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Effects of clear aligner therapy for Class II malocclusion on upper airway morphology and daytime sleepiness in adults: A case series

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Keywords
Clear aligner
Class II malocclusion
Upper airway

Summary

Introduction > To evaluate the effects of clear aligner therapy (CAT) on the upper airway dimensions and on daytime sleepiness in adults with dentoskeletal Class II malocclusion.
Methods > This study was conducted from August 2017 to February 2019. Inclusion criteria were healthy adults $\geq$ 18 years old, Angle Class II division 1 malocclusion, first-molar relationship of end-to-end or greater, overjet < 10 mm, and presenting for multi-arch comprehensive orthodontic treatment with aligners. Treatment mechanics included mandibular dentoalveolar advancement with Class II elastics without maxillary sequential distalization programmed into aligners. Post-treatment changes in dentoskeletal and upper airway dimensions were assessed using CBCT images. The treatment effect on daytime sleepiness was evaluated using an Epworth Sleepiness Scale (ESS).
Results > Eight subjects were included in this pilot study (mean age at treatment initiation = 44.6 -years [SD = 15.3]). The mean treatment duration was 12.2 months (SD = 3.4). No statistically significant treatment changes were observed in upper airway dimensions or dentoskeletal cephalometric analyses. Subjects with excessive daytime sleepiness at pre-treatment reported an improvement post-treatment, but no significant difference in the mean ESS score was found.
Conclusion > Treatment of Class II division 1 malocclusion in adults by mandibular dentoalveolar advancement using CAT has no statistically significant effects on the airway and dentoskeletal measurements, or daytime sleepiness.

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Mots clés
Gouttière
Malocclusion de classe II
Voies aériennes

Résumé

Effets de la thérapeutique par gouttière dans le cas de malocclusions de Class II sur la morphologie des voies aériennes supérieures et la somnolence diurne

Objectif > *Évaluer les effets de la thérapeutique par gouttière chez les patients adultes présentant des malocclusions dento-squelettique de Classe II sur la dimension des voies aériennes supérieures et la somnolence diurne.*

Méthodes > *Cette série de cas a été menée d'août 2017 à février 2019. Les critères d'inclusion étaient les suivants : adultes ≥ 18 ans, malocclusion de Classe II division 1 d'Angle, classe II molaire bout à bout ou plus, surplomb horizontal < 10 mm, avec une motivation pour un traitement complet par gouttières des deux arcades. La stratégie programmée dans la technique des gouttières prévoyait une mécanique d'avancée dentoalvéolaire mandibulaire par élastiques de Classe II sans distalisation séquentielle du maxillaire. Les changements dento-squelettiques et de dimension des voies aériennes supérieures ont été mesurés sur des images CBCT. L'effet thérapeutique sur la somnolence diurne a été enregistré avec l'échelle d'évaluation de la somnolence d'Epworth (ESS).*

Résultats > *Huit sujets ont été inclus dans cette étude pilote (la moyenne d'âge au début du traitement était de 44,6 ans [ET = 15,3]). La durée moyenne de traitement était de 12,2 mois (ET = 3,4). Aucuns changements statistiquement significatifs liés au traitement ont été observés dans les dimensions des voies aériennes supérieures ou dans les paramètres céphalométriques dento-squelettiques. Les patients avec une somnolence diurne excessive au début du traitement ont montré une amélioration après traitement mais aucune différence significative dans le score moyen ESS n'a été trouvé.*

Conclusion > *Le traitement de la malocclusion de Classe II division 1 chez les adultes par avancée mandibulaire dentoalvéolaire par gouttière ne présente aucun effet significatif sur les voies aériennes et les mesures dento-squelettiques, pas plus que sur la somnolence diurne.*

Introduction

Multiple studies have evaluated the effects of clear aligner therapy (CAT) on various malocclusions. A 2014 systematic review assessed the effectiveness of specific tooth movements utilizing clear aligners. Intrusive movements were most effective in maxillary (45%) and mandibular (47%) central incisors and least effective in maxillary lateral incisors (33%). Extrusion, the least accurate tooth movement, was most difficult with maxillary (18%) and mandibular (25%) central incisors. Canine rotations had a mean accuracy of 36%, and this increased to 43% when interproximal reduction was performed. Accuracy of rotation was also shown to depend on staging of rotations, with less than 1.5 degrees per aligner resulting in higher efficacy [1]. A more recent systematic review [2] reported similar findings and concluded that treatment outcomes with CAT are less accurate than those with fixed appliances.

Studies on transverse outcomes found that the mean accuracy of expansion is 72.8%, with 82.9% at the cusp tips and 62.7% at the gingival margins [3]. Additionally, to this date, there are no published prospective studies evaluating the efficacy or efficiency of anteroposterior Class II correction utilizing clear aligners.

Craniofacial morphology and the effects of orthodontic interventions on upper airway dimensions have received much attention during the last decade. It has been demonstrated that adult patients with Class II skeletal patterns have reduced airway volume [4]. Additionally, it has been documented that higher mandibular plane angles in Class II patients are associated with reduced pharyngeal airway measurements [4–7].

In regard to the effects of orthodontic interventions, Pliska et al. [8] evaluated the upper airway dimension of a non-growing adult population undergoing orthodontic treatment for Class II malocclusion. When comparing patients treated with and without extractions, they found a slight decrease in total airway volume and minimal cross-sectional area (MCA) in both groups, with no significant differences between the two.

Excessive daytime sleepiness (EDS) is defined as difficulty maintaining the alert awake state during the wake phase of the sleep cycle. Daytime sleepiness is associated with an increased risk for motor vehicle accidents and work-related accidents, and a higher prevalence of stroke, myocardial infarction, and diabetes [9]. EDS has been accepted as a proxy of obstructive sleep apnoea (OSA) risk assessment. Sleep questionnaires, such as the Epworth Sleepiness Scale (ESS) [10] is widely used to assess

TABLE I
Anatomic planes defining the upper airway.

Plane	Definition		
	NP	OP	HP
Superior	Plane parallel to FHP intersecting CB	Plane parallel to FHP intersecting PNS	Plane parallel to FHP intersecting C3as
Inferior	Plane parallel to FHP intersecting PNS	Plane parallel to FHP intersecting C3as	Plane parallel to FHP intersecting C4as

NP: nasopharynx; OP: oropharynx; HP: hypopharynx; FHP: Frankfort horizontal plane; CB: base of the clivus; PNS: posterior nasal spine; C3as: the most anterior superior point of C3; C4as: the most anterior superior point of C4; APW: anterior pharyngeal wall; PPW: posterior pharyngeal wall.

daytime sleepiness. Results from ESS correlate with similar measures of daytime sleepiness, including the multiple sleep latency test (MSLT) and the maintenance of wakefulness test (MWT) [9].

The 3D effects of CAT on the upper airway for the treatment of Class II malocclusion have not been investigated. The aims of this pilot study were to evaluate the post-treatment effects of CAT on the dimensions of the upper pharyngeal airway and on subjectively reported daytime sleepiness, in a population of skeletal Class II adults.

Our hypothesis was that the upper airway dimension will increase, and daytime sleepiness will decrease with correction. The proposed mechanism is that anterior repositioning of the mandibular incisors and molars will increase the tongue space and allow the tongue to follow anteriorly. This forward positioning could stretch the palatopharyngeal and palatoglossal arches, increase the velopharyngeal airway size and maintain its patency. It would also stretch the genioglossal and geniohyoid muscles and thus elevates the hyoid bone contributing to further improvement in the upper airway dimension.

Materials and methods

Study design and sample population

The protocol followed for this case series was approved by the Institutional Review Board at the University at Buffalo (00000725). All subjects were treated by an Invisalign (Align Technology Inc., Santa Clara, California) Diamond Plus provider (T.G.) at one private practice. The study was conducted from August 2017 until February 2019. All data were de-identified prior to removal from the treatment site.

The inclusion criteria were consecutively treated healthy females and males over the age of 18 years, Angle Class II division 1 malocclusion, first-molar relationship of end-to-end or greater, full permanent dentition from molar to molar, overjet < 10 mm, and presenting for non-surgical non-extraction multi-arch comprehensive orthodontic treatment with the Invisalign appliance. Treatment mechanics for Class II correction included mandibular dentoalveolar advancement with Class II elastics only without maxillary sequential distalization programmed into aligners. Subjects were excluded if they had a history of objectively diagnosed OSA, craniofacial anomalies

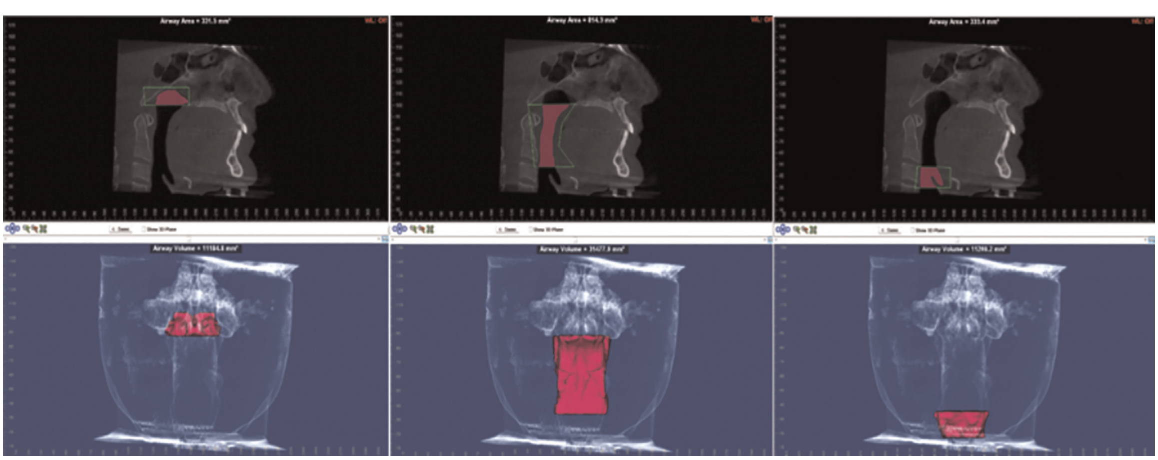

FIGURE 1
Upper airway anatomical regions, left to right: nasopharynx, oropharynx, and hypopharynx. Upper view (sagittal slice), and lower view (coronal slice)

Table II
Measurements of the upper airway.

Measurement	Definition
Total volume (cm^3)	Volume of full airway with upper limit at NP superior plane, lower limit at HP inferior plane, and lateral, anterior and posterior limits defined by the anterior and posterior pharyngeal walls
NP volume (cm^3)	Volume of airway space between NP superior and inferior planes
NP mCSA (mm^2)	Minimum cross-sectional area of airway within the defined NP
NP length (mm)	Longest anteroposterior distance at the plane of NP mCSA
NP width (mm)	Widest lateral width distance at the plane of NP mCSA
NP height (mm)	Longest vertical distance within the defined NP
OP volume (cm^3)	Volume of airway space between OP superior and inferior planes
OP mCSA (mm^2)	Minimum cross-sectional area of airway within the defined OP
OP length (mm)	Longest anteroposterior distance at the plane of OP mCSA
OP width (mm)	Widest lateral width distance at the plane of OP mCSA
OP height (mm)	Longest vertical distance within the defined OP
HP volume (cm^3)	Volume of airway space between HP superior and inferior planes
HP mCSA (mm^2)	Minimum cross-sectional area of airway within the defined OP
HP length (mm)	Longest anteroposterior distance at the plane of HP mCSA
HP width (mm)	Widest lateral width distance at the plane of OP mCSA
HP height (mm)	Longest vertical distance within the defined HP

NP: nasopharynx; mCSA: minimum cross-sectional area; OP: oropharynx; HP: horizontal plane.

with or without syndromes, pharyngeal pathology, or previous orthodontic treatment.

Study outcomes

Outcomes included changes in upper airway dimensions with Invisalign for Class II correction using CBCT scans; daytime sleepiness evaluation using the previously validated Epworth Sleepiness Scale (ESS) [9]; and dentoskeletal treatment changes using 2D lateral cephalograms constructed from the CBCT scans.

Study procedures

All subjects presenting for orthodontic treatment with clear aligners were screened for inclusion. Those that met the inclusion criteria were invited to participate in the study and sign a consent form after being informed about the risks and benefits of the study. Data were collected at T_1: pre-treatment (initial records), and at T_2: post-treatment (debond visit). One calibrated investigator collected routine pre- and post-treatment records, including intraoral and extraoral photographs and a 3D CBCT scan. Subjects also completed the ESS for daytime sleepiness determination at pre- and post-treatment. Subjects were seen for routine evaluation appointments every two months to monitor treatment progress.

Treatment protocol

Treatment with the seventh generation (G7) Invisalign appliances was initiated according to the standard procedures of the treating doctor at the private office. Clinchecks were designed with lower incisor retroclination to prevent proclination from Class II mechanics. A 0.5 mm or less of tooth movement was planned per aligner. If treatment in one arch completed before the opposing arch, passive aligners were prescribed to allow continued elastic wear. Aligner change was scheduled at seven-days. Anteroposterior Class II malocclusion correction was achieved through 6oz ¼ inch elastics (Ormco, Glendora, CA) attached from the maxillary canine or first premolar to the mandibular first or second molar. No maxillary sequential distalization was prescribed. At the conclusion of the first set of aligners, those subjects requiring further correction received refinement aligners. All patients were treated to a Class I occlusion. Upon treatment completion, clear retainers were delivered to all patients.

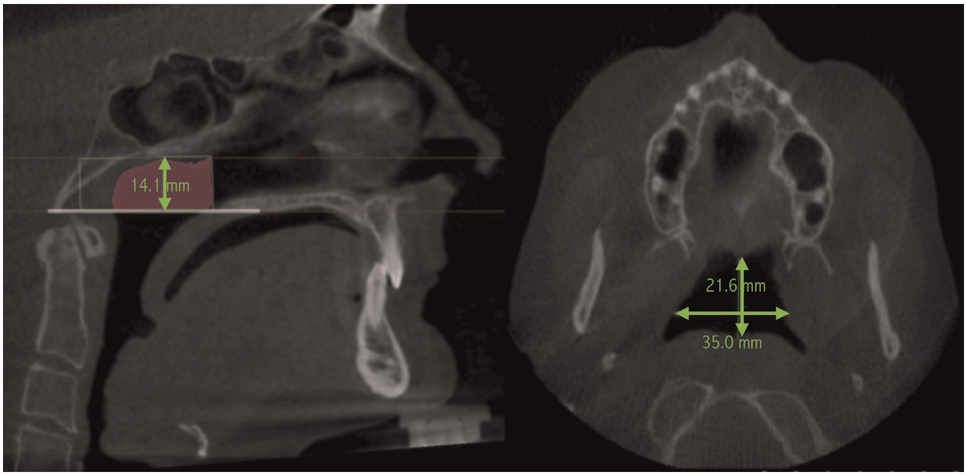

Figure 2

Example of nasopharyngeal airway height, length (sagittal view), and width (axial view) measurements

Table III

Angular and linear 2D lateral cephalometric measurements.

Variable	Definition
Skeletal	
Beta angle (°)	Angle formed between the A-B line and the perpendicular through point A from the apparent axis of the condyle (C)
Wits (mm)	Distance on occlusal plane between lines drawn from point A and point B perpendicular to the plane
SN-GoGn (°)	Mandibular plane angle formed by Sella-Nasion and mandibular plane (Go-Gn)
FMA (°)	Angle formed by FHP and mandibular plane
Facial angle	Angle formed by FHP and N-Pg (°)
Dental	
FMIA (°)	Angle formed by FHP and mandibular incisor
IMPA (°)	Angle formed by mandibular plane and mandibular incisor
U1-SN (°)	Angle formed by maxillary incisor and N-A line
Soft tissue	
NLA (°)	Nasolabial angle
Upper lip to E-Plane (mm)	Distance from most anterior point on upper lip to line from soft tissue nasal tip to chin
Lower lip to E-Plane (mm)	Distance from most anterior point on lower lip to line from soft tissue nasal tip to chin
Hyoid	
Hyoid angle (°)	Third cervical vertebra to hyoid to retrognathion
H-Rgn (mm)	Hyoid to retrognathion
C3-Rgn (mm)	Third cervical vertebra to retrognathion
H-C3 (mm)	Hyoid to third cervical vertebra
H to C3-Rgn (mm)	Hyoid to line connecting third cervical vertebra and retrognathion

FHP: Frankfort horizontal plane.

CBCT acquisition

All CBCT images were taken by one calibrated technician using an i-CAT scanner (Imaging Sciences International, Hatfield, PA). All scans were taken for 4.8 seconds at 5 mA and 120 kV with a 13 × 16 cm field of view. Each image data set included 328 slices with a slice thickness of 1 mm and 0.4 voxel size (14 gray scale). All scans were taken with the subject seated in an upright position with natural head position and teeth in maximum intercuspation. They were instructed to place the tongue in the roof of the palate and to refrain from swallowing during scanning. Images were converted to Digital Imaging and Communications in Medicine (DICOM) format then imported into Dolphin 3D^{TM} (Version 11.7.05.66 Premium, Dolphin Imaging and Management Solutions, Chatsworth, California) for dentoskeletal and airway analyses.

Airway measurements

The upper airway was divided into three regions: the nasopharynx (NP), oropharynx (OP), and hypopharynx (HP). The scans were first oriented in the frontal, sagittal and coronal planes. In the frontal view, a line intersecting the most inferior points on the inferior margins of the left and right orbits was oriented parallel to the horizontal plane. In the sagittal view, the Frankfort Horizontal Plane (FHP) was oriented parallel to the horizontal plane. If right and left planes were both visible, the midline between the two was used. From the coronal view, Crista Galli and the midline of Foramen Magnum were oriented parallel to the vertical plane.

The anatomical planes defining the upper airway regions are detailed in *table I* and *figure 1*. The airway measurements were based on Guijarro-Martinez and Swennen [11], *table II*. Volumetric analysis included the total and regional volumes of NP, OP, and HP. Additionally, minimum cross-sectional area and height of each region, and anteroposterior and lateral dimensions were determined (*figure 2*).

Cephalometric measurements

Lateral cephalograms were constructed from the oriented CBCT images at the two time points. The linear and angular measurements are described in *table III*. Linear measurements were made to the nearest 0.1 mm and angular measurements to the nearest 0.1 degrees. One calibrated examiner made all measurements (K.K.).

Daytime sleepiness

Each subject rated on a four-point scale how likely he/she is to doze off during various daily activities, with 0 indicating never

Table IV
Method error of linear measurements according to Dahlberg's formula.

Variable	Method error
Total volume (cm^3)	5.56
NP volume (cm^3)	1.02
NP mCSA (mm^2)	125.11
NP height (mm)	0.71
NP width (mm)	5.00
NP length (mm)	2.82
OP volume (cm^3)	3.55
OP mCSA (mm^2)	57.29
OP height (mm)	4.45
OP width (mm)	3.44
OP length (mm)	1.25
HP volume (cm^3)	1.79
HP mCSA (mm^2)	97.60
HP height (mm)	0.77
HP width (mm)	2.01
HP length (mm)	3.57

NP: nasopharynx; mCSA: minimum cross-sectional area; OP: oropharynx; HP: horizontal plane.

dozing and 3 indicating a high chance of dozing. Initial and final scores were obtained and assessed in comparison to a score of 11, above which daytime sleepiness was considered excessive.

Method error

To assess accuracy of the method, all CBCT measurements were completed by one investigator (K.K.) in duplicate separated by two weeks. A second investigator performed all measurements for inter-rater reliability determination. Intraclass correlation coefficients (ICC) were calculated and the method error was determined using Dahlberg's formula.

Statistical analysis

Data were analysed using SPSS™ software (Version 24.0, SPSS, Chicago, Ill.). Descriptive statistics were first conducted then data normality was assessed using the Shapiro–Wilk's test. T_1 and T_2 airway and 2D cephalometric measurements were compared using paired Student's *t*-tests and Wilcoxon signed-rank test. Daytime sleepiness from ESS was dichotomized into excessive sleepiness (score > 11) and acceptable (score < 11). Changes in daytime sleepiness were analysed using paired Student's *t*-test. The significance level was set at 5% using two tailed tests.

Results

The sample consisted of 8 (5 females, 3 males) healthy adult skeletal Class II subjects. The mean age of subjects at T_1 was 44.6 years (SD = 15.3). The mean treatment duration was 12.2 months (SD = 3.4) with a mean total of 81.4 aligners for both the upper and lower arches (SD = 30.6).

Method error

There was high reproducibility based on paired differences for all measurements except NP minimum cross-sectional area (mCSA) (r = 0.87), NP length (r = 0.84), and HP height (r = 0.83). The inter-rater reliability was good to excellent (ICC > 0.80), except for NP length (r = 0.78), NP height (r = 0.74), and HP height (r = 0.66). The average error is depicted on *table IV*.

Analyses of airway

Analysis of the normality of all CBCT data was completed using the Shapiro–Wilk test at the 5% level of significance. The variables NP volume (cm³), OP width (mm) and HP volume (cm³)

Table V
Initial (T_1), final (T_2), and change in airway measurements.

Variable	T_1		T_2		Paired differences		Sig
	Mean	SD	Mean	SD	Mean	SD	
Total volume (cm³)	35.05	14.02	32.24	9.16	−2.81	8.04	0.431
NP volume (cm³)*	9.47	1.80	8.98	1.73	−0.49	1.45	0.674
NP mCSA (mm²)	647.14	213.26	653.61	129.63	6.47	189.03	0.926
NP height (mm)	13.44	1.83	13.91	1.75	0.47	0.94	0.202
NP width (mm)	31.27	5.16	33.14	5.96	1.87	7.28	0.491
NP length (mm)	24.82	3.34	25.19	3.03	0.38	4.25	0.809
OP volume (cm³)	17.99	8.80	17.00	5.93	−0.98	5.26	0.614
OP mCSA (mm²)	256.23	144.72	243.49	111.74	−12.74	85.53	0.686
OP height (mm)	48.07	3.78	45.08	5.17	−2.99	5.91	0.195
OP width (mm)*	29.07	8.15	29.45	8.12	0.38	5.18	0.889
OP length (mm)	8.66	3.14	8.63	2.69	−0.04	1.88	0.957
HP volume (cm³)*	7.17	3.19	5.62	1.58	−1.54	2.20	0.345
HP mCSA (mm²)	357.00	166.22	284.82	78.38	−72.18	128.88	0.228
HP height (mm)	16.56	0.78	16.77	1.23	0.21	1.18	0.687
HP width (mm)	30.35	6.86	31.04	6.27	0.69	3.02	0.598
HP length (mm)	13.85	4.22	11.25	3.57	−2.60	4.73	0.236

NP: nasopharynx; mCSA: minimum cross-sectional area; OP: oropharynx; HP: horizontal plane.
*NP volume, OP width, and HP volume: analyzed using Wilcoxon Sign Rank test.
**$P < 0.05$.

were not normally distributed. The initial, final, and treatment changes for volumetric, area, and linear measurements are detailed in *table V*. No statistically significant treatment changes occurred for the reported measurements. Decreases were seen in mean total volume (2.81 cm^3, SD = 8.04), NP volume (0.49 cm^3, SD = 1.45), OP volume (0.98 cm^3, SD = 5.26), and HP volume (1.54 cm^3, SD = 2.20), although none of these changes were statistically significant. Additionally, mCSA of NP increased by 6.47 mm^2 (SD = 189.03), but mCSA of OP and HP decreased by 12.74 mm^2 (SD = 85.53) and 72.18 mm^2 (SD = 128.88), respectively.

Analysis of lateral cephalograms

All variables were normally distributed except for upper lip to E-plane T_2 measurements (*P*-value: T_1 = 0.434, T_2 = 0.045, difference = 0.152). Initial, final, and changes in the cephalometric measurements are detailed in *table VI*. Normal variables were analysed using the Student's *t*-test, while upper lip to E-plane was analysed with the Wilcoxon Sign Rank test.

Notable skeletal and dental treatment effects include a decreased Wits measurement (1.35 mm, SD = 2.49), maxillary and mandibular incisors retroclination by 2.85° (SD = 3.47) and 2.81° (SD = 7.07), respectively. Upper and lower lips retracted 1.48 mm (SD = 2.66) and 0.88 mm (SD = 1.98), respectively, with an increase in nasolabial angle of 2.68° (SD = 5.72). Hyoid bone position was unaffected. None of these reported changes were statistically significant.

Daytime sleepiness

Initial and final ESS scores are displayed in *table VII*. A mean change of −0.85 (SD = 1.96) occurred from initial to final, but this decrease was not statistically significant (*P* = 0.250) based on a paired Student's *t*-test. Six subjects started with ESS less

TABLE VI

Initial (T_1), final (T_2) and changes in cephalometric measurements.

	T_1		T_2		Paired differences		Sig
Variable	Mean	SD	Mean	SD	Mean	SD	
Skeletal							
Beta angle (°)	23.19	4.27	24.79	3.05	1.60	3.27	0.209
Wits (mm)	2.98	2.93	1.63	2.36	−1.35	2.49	0.169
SN-GoGn (°)	32.16	6.40	32.66	5.14	0.50	3.05	0.657
FMA (°)	24.65	7.91	28.15	4.05	3.50	6.51	0.172
Facial angle (°)	89.40	4.17	86.15	3.19	−3.25	5.11	0.115
Dental							
FMIA (°)	59.93	4.28	59.26	4.64	−0.66	5.83	0.757
IMPA (°)	95.41	8.74	92.60	3.48	−2.81	7.07	0.298
U1-SN (°)	97.25	11.10	94.40	9.94	−2.85	3.47	0.053
Soft tissue							
NLA (°)	110.44	8.36	113.11	7.29	2.68	5.72	0.228
U-E plane (mm)[1]	−4.49	3.62	−5.96	2.21	−1.48	2.66	0.123
L-E plane (mm)	−3.51	2.94	−4.39	2.51	−0.88	1.98	0.252
Hyoid							
Hyoid angle (°)	121.96	7.12	119.25	6.20	−2.71	7.47	0.339
Hy-Rgn (mm)	38.94	5.12	39.53	4.65	0.59	3.57	0.655
C3-Rgn (mm)	72.79	6.79	71.90	7.03	−0.89	6.79	0.722
Hy-C3 (mm)	35.79	4.14	35.38	4.08	−0.41	2.49	0.654
Hy to C3-Rgn (mm)	7.48	4.66	8.18	6.91	0.70	5.32	0.721

[1]U-E Plane: analyzed using Wilcoxon Sign Rank test.

TABLE VII

Changes in Epworth Sleepiness Scale scores.

Patient ID	T_1	T_2	Change
#1	6	8	2
#2	7	3	−4
#3	9	8	−1
#4	8	8	0
#5	11	10	−1
#6	6	5	−1
#7	3	4	1
#8	15	12	−3

than 11 and stayed below this value. The two subjects that started at 11 or above reported marginal improvement in scores.

Discussion

Class II malocclusion is present in approximately one third of the United States population. Several studies [4,11,12] have used CBCT imaging to document reduced airway dimensions in growing and non-growing Class II subjects, compared to Class I and Class III subjects. The aim of this study was to evaluate for the first time the effects of Class II CAT mechanics on the dimensions of the upper pharyngeal airway and the level of daytime sleepiness in adult subjects.

This study followed a prospective design. Eight patients with mild to moderate Class II malocclusion were included. Surgical options were presented to some of the patients, however, they all ended up being treated non-surgically and with CAT. Procedures were standardized for all included subjects. The consent process and ESS acquisition were standardized, and CBCT scans were taken by the same calibrated technicians using identical techniques. The treating doctor used consistent treatment mechanics for all subjects, including Class II correction through elastics alone without progressive maxillary distalization (*figure 3*). These factors allowed us to follow the cohort throughout treatment to observe changes in airway and ESS and limited bias in study methodology.

CAT continues to gain popularity in orthodontics as an effective and patient-friendly treatment modality. The Invisalign appliance is the most commonly used clear aligner, and as such was chosen for the current study. There are still very few reliable studies published investigating the efficacy and efficiency of Invisalign treatment, and to date, there are no published studies investigating the effects of Invisalign treatment on the airway. The mean treatment changes in airway measurements for the patient sample were not statistically significant, suggesting that

FIGURE 3

Example of pre- and post-treatment dentoalveolar correction with clear aligner therapy

dentoalveolar correction of a Class II malocclusion with CAT and Class II elastics may not affect airway morphology. Thus, the hypothesis was rejected. It is worth noting however that the mean NP mCSA, height, width, and length increased after treatment which is consistent with the direction of change seen with mandibular advancement splints (MAS) for OSA management where the changes in airway dimension are most noted in the velopharyngeal region as compared to the oro- and hypopharyngeal regions [13].

The lack of significant change in upper pharyngeal airway dimension seen in this study agrees with the work of Pliska et al. [8] who compared non-growing Class I and Class II patients undergoing orthodontic treatment with extraction compared to those receiving non-extraction treatment. They found no significant volumetric changes in either group following treatment. Conversely, numerous studies have documented that a mandibular advancement splint (MAS) has the effect of significantly increasing the upper pharyngeal airway dimensions of total volume, minimum CSA, and anteroposterior and transverse widths [14,15]. The device repositions the mandible forward and inferiorly, along with the connective tissue attachments of the genioglossal and suprahyoid muscles. While a direct comparison with Invisalign in normal subjects without OSA cannot be made, the effects of Class II malocclusion correction using Invisalign are not on a MADs.

It is possible that these apparent differences can be attributed to the use of CBCT for 2D and 3D analysis of the airway. While there is ample research to document the reliability of such measurements on CBCT, Guijarro-Martinez and Swennen suggested that a number of factors can contribute to changes in these values, namely respiration phase and tongue position [16]. Although all subjects were positioned in the same manner and received the same instructions prior to CBCT scans, it is impossible to ensure that conditions during T_1 and T_2 scans were identical. For this reason, the observed treatment effects could have differed greatly from patient to patient. Dynamic upper airway imaging using functional MRI is an accurate diagnostic tool that can be used to overcome this limitation. Numerous studies have evaluated the airway with this technique, which allows one to visualize respiratory-related changes [17,18].

In addition to limitations with the chosen imaging technique, the lack of significant airway changes in this study can be attributed to the insignificant change in tongue space. Although the Class II malocclusion was corrected through dentoalveolar changes in all subjects, without a significant increase in tongue space we would not expect significant changes in the airway dimension.

There were no statistically significant treatment changes in terms of cephalometric measurements for the sample studied. Because the sample consisted of non-growing patients, we would expect that there would be no changes in skeletal measurements with treatment. The slight decrease in Wits appraisal can be attributed to bone remodelling at points A and B that occurred as a result of changes in upper and lower incisor inclination.

Clear aligners have a thickness of 2 mm in each arch with a total of 4 mm of occlusion separation when inserted in the mouth. This vertical increase in the interdental dimension has not been anticipated to affect the airway morphology or daytime symptoms. Pitsis et al. [19] studied the effect of 4 mm and 14 mm bite opening by MAS on the treatment of OSA. They found no significant impact on treatment efficacy or side effects except for patient acceptance, which was higher in the 4 mm group. Future studies can determine the morphological changes in the upper airway with the aligners inserted.

Because of the small sample size, subgroup analyses were not performed on the basis of Class II division 1 versus 2 designation. In general, the mean change in maxillary incisor position was a reduction of the U1-SN value. It is also interesting to note that the Invisalign appliance with Class II mechanics did not result in significant mandibular incisor proclination. In fact, the mean IMPA angle decreased through treatment. This is because CAT involves full coverage and thus allows good control of incisor inclination. Soft tissue changes, although not statistically significant, correlated with the dental changes observed.

Previous literature suggests that orthodontic treatment of the Class II phenotype can affect the airway dimension by altering the tongue space and hyoid position [20]. Our results, in accordance with those of Ozdemir et al. [21] did not show any statistically or clinically significant changes in the position of the hyoid bone following treatment. This lack of change in hyoid position may be due to the small amount of anterior dentolaveolar changes that occurred.

Based on the lack of change in airway dimension, we would not expect to see a large change in daytime sleepiness levels, as is reflected in these values. It is important to note that only two patients reported an increase in sleepiness, but the changes were 1 and 2 points, which did not change their classifications. Additionally, it has been suggested that ESS is more suited to group-level comparisons based on its internal consistency [9]. However, ESS remains a commonly utilized risk assessment tool by medical and insurance providers.

No previous research exists in regard to the airway effects of Class II treatment mechanics with mandibular dentoalveolar advancement using the Invisalign appliance on a non-growing patient population. Thus, an accurate power analysis may not have produced an accurate sample size estimation. While the small sample of patients included in this study was a large limitation, results from this pilot study can be used to determine an appropriate sample size for future larger studies on this topic. Additionally, this study did not utilize a control group that received no treatment or Class II treatment with full-fixed conventional appliances. This study did not assess body mass index.

Fat deposition around the upper airway has been shown to increase the collapsibility of the upper airway.
Results of this study provide preliminary data for future studies to assess important outcomes such as changes in airway volume and mCOSA after CAT. Prospective studies could investigate whether treatment with CAT improves outcomes in subjects diagnosed with OSA through overnight sleep studies.

Conclusion

Treatment of Class II malocclusion in adults using clear aligners has no statistically significant effects on the airway morphology, dentoskeletal cephalometric measurements, or daytime sleepiness. Readers should interpret these effects with caution due to the sample included in this study. Future controlled studies with larger samples are warranted.

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