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A modified monobloc for the treatment of obstructive sleep apnoea in paediatric patients

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SUMMARY The aims of this study were to determine the differences in craniofacial morphology between children with obstructive sleep apnoea (OSA) and control subjects, and to investigate the effects of modified monobloc (MM) appliance treatment in OSA children.

The treatment group consisted of 20 OSA Caucasian subjects (10 boys and 10 girls) with ages ranging from 4 to 8 years (mean 5.91 years). The control group comprised 20 healthy Caucasian subjects without OSA (10 boys and 10 girls) with ages ranging from 5 to 7 years (mean 6 years). Polysomnography was used to establish the diagnosis of OSA and to evaluate the effects of MM treatment in the test group. Cephalometric radiographs and study models were obtained for all subjects.

A number of statistically significant differences were detected in craniofacial morphology between the treatment group and controls. The treatment group demonstrated a skeletal Class II pattern ($P = 0.04$), with a reduced mandibular length ($P = 0.03$) and a corresponding increase in overbite. The hyoid bone was located superiorly in the OSA group ($P = 0.04$). Analysis of the dental arches demonstrated a significantly smaller distance between the first and second inter-molar primary mandibular regions ($P = 0.03$ and $P = 0.04$, respectively) in OSA patients. Repeat polysomnography, with the MM *in situ*, after 6 months of wear, revealed a significant reduction in the apnoea–hypopnoea index in children with OSA ($P = 0.0003$).

The MM was found to reduce daytime sleepiness and to subjectively improve assessed sleep quality. The patients and their parents reported good compliance with MM treatment.

Introduction

Obstructive sleep apnoea (OSA) is caused by partial or complete collapse of the pharyngeal airway during sleep due to a combination of a reduction in muscle tone at sleep onset and structural factors such as retrognathia, micrognathia and macroglossia (Bennett *et al.*, 1998).

OSA is a common sleep disorder in adults that is increasingly recognized in the paediatric population. Failure to diagnose and treat OSA can result in serious consequences for the child, including enuresis, growth disorders, educational concerns, neurobehavioural problems, cardiorespiratory failure, or even death (Guilleminault *et al.*, 1976; Brouilette *et al.*, 1982; Rosen *et al.*, 1992). Adenotonsillar hypertrophy is the most common associated condition in otherwise normal children (Rosen *et al.*, 1992, 1994). However, children with a variety of medical conditions are also at increased risk for OSA, including trisomy 21, obesity, neuromuscular disorders, and other craniofacial and genetic disorders (Rosen, 1996).

Childhood OSA differs from OSA in adults in several important ways. The peak incidence, between 2 and 6 years, corresponds to the peak for normal lymphoid hyperplasia. In school-age children, the male/female ratio is approximately equal (Rosen *et al.*, 1992). In contrast to the predominance of obesity in adult OSA, the majority of children with OSA are of normal weight (Carroll *et al.*, 1995).

The polysomnographic features of childhood OSA also differ from those of adults. The number of obstructive events is lower. Instead of repetitive discrete obstructive apnoeas, children often exhibit a pattern of partial obstructive hypoventilation characterized by snoring, paradoxical rib cage motion, phasic oxyhaemoglobin desaturation, and hypercapnia (Brouilette *et al.*, 1982; Rosen *et al.*, 1992).

With the recent interest in sleep apnoea, oral appliances of various designs have been proposed and studied (Cartwright and Samelson, 1982; Cartwright, 1985; Bonham *et al.*, 1988; Cartwright *et al.*, 1988; Rider, 1988; Schmidt-Nowara *et al.*, 1991, 1995; Knudson *et al.*, 1992; Knudson and Meyer, 1993; Ferguson *et al.*, 1996; Hans *et al.*, 1997; Bernhold *et al.*, 1998; Gale *et al.*, 2000) and are increasingly used to treat sleep apnoea (Schmidt-Nowara *et al.*, 1995). The goal of oral appliance therapy is to modify the position of the upper airway structures so as to enlarge the airway or otherwise reduce its collapsibility (Schmidt-Nowara *et al.*, 1995; Bennett *et al.*, 1998; Bondemark, 1999; Petitjean *et al.*, 2000; Schoem, 2000). In addition to airway size, the effects on muscle function or airway compliance may also be important (Schmidt-Nowara *et al.*, 1995).

There are three types of oral appliance available for treating patients with sleep-related breathing disorders (Schmidt-Nowara *et al.*, 1995; Hans *et al.*, 1997; Bennett *et al.*, 1998; Lowe *et al.*, 2000; Petitjean *et al.*, 2000; Schoem, 2000): mandibular advancing devices (MAD), which act to advance or downwardly rotate the mandible and thus draw the tongue forward through its attachments to the genial tubercles (Schoem, 2000). These appliances also change the position of the hyoid bone and modify the airway space at the level of the tongue base (Hans *et al.*, 1997); tongue retaining devices (TRD) act to hold the tongue, through negative pressure, in an anterior position during sleep (Schoem, 2000); palatal lift devices aim to reduce the vibration of the soft palate, and thus snoring (Hans *et al.*, 1997).

The aims of the current study were two-fold:

1. To determine the differences in craniofacial morphology between OSA children and control subjects;
2. To describe the use and outcomes of a new orthodontic appliance [modified monobloc (MM)], incorporating the principles of the MAD and TRD, for children with OSA.

Subjects and methods

Subjects

The subjects for the present study were referred to the Department of Orthodontics, University of Rome 'Tor Vergata' from the Departments of Paediatric and Otolaryngology of the same university. The treatment group comprised 20 OSA Caucasian subjects (10 boys and 10 girls) with ages ranging from 4 to 8 years (mean 5.91 years) and a mean body mass index (BMI) of 16.02. The demographic data are summarized in Table 1.

All subjects in the treatment group had their diagnosis of OSA confirmed by overnight polysomnography. In addition, all OSA patients were screened with a validated questionnaire completed by the children's parents to assess excessive daytime sleepiness, the Italian version of the Epworth sleepiness scale (ESS). The ESS (Johns, 1991, 1993; Vignatelli *et al.*, 2003), which asks patients to estimate the likelihood that they would doze off or fall asleep in a sedentary situation, is a simple self-administered questionnaire which is shown to provide a measurement of the subject's general level of daytime sleepiness.

The mean ± standard deviation of the ESS score in OSA patients was 15.2 ± 4.9.

The control group comprised of 20 healthy Caucasian subjects (10 boys and 10 girls), with no reported symptoms of OSA and ranging in age from 5 to 7 years (mean 6 years) with a BMI of 20.98, referred from the Department of Paediatric Dentistry for early orthodontic diagnosis of eruption disturbances, trauma, etc., where radiographs had been taken. The demographic data are summarized in Table 1. All controls were also screened with the questionnaire. The results in the control group allowed excessive daytime sleepiness to be excluded (ESS score 6.0 ± 2.1).

Methods

All subjects underwent lateral cephalometric radiography and dental impressions to obtain study models.

Ethical approval for the study was obtained from the Comitato Etico Indipendente of the Policlinico Tor Vergata and the parents of the patients gave informed consent.

Cephalometric analysis. To obtain the radiographs, the child was seated with the median plane parallel to the film and in a position of maximal intercuspation, with the lips in light contact. Lateral cephalometric radiography has proved to be a very useful tool to assess cervicocraniofacial morphology and oropharyngeal airway dimensions (Tangugsorn *et al.*, 1995).

All of the lateral cephalometric radiographs were taken in a standardized manner. Each cephalogram was traced and 26 variables (13 linear and 13 angular) were measured (Figures 1–3).

The cephalometric measurements used were:

1. Sagittal analysis: SNA (degrees), SNB (degrees), ANB (degrees), ANS–PNS (mm), Go–Me (mm);

Table 1 Anthropometric data for patients and controls.

	Patients				Controls				
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	*P* value
Age (years)	5.91	1.14	4.00	8.00	6.00	0.71	5.00	7.00	0.827
Height (m)	1.26	0.14	1.00	1.45	1.23	4.53	1.19	1.30	0.743
Weight (kg)	27.73	8.04	15.00	38.00	31.80	2.77	29.00	36.00	0.377
BMI (kg/m^2)	16.02	3.40	8.23	20.80	20.98	0.48	20.48	21.53	0.002*

SD, standard deviation; BMI, body mass index.

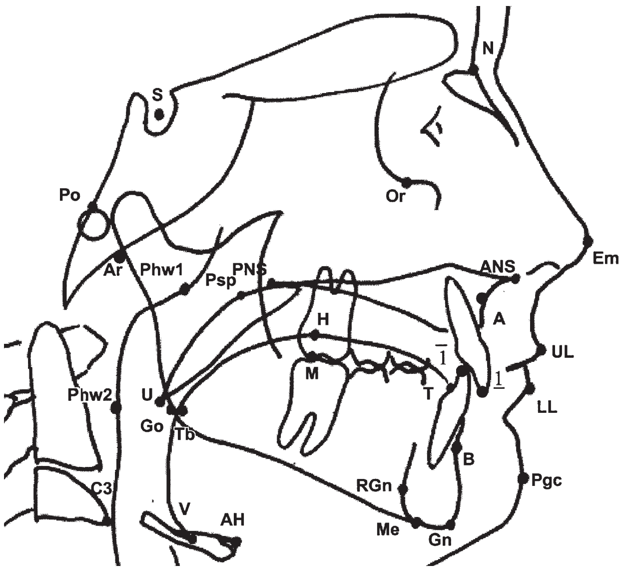

Figure 1 Cephalometric points: S, sella; N, nasion; A, point A; B, point B; Gn, gnathion; Me, menton; Go, gonion; Ar, articulare; Po, porion; Or, orbitale; ANS, anterior nasal spine; PNS, posterior nasal spine; Em, most prominent point of the tip of the nose; Pgc, soft tissue pogonion; UL, upper lip; LL, lower lip; $\underline{1}$, upper incisor; $\overline{1}$, lower incisor; M, posterior contact point of the first molars; Rgn, retrognathion; H, highest dorsal point of the tongue; T, tip of the tongue; AH, most anterior and superior point on the body of the hyoid bone; V, vallecula; C_3, third cervical vertebra; U, tip of the uvula; Phw1, upper pharyngeal wall; Phw2, lower pharyngeal wall; PsP, most superior posterior point of the soft palate; Tb, dorsum of the tongue on a line joining gonion (Go) and supramentale (B).

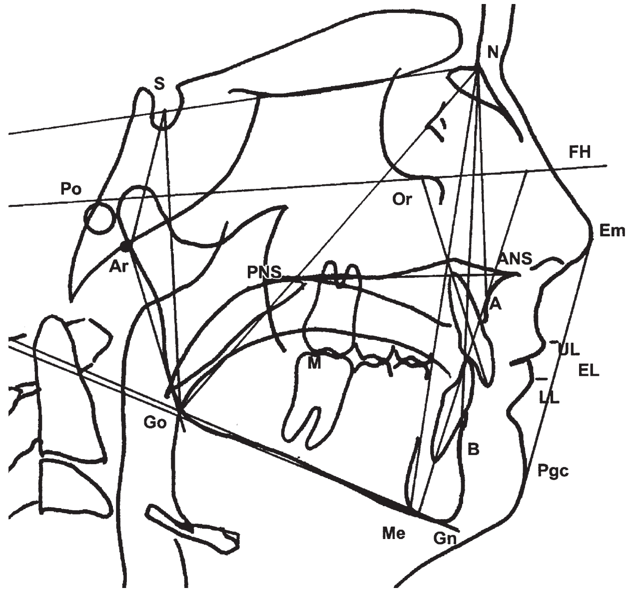

Figure 2 Cephalometric analysis. FH, Frankfort horizontal plane; GoMe, mandibular plane; EL, aesthetic line Em–PgC; sagittal analysis [SNA (degrees), SNB (degrees), Go–Me (mm), ANS–PNS (mm)]; vertical analysis [FMA (degrees), S–N to Go–Gn (degrees), S–Go/N–ME (percentage)]; dental analysis: [IMPA (degrees) ($\underline{1}$^GoMe); FMIA (degrees) ($\underline{1}$^Fh); $\underline{1}$^Fh (degrees); overjet (mm); overbite (mm)]; aesthetic analysis [UL–EL (mm); LL–EL (mm)]; growth prediction [N–S^S–Ar (degrees); S–Ar^Ar–Go (degrees); Ar–Go^Go–Me (degrees); Ar–Go^Go–N (degrees); N–Go^Go–Me (degrees)].

2. Vertical analysis: FMA (degrees), SN^Go–Gn (degrees), (S–Go)/(N–Me) (percentage);
3. Dental analysis: IMPA (degrees), FMIA (degrees), $\underline{1}$^FH (degrees), overjet (mm), overbite (mm);
4. Aesthetic analysis: UL–EL (mm), LL–EL (mm);
5. Growth prediction: NS^SAr (degrees), SAr^ArGo (degrees), ArGo^GoMe (degrees), ArGo^GoN (degrees), NGo^GoMe (degrees);
6. Hyoid bone: AH–C_3 horizontal (mm) (the horizontal distance from AH to C_3; AH is the most anterior and superior point on the body of the hyoid bone and represents the inferior part of the tongue; C_3 is the third cervical vertebra); AH–C_3 vertical (mm) (the vertical distance from AH to C_3); AH–FH (mm) [the distance from AH to Frankfort horizontal; measured according to Pracharktam *et al.* (1994) and Tangugsorn *et al.* (1995)]; AH–RGn (mm) (the horizontal position of the hyoid, determined by measurement in an anterior direction from the mandibular symphysis); AH–AH′ (mm) (the vertical position of the hyoid to the mandibular plane); AH–SN (mm) (the vertical position of the hyoid to the SN line).
7. Tongue dimensions measured according to Pracharktam *et al.* (1994) and Tangugsorn *et al.* (1995): V–T (mm) (the distance from the intersection of the epiglottis and the base of the tongue to the tip of the tongue); H perpendicular to V–T (mm) (representing tongue height); V–T^FH (degrees) (representing the vertical position of the tongue).
8. Soft palate and oropharyngeal dimensions measured according to Pracharktam *et al.* (1994) and Tangugsorn *et al.* (1995): Phw1–Psp (mm) (superior posterior airway space measured along a line parallel to B–Go); Phw2–Tb (mm) (inferior airway space measured between the posterior pharyngeal wall and the dorsum of the tongue on a line joining the gonion to point B); MPW (mm) [the middle pharyngeal width measured from the intersection of a perpendicular line from U (tip of the uvula) to the posterior pharyngeal wall]; U–PNS (mm) (the distance from U to PNS, representing the length of the soft palate); CL (mm) (the contact length between the dorsal contour of the tongue and the soft palate); SPT (mm) (the maximum thickness of the soft palate).

Dental measurement. Alginate dental impressions were used to fabricate a set of study models. Impressions were poured within 30 minutes of being taken using orthodontic stone. The following linear measurements

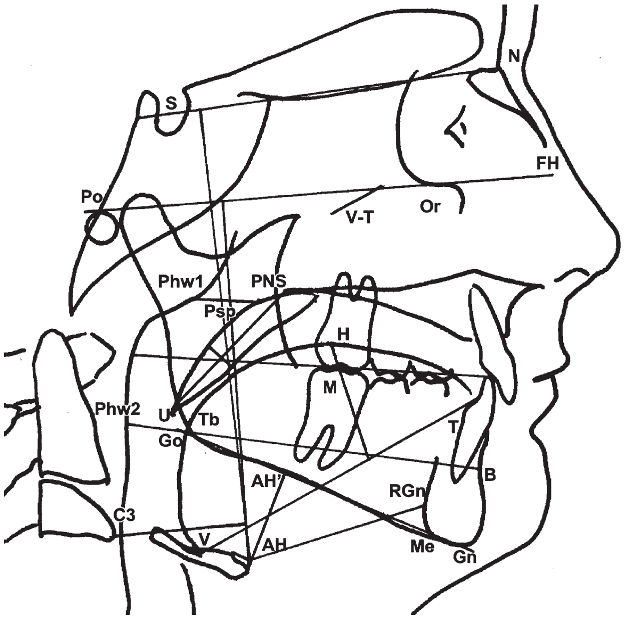

Figure 3 Cephalometric analysis. Tongue [VT (mm); H perp VT (mm); VT^FH (degrees)]; soft palate and pharynx [Phw1–Psp (mm); Phw2–Tb (mm); MPW (mm); PNS–U (mm)]; hyoid [AH–C_3 horizontal (mm), the horizontal distance from AH to C_3; AH–C_3 vertical (mm), the vertical distance from AH to C_3; AH–FH (mm), the distance from AH perpendicular to Frankfort horizontal; AH–RGn (mm), the horizontal distance from AH to RGn; AH–AH′ (mm), the vertical distance from AH to the mandibular plane (AH′); AH–S–N (mm), the vertical position from AH perpendicular to SN line].

were recorded separately from the upper and lower study models using a sliding calliper equipped with a vernier scale to a level of precision of 0.1 mm:

1. inter-canine primary distance, defined as the distance between the centroids of the canines, as described by Moyers *et al.* (1976);
2. first inter-molar primary distance, defined as the linear distance between the centroids of the first primary molars;
3. second inter-molar primary distance, defined as the linear measurement between the centroids of the second molars;
4. depth of the maxilla and the mandible, defined as the distance from the midpoint of the most labial surface of the central incisors to a point bisecting a line joining the distal midpoints of the second primary molars (Rakosi *et al.*, 1989; Seto *et al.*, 2001).

All measurements were carried out by a single operator (PC).

Sleep studies. The ‘gold standard’ for the diagnosis of OSA is regarded to be overnight polysomnography. Nocturnal polysomnography was performed by a trained sleep laboratory technician. Calculated respiratory variables were the number of apnoeas and hypopnoeas for hours of sleep (AHI) and minimum arterial oxygen saturation during apnoeas. Apnoea was defined as cessation of airflow for at least 10 seconds and hypopnoea as a reduction in the amplitude of airflow or thoraco-abdominal wall movement greater than 50 per cent of the baseline measurement for more than 10 seconds (oxygen desaturation need not occur), or the same reduction with an accompanying oxygen desaturation of at least 3 per cent (no time limit), and associated with arousal.

Appliance design. The MM appliance has been reported to improve the incidence of OSA (Clark *et al.*, 1993; Rose *et al.*, 2000, 2002). The MM was produced from a construction bite that positioned the mandible anteriorly into an edge-to-edge incisor relationship. As a general rule, the bite registration was obtained 3 mm short of maximum protrusion, with care being taken to ensure that lateral displacement did not occur. This custom-made appliance incorporated full occlusal coverage and a central maxillary screw, to allow for accompanying expansion as the mandible was advanced. The fabrication was relatively time-consuming and expensive. The MM appliance was selected for use in children with OSA, on the basis of achieving favourable skeletal and dentoalveolar changes during therapy (Figures 4–6), thus addressing the skeletal Class II pattern and reduced vertical dimension while simultaneously offering the advantage of good compliance. To avoid any undesirable anterior dental movements, the incisal edges and superior labial surfaces of the mandibular incisors were capped.

The subjects were instructed to wear their appliances full-time for the first week and then at nights only. During treatment, contact was maintained between the appliance and the maxillary posterior teeth. However, the mandibular posterior teeth were encouraged to erupt by trimming the acrylic from their occlusal surface. In addition to the MM appliance a lingual arch was also used to provide additional intermaxillary (Class II) anchorage and to limit any jaw opening during sleep (Figures 4, 5). The MM appliance also incorporated a Tucat’s pearl on a sliding wire for determining the reference point for the tip of the tongue (Figures 4, 6). A Tucat’s pearl allows the placement of the tongue tip against the palatal aspect of the alveolar process, behind the maxillary incisors, to improve muscle function and the habitual position of the tongue (Cozza *et al.*, 2002).

Initial problems with use of the MM included excessive salivation and discomfort on waking. However, these adverse effects gradually diminished following a few days of wear. A repeat sleep study was performed with the MM appliance *in situ*, following a period of 6 months of wear.

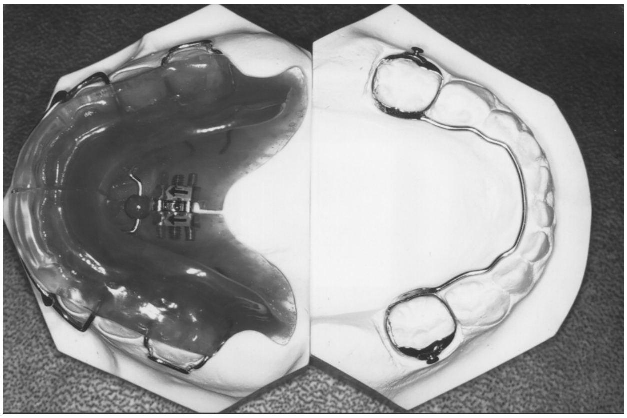

Figure 4 The design of the appliance used in the study. In the upper arch there is a monobloc mandibular advancement splint and in the lower jaw a lingual arch soldered to bands on the primary molars.

Figure 5 The modified monobloc: lateral view. The lower jaw was postured forward by the construction bite to increase the intermaxillary space and Class II intermaxillary elastics were used to prevent any jaw opening during sleep. Printed by permission of JCO, Inc.

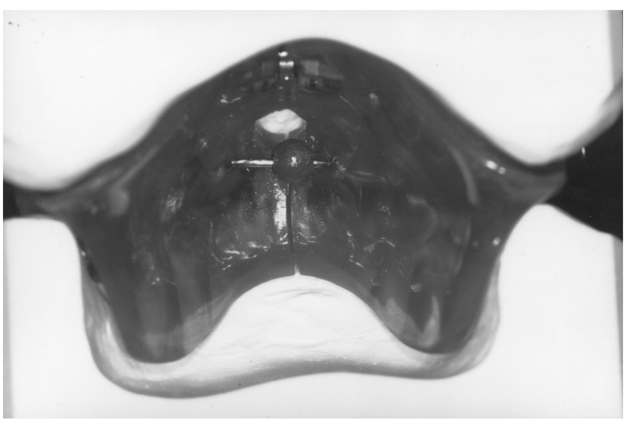

Figure 6 The modified monobloc: intra-oral view. A Tucat's pearl with a sliding wire for reference of the tip of the tongue. Printed by permission of JCO, Inc.

Method error

Each cephalogram and dental arch measurement was traced and measured by a single operator (PC). All measurements were randomly selected and repeated by the same investigator after a period of 7 days; the mean value of the two measurements was used. All measurement error coefficients were found to be close to 1.00 and within acceptable limits.

Statistical methods

Descriptive statistics included mean and standard deviations. Non-parametric statistical tests were used to analyse the data. Differences between the groups were tested using the Mann–Whitney *U*-test. The mean differences in polysomnographic data between pre- and post-therapy were examined using Wilcoxon's matched pairs test. The level of significance was set at $P < 0.05$.

Results

Cephalometric analysis (Table 2)

The morphologic cephalometric values revealed a significantly higher ANB angle in the OSA group compared with the control subjects (5.59 and 2.90 degrees, respectively). In addition, the OSA subjects demonstrated a significant decrease in mandibular length (58.82 and 65.40 mm, respectively) and a greater skeletal divergency angle; FMA was greater in the treatment group, but not significantly (28.86 and 24.80 degrees, respectively). The OSA subjects had a deeper overbite (2.45 and 1.20 mm, respectively). While the horizontal hyoid distance was found to be similar in both groups, it was located more superiorly in the OSA group, as determined from the vertical distance of AH to SN (85.18 and 91.20 mm, respectively). No statistically significant differences between the groups could be detected in the dimensions of the tongue and soft palate. Table 2 further reveals that there were no statistically significant differences between the two groups for any other cephalometric parameter.

Dental model analysis (Table 3)

The OSA patients had slightly narrower inter-tooth distances at all levels measured. However, statistical significance was only detected between the mandibular first and second primary inter-molar distances ($P = 0.034$ and $P = 0.042$, respectively). There were no significant differences in the depths of the maxilla or mandible between the OSA subjects and the controls.

Polysomnographic data analysis (Table 4)

The MM appliance was significantly more effective at reducing the AHI but not the minimum arterial oxygen

Table 2 Cephalometric analysis.

	Patients				Controls				
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	*P* value
Sagittal analysis									
SNA (°)	80.68	2.41	77.50	84.00	79.20	5.20	74.00	85.50	0.510
SNB (°)	75.09	3.86	68.00	80.00	76.30	4.51	71.00	81.50	0.583
ANB (°)	5.59	2.46	2.00	10.00	2.90	1.14	1.00	4.00	0.042*
ANS–PNS (mm)	48.45	4.41	42.00	56.00	50.20	3.49	44.00	55.00	0.305
Go–Me (mm)	58.82	6.01	46.00	65.00	65.40	5.08	58.00	72.00	0.028*
Vertical analysis									
FMA (°)	28.86	4.43	20.50	34.00	24.80	3.09	22.00	30.00	0.090
SN^GoGn (°)	35.64	4.89	30.00	44.00	35.10	4.84	29.00	42.00	1.000
(S–Go)/(N–Me) (%)	59.45	4.23	53.00	65.00	61.00	1.56	58.00	63.00	0.374
Dental analysis									
IMPA (°)	81.95	10.04	69.00	100.00	85.60	9.59	73.00	93.00	0.583
FMIA (°)	68.95	10.52	48.00	80.00	71.70	7.12	64.00	78.00	1.000
1^FH (°)	93.18	11.30	71.00	111.00	78.50	20.00	58.00	102.00	0.160
Overjet (mm)	4.45	2.05	2.00	8.00	2.90	1.71	0.00	5.00	0.101
Overbite (mm)	2.45	2.58	–3.00	7.00	1.20	1.03	0.00	3.00	0.034*
Aesthetic analysis									
Line UL–EL (mm)	–1.50	2.71	–5.00	3.00	–2.20	2.77	–5.00	2.00	0.583
Line LL–EL (mm)	–1.14	2.83	–5.00	3.00	–1.00	2.74	–4.00	3.00	0.913
Growth prediction									
NS^SAr (°)	122.64	7.53	112.00	135.00	123.90	5.66	118.00	132.00	0.583
SAr^ArGo (°)	142.95	6.17	133.00	152.00	142.90	3.36	139.00	147.00	1.000
ArGo^GoMe (°)	133.23	2.85	128.00	138.00	133.20	5.99	127.00	141.00	0.827
ArGo^GoN (°)	57.77	3.18	53.00	63.00	55.80	2.08	53.00	58.00	0.267
NGo^GoMe (°)	75.50	2.87	71.50	80.00	77.20	7.11	70.50	85.00	1.000
Hyoid									
AH–C3 hor. (mm)	30.64	4.11	24.00	37.00	31.40	3.65	28.00	37.00	0.661
AH–C3 vert. (mm)	5.18	7.64	–7.00	19.00	2.60	5.03	–5.00	9.00	0.583
AH–FH (mm)	68.64	6.77	59.00	80.00	74.60	6.39	67.00	82.00	0.145
AH–RGn (mm)	35.18	5.72	27.00	44.00	35.80	3.85	30.00	42.00	0.698
AH–AH' (mm)	12.82	5.67	5.00	22.00	12.40	5.27	6.00	22.00	0.888
AH–SN (mm)	85.18	7.57	73.00	101.00	91.20	6.66	82.00	100.00	0.043*
Tongue									
VT (mm)	66.36	4.27	58.00	72.00	66.40	5.13	58.00	71.00	0.827
H perp. VT (mm)	20.57	3.35	17.00	27.00	24.80	5.12	17.00	31.00	0.145
VT^FH (°)	21.95	7.08	13.00	37.00	20.80	3.01	17.00	25.00	0.734
Soft palate									
U–PNS (mm)	33.50	5.01	24.00	40.00	35.00	0.71	34.00	36.00	0.441
SPT (mm)	8.00	1.90	5.00	12.00	9.20	1.64	7.00	11.00	0.221
CL (mm)	8.00	9.60	0.00	26.00	8.20	9.20	0.00	19.00	1.000
Pharynx									
Phw1–Psp (mm)	9.00	2.93	4.00	13.00	6.80	2.68	4.00	11.00	0.180
Phw2–Tb (mm)	12.36	2.16	9.00	17.00	12.00	2.00	10.00	15.00	0.661
MPW (mm)	8.73	2.28	6.00	14.00	8.60	4.22	4.00	15.00	0.827

SD, standard deviation.

saturation. The median AHI score decreased after 6 months of MM therapy from 7.88 to 3.66.

Discussion

Several studies have used cephalometrics to examine anatomic differences in OSA subjects (Pracharktam *et al.*, 1994; Mayer and Meier-Ewert, 1995; Tangugsorn *et al.*, 1995). Research comparing OSA adults with controls demonstrates the former to have an increased hyoid to mandibular plane distance, a longer soft palate, a diminished sagittal cranial base dimension and a narrower posterior airway (Pracharktam *et al.*, 1994; Tangugsorn *et al.*, 1995; Bondemark, 1999; Gale *et al.*, 2000; Kulnis *et al.*, 2000). However, there is a distinct lack of research data available comparing craniofacial and oropharyngeal dimensions in OSA children. This study aimed to address these shortcomings in the literature.

Analysis of the lateral cephalograms revealed that the OSA children demonstrated a skeletal Class II pattern with a reduced mandibular length and an associated deep overbite. Furthermore, the hyoid bone was located superiorly in the OSA group. No other significant cephalometric differences could be detected between the two groups.

Table 3 Model analysis.

	Patients				Controls				
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	*P* value
Primary maxillary arch measurements									
Inter-canine distance (mm)	27.77	3.61	23.00	33.00	31.40	2.43	29.00	35.00	0.078
First inter-molar distance (mm)	31.45	3.59	27.00	37.00	34.40	2.82	32.00	38.00	0.098
Second inter-molar distance (mm)	36.50	3.29	32.00	41.00	37.50	2.74	34.00	41.00	0.687
Maxillary depth (mm)	28.41	1.80	25.00	31.00	28.70	2.64	26.00	33.00	0.819
Primary mandibular arch measurements									
Inter-canine distance (mm)	24.00	2.57	20.00	29.00	25.70	2.11	23.00	28.00	0.204
First inter-molar distance (mm)	28.45	1.27	27.00	31.00	30.40	1.56	29.00	33.00	0.034*
Second inter-molar distance (mm)	35.00	1.73	33.00	38.00	36.80	1.44	35.00	38.00	0.042*
Mandibular depth (mm)	24.36	1.63	21.00	26.00	25.00	1.46	24.00	28.00	0.816

SD, standard deviation.

Table 4 Results before and 6 months after treatment with a modified monobloc.

	Before treatment				6 months after treatment				
	Mean	SD	Minimum	Maximum	Mean	SD	Minimum	Maximum	*P* value
AHI	7.88	1.81	5.60	10.80	3.66	1.70	1.40	5.90	0.0003*
Arousal index	5.48	2.19	2.40	6.70	6.80	3.79	3.00	13.50	0.3668
SaO_2 (%)	97.39	0.66	96.00	98.00	96.87	0.85	95.00	97.50	0.4072

SD, standard deviation; AHI, the number of apnoeas and hypopnoeas for hours of sleep; SaO_2, minimum arterial oxygen saturation.

Model analysis revealed that the OSA patients had narrower maxillae and mandibles when compared with the control group. This was particularly the case with reference to the mandible. There were no statistically significant differences between the two groups in any other measurements.

On the basis of these findings, it could be proposed that the tongue may compensate for the reduced inter-arch dimensions and as such assume a more upward and backward position, which may justify the use of a mandibular advancement appliance. The present study attempted to investigate the effects of appliance treatment, in children with OSA, on polysomnographic variables. The MM was found to significantly reduce the AHI score, while the minimum oxygen saturation remained unchanged. Furthermore, the MM reduced daytime sleepiness and subjectively improved sleep quality (the ESS score after MM therapy was reduced from 15.2 ± 4.9 to 7.1 ± 2). All children and their parents reported good compliance with the MM.

The therapeutic effect of a mandibular advancement appliance in the treatment of obstructive sleep disorders in adults is controversial and the success rate, being subject to different definitions, varies substantially in clinical investigations (O'Sullivan *et al.*, 1995; Rose *et al.*, 2002). This might be due to differences in study protocols, appliance design, and subject selection.

The rationale for selecting the MM appliance in OSA children was to increase the intermaxillary space in which the tongue rests. Linked to this was the issue of correcting the underlying skeletal Class II pattern. However, the observation period was rather short, at 6 months, and there is a need for long-term evaluation.

Conclusions

1. OSA children demonstrated a skeletal Class II pattern, with a reduced mandibular length and increased overbite. The hyoid bone was found to adopt a more superior position, when compared with the control subjects. In addition, the children with OSA were found to have narrower mandibular inter-arch distances.
2. The results of this study show that the MM may be an effective therapeutic alternative in children with mild to moderate OSA.
3. The fabrication of the MM was relatively time-consuming and expensive. However, all children and their parents reported good compliance.

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