



Mandibular advancement splint improves indices of obstructive sleep apnoea and snoring but side effects are common

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Abstract

Aim To assess the efficacy of a mandibular advancement splint (MAS) in the treatment of obstructive sleep apnoea syndrome (OSAS).

Methods Nineteen patients using a MAS for symptomatic OSAS underwent polysomnography, with MAS use randomised to one half of the night. Indices of snoring and OSAS were compared. Side effects, compliance and treatment response were evaluated by questionnaire.

Results Use of the MAS improved total respiratory disturbance index (RDI) from 22.2 ± 19.8 (SD) events per hour to 16.5 ± 21.4 /hr ($p=0.03$), supine RDI (30.8 ± 23.8 /hr to 18.8 ± 22.1 /hr, $p=0.01$), arousal index (25.2 ± 18.9 /hr to 19.3 ± 14.2 /hr, $p=0.01$) and snoring intensity (52.7 ± 4.1 to 50.7 ± 2.7 dB, $p=0.02$) but not total snore frequency ($p>0.05$). Using polysomnographic criteria, MAS treatment was completely successful in four (21%) patients, partially successful in ten (52.6%) and a failure in five (26.3%). Treatment over a median of 6.5 weeks (range 2-48) was perceived as beneficial by ten of eleven partners. Fifteen patients (79%) reported side effects, 9 (46%) did not use the device every night and four (21%) used the device less than three nights per week.

Conclusion The use of the MAS resulted in significant reductions in indices of OSAS and snoring. However, a significant number of patients had difficulty tolerating and regularly using the device.

Nasal continuous positive airway pressure (nCPAP) regarded as the treatment of choice for obstructive sleep apnoea syndrome (OSAS),¹ although tolerance and compliance with this therapy is variable.²⁻⁴

A wide range of dental devices including the mandibular advancement splint (MAS) are being used for the treatment of snoring and OSAS without objective evaluation despite recommendations by international professional groups.⁵ MASs have been proposed as an alternative treatment to nCPAP in the prevention of sleep related upper airway obstruction by increasing upper airway dimensions via stable anterior protrusion of the mandible and advancing the tongue. Studies of dental devices generally report beneficial effect, especially for mild OSAS.⁶⁻¹¹ The effectiveness of MAS as a treatment for OSAS depends on number of patient-related variables, appliance design, its subsequent adjustment and a multitude of skeletal, soft tissue and functional factors.¹² Concern has been expressed by O'Sullivan et al.⁷ that long term treatment with a MAS may result in changes in occlusion.

The aim of this study was to objectively assess by polysomnography a MAS currently being used in New Zealand. The design of the MAS used in this study was modeled on a device reported to reduce snoring and improve wellbeing in over 80% of patients when surveyed subjectively.¹³

Methods

Subjects. 22 patients (21 male and 1 female) with polysomnographically confirmed OSAS (respiratory disturbance index (RDI) of >5 per hour and at least two symptoms (Epworth Sleepiness Score (ESS)>10,¹⁴ morning headaches, waking choking or snoring) were consecutively recruited from a sleep clinic population. Subjects were over eighteen years of age and either intolerant of nasal CPAP or requested the MAS as primary treatment. Patients with significant co-morbidity (respiratory, cardiac, cerebro-vascular or renal disease or a mental health problem), an additional sleep disorder or dental contraindications were excluded.

Mandibular advancement splint (MAS). All subjects had a custom-made MAS fabricated in the Dental Department, Capital Coast Health. The process involved five, 15-minute appointments; the first two for primary and secondary alginate impressions, the third and fourth for splint fitting and adjustment and the final appointment for review. Splints were of two types. Dentate patients had fixed type splints constructed using upper and lower laboratory-fabricated methyl methacrylate plates stabilized with ball clasps. These plates were located together in the protruded position with bite registration material that was then replaced with permanent self-curing acrylic. The plates were aligned using clinical judgement and a ruler to measure the distance between arbitrary mark points made on the outside surfaces of the plates. The aim was to achieve mandibular advancement to 75% of maximal protrusion and an inter-arch relationship of approximately 2-4mm, depending on the patient's overbite, comfort and provision of adequate breathing space. For semi-dentate and edentulous patients a soft-type splint was made using Mouth Guard Material ® (N=3). They were made to be in contact with remaining teeth and gingivae. Dentate splints were in contact with teeth only. Both splint types had breathing slots anteriorly (Figure 1).

Polysomnography. Subjects attended the WellSleep sleep laboratory overnight and were randomly assigned to wear their MAS for either the first or the second half of the night (ten subjects first half, nine subjects the second half). The effect of the MAS on indices of OSAS and snoring were objectively assessed by polysomnography in a sound-proofed bedroom using a computerised sleep system (W-Series Sleep system, Compumedics P/L Australia). Measurements included sleep stage (electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG) by surface electrodes), oronasal airflow (thermistor), ribcage and abdominal wall motion (piezoelectric bands), arterial oxygen saturation (SaO₂), and body position (mercury switch transducer). Sound intensity was measured with an integrating sound level meter (Rion NA-O5) positioned one meter from and directed at the sound source. A snore report was generated with specific 'snore software' (Replay V. 2 R. 2, Compumedics P/L Australia) to provide mean and maximum snore levels (dB) as well as the frequency of snores. Previously defined definitions for snoring were used (minimum increase of 5 dB over a baseline).⁷ The accuracy of these definitions was manually confirmed in a simultaneous research project. To allow a period of familiarisation with the MAS, studies were undertaken at least two weeks after final fitting and adjustment.

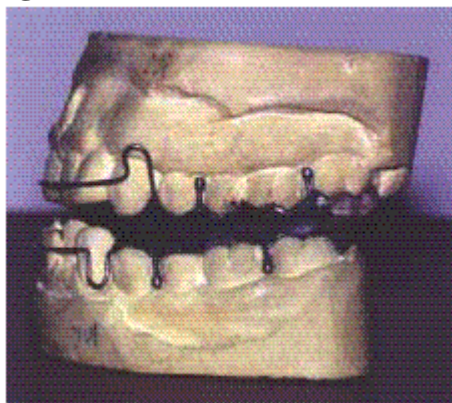
Questionnaire. All subjects completed a general health and sleep questionnaire which included an Epworth Sleepiness Score (ESS).¹⁴ A 10 cm Likert scale was used to assess treatment effect, satisfaction and side effects. Patients and partners were asked to place a mark on this line to reflect the change in symptom using MAS therapy. The mid-point represented no change in symptoms, far right indicating best ever and far left worst ever.

Sleep study analysis and measurements. Sleep studies were scored manually for sleep stage,¹⁵ arousals¹⁶ and respiratory events. Obstructive apnoea were defined as cessation of airflow for at least ten seconds (10s) accompanied by an ongoing respiratory effort. Central apnoea were defined as the cessation of airflow and respiratory effort for at least 10s. Hypopnoeas were defined as a greater than 50% decrease in two of the three respiratory channel amplitudes for at least 10s. Sound intensity and snores were measured and cross-referenced to sleep stage. Indices of OSAS severity and snoring indices were analysed and compared during sleep with and without MAS.

Statistical analysis. Statistical analysis was performed using the SAS package. A PROC MIXED procedure (to allow for fixed and random effects) was used to compare indices of OSAS and snoring with and without the MAS. Results of variables measured by Likert scale are expressed as a percent

change and were analysed by paired t test. Statistical significance was set at $p < 0.05$. All results are expressed as mean \pm standard deviation (SD) unless otherwise stated.

Figure 1. Mandibular advancement splint.



Results

Three of 22 patients initially enrolled were excluded due to identification of an additional sleep disorder: two had periodic limb movements of sleep (PLMS) and one significant central sleep apnoea. Nineteen patients (18 male, 1 female) with a mean age of 47.7 ± 10.1 years and a mean BMI of $31.9 \pm 4.6 \text{ kg/m}^2$ completed the research protocol. Initial diagnostic polysomnography showed OSAS severity to be mild (RDI 5-20 /hour) in eight subjects (42%), moderate (RDI 20-40/hour) in six subjects (32%) and severe (RDI >40 /hour) in five subjects (26%). Patients used the MAS for a median of 6.5 weeks (range 2-48 weeks) prior to the research study night.

Table 1. Polysomnography variables (n=19) with and without mandibular advancement splint (MAS).

Variable	No MAS Mean (SD)	MAS Mean (SD)	P Value *significant
RDI /hr	22.2 (19.8)	16.5 (21.4)	0.03*
Supine RDI	30.8 (23.8)	18.8 (22.1)	0.01*
RDI REM sleep	21.6 (25.5)	20.9 (19.1)	0.80
RDI NREM sleep	23.2 (22.0)	14.9 (22.8)	0.01*
AI/hr	25.2 (15.9)	19.3 (14.2)	0.01*
NREM Sleep (%)	77.6 (18.0)	78.5 (10.4)	0.82
Sleep Efficiency (%)	81.8 (9.9)	84.1 (11.8)	0.13
Maximum snore level (dB)	71.9 (7.3)	69.4 (5.1)	0.13
Mean Snore Level (dB)	52.7 (4.1)	50.7 (2.7)	0.048*
Snore frequency (snores/min)	6.7 (5.0)	6.0 (4.2)	0.31
Frequency of snores <50 dB	2.5 (2.4)	2.9 (2.5)	0.76
Frequency of snores $=50$ dB	4.3 (3.5)	2.9 (2.9)	0.048*

RDI =Respiratory Disturbance Index; REM =Rapid eye movement; NREM=non-rapid eye movement; AI =Arousal Index.

Polysomnography. Use of the MAS was associated with a significant improvement in polysomnographic indices of OSAS (Table 1) particularly when sleeping supine, where mean RDI decreased from 30.8 ± 23.8 to 18.8 ± 22.1 events per hour. Complete treatment success (RDI <5 /hr with MAS) was achieved in four (21.1%), partial success (RDI >5 /hr but $\geq 50\%$ reduction in pretreatment RDI) was achieved in ten

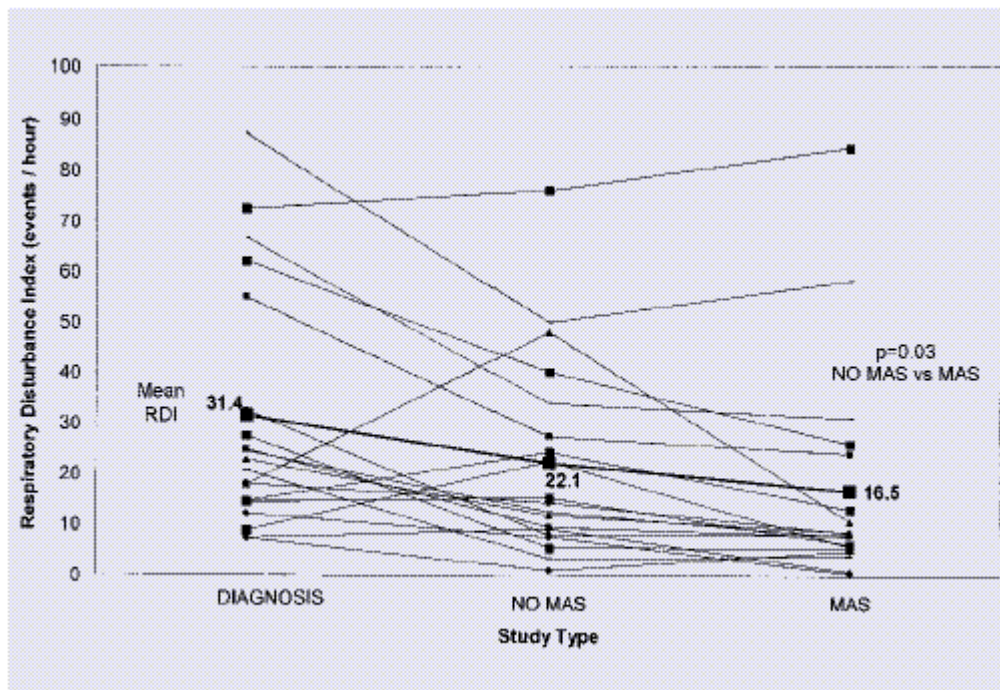
(52.6%) and treatment failure (RDI >5/hr and <50% reduction in pretreatment RDI) in five (26.3%) (Figure 2). Of the five patients classified as failures, one showed an increase in RDI when using the device on the research night. There were no significant differences between those patients who showed a complete or partial success with the MAS and those who were treatment failures in terms of initial RDI (p =0.36), BMI (p =0.29), age (p =0.09), neck circumference (p =0.35) or supine RDI (p =0.95). Positional data were obtained in thirteen subjects. The presence of supine-dependent OSAS did not correlate with a greater MAS treatment effect.

MAS use reduced the frequency of loud snores over 50dB (p =0.048) and mean level of snoring intensity (p =0.048) but did not change total snore frequency (Table 1).

Questionnaire results. Using a Likert scale, partners reported a mean improvement in snoring of 50. 8 ±27.4%, (p <0.001, n =11) with the MAS. Patients reported improved sleep quality (28 ±23.4% p <0.001) and daytime alertness (22 ±23.6%, p <0.001) but this was not reflected by a significant change in ESS (post treatment =10.4 ±3.7, pre treatment 12. 2 ±4.8, p =0.14).

MAS compliance and side effects. The MAS was used by ten patients (53%) every night, for more than three nights a week by five (26%) and four (21%) for less than this. Most patients 78.9%) used the MAS for the whole night when they used it. Fifteen (79%) of the nineteen patients reported side effects using the MAS and in five (26%) this regularly prevented use. Jaw pain (5, 26%) and sore teeth and gums (8, 42%) were the commonest complaints. Other reported side effects included: excessive salivation (2,10.5%), choking (2, 10.5%), difficulty breathing (2, 10.5%) and ejection of the device. Patients not using their MAS every night were not more likely to report side effects than those using the device every night (p >0.05).

Figure 2. Individual and mean respiratory disturbance index at diagnosis, half the night without mandibular advancement splint (MAS) and half the night with the MAS.



Dental effects of the MAS. MAS related dental measurements were available in eleven patients. The MAS produced an average mandibular advancement of $61.5 \pm 13.1\%$ of maximum protrusion and average vertical displacement of 11 ± 2 mm (n=11). The extent of mandibular advancement and vertical displacement were not related to improvement in RDI or side effects ($p > 0.05$).

Discussion

We have demonstrated significant objective improvements in OSAS and indices of snoring with a locally fashioned MAS. Polysomnographically determined treatment success was achieved in 73.7% of patients but was complete in only 21.1%. A significant number of subjects had difficulty tolerating the device with 42% not using the device every night but 79% using the device for the whole night when they did use it.

All partners surveyed reported improvement in snoring but objective measurement confirmed that snoring persisted in most with no change in the total snore frequency. We were able to show a significant reduction in loud snores and mean snore intensity which would presumably equate with the subjective improvements reported by partners. It is clear from our results that patients with OSAS should not expect abolition of snoring as a treatment outcome with the MAS device. A similar result has been reported by O'Sullivan et al (measuring sound intensity), where a significant reduction in loud snores with use of a MAS was seen but snoring was still present.⁷

The literature describes three main types of dental devices marketed for reducing snoring and OSAS. Tongue retainer devices (designed to pull the tongue forward), soft palate lifters, and mandibular advancement splints.¹⁷ The design of the current device was chosen with several factors in mind. Firstly, to minimise any teeth movement from the device, a large occlusal coverage was used. Secondly, the device was fitted aiming for 75% of maximum mandibular protrusion but ultimately depended on dental factors and patient tolerability. The mean mandibular protrusion in eleven subjects was 61.5% of maximum which was lower than ideal and may have reduced the success of this treatment. However we found no relationship between the degree of advancement and measures of OSAS improvement. The development of a titratable device, where the patient or dentist can progressively advance the mandible, might improve performance of the device. Pancer et al report 51% of OSAS patients having their RDI reduced to < 10 per hour with a titratable device.¹⁸

Many of the dental devices currently available in New Zealand and marketed as a treatment for snoring and OSAS have not been systematically evaluated and therefore claims of effectiveness seem difficult to substantiate. Although we have clearly demonstrated a significant treatment effect with our MAS device the variability of patient response and lack of predictive factors mandates objective re-evaluation by sleep study.

We have used the definition of treatment success proposed by Mehta et al¹¹ which considers a complete success when RDI is reduced to < 5 events per hour and a partial success if RDI is reduced by $> 50\%$ but still remains greater than 5 per hour. Using this definition 14/19 (73.7%) of our subjects were defined as complete or partial successes compared to original diagnostic PSG data. In a larger randomised controlled study, Mehta et al reported a similar success rate - 38% complete success and 25%

partial success.¹¹ Using less stringent criteria (success = RDI <10 per hour) Pancer reports a higher 54% complete success.¹⁸ Clinical and polysomnographic variables measured in our study were not predictive of MAS treatment success as has been reported by several others.^{10,18,19} Mehta et al report a predictive model for MAS treatment outcome using four variables (neck circumference, baseline RDI and two cephalometric measurements: retropalatal airway space and the angle between anterior cranial base and mandibular plane)¹¹ but this requires verification from a prospective study.

The average respiratory disturbance index (RDI) was lower during the research ½ night without MAS compared to the initial diagnostic study. There are several reasons why this might have occurred. It may reflect a treatment effect from using the MAS as a result of upper airway changes secondary to reduced mucosal oedema. This effect has been described in OSAS patients treated with nasal CPAP.^{20,21} However, this cannot be assumed given the persistence of snoring in most and partial obstruction in a significant proportion of the subjects using the MAS. There was no significant change in weight nor any difference in the percentage of time spent sleeping supine. Night-to-night variability in RDI may occur in OSAS.²² A 'first night effect' when studies are undertaken on consecutive nights in a sleep laboratory has been described but remains controversial with conflicting reports in the literature.^{22,23} Lifestyle changes such as increased sleep duration that might have occurred were difficult to take into account, making comparisons between the two nights problematic. For these reasons we chose to compare indices of snoring and sleep disordered breathing in subjects on the same night.

A significant proportion of our subjects (42%) chose not to use the MAS every night. MAS-related side effects were reported by 79% of patients with 26% stating that side effects prevented regular use. The most common side effect was sore teeth/gums which may be related to the large occlusal coverage and fixed type splint which lacks adjustable anterior protrusion, lateral and vertical movement. Ferguson et al reported 24% of their subjects had moderate to severe side effects but found that side effects were not related to degree of protrusion.²⁴

In conclusion we have demonstrated that the MAS, as used in this study, improves objective and subjective indices of OSAS and snoring. Side effects were common and in some cases prevented regular use of the device. MAS treatment is a viable alternative to nasal CPAP. However, follow up assessment (polysomnography or respiratory sleep study) is recommended as reliance on subjective response may be misleading. Further research will help decide which patient groups benefit most from MAS therapy while improvement in design and adjustability are needed to optimise patient comfort and long term tolerability.

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