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Effects and Predictions of Oral Appliances in Obstructive Sleep Apnea

Mitsunori Uno, Ryugo Nonogaki, Masakazu Kurachi, Hajime Ishigami

Department of Prosthodontics, Division of Oral Functional Science and Rehabilitation, Asahi University School of Dentistry, Mizuho, Japan
Email: uno@dent.asahi-u.ac.jp

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Abstract

Since April 2004, the Asahi University Medical and Dental Center (hereinafter referred to as our center) has been providing oral appliances (hereinafter referred to as OA) to treat patients diagnosed with obstructive sleep apnea. The effects of using the OA and progress of 71 patients who received treatment at our center by wearing OA from March 2005 to the end of March 2016 were examined through questionnaires sent by physical mail. In 21 of 24 patients who underwent polysomnography after wearing OA, the apnea-hypopnea index (hereinafter referred to as AHI) significantly decreased after wearing OA (9.44 ± 10.37) compared to that before wearing OA (24.02 ± 13.57) ($p = 8.7 \times 10^{-8}$). The results showed that for patients who continuously use OA, it is necessary to have sound sleep/sleep soundly; further, the patients experienced a decrease in snoring when wearing OA, with only a few side effects on the temporomandibular joints and teeth. In addition, the closer the distance from the plane of the lower margin of the mandible to the hyoid bone after wearing OA, the more likely it was for the AHI to decrease, which suggests that wearing OA contributes to the prediction of therapeutic effects.

Keywords

Oral Appliances, Polysomnography, Obstructive Sleep Apnea

1. Introduction

Treatment methods for obstructive sleep apnea (hereinafter referred to as OSA) include surgery, respiratory support therapy with nasal continuous positive airway pressure (hereinafter referred to as CPAP), mandibular advancement oral appliance (hereinafter referred to as OA) [1], and lifestyle guidance such as weight loss and abstinence from alcohol [2] [3]. From April 2004, patients diag-

nosed with OSA could be covered by insurance only if they received a request for OA treatment from the doctor in charge of the medical institution authorized to treat patients with health insurance coverage [4]. Usually, requests for OA production from nearby medical departments are mainly for those with mild-to-moderate disease [5].

In OSA, the upper airway is anatomically obstructed or partially narrowed, causing repeated apnea and hypopnea during sleep, resulting in low blood oxygen levels that cause awakening during the night and increased daytime sleepiness [6]. Forward movement of the mandible by the OA is an important maneuver to improve the blockage of nasal/oral airflow caused by upper airway obstruction [6]. However, use of an OA may cause symptoms, such as discomfort when wearing the OA, dry mouth during sleep, and discomfort in occlusion when waking up, pain in the temporomandibular joint and teeth, and in some cases, arousal during sleep. Moreover, the apnea index may not show improvement.

Furthermore, excessive forward movement causes side effects on the stomatognathic system. Therefore, at the Asahi University Medical and Dental Center (hereinafter referred to as the center), patients are instructed to wear OA in accordance with the "Guidelines for Oral Appliances for Obstructive Sleep Apnea" [5].

This study aimed to investigate the effects and course of treatment with OA and the side effects on the stomatognathic system using a questionnaire survey and patient data collected at the time of treatment.

2. Methods

2.1. Questionnaire Survey

The participants of the survey were 71 patients who wore OA at our center from March 2005 to the end of March 2016.

The consent form and questionnaire were mailed to the homes of patients with OA. Based on the responses, we analyzed whether or not the appliances were worn, for how long were they worn, how it felt to wear them, pain in the temporomandibular joint and teeth, dry mouth when wearing the appliances, and whether or not there was discomfort in occlusion when waking up (Table 1).

2.2. OA Production Method

Figure 1 shows the production method of OA. Impressions of the upper and lower jaws were taken using the agar-alginate combined impression method, and working models were made with anhydrite. Areas that could become severely undercut, such as lower hourglass-shaped voids and crowded areas, were blocked out with ordinary gypsum and a dental occlusal splint material (thickness: 1.5 mm) (Yamahachi Dental Industry, Aichi, Japan) was pressure-welded using DRUFOMAT-SQ (Dreve, Germany). Subsequently, OA was cut out with a cutting disk and shaped and polished using a carbide bar for laboratory use or a silicone point. At the time of the OA trial, compatibility and the presence of pain

Table 1. Sleep apnea questionnaire.

MM/DD/YY ID( ) Name( )

① Are you currently using a splint?
( ) Yes→② ( ) No→ ⑪
② How often do you use it?
( ) Almost every day ( ) Sometimes (___ days in a week)
③ Can you sleep well with a splint?
( ) Yes ( ) No ( ) Neither yes nor no
④ Does inserting a splint hurt the base of your chin (the front part of your ear)?
( ) Yes ( ) Sometimes ( ) No
⑤ Does inserting a splint make your teeth hurt?
( ) Yes ( ) Sometimes ( ) No
⑥ Does inserting a splint make your mouth dry?
( ) Yes ( ) Sometimes ( ) No
⑦ How do you take care of your splint?
( ) Clean with denture cleansers (including occasionally) ( ) Clean with tap water only
( ) I do not clean ( ) Other
⑧ Has your snoring decreased since you put a splint on?
( ) Disappeared ( ) Decreased a little ( ) Has not decreased ( ) Don't know
⑨ Did your daytime sleepiness improve?
( ) Yes ( ) A little ( ) No ( ) Don't know
⑩ How long have you been using the splint after production?
( ) I have never used it ( ) I used it 2 or 3 times/
( ) I used it for about a month. ( ) I used it for about half a year. ( ) Other.
⑪ For those of you who have not used the splint: Why did you choose not to use it?
(You may select multiple)
( ) The test results showed it was ineffective.
( ) It was difficult to use.
( ) I felt uncomfortable.
( ) I could not use it because it was damaged.
( ) My jaw or teeth started hurting.
( ) My mouth became dry.
( ) Other.

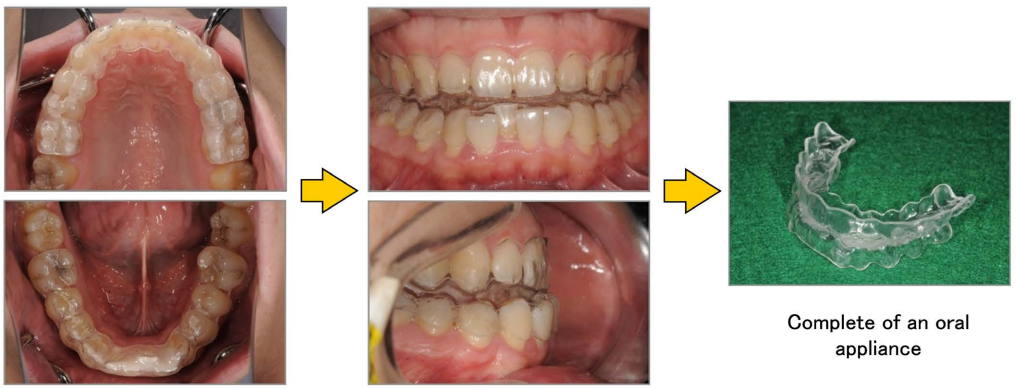

Figure 1. The production method of an oral appliance (OA).

in the teeth or periodontal tissue were confirmed, and the maxillo-mandibular relationship was recorded.

To record the maxillo-mandibular relationship, the distance of movement from the centric occlusion position to the most anterior position of the mandibular incisors was measured using a George gauge (JM Ortho.CO, Tokyo, Japan) or dental measure II (SHOFU, Kyoto, Japan), and it was set to move forward as little as possible between 50% and 75% of that distance while confirming that

there was no pain in the temporomandibular joint and teeth.

The OA was attached to the upper and lower jaws, temporarily fixed in the measured lower jaw position, and the presence of pain in the temporomandibular joint or teeth was checked. The mandible was fixed with UNIFAST II clear (GC, Tokyo, Japan) in the space between the mandibular OA.

2.3. Measurement and Analysis of Cephalometric X-Ray Films

We compared the position of the hyoid bone (hereinafter referred to as MP-H) from the plane of the lower margin of the mandible before and after wearing the OA from a standard cephalogram taken at the time of treatment (**Figure 2**). Measurements were taken using the software Cephalo Metrics A to Z (Yasunaga Computer System Co., Ltd., Fukui, Japan).

2.4. Analysis of Observational Data

We examined the correlation coefficient and regression equation between MP-H before wearing OA and the apnea hypopnea index (hereinafter referred to as AHI) measured by the requestor at the medical department.

AHI was measured in 24 patients who visited the requestor at the medical department after wearing OA. Subsequently, we divided the patients into two groups: patients whose AHI decreased after wearing OA (group A; n = 21) and patients whose AHI remained unchanged or increased (group B; n = 3). The Mann-Whitney-Wilcoxon test was used to compare the measured values of MP-H and AHI before and after wearing the OA between the two groups.

CORREL function of EXCEL (Microsoft, USA) was used to analyze the correlation

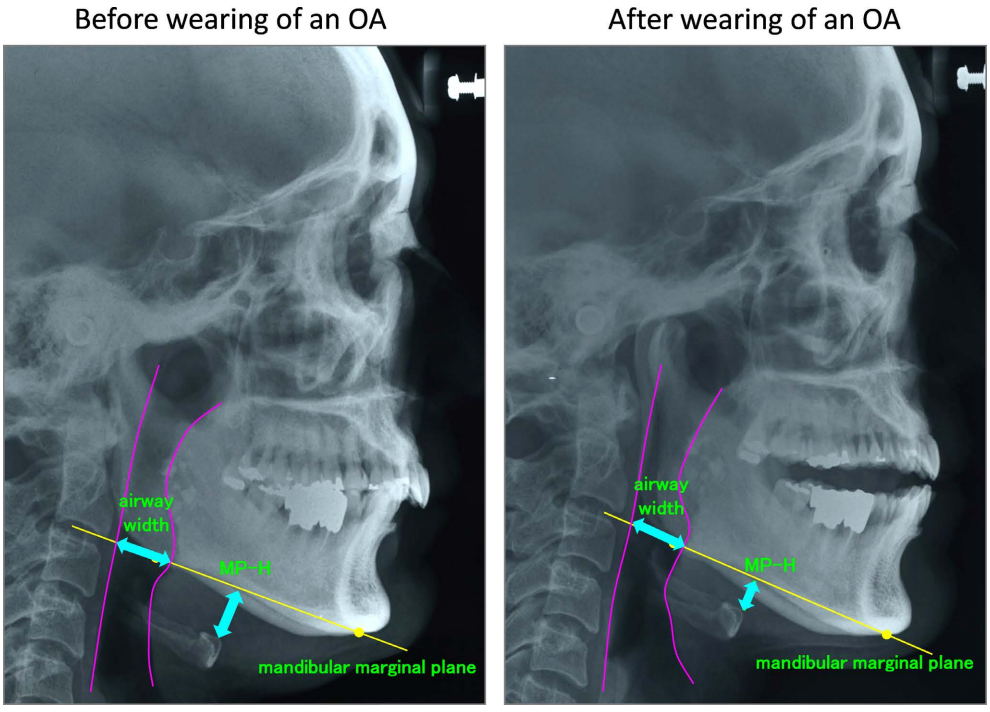

Figure 2. The cephalometric analysis before and after wearing of an oral appliance (OA).

between MP-H and AHI, and the Mann–Whitney–Wilcoxon test of EXCEL Statistics ver. 7.0 (Esumi, Tokyo, Japan) was used to compare MP-H and AHI before and after wearing OA between the two groups.

This study was conducted with the approval of the Asahi University School of Dentistry Ethics Committee (approval number 30024).

3. Results

3.1. OA Questionnaire Collection Rate and Usage

Of the 212 total patients, 152 were men and 60 were women, and their ages ranged from 14 to 77 years. Of these, 71 patients (response rate 33.5%) who agreed to participate in this study and responded to the questionnaire were included.

Figure 3 shows the results of surveys ① and ⑪ regarding the use of OA.

In total, 49 of 71 patients (69.0%) had been continuously using OA until the date the questionnaire was conducted, and 22 out of 71 (31.0%) had not used OA (Figure 3 ①). In terms of reasons for not using OA, 18 of 43 (41.9%) answered, "I feel uncomfortable and feel bad" and "I have pain in my jaw and teeth" (Figure 3 ⑪).

3.2. Questionnaire Survey on Patients Using OA

Figure 4 shows the survey results of questionnaires ② to ⑩ conducted on 49 patients using OA. In total, 35 participants (71.4%) used OA almost every day, and 14 participants (28.6%) used it occasionally (Figure 4 ②).

For the question, "Can you sleep well with OA?" 33 participants (67.3%)

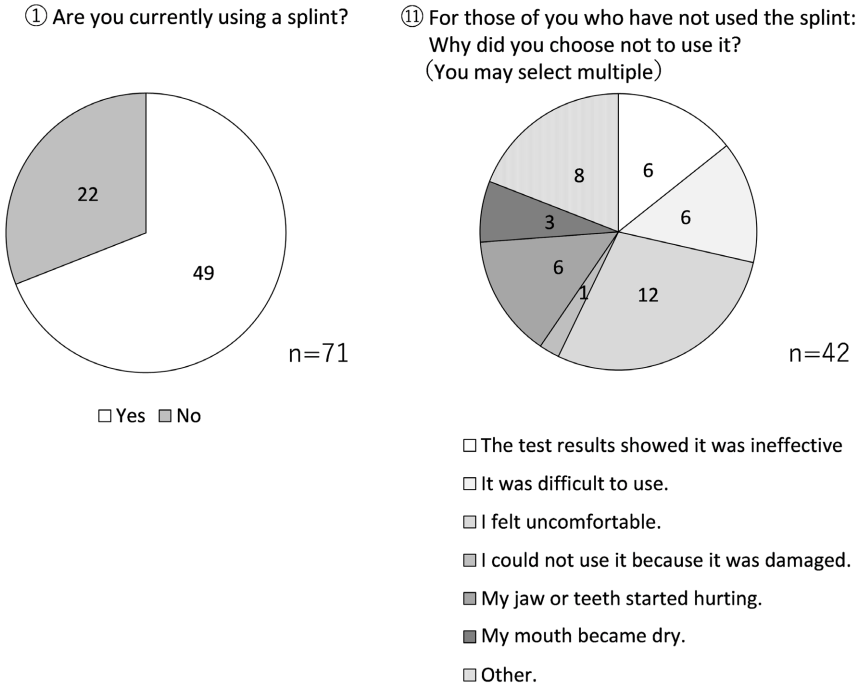

Figure 3. Use of an oral appliance and reasons for non-use in patients.

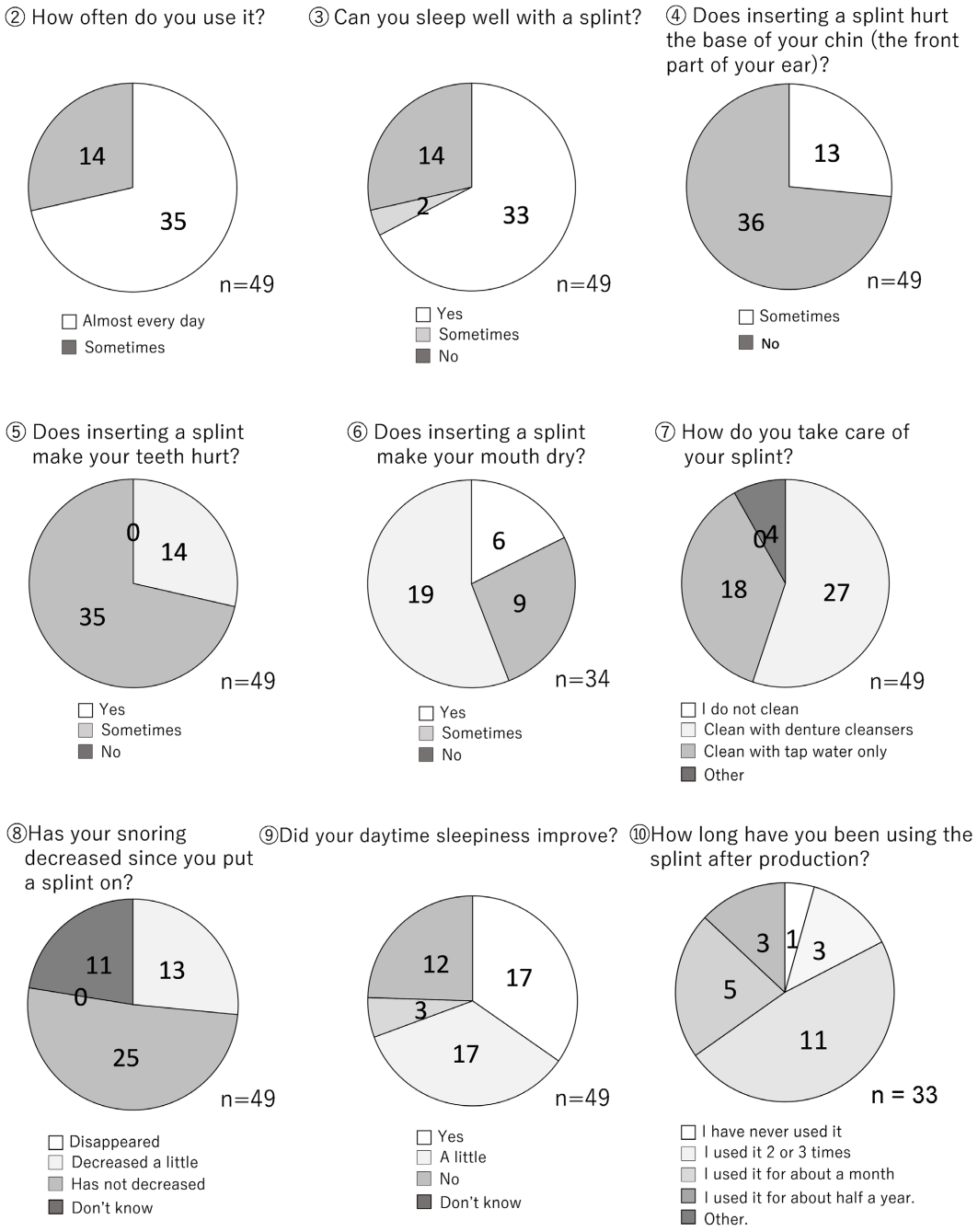

Figure 4. Questionnaire survey on patients using an oral appliance.

answered, "I can sleep," while 14 participants (28.6%) answered "neither yes nor no" (**Figure 4** ③). For the question, "Does the base of the chin (the front part of the ear) hurt when wearing OA?" 36 participants (73.5%) answered, "it does not hurt," while 13/49 participants (26.5%) answered, "it hurts sometimes" (**Figure 4** ④).

In addition, for the question "Does OA hurt your teeth?", 35 participants (71.4%) answered, "it does not hurt" (**Figure 4** ⑤). For the question "Does OA make your mouth dry?" 19/34 (55.9%) answered "it does not" (**Figure 4** ⑥).

For the question, "How do you take care of your OA?" 27 participants (55.1%) answered that they use a denture cleanser, and 18 participants (39.7%) answered that they cleaned it only with tap water (Figure 4 ⑦).

For the question, "Did your snoring decrease after using OA?" 38 participants (77.6%) answered that it "disappeared" or "slightly decreased" (Figure 4 ⑧).

For the question, "Did your daytime sleepiness improve?" 34 participants (69.4%) answered that "it improved" or "slightly improved" (Figure 4 ⑨). For the question on the "duration of use after production of OA," 11 participants answered about 1 month, five answered about half a year, and 26 participants did not answer (Figure 4 ⑩).

3.3. Correlation between AHI and MP-H before Wearing OA

Correlation coefficients between pre-OA MP-H and pre-OA AHI were $R = 0.245$, $p = 0.039$, and $R^2 = 0.060$ (Figure 5).

3.4. Variation before and after Wearing OA

MP-H in group A showed a significant ($p < 0.01$) decrease after wearing the OA (8.00 ± 6.16 mm) compared to that before wearing the OA (14.24 ± 5.28 mm). AHI showed a significant ($p < 0.01$) decrease after wearing the OA (9.44 ± 10.37 times/h) compared to that before wearing the OA (24.02 ± 13.57 times/h).

In group B, there was no significant difference in the MP-H before (15.67 ± 3.39 mm) and after (14.00 ± 4.97 mm) wearing the OA as well as the AHI before (10.27 ± 2.96 times/h) and after (19.13 ± 2.63 times/h) wearing the OA (Figure 6).

4. Discussion

Since OA has been covered by dental insurance from 2004, our center has received requests for OA production from nearby medical departments. However, OA use may cause side effects, such as discomfort when wearing, dry mouth

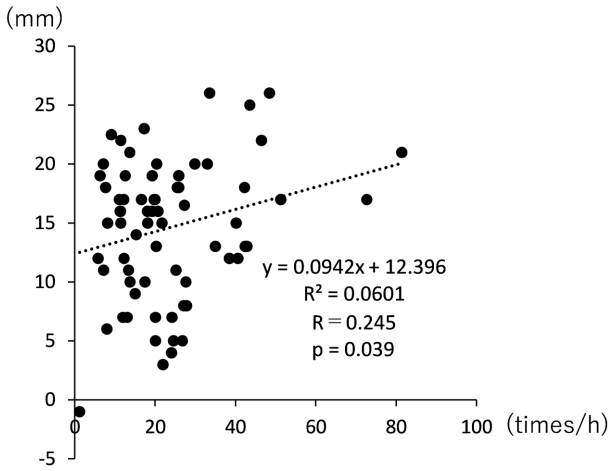

Figure 5. Correlation between the apnea hypopnea index (AHI) before wearing an oral appliance and the position of the hyoid bone from the mandibular plane (MP-H).

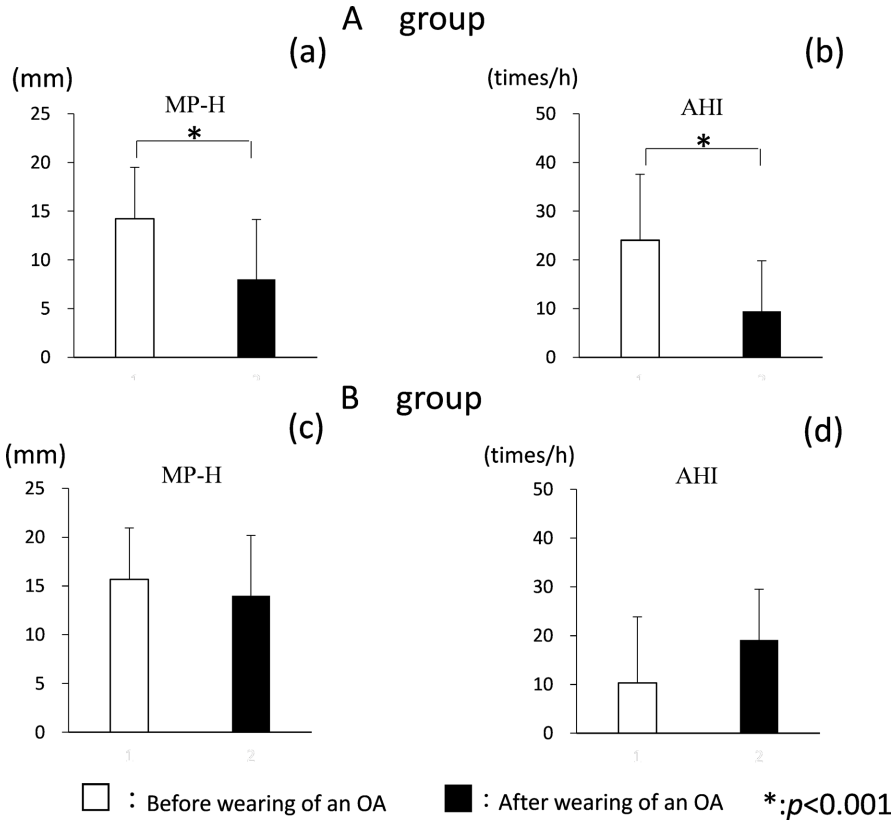

Figure 6. Comparison before and after wearing an oral appliance (OA). (a) MP-H of group A that compared after wearing the OA to before wearing the OA; (b) AHI of group A that compared after wearing the OA to before wearing the OA; (c) MP-H of group B that compared after wearing the OA to before wearing the OA; (d) AHI of group B that compared after wearing the OA to before wearing the OA.

during sleep, discomfort in occlusion when waking up, and pain in the temporomandibular joint and teeth. Since OSA anatomically obstructs or narrows the upper airway [4], the OA must establish a mandibular position that opens the upper airway [6] [7]. It is said that the upper airway expands maximally when the mandible is in the most anterior position [8] [9]. However, if the OA is worn while the mandible is in the most anterior position, pain and discomfort in the temporomandibular joint and masticatory muscles are likely to occur, which is unacceptable [10].

The Guidelines for Oral Appliances for Obstructive Sleep Apnea [5] state that OA is initially set at 75% but adjusted from 50% in patients with mild-to-moderate disease [5]. Changes in the coverage of the upper and lower teeth have also been reported to be associated with anterior mandibular movement [11] [12] and should not be left with excessive mandibular movement [5].

Since the target population in this study included patients with mild-to-moderate cases, our center confirmed the ease of nasal breathing, pain in the temporomandibular joint and teeth with a setting of between 50% and 75%, and reduction in the movement distance in case of pain, in accordance with the guidelines.

Regarding the therapeutic effect of OA, Doff *et al.* [13] reported that the suc-

cess rate of treatment at the 2-year follow-up was 52.9% for OA and 67.3% for CPAP, suggesting that CPAP was more effective; however, for mild-to-moderate cases, OA (56%) and CPAP (60%) had almost the same success rate of treatment. They also reported that OA is an alternative to CPAP in the treatment of mild and moderate OSA [13]. In addition, Uniken *et al.* [14] reported that both OA and CPAP were therapeutically effective and improved AHI and SpO_2 in self-reported patient outcomes from a 10-year follow-up.

On the other hand, Aarab *et al.* [6] reported that temporomandibular joint symptoms, a side effect of wearing OA, increased at 50% and 75% movement rather than at 0% and 25% movement. However, another systematic review concluded that Temporomandibular joint disorder (TMJ) symptoms did not worsen when OAs were used in patients with TMJ symptoms [15]. In the questionnaire survey conducted by our center, 18 of 42 patients (42.9%) cited discomfort when wearing OA and pain in the temporomandibular joint and teeth were reasons for not continuing to use it, which indicates that the side effects may appear early. Therefore, it is necessary to periodically adjust the mandibular position after wearing OA while paying attention to the occurrence of side effects.

Meanwhile, 49 of 71 patients (69%) wore OA, and of the 49 patients (28.6%) who occasionally used OA, 14 were currently using CPAP, and some used OA only when staying out overnight. Side effects of wearing an OA included occasional jaw pain in 13 of 49 patients (26.5%), occasional tooth pain in 14 of 49 patients (28.6%), and occasional dry mouth in 15 of 34 patients (44%). However, more than half of the patients did not experience side effects.

Regarding maintenance of OA, 27 of 49 participants (55.1%) used denture cleansers, 18 of 49 participants (36.7%) used only tap water, and others used toothpaste or dishwashing detergent. However, it is necessary to instruct participants not to use toothpaste when cleaning with a brush, as it leaves fine scratches on the OA surface and makes it susceptible to stains.

Snoring decreased or slightly decreased in 38 of 49 patients (77.6%), and more than half of the patients confirmed the effects of OA. Daytime sleepiness improved or slightly improved in 34 of 49 patients (69.4%), suggesting that incidences of night awakening decreased.

Regarding the duration of use of OA, 4 of 23 responses (17.4%) answered within 1 month after wearing the OA, and 16 out of 23 responses (69.6%) answered between 1 month and half a year, which suggests that it may be possible to wear OA for a longer period of time if the patient continuously had a sound sleep without experiencing side effects.

In the supine position during sleep, the soft palate, uvula, base of the tongue, and epiglottis sink due to gravity, narrowing the airway [4]. Therefore, we hypothesized that there is a correlation between the position of the hyoid bone (MP-H before OA placement) and AHI, although the correlation was not significant ($R = 0.245$).

The airway is not only affected by posture (the airway is smaller in the supine position than in the sitting position) but also because the neuromuscular me-

chanisms involved in airway patency differ between wakefulness and sleep, and the airway morphology is significantly different [16]. Although cephalograms can visualize the upper airway perimeter, we speculate that the lack of correlation is due to the fact that the airway during sleep was not evaluated.

Patients who showed a significant decrease in AHI after OA had their hyoid bone move upward by approximately 6 mm compared to that before OA. Previous studies have reported that the closer the distance between the mandibular inferior margin plane and the hyoid bone in the cephalogram, the greater the effects of OA [16], which suggests that the shorter the MP-H, the better the effects of OA even after wearing OA.

The above points suggest that the length of MP-H after wearing OA may be involved in the prediction of therapeutic effects.

According to the questionnaire survey, the patients did not wear OA because it "felt uncomfortable" and "it was troublesome to use." In addition, since side effects may occur early after wearing OA, early adjustment is necessary. Therefore, it is necessary to continue to conduct patient questionnaire surveys in the future and to examine the effects and prognosis of OA.

5. Conclusions

Patients who continuously use OA should be aware of having sound sleep and reduction in snoring when wearing OA. It is also important for the side effects on the temporomandibular joints and teeth to be minimal.

Patients who felt their snoring was markedly reduced showed a significant reduction in AHI on the polysomnography after wearing OA compared to before wearing OA. In addition, the closer the distance between the plane of the lower margin of the mandible and the hyoid bone after wearing OA, the more the AHI tended to reduce, which suggests that OA may be involved in the prediction of therapeutic effects.

Authors' Contribution

Mitsunori Uno, Ryugo Nonogaki, Masakazu Kurachi and Hajime Ishigami corrected the data. Mitsunori Uno and Hajime Ishigami drafted and wrote the manuscript. The concept of this manuscript was devised by Mitsunori Uno. All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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