

Dental Side Effects of an Oral Device to Treat Snoring and Obstructive Sleep Apnea

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Study Objectives: Snoring and obstructive sleep apnea (OSA) are common and related conditions—with major social and health implications—which can be treated successfully with dental devices that reposition the mandible. Despite wide use, side effects of these devices have not yet been systematically evaluated. The purpose of the study was to evaluate side effects of a mandibular advancement splint (MAS) previously described by the authors.

Design: Questionnaire survey and dental examination of a consecutive case series of patients treated with the MAS

Setting: Dental outpatient clinic

Patients: Attempts were made to contact all 191 patients treated over a 5-year period. All had snored loudly and habitually with or without OSA prior to treatment.

Measurements and Results: Of 191 patients treated, 132 agreed to complete the questionnaire. All were scheduled to attend for dental examination and 106 underwent examination. Of the 132 interviewed, patient and partner report indicated that the device was well tolerated and controlled snoring satisfactorily in 100 after 31 ± 18 (mean \pm SD) months of use. Dental side effects were reported in 107 patients, although these were mostly minor, and only 10 patients ceased using the device because of them. Side effects included excess salivation (in 40), xerostomia (in 30), temporomandibular joint pain (in 35), dental discomfort (in 35), myofascial discomfort (in 33) and bite changes (in 16). Of 106 patients examined, 30 had increased maximal opening and 76 had no change compared with pretreatment records. Temporomandibular joint noises were found in 9 patients, and occlusal changes (12m mylar strip and wax bite, relative to pretreatment) in 15. None of these effects could be related to degree of opening or protrusion produced by the MAS.

Conclusion: Dental side effects occur in a significant proportion of patients using the MAS. In most cases these are minor and their importance must be balanced against the efficacy of the MAS in treating snoring and OSA.

Key words: Dental appliances; snoring; sleep apnea; side effects

In recent years, dental devices have assumed an increasingly important role in the treatment of snoring and obstructive sleep apnea (OSA), particularly in its milder forms.¹⁻³ We have previously reported our early experience with a dental device that repositions the mandible during sleep,³ a treatment now commonly used. The device we use

advances the mandible to approximately 75% of maximum protrusion (between 3 and 16 mm in our patients), similar to the advancement used by other groups.⁴ While there is a growing literature demonstrating the efficacy of these devices in the treatment of snoring and OSA, their side effects have not been formally investigated. Knowledge of side effects and their likely prevalence is important in helping to optimize patient selection and monitoring of treatment. Furthermore, providing patients with this information is an essential element in obtaining informed consent for the proposed treatment plan. Of most concern is the potential that the device may occasionally exacerbate tem-

Accepted for publication August, 1998

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poromandibular joint dysfunction or induce occlusal change⁵—conditions which, if unrecognized and untreated, are sources of significant morbidity.

As the nature and extent of dental side effects of mandibular repositioning devices have not previously been evaluated systematically despite their wide use, we undertook a review of the first 5 years' use of our device to determine them. We regarded side effects such as occlusal change and temporomandibular joint dysfunction as likely to be related to the principle of treatment—mandibular repositioning—rather than the particular device used to achieve it. Hence the results of a survey of side effects of our device should be relevant to clinical practice with the wide variety of mandibular repositioning devices described elsewhere.^{1,2}

METHODS

Attempts were made to contact all patients treated with the mandibular advancement splint over a 5-year period (to late 1996). All patients had been referred for treatment by sleep physicians or otorhinolaryngologists because of loud habitual snoring with or without OSA. Polysomnography had been performed on most patients prior to referral, the only exceptions being some patients with no clinical evidence of OSA. Patients with an apnea-hypopnea index (AHI) >20 were referred only if nasal continuous positive airway pressure (nCPAP) therapy had been refused or was not tolerated.³

Each patient contacted was administered a questionnaire by a single observer (CCP) by telephone. Patients were asked about their compliance with treatment, whether their partner thought the device satisfactorily controlled the snoring, and about occurrence of side-effects, including disturbances of salivation, pain, and occlusal changes.

Following the questionnaire, each patient was asked to attend for dental examination, at which maximum opening, the temporomandibular joint, and occlusal relationships were assessed. Maximum opening was defined as the maximum vertical interincisal distance. Temporomandibular joint examination included assessment for the presence of joint noises and pain on palpation of the joint capsule and the muscles of mastication. Occlusal changes were assessed using shimstock (12 mm thick) passed through the occlusion with the patient biting in centric occlusion. In addition, a wax bite was taken to record the interarch relationship. This new bite registration was compared with original dental study models constructed prior to treatment.

All statistical analysis was carried out using the SPSS statistical package. Chi-square and two-tailed Student's *t* tests were used to analyze nominal and interval data respectively. A value of $p < 0.05$ was regarded as significant.

RESULTS

A total of 191 patients were treated over a 5-year period to late 1996. Of the 191 patients treated, 132 completed the questionnaire, while 46 (24%) could not be contacted, and 13 (7%) refused to be involved.

All of the 132 patients who completed the questionnaire (age 47.5 ± 9.9 years (mean \pm sd); 119 males) had complained of loud habitual snoring prior to treatment. Pre-treatment polysomnography, performed in 121 patients (see Methods), revealed a mean AHI of 22.1 ± 18.4 . AHI was >20 in 54 patients.

Questionnaire

Of the 132 patients interviewed, snoring was reported to them by their partners to be satisfactorily controlled in 107 (81%) but not in 18 (14%). Control of snoring was unknown in 7 (5%), as they did not have current partners.

A total of 100 patients (76%) reported continuing regular use of the appliance (duration of treatment 31 ± 18 months), while 32 (24%) had discontinued its use. The reasons for ceasing use in these 32 patients were: device not sufficiently effective in reducing snoring (by partner's estimate) in 11 (8%); side effects in 10 (7.5%); constant involuntary removal of device during sleep in 2 (1.5%); other treatment instituted even though device successful in controlling snoring in 4 (3%); and no specific reason in 5 (4%).

A total of 107 patients (81%) reported side effects. These included excessive salivation in 40 (30%), xerostomia in 30 (23%), temporomandibular joint pain in 35 (26%), dental pain in 35 (26%), myofascial pain in 33 (25%), and occlusal changes in 16 (12%). While most of these side effects were of a minor and temporary nature, 10 patients (7.5%) ceased treatment because of them, 8 because of pain (arising from the temporomandibular joint, facial muscles, or teeth), and 2 because of occlusal change.

Dental Examination

On completion of the questionnaire, all patients were scheduled for dental examination. Of the 132 patients interviewed, 106 were examined. Patients who answered the questionnaire but did not come in for examination ($n=26$) were not significantly different from those examined ($p > 0.05$) in the vertical opening or degree of mandibular protrusion produced by their device at the time of prescription or in the reported occurrence of temporomandibular joint pain, facial muscle pain, excessive salivation or occlusal change. However, a significantly greater proportion of partners reported that the device did not work in those who were not examined than those examined (36% and 9% respectively; $p < 0.002$). In addition, the group not examined had had the device for a significantly longer time

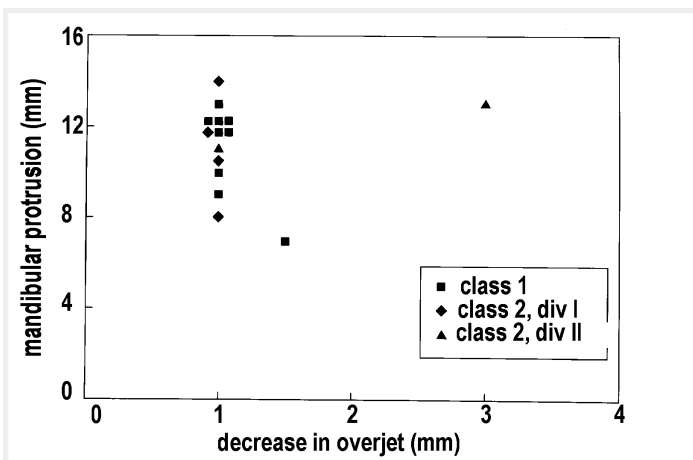


Figure 1.—The relationship between occlusal changes and degree of protrusion produced by the mandibular advancement splint in the 15 patients who developed clinically evident occlusal changes with its use. Class of malocclusion of each patient is indicated, using Angle's classification.⁷

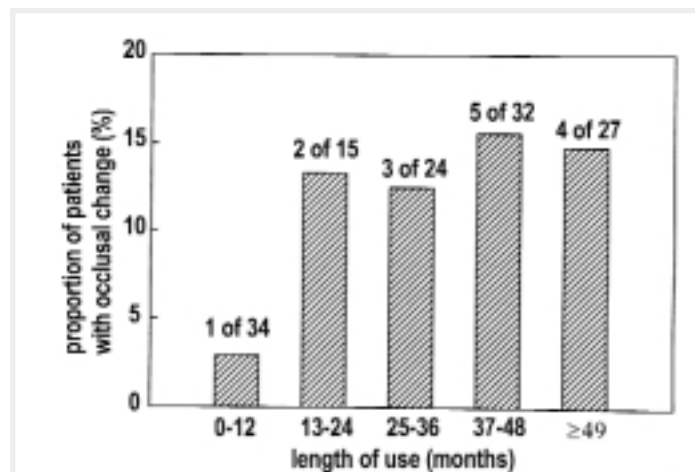


Figure 2.—The relationship between length of use of the mandibular advancement splint and proportion of patients with occlusal change. The number of patients with occlusal change relative to the total number of patients for each time interval is indicated above each bar.

than those who did (37.7 ± 14.2 and 30.3 ± 19.2 months respectively; $p < 0.05$).

Examination of the temporomandibular joints revealed noises in 9 of the 106 patients (8%) who did not have joint noises prior to treatment. No patients were found to have a decrease in mouth opening; however, increased mouth opening was found in 30 (28%).

Occlusal changes were detected on examination in 15 patients (14%). In each of these cases, a decrease in overjet of between 1 and 3 mm was observed. There was no significant ($p > 0.05$) relationship between the degree of change and either the degree of protrusion produced by the mandibular advancement splint or the type of malocclusion⁶ (see Appendix) present before treatment (Fig. 1). Eight of these 15 patients were not aware of their occlusal changes; conversely, 9 of the 16 patients who had reported bite changes during the questionnaire had no evidence of them on examination. The proportion of patients with occlusal change increased with length of use of the mandibular advancement splint up to 2 years. Beyond 2 years, the proportion remained relatively constant (Fig. 2).

DISCUSSION

This study demonstrates that side effects are common in patients treated for snoring (with or without sleep apnea) with a mandibular repositioning device. In most cases these were of a minor nature and decreased with continuing use of the device. In 7.5% of the patients, side effects were sufficient to cause them to stop treatment, the most common being temporomandibular joint pain. In only two patients were occlusal changes the reason for discontinuing treatment.

The development of these problems is not surprising,

given the significant forces applied to the teeth and temporomandibular joint in repositioning the mandible. In most cases the occlusal changes were minor and often not noticed by the patient, because the majority did not have loss of posterior occlusion or experience temporomandibular joint pain. Such problems were managed conservatively, using temporary cessation or reduction in the use of the device together with remedial exercises⁷ each morning following its removal. Our experience suggests that, with exercises, the occlusal changes resolve within 2 weeks of treatment cessation in most cases, consistent with the findings of others.⁸ Following satisfactory resolution, nightly treatment can resume with an ongoing exercise regimen and careful monitoring. We consider it reasonable to persist with treatment in the presence of occlusal change, providing that it is regularly monitored (by at least 6-month clinical reviews), not associated with unacceptable symptoms, not progressive, and that there is adequate posterior occlusal support. However, failure to respond to conservative management, particularly if there is a loss of posterior occlusion, may necessitate permanent treatment cessation, as was the case with two of our patients.

The satisfactory response of most patients to exercises, both initially to treat occlusal change and subsequently as a prophylactic measure, suggests that these problems develop because of a failure to reposition the mandible during the day following use rather than as the result of immutable changes in occlusion caused by the device overnight. The lack of a significant relationship between the degree of mandibular advancement produced by the device and the magnitude of occlusal change (Fig. 1) suggests that any degree of mandibular advancement could cause occlusal changes in predisposed individuals. The absence of a rela-

tionship between class of malocclusion⁶ (see Appendix) and magnitude of occlusal change (Fig. 1) suggests that such a predisposition cannot be predicted from the characteristics of the occlusion before treatment. The proportion of patients developing occlusal changes increased with length of use of the device over the first 2 years (to 13.3% of cases), and remained relatively constant thereafter (Fig 2). This implies that a patient's period of greatest vulnerability to these complications is within the first 2 years of treatment.

We considered whether these side effects were generic to mandibular repositioning or were device-specific. We believe that they are unlikely to be device-specific because the stresses on teeth and the temporomandibular joint are a corollary of mandibular advancement. The degree of mandibular advancement in our patients (range 3 to 16 mm) is similar to that used by others.⁴ Our device, the original version of which has been described elsewhere,³ was modified after the first 2 years of use to give full occlusal coverage to distribute the stresses over all the teeth. This modification did not significantly alter the occurrence of occlusal changes (Fig. 2) or other side effects.

The 191 patients accounted for in this case series represents our total experience over a 5-year period. Because of our practice of retaining the original study models (with wax bite to define the interarch relationship) taken prior to treatment in all patients, we were able to accurately assess occlusal change. A limitation of the study was our failure to obtain follow-up information in 59 of the patients. It is likely that they experienced side effects similar to those studied. As a result of our experience, we have become rigorous in the dental follow-up of patients treated with the device, as has been recommended by the American Sleep Disorders Association.⁹ Discussion between the treating physician and dentist is essential where side effects do occur so that their importance can be balanced against the efficacy of the device in treating the sleep-related breathing complaint.

The data relating to efficacy of treatment are subjective, as they are impressions of patients based on what they had been told about their snoring without and with the device. These data suggest that the device controls snoring in a high proportion of patients treated. Supporting this conclusion is the finding that 76% of patients continued to use their device regularly after 31±18 months of use, suggesting that they found it both tolerable and effective. While objective data on treatment efficacy are not available in all these patients, these subjective findings are consistent with our earlier report regarding results of therapy in the first 61 patients treated with our device, 51 of whom were assessed polysomnographically, including measurements of sound intensity of snoring.³

There have been no previous published analyses of the dental side effects of mandibular repositioning devices.

While these findings have cautionary implications, the major purpose of this report is to help guide sleep physicians and dentists in the satisfactory application of the treatment, which has a deserved place in the management of snoring and sleep apnea.

APPENDIX

Angle's Classification of Malocclusion⁶

Angle classified the occlusal relationship of maxillary and mandibular arches into three classes. The classification is applicable to the occlusion of all humans.

Class I:

Normal mesiodistal relation of the dental arches.

Class II:

The lower dental arch is distal to the upper on one or both lateral halves.

Division 1: bilaterally distal with protruding upper central incisors.

Division 2: bilaterally distal with retruding upper central incisors.

Class III:

The lower dental arch is mesial to the upper on one or both lateral halves with protruding lower incisors.

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