

Side effects of boil and bite type oral appliance therapy in sleep apnea patients

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Abstract

Introduction Based on a mail-out questionnaire, this study analyzed compliance and side effects of one commonly used (TheraSnore) boil and bite oral appliance (OA) in patients with obstructive sleep apnea.

Methods The questionnaire was sent to 84 patients 6 months after the delivery of the OA.

Results Fifty-eight percent ($n=47$) of the patients returned the questionnaire. There was no significant difference in baseline data [age, body mass index (BMI), apnea–hypopnea index or the Epworth Sleepiness Scale (ESS)] between the returned and nonreturned questionnaires. Of the responding patients, 74.5% ($n=35$) continued to use the appliance. Nonusers had a higher BMI and higher baseline ESS when compared with users. The majority (74.3%) of the users and 50.0% of the nonusers previously used a nasal continuous positive airway pressure machine. Some 82.9% of the users wore their OA more than 3 days a week. Of the nonusers, 77.8% stopped using the OA in the first 3 months, and the most frequent reason given was “uncomfortable.” Many users complained about a dry mouth and/or excessive salivation and nonusers significantly complained more about ill-fitting appliances. Over 80% of the users experienced improvement in their snoring, daytime sleepiness, and apnea. More than 60% of the users were satisfied with OA therapy.

Conclusion While this study demonstrated similar self-reported compliance as previous reports, there were different side effects from those reported for custom-made appliances. Difficulty in optimal fit is considered to be the main cause of the subsequent stopping of the use of the boil and bite appliance.

Keywords Sleep apnea · Side effect · Oral appliance · Questionnaire

Introduction

Obstructive sleep apnea (OSA) is a common sleep disorder affecting 4% of men and 2% of women in the middle-aged work force [1]. OSA is caused in part by repetitive dynamic obstruction of the oropharyngeal airway and is associated with a wide variety of adverse health outcomes. Nasal continuous positive airway pressure (nCPAP) is often the first choice for OSA therapy and shows high effectiveness, but resistance and intolerance is often reported with nCPAP use. A previous study suggested that when adherence is defined as greater than 4 h of nightly use, 46% to 83% of patients with obstructive sleep apnea are nonadherent to treatment [2]. Rosenthal et al. described that only 17% of mild OSA patients were selected for nCPAP, and 39% of these withdrew treatment after only 1 week [3]. Oral appliance (OA) use is one successful alternative treatment available for OSA. The American Academy of Sleep Medicine (AASM) reported that, although not as efficacious as nCPAP, OAs are indicated for use in patients with mild to moderate OSA who prefer OA to nCPAP therapy, or who do not respond to nCPAP, are not appropriate candidates for nCPAP, or who fail treatment attempts with nCPAP or treatment with behavioral measures such as

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weight loss or sleep position change [4]. The compliance and side effects of OA treatment differ depending on the type of appliance, disease severity, and perhaps patient management. Compliance rates for OA use have been shown to range from 48% to 84% [5–10]. A greater percentage of noncompliant patients have been revealed in the first 3 months [9], with an 82% to 62% reduction in compliance over a period of 2 to 4 years [6]. The main reasons for discontinuing treatment have been reported to be insufficient reduction of snoring and the presence of side effects. While side effects caused by OAs are reported to be dry mouth, excessive salivation, tooth discomfort, occlusal change, muscle tenderness, and jaw stiffness, these are usually described as mild and transient [11]. Generally OAs can be classified into two categories: the custom-made type and the prefabricated type, or so-called boil and bite appliance. The long term side effects or compliance rate of boil and bite type OAs have not been adequately investigated. The purpose of this study was to utilize a mail-out survey to evaluate the reported compliance and side effects in snoring and OSA patients who had been treated with a boil and bite type OA for 6 months.

Methods

Eighty-four patients who had been treated with an OA for snoring or OSA at the Kyushu Dental College in Japan between April 2004 and March 2005 were included in this study. All patients were referred by a sleep physician for OA therapy with a snoring or OSA diagnosis based on polysomnography. All patients used the TheraSnore™ appliance for treatment. TheraSnore™ is a boil and bite appliance made in one standard size; the lower section is adjustable forward in 1.5-mm increments. It consists of two trays of semirigid thermoplastic material supported by a framework of harder, heat-resistant polycarbonate. It does allow some mandibular movements because the appliance is not fully retentive to the mandible with a ramp behind the mandibular anterior teeth which promotes protrusion of the patient's mandible. In our clinic, a dentist adjusted the OA on the cast first and did not allow the patient to change the jaw position by themselves. The questionnaires were mailed to each patient. In a cover letter, it was explained that the follow-up questionnaire was part of routine care in OSA patient treatment and that the patients could refuse to answer without any consequences to their continuing medical or dental care. The data was analyzed retrospectively, and the patient's confidentiality was strictly maintained. A postage-paid, self-addressed reply envelope was included, and there were no further attempts to reach the patient if they did not answer. A self-reported questionnaire was created with select questions from a

previous study [9]. From the patient's chart, objective information on sex, age, body mass index (BMI), baseline Epworth Sleepiness Scale (ESS), nCPAP experience, and baseline and post treatment apnea–hypopnea index (AHI) were collected. The disease severity was categorized following the standards proposed by the AASM and scored as mild OSA for $5 \leq \text{AHI} < 15$, moderate for $15 \leq \text{AHI} < 30$, and severe for an $\text{AHI} \geq 30$. Compliance with OA therapy was determined by the number of nights per week that the patient reported wearing the OA. If the patients stopped wearing their appliance, they were asked when and why they had stopped. The questionnaire provided options for stopping OA wear such as ill-fitting, occlusal changes, no/little effect, uncomfortable, reduced problem, hassle using, dental work, apnea worsened, underwent surgery, lost appliance, and other reasons. Patients were asked about alternative or simultaneous treatments such as nCPAP, surgery, and other therapies. Questions about the ten symptoms for the evaluation of possible side effects while undergoing OA therapy were scored by a graded scale as (1) rarely, (2) sometimes, (3) frequently, or (4) always. Side effects included discomfort in the jaw or facial muscles, discomfort in the jaw joint area, discomfort in the ear area, discomfort in the teeth, discomfort in the oral tissue, bite changes, jaw joint noises, ill-fitting or loose appliance, excessive salivation, and dry mouth. Questions regarding sleepiness (ESS) and amount of change in snoring, apneas, daytime sleepiness, and other symptoms were also included. The questionnaire asked how satisfied the patient was with their OA. Sex differences were evaluated according to age, BMI, baseline, and post treatment AHI, improved awareness of snoring, sleepiness, apnea, and side effects. The questionnaire was sent to patients 6 months after insertion of the OA. Before the statistical analysis, data for the reasons for stopping the OA were recategorized. After returning the questionnaire, effects such as “no reduction of the problem, hassle using, appliance worsened, underwent surgery or lost appliance” were not provided as a reason to stop wearing the OA. Three other patients answered that the OA did not stay in the mouth. So we excluded the options that were not reported and added the response “OA didn't stay in the mouth as ill-fitting”. The SPSS software program (version 13.0 for windows, SPSS Inc, Chicago, IL, USA) was used to analyze the data. The data were presented as percentage or as mean±SD. To compare the nonreturned with the returned groups and the user with the nonuser groups, a Mann–Whitney test and Pearson's chi-square test were used. To assess statistical significance before and after treatment, a paired Student's *t* test was used. Differences between user and nonuser groups were analyzed with Pearson's chi-square test, and a *P* value of <0.05 was considered significant.

Results

Forty-seven (58.8%) patients returned the questionnaire, and three (3.5%) patients had an invalid address, which are excluded from following analysis. There was no significant difference in the baseline data for age, sex, BMI, AHI, nCPAP experience, or ESS between the returned and nonreturned questionnaires. Some 35 (74.5%) responding patients used the OA at the time of questionnaire distribution. The demographic data of these groups are provided in Table 1. Nonusers had a higher BMI and baseline ESS when compared with users. Twenty-six (74.3%) of the users and six (50.0%) of the nonusers had used a nCPAP machine before OA therapy (Table 1). Four users (11.4%) used an OA together with nCPAP. Only seven nonusers (58.3%) started or restarted their nCPAP (Fig. 1). At the time of this survey, 15 users (42.9%) and two nonusers (16.7%) underwent polysomnography with the OA in place. In user group, the AHI with the OA in place was significantly reduced from 22.1 ± 11.1 to 14.1 ± 9.1 h^{-1} ($p < 0.05$), and in five patients, the post-treatment AHI was less than 10. One nonuser exhibited no change in AHI while the other exhibited an AHI improvement with a reduction in AHI from 34 to 11.2 (Fig. 2).

Twenty nine (82.9%) of the users, which consists of 20 (57.1%) of “every night” and nine (25.7%) of “more than 3 times a week,” wore their OA more than 3 days a week (Fig. 3). Of the nonusers, 77.8% stopped using the OA in the first 3 months, and the most common reason given was “uncomfortable.” Other reasons were “no/little effect” ($n=4$), “ill-fitting” ($n=3$), “doesn’t stay” ($n=3$), “occlusion problem” ($n=1$), and “dental work” ($n=1$), respectively. Many users complained about a dry mouth and/or excessive salivation, and nonusers significantly complained more about ill-fitting appliances (Fig. 4). Users revealed no significant ESS change pretreatment vs posttreatment.

Over 80% of the users experienced an improvement in their snoring (91.2%), daytime sleepiness (87.2%), and witnessed apneas (94.1%), and specific users self-reported

the reduction of headaches and a decrease in blood pressure. More than 60% of the users were satisfied with their OA therapy, no one answered unsatisfied, and two patients answered “little unsatisfied.”

The percentage of men who stopped using the OA was 22.5%, whereas for the women, this percentage was 42.9%. There were no significant sex differences with respect to initial data such as age, BMI, AHI, and ESS. However, women reported a significantly higher number of side effects and reported a higher improvement in apnea symptoms than males ($p < 0.05$). Males were more satisfied with the OA treatment than females ($p < 0.05$).

Discussion

This report presents some interesting findings compared to previous reports on custom-made appliances. Some 58% of the patients responded to the questionnaire in our survey, and this was lower than a previous report [12]. This might be related to our experimental design, where we sent the questionnaire out only once, while most of the previous studies used telephone reminders or resent the questionnaire if they did not get a response from the subjects [12]. The compliance rate is $35/81=43.2\%$ in “the worst case scenario” if it is presumed that the nonreturned patients were nonusers; while in “the best case scenario,” the compliance rate is $69/81=85.2\%$. The returned and nonreturned group exhibited no differences with respect to apnea severity, sex, age, BMI, baseline ESS, or nCPAP experience. Although there could be some report bias, we consider that returned and nonreturned patients have similar baseline characteristics. Although the compliance of TheraSnore™ was almost the same as reported in previous reports [6–10], characteristics of the side effects and the reasons to stop using the appliance identified in the current study are different. The most frequent side effects that previous studies reported were muscle and tooth pain [8, 9], but in this study, dry mouth and excessive salivation were

Table 1 Subjects demographics and initial baseline data

| Variable | All patients | Not returned | Returned | |
|--------------------------------|--------------|--------------|------------|-----------------------|
| | | | Users | Nonusers |
| <i>N</i> | 84 | 34(42.0%) | 35(43.2%) | 12(14.8%) |
| Female/male | 19/65 | 10/24 | 4/31 | 3/9 |
| Age (year) | 53.1±15 | 47.7±12.3 | 54.3±15.4 | 49.5±13.7 |
| BMI (kg/m^2) | 24.2±3.1 | 24.6±4.27 | 23.6±2.7 | 26.2±3.4 ^a |
| AHI, events/h | 21.3±14.9 | 10.1±6.9 | 23.2±15.4 | 15.3±12 |
| ESS | 6.5±3.4 | 7.4±3.2 | 5.7±3 | 8.2±4 ^a |
| CPAP experience (<i>n</i>) | 52 (61.9%) | 19 (55.9%) | 26 (74.3%) | 6 (50.0%) |

Data is expressed as mean±SD
SD standard deviation, BMI body mass index, AHI apnea-hypopnea index, ESS Epworth Sleepiness Scale, CPAP continuous positive airway pressure

^a Indicates significant difference between users and nonusers

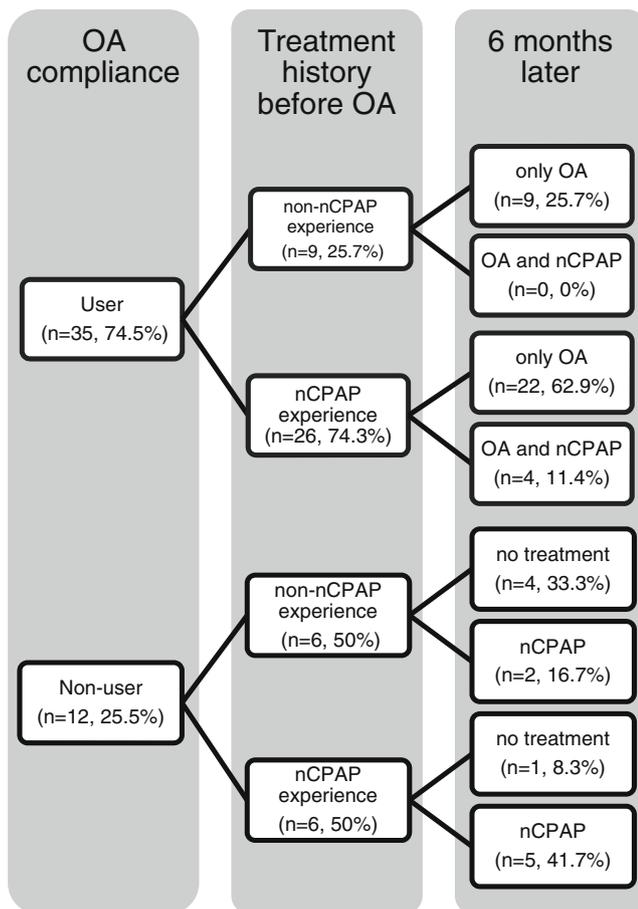


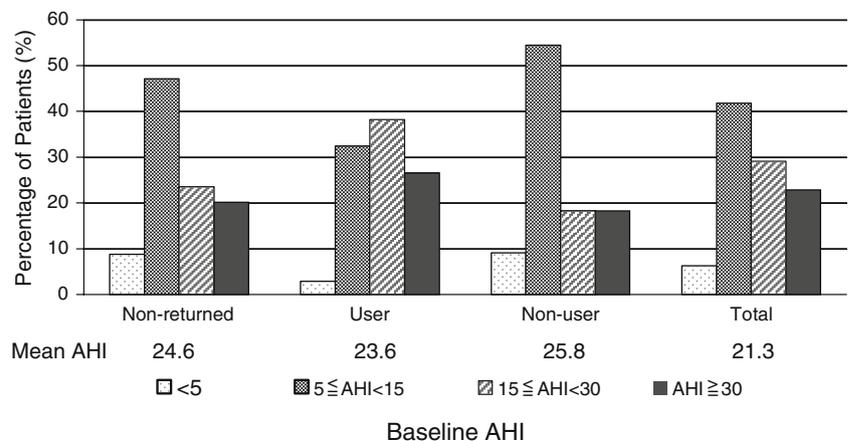
Fig. 1 OA compliance, treatment history before and after 6 months of OA wear

more common. The cause of this may be that we used TheraSnore™, which cannot hold the mandible as rigid when compared with custom-made OAs. Nonusers complained of “ill-fitting” more than the users, and “uncomfortable” was the most frequent reason to stop. TheraSnore™ is ready-made and available in only one

standard size; therefore, the chances of being uncomfortable in relation to other types of custom-made OAs are higher. Development of various appliance sizes in the future may improve compliance. Since this questionnaire was created based on previous report [9], we considered that the lack of retention would include “ill-fitting” category; therefore, our questionnaire did not have the specific option of lack of retention as reason to stop. We understand that some “ill-fitting” or “doesn’t stay” answers might have been caused from the lack of retention as mentioned by Vanderveken and collaborators [11] as a common problem of boil and bite appliances.

In the group of patients who returned the survey, 74.5% were users similar to a previous report [12]. This study was a mail-out survey with many limitations; however, we hypothesize that some patients might get a therapeutic effect if their dentition fits adequately into the prefabricated arch. We can also hypothesize that there are fewer side effects such as muscle pain because of poor retention with the TheraSnore™. Even though boil and bite appliances are not recommended as a long term OA therapy, this study was conducted in Japan, and this was the only appliance available at the time. Vanderveken et al. [11] demonstrated that a custom-made appliance turned out to be more effective than the boil and bite type in a randomized controlled cross-over trial and suggested that the boil and bite types should not be recommended as a therapeutic option. Although Vanderveken's study [11] showed significant differences in treatment effects between custom-made and boil and bite appliance, our results did not show a clear disadvantage in the boil and bite type, which is probably related to an overestimate of the boil and bite OA when using a subjective efficacy approach. Therefore, we agree with this previous work [11] and suggest that boil and bite appliances are not appropriate as screening tools to determine good candidates for mandibular advancement therapy.

Fig. 2 Baseline AHI severity (percentage) for nonreturned, user, nonuser, and total groups



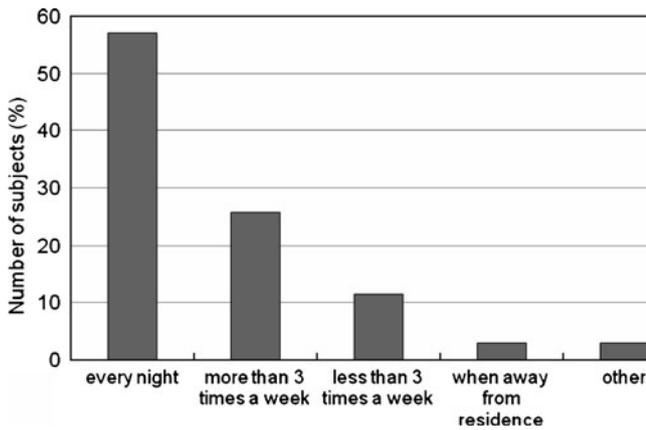


Fig. 3 Subject descriptions of frequency of OA use

Nonusers had higher ESS and higher BMI scores than users. Our results indicate that lower baseline BMI and ESS were predictors of OA compliance while disease severity did not affect the compliance. Some 58.3% of nonuser patients started or restarted nCPAP treatment after stopping OA therapy. Our subjects included not only patients who could not use nCPAP but also those who could use nCPAP but who wanted an alternative treatment such as an OA. There was no significant difference between baseline ESS and ESS with OA use in the user group. Because the average ESS of our subjects was in the normal range, this may be the reason we could not find a difference related to OA treatment as other studies have previously reported [13–16].

Most of the nonuser patients stopped using the OA in first 3 months which is similar to previous reports [9]. Although it is not comparable to objective data such as a PSG and professional assessment, this study estimated the self-reported subjective response; some users in this study also reported a reduction in headaches and a decrease in blood pressure [15, 17–20]. As this study had a small number of female subjects, we could not complete any statistical analysis for gender. However, differences between males and females were similar to a previous report [21]. Females experienced more side effects and had a greater tendency to stop using the OA than males, as 57.1% of the females who answered the questionnaire had discontinued use, compared to 22.5% of males. Although females are more likely to report an improvement in apnea symptoms than males, females stopped using the OA more often. In contrast, although male patients did not report as much of an improvement in apnea symptoms compared with females, they continued to use the OA with satisfaction. We hypothesize that females who stopped using the OA were more likely to answer the questionnaire. Considering no difference between the sexes with respect to age, BMI, AHI, or sleepiness, female noncompliance may be related to a greater perception or presence of side effects as reported previously [21].

This study differs from previous reports in the way that data was collected. The mail-out survey was sent 6 months after insertion of the OA in each patient. Usually, patients require some time to become accustomed to using the OA and side effects and compliance changes over time while this data reflects specific information only at the 6-month period.

Conclusion

Nonusers complained more about ill-fitting appliances when compared to users, and “uncomfortable” was the main reason given to discontinue therapy. Even though we did not have PSG results for every patient, TheraSnore™ does appear to be less effective than custom-made appliance. Since the TheraSnore™ is a ready-made appliance available in only one standard size, by design, it may result in a less than optimal fit and subsequently decrease overall compliance when compared to custom-made appliances. This study suggests that boil and bite appliances may not be always the alternative for custom-made appliances.

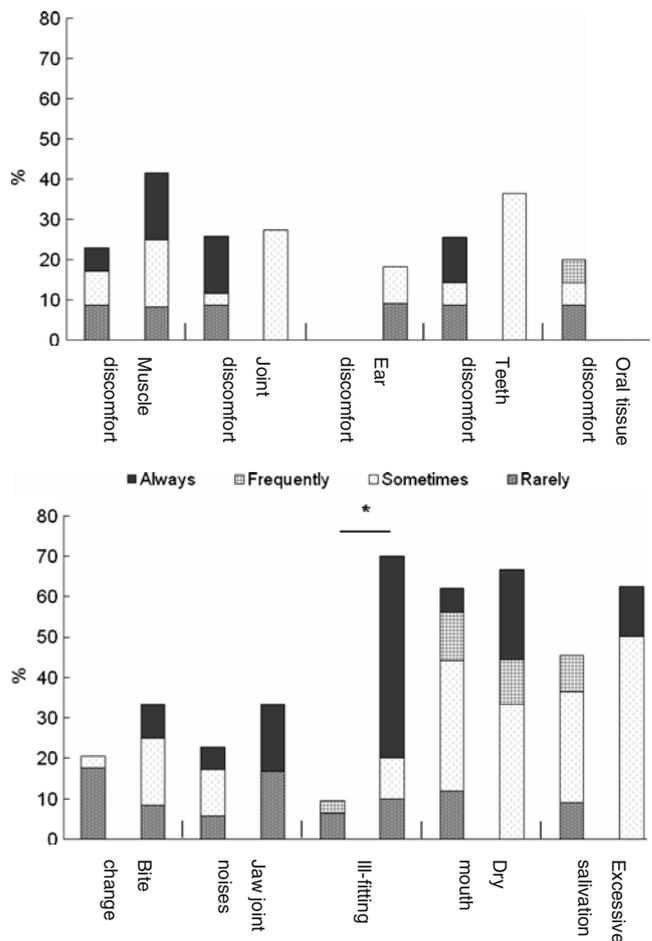


Fig. 4 Subject descriptions of side effects of OA use. Left bar user, right bar nonuser

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