

Three-dimensional Pharyngeal Volume Evaluation after Functional Appliance Therapy

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Abstract

Background: Functional appliances are mostly used in the treatment of skeletal Class II malocclusion by stimulating mandibular growth through its anterior placement. Functional appliances also cause anterior displacement of the tongue, which results in the broadening of the oropharyngeal airway. This study was carried out to evaluate the cephalometric and volumetric changes in pharyngeal airway space after functional appliance therapy in growing patients. **Materials and Methods:** Pre-treatment (Group T1) and post-treatment (Group T2) cephalometric radiograph and CBCT of 15 subjects were considered to evaluate the changes in the dimensions of the pharyngeal airway. Paired t-test was used to analyze the changes in pharyngeal width, pharyngeal volumes after functional appliance therapy and Pearson's correlation coefficient were used to analyze the correlation between linear and three-dimensional airway measurements. **Results:** Statistically significant changes were found in the pharyngeal airway volumes ($P = 0.001$), anterior, posterior dimensions of the upper and lower pharyngeal airway space ($P = 0.001$). **Conclusion:** Functional appliance therapy plays a significant role in the improvement of pharyngeal airway volume. There is a significant and positive change in the pharyngeal airway volume, upper pharyngeal airway width (UPAW), and lower pharyngeal airway width (LPAW). There is a good positive correlation between post-pharyngeal airway volume and post-LPAW suggesting there is an increase in pharyngeal airway volume with the lower airway dimension.

Keywords: Pharyngeal airway volume, CBCT, Functional appliance therapy.

INTRODUCTION

The simple function of the upper airway is to permit the unimpeded movement of humidified air to the tracheobronchial tree.^[1] The commonly encountered impedance of airflow can be due to morphologic, pathologic, or functional abnormalities. The growth and function of the nasal cavities, the nasopharynx and the oropharynx, are closely associated with the normal growth of the craniofacial structures. Several craniofacial anomalies may be important predisposing factors of airway impedance, such as midfacial hypoplasia, retrognathic mandible, narrow maxillary arch, and increased mandibular angle.^[2] Orthodontists have thus been involved in the early diagnosis and treatment of the potential risk as well as predisposing factors responsible for this debilitating condition.^[3] Functional appliances that serve as a modality for modulation of the maxillary and mandibular growth can also have their effect on the dimensional changes in the structures and thus effecting the air flow.^[4] Some studies have reported enlarged pharyngeal dimensions following functional appliance therapy.^[5,6] However, its efficacy and the stability of the altered growth and positional changes in the mandible are still questionable.^[7,8]

The soft-tissue changes due to increasing age, obesity, and genetic factors result in a decrease in the primary oropharyngeal airway, making a person more prone to obstructive sleep apnea (OSA) and snoring.^[8] Isono *et al.* (1997) stated that an increase in the airway dimensions results from anterior displacement of the mandible even in obese individuals without failure.^[9] Some studies claimed that the appliances increase genioglossus muscle activity and others observed mechanical property changes in the pharyngeal conduit with the appliance in the mouth.^[10-12] Studies on the dimensional changes in the pharyngeal airway after placement of the functional appliance have also not been conclusive.^[13,14] Studies were also there to see the effect of surgical mandibular advancement on airway.^[15,16] Hence, there is a need to study the dimensional

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changes in the oropharyngeal airway space after the functional appliance therapy.

The lateral cephalogram is recommended as a useful screening tool for two-dimensional assessment of the upper airway. McNamara (1984) provided reference values for the upper pharynx and the lower pharynx for Caucasian adults.^[17]

A study performed by Mattos *et al.* showed that a CBCT evaluation of the airway could accurately be made by a resident, orthodontist, or an oral radiologist. They found that the most reliable measurements were anteroposterior linear measurements; cross-sectional areas at the levels of the palatal plane, soft palate, and tongue; and sagittal area; and volume. Other measurements were statistically significantly accurate at the level of the vallecula and minimum axial area.^[18]

MATERIALS AND METHODS

The present study was done on untreated orthodontic patients selected from the subjects who visited to the OPD at Department of Orthodontics and Dentofacial Orthopaedics, Seema Dental College and Hospital, Rishikesh and by conducting free camps in various schools of nearby places in and around Rishikesh city. The study comprised total number of 15 subjects in growing age. Treatment protocol was informed and explained to the subjects and the parents before intervention. All the pre-treatment and post-treatment records and the functional appliance treatment were undertaken with informed consent. The subjects were categorized into two groups.

Group T1

Pretreatment CBCT and lateral cephalograms of 15 growing skeletal Class II subjects (ANB >4 and Beta Angle <24 and maxillary base to mandibular base ratio >2:3) due to the retrognathic mandible (SNB <76, saddle angle >127 degree, and facial angle <82 degree, mandible to cranial base ratio <21:20) and fitting the criteria of myofunctional appliance therapy (Jarabak Rakosi Analysis) and positive VTO.

Group T2

Group T2 shows post-treatment CBCT and lateral cephalograms of same subjects after the completion of functional appliance therapy.

Both the groups were compared, and the evaluation was done for changes in volumes of the pharyngeal airway.

Methodology

A total of 800 numbers of subjects were screened at the Outpatients Department of Seema Dental College and Hospital and by examining the general population by conducting camps in various schools of Rishikesh city and adjoining areas.

Selection criteria

A total number of 38 subjects with a convex profile, increased overjet, none to mild crowding, and positive VTO on clinical evaluation were selected for the purpose of the study. Lateral cephalograms of the selected sample, taken in Natural Head Position, were evaluated for Skeletal Class II (ANB of >4°

and Beta Angle <24°), posterior dimensions of the airway (Mcnamara Airway analysis), and functional analysis (Jarabak Rakosi Functional analysis). A sample of 18 was finally selected for the purpose of the study. Pretreatment records, that is, the photographs, impressions, CBCT and MP3 radiographs, were taken for all the patients and diagnosis and treatment planning was done, and 15 patients were finally included in the study. The treatment protocol was informed and explained to all the subjects. All the records and treatment were undertaken after informed consent

CBCT image acquisition and data collection

All CBCT images were taken at Cosmo Shiva Dental clinic using MYRAY Hyperion X5. Images were taken with a 10 × 10 cm field of view and a pulsed exposure time of 6 s set to 110 kV. All patients were instructed to occlude into maximum intercuspation, hold their tongue in a resting position, and avoid swallowing, breathing or moving their head or tongue during image acquisition.

Images captured were exported in Digital Imaging and Communications in Medicine format then imported into Dolphin 3D TM 11.7 (Dolphin Imaging Solutions, Chatsworth, CA, USA) for three-dimensional evaluation of the volumetric, cross-sectional area, and linear measurements of the pharyngeal airway space. All patients also had a T1 and T2 lateral cephalogram taken on a Sirona Orthopos XG Plus TM machine (Dentsply Sirona, York, PA, USA) and imported into Dolphin Imaging TM software (Dolphin Image Solutions, Chatsworth, CA, USA).

Radiographic method

All digital cephalometric radiographs were taken using a standardized technique with the patient in his/her Natural Head Position, jaws in centric relation, posterior teeth in occlusion with lips relaxed and patients were instructed not to swallow during cephalometry. The subjects stood with the sagittal plane parallel to the film and with bilateral ear rods gently inserted into the external auditory meatus to stabilize the head position during exposure and the subject standing with the Frankfort Horizontal plane parallel to the floor. All cephalograms were taken using Kodak 8000C Panoramic and Cephalometric unit at a Tube voltage of 60–90kVp, Digital sensor CCD with 1360×1840 Pixels and magnification of 1:1%.

The palatal plane (ANS-PNS) is a plane that connects ANS and PNS. This plane was used as our reference plane as it is a consistent hard-tissue reference (Figure 1, Table 1). Five reference planes were constructed to measure the cross-sectional areas, lengths, and widths along the airway (Table 2).

Table 1: Cephalometric planes

Planes	Definitions
Plane A	Plane extending from PNS to PPW*, parallel to palatal plane
Plane B	Plane extending from P Point to PPW, parallel to palatal plane
Plane C	Plane extending from Et Point to PPW, parallel to palatal plane
Plane D	Plane extending from V Point to APW**, parallel to palatal plane

Plane A represents the upper boundary of the velopharynx. Plane B represents the boundary between the velopharynx and the oropharynx. Plane C represents the boundary between the oropharynx and the hypopharynx, and Plane D represents the lower boundary of the hypopharynx. Volume acquisition was made using the Dolphin 3DTM Sinus Airway Tool (Table 3). This program required boundary points enclosing the desired airway to be measured. Boundary points were marked first at PNS, along A Plane, posterior to the PPW, and continued down to the most inferior limit of the airway at Plane D. The airway boundary line was then extended along with Plane D anterior to the anterior pharyngeal wall, back up to the level of Plane B to P point and along the soft palate back to PNS (Figure 2). Five seed points were marked along the entire airway for the desired radiolucent airway recognition (Figure 3). The best-fit volume was then rendered by adjusting the Volume Sensitivity Tool and then was calculated in mm³ using Dolphin 3DTM program (Figure 4).

Table 2: Cephalometric landmarks

Cephalometric landmark	Abbreviation	Definition
Anterior Nasal Spine	ANS	Most anterior point of anterior nasal spine
Posterior Nasal Spine	PNS	Most posterior point of posterior nasal spine
Palate point	P	The most inferior tip of soft palate
Tip of epiglottis	Et	The most superior point of epiglottis
C3 Point	V	The most anterior inferior point of third cervical vertebrae

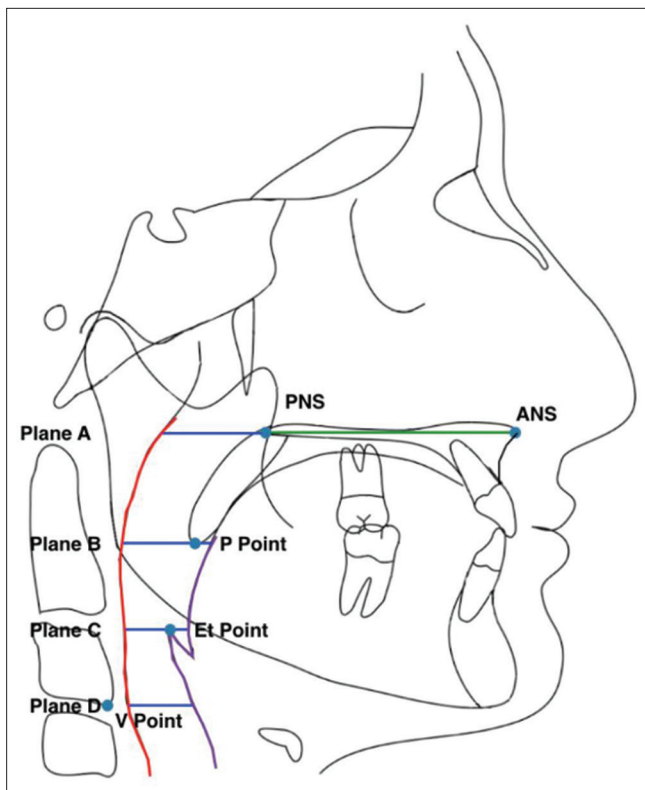


Figure 1: Cephalometric landmarks and pharyngeal airway planes

Cross-sectional area acquisition was made using the Dolphin 3DTM Slice Area Tool. Each of the Planes, A, B, C, and D, was identified in the axial view by identifying the cephalometric landmark points made earlier. At Plane A, the ANS and PNS markers were located in the axial view, and the Slice Area Tool was chosen. Using this tool, a point was placed along the border of the radiolucent pharyngeal airway, and the boundary was outlined in a continuous series of points until the first initial point was reached and the area calculated in mm². The same steps were carried out for each of the areas A, B, C, D, and E.). Length and width measurements at each plane were carried out using the Dolphin Line Tool. The length was defined as the largest distance on the anterior border of the pharyngeal wall to the posterior border of the wall perpendicular to the bottom of the screen. The width was defined as the distance between the largest points of the lateral walls of the pharyngeal airway space parallel to the bottom of the screen.

RESULTS

The data were compiled in a Microsoft excel sheet and transferred to version 20 SPSS software. The data provided shows a near-normal distribution; therefore, parametric analysis was used.

The values were subjected to the Kolmogorov–Smirnov test and Shapiro–Wilk test. A significant difference was not

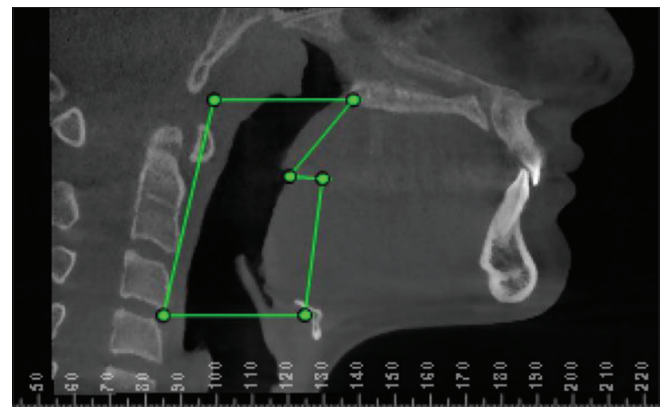


Figure 2: Airway volume boundary. Boundary points depicted in green

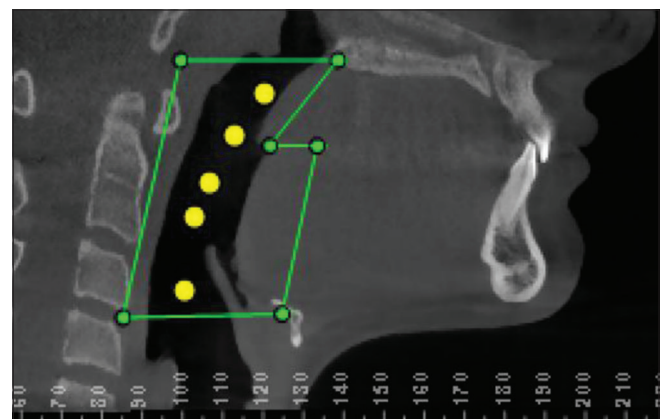


Figure 3: Airway volume seed points

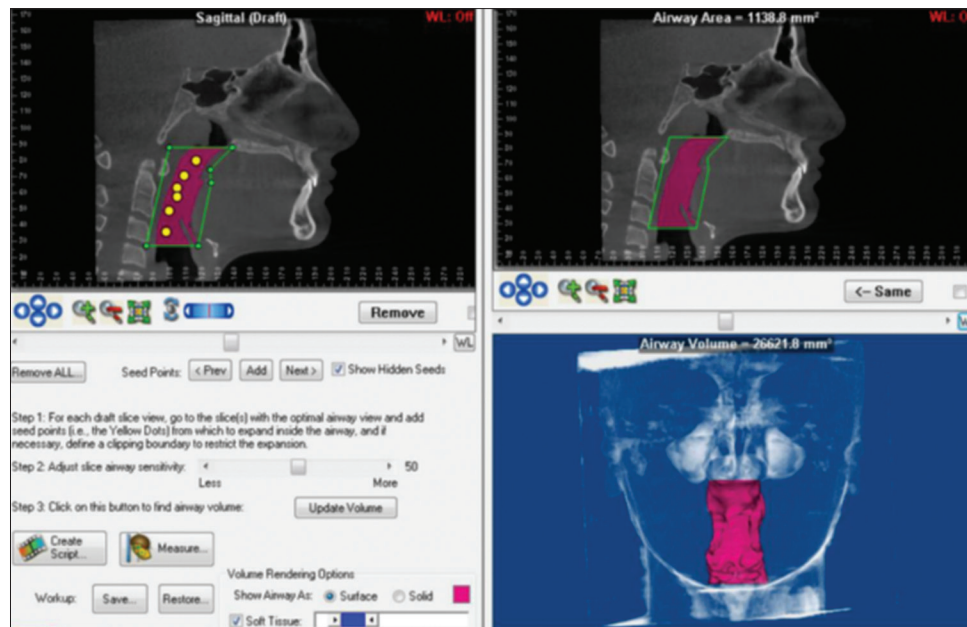


Figure 4: 3D Sinus/Airway Tool. The tool used to digitize and measure the airway volume. The upper left depicted boundary limits and placement of seed points. The upper right depicts a sagittal view of volume rendering. Lower right displays the region of volume in 3D view

observed in the Kolmogorov–Smirnov test with a Statistical Probability value of 0.200. A significant difference was not observed in the Shapiro–Wilk test. The data represented show a near-normal distribution

Pharyngeal airway

As shown in Table 4, the mean values for VOL in Group T1 were $9511.8 \pm 1963 \text{ mm}^3$, and in Group T2 were $9829.6 \pm 1991 \text{ mm}^3$. In a comparison of the mean values of Group T1, VOL- (mm^3) and Group T2 VOL (mm^3), the mean values of Group T2 VOL (mm^3) are higher with a difference of 317.9 mm^3 is statistically significant with $P = 0.001$.

As shown in Table 4, the mean values for ANB in Group T1 were 6.04 ± 0.6 degree, and in Group T2 were 3.8 ± 0.6 degree. In a comparison of the mean values of Group T1 ANB (deg) and Group T2 ANB (deg), the mean values of Group T2 ANB (deg) are higher with a difference of 2.2(deg) is statistically significant with $P = 0.001$.

As shown in Table 4, the mean values for upper pharyngeal airway width (UPAW) in Group T1 were $11.7 \pm 1.1 \text{ mm}$, and in Group T2 were $13.4 \pm 1.4 \text{ mm}$. In a comparison of the mean values of Group T1 UPAW (mm) and Group T2 UPAW (mm), the mean values of Group T2 UPAW (mm) are higher with a difference of 1.6 mm is statistically significant with $P = 0.001$.

As shown in Table 4, the mean values for lower pharyngeal airway width (LPAW) in Group T1 were $8.3 \pm 0.89 \text{ mm}$, and in Group T2 were $9.4 \pm 0.88 \text{ mm}$. In the comparison of the mean values of Group T1 LPAW (mm) and Group T2 LPAW (mm), the mean value of Group T2 LPAW post (mm) is higher with a difference of 1.04 mm is statistically significant with $P = 0.001$.

Karl Pearson Correlation Coefficient was used to find the correlation coefficient between the CBCT and other radiographic

parameters, and their significance was evaluated by *t*-test at 5 % level of significance with and is shown in Table 5.

There is a significant positive moderate correlation between Group T1 VOL and Group T1 LPAW with an *r*-value of 0.611 and $P < 0.05$ in T1 group using the Pearson correlation coefficient test.

Similarly, there is a significant positive moderate correlation between Group T2 VOL and Group T2 LPAW with an *r* value of 0.678 and $P < 0.05$ in T2 test group.

There is a significant positive moderate correlation between Group T2 UPAW and Group T2 LPAW with an *r* value of 0.515 and $P < 0.05$ in T2 group.

There is a non-significant negative correlation between Group T1 VOL and Group T1 ANB with *r* value of - 0.107 and $P = 0.705$.

There is a non-significant positive correlation between Group T1 VOL and Group T1 UPAW with *r* value of 0.381 and $P = 0.162$.

There is a non-significant negative correlation between Group T1 ANB and Group T1 UPAW with *r* value of -0.008 and $P = 0.978$.

There is a non-significant positive correlation between Group T1 ANB and Group T1 LPAW with *r* value of 0.109 and $P = 0.698$.

There is a non-significant positive correlation between Group T1 UPAW and Group T1 LPAW with *r* value of 0.363 and $P = 0.184$.

There is a non-significant negative correlation between Group T2 VOL and Group T2 ANB with *r* value of - 0.402 and $P = 0.137$.

There is a non-significant positive correlation between Group T2 VOL and Group T2 UPAW with r value of 0.387 and $P = 0.154$.

There is a non-significant negative correlation between Group T2 ANB and Group T2 LPAW with r value of - 0.427 and $P = 0.112$.

There is a non-significant negative correlation between Group T2 ANB and Group T2 UPAW with r value of - 0.095 and $P = 0.735$.

Interobserver and intraobserver errors

Fisher's intraclass correlation test (Table 6) was used for interobserver and intraobserver agreement with a 95% confidence interval with the true value of 0. As shown in Table 5, it was estimated that there is reliability between the readings performed by two observers. As shown in Table 5, it was estimated that there is reliability between

the readings performed by a single observer at the interval of 8 days.

OSA is a problem resulting from repeated obstruction of the upper respiratory tract during sleep. It is diagnosed as sleep-disordered breathing in children (with Apnea-Hypopnea Index, AHI>1). Even though the exact pathology of OSA is not recognized completely, mandibular retrognathism is one of the proposed causes. After the completion of growth, the only modality for correction of mandibular retrognathism is mandibular advancement surgery and various researchers have reported the improvement in the condition of adult OSA after mandibular advancement surgeries. However, dealing with this causative factor during growth phase with the functional appliance therapy not only prevents the patients, with less than normal airway space, from adding to the potential risk factors of OSA, it also minimizes the risk of mandibular advancement surgeries after growth completion. Hence, functional appliances can be utilized for growth modulation and anterior positioning of mandible and hence obviating one of the causes of OSA.^[19]

It has been determined that the anterior displacement of the mandible by the functional appliances influences the position of hyoid bone and, consequently, the position of the tongue and thus improves the morphology of the upper airways. If these reported effects are stable, functional therapy can be very important in the improvement of the airway. Soghra *et al.* (2012) evaluated the changes in the tongue position hyoid bone and the airway dimensions following treatment with Faramund appliance and concluded that functional appliance has the potential to increase pharyngeal airway dimensions and changes in tongue and hyoid position, and these changes seemed to be stable for up to 4 years on average.^[4] The present study evaluates the anteroposterior changes in the upper and lower pharyngeal airway space pharyngeal airway volume changes after the functional appliance therapy.

The growing patients with the CVMI 3 and 4 were considered in the study as the greatest increment of mandibular and craniofacial growth is determined to occur during this stage. Clinical research has demonstrated that the greatest effect of functional appliances takes place when the peak in mandibular growth is included in the treatment period.^[2] Although the airway changes can be best evaluated by the 3D imaging

Table 3: Airway measurements

Measurements	Definition
Volume	Volume of airway, upper limit defined at the level of the palatal plane, lower limit defined by Plane D, lateral limits defined by interior soft-tissue wall of pharynx, and airway space
A Area	Cross-sectional area of airway at Plane A, limits defined by interior soft-tissue wall of pharynx and airway space
A Length	Longest anteroposterior distance along Plane A
A Width	Widest lateral width distance along Plane A
B Area	Cross-sectional area of airway at Plane B, limits defined by interior soft-tissue wall of pharynx and airway space
B Length	Longest anteroposterior distance along Plane B
B Width	Widest lateral width distance along Plane B
C Area	Cross-sectional area of airway at Plane C, limits defined by interior soft-tissue wall of pharynx and airway space
C Length	Longest anteroposterior distance along Plane C
C Width	Widest lateral width distance along Plane C
D Area	Cross-sectional area of airway at Plane D, limits defined by interior soft-tissue wall of pharynx and airway space
D Length	Longest anteroposterior distance along Plane D
D Width	Widest lateral width distance along Plane D

Table 4: Comparison between Group T1 (Pre) and Group T2 (Post) of CBCT and Radiographic data

	Parameters	Mean	S. D.	Mean difference	Std. Error Mean	95% Confidence Interval of the Difference		t	p value
						Lower	Upper		
CBCT	T1 VOL	9511.8 (mm ³)	1963.15 (mm ³)	-317.86 (mm ³)	62.7	-452.5	-183.2	-5.06	0.001**
	T2-VOL	9829.6 (mm ³)	1991.08 (mm ³)						
Radiograph	T1 ANB	6.04°	0.6°	2.2°	0.2	1.7	2.68	10.84	0.001**
	T2 ANB	3.8°	0.6°						
	T1 UPAW	11.7 (mm)	1.1 (mm)	-1.6 (mm)	0.17	-2.01	-1.2	-9.46	0.001**
	T2 UPAW	13.4 (mm)	1.4 (mm)						
	T1-LPAW	8.3 (mm)	0.89 (mm)	-1.04 (mm)	0.11	0.11	-0.80	-9.31	0.001**

modalities, especially the CBCT, as the increment in the airway is evaluated by both transverse as well as anteroposterior changes, that is, the net increase in the volume, it accounts for the increment in the radiation dose and also the additive cost of the procedure, for accuracy and three-dimensional assessment of pharyngeal airway volume CBCT was used in the present study. There was no categorization of any particular functional appliance as the basic aim of the study was to evaluate the airway changes by modulation of the mandibular

and craniofacial growth utilizing the best treatment modality for the patient.

DISCUSSION

There is a mean increase of 318 mm³ in the pharyngeal airway volume, which is statistically significant ($P = 0.001$) as coinciding with the study by Iwasaki *et al.*, (2014), that also suggests the significant increase in pharyngeal volume after functional appliance therapy.^[20] One hypothesis could be that the dentoalveolar modifications occurring after functional appliance therapy guide the tongue to a more forward position, thus indirectly enlarging the posterior airway space. Indeed, a forward displacement of the tongue is part of a typical surgical strategy when treatment of sleep disorder breathing is required.^[5]

There is a significant increase in the UPAW ($P > 0.001$) in our study, which is similar to the study performed by Jena *et al.* (2011) that shows a significant change.^[21] There is an improvement in the UPAW by an average of 1.6 mm following functional appliance therapy in our study, which might have occurred due to two possible mechanisms. First, the base of the tongue is situated in front of the anterior wall of the soft palate, and the forward displacement of the tongue reduces its gravitational effect on the soft palate. Second, as the sidewall of the soft palate is attached to the base of the tongue by the palatoglossal muscle, it is possible that the anterior displacement

Table 5: Correlation between variable based on pre-test and post-test using Pearson correlation coefficient

Correlation between groups (pre test)		r-value	P-value
PRE-VOL	PRE-ANB	-0.107	0.705
PRE-VOL	PRE-UPAW (mm)	0.381	0.162
PRE-VOL	PRE LPAW	0.611	0.016*
PRE-ANB	PRE-UPAW (mm)	-0.008	0.978
PRE-ANB	PRE LPAW	0.109	0.698
PRE-UPAW (mm)	PRE LPAW	0.363	0.184
Correlation between groups (post test)			
POST-VOL	POST ANB	-0.402	0.137
POST-VOL	POST-UPAW (mm)	0.387	0.154
POST-VOL	POST LPAW (mm)	0.678	0.005*
POST ANB	POST-UPAW (mm)	-0.095	0.735
POST ANB	POST LPAW (mm)	-0.427	0.112
POST-UPAW (mm)	POST LPAW (mm)	0.515	0.05*

Table 6: Interobserver and interobserver error

Intraclass correlation		95% Confidence interval		F test with true value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
ANB angle							
Single measures	0.049 ^a	−0.038	0.335	2.143	7	7	0.168
Average measures	0.094	−0.078	0.502	2.143	7	7	0.168
Beta angle							
Single measures	0.418 ^a	−0.05	0.848	14.565	7	7	0.001
Average measures	0.59	−0.106	0.917	14.565	7	7	0.001
LPAW							
Single measures	0.388 ^a	−0.135	0.82	4.478	7	7	0.033
Average measures	0.559	−0.312	0.901	4.478	7	7	0.033
UPAW							
Single measures	0.607 ^a	−0.051	0.922	28	7	7	0
Average measures	0.755	−0.108	0.959	28	7	7	0
Articular angle							
Single measures	0.588 ^a	−0.09	0.902	6.714	7	7	0.011
Average measures	0.741	−0.199	0.948	6.714	7	7	0.011
Jaraback ratio							
Single measures	1.000 ^a	0	0	0	7	7	0
Average measures	1	0	0	0	7	7	0
Saddle angle							
Single measures	0.922 ^a	0.171	0.987	64.385	7	7	0
Average measures	0.959	0.292	0.993	64.385	7	7	0
Gonial angle							
Single measures	1.000 ^a	0	0	0	7	7	0
Average measures	1	0	0	0	7	7	0

^aP<0.001

of the mandible pulls the soft palate forward through its connections and results in the opening of UPAW.^[20,22,23] The increase in UPAW in our study is significantly contrary to other studies by Ozbek *et al.* (1998) and Yassaei *et al.* (2007).^[19,24] Bonham *et al.* (1988) reported a mean significant increase of 2.76 mm in the superior airway space after modified functional appliance therapy.^[25] Iwasaki *et al.* (2014)^[20] also reported an increase in the depth of the oropharynx and the depth of the hypopharynx following Herbst appliance treatment.^[5]

There is a mean increase of 1.04 mm in LPAW which is statistically significant ($P > 0.001$) and in agreement with Takemoto *et al.* where a significant increase was seen in LPAW. The improvement of the airway is caused by the forward relocation of the tongue following various functional appliance therapy and suggests that retroglossal or more rostral levels are most affected by the functional appliances.^[26]

CONCLUSION

This descriptive-analytical study was done on 15 growing subjects to evaluate three-dimensional changes in the pharyngeal volume after the functional appliance therapy. Mean treatment time was 9.6 months, and the pre-treatment and post-treatment CBCTs were evaluated to assess the changes. The results indicated that:

1. Functional appliance therapy plays a significant role in the improvement of pharyngeal airway volume. There is a significant and positive change in the pharyngeal airway volume UPAW, LPAW
2. There is a good positive correlation between post-pharyngeal airway volume and post-LPAW suggesting there is an increase in pharyngeal airway volume with the lower airway dimension.

These factors collectively form a cascade that improves the uvuloglossopharyngeal airway space, hence, obviating the potential of negative factors of the reduced pharyngeal airway. Hence, it can be postulated that the myofunctional appliance therapy brings about a considerable improvement in airway dimensions, thus establishing its efficacy in growing patients with reduced airway dimensions.

Follow-up studies are further needed to assess the stability of pharyngeal airway space after a period of 5 years and 10 years. Moreover, three-dimensional studies with the increased sample size would be a conclusive one to predict the efficacy of functional appliances as an adjunct to the treatment of reduced airway space in growing children.

CONFLICTS OF INTEREST

The authors declare that they have no potential conflict of interests regarding this article.

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