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## Original article

# Complications causing patients to discontinue using oral appliances for treatment of obstructive sleep apnea



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### ABSTRACT

**Purpose:** Oral appliances (OAs) are commonly used as a noninvasive treatment for obstructive sleep apnea syndrome (OSAS). These devices are worn during sleep and create mandibular anterior traction to enlarge the upper airway. Continuous use of the device is essential for the success of OA therapy, but some patients stop using the OA for various reasons. The purpose of this research was to investigate complications in OA therapy that might prevent continuous use of these devices.

**Methods:** The progress of 90 OSAS patients who visited Tokushima University Hospital and underwent OA therapy was investigated with a mailed questionnaire. All patients had been receiving OA therapy for more than 12 months.

**Results:** Forty patients responded to the questionnaire and of these, 22 were not wearing their OA during sleep. The average period before stopping OA therapy was 9.6 months. Answers from 38 patients who were treated with two-piece Herbst<sup>®</sup>-type oral appliances were analyzed. The main reasons for stopping OA therapy were: (1) it was bothersome to use; and (2) it did not effectively prevent sleep apnea. Comparison of OA complications between current OA users and nonusers revealed significant differences for the items “difficulty sleeping” and “stifling feeling”. OA users recorded better scores for sleep quality than nonusers.

**Conclusions:** The results of this study indicate that patients discontinued OA therapy because the appliance was “bothersome to use” and because it had “little or no effect” rather than because they experienced the typical complications of OA therapy.

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## 1. Introduction

Obstructive sleep apnea (OSA) is a syndrome in which nasal and oral airflow ceases in spite of continued diaphragmatic efforts [1]. To prevent obstruction in the upper airway in this syndrome, various approaches have been used, including surgical, conservative, and instrumental therapy. These approaches involve a variety of treatments such as tracheostomy, surgery of the soft palate and oropharynx, reconstructive surgery of the facial skeleton, medications, weight reduction, nasal continuous positive airway pressure (CPAP) and oral appliance (OA) [2,3].

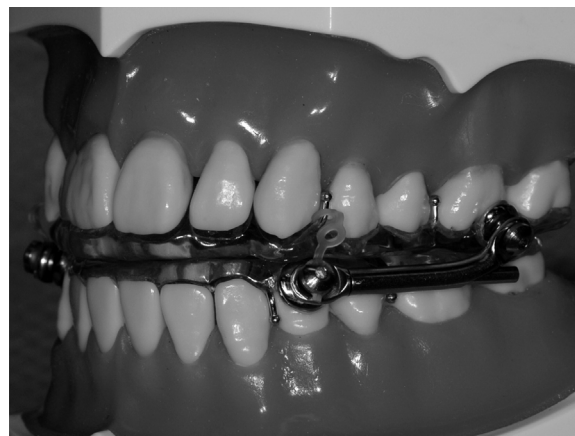
Because the effect of OSAS treatment without modification of the upper airway morphology does not continue when the patient stops treatment, continuous monitoring of the treatment is required for it to succeed. Because OAs are typically used for mild cases of sleep apnea, some of these patients might be unaware of the symptoms and are not eager to receive treatment. Undoubtedly, patient compliance for the treatment is the primary requirement for continuous treatment. Patient compliance is influenced by a number of factors. Symptoms such as xerostomia, tooth and gingival pain, hypersalivation, and temporomandibular and myofascial discomfort are known to be complications of OA therapy [3-10]. If these complications affect the continuation of OA therapy, such information will be helpful for modifying the structure of OAs to increase the continuous user ratio among OA therapy patients. The purpose of this research was to investigate the continuous-use ratio of OA therapy among OSAS patients through a questionnaire and to examine the complications that might cause discontinuation of OA therapy.

## 2. Materials and methods

Ninety OSAS patients who visited the Department of General Dentistry at Tokushima University Hospital during the 10 years from 2004 to 2013 were invited to participate in the investigation. The inclusion criterion for this investigation was any patient who had undergone OA therapy in this department between 2004 and 2013.

All of these patients underwent sleep examinations at medical hospitals for diagnosis of sleep apnea and were referred to our clinic to receive OA therapy. A two-piece Herbst<sup>®</sup> bite-jumping OA (Ormco Corp., CA, USA) was provided for most of these patients (Fig. 1) [11]. The maximum range of frontal mandibular movement of each patient was measured with a ruler and a 50-75% forward position from intercuspation was chosen as the tractive mandibular position for the OA [12]. The degree of mandibular opening was set at 5 mm at the incisal point [13]. The clinical procedure for occlusal registration for OA fabrication was described in a previous report [14].

Questionnaires were mailed to these patients at least one year after the start of OA therapy. The questionnaire included questions about the continuous use of OA therapy, frequency of OA use, period of total OA use, any complications with the OA, reasons for stopping OA therapy if a nonuser, loudness of snoring, daytime sleepiness, sleep sufficiency over the last



**Fig. 1 – Two-piece Herbst<sup>®</sup> bite-jumping oral appliance (OA) used to treat obstructive sleep apnea syndrome.**

month, the Epworth Sleepiness Scale (ESS) [15], and the Pittsburgh Sleep Quality Index (PSQI) [16].

Subjects were asked to grade their experience with complications of OA, snoring and sleep quality as follows: almost never: 0, sometimes: 1, frequently: 2, very frequently: 3, unknown: NA. Apnea Hypopnea Index (AHI) of the subjects at their initial visit was assessed from the medical records.

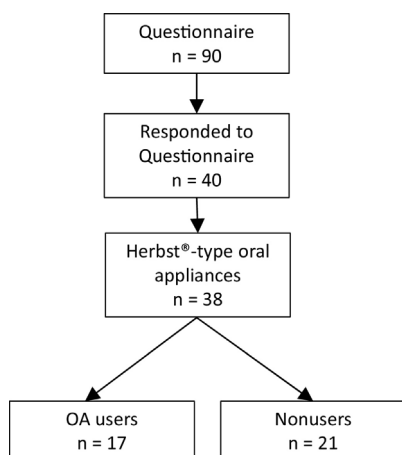
Then those subjects were separated into two groups: the current OA user group, and the nonuser group who had discontinued OA therapy. We compared the two groups using the Mann-Whitney *U* test. ESS scores at the initial visit and the follow-up visit were compared using the Wilcoxon signed-rank test. To assess the correlations between the self-evaluation for sleep quality and the follow up ESS scores, Spearman's rank correlation was performed. Statistical analysis was performed with SPSS-15.0J for Windows (SPSS Japan, Inc., Tokyo, Japan) and a 5% significance level was adopted for analysis.

This research was approved by the Research Ethics Committee of Tokushima University Hospital, Tokushima, Japan (No. 1149) and informed consent was taken from all participating patients.

## 3. Results

### 3.1. Respondent data

Forty patients out of 90 (44.4%) responded to the mailed questionnaire (28 males and 12 females; average age, 57.8 years). Twenty-two (55.5%) of these respondents had already stopped OA therapy. The average period of OA therapy for nonusers was 9.6 months (range, 2 weeks to 31 months). The average period of therapy for the 18 current OA users was 34.4 months. The longest period of OA use was 6 years in this investigation. About half of the OA users were wearing the OA every night. Two patients (one current OA user and one nonuser) had been fitted with a mono block-type OA and were excluded from the analysis. The other 38 patients had been fitted with Herbst<sup>®</sup> appliances (17 current OA users and 21 nonusers) as outlined in Fig. 2. The Herbst<sup>®</sup> appliance



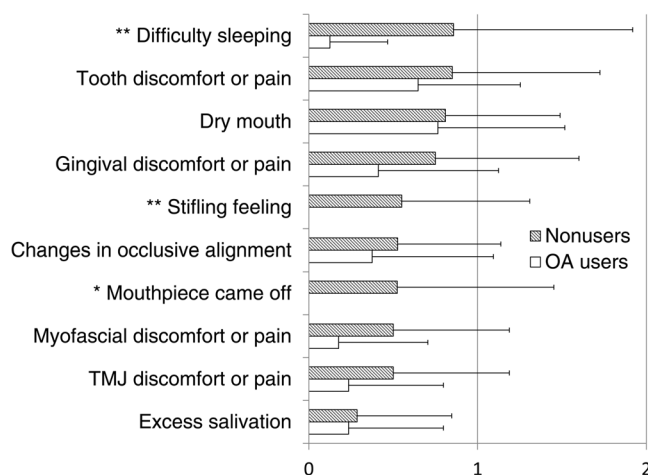
**Fig. 2 – Flow diagram showing participant flow in this investigation.**

allows the mandible to have some side-to-side and opening movement, imposing fewer restrictions on patients than the mono-block-type appliance [12]. Because this appliance inhibits mouth breathing less than other appliances, it could be indicated for OSA patients with nasal obstruction.

**3.2. Causes of discontinuation**

Table 1 lists the causes that led to discontinuation of OA therapy for nonusers. This question involved 18 items, and the respondents selected the primary cause for stopping OA therapy. Respondents were then asked to choose any accompanying causes for discontinuation from the same list. If the patients selected a cause other than these items, a detailed description was required. The most common causes

Table 1 – Causes of discontinuation of OA therapy in 21 nonusers.		
Cause of discontinuation	Primary cause	Related causes
Bothersome to use	19.0%	38.1%
Little or no effect	19.0%	28.6%
Other reason	14.3%	23.8%
Tooth discomfort or pain	9.5%	33.3%
Difficulty sleeping	9.5%	28.6%
Poor adaptation after dental treatment	4.8%	14.3%
Gingival discomfort or pain	4.8%	14.3%
Temporomandibular joint discomfort or pain	0.0%	9.5%
Dry mouth	0.0%	9.5%
Switched to other treatment	0.0%	9.5%
Mouthpiece came off	0.0%	4.8%
Stifling feeling	0.0%	4.8%
No reason	0.0%	4.8%
Mouthpiece breakage	0.0%	0.0%
Myofascial discomfort or pain	0.0%	0.0%
Excess salivation	0.0%	0.0%
Changes in occlusive alignment	0.0%	0.0%
Apnea dismissed	0.0%	0.0%



**Fig. 3 – Comparison of the complications of OA therapy in users and nonusers (\*p < 0.05, \*\*p < 0.01, Mann-Whitney U test).**

were that the OA was “bothersome to use” and that the OA had “little or no effect” on their sleep apnea; approximately half of nonusers selected these items. Other frequently occurring items included “tooth discomfort or pain”, and “difficulty sleeping” with the OA. Other causes apart from the listed items included separation from family who complained about snoring, the effect of a new pillow, and a 16-kg weight loss.

**3.3. Complications of OA**

Fig 3 illustrates the severity of OA complications. The grade of the complication was expressed numerically, then the average for each item was evaluated for the representative score. All of these complications exhibited higher scores for nonusers than users, and significant differences were found in the scores for “difficulty sleeping”, “stifling feeling”, and “mouthpiece came off”.

**3.4. Evaluation of sleep quality**

Fig 4 shows the items relating to self-evaluation of sleep quality over the month prior to the questionnaire. OA users recorded lower scores for “snoring” (loudness of snoring), “daytime sleepiness” and “sufficiency of sleep” than nonusers, but there were no significant differences between these two groups. OA users recorded significantly lower total scores than nonusers for self-evaluation of sleep quality obtained by adding scores for “snoring”, “daytime sleepiness” and “sufficiency of sleep”.

Fig 5 presents the correlation of the total scores for self-evaluation of sleep quality and follow-up ESS scores for all patients. Spearman’s rank correlation exhibited a significant correlation between these scores.

Fig 6 shows the items used to evaluate sleep quality. No significant difference was found between OA users and nonusers for these items. There was a significant decrease in ESS scores between the initial visit and the follow-up visit in

OA users. ESS scores for nonusers also decreased slightly in the follow-up period, but the difference was not significant.

## 4. Discussion

### 4.1. Respondent data

Previous studies investigating long-term OSAS treatment reported a relatively low continuation ratio for OA therapy [17–22]. In this study, patients who started OA therapy more than 12 months prior to the questionnaire were investigated, and 55.5% of patients had stopped OA therapy within a year. Because the follow-up period in our study differed from previous studies, it was difficult to make exact comparisons. However, the percentage of continuous OA users and nonusers was the almost the same as in the previous reports.

In this investigation, 50 patients did not respond to the mailed questionnaire. One of these patients was confirmed to have died of pancreatic cancer; thus, the patient's death was not likely to have been related to sleep apnea. Five patients had moved away and did not receive the questionnaire. We could not establish the reason for the other patient's failure to respond to the mailed questionnaire.

Two patients who responded to the questionnaire had been treated with mono block-type OAs. Given that the structure of mono block-type OAs is quite different from the Herbst<sup>®</sup> appliance, we excluded these two patients' data from the analysis. Only the data of patients treated with Herbst<sup>®</sup> appliances were compared.

### 4.2. Causes of discontinuation

In this investigation, one of the main causes for stopping OA therapy was that the OA was “bothersome to use”. Half of the patients selected this reason as the cause of their discontinuation when the additional question requesting a related cause for stopping OA therapy was taken into account. Given that “bothersome to use” is a subjective impression, it is difficult to cite this reason as an OA therapy complication. Because OA therapy requires the patient to keep the OA in the mouth while sleeping, we presume that it is a difficult procedure to insert the OA into the mouth before sleep, and/or it is uncomfortable to wear the OA; therefore, these patients feel that OA therapy is “bothersome”. Because Herbst<sup>®</sup> appliances are composed of two occlusal appliances connected by a metal retainer (tube and rod), the complicated design of the appliance could exacerbate these feelings.

Another main cause for stopping OA therapy was that patients felt that the OA had “little or no effect” in preventing sleep apnea. In general, OA therapy is recommended for mild or moderately severe cases of sleep apnea [2,3]. However, the average AHI of nonusers at the initial visit was more than 30, and some of these patients should be classified as severe cases. The average AHI of patients who cited “little or no effect” for the main or related cause for stopping OA therapy was 45.3. Fukuda et al. reported that the success rate of OA therapy depended on the response criteria for evaluation of treatment outcomes, and non-responders to OA therapy were

more frequently found in severe OSA patients than in mild and moderately affected patients [23]. In addition to the AHI score, several factors such as sleeping posture, amount of mandibular advancement, obstruction site, and craniomandibular morphology as evaluated with lateral cephalometric radiographs could predict the effectiveness of OA therapy [24]. Because we did not evaluate these objective factors except for the pre-OA therapy AHI score, it was difficult to speculate about the exact reason why certain patients did not respond to OA therapy. However, it is possible that those patients who reported that OA therapy was not effective were non-responders for OA therapy.

Typical complications of OA therapy, such as dental and/or gingival discomfort or pain, or difficulty sleeping, were also reported as the primary cause of discontinuation by some patients. However, more patients discontinued OA therapy for reasons other than the typical complications mentioned above.

### 4.3. Complications of OA

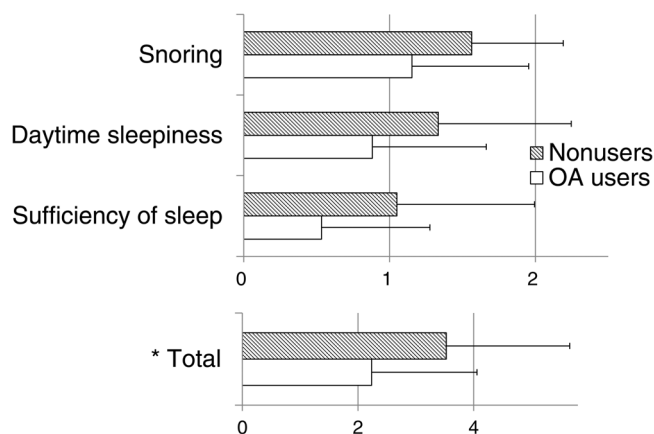
The most frequent complication for nonusers was “difficulty sleeping”, for which a significant difference was observed between OA users and nonusers. Significant differences were also observed for “stifling feeling”, and “mouthpiece came off” between OA users and nonusers.

The complications listed in our questionnaire have also been reported in previous research. The most typical and frequent complications reported in previous research into OA therapy were tooth and gingival pain, dry mouth, temporomandibular and myofascial discomfort and excess salivation [3–10]. In this research, these typical symptoms were found in both OA users and nonusers, and there was no marked difference in the prevalence of these complications. Because the most frequent causes for stopping OA therapy were “bothersome to use” and “little or no effect”, these major complications may not have been critical issues for nonusers. Because “difficulty sleeping” and “stifling feeling” could be associated with the discomfort of keeping the OA in the mouth during sleep, this bothersome impression of the OA prevents continuous use of the OA for these patients.

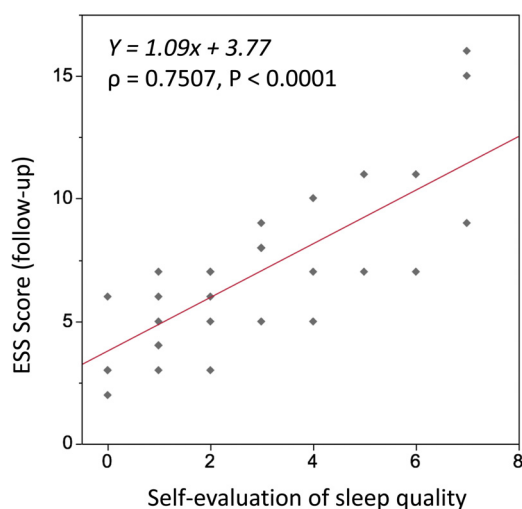
### 4.4. Evaluation of sleep quality

In this research, AHI at the initial visit was not significantly different between OA users and nonusers. Given that AHI indicates the severity of sleep apnea, we initially thought that OA users would have higher AHI scores. Because patients with higher AHI scores should have greater motivation for treatment, it could be speculated that these patients should be eager to have OA therapy. However, almost 30% of the nonusers stopped OA therapy, citing an insufficient effect on sleep apnea, and these patients also exhibited high AHI scores. As mentioned previously, many factors affect the effectiveness of OA therapy, and this research could not isolate the reason why OA therapy was ineffective in these patients. However, this paradoxical relationship between AHI score and the demand for OA therapy seems to negate a direct association between AHI score and continuous use of OA therapy.





**Fig. 4 – Comparison of sleep quality over the month before the questionnaire in OA users and nonusers (\**p* < 0.05, Mann-Whitney U test).**

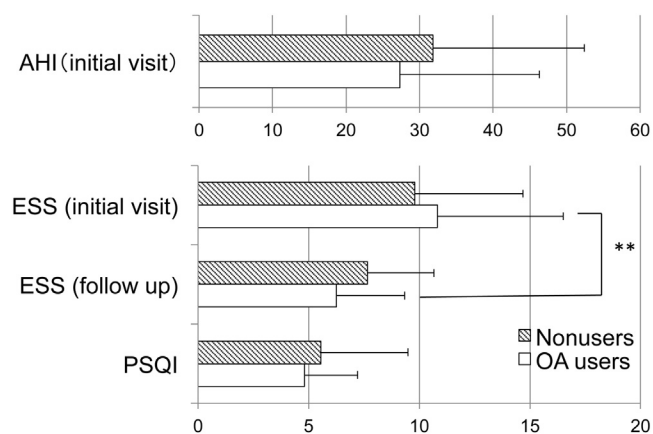


**Fig. 5 – Correlation of self-evaluation of sleep quality and follow-up ESS scores for all patients. The horizontal lines represent the total scores for self-evaluation of sleep quality. The linear equation shows the regression line in the scatter plots (Spearman’s rank correlation coefficient).**

Self-evaluation of sleep quality was performed with three-grade scales for “snoring” (loudness of snoring), “daytime sleepiness” and “sufficiency of sleep”. Since the totals of these scores exhibited a positive correlation with follow-up ESS scores, we suggest that these three items could have some validity for evaluating sleep quality. The total scores of these three items for OA users were significantly higher than those for nonusers (Fig. 4), and the follow-up ESS scores of OA users were significant lower than those at the initial visit. These data suggest that OA users experience better sleep quality than nonusers.

**4.5. Limitations of this investigation**

This research was based on the patients’ subjective impressions of OA therapy, which were investigated with a mailed



**Fig. 6 – Comparison of sleep quality in OA users and nonusers. A significant decrease in the ESS score was observed in the follow-up investigation in OA users (\*\**p* < 0.01, Wilcoxon signed-rank test).**

questionnaire. This research did not evaluate objective data except for pre-treatment AHI scores. To clarify the conditions that promote the efficacy of and compliance with OA therapy, further research that includes evidence from objective data such as post-treatment AHI scores and other related factors is required.

**5. Conclusion**

A follow-up investigation of OSAS patients indicated that about half of the patients stopped OA therapy, and the average period of OA use was 9.6 months. The main causes that led to discontinuation of OA therapy were that the OA was “bothersome to use”, and had “little or no effect” in preventing sleep apnea. Distinctive complications for nonusers were “difficulty sleeping” and “stifling feeling”.

**Conflict of interest**

The authors declare that they have no conflicts of interest with respect to their authorship or the publication of this article.

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