An Investigation into the Changes in Airway Dimension and the Efficacy of Mandibular Advancement Appliances in Subjects with Obstructive Sleep Apnoea

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Abstract This prospective clinical study evaluates a group of 37 male Caucasians with obstructive sleep apnoea for changes in airway dimension and the efficacy associated with the use of mandibular advancement splints. Lateral skull radiographs were obtained with the subjects—upright in occlusion, supine in occlusion, and supine in protrusion. Each radiograph was traced and digitized, and changes in mandibular position, airway dimensions, and hyoid were examined. Subjects were invited to complete pre- and post-treatment questionnaires, and interviewed following fitting of a removable Herbst mandibular advancement splint.

Significant changes were recorded in the airway dimensions in response to both a change in position, from upright to supine, and in response to mandibular advancement. A compliance rate of 76 per cent was achieved with no reported serious complications associated with the use of mandibular advancement devices.

Index words: Mandibular Advancement Splints, OSA, Supine Films.

Introduction

Obstructive Sleep Apnoea (OSA) is a potentially lifethreatening breathing disorder, characterized by repeated collapse of the upper airway during sleep, with cessation of breathing. The prevalence of OSA is though to be the order of 4 per cent of middle-aged men and 2 per cent of middleaged females, and is reported to increase with age (Young *et al.*, 1993). The aetiology is somewhat complex and incompletely understood, but is thought to arise from a combination of anatomical and pathophysiological factors, which predispose to narrowing of the upper airway.

Clinically, OSA subjects exhibit both nocturnal (snoring, choking during sleep, abnormal motor activity, and nocturia) and diurnal symptoms (excessive daytime sleepiness, depression, sexual problems, and headaches). In addition, these patients are at risk of developing a range of severe medical complications secondary to recurrent nocturnal hypoxia and hypercapnia, most notably cardiovascular morbidity and mortality.

The diagnosis of OSA is made following a comprehensive history (supported by the use of questionnaires such as the Epworth Sleepiness Scale), and ear, nose and throat examination, Body Mass Index calculation (determined from the subject's height and weight) and overnight polysomnography. The latter investigation is regarded as the definitive investigation for the diagnosis of OSA, permitting the physician to distinguish between simple snoring and true obstructive sleep apnoea. Lateral cephalometry is an established tool in the investigation of the airway in OSA subjects for both diagnostic purposes and to monitor the changes in the airway in response to mandibular protrusion (Lowe *et al.*, 1986; Lyberg *et al.*, 1989; Schmidt-Nowara *et al.*, 1991, Eveloff *et al.*, 1994). Posture has been demonstrated to have a significant effect on upper airway dimensions (Yildirim *et al.*, 1991; Mohammed *et al.*, 1994) and, as a consequence, the use of supine rather than traditional upright radiographs has reported to be more meaningful (Eveloff *et al.*, 1994; Lowe, 1994).

Recognizing the multifactorial nature of OSA, current management strategies focus around a multi-disciplinary approach involving a thoracic physician, ENT surgeon, orthodontist, and oral surgeon. Nasally-applied continuous positive airway pressure (CPAP) is highly effective and has become the major non-surgical, long-term form of treatment, the so-called 'gold standard' (Sullivan et al., 1981). However, long-term compliance with CPAP has been estimated at between 60 and 70 per cent (Engleman et al., 1994). As a consequence, the use of intra-oral advancement mandibular devices has been investigated by a number of workers (Bonham et al., 1988; Schmidt-Nowara et al., 1991; Eveloff et al., 1994; L'Estrange et al., 1996). The rationale for appliance use is that they may increase the size of the airway by drawing the tongue and soft palate forwards, and thus maintain its patency during sleep. The orthodontist can play a key role in the cephalometric evaluation, design, and provision of these appliances.

Limited follow-up data are available comparing the risk to benefit ratio associated with the use of mandibular advancement therapy. Furthermore, the use of supine films demonstrating the airway changes with mandibular advancement splints in place does not appear to have been used in a diagnostic or prognostic capacity (Yildirim *et al.*, 1991; Eveloff *et al.*, 1994).

The aims of the present study were:

- 1. Evaluate the changes in upper airway dimension between upright and supine films in occlusion.
- 2. Evaluate the changes in upper airway dimension, which resulted from the lower jaw being postured forward in the supine position.
- 3. Evaluate the reported benefits, compliance and side effects of mandibular advancement splints.

Subjects

The material for this study comprised:

- 1. Lateral skull radiographs of 37 male dentate, Caucasian subjects recorded in upright in occlusion, supine in occlusion, and supine postured positions.
- 2. All 37 subjects had a diagnosis of obstructive sleep apnoea, which had been confirmed by polysomnography at the Royal National Ear, Nose and Throat Hospital, and judged to benefit from the construction of a mandibular advancement splint.
- 3. Apnoea/hypopnoea Index (AHI), Body Mass Index (BMI), and pretreatment Epworth Sleepiness Scale Scores.

Methods

All subjects were supplied with a custom made removable Herbst mandibular advancement splint (Figure 1). The appliance was designed to advance the mandible by the maximum comfortable amount of protrusion possible, frequently about 75 per cent of maximal protrusion. The splint was to be used only at night with short intermaxillary elastics to prevent any jaw opening.

All subjects were invited to complete an Epworth Sleepiness Scale and a snoring questionnaire, prior to fitting the mandibular advancement device. At subsequent follow-up, subjects and their partners were interviewed, and again invited to complete an outcome questionnaire.



FIG. 1 Removable Herbst mandibular advancement splint with intermaxillary elastic to prevent any jaw movement.

Radiographic Technique

Standard lateral skull cephalometry and supine radiographs were undertaken prior to fitting the appliances. Supine films were obtained both in occlusion and with the lower jaw in a position of maximum comfortable protrusion. The latter view was taken with the aid of the wax record used in appliance fabrication. Subjects were instructed to hold their tongues in as normal a position as possible and all films were exposed at the end of expiration to ensure consistency of hyoid location. A thin layer of barium sulphate paste was applied to the dorsum of the tongue to enable its outline to be clearly seen. The supine films were taken with the subject in a foam head support, and head position carefully aligned and checked by the radiographer. The magnification associated with each film was recorded.

Cephalometric Analysis

Radiographs were traced, orientated with the maxillary plane horizontal, and 11 hard tissue points identified (Figure 2). Sixteen additional points relating to the cervical vertebrae, oro-pharynx, epiglottis, soft palate, and tongue were recorded also (Figure 3). Definitions of the additional landmarks and of those not conforming to British Standards (British Standards, 1983) are given in the accompanying legends. Points were digitized twice in a predetermined sequence by one author (AJ) to a tolerance of 0·1 mm and the mean value taken. The outlines of the tongue, soft palate, and oro-pharynx were also recorded.

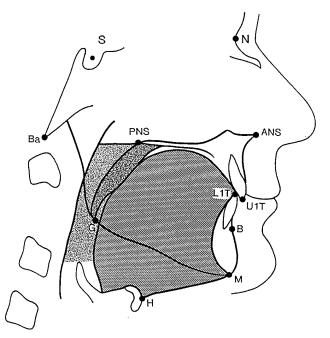


FIG. 2 The cephalometric points recorded. Except where listed below, points, lines, and planes conformed to British Standard definitions (British Standards Institution, 1983). ANS, anterior nasal spine; B, point B; Ba, basion; G, gonion (the point where the bisector of the angle between the posterior and lower mandibular border tangents meets the mandibular angle); H, hyoid (the most anterior point on the hyoid bone); L1T, lower incisor tip; M, menton (the point of intersection of the lower mandibular border and the symphysial outline); N, nasion; PNS, posterior nasal spine; S, sella; U1T, upper incisor tip; oropharyngeal, bounded superiorly by a backward extension of the maxillary plane and inferiorly by a line through the tip of the epiglottis.

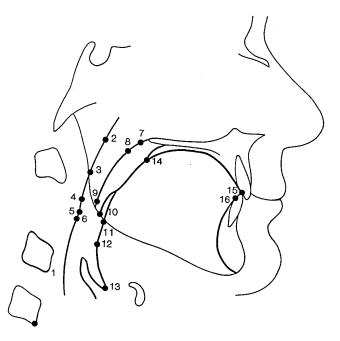


FIG. 3 (1) The most anterior inferior point on C3. (2) The point on the posterior pharyngeal wall at the same horizontal level as point 7. (3) The point of intersection of the occlusal plane with the posterior pharyngeal wall. (4) The point on the posterior pharyngeal wall where the airway behind the soft palate is at its narrowest. (5) The point on the posterior pharyngeal wall at the same horizontal level as the tip of the soft palate (point 10). (6) The point on the posterior pharyngeal wall where the airway behind the tongue is at its narrowest. (7) The point on the nasal surface of the soft palate at the level of the Maxillary plane (opposite point 2). (8) The point on the nasal surface of the soft palate to determine its maximum thickness (in conjunction with point 14). (9) The most posterior point on the contour of the soft palate. (10) The tip of the soft palate (uvula). (11) The point on the posterior surface of the tongue where the post-lingual airway is at its narrowest. (12) The most posterior point on the contour of the tongue. (13) The deepest point of the vallecula. (14) A point on the oral surface of the soft palate where the palatal width is at its maximum. (15) The tip of the tongue. (16) The point of intersection of the occlusal plane with the lingual contour of the lower incisor.

Films were automatically re-aligned to the maxillary plane and a vertical reference line was drawn perpendicular to this plane through the sella. All calculations were made with this orientation and all measurements converted to life size. Fifty linear, angular, and proportional measurements were computed, together with the areas of the oro-pharynx, soft palate, and tongue.

Method Error

Duplicate tracings of 20 films were made and the random method of error assessed. Systematic error and coefficient of reliability were determined as suggested by Houston (1983). Errors were normally less than one unit, ranging from 0.19 mm for soft palate area to 1.69 mm for the gonion to menton measurement. Systematic errors were detected in a few measurements, but were not in any consistent direction. Coefficients of reliability ranged from 87.7 per cent for the gonion to menton distance to 99.5 per cent for lower anterior face height.

Statistical Evaluation

Data were analysed using SPSS PC+. The data were checked for normality and means, standard deviations, and ranges were calculated. Differences in hyoid position, oro-pharyngeal airway dimensions, and other related measurements between the upright and supine intercuspal, and the supine intercuspal and protrusive film pairs were computed by subtraction. Statistical tests (i.e. paired *t*-tests) were applied to determine levels of significance between pairs of films in occlusion and in the supine position.

Results

Subject Demographic Data

Table 1 illustrates the age and other physical characteristics of the 37 male subjects. Their mean age was $52 \cdot 1$ years with a range of $34 \cdot 5$ – $74 \cdot 2$ years. Most were overweight, with a body mass index of $27 \cdot 8 \text{ kg/m}^2$ (range $23 \cdot 0$ – $34 \cdot 1$). All subjects were diagnosed as having mild to moderate OSA with a mean Apnoea/Hypopnoea Index $32 \cdot 6$ (range $10 \cdot 0$ – $78 \cdot 0$). The mean Epworth Sleepiness Scale score was $11 \cdot 3$ (range $3 \cdot 0$ – $21 \cdot 0$).

Cephalometric Findings

Changes in airway dimension from upright to supine position with the teeth in occlusion. Significant changes occurred in airway dimensions and hyoid location (Table 2) between the upright and supine positions. A mean reduction in the minimum post-palatal and post-lingual airways of 2·3 mm (P < 0.001) and 1·6 mm (P < 0.05), respectively. Highly significant increases occurred in tongue proportion and soft palate area of 44 per cent, and 2·2 mm², respectively. The hyoid moved significantly anteriorly in relation to ANS, and menton and gonion by 7·1 and 5·5 mm, respectively. In the vertical plane, hyoid dropped by 3·0 mm in relation to both gonion and the maxillary plane.

Cephalometric changes between intercuspal and protrusive supine films. Table 3 demonstrates the degree of jaw advancement undertaken in the subjects. The mean change which occurred in the menton to sella vertical distance was 4.6 mm. This was accompanied by a mean reduction in overjet and overbite of 5.9 and 6.8 mm, respectively. These changes were highly significant (P < 0.001).

The position of hyoid was recorded in relation to the mandible, maxilla and cervical spine (Table 2). With respect to the mandible (which itself had moved down-

TABLE 1 Age and other physical characteristics (mean \pm SD)

	Mean \pm SD	Minimum	Maximum
Age	52.1 ± 9.8	34.5	74·2
Apnoea/Hypopnoea index	32.6 ± 15.4	10.0	78.0
Body Mass Index	27.8 ± 3.0	23.0	34.1
Epworth Sleepiness Scale	11.3 ± 4.8	3.0	21.0

The normal values for the Apnoea/Hypopnoea and Body Mass Index are <5 and 20–25, respectively. A normal value for the Epworth Sleepiness Scale has not been reported, but a value >10 is regarded as pathological).

TABLE 2 Cephalometric data (mean \pm SD) for 37 OSA subjects, illustrating the changes in airway dimension and hyoid position between the upright and supine intercuspal, and the supine intercuspal and protrusive film pairs. All measurements are recorded in millimetres except where indicated

	Upright (U)	Supine in occlusion (So)	Diff. (So–U)	Signif.	Supine in protrusion (Sp)	Diff. (Sp–So)	Signif.
Minimum post-palatal airway	5.5 ± 3.5	3.2 ± 2.6	-2.3	0.000	3.9 ± 2.8	0.7	0.100
Minimum post-lingual airway	9.1 ± 4.5	7.5 ± 3.1	-1.6	0.013	8.9 ± 3.9	1.4	0.003
Oropharyngeal area (mm ²)	6.4 ± 2.3	7.0 ± 2.5	0.6	0.069	8.0 ± 3.2	0.9	0.015
Soft palate length	38.7 ± 5.4	38.9 ± 6.9	0.2	0.935	37.7 ± 6.2	-1.2	0.167
Soft palate thickness	12.1 ± 1.5	12.3 ± 1.8	0.2	0.450	12.5 ± 1.8	0.2	0.552
Soft palate area (mm ²)	4.6 ± 0.6	6.7 ± 1.2	2.2	0.000	6.4 ± 1.1	-0.3	0.045
Hyoid to ANS	62.4 ± 8.3	$55\cdot3\pm7\cdot2$	-7.1	0.000	54.9 ± 8.5	-0.5	0.585
Hyoid to menton	46.3 ± 5.6	40.8 ± 4.3	-5.5	0.000	45.0 ± 4.8	4.2	0.000
Hyoid to C3	37.6 ± 5.7	36.2 ± 5.2	-1.4	0.080	37.7 ± 5.5	1.5	0.003
Hyoid to mandibular plane	25.0 ± 6.0	25.6 ± 8.2	0.6	0.501	21.3 ± 8.2	-4.4	0.000
Hyoid to maxillary plane	72.6 ± 6.3	75.7 ± 8.5	3.1	0.013	74.0 ± 8.3	-1.7	0.080
Hyoid to gonion	37.8 ± 8.2	40.8 ± 10.2	3.0	0.004	34.2 ± 10.1	-7.6	0.000
Tongue proportion (%)	110.0 ± 12.5	154.0 ± 22.6	44.0	0.000	121.3 ± 17.2	-32.7	0.000

Significance: P > 0.05, NS; P < 0.05, just significant; P < 0.01, moderately significant; P < 0.001 highly significant.

TABLE 3 Degree of jaw advancement and accompanying changes inoverjet and overbite (mean \pm SD, range), recorded with mandible in aposition of maximum comfortable protrusion

	Mean	Minimum	Maximum
Overjet (mm)	-5.9 ± 2.2	-1.7	-11.5
Overbite (mm)	-6.8 ± 3.2	-1.4	-14.3
Menton to sella vertical (mm)	-4.6 ± 3.7	-2.7	-11.5

wards and forwards), hyoid became 4.2 mm closer to menton and 4.2 mm nearer to the mandibular plane. In the vertical plane, the distance between hyoid and gonion decreased by 7.6 mm. With respect to the maxilla, hyoid movement was very much less: vertically it was elevated by 1.7 mm and antero-posteriorly it moved forwards by 0.5 mm. Neither of these alterations was significant. When compared with its antero-posterior distance from the third cervical vertebra, a significant increase of 1.5 mm was recorded.

Despite the significant alterations in the majority of mandibular and hyoid measurements, linear oro-pharyngeal dimensions altered rather less in response to mandibular protrusion (Table 2). The minimum distances between the posterior pharyngeal wall, and both the soft palate and tongue increased by 0.7 and 1.4 mm, respectively. In percentage terms, however, these changes were equivalent to those of the lower jaw. Significant changes were detected in the oro-pharyngeal area, which increased by 0.9 mm² (P < 0.05) and tongue proportion, which reduced by 32.7 per cent (P < 0.001).

Post-treatment Questionnaires

From the post-treatment questionnaire and interviews, 28 subjects (76 per cent) reported the splint to be effective with an improvement in the following symptoms: elimination or acceptable reduction of snoring, apnoeas, and day-time sleepiness. Subjects had worn their appliances for an average of 13.4 months (range 2–24 months). Two subjects reported they could not tolerate the splint, whilst the

outcome in the remaining seven subjects is unknown due to cancelled and failed appointments.

Of the 28 subjects successfully wearing their splints, all reported a variety of the following short-term problems: discomfort in the muscles of the face, abnormal bite on awakening, dry mouth, and excessive salivation during the night. None of the subjects reported lasting discomfort in the muscles of the face or in their jaw joints. Eight subjects required adjustment to their splints for maximum effect and in five instances breakages occurred where the Herbst attachment became wrenched out of the acrylic.

Each removable Herbst mandibular advancement appliance requires 4 hours for construction, at an estimated cost of £150.00.

Discussion

Changes in Airway Dimension from Upright to Supine Position with the Teeth in Occlusion

Reductions in the airway behind the soft palate of between 1.5 and 2.7 mm have been reported in the literature (Yildirim *et al.*, 1991; Pae *et al.*, 1994; Lowe *et al.*, 1996). These are thought to result from a change in soft palate shape. In the upright subject, the soft palate is vertically dependent, and therefore longer and thinner, whilst in the supine position, under the influence of gravity the soft palate becomes thicker. A significant reduction (2.3 mm) in the airway behind the soft palate was found in the present study, which was accompanied by a highly significant increase in soft palate area adding confirmation to the above hypothesis.

Changes in the airway behind the tongue have been variously described as being reduced (Pae *et al.*, 1994), maintained (Miyamoto *et al.*, 1997), or increased (Yildirim *et al.*, 1991; Eveloff *et al.*, 1994). These findings may be explained by the fact that few authors have attempted to control the phase of respiration, during which the films were taken and that the exact level at which measurements are taken depends very much upon the horizontal plane used to orientate the films. Subjects in the present study demonstrated a mean reduction of 1.6 mm.

Cephalometric changes between intercuspal and protrusive supine films

Clark *et al.* (1996) based on their clinical experience suggested the optimum distance for forward positioning of the mandible to be 75 per cent of the subject's maximum protrusion. The authors further quantified this movement as being 7 mm or more, in order to obtain the maximum reduction in AHI. In the present study, maximum comfortable protrusion resulted in a mean overjet reduction of 5.9 mm.

Although studies have reported the changes in airway dimensions between the upright and supine positions (Yildirim *et al.*, 1991; Lowe *et al.*, 1996) and the response to mandibular protrusion in the upright subject (Bonham *et al.*, 1988; Schmidt-Nowara *et al.*, 1991; Eveloff *et al.*, 1994), there are no reports of protrusion when the subject is supine. Any comparisons with previous work will therefore be indirect only.

The cephalometric changes in the airway dimensions appear rather small, however, if these are considered in percentage terms they are similar to changes recorded for mandibular advancement. Where the soft palate was at its thickest, the airway opened by 0.7 mm (or 22 per cent). These findings are in broad agreement with Bonham *et al.* (1988) in upright subjects. Behind the tongue, the airway increased from 7.5 to 8.9 mm, despite a more posterior position taken by the tongue to accommodate the interocclusal record. This is a 19 per cent improvement and is greater than the increment described by Bonham *et al.* (1988) in the upright position.

In examining the behaviour of hyoid in relation to the mandibular plane, mean hyoid movement was upwards and forwards. The mean reduction in the hyoid to mandibular plane of 4.4 mm compares with the 3.0 mm decrease described by Bonham *et al.* (1988). Hyoid behaviour in relation to the maxilla was again in an upwards and forwards direction, but to a lesser extent. The hyoid and its musculature occupy a key role in regulation of the pharyngeal airway and its position, as has been demonstrated, is affected by the location of both the mandible and the tongue.

The Efficacy of Mandibular Advancement Splints

All published clinical studies in which snoring was assessed, using a variety of devices, and based on reports of patients or bed partners, show improvement in a high proportion of patients (Schmidt-Nowara et al., 1995). In the present study, 76 per cent of subjects reported an improvement in snoring and day-time sleepiness. Possible mechanisms for the improvement in snoring include an increase in oropharyngeal and hypopharyngeal dimensions with associated reduction in turbulent airflow in the region and/or an increase in pharyngeal wall tone (O'Sullivan et al., 1995). The American Sleep Disorders Association and Sleep Research Society (1995), recommend follow-up reviews and sleep studies of subjects being treated with oral appliances in order to ensure satisfactory therapeutic benefit. Whilst the former was undertaken in the present study supplemented by the use of outcome questionnaires, the latter was not owing primarily to limited financial resources. This is an issue currently being addressed, and would offer valuable information in conjunction with patient and partner interviews.

Excessive salivation and transient discomfort in the muscles of mastication for a brief time after awakening are commonly reported with initial use of oral appliances (Schimdt-Nowara *et al.*, 1991; O'Sullivan *et al.*, 1995). Later complications may include TMJ discomfort and changes in occlusion, and have been reported as reasons for discontinuing treatment. In the present study, all subjects reported some short-term discomfort. Muscle discomfort normally disappeared after two nights and abnormal bite, if it occurred, recurred each morning, but was considered acceptable. There was one report of TMJ problems after a period of 15 months wear, which settled after adjustment to the splint. Two subject's discontinued treatment on the basis of poor tolerance. The long-term risk of these complications are as yet, not well defined.

Data on long-term compliance are limited in number, with a range from 52 to 100 per cent being reported in the literature (Schimidt-Nowara *et al.*, 1995). A compliance rate of 76 per cent was achieved in the present study. The reasons for discontinuing appliance use include the side effects noted above and lack of efficacy. Only two of the 37 subjects in this study discontinued treatment, both due to poor tolerance. The remaining seven subjects have not been evaluated as a result of cancelled or failed appointments, making compliance with the splint difficult to determine.

Conclusions

- 1. Significant changes in airway dimension accompany a change in posture, from the upright to supine position. Thus, the airway should be evaluated in the supine position.
- 2. For OSA subjects, more meaningful measurements of changes in airway dimension are obtained utilizing supine in occlusion and protrusion films. These demonstrate that mandibular protrusion is associated with proportionate increases in oro-pharyngeal dimensions.
- 3. In a sample of 37 subjects a compliance rate of 76 per cent was obtained with an improvement in clinical symptoms and no serious complications.

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