

Do oral appliances enlarge the airway in patients with obstructive sleep apnoea? A prospective computerized tomographic study

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SUMMARY This study evaluated the effect of an anterior mandibular positioning appliance (AMPA) on minimum pharyngeal cross-sectional area (MPCSA) in 32 conscious supine obstructive sleep apnoea (OSA) subjects. The change in MPCSA was measured using low dose computerized tomography, with and without an AMPA *in situ*.

The results showed that the mean presenting respiratory disturbance index (RDI) was 26.6 events/hour, with a body mass index of 28.6 kg/m² and mean age of 51.5 years. There was a statistically significant increase in MPCSA of 28.34 mm² on appliance insertion (SD = 59.06 mm²; range –145 to +190 mm²; $P = 0.011$). The mean mandibular displacement was 5.73 mm (SD = 2.51 mm) in protrusion and 8.27 mm (SD = 4.51 mm) inferiorly. A poor correlation was found between the size of the mandibular displacement and the change in MPCSA (protrusion $r = 0.268$; inferiorly $r = 0.240$, $P > 0.05$).

In conclusion, the AMPA significantly increased MPCSA, suggesting that it may be an effective therapy for OSA. There was, however, a wide but unpredictable individual variation of response. As a small number of patients may worsen in their condition with temporary mandibular advancement (TMA), it is essential that all patients treated with TMA should be investigated by polysomnography both before and after treatment.

Introduction

Obstructive sleep apnoea (OSA) is a common disease affecting 5–10 per cent of males and 2.3–7 per cent of females in the middle aged population (McNamara *et al.*, 1993). The main morphological feature of OSA is upper airway narrowing during sleep, which is associated with snoring and excessive daytime sleepiness (Young *et al.*, 1993). Some evidence links OSA to an increased risk of mortality (He *et al.*, 1988), but the pathogenesis of this relationship is still not entirely clear.

The most effective therapeutic option has been nasal continuous positive airway pressure

(nCPAP) (Sullivan *et al.*, 1981). Unfortunately, some people find this difficult to tolerate, with compliance averaging 80 per cent (Sullivan *et al.*, 1981; Hoffstein *et al.*, 1992). Surgical procedures, such as uvulopalatopharyngoplasty (UPPP), maxillofacial advancement, hyoid repositioning procedures, and tracheostomy (McNamara *et al.*, 1993), can also be used to reduce the apnoea index. Despite the unwanted effects of surgery, only 67 per cent of a heterogeneous group of maxillofacial surgical subjects retrospectively demonstrated a post-treatment apnoea index of less than 20 (Riley and Powell, 1990). A prospective longitudinal study of the UPPP procedure revealed that only 36 per cent of subjects

maintained an apnoea index below 20 after 2 years (Larsson *et al.*, 1991). Tracheostomy is always effective, but poorly tolerated.

As a result considerable interest has arisen in alternative, non-invasive treatment options. One such therapy is temporary mandibular advancement (TMA), which in a number of studies (Bonham *et al.*, 1988; Schmidt-Nowara *et al.*, 1991; Clark *et al.*, 1993; Lowe, 1994) is associated with a significant reduction in sleep apnoea severity by 50 per cent.

Diagnosis and evaluation of treatment

There are two main methods of measuring OSA:

1. Polysomnography (PSG), which measures the number of apnoeic episodes per hour of sleep and is expressed as the respiratory disturbance index (RDI), together with measurements of chest and abdominal effort, and oxygen saturation (Rechtschaffen and Kales, 1968).
2. Measurement of airway dimensions with the assumption that this measure is associated with the RDI. It may also demonstrate an anatomical basis for OSA.

Airway imaging and temporary mandibular advancement (TMA)

Cephalometrics. Within large samples, studies have shown a statistically and clinically significant association between the RDI and cephalometric anteroposterior airway dimensions, when comparing OSA and control groups (Andersson and Brattström, 1991; Tangugsorn *et al.*, 1995). This association has also been demonstrated within TMA treatment groups (Bonham *et al.*, 1988; Schmidt-Nowara *et al.*, 1991; Clark *et al.*, 1993). However, for the individual, the validity of imaging to explain morphological changes in OSA severity on TMA appliance insertion is unclear (Lowe, 1993). The anterior superior airway space (ASAS) was defined by Bonham *et al.* (1988) as the minimum anteroposterior distance from the dorsum of the tongue to the anterior surface of the soft palate. When investigating 12 OSA subjects, they were able to demonstrate that the pre-treatment ASAS correlated well with PSG

changes. However, this airway measurement was not significantly different following appliance insertion and subsequent well-conducted confirmatory studies have been absent.

The diagnostic uncertainty for the individual derives from the inter-play of multiple confounding variables, such as neck extension, level of consciousness, respiration, swallowing, body mass index (BMI), age, and sex. Incomplete imaging of the entire 3D pharynx and poor landmark discrimination may also have limited the validity and reproducibility of airway measurements.

Three-dimensional imaging. Schwab (1996) has clearly demonstrated that there is a marked variation of the lateral pharyngeal dimension in OSA subjects, indicating that 3D imaging has important advantages over cephalometric airway measurement. Recently, the relationship between TMA and the 3D morphology of the pharynx, has been investigated, but only at the case report level of evidence. Smith (1996), found that pharyngeal volume increased from 5.8 to 8.7 cm³ and Lowe (1990) noted that minimum pharyngeal area increased from 41.6 to 92.3 mm². Both authors showed an increase in pharyngeal dimensions on TMA. However, a higher level of evidence was lacking until a prospective cross-over study by Cobo *et al.* (1995). They reported the effects of TMA on pharyngeal volume in 10 conscious OSA subjects, describing a statistically significant mean increase of 1.08 cm³ on appliance insertion. This interesting study is an important contributor to the investigation of pharyngeal morphology in TMA therapy, as BMI, age and sex were well controlled by the design of the study. One limitation may be that the pharyngeal image only extended to 8 mm inferior to the hard palate, so preventing the detection of obstructions below the oropharynx. There is also some debate as to whether pharyngeal volume or minimum pharyngeal cross-sectional area (MPCSA), most accurately measures the effects of TMA treatment in OSA subjects. The aerodynamic calculations to answer this dilemma are complex and beyond the scope of this investigation, but both Hapnoik *et al.* (1983) and Schwab (1996), using computerized tomography (CT), chose MPCSA as their outcome measure, to

significantly demonstrate airway differences between OSA and non-OSA subjects.

Aims and null hypothesis

In a recent meta-analysis of the association between craniofacial structure and OSA, Miles *et al.* (1996) implied that tighter control of confounding variables could lead to a reliable and valid imaged measurement of OSA, within the individual. If validated, this measure could reduce the costs of managing OSA patients by avoiding the use of polysomnography.

This prospective cross-over study investigated the relationship between the change in MPCSA and TMA therapy, using low dose CT. Consequently, the null hypothesis stated that there was no change in MPCSA ($P < 0.05$) on TMA.

Subjects and methods

The study was of a cross-over comparative design, allowing each subject to act as their own control. Ethical committee approval and consent was received, and a sample size calculation indicated that 32 subjects would be necessary in order to detect a clinically significant increase of 20 mm² in MPCSA. The sample frame consisted of patients referred consecutively to the sleep laboratory for investigation of OSA and who had subsequently been unable to tolerate treatment with nCPAP. In addition, grossly retrognathic subjects were also accepted without initially attempting nCPAP, based upon evidence from the Vancouver studies (Ferguson *et al.*, 1995; Lowe *et al.*, 1995). This heterogeneity of the sample reflected the department's normal referral pattern.

Subjects were excluded on the basis of age (<30 to >76 years), the absence of an adequate dentition (<10 teeth per arch), and the presence of pre-existing lung disease or temporomandibular dysfunction. Accepted subjects had an anterior mandibular positioning appliance (AMPA) constructed, after which MPCSA was measured, with and without the appliance *in situ*, using axial CT.

At AMPA construction, 75 per cent of maximum protrusion (Clark *et al.*, 1993) was recorded using a 'George Gauge' (American Orthodontics

Serial No. 852–800, Wisconsin, USA), with a 2-mm inter-incisal vertical opening. The AMPA consisted of a pair of 3-mm thick polythene occlusal coverage splints constructed from Erkoflex 82™ (Erkodent GmbH, Pfalzgrafenweiler, Germany) material, heat-welded together (Figures 1 and 2).

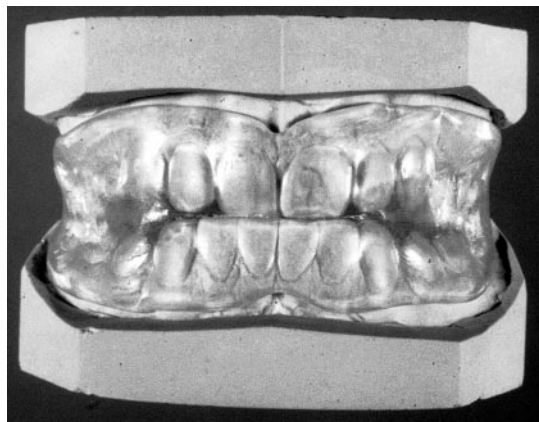


Figure 1 Anterior view of the anterior mandibular positioning appliance (AMPA).

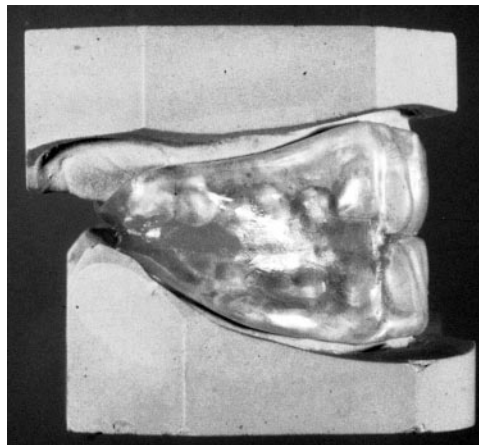


Figure 2 Lateral view of the anterior mandibular positioning appliance (AMPA).

Imaging procedure

All subjects were radiographed whilst conscious and supine using a Picker PQ CT machine (Picker, Ohio, USA), which delivered an effective dose of 0.05 mSv per CT scan. A rigid head-holding device was used to control neck extension, with the head resting on a standardized 5-cm

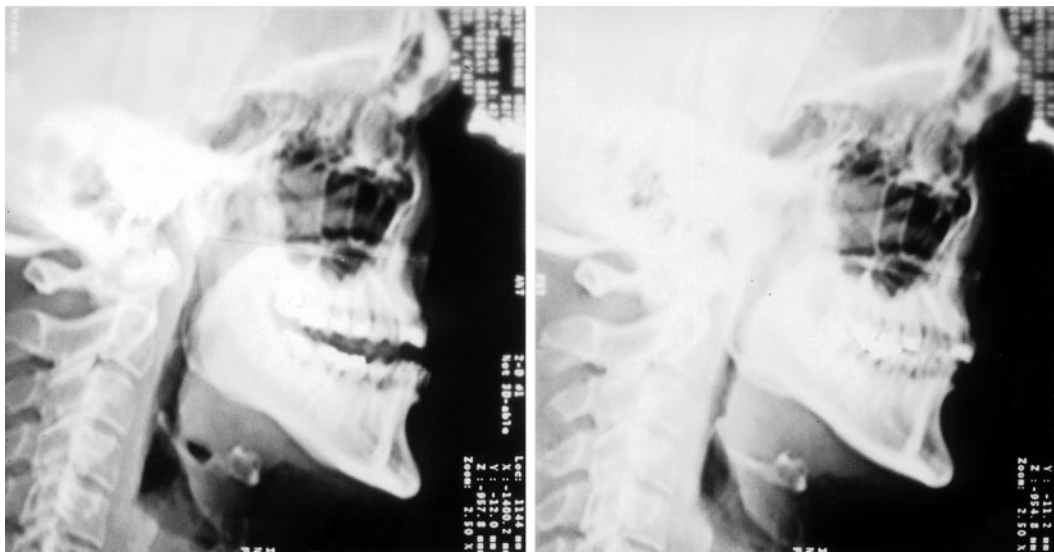


Figure 3 CT generated lateral cephalometric image with and without AMPA.

rest. First, with no appliance *in situ*, a two-dimensional lateral scan projection (similar to a cephalogram) was recorded, with the teeth held lightly in centric occlusion. Immediately afterwards, a spiral CT was taken of the pharyngeal morphology from the nasal floor to the hyoid bone, in approximately 15–20 seconds. This process was then repeated with the appliance *in situ*. Immediately prior to each exposure, the subject was instructed to swallow and then breathe ‘normally’ (regular, quiet, and shallow), without swallowing, during the exposure. Following the imaging, the subject was asked if they had swallowed within the exposure time, the investigation being repeated if they had. Each subject required three-and-a-half hours for image digitization and measurement. A tube potential difference of 130 kV and current of 30 mA was used. Identical CT parameters were used with the AMPA *in situ*. Image data was then processed into 4-mm thick overlapping slices, within the horizontal plane, at 2-mm intervals, ready for digitization.

Measurement

The lateral scan projection was printed as a hardcopy (film) and traced manually (Figure 3). Mandibular position was measured by relating

the upper and lower incisor co-ordinates. Linear measurements were corrected for magnification. Greater than 5 degrees difference in head angulation led to exclusion of that data set from the study.

Transverse pharyngeal image slices were electronically prepared into two files (with and without the appliance *in situ*; Figure 4) on the Picker Voxel Q workstation. An image intensity window of 1000 HU was set, with a mid-level of –650 HU, to account for electronic background noise and the partial volume effect. A boundary between air and fluid or tissue was consequently defined. Automatic computerized tagging of this boundary allowed software measurement of the pharyngeal cross-sectional area for each slice from the nasal floor to the hyoid bone (Figure 5). The difference in MPCSA between the first and second scan for each subject was recorded as the outcome measurement.

Statistical analysis

Hypothesis testing, descriptive statistics and associations. The change in MPCSA and mandibular positioning measurements were checked for normality and a two-tailed paired *t*-test was carried out to determine whether there was a statistically significant difference in

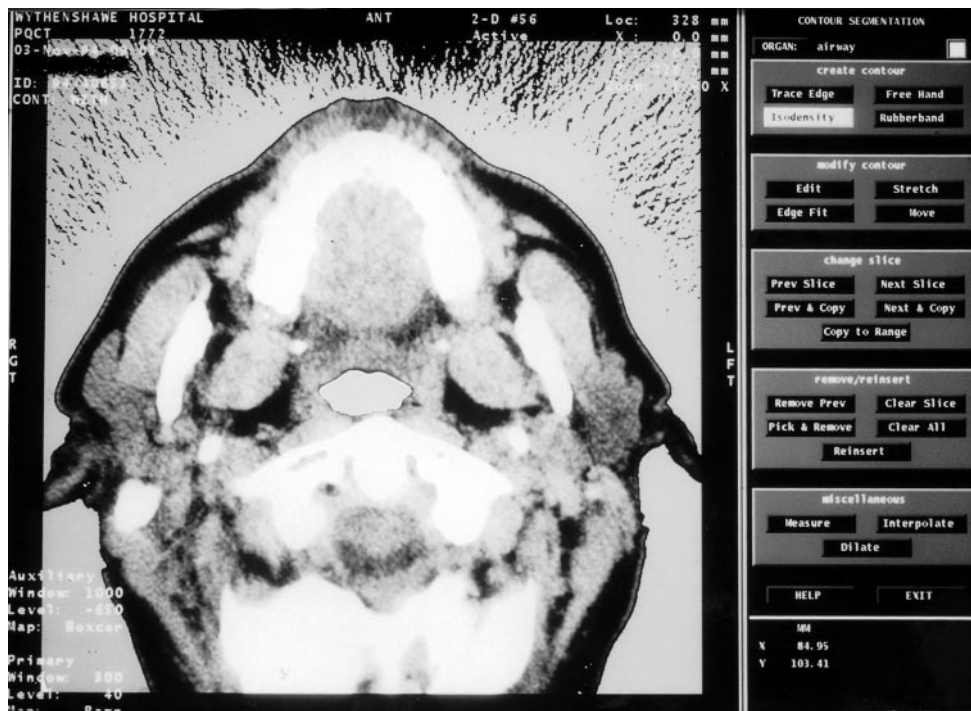


Figure 4 Transverse CT image of the airway showing anatomical detail.

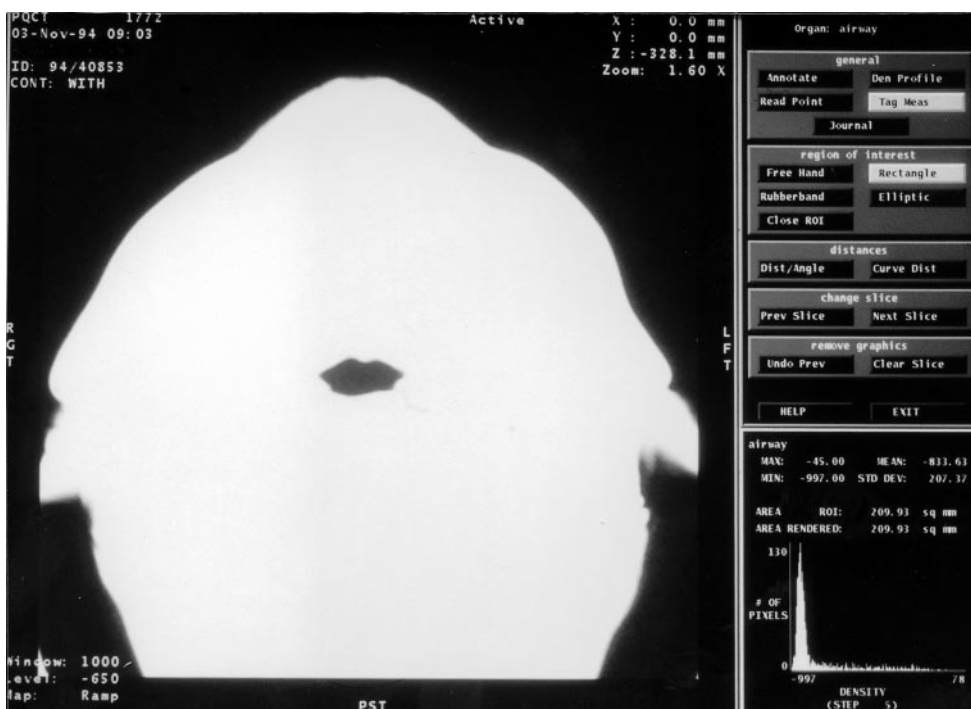


Figure 5 Transverse CT image of the airway measuring the tagged airway.

MPCSA ($P < 0.05$), following AMPA insertion. In addition, descriptive statistics were applied to the changes in mandibular position and head angulation. The relationship between the difference in mandibular position and the change in MPCSA was investigated with Pearson's correlation coefficient.

Estimation of errors. By study design, each subject was appointed as his or her own control, which reduced the effect of systematic error on the outcome. Due to ethical reasons, it was impossible to repeat radiological exposures to directly estimate error. Although each subject received two identical scans, it was not possible to consider any part of the soft tissue to be unchanged by the appliance. Consequently, it was not possible to determine the radiographic standard error from the data set itself. However, validity was evaluated by imaging and then physically by measuring a Perspex model pharynx. In addition, the reliability of the digitization and measurement technique was estimated by re-measuring the images of 10 randomly chosen subjects. The limits of agreement for each measurement (i.e. the mean difference $\pm 2 \times$ the standard error of the mean differences) were then calculated.

Results

Forty-one subjects were referred. Four of these subjects were ineligible on the following grounds: two had a gag reflex, one had temporomandibular joint dysfunction, and one failed to attend, despite repeated re-appointments and telephone calls. From the eligible sample of 37 subjects who met the inclusion criteria, a further

five were excluded on the following basis: three subjects refused to give consent to be imaged and two subjects were incorrectly imaged (one subject was not in occlusion and in the other, the lower incisors were imaged, but lost on data reprocessing). No subject failed to maintain head position within 5 degrees.

The final imaged sample therefore consisted of 27 males and five females, with a mean age of 51.5 years (SD = 11.9 years) and a BMI of 28.6 kg/m² (SD = 4.5 kg/m²). This data, together with the initial RDI and MPCSA is documented in Table 1. Fifteen study subjects had previously used nCPAP. Of the nine excluded subjects, six were male, and the group had a mean age of 51 years (SD = 9 years) and a BMI of 29.0 kg/m² (SD = 2.5 kg/m²).

The initial MPCSA was 80.22 mm² (SD = 48.13 mm²). A normal frequency distribution of the change in MPCSA was demonstrated, confirming that parametric statistical analysis was appropriate. The maxillary plane was measured at a mean of 98.9 degrees (SD 8.0 degrees) to the horizontal plane (z axis). There was a mean increase in MPCSA of 28.34 mm² on appliance insertion ($P = 0.011$) for the whole group. There was no significant difference in the change in MPCSA on appliance insertion, between subgroups classified by previous nCPAP use ($P = 0.51$). Table 2 reports the dependent and independent variable descriptive statistics, along with change in head angulation. Figure 6 shows a 3D reconstruction of the tube of air within the pharynx, before (right) and after (left) insertion of an AMPA, in a successful subject. This subject was temporarily obstructing during the pre-treatment scan. The standard deviation of the change in MPCSA was 59.06 mm², with a

Table 1 Pre-treatment data of included and excluded subjects.

	<i>n</i>	BMI (kg/m ²)	Age (years)	Sex	Initial MPCSA	RDI
Included subjects	32	28.6 (4.5)	51.5 (11.9)	5 female 27 male	80.2 (48.1)	26.6 (19.3)
Excluded subjects	9	29.0 (2.5)	51.0 (9.0)	3 female 6 male	NA	21.5 (30.4)

BMI, Body Mass Index; NA, not applicable.
Figures in parentheses indicate SD.

Table 2 Differences associated with AMPA insertion.

	Mean	SD	Minimum	Maximum	95% CI
Difference in MPCSA (mm ²)	28.34*	59.06	-145	190	-89.78 to 146.46
Head angulation change (°)	0.55	1.52	-3	4	-2.49 to 3.59
Anteroposterior mandibular change (mm)	5.73	2.51	0.0	11.6	0.70 to 10.76
Superoinferior mandibular change (mm)	-8.27	4.51	-17.7	0.9	-19.69 to 3.15

*Significance; $P = 0.011$ between pre- and post-treatment MPCSA.



Figure 6 3D reconstruction showing the pharyngeal air-tube in a successful subject, before (right) and after (left) AMPA insertion.

range of -145 mm^2 to $+190 \text{ mm}^2$ and Table 2 gives the 95 per cent confidence intervals.

Mandibular position was evaluated from the lateral scan projection of the incisor region. The lower incisor tip was shown to move anteriorly relative to the upper incisor tip by a mean of 5.73 mm, with a SD of 2.51 mm and a range of 0 to 11.6 mm (Table 2). The lower incisor tip was also shown to have moved inferiorly relative to the upper incisor tip by a mean of 8.27 mm with a SD of 4.51 mm and a range of -17.7 to $+0.9$ mm.

Correlations

Table 3 shows the association of the change in MPCSA with the change in mandibular position. Pearson's correlation coefficients were 0.268 and 0.240, respectively, for anterior and inferior mandibular movement, with appliance insertion. The ratio of each subjects' mandibular advancement, to their maximum possible mandibular protrusion, produced a lower correlation coefficient of 0.107 with the change in MPCSA.

Table 3 Pearson's correlation coefficients.

Variables	<i>r</i> value
Initial RDI and initial MPCSA	-0.300
Difference in MPCSA and anteroposterior mandibular change	0.268
Difference MPCSA and superoinferior mandibular change	0.240
Difference MPCSA and anteroposterior mandibular change/maximum mandibular protrusion	0.107
Difference in MPCSA and initial MPCSA	-0.404

No values significant at 5 per cent level.

The initial MPCSA also correlated poorly with the change in MPCSA. No correlations were significant at the 5 per cent level.

Error estimation

The physical cross-sectional area of the Perspex pharynx was 2022.84 mm², with the corresponding imaged area being 2022.10 mm²; a difference of -0.037 per cent. There was a mean difference in the repeated maxillary plane angle measurements of 0.55 degrees (Table 4). For the outcome measure (change in MPCSA), the standard error of the differences was 3.60 mm², with a limit of agreement of -7.30 mm² to 7.10 mm². Related statistics are also shown in Table 4.

Discussion

A mean increase in MPCSA was observed of 28 mm² ($P = 0.011$) on appliance insertion. However, there was a wide variation (SD = 59.06 mm²) with 23 out of the 32 subjects demonstrating

an increase in MPCSA, following appliance insertion. Nine subjects showed no airway enlargement. MPCSA increased by more than 20 mm² in 16 of the subjects. Nine subjects demonstrated an increase greater than 50 mm². There was no statistically significant difference in the change in MPCSA ($P > 0.05$) between the failed nCPAP subjects and those subjects who clinically appeared retrognathic to the referring physician. At this sample size, there is no evidence that the AMPA had a different effect within each referral sub-group.

To our knowledge, no study has reported the minimum airway cross-sectional area necessary for normal respiration. Although this is a complex issue, it is suggested that at least a 20-mm² aperture is necessary for normal respiration. This figure, derived from simple observation, approximates to the minimum nares cross-sectional area that an individual can breathe normally through. The average subject within this study increased their airway aperture by more than this amount. The initial mean MPCSA

Table 4 Reproducibility measurements.

	Mean Differences	SD	Limit of agreement		Pearson's correlation coefficient
			From	To	
Difference in MPCSA (mm ²)	-0.10	3.60	-7.30	7.10	0.994 $P < 0.0001$
Head angulation change (°)	0.55	1.21	-1.87	2.97	0.866 $P < 0.003$
Anteroposterior mandibular change (mm)	-0.15	1.06	-2.27	1.97	0.919 $P < 0.0001$
Superoinferior mandibular change (mm)	0.25	1.06	-1.87	2.37	0.957 $P < 0.0001$

of 80.22 mm² had a large SD of 48.13mm². A given airway enlargement may be clinically more significant in subjects with a small initial MPCSA. Post-treatment polysomnography was not completed for the sample and, therefore, a clinical evaluation of the change in MPCSA cannot be made.

The large variability in response to TMA complicates OSA management. Consequently, a predictor of TMA efficacy would be very desirable, in order to direct clinical resources towards those patients who will greatly benefit. Unfortunately, in the current study, no association of the change in MPCSA with the absolute or relative amount of mandibular protrusion or opening was found. This may reflect the large variation in the change in MPCSA, combined with the relatively small sample size. Consequently, interpretation of the change in MPCSA from this data set can only be implied to large groups. No other predictors of MPCSA change were found and it is therefore recommended that post-treatment PSG is carried out for each individual TMA patient, as described in the American Sleep Disorders Association Report (1995).

The referred patients to this orthodontic unit included both unsuccessful nCPAP and grossly retrognathic subjects. Therefore, as this study consecutively accepted these subjects for investigation, the extrapolation of the results to different referral groups should be carried out with caution. Thirty-two of the 41 referred subjects were fully investigated, with imaged and non-imaged (excluded) groups being almost identical in terms of age and BMI. It is therefore unlikely that there was significant exclusion bias.

Schwab (1996) has identified that the lateral pharyngeal wall is significantly different in OSA subjects, throwing doubt on the efficacy of cephalometric investigations within the individual. Based on evidence from previous studies of OSA groups when compared with normal controls, Rodenstein *et al.* (1990) used mean PCSA. Importantly, they had less success in demonstrating a difference between groups than Haponik *et al.* (1983), who used MPCSA. In addition, as it could be expected that airflow is more dependent upon the minimum than the mean airway aperture, the change in MPCSA

was chosen as the outcome measure, in the current study.

Recently, Cobo *et al.* (1995) measured pharyngeal volume using magnetic resonance imaging in association with TMA, but only for an 8-mm deep slice of the pharynx. It is possible that there was obstruction more inferiorly than was imaged and that an increase in mean pharyngeal volume may have existed, despite a local airway obstruction in one individual slice. The present study measured MPCSA for the entire pharynx between the nasal floor and the hyoid bone, and therefore may have more validity in the measurement of OSA, than previous investigations.

Re-digitizing of the images showed measurement error to be clinically insignificant. Validation using a Perspex pharynx showed a 0.037 per cent difference between imaged and physical structures, which compares well with previous error estimations of 5 per cent by Schwab *et al.* (1993). Anteroposterior mandibular position, head position and pharyngeal landmark identification were all well controlled. Swallowing and breathing were considered adequately controlled. However, as with the majority of previously published OSA image based studies, the subjects were conscious and therefore this variable was not controlled.

Variations in overbite and incomplete appliance seating increased the desired vertical mandibular opening to an excessive mean of 8 mm. L'Estrange *et al.* (1996) found a reduction in airway dimensions on vertical mandibular opening. In the current study, poor correlation of mandibular position and the change in MPCSA was seen, suggesting a complex multifactorial interplay of confounding variables, which require further investigation.

Conclusions

There was a statistically significant increase in MPCSA of 28 mm² following AMPA insertion. However, there was a wide individual variation which could not be predicted from the amount of mandibular repositioning, but may be a result of multiple confounding variables or an intrinsic biological variation between subjects. This study controlled many of these confounding variables,

although further investigation is needed to explain why individuals differ so much in their response to a standardized AMPA therapy.

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