

A thermoplastic mandibular advancement device for the management of non-apnoeic snoring: a randomized controlled trial

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SUMMARY This randomized, controlled, crossover trial assessed the effectiveness of an adjustable, thermoplastic, mandibular advancement device (MAD), the TheraSnore™, in the management of non-apnoeic snoring.

Twenty-three adults who had been referred for a MAD wore the appliance in both a non-advanced and advanced position for 4–6 weeks: the starting position of the MAD was randomized. The outcomes were assessed at baseline and after each phase of MAD wear using questionnaires [(Epworth Sleepiness Scale, snoring history, sleep disturbance, side-effects of the appliance) and a visual analogue scale (daytime sleepiness)]. Eleven subjects had overnight sleep studies at baseline and with the appliance in each position to assess snoring frequency (snores/hour), oxygen saturation, and apnoea hypopnoea index. Supine radiographs were used to examine the oropharyngeal airway at baseline and in response to both appliance positions.

In comparison with the non-advanced appliance, the advanced MAD reduced the snores per hour from a median of 398 to 17 ($P = 0.002$). Sleeping partners reported a marked improvement in their own daytime tiredness ($P = 0.002$) and sleep disturbance ($P = 0.001$) when the subject wore the active appliance. The most common side-effect was a dry mouth and 64 per cent of subjects considered the appliance bulky. Radiographic analysis revealed significant vertical opening associated with the appliance and small but significant post-lingual changes with protrusion.

The results suggest that the advanced TheraSnore™ MAD is effective in the treatment of snoring in two out of three non-apnoeic snorers, their sleeping partners derive benefits from this form of treatment, and that complaints of bulkiness and dry mouth may to be related to the inherent vertical opening of the TheraSnore™.

Introduction

Snoring is a common acoustic phenomenon that may precipitate social disharmony (Hoffstein *et al.*, 1996). A 40 per cent prevalence rate has been reported by Ohayon *et al.* (1997) in the British adult population. In addition, snoring is a cardinal sign of obstructive sleep apnoea (OSA), a sleep-related breathing disorder with a prevalence of 4 per cent in men and 2 per cent in women in the 40- to 65-year age group (Young *et al.*, 1993). However most snorers do not have OSA and not all OSA patients snore. Despite findings that OSA subjects had higher risks for stroke and myocardial infarction, this has not been proved for non-apnoeic snorers (Mohsenin, 2001).

The aetiology of sleep-related breathing disorders is multi-factorial. Non-apnoeic snoring is characterized by audible high frequency oscillations of the pharyngeal soft tissues and alternating rapid partial occlusions and openings of the pharynx (Liistro *et al.*, 1991) without episodes of apnoea. In OSA, airway collapsibility is greater and periodic pharyngeal obstruction occurs. Nocturnal polysomnography is used to differentiate non-apnoeic snoring from OSA,

whilst sleep nasendoscopy (SNE) may identify the site or sites of airway obstruction or narrowing (Pringle and Croft, 1993)

Management of snoring and OSA aims to increase upper airway patency and reduce airway resistance. Conservative measures include lifestyle adjustments to an exacerbating factor, such as weight loss and alcohol abstinence: however subjects frequently resist change. Nasal continuous positive airway pressure (nCPAP) is highly effective in conservative management of moderate and severe OSA (American Sleep Disorders Association, 1995) but compliance (Ferguson *et al.*, 1996) and cost preclude its use in the treatment of non-apnoeic snoring. Surgical treatment for snoring includes laser-assisted uvulopalatoplasty (Pépin *et al.*, 1996) and uvulopalatopharyngoplasty (Utley *et al.*, 1997), but reported success rates are variable. Research would suggest that mandibular advancement devices (MADs) are appropriate in the treatment of milder OSA and non-apnoeic snoring (Ferguson *et al.*, 1996).

Familiarity with the construction of custom-made, functional orthodontic appliances has led to the involvement

of the orthodontic profession in the management of snoring and OSA. Oral appliances act to modify the upper airway dimensions and biomechanics during sleep. MADs have variable efficacy for the treatment of snoring (Johnston *et al.*, 2001) and OSA (Marklund *et al.*, 1998; Johnston *et al.*, 2002). This may be related to differences in MAD design, patient selection, or anatomical differences. The initial comfort (Lamont *et al.*, 1998) and the degree of vertical opening induced by an appliance would appear to have an effect on patient tolerance (Pitsis *et al.*, 2002). In addition, mandibular opening above a specific level may lead to a reduction in airway dimensions (L'Estrange *et al.*, 1996). The appliances are usually worn each night indefinitely for symptomatic relief, so breakage and renewal of appliances is not uncommon. These factors have financial implications for both hospital budgets and patients. A relatively inexpensive, durable, adjustable appliance that can be fabricated at the chairside would have clear advantages.

Randomized, controlled trials provide scientific evidence for the evaluation of treatment modalities and there appears to be only one such trial for the effectiveness of a MAD in treatment of non-apnoeic snoring (Johnston *et al.*, 2001). The aims of the present prospective, randomized, crossover study were to assess:

1. the effectiveness of an adjustable thermoplastic MAD, the TheraSnore™ (Distar, L.L.C., Albuquerque, New Mexico, USA) in managing non-apnoeic snoring.
2. whether a reduction of snoring loudness could improve the sleep quality of the subject's sleeping partner;
3. the side-effects of the TheraSnore™.

The TheraSnore™ in the non-advanced position was used in the non-active arm of the study as a close approximation to a placebo appliance.

Subjects and methods

Twenty-seven adults (17 males and 10 females) were included in the trial after informed consent was obtained. Ethical approval was obtained from the local health authority research ethics committee. The patients were consecutively referred to the Royal London Hospital Orthodontic Department over a 9-month period for construction of a MAD. Nocturnal polysomography had established a diagnosis of non-apnoeic snoring and SNE identified a tongue base contribution to the snoring. If temporary mandibular advancement reduced the snoring during the SNE, the subjects were invited to participate in the clinical study. Basic demographic data and details of sleep and dental histories were obtained. The subject's height, weight, and neck circumference were recorded and the body mass index (BMI; weight kg/height m²) and percentage of predicted neck circumference (PNCC) were calculated (Davies and Stradling, 1990). A detailed examination of the

dental and periodontal condition, including assessment of the temporomandibular joints and functional occlusion, was carried out. Exclusion criteria were (1) an inadequate number of sound teeth, (2) epilepsy, (3) temporomandibular joint dysfunction and (4) a dental arch too wide for the appliance.

Sample size

Calculation of sample size using Altman's nomogram suggested that 23 subjects would give an 80 per cent probability of detecting a real difference between the two TheraSnore™ appliance positions at a statistically significant level of 5 per cent (Altman, 1995).

Appliance design

The adjustable TheraSnore™ MAD (Figure 1) is a 'boil-and-bite' appliance that is customized at the chairside following heating. It is made in one standard size and the lower section is adjustable forwards in 1.5 mm increments. It consists of two trays of semi-rigid thermoplastic material supported by a framework of harder, heat-resistant polycarbonate.

Sequence of treatment

The appliance was worn in two positions: no mandibular advancement (the sham appliance) and mandibular advancement (the active appliance) at 75 per cent of maximum protrusion, for consecutive study periods of 4–6 weeks. Randomization was used to decide in which position the appliance was worn first. A one-night washout period, with no appliance, was employed between the two periods of appliance wear (Johnson *et al.*, 2001).

Questionnaires

Subject questionnaires and visual analogue scales (VAS) were used at baseline and after each period of appliance wear to assess sleep history (Flemons *et al.*, 1994), daytime sleepiness [Epworth Sleepiness Scale (ESS); Johns, 1993], and the side-effects of the MAD. All patient questionnaires were checked

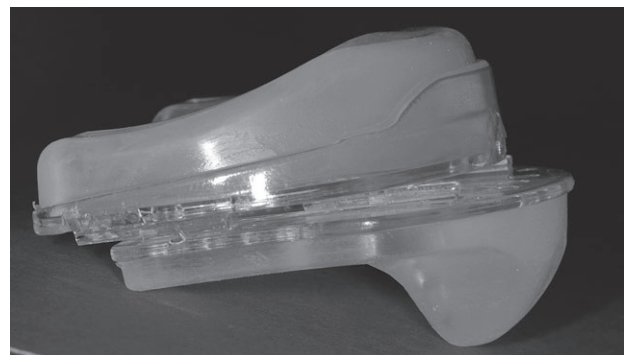


Figure 1 The TheraSnore™ appliance.

for full completion at the chairside. Sleeping partners' questionnaires (Gliklich and Wang, 2002) and VAS were completed at home to assess the subject's snoring loudness and the sleeping partner's own daytime sleepiness and sleep disturbance. All partner questionnaires were checked on return and if incomplete were completed by telephone.

Epworth Sleepiness Scale. The ESS is widely used as a subjective means of assessing a subject's perception of their daytime sleepiness (Johns, 1993). The ESS score may be between 0 and 24, with normal values being less than 10.

Sleep history questionnaire. The sleep history questionnaire used a Likert Scale (Flemons *et al.*, 1994), which assessed the frequency of the subject's symptoms. This used a scoring system of 1–7, where 1 represented always refreshed on waking and 7 more tired than when the subject went to bed.

Partner sleep quality questionnaire. A validated five-point questionnaire was used to assess the partner's daytime tiredness and sleep disturbance (Gliklich and Wang, 2002).

Visual analogue scales. A VAS is a line that represents the continuum of the symptom being rated and is a simple way to record subjective estimates of a symptom. Partners completed VAS to assess the subjects' level of snoring loudness. The VAS score was rated from 0 to 10, where 0 represented no snoring and 10 very loud snoring.

Quality of life questionnaire (SF-36). The SF-36 questionnaire (Stewart *et al.*, 1988) was used to assess the subject's quality of life prior to and after wearing the MAD in both positions. The questionnaire assesses three major health attributes: functional status, well-being, and overall health by assessing nine domains (physical function, physical role limitation, emotional role limitation, social function, mental health, pain, general health perception, change in health, energy/vitality) of the subject's life. Scores from each of the nine domains were transformed using an algorithm equation into a score of 0–100 per cent.

Domiciliary sleep monitoring

A Densa Compact (Ferraris Medical Ltd, Enfield, Middlesex, UK) sleep apnoea screening system was used for the home sleep studies at baseline and after each period of appliance wear. This recorded the number of snores per hour over 45 decibels (dB), arterial oxygen saturation (SaO₂), and apnoea hypopnoea index (AHI). The Densa Compact equipment is designed to minimize background noise with the microphone sited at the sternal notch. The World Health Organisation (1999) has suggested a guideline of 45 dB when noise events are non-continuous

to minimize annoyance and sleep disturbance effects. A guide to noise levels includes: background noise, 40–50 dB; normal conversation, 50–60 dB; whilst 60–75 dB corresponds to a loud radio. A sound level change of 1 dB can be perceived by the human ear, and an increase of 10 dB within the hearing range is perceived as a doubling in loudness and a decrease of 10 dB as a halving in loudness.

Supine radiography

Three supine lateral post-nasal space radiographs were taken using an adjustable Orbix machine (Siemens PLC, Croydon, Surrey, UK) on the day the appliance was fitted. Subjects lay supine with a foam head support and the clinician (MEC) checked the lateral head position. Barium contrast medium was applied to the dorsal tongue surface to delineate the oropharyngeal outline. Radiographic exposures were taken at the end of expiration to standardize the hyoid position. The first radiograph was taken with the subject's teeth in maximum intercuspation, the second with the appliance *in situ* in the non-advanced mode, and the third with the appliance at 75 per cent of maximum protrusion; Battagel *et al.* (1999) have previously described the method of analysis (Figure 2).

Appliance outcome questionnaire

The appliance outcome questionnaire was used to determine the response to the appliance 4–6 weeks after wearing the TheraSnore™ device in both the non-advanced and advanced modes. The questions related to excess salivation, dry mouth, muscle discomfort, temporomandibular joint discomfort, and abnormal bite after removal of the appliance. The patient answers were either 'yes' or 'no'.

Statistical analysis

The Statistical Package for Social Sciences (version 11.0 for Windows, SPSS Inc, Chicago, Illinois, USA) was used to analyse the data. Non-parametric tests were employed for the analysis because of the small sample size. Due to the crossover design, Wilcoxon matched-pairs signed-ranks tests were used for the paired data, including all the questionnaires, VAS, and the cephalometric study. The level of agreement between the subject and the partner questionnaires was tested with Spearman's rank correlation at the 10 per cent level. Independent Wilcoxon signed-ranks tests were used to determine the randomization order and treatment order effects. The central tendency of the data was described using the median value and the range expressed as maximum and minimum values.

Method error—radiographic examination

Random error was assessed using duplicate tracings of 20 of the radiographs as described by Dahlberg (1940) and

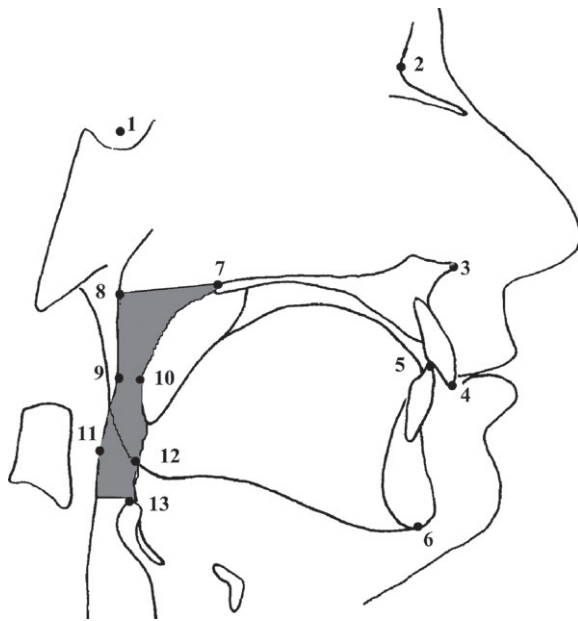


Figure 2 Cephalometric and oropharyngeal points and measurements. 1, sella; 2, nasion; 3, anterior nasal spine (ANS); 4, upper incisor tip; 5, lower incisor tip; 6, menton; 7, posterior nasal spine (PNS); 8, point on the posterior pharyngeal wall at the level of PNS; 9, point on the posterior pharyngeal wall where the post-palatal airway is at its narrowest; 10, point on soft palate where the post-palatal airway is at its narrowest; 11, point on the posterior pharyngeal wall where the post-lingual airway is at its narrowest; 12, point on the dorsal aspect of tongue where the post-lingual airway is at its narrowest; 13, tip of the epiglottis. Cephalometric measurements: skeletal—lower anterior face height (menton to ANS), upper anterior face height (nasion to ANS); dental—overjet (horizontal distance between points 4 and 5), overbite (vertical distance between points 4 and 5). Pharyngeal measurements: pharyngeal length (mm) = vertical distance between distal projection of the maxillary plane and point 15; minimum post-palatal airway (mm) = distance between points 9 and 10; minimum post-lingual airway (mm) = distance between points 11 and 12. The oropharyngeal area (grey) is outlined by the pharyngeal wall posteriorly and the dorsal surfaces of the tongue and soft palate anteriorly. The vertical boundaries are lines parallel to a line at 7 degrees to S–N, superiorly at the level of PNS and inferiorly at a tangent to the tip of the epiglottis.

Houston (1983). Of note was that five of the measurements with larger errors were related to gonion, a point with a large envelope of error (Baumrind and Frantz, 1971). Dahlberg values were also expressed as percentages and this indicated that small measurements had relatively high errors. The coefficient of reliability (Houston, 1983) produced a reliability index greater than 90 per cent for all but one measurement (the pharynx at the PNS level), indicating a generally low random error. Systematic error (bias) was assessed using a one-sample *t*-test at the 10 per cent level of significance. Ten measurements showed bias. Three of these were related to the lower incisor and six to soft tissue measurements. Lack of examiner experience in accurate identification of landmarks (Houston, 1983) and the reduced quality of the supine radiographs compared with standard, upright, cephalometric radiographs may be implicated in the greater errors associated with the soft tissues of the airway. With respect to the lower incisor inclination and the

pharynx at the PNS level, both the Dahlberg value and Houston's coefficient of reliability together suggest that significant error is associated with these measurements.

Results

Twenty-three adults completed the study. Of the four dropouts, two were unable to tolerate the appliance, one withdrew, and one failed to return after the initial appointment. Baseline characteristics of the remaining 23 patients included a median age of 44.7 years (range, 29.2–63.5 years) and median BMI of 27.1 kg/m² (range, 20.3–35.1 kg/m²). Five subjects were obese with a BMI greater than 30. However, the PNCC (median 87.5 per cent and range 78.0 to 107.1 per cent) suggested that most of the subjects were not overweight, with only two subjects having a PNCC greater than 100 per cent. Baseline data for the four individuals who withdrew did not differ from those who completed the study.

Treatment order effects

Independent Wilcoxon signed-ranks tests confirmed there was no allocation bias and no carryover effects related to the sequence of appliance wear.

Subjects' symptoms

Data from the sleep history questionnaire, the ESS, and the sleeping partners snoring VAS were used to compare the clinical effectiveness of the two appliance positions with the baseline data (Table 1). One subject did not have a regular sleeping partner and thus his data were excluded from the analysis of snoring loudness.

- Waking unrefreshed: the subjects' median baseline scores for waking unrefreshed in the morning remained unchanged at 5.0 with the non-advanced MAD (Table 1). However, a significant improvement from baseline with the advanced MAD (to 4.0) was found ($P = 0.015$). When the frequency distribution was examined for both appliance positions compared with baseline (Figure 3a), considerable individual variation was noted. Four subjects (17 per cent) with the non-advanced MAD compared with 11 (48 per cent) with the advanced MAD reported an improvement in their symptoms. However nine subjects (39 per cent) experienced no change and three (13 per cent) reported poorer sleep with the advanced MAD.
- ESS: the median value at baseline of 8.0 remained unchanged for the non-advanced MAD and reduced to 7.0 with the advanced MAD. A statistically significant difference was found between the two appliance positions ($P = 0.036$). It is noteworthy to look at the frequency of the reported changes in the ESS compared with baseline (Figure 3b). With the non-advanced MAD nine subjects (39 per cent) reported a worsening of the symptoms assessed by the ESS, seven (30 per cent) reported no change, and seven (30 per cent) reported an improvement.

Table 1 Subject's symptoms with the TheraSnore™, compared with baseline.

Variable	Position of mandible	Median	Range (minimum–maximum)	Statistical significance	
				Baseline/Non-Adv and Baseline/Adv	Non-Adv and Adv
Unrefreshed on waking (<i>n</i> = 23)	Baseline	5	2–7	NS, <i>P</i> = 0.421 <i>P</i> = 0.015*	<i>P</i> = 0.006**
	Non-Adv	5	2–7		
	Adv	4	1–7		
Epworth Sleepiness Scale (<i>n</i> = 23)	Baseline	8	2–19	NS, <i>P</i> = 0.655 NS, <i>P</i> = 0.201	<i>P</i> = 0.036*
	Non-Adv	8	2–21		
	Adv	7	1–21		
Snoring loudness (partner reported, <i>n</i> = 22)	Baseline	9	6–10	NS, <i>P</i> = 0.763 <i>P</i> = 0.001***	<i>P</i> = 0.013*
	Non-Adv	8	6–10		
	Adv	6	2–10		

Adv = advanced/active; Non-Adv = non-advanced/sham.

Statistical significance: NS = non-significant; **P* < 0.05; ***P* < 0.01; ****P* < 0.001.

Of particular interest is that eight subjects (35 per cent) reported a worsening of the ESS with the advanced MAD.

- c) Snoring loudness: partners reported significant reductions in snoring loudness whilst the advanced MAD was worn (*P* = 0.001) compared with baseline (Table 1). Examination of the frequency distribution (Figure 3c) showed a reduction in snoring loudness for nearly two out of three of the subjects (64 per cent) with the active appliance. For five subjects the partners perceived an increase in snoring loudness with the non-advanced MAD and for two subjects (9 per cent) with the advanced MAD.

SF-36 quality of life questionnaire

Assessment of the nine domains of the SF-36 questionnaire revealed no significant difference between baseline and either appliance position or between the appliance positions for any of the nine dimensions. However, a difference between the two appliance positions for the energy/vitality domain appeared to be approaching statistical significance (*P* = 0.072).

Overnight sleep study data

Snoring. Only 11 of the 23 subjects completed the three domiciliary sleep recordings (Table 2). This was due to numerous failures of the recording equipment during the course of the study.

The median number of snores per hour measured at 45 dB was significantly reduced (*P* = 0.002) from 398, at baseline, to 17 with the MAD advanced whereas the non-advanced MAD had no effect (Table 2). The advanced MAD was therefore the more effective appliance position in reducing snoring.

SaO₂. No statistically significant difference was found for the changes in SaO₂ values between baseline and the two MAD positions. However there was a tendency towards improvement with the advanced MAD and the '*P*' value (0.057) may be the result of a type II error due to the small sample size in this part of the study. Compared with the non-advanced position, the advanced mode appeared to be the more effective position (*P* = 0.011).

AHI. No statistically significant differences in median AHI values were found between baseline (5.5) and with the TheraSnore™ appliance in either the non-advanced (5.5) or advanced positions (4.0).

Partner symptoms. The partner's report of their own sleep quality remained unchanged with the non-advanced MAD (4.0) but reduced to 2.0 when the MAD was advanced. This was found to be statistically significant (*P* = 0.001; Table 3). No partner reported a worsening of the disturbance when the subject was wearing the advanced MAD (Figure 4a).

The partners felt less tired during the day when the subjects wore the active MAD (*P* = 0.005), and whilst no statistically significant reduction in daytime tiredness was found with the non-advanced MAD, 10 partners (45 per cent) reported a reduction in their daytime sleepiness (Figure 4b)

Radiographs

Overjet. Radiographic analysis revealed that insertion of the non-advanced TheraSnore™ increased the median overjet from 3.1 mm in occlusion to 6.6 mm (*P* = 0.000) as the mandible dropped down and back (Table 4). Conversely, the advanced MAD reduced the overjet to a median value of –1.0 mm with mandibular protrusion. The difference between the two positions was highly significant (*P* = 0.000).

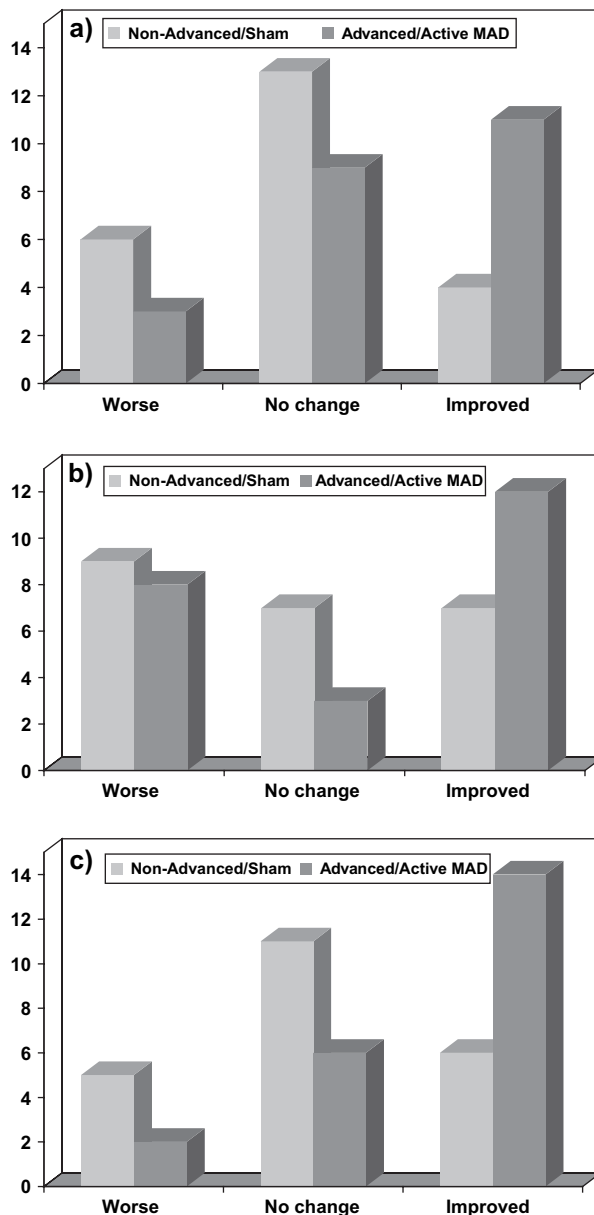


Figure 3 Subject symptoms: (a) awakes unrefreshed, (b) Epworth Sleepiness Scale, (c) snoring loudness.

Bite opening. Bite opening with both TheraSnore™ positions reduced the overbite from 1.3 mm in occlusion to -10.5 mm ($P = 0.000$), with the non-advanced MAD and -11.7 mm with the advanced MAD ($P = 0.000$). In addition, the difference in bite opening between the two positions was found to be significant ($P = 0.002$).

Effect on the airways. The effects on the airways are as follows:

- Pharyngeal width: pharyngeal airway width at the PNS level increased by 2.5 and 1.8 mm with the non-advanced and advanced MAD, respectively, but was only statistically significant for the former ($P = 0.036$) compared with

baseline. The minimum post-palatal airway width reduced by 0.1 mm ($P = 0.794$) and 0.7 mm ($P = 0.664$) for the non-advanced and the advanced MAD positions, respectively. However the median value of the minimum post-lingual airway was reduced by 0.7 mm with the non-advanced MAD but increased by 0.7 mm with the protrusive position. This increase was found to be significant ($P = 0.013$), while the difference between the two appliance positions was also significant ($P = 0.002$).

- Pharyngeal length: pharyngeal length was increased significantly ($P = 0.001$) for the non-advanced TheraSnore™ but reduced with the protrusive mode. The difference between the two positions was also highly significant ($P = 0.000$).
- Oropharyngeal area: no statistical significance was associated with the changes in the oropharyngeal area.

Compliance and side-effects of the appliance

For the duration of the study there appeared to be consistent wear of the TheraSnore™ appliance, with 18 out of 23 subjects (78 per cent) wearing it for more than 5 hours per night and 17 out of 23 (74 per cent) wearing it 5–7 nights per week. The side-effects were examined after 1 week and 4–6 weeks (Table 5). All side-effects were more severe initially, except for a dry mouth. The advanced appliance had a higher percentage of side-effects, except for excessive salivation. Fifteen subjects (65 per cent) reported the appliance to be bulky or large.

Discussion

The demand for oral appliances in the treatment of sleep-related breathing disorders has increased in recent years. Long-term wear for symptomatic relief is not unusual and an inexpensive adjustable appliance, such as the TheraSnore™, that is easy to fit at the chairside would have advantages. The choice of a particular MAD by dental practitioners appears to be an individual preference and the evidence for clinical use of many has not been fully evaluated (Johnston *et al.*, 2001).

Limitations of the study

A larger number of subjects may have given greater statistical significance to the findings. The greatest limitation encountered was that of the recurrent technical problems with the domiciliary Densa sleep recording equipment, both from equipment design and technical support aspects. This limited the objective data collected during the study period.

The length of the study period did not allow for long-term follow-up regarding compliance and the side-effects of the TheraSnore™ and it is recognized that unwanted side-effects can occur in the long term (Bondemark and Lindman, 2000).

Table 2 Sleep study data compared with baseline.

Variable (<i>n</i> = 11)	Position of mandible	Median	Range (minimum–maximum)	Statistical significance	
				Baseline/Non-Adv and Baseline/Adv	Non-Adv and Adv
Snore per hour	Baseline	398	51–633	NS, <i>P</i> = 0.728 <i>P</i> = 0.002**	<i>P</i> = 0.003**
	Non-Adv	427	48–652		
	Adv	17	11–324		
Oxygen saturation (%)	Baseline	90	82–96	NS, <i>P</i> = 0.725 NS, <i>P</i> = 0.057	<i>P</i> = 0.011*
	Non-Adv	89	85–91		
	Adv	91	88–98		
Apnoea hypopnoea index	Baseline	5.5	2.0–8.0	NS, <i>P</i> = 0.967 NS, <i>P</i> = 0.142	NS, <i>P</i> = 0.116
	Non-Adv	5.5	2.0–9.0		
	Adv	4.0	1.0–8.0		

Adv = advanced/active, Non-Adv = non-advanced/sham.
Statistical significance: NS = non-significant; **P* < 0.05; ***P* < 0.01.

Table 3 Partners' symptoms when TheraSnore™ worn, compared with baseline.

Variable (<i>n</i> = 22)	Mandible position	Median	Range (minimum–maximum)	Statistical significance	
				Baseline/Non-Adv and Baseline/Adv	Non-Adv and Adv
Sleep disturbance	Baseline	4	2–4	NS, <i>P</i> = 0.739 <i>P</i> = 0.001***	<i>P</i> = 0.001***
	Non-Adv	4	2–4		
	Adv	2	1–4		
Daytime tiredness	Baseline	4	1–5	NS, <i>P</i> = 0.157 <i>P</i> = 0.005**	<i>P</i> = 0.002**
	Non-Adv	4	1–5		
	Adv	3	1–5		

Adv = Advanced/active, Non-Adv = Non-advanced/sham.
Statistical significance: NS = non-significant; ***P* < 0.01; ****P* < 0.001.

The use of supine radiographs with the appliance *in situ* revealed valuable information regarding the effect of vertical opening on the airway in this sample population. However, complete standardization of the head position, as with upright cephalometric radiography, would be preferable to allow visualization of the soft tissue profile and more accurate identification of anatomical bony landmarks.

Subject selection

The employment of SNE at diagnosis ensured that all the subjects in the trial should have benefited from the device. This allowed the investigators to test the efficacy of the TheraSnore™ alone rather than the referring physician's opinion and the TheraSnore™ together. Temporary mandibular advancement during SNE is employed to mimic the action of an active MAD and

thus the reduction in snoring during SNE should be reproduced by the appliance. The technique has been found helpful in indicating treatment success with the Herbst appliance (Battagel *et al.*, 2005). However, the TheraSnore™ does not rigidly hold the mandible in protrusion. In addition the appliance leads to downward and backward rotation of the mandible and this is not accounted for during SNE. It is recognized that SNE is not routinely undertaken by ear, nose, and throat surgeons and therefore the results of this study cannot be generalized to the management of all groups of non-apnoeic snorers.

Demographic data

The subjects were generally overweight (BMI greater than 25) with 21 per cent of the sample being obese. Both

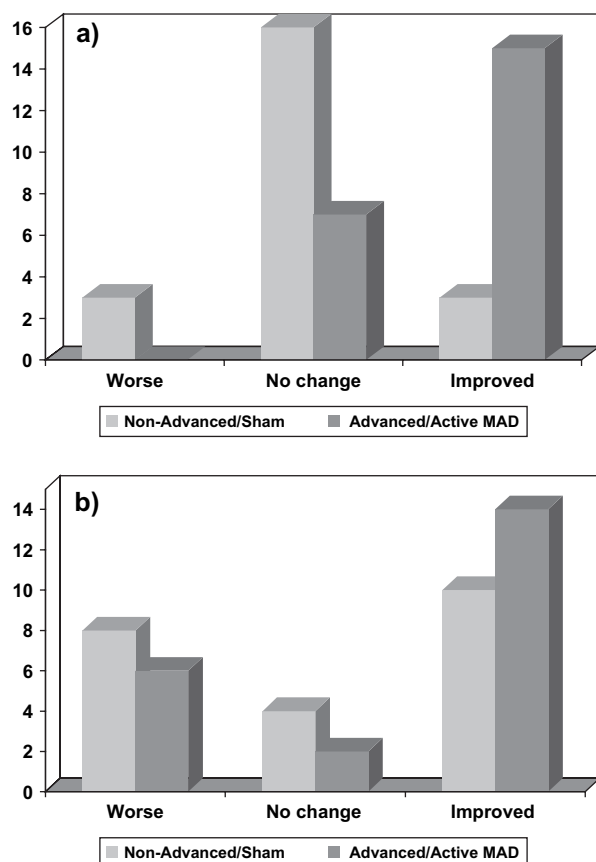


Figure 4 Sleeping partner symptoms: (a) sleep disturbance, (b) daytime sleepiness.

BMI and median age reflect current evidence that sleep-disordered breathing is more common in overweight, middle-aged adults (Ohayon *et al.*, 1997), with an increase in habitual snoring where the BMI is greater than 27 (Katz *et al.*, 1990). Snoring has been found to correlate best with PNCC (Stradling and Crosby, 1991). However in this sample of non-apnoeic snorers, only two subjects had a PNCC measurement greater than 100 per cent. This may reflect the fact that BMI is not a reliable indicator of fat distribution.

Treatment effects—subjective data

Snoring. Previous studies have used questionnaires to assess snoring prevalence and severity (Stradling and Crosby, 1991) and treatment outcomes with a MAD. The addition of a VAS provides a simple way to record subjective estimates of snoring. (Johnston *et al.*, 2001). Sleeping partners can supply more information about the subject's snoring (Wiggins *et al.*, 1990) and complaints from the partner in relation to snoring are often the main reason for snorers to seek treatment (Hoffstein *et al.*, 1996). Good agreement between the subjects' and the partners' perceptions of symptoms in this study confirmed the value of subjective outcome measures. Sleeping couples appeared to perceive

the direction of change in symptoms during the study similarly, for example, improving or worsening, although not necessarily at the same level. As this was a crossover study design, each pair, subject and partner, acted as their own controls, minimizing the variation in questionnaire responses. However, the 65 per cent success rate recorded by the partners in the reduction of snoring loudness with the advanced MAD was nearly 20 per cent less than previously reported for alternative appliances (Cameron *et al.*, 1998; Johnston *et al.*, 2001).

Daytime sleepiness. The ESS is widely used as a scale for subjects to score their perceived daytime sleepiness. However, as daytime sleepiness is not usually a complaint of non-apnoeic snorers, it is not surprising that there was no significant difference between the groups at baseline or with the MAD in either of the positions. However, some subjects reported daytime hypersomnolence and it may be that these subjects were suffering from upper airway resistance syndrome, where a normal AHI may occur in the presence of an elevated ESS.

Effects on the sleeping partner. Snoring is an unpredictable noise that may cause annoyance to sleep partners leading to irritability and social tension. The findings in the present study agree with the evidence that sleeping partners of heavy snorers report greater sleep disturbance than those of non-snorers (Ulfberg *et al.*, 2000). Only four (18 per cent) of the partners reported having a good quality of sleep at baseline. Subsequently, 63 per cent of the partners reported a significant improvement in their own sleep quality and a highly significant reduction in sleep disturbance between the non-advanced and the advanced positions of the TheraSnore™. These findings highlight the value of sleeping partners in assessing treatment outcome of MAD in non-apnoeic snorers and the potential benefits for social relationships.

Placebo response. The word 'placebo' is used in the medical lexicon as a term for fake remedies. In order to determine the true effect of a proposed treatment/drug, a placebo is frequently employed in clinical trials as a control. Ideally the placebo should be identical in every way to the treatment being tested except for the crucial component (Evans, 2003), for example, the use of 'sham' nCPAP (Jenkinson *et al.*, 1999). However, the physical nature of a MAD does not allow double blinding to occur as the crucial component can be viewed as present or absent. In relation to a MAD the mandibular advancement is the crucial component. The physical volume of a MAD once given to a patient will not be altered and thus in order to assess the placebo response of a MAD it would appear to be appropriate to fit the device in the non-active form. It can be argued that previous studies that employed a placebo appliance, for example, the maxillary appliance without a mandibular component (Johnston, *et al.*, 2001, 2002), do not represent the

Table 4 Radiographic data.

Variable (n = 23)	Mandible position	Median	Range (minimum–maximum)	Statistical significance	
				Occ/Non-Adv and Occ/Adv	Non-Adv and Adv
Overjet (mm)	Occlusion	3.1	-1.4 to 6.99		
	Non-Adv	6.6	-1.3 to 14.8	<i>P</i> = 0.000***	<i>P</i> = 0.000***
Overbite (mm)	Adv	-1.0	-7.3 to 9.63	<i>P</i> = 0.002**	
	Occlusion	1.3	-1.9 to 6.2		
LAFHt (%)	Non-Adv	-10.5	-15.6 to -0.6	<i>P</i> = 0.000***	<i>P</i> = 0.002**
	Adv	-11.7	-16.8 to 7.0	<i>P</i> = 0.000***	
Pharynx at PNS (mm)	Occlusion	56.9	53.7–61.9		
	Non-Adv	60.2	54.9–64.8	<i>P</i> = 0.000***	<i>P</i> = 0.000***
Minimum post-palatal airway (mm)	Adv	60.6	57.9–65.2	<i>P</i> = 0.000***	
	Occlusion	18.7	7.7–28.2		
Minimum post-lingual airway (mm)	Non-Adv	21.2	13.7–31.4	<i>P</i> = 0.036*	NS, <i>P</i> = 0.976
	Adv	20.5	12.8–27.1	NS, <i>P</i> = 0.052	
Pharyngeal length (mm)	Occlusion	3.9	0.3–7.8		
	Non-Adv	3.8	0.2–11.9	NS, <i>P</i> = 0.794	NS, <i>P</i> = 0.685
Oropharyngeal area (cm ²)	Adv	3.2	0.5–10.2	NS, <i>P</i> = 0.664	
	Occlusion	8.7	0.2–16.8		
Pharyngeal length (mm)	Non-Adv	8	3.8–14.9	NS, <i>P</i> = 1.000	<i>P</i> = 0.002**
	Adv	9.3	6.7–21.7	<i>P</i> = 0.013*	
Oropharyngeal area (cm ²)	Occlusion	61.9	48.3–78.2		
	Non-Adv	66.5	46.8–77.2	<i>P</i> = 0.001***	<i>P</i> = 0.000***
Oropharyngeal area (cm ²)	Adv	61.8	44.2–76.7	NS, <i>P</i> = 0.274	
	Occlusion	4.3	2.2–7.3		
Oropharyngeal area (cm ²)	Non-Adv	4.7	2.4–8.2	NS, <i>P</i> = 0.128	NS, <i>P</i> = 0.670
	Adv	4.1	2.5–7.4	NS, <i>P</i> = 0.543	

Adv = advanced/active, Non-Adv = non-advanced/sham. Statistical significance: NS = non-significant; **P* < 0.05; ***P* < 0.01; ****P* < 0.001.

Table 5 Side-effects of the TheraSnore™ appliance.

Side-effect (n = 23)	Non-advanced MAD		Advanced MAD	
	Short term (%)	Longer term (%)	Short term (%)	Longer term (%)
Muscular discomfort	39	13	74	26
Temporomandibular joint discomfort	26	9	61	22
Abnormal bite on waking	39	9	57	17
Excessive salivation	65	26	65	22
Dry mouth	21	52	26	70

closest approximation to a placebo due the differences in volume/bulk between the single-arch appliance and the active MAD. More recently Voudouris *et al.* (2003) used an inactive Herbst as a sham appliance in a study to assess the effect on the condyle–fossa during Herbst treatment. In the present study the non-advanced TheraSnore™ was used as the most appropriate sham appliance. The non-advanced TheraSnore™ appeared to reduce the snoring loudness for six individuals and improved morning wakefulness for four subjects. Partners also reported improved symptoms when the snorer wore the sham appliance; three partners slept better whilst 10 were less sleepy during the

daytime. Whilst it is tempting to suggest that the individuals whose symptoms improved when wearing the non-advanced TheraSnore™ were placebo responsive, this cannot be verified. The design of the TheraSnore™ does not stabilize the mandible or prevent it from opening. Indeed, a partial response may have been elicited as the mouth opens when any intraoral device is worn (Lamont *et al.*, 1998) or the response may be attributed a change in oropharyngeal muscle tone (Johnston *et al.*, 2001).

Treatment effects—objective data

Only 11 of the 23 subjects managed to complete all three of the sleep studies. Failure to follow the sequence of instructions led to loss of data from a number of subjects. Three subjects refused to take the equipment home at any stage during the study despite having agreed initially.

- a) Snoring: snoring data confirmed that the advanced TheraSnore™ was the more effective mode for reducing snoring. However there was little change in the snoring for one subject when wearing the advanced MAD, although both subject and partner were subjectively satisfied with the appliance. This may reflect individual nocturnal variation in the snoring pattern.
- b) AHI: subjects in this study were non-apnoeic snorers who had an AHI close to normal (range greater than 5) at

baseline. This was probably responsible for the fact that no significant differences in median AHI scores were found between baseline (5.5) and with TheraSnore™ appliance in either the non-advanced (5.5) or advanced position (4.0). This is in agreement with the findings of Marklund *et al.* (1998), who reported that the AHI reduction with a MAD was inversely related to disease severity.

- c) SaO₂: the improvement in minimum SaO₂ with the advanced MAD position compared with baseline may explain the reduction in daytime sleepiness experienced by the subjects. Similar, small but significant increases in minimum SaO₂ were noted by Rose *et al.* (2002) in a comparative study of the Silensor and Karwetzky appliances. In addition, Miyazaki *et al.* (1997), using the TheraSnore™ appliance in an OSA group, found that the lowest SaO₂ significantly improved from 74.5 to 84.9 per cent. In the present study it was noted that the median nadir reduced from 90 per cent at baseline to 89 per cent with the non-advanced MAD. This reduction approached significance ($P = 0.057$) and may be a type II error due to the small sample size in this part of the study. It may be possible to speculate that the unwanted reduction in SaO₂ is secondary to the downward and backward movement of the mandible due to the degree of opening with the non-advanced MAD.

Non-significant changes in the AHI would suggest that for non-apnoeic snorers, equipment that would record snoring and SaO₂ in conjunction with the subjective questionnaire data is appropriate to objectively assess the success of a MAD without the need to assess respiratory effort once the initial diagnosis has ruled out the presence of OSA. This reflects the similar view expressed by Johnston *et al.* (2001). However subjective assessment of snoring in OSA subjects cannot be used as the sole parameter for assessment of treatment success (American Sleep Disorders Association, 1995). Standardization of objective measurement techniques and threshold limits for snore loudness need to be established to allow direct comparison of data between studies. In addition, the fewer parameters measured in home sleep studies the less the risk of technical failure (Coleman, 1999).

Radiographs

Radiographic evaluation confirmed significant opening and backward rotation of the mandible associated with the TheraSnore™ appliance. The vertical opening of 13 mm was greater than the mean 8.27 mm reported by Gale *et al.* (2000), with a customized MAD, and this may have negated some of the protrusive effect. Nonetheless, the minimum post-lingual airway was significantly increased with the advanced MAD. A good lingual response was not unexpected in this sample group since they had been selected on the basis of a prominent tongue base being the major cause of

the snoring. This response represented a median percentage increase of 6.5 which is less than the mean 10 per cent change in males reported by Battagel *et al.* (1999). L'Estrange *et al.* (1996) found a reduction in airway dimensions on vertical mandibular opening and this may explain why the magnitude of airway dimension response in the present investigation appeared to be less than in other studies (Battagel *et al.*, 1999). However, individual variation was great and one subject experienced a 92 per cent increase. Previous investigators postulated that a given airway enlargement may be clinically more significant in subjects with small initial airway dimensions (Gale *et al.*, 2000).

Side-effects

The present study should be viewed as a short-term clinical trial where short-term side-effects reflect the first week of wear in each arm of the study and the longer term side-effects refer to the remaining period of appliance wear. All subjects experienced at least one initial side-effect: in contrast Miyazaki *et al.* (1997) found that 27 per cent of subjects who used the TheraSnore™ appliance experienced no side-effects. Seventy per cent of subjects reported a dry mouth in the longer term. This contrasts with the findings of Shadaba *et al.* (2000), who found that 36 per cent of subjects had a dry mouth with a Herbst MAD. The degree of vertical opening associated with the TheraSnore™ may be implicated in the subjects' reduced ability to easily obtain a lip seal (Figure 5). During the study, 66 per cent of subjects reported that the short-term benefits outweighed the disadvantages of the advanced TheraSnore™. This suggests a long-term 34 per cent non-compliance rate that requires follow-up and is similar to other studies (Shadaba *et al.*, 2000). It is noteworthy that 65 per cent of subjects complained that the appliance was bulky. In addition two subjects dropped out after the initial fit as they deemed the appliance too cumbersome. One precondition for acceptance of appliance wear is comfort (Lamont *et al.*, 1998).

Appliance design

The TheraSnore™, unlike the Herbst or Silensor, does not 'hold' the mandible rigidly in protrusion but relies upon the lingual extension to guide the mandible forward along the arc of mandibular closure. Miyamoto *et al.* (1998) noted that the mandible is more open during sleep than wakefulness and postulated that if the mandible is not fixed, contraction of the genioglossus and geniohyoid muscles may further depress the mandible, reducing upper airway dimensions. These factors may be at work in the TheraSnore™, with the lack of positive mandibular retention leading to a reduction in appliance efficacy. However Clark and Nakano (1989) found that allowance of some lateral and vertical jaw movements for yawning and swallowing, when evaluating the Herbst MAD, was an advantage compared with more rigid MADs.

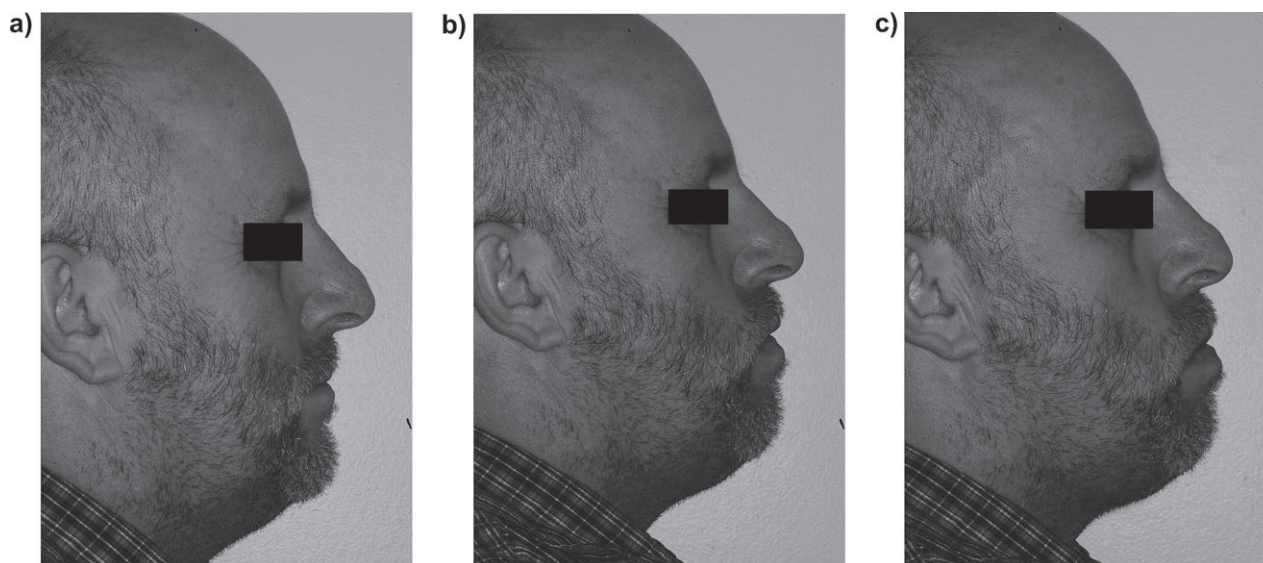


Figure 5 Profile of a subject with: (a) no appliance, (b) non-advanced TheraSnore™ *in situ*, (c) advanced TheraSnore™ *in situ*.

As previously reported (Miayazaki *et al.*, 1997), the TheraSnore™ may be fitted and adjusted at the chairside. This negates the requirement for laboratory support. Similar reports regarding the ease of manipulation of thermoactive acrylic have been made in relation to the Snore Guard (Ferguson *et al.*, 1996) and the Klearway (Lowe *et al.*, 2000). However the TheraSnore™ material is relatively soft and two subjects in the study wore through the thermoplastic material to the harder polycarbonate frame after 2–3 months. Thus, the appliance may be contraindicated in heavy bruxers, although the lack of rigid mandibular protrusion may be viewed as an advantage for these subjects.

The TheraSnore™ would not appear to be suitable for an edentulous subject due to lack of retention during sleep to retain the device. In addition, the appliance should not be fitted in patients with periodontally compromised lower teeth, in particular incisors and canines, as the lingual extension rests against the lingual aspects these teeth on the mandibular arc of closure. Ferguson *et al.* (1996) made similar suggestions for the thermoplastic Snore Guard as it is fitted only to the anterior teeth.

Adjustable devices, including the TheraSnore™, Silensor, Herbst, and Klearway appliances, allow gradual titration of mandibular advancement without the necessity of remaking the appliance when an adjustment is required. This has considerable implications for cost-effectiveness due to a reduction in both clinical and laboratory time. However, with the TheraSnore™ only five, incremental 1.5-mm advancements are possible. During this study one male subject was considered a treatment failure as the appliance could not be advanced sufficiently to alleviate his snoring symptoms, although 7.5 mm was greater than 75 per cent of his maximum protrusion. He was subsequently successfully treated with a Herbst MAD.

Conclusions

1. The advanced TheraSnore™ is effective in the treatment of snoring in two out of three non-apnoeic snorers.
2. Sleeping partners also derive benefits from this form of treatment for their snoring partners.
3. The complaints of bulkiness and dry mouth may be related to the inherent vertical opening of the appliance.

Recommendations for prescribing the TheraSnore™

Indications: non-apnoeic snorers with good dentitions; no laboratory support available.

Contraindications: high maxillomandibular plane angle; periodontally compromised teeth; and inadequate teeth to retain appliance.

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