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Improvement in Soft Tissue Profile & Upper Airway Dimensions Following Forsus FRD – A Prospective Clinical Study

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Abstract

Aim: To assess improvement of soft tissue profile and upper airway dimensions in skeletal Class II adolescent patients treated with Forsus Fatigue Resistant Device (FRD). **Material and Methods:** This prospective observational study was planned with a sample size of 15 subjects (5 male & 10 female) diagnosed with mandibular hypoplasia as a cause of Class II malocclusion, requiring fixed functional therapy, with the inclusion criteria of age of 16-25 yrs with the ANB value range of 4°+2° with a non-extraction treatment plan. Pre-functional records were recorded once the leveling and alignment phase was complete and Forsus FRD attachments were placed. Treatment continued till the desired objectives were achieved. Post functional records were made at the end of functional therapy, after removal of Forsus FRD. Along with soft tissue analysis on lateral cephalogram, Acoustic Pharyngometry (AP) was recorded for each patient (Eccovision®" (sleep group solutions Florida, US) for airway changes before and after Forsus FRD. **Results:** Post functional treatment indicated statistically significant changes in nasolabial angle, upper lip position, upper lip strain, H angle and mento-labial sulcus. On evaluation of upper airway dimensions of the subjects by pharyngometry , there were statistically significant changes in mean upper airway volume and area. **Conclusion:** Study concluded that Forsus FRD is an effective method for correction of skeletal Class II malocclusion among adolescent patients, enhancing marked improvement in soft tissue profile of the patients, along with significant increase in volume and area of hypopharyngeal and oropharyngeal spaces, thus improving the upper airway patency.

Keywords: Acoustic Pharyngometry, Forsus FRD, Soft Tissue Profile, Upper Airway

1. Introduction

Growth and development of dento-facial structures is a delicate mixture of the individual's genetic composition and environmental expression in the hard and soft tissue structures of the face. Any discrepancy in development will lead to varying degree of mild to severe forms of skeletal deformity along with compensation in the dental components, thereby affecting the appearance, mastication, speech and breathing of the individual[1]. Skeletal Class II malocclusions is frequently encountered problem in orthodontics wherein skeletal Class II with mandibular hypoplasia is relatively more common skeletal malocclusion compared to maxillary prognathism[2]. Treatment modalities for correction of skeletal Class II malocclusion with mandibular hypoplasia aim to correct the skeletal base by redirecting the mandibular growth in desired direction in growing patients. In post-pubertal patients, camouflage or surgically repositioning the hypoplastic segment of the mandible is considered[3].

Amongst the various treatment modalities used to treat Class II malocclusion, Fixed Functional Appliances (FFA) are most commonly used due to compliance issues in adolescents[4]. A number of FFAs have gained popularity in recent years. One such appliance is Forsus Fatigue Resistant Device (FRD), which is termed as a hybrid FFA, which is a combination of rigid and flexible fixed functional appliances for the correction of Class II non-compliant patients[5].

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Since the advent of Forsus FRD, various studies have been conducted to evaluate the changes in dentofacial structures post functional and the results have been accepted by the researchers. Studies have been conducted to assess the soft tissue changes brought about by fixed functional appliances which are mainly based on the Herbst appliance and Jasper Jumper[6]. Airway assessment and its association with obstructive sleep apnea (OSA) has been the recent trend in the field of orthodontics. Retrognathic mandible is one of the known contributing etiologic factors for OSA. Various studies have assessed the changes in airway post Forsus FRD treatment[7]. These studies have been able to predict the obvious changes post functional with FFA, but no study have tried to quantify the 3-dimensional airway changes in upper pharyngeal airway space. Acoustic pharyngometry is a noninvasive reliable tool to assess the dynamic 3D upper airway pharyngeal cross-sectional area. Hence this study was conducted to evaluate the soft tissue changes brought in by Forsus FRD, with the standard soft tissue parameters selected from various soft tissue analysis on lateral cephalogram and also to assess the changes in upper airway in adolescent patients with skeletal Class II malocclusion treated with Forsus FRD, using acoustic pharyngometry.

2. Methodology

This prospective observational study was planned with a sample size of 15 subjects (5 male & 10 female) diagnosed with mandibular hypoplasia as a cause of Class II malocclusion, requiring fixed functional therapy, with the inclusion criteria of age of 16-25 yrs with the ANB value range of 4°+2° with a non-extraction treatment plan. Patients who have previously undergone orthodontic treatment, cleft lip and palate patients and patients with poor periodontal condition were excluded from the study. Standard pretreatment orthodontic records (T0) i.e., photographs (intra oral & extra oral), radiographs (lateral cephalogram, OPG), study models were made.

In addition to the standard orthodontic records Acoustic Pharyngometry (AP) was recorded for each patient. "Eccovision®" (sleep group solutions Florida, US), was the equipment used for recording of AP (Figure 1 & 2). The methodology for recording of AP includes making the patients sit with head and back straight, as if gazing at distant area and breathing normally. Wave tube with mouth piece was placed in the mouth, oriented horizontally to the ground. Patients were asked to mildly occlude the teeth, and place the tongue in the normal neutral position. Patients were instructed to occlude the nostrils to prevent any air leak through the nose using their left hand and advised to breathe normally through mouth. Once they were acquainted, AP readings were recorded. Total time required for recording of AP for one patient was less than 10 minutes. The results of AP are elicited as graphical representation of area and volume of the upper airway (Pharyngogram) on the computer screen (Figure 3).

Selected patients were bonded with fixed orthodontic Pre adjusted edgewise appliance (PEA) with 0.018" Roth prescription. Conventional wire sequence was followed



Figure 1. Acoustic pharyngometry apparatus.

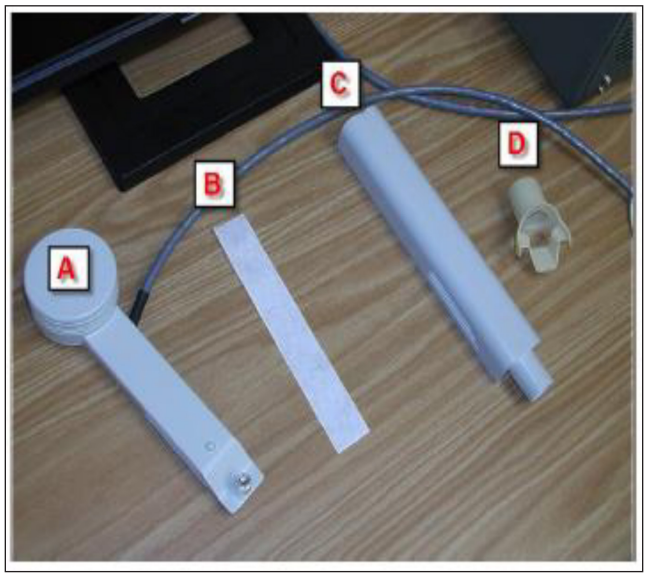


Figure 2. Components of acoustic pharyngometry apparatus (A) electric platform (B) filter strip (C) wave tube & (D) mouth piece.

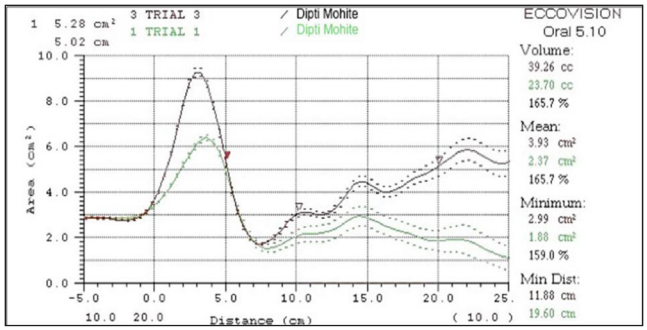
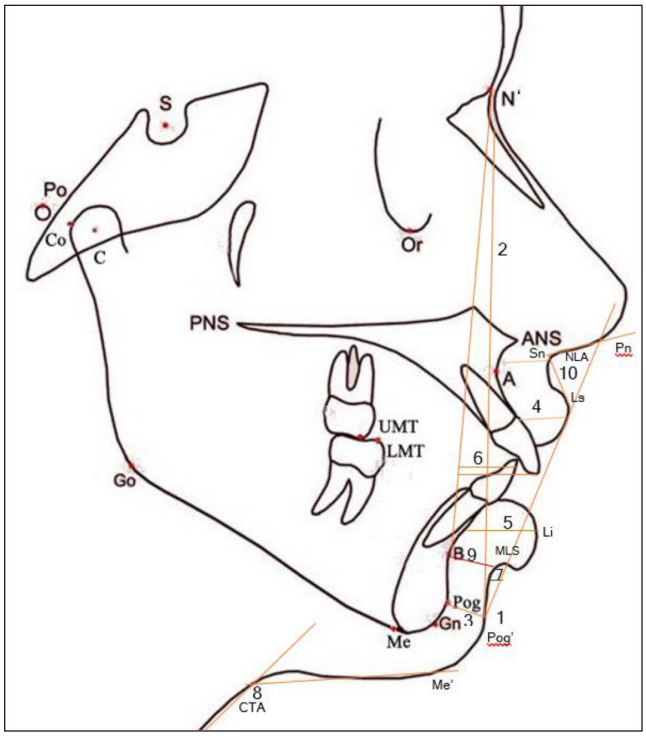


Figure 3. Pharyngogram (depiction of volume and area on computer screen).

till 0.017"x0.025" SS arch wire was placed. At this stage pre Forsus insertion records were recorded (T1) followed by insertion of maxillary and mandibular components of Forsus FRD, enabling the complete compression of the springs. Functional phase with Forsus FRD continued till the desired objectives were achieved i.e., achieving Angel's Class I, 1st molar relation with an optimum overjet of 2-3 mm as well as satisfactory improvement in soft tissue profile. Post functional lateral cephalometry and acoustic pharyngometry records were made at the end of functional therapy, after removal of Forsus FRD (T2). The mean duration of the functional phase with FRD was 06 months. Effects of Forsus FRD on soft tissue profile of the subjects were assessed by angular and linear measurements made on lateral cephalography (Figure 4) using Holdaway analysis and Cephalometric analysis for Orthognathic Surgery (COGS) which included 03 angular, 03 linear and 01 proportional measurement. Hard tissue and soft tissue cephalometric landmarks were identified and lateral cephalographs were traced on acetate sheet of 03-micron thickness using 3H pencil following which linear and angular measurements of foresaid analysis were made.

3. Statistical Analysis

The data collected for the study was in form of linear and angular measurements recorded on lateral cephalograms at T1 and T2, along with area and volume of upper airway space calculated on acoustic pharyngometer at T1 and T2. The data on categorical variables are shown as n (% of cases) and the data on continuous variables are presented as Mean and Standard deviation (SD). The



1. H Line (Holdaway line)
2. N'-Pog' line
3. Pog' thickness
4. Upper lip strain (Pt A – Sn Anterior surface of maxillary anterior – labre superioris (Ls)
5. Lower lip protrusion
6. Holdaway ratio (labial surface of L1-NB/Pog-NB)
7. Mento-labial sulcus
8. Chin throat angle
9. Lower lip strain (Pt B –mentolabial sulcus Anterior surface of mandibular anterior – labreinferioris (Li)
10. Naso labial angle.

Figure 4. Landmarks and measurements for Soft tissue Cephalometric analysis.

statistical significance of pair-wise difference of means of continuous variables is tested using paired t test. Correlation analysis is done using Pearson's method. The underlying normality assumption was tested before subjecting the study variables to the 't' test and Pearson's correlation analysis (Table 1 & 2). In the entire study, the p-values less than 0.05 was considered to be statistically significant. The entire data is statistically analyzed using Statistical Package for Social Sciences (SPSS version 21.0, IBM Corporation, USA) for MS Windows.

Table 1. Distribution of pre-functional and post-functional soft tissue parameters

	Pre-functional (n=15)		Post-functional (n=15)		Mean Difference (95% CI)	P-value
	Mean	SD	Mean	SD		
NLA (Deg)	96.47	5.62	104.07	7.09	-7.60 [-9.91 to -5.29]	0.001***
CTA (Deg)	124.60	8.19	118.93	8.47	5.67 [2.83 to 8.50]	0.001***
H Line (Deg)	23.40	4.87	18.87	3.83	4.53 [3.29 to 5.77]	0.001***
Holdaway Ratio	1:04	--	1:05	--	--	0.002**
Lower lip Protrusion (mm)	1.67	2.09	2.47	1.41	-0.80 [-1.85 to 0.25]	0.125NS
Pog' (mm)	9.20	2.83	10.53	1.92	-1.33 [-2.57 to -0.10]	0.036*
Upper lip strain (mm)	3.60	1.12	1.27	0.79	2.33 [1.83 to 2.83]	0.001***
Lower lip strain (mm)	1.60	1.45	1.00	0.65	0.60 [-0.21 to 1.40]	0.132NS
Mento labial sulcus (mm)	5.53	1.88	3.73	1.33	1.80 [1.20 to 2.40]	0.001***

Table 2. Distribution of pre-functional and post-functional acoustic pharyngometry airway parameters

	Pre-functional (n=15)		Post-functional (n=15)		Mean Difference (95% CI)	P-value
	Mean	SD	Mean	SD		
Volume (cc)	33.29	7.26	36.32	8.39	-3.04 [-6.07 to -0.001]	0.050*
Area (cm^2)	3.33	0.72	3.63	0.84	-0.30 [-0.60 to -0.005]	0.047*

4. Results

Post functional records indicate statistically significant changes in nasolabial angle, upper lip position, upper lip strain, H angle and mento-labial sulcus. Study also elicited changes in lower lip strain, chin thickness at soft tissue Pog' and in Holdaway ratio, post Forsus FRD removal, but were not statistically significant. On further evaluation of chin throat angle, the present study found there was significant reduction in the chin throat angle, which needs to be assessed by further studies. On evaluation of upper airways of the subjects, post functional treatment, there were statistically significant changes in mean upper airway volume and area. Thus, this study elicits that the Forsus FRD do bring about changes in soft tissue contours of orofacial structures, aiding to improvement in facial profile of the subjects. Post treatment airway assessment of the subjects depicts improvement in upper airway volume and area, thus improving the airway patency in retrognathic mandible.

5. Discussion

Skeletal Class II malocclusion is the second most prevalent malocclusion globally[8] and also in Indian population[9] with mandibular retrusion is more common than maxillary prognathism[2].

Forsus FRD was introduced by W Vogt[10] as hybrid Class II corrector, has become one of the most commonly used FFA in contemporary orthodontics. Studies have confirmed that Forsus FRD does bring about more of a dentoalveolar changes[11,12] and less of skeletal changes[13,14], but limited studies are available to highlight changes brought in soft tissue[15–17].

Skeletal, dental and soft tissue changes by Herbst, Jasper Jumper and Forsus FRD were studied by Gohilot et al.[17] and it was observed that these appliances do bring improvements in nasolabial angle, upper and lower lip position using Ricketts esthetic line, and results were found to be statistically insignificant. Similar parameters were assessed in present study matching the age group; there was statistically significant improvement in nasolabial angle, upper lip position and lip strain. The present study is in agreement with the assessment of lower lip position, which found no statistically significant changes in position of lower lip position post treatment. The results obtained with Forsus FRD in our study are comparable to the results of Herbst Group in the above study.

A systemic review[16] on soft tissue changes with FFA in treating skeletal Class II malocclusion concluded that FFA

does produce changes in facial soft tissues but the results obtained cannot be stated as statistically significant. Contrary to this systemic review, present study highlights the soft tissue changes brought by Forsus FRD which are statistically significant.

Soft tissue changes with Forsus FRD do bring about statistically significant differences in H angle, chin thickness and mento-labial sulcus[15] among adolescent patients. The results of the present study with similar age group are comparable to the previous study as there was a marked decrease in skeletal convexity, H angle, and mento-labial sulcus post treatment. However, the present study found no statistical difference in chin thickness post-treatment, which is contradictory to the above study. On evaluation of chin throat angle, the present study found that there is significant reduction in the chin throat angle (CTA), which also improves the facial profile and esthetics of the subject.

6. Upper Air Way Changes with Forsus Frd

Changing trends in the field of orthodontics is focused on application of FFA to improve the airway parameters in patients affected with obstructive sleep apnea (OSA) and to evaluate its effects and outcome[18–21]. Present study used acoustic pharyngometer to assess the upper airway space (oropharynx and hypopharynx extending up to glottis)[22]. Acoustic pharyngometer, is a non-invasive method used to assess the airway dimensions is as accurate as 3D CBCT without serious consequence of radiation exposure[19].

Use of functional appliances and its effects on airway dimensions were studied by Vompi et al.[23] and Xiang et al.[24], it was observed that these appliances do bring about positive effects on upper airway by anterior displacement of mandible, forward movement of hyoid bone and adaptive changes of the soft palate. However, no statistically significant changes were observed in the airway parameters. Present study evaluated the upper airway dimensions using acoustic pharyngometry and results obtained are significant increase in upper airway volume post treatment. The results of the present study are not in consensus with these studies as present study employed 3-dimensional wave propagation mode of recording the airway dimensions whereas earlier studies used lateral cephalogram and CBCT.

Oropharynx and hypopharynx volume studied by Temani et al.[25] on patients with skeletal Class II malocclusion treated with FFA has confirmed significant increase in both volumes post treatment. The results of present study are in agreement with this study as there is a significant increase in upper airway volume post treatment. However, present study employed a non-invasive and dynamic method to evaluate the upper airway dimensions.

7. Limitations of the Study

Absence of age matched control group in this study makes it difficult to quantify the amount of changes produced are a part of growth process or the changes attributed to the appliance. Sample size of this study is relatively small, recommended to confirm the results with a larger sample with a multi centric trial. Lack of uniformity in gender distribution in the study; gender-based comparison could not be carried out. Study conducted was of relatively short duration, hence stability of the results achieved cannot be established at this short span.

Even though AP is one of the reliable indicators for OSA, but it does not provide insights to detect the mechanism of underlying airway obstruction, it only evaluates the airway while awake and seated, but disregards dynamic and sleep state changes and it undermines the involvement of anatomical structures e.g., tongue anatomy, submental fat deposition and mandibular structures which also play role in evaluating OSA in subjects.

8. Conclusion

Forsus FRD is an effective method for correction of skeletal Class II malocclusion among preadolescent patients. There has been a marked improvement in soft tissue profile of the patients treated with Forsus FRD, the same has been confirmed using different soft tissue parameters on lateral cephalograms of the patients. Study also signifies the increase in volume and area of oropharyngeal and hypopharyngeal spaces following correction of skeletal Class II malocclusion with Forsus FRD.

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