those patients who tolerate it well.

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