Effect of two types of mandibular advancement splints on snoring and obstructive sleep apnoea

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SUMMARY Snoring and obstructive sleep apnoea (OSA) both seem at least to be associated with narrowing of the upper airway and sleep-induced loss of muscle-tone. Mandibular advancement splints (MAS) have been proposed as a relatively simple method to increase oro- and hypo-pharyngeal dimensions thereby increasing the size of the airway. However, data on their effectiveness are conflicting and there are no clear indications as to which design is most effective or when they should be used. The effects of two designs of splint (types A and B) have been evaluated in 14 and nine subjects, respectively, using the Epworth Sleepiness Score (ESS) and domiciliary sleep monitoring on separate nights. Both splints reduced the median ESS (type A from 12 to 4.5; \( P = 0.003 \), type B from 7 to 4; \( P = 0.005 \)). The apnoea-hypopnoea index was not affected by type A, but was reduced from 7.1 to 0.8; \( P = 0.005 \) by type B splints. There was evidence of a small improvement in overnight oxygen saturation for type B splints (\( P = 0.02 \)). The splints were well tolerated and continued to be used nightly by 18 subjects. Mandibular advancement splints may offer a simple and effective alternative for the treatment of snoring and mild OSA in selected patients. Splint design may have considerable bearing on efficacy.

Introduction

Treatment options for obstructive sleep apnoea (OSA) are limited. The most effective option is a nasal continuous positive airway pressure (CPAP) device, but treatment is relatively invasive and requires a high level of compliance (Roffe et al., 1991). Patients who snore or who have mild OSA are less likely to tolerate a CPAP device since they are less sleepy (Stradling and Crosby, 1991). Other treatments are generally more invasive such as uvulopalatopharyngoplasty but have questionable long-term efficacy (Polo et al., 1989). Mandibular advancement splints have been proposed as an alternative in patients who have simple snoring or mild OSA but data on effectiveness are conflicting (Clark and Nakano, 1989; Meyer and Knudson, 1990; Schmidt-Nowara et al., 1991; Lowe, 1994; Yoshida, 1994; O’Sullivan et al., 1995). This may be a result of differing splint designs and research methodology. The aim of this study was to measure the effect of two types of splints on daytime sleepiness, snoring and domiciliary sleep in a sample of patients who might benefit from an alternative treatment to a CPAP device, i.e. those with snoring alone or OSA with intolerance of the CPAP.

Subjects and methods

Subjects

Twenty-four subjects (21 male, three female) who had been fitted with one or other of two different types of splints were enrolled consecutively. All patients were snorers and seven were known to have OSA, but were unable to tolerate the CPAP device. All patients gave written consent and the study was approved by the North Health Ethics Committee (Auckland).
Protocol

All patients underwent a minimum period of 1 week in which they did not use the device. At the end of this period the subjects completed the Oxford Questionnaire and an Epworth Sleepiness Score (ESS). The Oxford Questionnaire has 28 questions relating to sleepiness, snoring, symptoms of sleep disorders (including narcolepsy and periodic leg movements), rhinitis and previous nasal or palatal surgery. It has been used in a large community survey (Stradling and Crosby, 1991). The ESS is derived from eight questions about the likelihood of sleep during a variety of activities or situations. It has been shown to correlate with severity of sleep apnoea (Johns, 1991). They then underwent overnight domiciliary sleep studies. The splint was then used for a period of 1 week after which a further ESS was completed and sleep studies repeated with the splint in place.

Sleep studies

EdenTec® domiciliary polysomnographs (Eden Prairie, MN, USA) were used which record chest movement, oxygen saturation, airflow (amplitude), heart-rate, and noise. Apnoea was defined as cessation of chest movement or airflow for at least 10 seconds and an hypopnoea as a reduction in airflow of 50 per cent below average amplitude for at least 10 seconds with a fall of 4 per cent oxygen saturation. Desaturation was defined as a fall of more than 4 per cent below baseline (measured during the most recent period of normal breathing) for at least 10 seconds. The snoring intensity was measured as low at 90 ± 4 dB at 500 Hz, and high at 96 ± 4 dB at 500 Hz.

Mandibular advancement splints (MAS)

Both devices reposition the mandible forward and open the vertical dimension of occlusion to a variable degree depending on individual anatomy. When a splint is used, the mandible rotates down and forward, and the base of the tongue advances to open the airway. Type A devices produced maximal mandibular protrusion, with a 3–4 mm inter-incisal opening depending on the patient’s overbite. Type B permitted up to 70 per cent maximal protrusion, and an opening of 6–9 mm, depending on the overbite. They both contained a breathing slot anteriorly. The devices were made of transparent, soft acrylic resin which is physiologically harmless, insoluble in water, odour-free, and inactive (Figure 1).

Statistics

The Wilcoxon signed rank test and Mann–Whitney U-test were applied for paired and unpaired non-parametric data.

Results

Twenty-three subjects aged 31–70 years completed the study. One female was unable to tolerate the MAS and was withdrawn from this study. Fourteen patients used splint type A and nine type B. Eight of the subjects using type A splints and five of those using type B had received previous palatal surgery with regard to snoring. At the initial assessment there were six subjects with apnoea-hypopnoea indices (AHIs) greater than 10 and 10 had AHI values less than 5 (Figure 2).

Symptoms (Oxford Questionnaire) and tolerance of MAS

Twenty-two subjects (95.6 per cent) indicated that they often snored. Thirteen (56.5 per cent) had snored for longer than 10 years and 20
(87 per cent) for 4 or more years. Twenty-one (91 per cent) said they snored in all body positions. Thirteen (56.5 per cent) reported that they had been told they had stopped breathing by their partner and 12 (52 per cent) reported that they sometimes awoke with choking sensations at night. Common complaints about the splints were excess salivation, tooth and gum discomfort, mild jaw discomfort, and a gag-type reflex experienced when they first began using the appliance. Most felt these side-effects were minor compared with the benefits of the splints.

Daytime sleepiness (Figure 3 and Table 1)
The median initial ESS score was reduced significantly after 1 week for both types of splint. All but two subjects using type B splints reported an improvement in snoring and a more refreshed feeling in the morning. Ten (71 per cent) of the subjects using type A and all of those using type B splints continued to use them every night.

Sleep studies
There were important differences between type A and type B splints. Type A improved AHI and the number of apnoeas, but had no significant effect on other measurements (Table 1). The duration of loud snoring showed a non-significant trend towards an increase, which was explained by the effects in two patients. In contrast, type B splints showed significant improvements in all measurements including loud snore duration (Table 1). AHI was reduced from a median of 7.1 to 0.8 per hour and loud snore duration from 27.1 to 11.4 minutes.

Discussion
The efficacy of mandibular advancement splints in snoring and OSA quoted in previous reports is variable (Clark and Nakamo, 1989; Meyer and Knudson, 1990; Schmidt-Nowara et al., 1991; Lowe, 1994; Yoshida, 1994; O’Sullivan et al., 1995). It is likely that this is related to differences in splint design as well as patient selection. The present study showed that both splints produced a reduction in daytime sleepiness and number of apnoeas. Type B was effective in reducing all measures of sleep apnoea, including oxygen saturation and snoring. The differences in efficacy underline the need for research into the most effective design. Other studies have shown splints with as much as 15 mm mouth opening to be effective (Lowe, 1994), although the degree of mandibular advancement has more often been emphasized with the latter usually measured in
absolute units rather than, as in the present study, as a percentage of maximal protrusion. Splints can be effective in reducing the AHI even in some patients with severe OSA (Figure 2). Seven patients had AHIs of 20 or more and all but one improved. Only two patients from this subgroup had AHIs within normal limits after 1 week’s treatment with a splint and two had values of more than 20 which has been shown to be associated with excess mortality (He et al., 1988). This suggests that splints should only be used to treat OSA when there has been an adequate reduction in AHI proven by a sleep study. Electroencephalographic recording was not undertaken so we are unable to comment on the influence of the splints on sleep quality or arousal.

O’Sullivan et al. (1995) have recently reported a study of mandibular advancement splints in patients with snoring and OSA. That study also suggested that splints are efficacious in selected patients, but differed in that patients were studied for half a night with and without the splint. The latter method was employed to provide controls for inter-night variability, but this is not ideal since the two halves of the night are different in terms of sleep physiology.

The 1-week ‘washout’ period in the present study allowed the measurement of daytime sleepiness, one of the important indications for intervention, and may have allowed some return of the soft tissues in the oropharynx to the pre-treatment state. It is not known whether MAS modify the soft tissue swelling which is known to occur in OSA. A study employing some form of quantitative imaging before and after use of a device would be required to answer this question.

In neither the present study nor that by O’Sullivan et al. (1995) was a placebo device used. Whatever the design of a placebo splint, it is likely that it will have some influence on oropharyngeal anatomy. The mouth will be opened to some degree and there may be some increased resistance to mouth breathing. Thus, we elected not to use a placebo in case a detrimental effect on sleep resulted from its use. Future research might employ an adjustable device, allowing different settings for mouth opening and mandibular advancement.

**Conclusions**

The selection of patients in whom splints are the most appropriate therapy has not yet been

<table>
<thead>
<tr>
<th>Measure</th>
<th>Before splint</th>
<th>After splint</th>
<th>P value (Wilcoxon)</th>
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<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Range</td>
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<tr>
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<td>Number of A/H</td>
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<td>1–553</td>
<td>26</td>
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<tr>
<td>AHI (per hour)</td>
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<td>0.1–70</td>
<td>3.5</td>
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<td>Total A-H duration (min)</td>
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<td>Loud snore duration (min)</td>
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<td>Percentage time O₂ sat &gt;90 per cent</td>
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<td>12–100</td>
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<tr>
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<tr>
<td>AHI (per hour)</td>
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<tr>
<td>Loud snore duration (min)</td>
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<td>11.4</td>
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<tr>
<td>Percentage time O₂ sat &gt;90%</td>
<td>98</td>
<td>75–100</td>
<td>99</td>
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</table>
widely agreed. However, in view of the marked improvement in symptoms for patients with snoring alone shown by the present study and those of others, splints may be an appropriate non-invasive first line therapy for such cases.

Many of the patients in this study had had previous palatal surgery with no lasting post-operative cure yet still derived considerable benefit from their splint. However, as the splints may not produce adequate improvement in AHI in some patients, it is important that objective screening for OSA, possibly using oximetry or a more comprehensive sleep study, should also be employed.

In patients with OSA, it is clear that with splint therapy both symptoms and the AHI may be reduced to acceptable levels in some patients, but further work is needed to evaluate long-term efficacy and patients need to be studied with a device in place.

The present study confirms the findings of others that mandibular advancement splints may be a useful alternative or adjunct to the use of the CPAP device in selected patients with snoring and mild OSA.

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