Original Article

Long-term therapeutic efficacy of oral appliances in treatment of obstructive sleep apnea-hypopnea syndrome

Xu Gong[a]; Jingjing Zhang[b]; Ying Zhao[c]; Xuemei Gao[d]

ABSTRACT

Objective: To investigate the long-term efficacy and safety of oral appliances (OAs) in treating obstructive sleep apnea-hypopnea syndrome (OSAHS) by length of treatment.

Materials and Methods: This is a retrospective study to review the usage of OAs in Chinese OSAHS patients in recent decades. Ninety-four valid questionnaires were returned by 412 patients with OSAHS receiving OA treatment. Among the wearers, 22 agreed to follow-up polysomnography, and 25 agreed to follow-up cephalograms. Tolerance and side effects of OAs were assessed by a survey. Comparisons of efficacy were carried out between the initial and follow-up polysomnography measurements. Cephalometric analysis was used to investigate skeletal and occlusal changes to determine safety of the OAs.

Results: The longest treatment extended to 147 months, with a median of 74 months (first and third quartiles, 30 and 99 months, respectively). Among the participants, 14.9% had been treated for more than 120 months. Side effects were temporary and relatively minimal and included tooth soreness (37.2%), dry mouth (33.0%), odd bite feeling (31.9%), and excess salivation (30.8%). Polysomnography proved that OAs remained effective for the treatment of OSAHS in the long term; initial Apnea-Hypopnea Index values were reduced from a median of 24.50 (quartiles, 14.65, 54.05) without the OA to 7.40 with the OA (2.12, 10.00), and follow-up median values were 25.55 without the OA (11.71, 43.65) and 4.25 with the OA (1.38, 7.70). Cephalometric analysis indicated mild and slow changes in the skeleton and occlusion after average treatment duration of 5 years.

Conclusion: OAs provided effective and safe long-term therapy for patients with OSAHS. Follow-up supervision is recommended since long-term alterations take place, although these appear to be minimal. (*Angle Orthod.* 2013;83:653–658.)

KEY WORDS: Obstructive sleep apnea-hypopnea syndrome; Oral appliance; Efficacy

INTRODUCTION

Obstructive sleep apnea-hypopnea syndrome (OSAHS) is characterized by recurrent upper airway obstruction during sleep. Many studies have indicated a short-term benefit of using oral appliances (OAs) for OSAHS.[1–4] Research has confirmed the therapeutic effect of OAs by a comparison of nocturnal polysomnography before and after wearing OAs for 1–6 months, 1–4 months, or even as long as 9 months.[5]

Currently, for treatment of OSAHS, OAs usually serve as a lifelong therapeutic choice. However, it is unknown whether OAs remain effective, stable, and safe over time, especially when compared with short-term observations. Long-term observations by several studies[6–10] concluded that obvious effects can be generated by OAs in OSAHS.

The current study aimed to investigate the efficacy and safety of OA use in various patients over time by questionnaire survey, assessment of nocturnal polysomnography, and cephalometric analysis.

MATERIALS AND METHODS

Selection of Patients

All included patients began treatment no later than December 2007 to ensure that all had been treated

[a] Resident, Department of Orthodontics, Peking University School and Hospital of Stomatology, Beijing, China.

[b] MS student, Department of Orthodontics, Peking University School and Hospital of Stomatology, Beijing, China.

[c] Professor, Department of Stomatology, Capital Medical University, Xuanwu Hospital, Beijing, China.

[d] Professor, Department of Orthodontics, Peking University School and Hospital of Stomatology, Beijing, China.

Corresponding author: Dr Xuemei Gao, Professor, Department of Orthodontics, Peking University School and Hospital of Stomatology, 22 South Ave, ZhongGuanCun, HaiDian District, Beijing, 100081, People's Republic of China.

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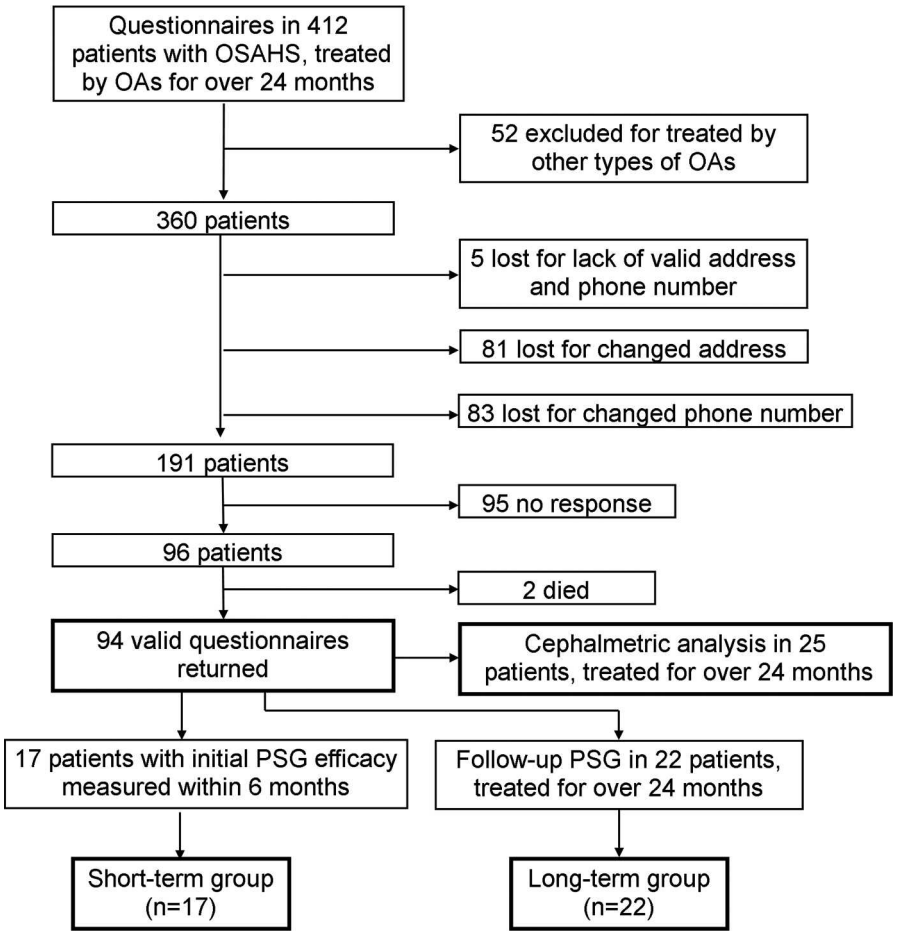

Figure 1. Tree view of the study.

with OAs for at least 2 years. Records of all patients who started treatment before December 2007 were obtained. A total of 412 patients were involved; all were diagnosed with OSAHS by nocturnal polysomnography and used OAs for therapy. Follow-up by questionnaires was done by way of mail or phone calls, with contact information obtained from medical records. We lost contact with many of them due to changes in address or phone number (Figure 1). Therefore, 94 valid questionnaires were returned. Among the patients who wore OAs every night during sleep, 22 agreed to follow-up polysomnography, and 25 agreed to follow-up radiography.

The Institutional Review Board of Peking University School and Hospital of Stomatology approved the study protocol, and all patients provided written informed consent to participate.

Questionnaires

Questionnaires were designed to examine subjective effects and side effects of OAs. They also inquired about frequency and duration of OA usage.

Polysomnography

Each patient had undergone overnight polysomnography as a pretreatment baseline in qualified sleep laboratories in various sleep centers. Follow-up polysomnography at the same sleep laboratory was recommended to determine initial (within 6 months) and long-term efficacy. Twenty-two patients eventually agreed to follow-up polysomnography and made up the long-term group. Seventeen patients with complete baseline and follow-up polysomnography data within 6 months composed the short-term group. The longest treatment in the long-term group patients extended to 108 months, while the shortest treatment was 24 months; the median length of treatment was 35.5 months (first and third quartiles, 29.0 and 61.5 months, respectively).

Sleep and its stages were documented by standard electroencephalography, electrooculography, and electromyography. Electroencephalographic activity was recorded with electrodes applied at C3–A2 and C4–A1 (according to the international 10–12 system) and electromyographic activity was recorded from the submental muscles. Oronasal airflow was recorded by a nasal cannula pressure sensor (Respironics,

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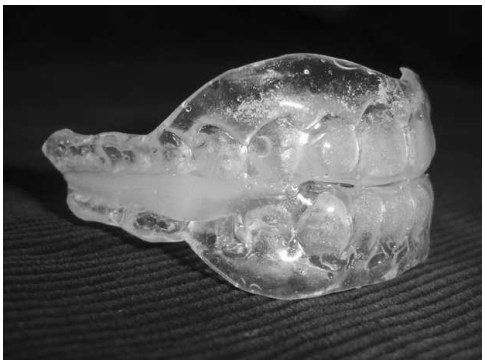

Figure 2. OA used for treatment.

Pittsburgh, PA). A single electrocardiographic lead (modified V2) was attached to monitor for cardiac arrhythmias. Oxygen saturation (SaO_2) was monitored continuously with a pulse oximeter attached to the index finger. Chest wall movement was monitored by a respiratory inductive plethysmograph. The data were recorded on a polygraph (Polywin, Respironics, Pittsburgh, PA, USA).

Obstructive apneas were defined as the cessation of airflow for at least 10 seconds accompanied by ongoing respiratory effort. Central apneas were defined as the cessation of airflow and respiratory effort for at least 10 seconds, and mixed apneas were defined as a combination of obstructive and central apneas lasting at least 10 seconds. Hypopneas were defined as a decrease of more than 50% in oronasal airflow for at least 10 seconds associated with a decrease of more than 4% in oxyhemoglobin saturation from the baseline level and/or arousal. The severity of OSAHS was defined as the number of apneas or hypopneas per hour of sleep (ie, the Apnea-Hypopnea Index [AHI]).

Cephalometric Analysis

Lateral cephalograms were obtained routinely before treatment. Twenty-five of the 94 patients who returned a questionnaire were willing to undergo follow-up cephalograms. Treatment ranged from 24 to 130 months, with a median value of 33 months (first and third quartiles, 28 and 101 months).

The cephalometry equipment was made in Japan (Unipano CP 80, Kyoto, Japan). The film was taken at the end of respiration when the patient sat upright with Frankfort plane parallel to the ground, naturally closed lips, and the bite in intercuspal occlusion with relaxation of the tongue and perioral muscles. A variety of distances and angles was measured on the cephalograms.

Design of Appliances

The OA used in this study is a kind of mandibular repositioner (Figure 2). A bite registration with the mandible in an anteroinferior position was obtained using a wax wafer. The OAs covered all tooth surfaces in both the maxilla and the mandible. The OA positioned the mandible at 60%–70% of the maximal advancement position and resulted in a 4- to 5-mm incisor separation. Patients were instructed to wear the appliance during sleep, 6–8 hours per day, for 5–7 days per week.

Data Analysis

The software package SPSS 11.0 (SPSS, Inc, Chicago, Ill) was used for statistical analysis. If primary analysis of the raw data indicated a mean value that was greater than twice the standard deviation (SD), the data distribution was considered at least similar to, if not completely in agreement with, normal distribution, and data were expressed in the form of means $\pm$ SDs. If not, data were expressed in the form of median (quartiles).

When the distribution of samples was consistent with normal distribution, paired-sample *t*-tests were used to compare the differences before and after treatment; when it was not, the Wilcoxon test was used to compare the variances in sleep breathing disorder parameters before and after treatment. The significance level was set at .05.

RESULTS

Analysis of Questionnaire

The longest treatment in the 94 participating patients extended to 147 months, with a median value of 74 months (first and third quartiles of 30 and 99 months, respectively). Fourteen patients (14.9%) had been under treatment for more than 120 months.

With respect to use of the OAs, 60 patients (63.8%) wore OAs every night during sleep, 11 (11.7%) used them a couple of times per week, 18 (19.1%) used the OA occasionally, and two (2.1%) never used the OA. One patient used a continuous positive airway pressure (CPAP) machine before 4 AM and wore the appliance after this, and the remaining two patients could not be traced. Fifty-eight patients (61.7%) used an OA as the only treatment for their OSAHS.

Seventy-five of the 94 patients complained of morning symptoms before treatment, but the treatment with OAs effectively relieved the symptoms. Four patients (5.1%) reported complete disappearance of their symptoms, while 41 (52.6%) reported significant improvement. Seventy-six patients complained of sleepiness during the daytime before treatment. After wearing OAs, six patients (7.7%) reported a complete disappearance of sleepiness, while 32 (41.0%) reported significant improvement in this regard.

Meanwhile, 78 patients complained of a few side effects of OA treatment, including excess salivation,

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Table 1. Side Effects in OSAHS Patients Treated with OAs

Side Effect	Number of Cases (%)	Disappeared in Short Term (%)	Disappeared Later (%)	Did Not Disappear (%)
Excess salivation	29 (30.9)	16 (55.2)	10 (34.5)	3 (10.3)
Dry mouth	31 (33.0)	14 (45.2)	11 (35.5)	6 (19.4)
Single sore teeth	35 (37.2)	25 (71.4)	9 (25.7)	1 (2.9)
Dental discomfort	9 (9.6)	3 (33.3)	2 (22.2)	4 (44.4)
Buccal sourness	27 (28.7)	18 (66.7)	5 (18.5)	4 (14.8)
Odd bite feeling	30 (31.9)	24 (80.0)	2 (6.7)	4 (13.3)
No side effects	16 (17.0)	—	—	—

dry mouth, single sore teeth, buccal sourness, and an odd bite feeling in the morning. Most of these resolved within a short time (Table 1).

Analysis of Nocturnal Polysomnography

With respect to the nocturnal polysomnography, no significant difference in age at presentation and AHI was observed between the short-term and the long-term groups. AHI was significantly reduced after treatment in both groups. Details of the respiratory variables before and after treatment are shown in Table 2.

Cephalometric Findings

Cephalometric analysis indicated a mild tendency toward increased mandibular plane angle, along with upper incisor retraction and labial inclination of the lower incisors (Table 3). Together, these might produce overbite and decrease overjet (Table 3).

DISCUSSION

Analysis of Sample Features

The response rate in this study was only 23%. We lost contact with many patients because of retirements (when patients had provided their work address) and moving. Most patients who responded to the questionnaire in this study complied well with treatment. Therefore, the result of the study reflects the situation only of patients with good compliance and tolerance, rather than the overall situation of OA treatment. Such selection bias may have led to a higher usage rate compared to actual usage rates with more typical OSAHS treatment. Recalling patients is difficult for all researchers. Jauhar et al[11] attempted follow-up of 180 patients who had been provided with mandibular advancement devices 10 years prior. All were sent questionnaires, and the response rate was 40%.

A limitation of the analyses of nocturnal polysomnography and cephalograms was the small sample size in each group. Follow-up polysomnography was done in qualified sleep laboratories with no direct connection with us, contributing to relative objectivity but restricting sample size. A small sample size usually leads to selection bias. Those with a good treatment outcome are more likely to cooperate with researchers, even to the point of being willing to tolerate radiography and whole-night polysomnography.

Tolerance of OAs

Long-term usage of OAs in the present study suggested good tolerance of OA therapy. The side effects of OAs, which included excess salivation, dry mouth, single sore teeth, buccal sourness, and an odd bite feeling in the morning,[12] were mostly mild and temporary and rarely led to termination of treatment.[12–15] Long-term tolerance of OAs has been shown by many

Table 2. Sleep Apnea Index in Short-Term and Long-Term Groups With and Without OAs (Wilcoxon Test)

	Initial	With OA	*P*
Short-term group (n = 17)[a]			
AHI (events/h)	24.50 (14.65, 54.05)[b]	7.40 (2.12, 10.00)[b]	< .001*
Longest apnea time(s)	57.00 (37.70, 61.50)[b]	25.00 (15.90, 33.50)[b]	< .001*
Average apnea time(s)	21.40 (17.90, 23.92)[b]	16.70 (9.75, 17.50)[b]	.008*
Lowest SaO_2 (%)	74.18 ± 7.96	84.06 ± 7.67	.001*
Long-term group (n = 22)[a]			
AHI (events/h)	25.55 (11.71, 43.65)[b]	4.25 (1.38, 7.70)[b]	< .001*
Longest apnea time(s)	43.75 (33.43, 59.25)[b]	18.75 (0.00, 35.80)[b]	.001*
Average apnea time(s)	18.60 (14.25, 22.83)[b]	12.70 (0.00, 20.33)[b]	.006*
Lowest SaO_2 (%)	76.05 ± 10.31	83.23 ± 5.17	.007*

[a] Short-term group: less than 6 months; long-term group: 24–108 months.
[b] For data with nonnormal distribution, the data are expressed in the form of median values (with quartiles).
* $P < .05$.

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Table 3. Cephalometric Analysis[a] of OSAHS Patients Treated by OAs (Paired Sample *t*-Tests, n = 25)

	Before Treatment	After Treatment	Change	*P*
N-S (mm)	65.08 ± 3.99	65.18 ± 4.34	0.10 ± 0.72	.495
ANS-PNS (mm)	46.76 ± 3.12	46.80 ± 2.89	0.04 ± 0.99	.841
Gn-Go (mm)	73.82 ± 4.12	74.32 ± 3.69	0.50 ± 1.49	.107
Ar-Go (mm)	48.46 ± 6.51	48.86 ± 5.10	0.40 ± 2.95	.505
MP-FH (°)	25.42 ± 7.45	26.78 ± 7.37	1.36 ± 1.41	< .001*
MP-SN (°)	33.92 ± 7.42	35.24 ± 7.17	1.32 ± 1.35	< .001*
SNA (°)	82.52 ± 4.00	81.96 ± 4.07	−0.56 ± 1.36	.051
SNB (°)	76.28 ± 4.26	75.76 ± 3.87	−0.52 ± 1.20	.041*
ANB (°)	6.36 ± 1.75	6.20 ± 2.03	−0.16 ± 1.34	.555
U1-SN (°)	100.26 ± 7.49	96.92 ± 7.82	−3.34 ± 3.36	< .001*
L1-MP (°)	100.76 ± 8.06	102.54 ± 8.84	1.78 ± 3.06	.008*
U1-L1 (°)	124.86 ± 10.62	125.80 ± 10.38	0.94 ± 3.87	.236
OJ (mm)	4.38 ± 1.58	3.26 ± 1.85	−1.12 ± 0.99	< .001*
OB (mm)	4.04 ± 1.74	2.58 ± 2.34	−1.46 ± 1.12	< .001*

* $P < .05$.

[a] N-S indicates anterior cranial base (nasion-sella); ANS-PNS, palatal plane; Gn-Go, length of mandibular body (gnathion-gonion); Ar-Go, length of mandibular ramus (articulare-gonion); MP-FH, mandibular plane angle, the angle between the FH plane and MP plane; MP-SN, mandibular plane angle, the angle between the SN plane and MP plane; SNA, angle between sella and point A at nasion; L1-MP, lower incisor edge to mandibular plane; U1-L1, interincisor angle; OJ, overjet; and OB, overbite.

researchers.[13,16–18] Such long-term tolerance may result from quitting time concentrating in the first 3 months of treatment. Patients with little tolerance usually gave up early, that is, those who did not kept using the OA for a long time.[14,18]

Tolerance of OAs is better than tolerance of CPAP devices in the long term. In the research done by Gagnadoux et al.,[3] a two-way cross-classification experiment of OAs and CPAP devices indicated that OAs processed significant advantages in comfort, and most patients chose OAs if both methods were equally effective.

Long-Term Efficacy of OAs

The current study found no significant differences between short-term and long-term groups. It agreed with the research done by Marklund et al[7]; among the 19 patients followed up in that study, the data after 5 years showed no difference versus the short-term examinations. Other studies have revealed similar long-term efficacy of OAs.[8–10]

However, Rose et al. found that effects generated by OAs in OSAHS became somewhat impaired over time.[6] The mean AHI fell from 17.8 events per hour to 4.2 during a short-term observation. However, mean AHI increased to 8.2 events per hour after 6–12 months and 8.3 events per hour after 18–24 months. Marklund et al.[7] also observed that patients who had their devices replaced or adjusted experienced a better long-term effect than patients who were still using their original OA.

Safety of OAs

Mild variations in skeletal and occlusal measurements occurred after years of usage of OAs. Those changes were so mild that patients in this study hardly noticed any change. Variances were obviously bearable for every patient, especially compared with the efficacy of the OAs. However, all patients did not experience the same change; some patients even showed changes in the opposite direction. For example, one patient experienced a statistically insignificant increase in overbite.

After tracing normal adults for 20 years, Forsberg et al.[19] found that face height increased by 1.6 mm, mainly in the lower face, and average backward mandibular rotation was 0.3°, but no changes in overbite and overjet were apparent. Recent research indicated that skeletal and occlusal variances in patients with OSAHS exceeded that exhibited during normal physiological aging after long-term usage of OAs, and trends were sometimes even reversed. Such variances usually included decreased overbite and overjet, lingual inclination of the upper incisors, labial inclination of the lower incisors, open bite of the posterior teeth, and increased lower face height.[8,10,12,13,16,20–23]

Skeletal and occlusal changes do not always lead to adverse effects. For example, bite opening and a decrease in overjet are good for deep overbite and overjet, but they worsen crossbite and open bite. It is good for patients with a small mandibular angle, but not those with a large mandibular angle, to experience backward rotation of the mandible. Therefore, it is advisable for clinicians to consider the effects of OAs comprehensively and treat patients on an individual basis. It appears to be better to design individual appliances and reinforce follow-up supervision.

CONCLUSIONS

- OAs provide an effective and safe long-term therapy for patients with OSAHS.

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- Although mild and slow changes in the skeleton and occlusion may take place, it is still safe for patients to use OAs.

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