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Mandibular advancement splints and continuous positive airway pressure in patients with obstructive sleep apnoea: a randomized cross-over trial

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SUMMARY This prospective, randomized, cross-over trial was designed to compare the efficacy of a mandibular advancement splint (MAS) with that of nasal continuous positive airway pressure (nCPAP) in patients with obstructive sleep apnoea (OSA). Twenty-four patients (20 males and four females) with mild to moderate OSA (AHI between 10 and 49 events per hour) were enrolled in the study. Each patient used both MAS and nCPAP, with the initial therapy being allocated at random. Treatment periods lasted for two months with a two-week wash-out interval between. Polysomnography was performed prior to the study and after each clinical intervention. Patient and partner questionnaires were used to assess changes in general health and daytime somnolence.

The AHI decreased from 22.2 to 3.1 using nCPAP, and to 8.0 using the MAS ($P < 0.001$ for both devices) and there was no statistically significant difference between the two treatments. The Epworth Sleepiness Score (ESS) fell from 13.4 to 8.1 with nCPAP, and to 9.2 with MAS ($P < 0.001$), again with no differences between the use of MAS or nCPAP. The questionnaire data showed an improvement in general health scores ($P < 0.001$) after both treatments, but daytime sleepiness only improved significantly using nCPAP ($P < 0.001$). Despite this, 17 out of the 21 subjects who completed both arms of the study preferred the MAS.

The splints were well tolerated and their efficacy suggests that the MAS may be a suitable alternative to nCPAP in the management of patients with mild or moderate OSA.

Introduction

Obstructive sleep apnoea (OSA) is recognized as a medical condition for which appropriate therapy should be provided (Rapoport, 1994; Gibson *et al*., 1998). Despite seemingly adequate hours of rest, subjects experience a poor quality of sleep and wake unrefreshed. As a consequence, they may complain of increasing daytime somnolence and an inability to concentrate at work. The typical patient is middle-aged, male, overweight, and with an increased neck circumference; however, females are also at risk (Young *et al*., 1993; Davies and Stradling, 1996).

The gold standard treatment of OSA is nasal continuous positive airway pressure (nCPAP), delivered via a nasal mask (Sullivan *et al*., 1981; Loube *et al*., 1999). The value of nCPAP in the management of OSA is undoubted (Kribbs *et al*., 1993; Engleman *et al*., 1998, 1999; Jenkinson *et al*., 1999), and randomized controlled trials of nCPAP versus an oral placebo (Engleman *et al*., 1998, 1999) or sham nCPAP (Jenkinson *et al*., 1999) have shown significant improvements in subjects' symptoms. Nevertheless, these studies also showed that the nCPAP was not universally tolerated and was worn less frequently than required. Overall, compliance was approximately

40–50 per cent (Waldhorn *et al*., 1990; Rolfe *et al*., 1991), but the milder the symptoms of OSA, the less likely were the subjects to accept nCPAP (Engleman *et al*., 1994).

During the last decade, increasing attention has been given to the provision of intra-oral appliances as an alternative management option (Schmidt-Nowara *et al*., 1991, 1995; Clark *et al*., 1993, 1996; Eveloff *et al*., 1994; O'Sullivan *et al*., 1995; Ferguson *et al*., 1996, 1997; Marklund *et al*., 1998; Bloch *et al*., 2000). Following a review of the available literature, the American Sleep Disorders Association (Schmidt-Nowara *et al*., 1995) recommended that these devices might be an appropriate therapeutic option in selected subjects: those with mild to moderate OSA, non-apnoeic snorers and subjects who were unable to tolerate nCPAP. Both one- and two-piece appliances have been described. The former may be simple vacuum-formed splints with upper and lower elements fused together (Cameron *et al*., 1998; Stradling *et al*., 1998), or clasped acrylic appliances (Bonham *et al*., 1988; Marklund *et al*., 1998). A snap fit monobloc, recently described by Bloch *et al*. (2000) was both effective and popular with patients. Other one-piece devices do not hold the mandible rigidly, but merely guide it forwards e.g. the 'Snore Guard' (Ferguson *et al*., 1996). Two-piece splints, where upper and lower elements are connected by rigid or plastic lateral connectors, allow some freedom of mandibular movement and facilitate oral breathing. The Herbst (Clark *et al*., 1993, 1996; Eveloff *et al*., 1994; Johal and Battagel, 1999; Bloch *et al*., 2000), anterior mandibular positioner (Ferguson *et al*., 1997), 'Silensor', and elastic mandibular advancement device (Henke *et al*., 2000) are current examples.

The apnoea/hypopnoea index (AHI) is used as a measure of the number of abnormal breathing events per hour of sleep and indicates the severity of the OSA. A reduction in AHI of at least 50 per cent or an AHI of less than 10 are the commonest post-treatment goals, and the latter is generally agreed to be acceptable (Eveloff *et al*., 1994; Ferguson *et al*., 1996, 1997). However, most studies of the effectiveness of mandibular advancement splints (MAS) have not restricted patient selection to those with mild or moderate disease and the results of treatment have been very variable. Mean reductions in AHI produced by mandibular advancement devices ranged from 37 per cent (Bonham *et al*., 1988) to 75 per cent (Clark *et al*., 1993) with between 40 and 71 per cent of subjects achieving a post-treatment AHI of less than 10 (Ichioka *et al*., 1991; Schmidt-Nowara *et al*., 1991, 1995).

Where studies have compared both MAS and nCPAP in the same subjects, the nCPAP appears to be more effective in controlling symptoms, especially in those with more severe disease (Cartwright *et al*., 1991; Schmidt-Nowara *et al*., 1991; Henke *et al*., 2000). Despite this, the MAS is generally preferred by the majority of patients (Clark *et al*., 1996; Ferguson *et al*., 1997). Other advantages of the MAS are that it is less cumbersome and the short-term side effects of its wear are relatively mild (Schmidt-Nowara *et al*., 1991; Clark *et al*., 1996; Ferguson *et al*., 1996, 1997).

Wright *et al*. (1997) underlined the need for further evaluation of all methods of treatment for OSA and the establishment of multi-disciplinary guidelines. Increasingly, such clinics are being set up to cater for these patients and members of the dental profession are being asked to fabricate mandibular advancement devices. Well-documented and adequately controlled studies of oral appliances in subjects with OSA are scarce, and none has been reported in the UK (Clark *et al*., 1996; Ferguson *et al*., 1997).

The aim of the present study, therefore, was to compare the results of treatment with a MAS with the 'gold standard' of nCPAP in a group of subjects with mild or moderate OSA using a prospective, randomized, cross-over design.

Subjects and methods

Subjects

Consecutive patients attending multidisciplinary sleep clinics at University College London Hospital (UCLH) and the Royal Brompton Hospital (RBH) were invited to enter the study. The severity of OSA was determined by full polysomnography, and all patients who fulfilled the entry criteria of mild or moderate OSA (AHI less than 50) were invited to participate.

An examination was also performed to assess need for any ear, nose, or throat treatment prior to the study being undertaken.

Entry criteria included males and females over the age of 18 years, an adequate dentition and periodontal status for support and retention of the oral appliance, no temporomandibular joint dysfunction, and no medical contraindications. Patients also had to be able to attend the sleep clinic and sleep laboratory as requested for the requirements of the study. Exclusion criteria included: significant heart disease—myocardial infarction in the last 3 years, angina, and uncontrolled hypertension; co-existent chronic obstructive pulmonary disease; regular hypnotic use; epilepsy; an inadequate dentition; an arterial oxygen saturation of less than 60 per cent during the initial sleep study; and failure to understand the purpose of the study because of language difficulties.

Forty-six consecutive subjects were assessed. Twelve were unsuitable because of underlying medical conditions or failure to understand the purpose of the study, and another seven refused to consider one or both treatments. Twenty-seven agreed to enter, but two withdrew for medical reasons and another failed to attend the clinic and was lost to follow-up. Twenty-four subjects entered and took part in one or both arms of the study with 21 completing both arms. The study was approved by the Ethics Committees of both participating hospitals and all patients gave informed, written consent.

Methods

Study design. Baseline overnight polysomnography was performed (T1) and baseline questionnaires completed. These included an Epworth Sleepiness Score questionnaire (ESS; Appendix) and the general health and daytime sleepiness sections of the health questionnaire described by Flemons *et al*. (1994). Body mass index (BMI) was calculated from the subject's height and weight as follows:

$$\text{BMI} = \text{weight in kg/height in m}^2.$$

Patients were then randomized to two months' treatment with either nCPAP or the MAS. If randomized to nCPAP, the patient was familiarized with the system and a sleep study arranged to ascertain the optimal nCPAP pressure required to abolish the OSA. The patient then commenced the two-month trial period with instructions to contact the laboratory if problems developed. Routine appointments at the sleep laboratory were given for two and six weeks into the treatment period. At the end of the two months (T2), the patient had a second sleep study, and completed a second ESS and health questionnaires. The patient was also instructed to bring along the partner's questionnaire, completed during the previous three days.

If randomized to MAS, impressions were taken for appliance construction and lateral skull radiographs were obtained. Once the MAS had been fitted, patients were instructed to contact the clinician if unforeseen problems or breakages occurred, and were given appointments at two- and six-week intervals. Any adjustments to the appliance were made at the two-week clinic visit.

For subjects using nCPAP first, the MAS was constructed during the two-month period of nCPAP wear. Following a two-week wash-out period, the second phase of the study commenced. At the end of this arm (T3), both patient and partner questionnaires, and the overnight sleep study were repeated again. The wash-out period was required to eliminate the effects of the first intervention and, where necessary, to allow for completion of construction of the oral appliance.

From the overnight sleep study, the following data were examined: AHI, mean blood oxygen desaturation during the period of the study, and the duration of these desaturations. The number of arousals per hour and the sleep efficiency were also examined, together with the percentage of time spent in rapid eye movement (REM) sleep.

Treatment success was defined as wearing the device for the two-month study period and an AHI of less than 10 at the end of that part of the study. Failure was defined as being unable to complete two months using the device, and/or an AHI of more than 10. At the end of the study, each patient was asked to express his/her preference for the devices. All sleep studies were read by a technician who was aware of the

purpose of the study, but assessment was carried out in a random order and with all patient identification removed.

The oral appliance. A soft, one-piece MAS was selected initially, similar to that described by Stradling *et al*. (1998). This vacuum-formed appliance was simple and cheap to construct, and designed to hold the mandible forward at the maximum comfortable protrusion, with no deviation to either side and minimal jaw opening. The initial protrusive position approximated 75 per cent of maximal possible protrusion. Four-millimetre thick ethyl vinyl acetate blanks were processed over the models and two laterally placed breathing ports added buccally (Figure 1). A space was left between the upper and lower incisors to allow for nocturnal oral breathing if necessary. Progressive advancement of the mandible was possible by taking a new jaw record and modifying the appliance.

The first 10 subjects were treated in this way, but two subjects complained of inadequate nocturnal oral respiration and were unable to tolerate the device. The two-part, semi-rigid Silensor (Erkodent Gmbh, Tuttlingen, Germany) was therefore used for the remainder of the study (Figure 2). Upper and lower elements were joined by plastic straps running from the upper canine to the lower molar regions, thus allowing some mouth opening during sleep. This orientation of the connectors permitted only forward movement of the mandible during opening, thus avoiding the reduction of the airway normally associated with mandibular opening. A further advantage of the Silensor was its ease of adjustment. The buccal connectors are available in four lengths and the mandible may be readily advanced by replacing the original connector by a shorter one. Since modification of the splint design could have had an effect on outcome, results for the two types of splint were compared both separately and for the group as a whole.

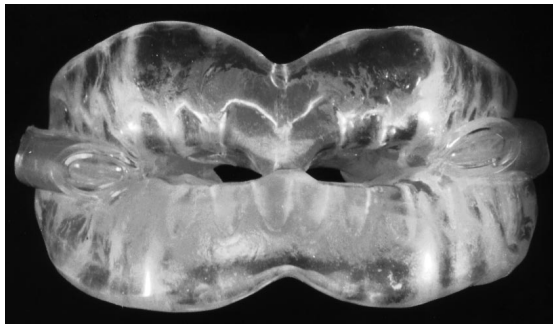

Figure 1 One piece vacuum-formed appliance.

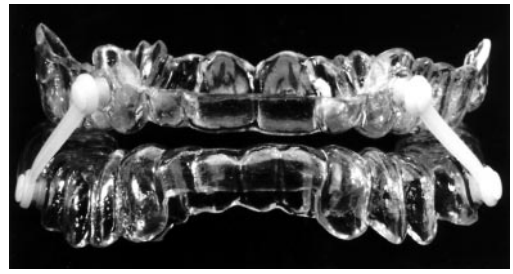

Figure 2 Modified Silensor appliance.

Nasal continuous positive airway pressure (nCPAP). nCPAP was provided using the REM Star Choice machine (Respironics Inc., Medic-Aid, West Sussex, UK) at UCLH and the Sullivan Elite machine (Resmed UK Ltd, Abingdon, UK) at RBH. A comfortable nasal mask was selected and nasal corticosteroid sprays were prescribed to relieve nasal congestion if necessary. This symptom did not require treatment during the MAS arm of the study in any individual. Correct nCPAP pressures were titrated individually.

Diagnostic polysomnography. All patients had a diagnostic polysomnography before entry into the study. At UCLH, the equipment was a Compumedics system (Compumedics Ltd, Victoria, Australia), which recorded sleep and its stages by electroencephalographic (EEG), electro-oculographic, and electromyographic (EMG) criteria. EEG was recorded with electrodes placed at C3–A2 and C4–A1 (according to the international 10–20 system). EMG activity was recorded from the submental muscles. A single pair of electrocardiographic chest leads was used to monitor heart rate. Arterial oxygen saturation was monitored continuously by a pulse oximeter attached to an index finger. Thoraco-abdominal wall movement was monitored by inductive plethysmography using thoracic and abdominal respi-trace bands. Air flow was measured at the

nose and mouth by a heat sensitive thermistor. The data were recorded on an S-Series Sleep System V4 (Compumedics Ltd). Body position was obtained by mercury switch sensors, which were positioned on any flat surface, usually the upper body area. Leg movements were measured by sensors positioned on each tibialis anterior muscle. An obstructive apnoea was defined as the cessation of air flow for at least 10 seconds accompanied by an ongoing or increasing respiratory effort. Hypopnoea was defined as a greater than 50 per cent decrease in thoraco-abdominal movement for at least 10 seconds, accompanied either by a drop in blood oxygen saturation of at least 4 per cent or an arousal. An arousal was noted as distinct changes in the EEG for more than 3 seconds and, if REM sleep occurred, together with an accompanying increase in EMG amplitude. The equipment used at the RBH was the Neuromapper system (Neurosciences Ltd, Essex, UK) combined with pneumography (Densa, Ferraris Medical Ltd, Middlesex, UK).

Questionnaires. At the beginning of the study (T1), all subjects were asked to complete the general health and sleepiness sections of a previously validated questionnaire (Flemons *et al*., 1994). This exercise was repeated at the end of each two-month study period (T2) and (T3). Regular partners of subjects were asked to complete a similar questionnaire. A Likert scale from 1–8 was employed for all questions and responses were converted to a scale of 0–3 as described by Flemons *et al*. (1994). The values for each individual were summed and a single score was then obtained. The general symptoms part of the questionnaire contained 11 questions and the daytime somnolence section, 8. The Likert scale was scored as: never, rarely (1–2 times per year), occasionally (3–8 times per year), sometimes (1–2 times per month), often (1–2 times per week), usually (3–5 times per week), and always (6–7 times per week). Scores for each part of the questionnaire were compared at T1, T2, and T3. The ESS was also completed at the same time points.

Statistical analysis. Mann–Whitney *U* tests were used to investigate any treatment order effects and any differences between the two types of splint used. Wilcoxon matched pairs signed ranks tests were used to compare baseline and treatment arms, and to examine any differences between the two types of treatment. No significant treatment order effects were found and therefore the data were pooled and analysed using Friedman's two-way analysis of variance, allowing the use of repeated measures in non-parametric data. A *P* value of less than 0.05 was taken to express significance throughout.

Results

Of the 24 patients who began the study, two did not tolerate nCPAP and one could not tolerate the MAS. These three subjects each completed one arm of the study and were included in the overall analysis. The remaining 21 subjects completed the entire study. Ten subjects had been randomized to MAS first and 14 to nCPAP. There were no significant differences for any treatment effect between these two groups and, therefore, the data were pooled.

Demographic data (Table 1)

Twenty subjects were male and four were female; the mean age of the combined group was 50.9 ± 10.1 years (48.9 ± 8.1 years for males and 60.8 ± 5.5 years for females). Most subjects

Table 1 Demographic data.

	Whole group (n = 24) mean ± SD	Whole group (range)	Males (n = 20) mean ± SD	Females (n = 4) mean ± SD	Difference (males–females)	Significance of difference
Age (years)	50.9 ± 10.1	34.9–70.3	48.9 ± 9.6	60.8 ± 5.5	–11.9	$P < 0.05$
Body mass index (weight/height^2)	31.9 ± 6.8	22.6–52.7	31.0 ± 4.9	36.2 ± 13.2	–5.2	NS

were overweight or obese with a mean BMI of 31.9 ± 6.8 (31.0 ± 4.9 in males and 36.2 ± 13.2 in females).

Polysomnography (Table 2, Figure 3)

Results of the overnight sleep study parameters together with the ESS at baseline and after each arm of the study are given in Table 2. Prior to treatment mean AHI was 22.2 ± 9.6. No attempt was made to measure AHI separately in REM and non-REM sleep. Mean oxygen desaturations were 7.1 per cent from each subject's baseline and the average length of each desaturation was 19.4 seconds. The number of arousals that occurred per hour of sleep was 19.3. Sleep efficiency, the time spent asleep as a percentage of the total sleep study time, was 81.6 per cent and the proportion of time spent in REM sleep was 12.7 per cent.

Effects of nCPAP. There were significant improvements from baseline in AHI, blood oxygen saturation and the number of arousals experienced. The AHI reduced to 3.1 ($P < 0.001$, Figure 3), desaturations reduced to 3.3 per cent ($P < 0.01$), and arousals to 9.8 per hour ($P < 0.01$). Alterations in sleep efficiency and REM sleep were not significant. In all 22 patients who tolerated nCPAP the AHI was less than 10.

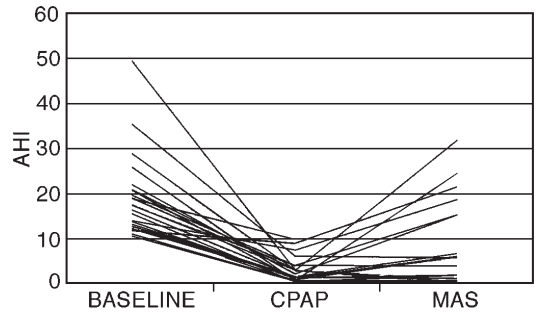

Figure 3 The individual apnoea/hypopnoea indices before treatment, with nasal continuous positive airway pressure and with the mandibular advancement splint.

Effects of MAS. The first 10 patients wore a one-piece, vacuum-formed appliance and the next 14 used the Silensor. There was no significant difference in the efficacy of the two devices in terms of AHI, and data for the two groups were pooled.

The MAS provided a highly significant reduction in AHI from 22.2 to 8.0 ± 5.1 (Figure 3). The number of arousals dropped significantly, to 11.6 per hour ($P < 0.01$). Increases in blood oxygen

Table 2 Polysomnographic findings and Epworth sleepiness score at baseline and after each arm of treatment: whole group ($n = 24$).

	Baseline (mean ± SD)	Baseline range	Continuous positive airway pressure (mean ± SD)	Continuous positive airway pressure (range)	Mandibular advancement splint (mean ± SD)	Mandibular advancement splint (range)	*P* value	
							From baseline	Between treatments
Epworth sleepiness score (ESS)	13.4 ± 4.6	4.0–20.0	8.1 ± 4.1	0.0–15.0	9.0 ± 5.1	0.0–18.0	***	NS
Apnoea/hypopnoea index (AHI)	22.2 ± 9.6	10.8–49.6	3.1 ± 2.8	0.3–10.0	8.0 ± 10.9	0.0–35.5	***	NS
Oxygen desaturation (%)	7.1 ± 2.7	3.3–13.3	3.3 ± 1.6	0.9–7.8	4.8 ± 2.7	0.0–10.4	(CPAP)**	NS
Duration of apnoea-related desaturations (seconds)	19.4 ± 4.9	12.8–29.4	19.7 ± 4.6	12.0–30.5	18.0 ± 6.1	0.0–29.0	NS	NS
Arousals/hour	19.3 ± 9.6	6.0–39.2	9.8 ± 6.6	3.0–25.1	11.6 ± 5.6	1.0–19.3	**	NS
Sleep efficiency (%)	81.6 ± 10.4	61.3–96.4	87.2 ± 8.1	72.0–99.3	83.2 ± 8.1	50.0–99.2	NS	NS
REM sleep (%)	12.7 ± 5.8	3.3–24.2	18.5 ± 6.1	5.3–25.6	13.8 ± 5.6	1.2–30.8	NS	NS

**$P < 0.01$; ***$P < 0.001$.

saturation were not significant and sleep architecture was unchanged. There were no significant differences between the MAS and nCPAP groups for any of the post-treatment polysomnographic data. Seventy per cent of the 23 subjects who tolerated the MAS showed an AHI of less than 10; seven out of 10 patients using the vacuum-formed device and nine out of 14 wearing the Silensor. Overall, 20/23 (87 per cent) of subjects had a reduction in AHI with the MAS and 18/21 (86 per cent) showed a reduction in ESS.

Questionnaires

Epworth Sleepiness Score (Table 2). The mean ESS at baseline was 13.4. Using nCPAP, this decreased to 8.1 and with the MAS, to 9.0. Both of these reductions were highly statistically significant ($P < 0.001$) and there was no difference between them.

Patient and partner questionnaires (Table 3). The general health and daytime sleepiness domains of the questionnaire were analysed separately. The lower the score, the better the parameter measured. At baseline, their general health was rated at 17.4 by the patients and their daytime sleepiness at 10.0. After two months of nCPAP, these values had dropped significantly to 6.5 and 5.2 ($P < 0.001$), respectively. With the MAS, the score of 10.2 for general health was also significant at the 1 per cent level, but that of 7.7 for daytime sleepiness was not. No significant differences between the two types of treatment were revealed.

The partners' assessments of the patients were similar to those of the subjects themselves. Prior to the study, the general health of their partners was rated at 18.3 and with nCPAP this reduced to 6.5. With MAS, the score dropped to 9.8 and both differences were significant ($P < 0.001$). Daytime sleepiness scored 8.6 at baseline, 5.7 with nCPAP, and 6.0 with MAS. The difference with nCPAP was just significant ($P < 0.05$), but that with MAS was not. Again, there were no significant differences between treatments.

Discussion

The mandibular advancement splints

Although there were no statistically significant differences for the efficacy of the two types of MAS, this may be attributable to the small numbers involved and should be confirmed by a larger study. The Silensor, by permitting some mandibular opening during sleep, was equally suitable for subjects who were oral breathers as for those who breathed through their noses. Local, often seasonal factors, e.g. infections, nasal congestion, and allergic rhinitis can influence the mode of respiration, and it is more convenient if both oral and nasal respiration are facilitated.

It is arguable that if the change to the Silensor had not been made, the number of failures in terms of compliance would have been greater. Although no differences in the effectiveness of the two splints were apparent this could have been due to the small numbers of subjects in the study. The limited data on the efficacy of

Table 3 Patient and partner questionnaire.

	Baseline (mean ± SD)	After continuous positive airway pressure (mean ± SD) and significance of difference	After mandibular advancement splint (mean ± SD) and significance of difference	Significance of difference between treatments
Patient (± SD)				
General health	17.4 ± 7.5	6.5 ± 5.9***	10.2 ± 9.9***	NS
Daytime sleepiness	10.0 ± 7.3	5.2 ± 5.1***	7.7 ± 7.0 NS	NS
Partner (± SD)				
General health	18.3 ± 7.8	6.5 ± 6.0**	9.8 ± 10.7**	NS
Daytime sleepiness	8.6 ± 5.2	5.7 ± 5.5*	6.0 ± 4.9 NS	NS

*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.

one-piece, thermoformed devices in the management of OSA (Cameron *et al*., 1998), are not encouraging. One-piece acrylic or semi-flexible resin splints where provision is made for oral breathing and the mandible is held securely in the protruded position appear to be more successful (Marklund *et al*., 1998; Bloch *et al*., 2000). In subjects with mild and moderate OSA, Marklund *et al*. (1998) reported reductions in AHI from 11 to 5 and from 27 to 7 events per hour, respectively. In the 24 subjects treated by Bloch *et al*. (2000), mean AHI decreased from 26.7 to 7.9, a reduction comparable to that in the present study.

The two-piece Silensor has other advantages over the vacuum-formed splint. The lateral connectors permit further mandibular advancement where necessary and this can be carried out at the chairside. Furthermore, the position of the connectors (from upper canine to lower molar) ensures that any attempts to open the mouth during sleep are associated with further mandibular advancement, rather than the downwards and backwards hinging seen with the Herbst appliance, with possible loss of MAS efficiency. The role of sequential activation may also be a factor to be considered in the minimization of temporomandibular joint discomfort associated with MAS wear (Henke *et al*., 2000).

No attempt was made in this study to examine potential predictors for MAS success: the numbers were too small to provide a suitably robust model.

Nasal continuous positive airway pressure

Two different models of nCPAP compressors were used, but there is no evidence that differing compressor/mask systems, producing similar nCPAP pressures, result in changes in patient compliance.

Comparison between nCPAP and MAS

AHI. The AHI showed mean reductions to within acceptable values (<10) with both MAS and nCPAP ($P < 0.001$) with no significant difference between devices. However, the mean AHI of 8.0 with MAS was higher than with nCPAP (AHI = 3.1). This difference accords with that in other MAS/nCPAP trials (Ferguson *et al*., 1996, 1997). The literature reveals three recent, randomized, cross-over studies with which the present data may be compared directly (Clark *et al*., 1996; Ferguson *et al*., 1996, 1997), together with studies reporting the efficacy of mandibular advancement devices only (Bonham *et al*., 1988; Schmidt-Nowara *et al*., 1991; Clark *et al*., 1993, 1996; Eveloff *et al*., 1994; Yoshida, 1994; O'Sullivan *et al*., 1995; Marklund *et al*., 1998; Bloch *et al*., 2000; Henke *et al*., 2000). Many of the latter investigations did not restrict their subjects to those with mild and moderate OSA, and thus their success rates were correspondingly poorer. Only those studies that are comparable to the present investigation will therefore be considered in the following discussion.

The reduction in AHI with the mandibular advancement devices was better than that demonstrated by Ferguson *et al*. (1997) using the 'anterior mandibular positioner', but comparable to those of Ferguson *et al*. (1996), Marklund *et al*. (1998), and Bloch *et al*. (2000). Since the 'Snore Guard' used by Ferguson *et al*. (1996) did not hold the mandible rigidly, whereas the appliances used by Clark *et al*. (1996) and Ferguson *et al*. (1997) were firmly fitting, one-piece devices with some anterior opening, this might suggest that the precise design of the appliance is not critical where the degree of OSA is not severe. However, six out of the 25 subjects (24 per cent) prescribed the 'Snore Guard' (Ferguson *et al*., 1996) were compliance failures because they were unable to keep the loosely fitting appliance in place. A more rigidly fitting device thus seems to be desirable.

Although the cross-over study undertaken by Clark and co-workers (1996) was similar in concept to the present work, baseline AHI was higher (33.9) and the length of time for which appliances were worn before testing was only two weeks. The results were less good: the MAS reduced the AHI by 39 per cent compared with 60 per cent with nCPAP, although even with nCPAP the AHI was still unusually high (AHI = 11.2). These results may be due to the short period for which the devices were worn before the patients were restudied. The two weeks may

have been insufficient to allow subjects to adapt to their treatment or for any adjustment to the appliances to be made to allow them to function optimally.

In the present study, the two months' treatment period included the time taken for the subjects to adapt to wearing the MAS, which in some may have reduced the total treatment period by a few days. Although the nCPAP was titrated to give optimal pressures from the first night, some of the MASs may not have been working optimally until after the two-week review. Thus, in theory the MAS might have been effective for a slightly shorter period than the nCPAP. However, repeat polysomnography was not carried out for two months, giving sufficient time for the effects of the appliance to be established. Although a two-week wash-out phase was included, the studies of Ferguson *et al*. (1996, 1997) suggest that this may not have been necessary.

Patient and partner questionnaires. The responses of the partners were similar to those of the patients, confirming the subjects' observations. Both reported significant improvements in the patients' general health score after each device, and an improvement in daytime sleepiness. Whilst daytime sleepiness improved significantly using the ESS for both appliances, only nCPAP demonstrated such a reduction with the general health and daytime sleepiness questionnaires. It is interesting that, despite no detectable improvement in daytime tiredness from the questionnaire scores, both patients and their partners considered that treatment had a useful impact on the subjects' quality of life.

Treatment success

Treatment with an intra-oral appliance was successful in 16 out of the 23 subjects (70 per cent): that is, subjects completed two months of MAS wear and achieved an AHI of less than 10. In three of the unsuccessful patients, the AHI increased slightly as a result of MAS wear, but all were successfully controlled by nCPAP. In other comparable studies slightly lower success rates were achieved: Ferguson *et al*. (1996, 1997) reported a success rate of 62 per cent for the 'Snore Guard' and 55 per cent for the 'anterior mandibular positioner'. In non-comparative studies, Eveloff *et al*. (1994) reported a success rate of 53 per cent, Clark *et al*. (1993) 58 per cent and, using an AHI of 20 as a measure of adequate therapy, O'Sullivan *et al*. (1995) suggested that 54 per cent were satisfactorily controlled. More recently, Bloch *et al*. (2000) confirmed success rates of 75 per cent with a Monobloc and 67 per cent with a Herbst device. However, although the present study compares favourably with the reports of other authors, it must be noted that all subjects who could tolerate the apparatus (92 per cent) showed satisfactory control of their disease with nCPAP. Furthermore, subjects in the present study exhibited only mild or moderate OSA. In the absence of clear predictors of MAS success, it would therefore seem vital to monitor all subjects who have had a MAS fitted, with a further overnight sleep study, to check that the appliances are providing satisfactory control (Schmidt-Nowara *et al*., 1995).

Side-effects

The MAS was, in general, very well tolerated. Most patients needed an additional appointment to achieve a comfortable fit and one adjustment to the mandibular protrusion to advance the lower jaw further. Twelve out of the original 24 patients had some initial jaw discomfort early in the morning but only one could not adapt to the device. There were no dental problems. Some degree of discomfort in the TMJ, facial musculature, or teeth on waking have been reported previously: these are normally mild and improve with time (Schmidt-Nowara *et al*., 1991; Ferguson *et al*., 1996, 1997). Two patients could not tolerate nCPAP and discontinued treatment. Apart from some nasal stuffiness, there were no side-effects with nCPAP: this was controlled by nasal sprays and was not a reason for cessation of treatment.

Patient preference

When asked which appliance they preferred, 17 of the 21 individuals who completed both arms of the study preferred the MAS and four chose

nCPAP. This is in agreement with the preferences noted in previous studies (Clark *et al*., 1996; Ferguson *et al*., 1996, 1997) and reflects the more compact nature of the intra-oral device. nCPAP is bulky, noisy, requires a suitable electrical supply and is also more difficult to sleep with. Thus, despite its greater efficacy, nCPAP is perceived as a less desirable form of treatment. Although the present study was not able to measure compliance objectively using a logging device, there was no obvious discordance between the subject's and partner's assessment of treatment benefits.

Conclusions

1. The MAS may be a suitable alternative to nCPAP in patients with mild or moderate OSA.
2. However, larger studies will be required, as well as data on the longer-term efficacy of the MAS before it can be offered as a definitive alternative to nCPAP.
3. MAS were well tolerated and preferred by the majority of subjects.

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Appendix: the Epworth Sleepiness Scale

How likely are you to doze off or fall asleep in the following situations (in contrast to feeling just tired)?

Even if you haven't been in some of these situations recently, try to work out how they would have affected you.

Use the 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	Chance of dozing
Sitting and reading	.....
Watching TV	.....
Sitting, inactive in a public place (e.g. a theatre or a meeting)	.....
As a passenger in a car for an hour without a break	.....
Lying down to rest in the afternoon when circumstances permit	.....
Sitting and talking to someone	.....
Sitting quietly after a lunch without alcohol	.....
In a car, while stopped a few minutes in the traffic	.....
Total score	.....

Thank you for your help