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# Long-Term Compliance and Side Effects of Oral Appliances Used for the Treatment of Snoring and Obstructive Sleep Apnea Syndrome

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**Study Objective**: This study, by means of a mail survey, quantified the compliance with and side effects of the use of an oral appliance for more than five years in patients with snoring or obstructive sleep apnea.
**Methods**: A questionnaire was mailed to 544 patients who used an oral appliance for the treatment of snoring or obstructive sleep apnea.
**Results**: Some 46.1% of the patients returned the questionnaire, 37.8% did not, 15% had an invalid address, and 0.9% were deceased. The mean time period between oral appliance insertion and the return date of these surveys was 5.7 ± 3.5 years. Of the returned sample, 64.1% were wearing their oral appliance (users). There was no significant difference in the baseline and post-titration respiratory disturbance index between the returned and not-returned groups or between patients who had stopped wearing the oral appliance (nonusers) and users. Within the users group, 93.7% used the oral appliance more than 4 nights per week, 100% wore it more than half of each night, and 95% were satisfied with the treatment. The most frequent reasons why patients discontinued wear were uncomfortable (44.4%), had little or no effect (33.6%), or switched to nasal continuous positive airway pressure (23.3%). Snoring was satisfactorily controlled in 75.6% of users and in 43.2% of nonusers. Side effects, such as dry mouth and tooth and/or jaw discomfort, were more frequent and more severe in the nonusers ($P < .05$). With oral appliance usage, both users and nonusers reported an increase in temporomandibular joint symptoms, but there was no difference in the degree of change.
**Conclusions**: Subjects who were compliant with oral appliance therapy reported long periods of use and adequate control of snoring.
**Key Words**: Oral appliance, sleep apnea, side effects, compliance
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Obstructive Sleep Apnea (OSA) is a common sleep disorder affecting 4% to 19% of the middle-aged population.[1,2] OSA is a progressive disease and is associated with excessive daytime sleepiness and long-term cardiovascular morbidity.[3] Oral appliance (OA) use is one successful treatment available, and it has been recommended as an alternative to nasal continuous positive airway pressure (CPAP) for patients with moderate to severe OSA who refuse or are unable to tolerate nasal CPAP and as a primary treatment for mild OSA, upper airway resistance syndrome, and snoring.[4] OA use reduces apneas because the device advances the mandible and enlarges the upper airway.[5] Randomized trials have documented significant decreases in the respiratory disturbance index (RDI) and sleepiness, confirming the effectiveness of this therapy for OSA.[6-13] Recently, 2 studies have reported that OAs significantly improve oxygen desaturation and reduce systemic blood pressure in patients with OSA.[14, 15]

CPAP is the most common form of therapy and is highly effective for OSA, but there is resistance and intolerance to CPAP use, which compromises its long-term efficacy.[16] The literature suggests failure rates for complying with treatment that range between 25% and 50%,[17,18] and it appears that only 60% of the patients use CPAP on a daily basis.[19] Rosenthal et al[20] reported that, in mild cases, only 17% of the patients opted for CPAP and 39% of those withdrew treatment after only 1 week. Side effects such as pressure sores, mask dislodgement, claustrophobia, air leakage, and eye discomfort occur in up to 50% of OSA patients. Nasal problems such as nasal congestion, dripping, and mucosal drying have been observed in 15% to 45% of patients.[21]

OA treatment also exhibits problems with compliance and side effects. OA compliance might differ depending on the type of the appliance, disease severity, and perhaps patient management. Within a period of approximately 2 years, compliance rates of OA use have been shown to range from 48% to 84%.[22-28] A greater percentage of noncompliant patients have been revealed in the first 3 months,[22] with 82% to 62% reductions in compliance over a period of 2 to 4 years.[26] The main reasons for discontinuing treatment have been reported to be insufficient reduction of snoring and the presence of side effects.[22-27] Neither supine-dependent OSA, age, obesity, sex, or sleepiness seem to be related to OA tolerability.[28]

Short-term side effects of OAs are usually described as mild and transient. Subjective side effects include dry mouth, excessive salivation, tooth discomfort, muscle tenderness, and jaw

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stiffness, but none of these symptoms appear to lead patients to abandon treatment.[23-25,29] Problems such as pain and occlusal changes have been related to discontinuation of OA use in 7.5% to 25% of cases.[23,25] Interestingly, a much higher percentage of tooth movement and occlusal change have been seen in objective measurements after 1 to 4 years of follow-up, but these changes have not been reported as being related to treatment withdrawal.[22,26,30-32]

Although a limited number of studies have investigated OA use and their long-term side effects, OAs are a life-long treatment and a follow-up of side effects after more than 5 years of treatment has not yet been completed. An increased understanding of the long-term efficacy, compliance with, and long-term risks of the side effects is essential to better understand this therapy and to develop a specific clinical protocol to monitor treatment over time. The purpose of this study was to utilize a mail survey to evaluate the reported compliance and side effects in snoring and OSA patients who had been treated with an OA for more than 5 years.

## METHODS

This was a questionnaire-based survey developed to evaluate long-term OA treatment. All 544 patients who had been treated with an OA for snoring, OSA, or both at The University of British Columbia or in the orthodontic practice of 1 of the authors (AAL) between February 1989 and June 2001 were included in this study. One copy of the questionnaire was sent by mail to each patient (see Appendix). In the cover letter, it was explained that their participation in the study was entirely voluntary and that the patient could refuse to answer without any consequences to their continuing medical or dental care. A postage-paid, self-addressed reply envelope was included. If the patients did not answer, a second and a third copy were sent after 1-month intervals. Patients were asked to identify themselves at the end of the survey if they wished. The study was approved by the Ethics Committee of The University of British Columbia.

Within the period mentioned above, the family and/or sleep doctors had primarily referred patients for OA therapy if the patient was a snorer or had mild sleep apnea without associated comorbities such as sleepiness or health related issues, or moderate to severe patients who were not compliant with CPAP therapy. The sleep apnea dental clinic always required a physician's referral prior to OA insertion and then treated these patients according to certain protocols, which included selecting the proper type of OA, titrating into the optimum jaw position as evaluated subjectively by the dentist and bed partner, and then referring the patient back to the physician for follow-up. Depending on the severity of each case and the accessibility of polysomnography, patients were reassessed with overnight polysomnography or oximetry only. If there was a positive but insufficient reduction in the RDI, attempts were made to further titrate the OA with 1 more follow-up evaluation. This clinical protocol requires 2 to 10 months, depending upon the patient, and the patients were encouraged to return after their doctor's posttitration evaluation of treatment and every 2 years after this date. There were no systematic follow-up letters or procedures.

A specially designed self-reported questionnaire was created with select questions from previous studies.[23-25] From the patient's chart, a database was compiled and objective information on sex, age, body mass index (BMI), baseline and OA RDI were collected. RDI was defined as the apnea and hypopnea index from full-night polysomnography or an oxygen desaturation index greater than 4% per hour from an overnight oximetry study. The disease severity was categorized following the standards proposed by the American Academy of Sleep Medicine[33] as *snorer* for an RDI < 5, mild OSA for 5 ≤ RDI <15, moderate for 15 ≤ RDI < 30, and severe for RDI ≥ 30. Compliance with OA therapy was divided into the number of nights per week and percentage of each night of OA use. If patients stopped wearing their appliance, they were asked to provide the number of months for which they had used the appliance and to specify the reasons why they had stopped. The date of first appliance insertion and the type of the current or last appliance used was added to the data analysis. Questions regarding sleepiness (Epworth Sleepiness Scale[34]) before and during OA therapy, amount of change in the snoring, apneas, daytime fatigue, and bed partner's subjective satisfaction were also included.

A 14-symptom questionnaire for the evaluation of possible side effects while undergoing OA therapy was initially scored as present or not present; then according to frequency as rarely (1), sometimes (2), or often (3); and in terms of severity as mild (1), moderate (2), or severe (3). The maximum score per question was therefore 6, and the total maximum score per patient was 84 (14 questions x 6 points). If the patients answered any of the questions in this section, the blank ones were considered as an absence of the symptom (score 0), but if the whole section was left blank, it was considered as missing data. A questionnaire for temporomandibular joint (TMJ) symptoms was included with 13 questions, and each absent symptom was scored as a 0 and each present symptom scored as 1, the maximum score then being 13. All data were entered into a template; questions with multiple answers were scored under the "worst case scenario," and written answers were interpreted and converted into a code by 1 of the authors (FA). Sex differences were evaluated according to age, BMI, baseline and posttitration RDI, improvement of snoring, and amount of general and TMJ side effects.

Statistical analysis was performed using SPSS software program (SPSS, Inc., Chicago, Ill). Data were presented as percentages or as mean ± SD. To assess statistical significance before and after treatment, a paired Student *t* test was used. To compare the nonreturned, users, and nonusers groups, an analysis of variance was conducted. Changes of symptoms before and during treatment were analysed with a Wilcoxon paired matched test or a Yates corrected $\chi^2$ test. Differences between users and nonusers were evaluated using the Fisher exact 2-tail test. Correlations ($r$) were carried out with Pearson correlation tests for parametric variables and Spearman correlation tests for nonparametric variables. A $P$ value of $< .05$ was considered significant.

## RESULTS

All patients were referred for OA treatment by sleep physicians, otolaryngologists, or family physicians because of a confirmed diagnosis of OSA, disturbing snoring, or both. Of the 544 surveys mailed, 251 (46.1%) were returned. Of the patients who did not return surveys (53.7%), 0.9% were deceased, 15% of surveys were returned to us with an invalid address, and 37.8% were not returned. Out of the group that returned the questionnaire, 161 (64.1%) were still wearing their OA (users) and 90 patients (35.9%) had stopped treatment (nonusers). The mean ± SD time period between oral appliance insertion and the return date of

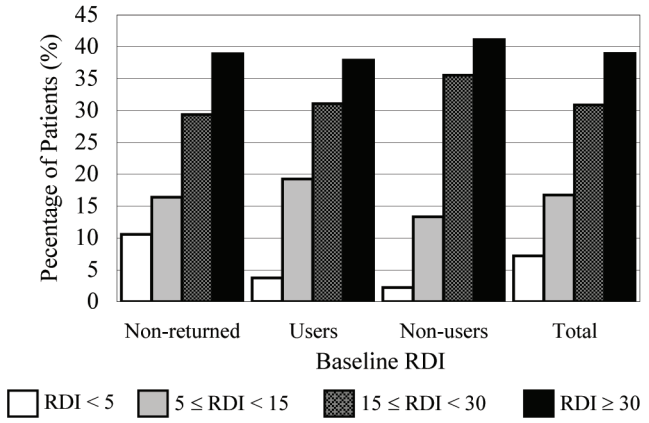


**Figure 1—**Baseline respiratory disturbance index (RDI) severity (%) in the non-returned, user, and nonuser groups. There was no statistically significant difference between the severity distribution within these groups.

these surveys was 5.7 ± 3.5 years (range 0.11-16.5 years). This interval was significantly smaller for the users (3.8 ± 3.2 years) (range 0.19-16.5 years) than the nonusers (6.2 ± 3.3 years) (range 0.21-13.2 years) and the nonreturned group (6.7 ± 3.4 years) (range 0.11-13.2 years). Of the initial 544 patients, 80.5% were men and 19.5% women; the sex distribution (men/women) for the nonreturned, users, and nonusers groups were 80.3%/19.7%, 84.2%/15.8% and 74.7%/25.3%, respectively. The mean age of the entire sample was 49.7 years, and the mean BMI was 29.0 kg/m$^2$; both characteristics presented similar values in the nonreturned, users, and nonusers groups. We did not have access to 34 of the 544 polysomnography or oximetry studies performed prior to the beginning of treatment. The baseline RDI of the entire sample was 29.2 ± 20 per hour; the nonreturned group showed a mean baseline RDI of 30.2 ± 20.4 per hour, while users and nonusers showed baseline RDIs of 28.6 ± 19.2 per hour and 31.9 ± 19.7per hour, respectively. The distribution according to disease severity showed a greater percentage of patients at baseline with OSA in the moderate to severe range (Figure 1). None of the groups were significantly different from each other with regard to OSA severity, age, BMI, baseline and posttitration RDI, or sex. The RDI with OA use significantly improved in all groups. The demographic data of these groups are provided in Table 1.

Within the users, 82.3% reported wearing the OA every night, and 10.3% used it 4 to 6 nights per week. Some 90.3% wore it for the whole night, and 9.7% for more than half of each night. Some 18% of the nonusers stopped wearing their appliance during the first month, 32% in the following 6 months, and another 22% before the end of the first year. The remaining 27% of nonusers withdrew treatment after 1 to 4 years of use, as illustrated in Figure 2. As shown in Table 2, the most frequent reasons why patients discontinued wearing the OA were that it was uncomfortable (44.9%), had little or no effect (36.0%), switched to nasal CPAP (23.6%), or had experienced a dry mouth (20.2%). A higher BMI was related to the choice to switch to CPAP, but it was not correlated to baseline or follow-up RDI. Reasons such as *uncomfortable* and *incovenient* were present more frequently in patients who stopped treatment within 6 months of OA use, and *changes in occlusion* was more frequently pointed out by patients who used their appliance for periods longer than 6 months. Some 18% underwent some form of surgery for snoring or OSA. Regarding the type of OA, 52 patients (9.4%) received an appliance other than Klearway™ in the entire sample; 17 of those were tongue-retaining device (TRD), and 25 were other mandibular repositioners (MR). In the users group, there were 3 TRD, 3 MR, and 154 Klearway™ appliances; in the nonusers groups, there were 9 TRD, 15 MR, and 66 Klearway™ appliances. The number of appliances used other than Klearway™ was statistically higher in the nonuser group.

At the time of this survey, 69.3% of users and 36.2% of nonusers had polysomnography or oximetry with the OA in place. The interval between the baseline and follow-up polysomnogram varied from 5 months to 4 years. We had access to follow-up records in 43% of users, 20% of nonusers, and 26% of the nonreturned group. The mean RDI with the OA in place was significantly reduced in all groups, from 28.6 ± 19.2 per hour to 15.4 ± 13.9 per hour for users, from 31.9 ± 19.7 per hour to 19.9 ± 16.6 per hour for nonusers, and from 30.2 ± 20.4 per hour

**Table 2—**Percentage of Patients Who Indicated Specific Reasons to Discontinue Oral Appliance Use

| Reason to discontinue | % of patients |
|---|---|
| Discomfort or cumbersome | 44.9 |
| No or little effect | 36.0 |
| Started continuous positive airway pressure | 23.6 |
| Mouth became too dry | 20.2 |
| Inconvenient to use | 18.0 |
| Painful | 15.7 |
| Dental work changed | 15.7 |
| Occlusion or jaw changes | 12.4 |
| Appliance doesn't fit any more | 7.9 |
| Lost weight, apnea lessened | 7.9 |
| Claustrophobic | 5.6 |
| Could not swallow | 5.6 |
| Apnea worsened | 2.2 |
| Lost the appliance | 1.1 |

**Table 1—**Baseline Demographic Characteristics for the Total Sample and Nonreturned, User, and Nonuser Groups

| | Total Sample | Nonreturned | Users | Nonusers |
|---|---|---|---|---|
| No. | 544 | 293 | 161 | 90 |
| Age, y | 49.7 ± 10.6 | 48.8 ± 11.1 | 50.6 ± 9.7 | 51.5 ± 10.2 |
| BMI, kg/m$^2$ | 29.0 ± 5.2 | 29.1 ± 5.2 | 29.0 ± 5.5 | 28.6 ± 4.6 |
| Baseline RDI, no./h | 29.2 ± 20.0 | 30.2 ± 20.4 | 28.6 ± 19.2 | 31.9 ± 19.7 |
| Posttitration RDI, no./h | 16.3 ± 14.9* | 16.1 ±15.4* | 15.4 ±13.9* | 19.8 ±16.6* |

There was a significant difference between baseline and posttitration respiratory disturbance index (RDI) (*$P$ < .05), but no differences within the subgroups. BMI refers to body mass index.

**Table 3**—Subjective Treatment Outcome Characteristics of User and Nonuser Groups

| | Users | Nonusers |
|---|---|---|
| Baseline ESS | 11.0 | 11.1 |
| ESS with oral appliance | 7.0 | 8.1 |
| Patient's snoring controlled, % | 75.6 | 43.2* |
| Patient's apnea improved, % | 59.4 | 26.7* |
| Patient's fatigue improved, % | 71.2 | 25.5* |
| Bed partner satisfied, % | 82.2 | 46.4* |

*$P < .05$
ESS refers to Epworth Sleepiness Scale.

to 16.1 ± 15.4 per hour for the nonreturned group. The baseline RDI was significantly correlated with the ESS score from the pretreatment questionnaire ($P < .001$). ESS scores for users and nonusers before treatment were similar (Table 3). A significant improvement in ESS was found in both groups, and there was no improvement difference between the groups. The snoring was satisfactorily controlled in 75.6% of users, and it was statistically less controlled in nonusers (43.2%). Similar significant results were reported regarding subjective improvement of apnea and fatigue, which was satisfactorily controlled in 59.4 and 71.2% of users and 26.7 and 25.5% of nonusers, respectively. Bed partner's satisfaction with the treatment outcome was significantly higher in users ($P < .05$). A subjective assessment of the sleep apnea and related symptoms is provided in Table 3.

With all side effects plotted together, 46% of the users and 59.1% of the nonusers reported the presence of 1 or more side effects (Table 4). From a total of 14 side effects, the mean number of side effects present per patient was statistically higher in the nonusers when compared to users: 9.1 ± 4.3 and 6.6 ± 3.3 side effects, respectively. A significantly greater percentage of the users, when compared to the nonusers, experienced fewer side effects, such as difficulty chewing with the back teeth, dry mouth, morning headaches, teeth apart in the morning, tongue discomfort, jaw discomfort, gum discomfort, sense of suffocation, movement of one or more teeth, and movement of the teeth so that the upper and lower jaws no longer meet properly. Side effects such as dry mouth and tooth and/or jaw discomfort were more frequent in non-users. Non-users scored higher for the following side effects: tongue discomfort, sense of suffocation, and movement of 1 or more teeth ($P < .05$). After OA therapy, 42.7% of the patients in the nonusers group classified their side effects as moderate to severe, compared to 32.8% of the users. The incidence of TMJ symptoms was calculated as less than 1 symptom per patient in the pretreatment evaluation, and it changed significantly for users and nonusers while under OA therapy, but there was no difference between the groups.

The percentage of men who stopped using the OA out of the men who returned the questionnaire was 32.8%, whereas for the women, this percentage was 46.8%. In the assessment of OSA, men had statistically more severe OSA at baseline than women. Women reported a significantly smaller reduction in their snoring and showed higher scores in the evaluation of the side effects related to OA use ($P < .05$) (Table 5). There were no significant sex differences according to the percentage who stopped using the OA, age, BMI, posttitration RDI, baseline, and an increase in TMJ symptoms.

## DISCUSSION

This questionnaire-based study presented a response rate of 46.7%. The returned and nonreturned groups had no differences with respect to apnea severity, sex, age, or type of appliance used, and, therefore, the 251 patients with snoring, OSA, or both who returned this survey were analysed as being representative of our

**Table 4**—Sides Effects in Patients Who Did and Did Not Use Oral Appliances

| Side effect | Frequency | | | | | | | | Severity | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Never | | Rarely | | Sometimes | | Often | | Mild | | Moderate | | Severe | |
| | U | N | U | N | U | N | U | N | U | N | U | N | U | N |
| Difficulty chewing in the morning | 45.8 | 37.1 | 18.1 | 5.6 | 13.5 | 6.7 | 18.7 | 11.2 | 24.0 | 10.1 | 14.3 | 7.9 | 5.8 | 4.5 |
| Difficulty chewing with back teeth | 51.6 | 36.0* | 14.8 | 6.7 | 15.5 | 6.7 | 14.2 | 12.4 | 20.0 | 9.0 | 13.5 | 9.0 | 5.8 | 5.6 |
| Excessive salivation | 31.0 | 31.8 | 14.2 | 11.4 | 28.4 | 11.4 | 20.0 | 9.1 | 24.5 | 12.4 | 20.6 | 9.0 | 3.2 | 3.4 |
| Dry mouth (xerostomia) | 36.1 | 18.2* | 20.6 | 13.6 | 22.6 | 17.0 | 14.2 | 20.5* | 23.2 | 11.2 | 16.8 | 18.0 | 3.2 | 10.1* |
| Morning headaches | 59.4 | 39.3* | 16.8 | 5.6 | 16.1 | 10.1 | 2.6 | 2.2 | 18.1 | 11.2 | 9.0 | 6.7 | 0.6 | 0.0 |
| Tooth discomfort | 26.5 | 18.0 | 24.5 | 6.7 | 28.4 | 19.1 | 14.8 | 22.5* | 40.0 | 5.6 | 13.5 | 25.8 | 1.9 | 9.0* |
| Teeth apart in the morning | 52.3 | 25.0* | 13.5 | 6.8 | 5.8 | 8.0 | 12.3 | 11.4 | 16.2 | 10.1 | 7.8 | 9.0 | 2.6 | 3.4 |
| Tongue discomfort | 58.7 | 33.0* | 14.2 | 6.8 | 16.1 | 9.1 | 5.8 | 8.0 | 16.1 | 3.4 | 8.4 | 14.6 | 2.6 | 4.5* |
| Jaw discomfort | 33.5 | 16.9* | 26.5 | 6.7 | 28.4 | 28.1 | 8.4 | 19.1* | 29.7 | 13.6 | 15.5 | 25.0 | 3.9 | 11.4* |
| Gum discomfort | 51.3 | 32.6* | 27.3 | 11.2 | 11.0 | 10.1 | 2.6 | 1.1 | 21.3 | 7.9 | 11.0 | 5.6 | 0.6 | 2.2 |
| A sense of suffocation | 74.8 | 42.7* | 10.3 | 6.7 | 8.4 | 7.9 | 0.6 | 3.4 | 11.6 | 4.5 | 3.9 | 9.0 | 0.0 | 2.2* |
| Movement of 1 or more teeth | 59.6 | 31.5* | 13.1 | 5.6 | 9.2 | 4.5 | 9.2 | 12.4 | 14.8 | 2.3 | 7.1 | 9.1 | 3.9 | 3.4* |
| Movement of the teeth so that upper and lower jaws no longer meet properly | 47.7 | 29.2* | 10.5 | 3.4 | 9.2 | 9.0 | 17.0 | 12.4 | 16.8 | 7.9 | 8.4 | 9.0 | 7.1 | 7.9 |

Differences between oral appliance users (U) and nonusers (NU), expressed as percentage of patients who never experienced a specific side effect and the frequency and severity of those who did report side effects. *$P < .05$

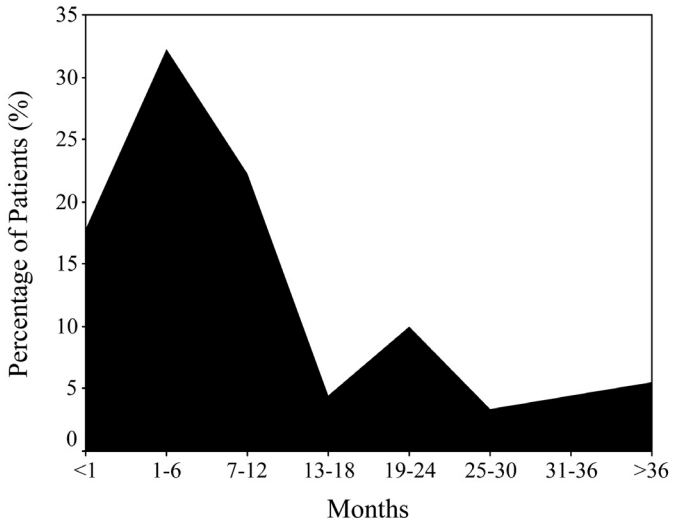


**Figure 2—**Percentage of patients who discontinued oral appliance use according to duration (months) of wear.

clinic population. After a mean of 5.7 years, 35.9% of the patients stopped OA treatment (nonusers); 72% of those did so during the first year of treatment. All groups showed a significant reduction in RDI and sleepiness. OA users had their snoring and fatigue better controlled, and their bed partners were more satisfied with treatment, as compared to nonusers.

We anticipated lower compliance among the severe cases due to the possible reduced efficacy of the OA in those cases, but the present results demonstrate that neither disease severity nor baseline sleepiness were predictors of OA compliance. When compared to CPAP studies, the OSA severity of patients in our study is less severe, although 69% of the patients had OSA in the moderate to severe range. OAs are effective for treating snoring and mild OSA, but, for moderate and severe cases, the success rate ranges only from 35% to 60%.[14,35] The percentage of patients referred for OA therapy with an RDI < 20 per hour has been reported to be as high as 59% to 72%.[25,28] In contrast, our sample showed that only 36.4% of the patients had an RDI < 20 per hour, which suggests that most were CPAP failures. In this sense, our sample was biased, since these patients were already in a second type of treatment. This could be related to a more symptomatic population, a group of patients with a greater understanding of the present disease consequences, or both. Because of the expertise of the University of British Columbia group in the OA field, the referrals to OA therapy in this setting might be biased toward more-complicated cases, and the greater percentage of patients complaining of the lack of OA efficacy in the present study could be explained by the severity of the disease of the patients evaluated. Marklund et al[28] evaluated a population with less-severe OSA and reported that 22% of the patients who discontinued treatment reported a poor effect on snoring. Patients tended to discontinue OA treatment in this report not only due to side effects, but also because some 35% of the nonusers reported little or no effect of the OA. The rate of noncompliance was not correlated to the baseline OSA severity or sleepiness, similar to data described by McGown et al.[24] Since there are different devices that have been used by different clinicians, the generalizability of these results toward populations with more-severe OSA should be interpreted with caution, and further studies with less population bias are still needed.

**Table 5**—Sex Differences in the Returned Sample

| | Men | Women |
|---|---|---|
| Stopped treatment, % | 32.8 | 46.8 |
| Age, y | 50.9 | 50.7 |
| BMI, kg/m$^2$ | 28.3 | 31.9 |
| RDI, no./h | | |
| Baseline | 31.8 | 21.3* |
| With oral appliance | 17.6 | 9.3 |
| Patient's snoring controlled, % | 68.8 | 51.2* |
| Side-effect score† | 16.2 | 20.6* |
| TMJ symptom score‡ | | |
| Baseline | 0.8 | 1.4 |
| Increase with use of oral appliance | 1.3 | 1.9 |

*$P < .05$

†A maximum score of 84 is calculated from 14 questions, each worth 6 points.

‡The score is calculated based on responses to 13 questions regarding temporomandibular joint (TMJ) symptoms being absent (0) or present (1). Maximum score is 13.

Failure to comply with CPAP treatment has been reported to be 83% in mild apneics,[20] and resistance to this type of therapy has been described to be as high as 25% to 50% in the general sleep apnea population.[17,18] Although the present study was based on self-reported compliance, users reported good compliance for more hours per night (90.3% use it all night) and more days per week (82.3% use it every night). McGown et al[24] found similar results with patients using the OA for a mean period of 6.6 hours after a 22-month period. The treatment compliance rate after a mean period of 5.7 years in this study was 64.1%, which appears to be a well-accepted treatment modality for this type of disease. The present study results are in agreement with previous reports in which the compliance rates for the first year range from 48% to 84%[22,23] and drop after more than 4 years to 62% to 76%.[26,30] Since these are survey data, all the nonreturned questionnaires could be interpreted as compliance failures, and then the compliance rate of the OA should drop to 29.3%. However, we did rely on a representative response of the questionnaires, and since there were no differences between the returned and nonreturned questionnaires regarding apnea severity, sex, age, or type of appliance used, we have considered the OA compliance to be 64.1%. Our study relied on subjective questionnaires with obvious limitations, which could be an overestimation of OA use. With the use of a temperature-sensitive compliance monitor, a mean OA use of 6.8 hours per night has been documented in 1 study,[35] but long-term objective OA compliance data is still unavailable. Low levels of compliance have been suggested to decrease the effectiveness of CPAP.[36] It is still unclear whether OAs, even though less effective than CPAP, could achieve the same effectiveness if used for more hours per night. Although the majority of our cases with moderate to severe OSA were unable or unwilling to use CPAP, 23% of our nonusers did switch back to CPAP after the OA trial. From our analysis, the higher the BMI, the more likely the patient was to accept CPAP treatment after OA failure, but there was no correlation with RDI.

In the group that discontinued treatment (nonusers), 27% wore an appliance other than Klearway™, compared to 1.5% in the users group. Even though the number of patients wearing an OA other than Klearway™ was small, we found a statistically better

tolerability with this appliance. Pitsis et al,[37] in a randomized controlled trial, reported that patients had a higher preference for OAs with a smaller degree of opening. The degree of mandibular advancement has a positive correlation with the efficacy of the OA.[38,39] Appliances with a design similar to Klearway™ have shown comparable compliance rates,[22,23] but there is still a need for longer clinical trials with the same clinical management to compare different types of OAs. Although there are no large clinical trials comparing TRD with MR, it has been reported that TRD are less effective than titratable MR.[40,41] TRD may be more difficult to wear and tolerate, as evidenced by the 75% of the TRD patients in this study who discontinued treatment.

Although our study is retrospective, it is interesting to evaluate side effects at different intervals of OA use. As shown previously, we also found that, when compared to users, nonusers reported a significantly greater number of side effects per patient;[24] more-frequent and severe dry mouth or tooth or jaw discomfort; and more severe tongue discomfort, sense of suffocation, movement of teeth and also excessive salivation, which is a short-term side effect that tends to improve over time.[23,29,30] In the evaluation of nonusers, our data suggest that patients who feel uncomfortable with the appliance and experience more side effects tend to stop using it sooner. Patients who are able to use it for longer periods might have experienced milder problems, which encouraged them to get used to wearing the appliance. Otsuka et al[42] reported an objective decrease in occlusal contact and bite force in the morning after OA use. Interestingly, our patients reported that difficulty chewing with the back teeth or in the morning decreased with the longer use of an OA. According to patient reports, subjective benefits of OA therapy outweigh these side effects, and patients did not perceive most tooth movements unless their dentist brought it to their attention.[29] As expected, with only a subjective evaluation of the side effects, the current study found fewer dental changes than the above-mentioned authors. For nonusers, occlusal changes given as a reason to discontinue treatment showed a positive correlation with increasing length of OA use and appear to be an important reason only after a year of OA use. We hypothesize that some patients adapt to this type of side effect, changing their eating habits in the morning or their masticatory pattern, because it is unlikely that such a side effect would decrease over time. Of the 14 side effects investigated in this survey, 50% of users and 54% of nonusers reported no side effects. The difference in long-term use seems to be related not only to the number of side effects,[24] but also to the impact of the side effects, since nonusers experienced more frequent and more severe side effects, as shown by reporting their side effects to be more often in the moderate to severe categories.

TMJ symptoms increased with OA use but were not related to the discontinuation of treatment or sex. In contrast to previous studies,[23,25] we could not find a higher incidence of TMJ discomfort in early treatment, but this could be because of the retrospective nature of this study. Similar to TMJ disorder incidence studies,[43,44] women in our sample had more TMJ complaints, but OA use did not show any different increase in those symptoms when compared to men. Since the questionnaire used for the TMJ assessment had some questions that represent common side effects of OAs as well as TMJ symptoms, we interpret the increase of a mean of 1.3 symptoms to be potentially related only to occlusal changes with respect to OA use.

Women experienced more side effects and seemed to have a greater tendency to abandon treatment than did men, as 46.8% of the women who answered the survey had discontinued use, compared to 32.8% of men. Although women are more likely to have treatment success,[28] we discovered that a higher percentage of women discontinued treatment. Considering no differences between sexes according to age, BMI, or sleepiness, women's noncompliance may be related to a greater perception or presence of side effects.

The present study has several potential limitations. The response sample was considered representative, and it may have resulted in a sample bias in favor of a good response to OA therapy. As a retrospective study, we have to consider that the data were collected from different patients at different time intervals, and longer and larger-sample prospective studies on OA use are required. With regard to the different OA types, the expertise of the dental staff in this study was higher with the Klearway™ appliance, and crossover studies could produce more reliable results. As a retrospective study, we did not have access to polysomnography records for all subjects, but this might be representative of the majority of clinics dealing with patients with OSA. A questionnaire-based survey always evaluates subjective symptoms, since it is the nature of such protocol, but it is still of great importance in the assessment of a large number of patients to gain an overall understanding of compliance and side effects. Despite the numerous types of OAs and the new development of titratable appliances, dentists in the sleep field may not be fully aware of the need for educational intervention and to include, based on this study, a more aggressive follow-up protocol to improve compliance, reduce side effects, and consequently increase the effectiveness of OA therapy.

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## REFERENCES

1. Young T, Palta M, Dempsey J, Skatrud J, Weber S, Badr S. The occurrence of sleep-disordered breathing among middle-age adults. N Engl J Med 1993;328:1230-5.
2. Durán J, Esnaola S, Rubio R, Iztueta A. Obstructive sleep apnea-hypopnea and related clinical features in a population-based sample of subjects aged 30 to 70 yr. Am J Respir Crit Care Med 2001;163:685-9.
3. Lindberg E, Janson C, Svärdsudd K, Gislason T, Hetta J, Boman G. Increased mortality among sleepy snorers: a prospective population based study. Thorax 1998;53:631-7.
4. American Sleep Disorders Association Standards of Practice Committee. Practice parameters for the treatment of snoring and obstructive sleep apnea with oral appliances. Sleep 1995;18:511-3.
5. Tsuiki S, Lowe AA, Almeida FR, Fleetham JA. Effects of an anteriorly titrated mandibular position on awake airway and obstructive sleep apnea severity. Am J Orthod Dentofacial Orthop 2004;125:548-55.
6. Villa MP, Bernkopf E, Pagani J, Broia V, Montesano M, Ronchetti

R. Randomized controlled study of an oral jaw-positioning appliance for the treatment of obstructive sleep apnea in children with malocclusion. Am J Respir Crit Care Med 2002;165:123-7.
7. Hans MG, Nelson S, Luks VG, Lorkovich P, Baek SJ. Comparison of two dental devices for treatment of obstructive sleep apnea syndrome (OSAS). Am J Orthod Dentofacial Orthop 1997;111:562-70.
8. Randerath WJ, Heise M, Hinz R, Ruehle KH. An individually adjustable oral appliance vs continuous positive airway pressure in mild-to-moderate obstructive sleep apnea syndrome. Chest 2002;122:569-75.
9. Johnston CD, Gleadhill IC, Cinnamond MJ, Peden WM. Oral appliances for the management of severe snoring: a randomized controlled trial. Eur J Orthod 2001;23:127-34.
10. Tan YK, L'Estrange PR, Luo YM, et al. Mandibular advancement splints and continuous positive airway pressure in patients with obstructive sleep apnoea: a randomized cross-over trial. Eur J Orthod 2002;24:239-49.
11. Rose E, Staats R, Virchow C, Jonas IE. A comparative study of two mandibular advancement appliances for the treatment of obstructive sleep apnoea. Eur J Orthod 2002;24:191-8.
12. Mehta A, Qian J, Petocz P, Darendeliler MA, Cistulli PA. A randomized, controlled study of a mandibular advancement splint for obstructive sleep apnea. Am J Respir Crit Care Med 2001;163:1457-61.
13. Gotsopoulos H, Chen C, Qian J, Cistulli PA. Oral appliance therapy improves symptoms in obstructive sleep apnea: a randomized, controlled trial. Am J Respir Crit Care Med 2002;166:743-8.
14. Gotsopoulos H, Kelly JJ, Cistulli PA. Oral appliance therapy reduces blood pressure in obstructive sleep apnea: A randomized, controlled trial. Sleep 2004;27:934-41.
15. Barnes M, McEvoy RD, Banks S, et al. Efficacy of positive airway pressure and oral appliance in mild to moderate obstructive sleep apnea. Am J Respir Crit Care Med 2004;170:656-64.
16. Zozula R, Rosen R. Compliance with continuous positive airway pressure therapy: assessing and improving treatment outcomes. Curr Opin Pulm Med 2001;7:391-8.
17. Reeves-Hoche MK, Meck R, Zwillich CW. Nasal CPAP: an objective evaluation of patient compliance. Am J Respir Crit Care Med 1994;149:149-54.
18. Krieger J. Long-term compliance with nasal continuous positive airway pressure (CPAP) in obstructive sleep apnea patients and nonapneic snorers. Sleep 1992;15(6 Suppl):S42-6.
19. Grunstein, RR. Sleep-related breathing disorders. 5. Nasal continuous positive airway pressure treatment for obstructive sleep apnoea Thorax, Oct 1995; 50:1106-13.
22. Fransson AM, Tegelberg A, Leissner L, Wenneberg B, Isacsson G. Effects of a mandibular protruding device on the sleep of patients with obstructive sleep apnea and snoring problems: a 2-year follow-up. Sleep Breath 2003;7:131-41.
23. Clark GT, Sohn JW, Hong CN. Treating obstructive sleep apnea and snoring: assessment of an anterior mandibular positioning device. JADA 2000;131:765-71.
24. McGown AD, Makker HK, Battagel JM, L'Estrange PR, Grant HR, Spiro SG. Long-term use of mandibular advancement splints for snoring and obstructive sleep apnoea: a questionnaire survey. Eur Respir J 2001;17:462-6.
25. Pantin CC, Hillman DR, Tennant M. Dental side effects of an oral device to treat snoring and obstructive sleep apnea. Sleep 1999;22:237-40.
26. Ringqvist M, Walker-Engström ML, Tegelberg A, Ringqvist I. Dental and skeletal changes after 4 years of obstructive sleep apnea treatment with a mandibular advancement device: a prospective, randomized study. Am J Orthod Dentofacial Orthop 2003;124:53-60.
27. Rose E, Staats R, Schulte-Mönting J, Ridder GJ, Jonas IE. Long term compliance with an oral protrusive appliance in patients with obstructive sleep apnoea. Dtsch Med Wochenschr 2002;127:1245-9.
28. Marklund M, Franklin KA, Persson M. Orthodontic side-effects of mandibular advancement devices during treatment of snoring and sleep apnoea. Eur J Orthod 2001;23:135-44.
29. Fritsch KM, Iseli A, Russi EW, Bloch KE. Side effects of mandibular advancement devices for sleep apnea treatment. Am J Respir Crit Care Med 2001;164:813-8.
30. Marklund M, Stenlund H, Franklin KA. Mandibular advancement devices in 630 men and women with obstructive sleep apnea and snoring: tolerability and predictors of treatment success. Chest 2004;125:1270-8.
31. Bondenmark L. Does 2 years' nocturnal treatment with mandibular advancement splint in adult patients with snoring and OSAS cause a change in the posture of the mandible? Am J Orthod Dentofacial Orthop 1999;116:621-8.
32. Robertson C, Herbison P, Harkness M. Dental and occlusal changes during mandibular advancement splint therapy in sleep disordered patients. Eur J Orthod 2003;25:371-6.
33. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The Report of an American Academy of Sleep Medicine Task Force. Sleep 1999;22:667-89.
34. Johns MW. A new method for measuring daytime sleepiness: the Epworth Sleepiness Scale. Sleep 1991;14:540-5.
35. Lowe AA, Sjöholm TT, Ryan CF, Fleetham JA, Ferguson KA, Remmers JE. Treatment, airway and compliance effects of a titratable oral appliance. Sleep 2000;23:S172-8.
36. Marshall M, Coughlin S. Does positive airway pressure therapy provide a symptomatic benefit at low levels of compliance? Sleep 2004;27:210.
37. Pitsis AJ, Darendeliler MA, Gotsopoulos H, Petocz P, Cistulli. Effect of vertical dimension on efficacy of oral appliance therapy in obstructive sleep apnea. Am J Respir Crit Care Med 2002;166:860-4.
38. de Almeida FR, Bittencourt LR, de Almeida CIR, Tsuiki S, Lowe AA, Tufik S. Effects of mandibular posture on obstructive sleep apnea severity and the temporomandibular joint in patients fitted with an oral appliance. Sleep 2002;25:507-13.
39. Kato J, Isono S, Tanaka A, et al. Dose-dependent effects of mandibular advancement on pharyngeal mechanics and nocturnal oxygenation in patients with sleep-disordered breathing. Chest 2000;117:1065-72.
40. Ono T, Lowe AA, Ferguson KA, Fleetham JA. A tongue retaining device and sleep-state genioglossus muscle activity in patients with obstructive sleep apnea. Angle Orthod 1996;66:273-80.
41. Barthlen GM, Brown LK, Wiland MR, Sadeh JS, Patwari J, Zimmerman M. Comparison of three oral appliances for treatment of severe obstructive sleep apnea syndrome. Sleep Med 2000;1:299-305.
42. Otsuka R, Almeida FR, Lowe AA. The effects of oral appliance therapy on occlusal function in patients with obstructive sleep apnea: a short-term prospective study. Am J Orthod Dentofacial Orthop 2005: In Press.
43. Gesch D, Bernhardt O, Alte D, Schwahn C, Kocher T, John U, Hensel E. Prevalence of signs and symptoms of temporomandibular disorders in an urban and rural German population: results of a population-based Study of Health in Pomerania. Quintessence Int 2004;35:143-50.
44. Hiltunen K, Peltola JS, Vehkalahti MM, Närhi T, Ainamo A. 5-year follow-up of signs and symptoms of TMD and radiographic findings in the elderly. Int J Prosthodont 2003;16:631-4.

## APPENDIX

*Side Effects and Long-Term Compliance of Oral Appliances Used for the Treatment of Snoring and Obstructive Sleep Apnea*

**1. Are you still wearing your oral appliance (OA)?**

If ☐ **Yes** answer here: ⇊

**2a. How many nights do you use it?**
- ☐ Every night
- ☐ 4 to 6 nights a week
- ☐ 1 to 3 nights a week
- ☐ Less than once a week

**3a. How much of the night do you use it?**
- ☐ All night
- ☐ More than half of the night
- ☐ Half of the night
- ☐ Less than half of the night

**4a. How satisfied are you with the OA?**
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

**5a.What is the frequency of complications related to the appliance?**
- ☐ None
- ☐ Less than once a month
- ☐ Once a month
- ☐ Every second week
- ☐ 1 to 3 times a week
- ☐ 4 to 6 times a week
- ☐ Every day

If ☐ **No** answer here: ⇊

**2b. How long did you use the oral appliance?**

_____Years _____Months

**3b. Have you undergone any other treatment for snoring or apnea?**

☐ No ☐ Yes

If Yes, which? _____

_____

When? _____Year _____Month

**4b. When did you stop using the oral appliance?**

_____Year _____Month

**5b. Why did you stop wearing the OA? Mark all that apply to you.**
- ☐ No/little effect
- ☐ Occlusion/jaw changes
- ☐ Uncomfortable/cumbersome
- ☐ Painful
- ☐ Inconvenient to use
- ☐ Dental work changed
- ☐ Appliance doesn't fit any more
- ☐ Apnea worsened
- ☐ Lost weight, apnea lessened
- ☐ Started CPAP
- ☐ Lost the appliance
- ☐ Claustrophobic
- ☐ Could not swallow
- ☐ Mouth became too dry
- ☐ Other (Please Specify)

_____

_____

**6. Do you/did you experience any of these side effects while wearing the oral appliance?**

| Side Effect | Frequency = How Often | | | | Severity = How Much | | |
|---|---|---|---|---|---|---|---|
| | Never | Rarely | Sometimes | Often | Mild | Moderate | Severe |
| a. Difficulty chewing in the morning | | | | | | | |
| b. Difficulty in chewing on your back teeth | | | | | | | |
| c. Excessive salivation | | | | | | | |
| d. Dry mouth (xerostomia) | | | | | | | |
| e. Morning headaches | | | | | | | |
| f. Tooth discomfort | | | | | | | |
| g. Teeth apart in the morning | | | | | | | |
| h. Tongue discomfort | | | | | | | |
| i. Jaw discomfort | | | | | | | |
| j. Gum discomfort | | | | | | | |
| k. A sense of suffocation | | | | | | | |
| l. Movement of one or more teeth | | | | | | | |
| m. Movement of the teeth so upper & lower jaws no longer meet properly | | | | | | | |
| n. Other (Please specify) | | | | | | | |

Please continue on next page….

**7. Do you/did you experience any of these situations after the oral appliance?**

| Situation | Before OA | | While Wearing | |
|---|---|---|---|---|
| | Yes | No | Yes | No |
| a. Difficulty and/or pain e.g. when yawning? | | | | |
| b. Does your jaw get "stuck", "lock", or "go out"? | | | | |
| c. Difficulty closing your jaw after it is open? | | | | |
| d. Difficulty and/or pain when using your jaws (chewing/talking)? | | | | |
| e. Difficulty eating chewy foods (breads, meats) | | | | |
| f. Difficulty biting into hard foods (raw vegetables, apples)? | | | | |
| g. Noises coming from the jaw joints? | | | | |
| h. Stiff, tight or tired feeling jaws? | | | | |
| i. Pain in or around ears, temples or cheeks? | | | | |
| j. Frequent headaches, neck aches or tooth aches? | | | | |
| k. An injury to your head, neck or jaw? | | | | |
| l. Changes in your bite? | | | | |
| m. Have you been treated for a jaw joint problem? | | | | |

**8. How likely are you/were you to doze off or fall asleep in the following situations, in contrast to just feeling tired? Even if you have not done some of these things recently, try to work out how they would have affected you.**

Please use the following scale to choose the most appropriate number for each situation:
0 = would never doze
1 = slight chance of dozing
2 = moderate chance of dozing
3 = high chance of dozing

| Situation | Before Appliance | With Appliance |
|---|---|---|
| a. Sitting and reading | | |
| b. Watching TV | | |
| c. Sitting, inactive in a public place (theatre, meeting) | | |
| d. As a passenger in a car for an hour without a break | | |
| e. Lying down to rest in the afternoon when circumstances permit | | |
| f. Sitting and talking to someone | | |
| g. Sitting quietly after a lunch without alcohol | | |
| h. In a car, while stopped for a few minutes in traffic | | |

**9. How satisfied is/was your partner with the use of the appliance?**

☐ Very satisfied ☐ Moderately satisfied ☐ Moderately dissatisfied ☐ Very dissatisfied ☐ Not Applicable

**10. How would you classify your side effects?**

☐ None ☐ Mild ☐ Moderate ☐ Severe

**11. Did you return to the sleep specialist to have a repeat overnight study with the appliance in place?**

☐ No ☐ Yes When? _____Year _____ Month

**12. Did you return to the sleep specialist to have a repeat home oximetry test with the appliance in place?**

☐ No ☐ Yes When? _____Year _____ Month

**13. How common is/was your breath cessation (apneas)?**

**a. Before Appliance**
- ☐ None/Not Applicable
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ I don't know

**b. With Appliance**
- ☐ No change
- ☐ Totally controlled
- ☐ Satisfactorily controlled
- ☐ Not satisfactorily controlled
- ☐ I don't know

Please turn page over ….

**14. How significant is/was your sleepiness (fatigue)?**

**a. Before Appliance**
- ☐ None/Not Applicable
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ I don't know

**b. With Appliance**
- ☐ No change
- ☐ Totally controlled
- ☐ Satisfactorily controlled
- ☐ Not satisfactorily controlled
- ☐ I don't know

**15. How significant is/was your snoring?**

**a. Before Appliance**
- ☐ None/Not Applicable
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ I don't know

**b. With Appliance**
- ☐ No change
- ☐ Totally controlled
- ☐ Satisfactorily controlled
- ☐ Not satisfactorily controlled
- ☐ I don't know

**16. Were there any other problems with your oral appliance? Do you have any additional comments?**

_____

_____

We need to calculate your body mass index as a predictor of sleep apnea severity, and to do so we require both your current height and weight.

Height: _____ ft _____in or _____cm
Weight: _____lbs or _____kg

Your Name: _____ Date:_____

Thank You