

EVALUATION OF THE DENTOSKELETAL AND SOFT TISSUE PROFILE CHANGES IN SKELETAL CLASS II PATIENTS TREATED WITH ADVANSYNC™ 2 FIXED FUNCTIONAL APPLIANCE – A PROSPECTIVE CLINICAL TRIAL

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Abstract

Introduction- Malocclusion is considered to be the most predominant oral pathology, subsequent to dental decay & periodontal diseases and it ranks 3rd among global disease.¹ Class II malocclusion as defined, when the mesio-buccal cusp of the maxillary permanent first molar occludes in between the embrasure area between the mandibular second premolar and the mandibular permanent first molar or farther mesial.

Materials and Methods- lateral cephalogram of total ten subjects were taken at Pre-treatment (T1) and Post-treatment after removal of AdvanSync™2 (T2) and composite cephalometric analysis is done.

Results: Results of this study shows that AdvanSync™2 has restraining effect on maxilla with simultaneous advancement of mandible.

Conclusions: To conclude AdvanSync™2, a fixed functional appliance is quite proficient for correcting skeletal Class II malocclusion thereby shows significant improvement in the facial profile of the patient.

Key words: Skeletal Class II malocclusion, AdvanSync™2, Fixed functional appliance, Dental Class II malocclusion.

Introduction

Malocclusion is considered to be the most predominant oral pathology, subsequent to dental decay & periodontal diseases and it ranks 3rd among global disease.¹

Edward Hartley Angle, father of modern orthodontics, classified malocclusion in the anteroposterior plane based on the dental component and ignoring the skeletal component into Class I, II and III. Class II malocclusion occur due to maxillary prognathism, mandibular retrusion or a combination of both.²

For correcting Class II malocclusion various treatment modalities have been proposed such as delivering orthopedic forces with headgear, functional appliances, selective extraction patterns for camouflaging and orthognathic surgery as well to correct jaw discrepancy.

For managing skeletal Class II malocclusion, functional appliances have been used over centuries that produces skeletal and dental effects in growing patients. Owing to fixed functional appliance usage condylar growth changes is a highly debated topic, as the experimental study on growing monkey had shown that functional appliances do effect the functional forward displacement of condyle but clinical study on humans are contradictory to this experimental finding.³

Functional appliance classified by **Ritto A. Korrodi**, as quoted by Prateek et al⁴

- A. Rigid fixed functional appliance (Herbst® and its modification, Mandibular Protraction Appliance (MPA), Mandibular Anterior Repositioning Appliance (MARA), The Ritto Appliance, IST-Appliance, Biopedic Appliance, AdvanSync™2)

- B. Flexible Fixed Functional Appliances (Jasper Jumper, Adjustable Bite Corrector, Churro Jumper, Amoric Torsion Coils, Scandee Tubular Jumper, Klapper Super Spring, The Bite Fixer)
- C. Hybrid Fixed Functional Appliances (Eureka Spring, FORSUS®- Fatigue Resistant Device, The Twin Force Bite Corrector, Alpern Class II Closers, Calibrated Force Module)

The vital dissimilarities between a removable and fixed appliance is in their mode of action, as in fixed appliance duration for which mandible is in protruded position is much more than removable and the amount of vertical opening in fixed is less contributing to increase in mandibular length and skeletal adaption is more.⁴

Skeletal adaption is more as continuous horizontal force is applied through fixed functional appliance.⁴ Patient compliance is greatly reduced by fixed functional appliances but this requires additional chair side time, and are prone to catastrophic breakage. AdvanSync™2 appliance is a modification from Mini Scope Herbst.⁵

As AdvanSync™2 (Molar to Molar appliance; marketed by Ormco™) is the latest advancement in fixed functional therapy, designed to be used concurrently with fixed orthodontic therapy during deceleration growth phase to produce desired skeletal dental and soft tissue changes. It consists of crowns cemented on maxillary and mandibular permanent first molars, a position where orthopaedic forces are applied.⁶

AIMS AND OBJECTIVES

The aim of this prospective clinical study is

1. To evaluate skeletal, dento-alveolar and soft tissue profile changes produced by AdvanSync™2 fixed functional appliance.
2. To evaluate the active-treatment effects of the AdvanSync™2 during comprehensive correction of Class II malocclusion.
3. To evaluate time duration of active treatment using AdvanSync™2 fixed functional appliance.

Materials and Methods

This study was conducted in the Department of Orthodontics & Dentofacial orthopaedics, and patients were selected based on following inclusion and exclusion criteria.

Inclusion Criteria

1. Skeletal Class II malocclusion patients, with posterior divergence.
2. Full Class II or Class II tendency molar relationship or edge-to-edge relationship.
3. Growing patient with age group 12 to 16 years.
4. Overjet ≥ 5 mm.
5. ANB angle $\geq 5^{\circ}$.
6. All patients with positive virtual treatment objective (VTO).
7. Horizontal growth pattern.
8. Mandibular crowding ranged from mild (<3 mm) to moderate (=3 mm).
9. No missing tooth (excluding third molars)
10. None of the subjects have undergone any previous orthodontic therapy or serial extraction therapy.

Exclusion Criteria

1. Malocclusion associated with craniofacial anomalies like cleft lip & palate.
2. Malocclusion associated with craniofacial syndromes.
3. Subjects using the headgear or any other functional appliances, or any eruption guided appliances.

Materials and equipment's used in this study are: -

1. AdvanSync™2 kit, a fixed functional appliance (Ormco™ Corporation).
2. MBT™ Versatile Bracket prescription of 0.22" X 0.28" slot (3M Unitek™ Gemini Metal Brackets)
3. X -RAY machine and digital X-ray printer (Planmeca Proline™ XC X-ray with serial number of XC432667, 2012-09).
4. Pre-treatment (T1) and Post-treatment after removal of AdvanSync™2 (T2) Lateral cephalogram of all patients.

5. Acetate matte tracing paper (Garware Polyester Ltd, Mumbai).
6. Sharp 0.3 mm Staedtler® pencil.
7. Divider.
8. Pair of set squares.
9. Mouth mirror.
10. Straight probe.
11. Bracket holding plier.
12. Etchant (FROST®)
13. Bonding agent (3M Unitek Transbond™ XT)
14. Enlight Light Cure Adhesive (ORMCO™)
15. Curing light (Dentmark™)
16. GC Gold Label luting & lining Cement (GC Corporation™, Tokyo, Japan)

Methodology

After proper diagnosis patients with skeletal Class II malocclusion in their growth phase, were selected with all preliminary records. Initially pre-treatment lateral cephalogram is taken and designated as T1 and second at post-treatment after appliance removal designated as T2.

At initial appointment AdvanSync™2 with proper size is selected and placement is done following universal protocol, along with complete upper and lower bracket placement (MBT prescription of 0.022" X 0.028" dimension). Patient was reviewed every month and activation of AdvanSync™2 appliance is done in increments of 2mm in 2-3 months, until a desired Class I molar relationship was achieved. Total treatment timing for wear of functional appliance is 8-12 months and activation schedule of every 2-3 months.

After achievement of desired correction appliance is removed and a prefabricated band of proper size is placed to complete the treatment further ahead. At this stage lateral cephalogram of the patient was taken (T2).

Now obtained cephalograms of all subjects at T1 and T2 was evaluated using standard cephalometric analysis (Down's Analysis, Steiner's Analysis, Tweed Analysis, Wits Appraisal, Mcnamara Analysis, Rickets Analysis, Beta/Yen/W Angle, Rakosi Analysis, Holdaway Soft Tissue Analysis, Schwartz Analysis) for evaluating skeletal, dental and soft tissue changes

Tests employed for Statistical analysis is Paired or Dependent t-test.

The *p-value* ($p < 0.05$) less than 0.05 is considered statically significant.

Variables	Pre-treatment		Post-treatment		Mean difference	Paired t-test value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
UI to LI	117	6	126.9	9.54	-10.3	-3.544	0.006*
U1 to A-Pog	8.5	1.84	5.9	2.13	2.6	4.333	0.002*
SNA	81.8	2.35	78.8	2.78	3	2.905	0.017*
SNB	74.4	1.51	77.5	2.27	-3.1	-6.433	0.001*

ANB	7	1.83	3.7	1.64	3.3	15.46	0.001*
U I to N-A(mm)	6.8	1.14	4.3	0.95	2.5	7.319	0.001*
U I to N-A(angel e)	29	3.3	23.1	2.6	5.9	6.556	0.001*
U I to LI	117	6	126.2	9.38	-9.6	-3.29	0.009*
Upper lip	3.13	1.85	1.9	0.74	1.23	2.097	0.045*
Lower lip	4.96	4.91	3.9	4.89	1.06	2.776	0.022*
Female (AO & BO) coincides)	4.8	1.64	3.2	1.48	1.6	4	0.016*
Male (BO ahead of AO)	4.54	2.13	2	1	2.54	4.112	0.015*
Effective maxillary length	81.6	6.43	84.9	4.46	-3.3	-2.191	0.046*
Effective mandibular length	99.2	6.34	107.1	4.63	-7.9	-4.52	0.001*
Maxillo-mandibular differential	19.6	9.57	23.3	8.23	-3.7	-2.185	0.047*
U I to point A distance	7.2	1.81	4.7	0.95	2.5	5.839	0.001*
Upper airway	12.2	1.75	12.8	1.62	-0.6	-1.203	0.26
Lower airway	10.2	1.69	11.6	1.96	-1.4	-2.492	0.034*
Facial angle depth	83.8	7.89	88	7.09	-4.2	-2.243	0.042*
Facial taper	63.1	4.95	61	5.58	2.1	2.302	0.047*
Lower facial height	35.5	9.35	40.2	8.77	-4.7	-5.403	0.001*
Convexity of point A	4.7	1.83	2.7	1.25	2	3.721	0.005*
Lower incisor to A - Pog	2.35	1.25	4	2.36	-1.65	-2.236	0.042*
Mandibular incisor inclination	31.5	21.14	33.45	19.6	-1.95	-2.079	0.049*

Beta angle	22.2	5.69	30.3	8.04	-8.1	-5.057	0.001*
Yen angle	112	6.29	117.8	4.96	-5.6	-4.652	0.001*
W angle	46.7	5.17	52	4.71	-5.3	-3.059	0.014*
Facial Angle	84.3	5.03	87.9	4.91	-3.6	-5.125	0.001*
upper lip curvature	4	2	2.95	1.54	1.05	4.846	0.001*
H-line angle	21.5	4.74	17.5	3.84	4	4.353	0.002*
Upper sulcus depth	8.8	2.74	6.35	1.92	2.45	3.973	0.003*
Pronasale to H-line	5	3.59	4.3	2.45	0.7	0.716	0.492
Upper lip thickness	13.8	1.87	13	1.56	0.8	1.395	0.196
Upper lip strain	11.2	1.48	12.2	2.1	-1	-1.342	0.213
Li to H-line	3.8	2.97	3.4	3.2	0.4	0.629	0.545
Lower sulcus depth	5.2	2.82	4.7	2.54	0.5	0.529	0.61
Soft tissue chin thickness	10.1	2.36	9.7	2.31	0.35	0.664	0.523
Occlusal plane to mandibular plane	12	4	20.1	25.6	-8.1	-2.991	0.034*
Y-axis	68.1	3.35	69.4	3.13	-1.3	-3.284	0.009*
Interincisal angle	117	6	124.2	11.6	-7.6	-2.323	0.034*
Upper incisor to S-N plane	113	4.89	106.7	8.37	6.4	2.927	0.017*
Upper incisor to palatal plane	67.2	14.04	73.7	13.1	-6.5	-2.313	0.042*
Angle of inclination	83.3	4.85	82.3	4.79	1	0.741	0.478
Extent of mandibular bases	69.7	11.54	74.3	11.2	-4.6	-4.355	0.002*

Table – 1 paired Figure 1- t-test of different variables from standard cephalometric analysis

Sample size calculation

The sample size was calculated using the **nMaster 2.0 software**. The power of the study was taken to be 80% and Confidence Interval (C.I.) of 95% was taken. The sample size calculation was done as per the article by *AL-JEWAIR et al.* The sample size was estimated to be a minimum of 10.

Analysis:	A priori: Compute required sample size	
Input:	Effect size f	=
	4.2197946	
	α err prob	= 0.05
	Power (1- β err prob)	= 0.95
	Number of groups	= 2
Output:	Noncentrality parameter λ	=
	106.84	
	Critical F	=
	9.552094	
	Numerator df	= 2
	Denominator df	= 3
	Sample size per group	= 10
	Actual power	=
	0.958128	

Method error

To remove inter-observer bias all tracing were done by same operator twice. the second tracing was chosen for analysis. Three different observers had checked the second tracing for different landmark identification, following this measurement of values and angles was done by single investigator.

To determine accuracy of the landmark, 10 randomly chosen cephalograms were remeasured 2 weeks apart by other investigator using the same landmarks and variables included in this study. The intra-examiner reliability was assessed using the intra-class correlation coefficient, which varied from 0.882 to 0.922 showing good to excellent correlation.

Any of the observers did not know the research criteria to make the study blind.

Results

From Table 1 it is evident that UI to LI, U1 to A-Pog, SNA, SNB, ANB, U I to N-A(mm), U I to N-A(angle), U I to LI, Upper lip, Lower lip, Wits appraisal, Effective maxillary length, Effective mandibular length, Maxillo-mandibular differential, U I to point A distance, Lower airway, Facial angle depth, Facial taper, Lower facial height, Convexity of point A, Lower incisor to A –Pog, Mandibular incisor inclination, Beta angle, Yen angle, W angle, Facial Angle, upper lip curvature, H-line angle, Upper sulcus depth, Saddle angle, Occlusal plane to mandibular plane, Y-axis, Interincisal angle, Upper incisor to S-N plane, Upper incisor to palatal plane, Extent of mandibular base had shown significant difference at T1 and T2.

Discussion

SKELETAL PARAMETERS

Maxilla

To explain maxilla various angular and linear measurement from different cephalometric analysis (for example SNA, convexity at point A, facial taper, effective maxillary length) was taken, that are significant with *p* value <0.05. SNA angle itself tells the prognathism and retrognathism of maxilla, and in this study a decrease in SNA was observed from T1 to T2 that concludes that appliance has a restraining effect on maxilla, this similar result was found in a study conducted by Antony T et al.⁷ Angle of convexity has decreased after the usage of appliance. In the linear measurement of upper molar to Ptv at T1 and T2 time interval suggesting distal movement of upper molar. This finding is in correlation with study by Jena A k et al.⁸ This distal movement is because of the reciprocal force acting distally on the maxillary dental arch when the mandible was postured forward by the appliance.⁹ Facial taper is the angle between Basion-Nasion- Point A (B-N-A) according to Rickets analysis this also explains the prognathic or retrognathic position of maxilla. Decrease in facial taper suggests retrognathic position of maxilla after the use of appliance.

Mandible

Effect of AdvanSync™2 on mandible, as observed from various cephalometric analysis, is an increase in length of mandible, more prognathic position of mandible. SNB angle has increased from T1 to T2 making mandible more prognathic as compared to the pre-treatment. This similar finding is observed in a study conducted by Caldwell S, Marques G A et al.^{7,8} An increase in Saddle angle from T1 to T2 suggest posterior positioning of condyle, as observed in a study conducted by Ruf S.¹⁰ The mean Extent of mandibular base has increased significantly from T1 to T2, in accordance with study conducted by Marques G A et al, Ruf S.¹⁰ Facial angle depth has increased significantly from T1 to T2, that shows a more prognathic mandible, according to Rickets analysis.

Maxilla to mandible

ANB has decreased significantly from T1 to T2, in the same way in a study conducted by V ZF et al,Ruf S.^{10,11} The mean Beta angle, Yen angle and W angle increased significantly from T1 to T2. Wits Female (AO & BO coincides) and Male (BO ahead of AO) decreased significantly as observed in Marques G A et al, Ruf S.^{10,12,13}

Vertical changes

Y-axis had increased from T1 to T2, this increase suggests the vertical growth pattern of the subjects after appliance therapy in Rakosi analysis. Lower facial height has also increased suggesting more protrusive chin when compared at T1 and T2 as inferenced from the Rickets analysis. These changes after use of fixed functional appliance has been mentioned in literature from various studies.^{10,13}

Airway

As observed in McNamara analysis there was statistically significant increase in lower airway, similar observation is found in other studies. Fixed functional appliances can be an effective tool for correcting obstructive sleep apnoea in growing adults owing to an increase in lower airway patients treated with fixed functional appliance.^{8,14,15}

DENTAL PARAMETERS

Maxillary dentition

A decrease in upper incisor to palatal plane and upper incisor to S-N plane suggests that proclination of upper incisor had reduced from T1 to T2 after usage of appliance, this similar finding can be quoted from Vasileios Z F et al, Ruf S.^{10,13} U I to N-A (angular and linear) has decreased significantly with p -value <0.05 as noticed in other studies also.^{10,13}

Mandibular dentition

Lower incisor to A-Pog and mandibular incisor inclination value had increased suggesting flaring of lower incisors, this is most commonly observed disadvantage of any fixed functional appliance, supported by many studies.^{7-9,13}

Maxillary and mandibular dentition

An increase in interincisal angle (UI to LI) suggests that proclination of maxillary dentition has reduced but proclination of mandibular dentition has increased from pre-treatment, both contributing to correction of interincisal angle. This finding is reinforced by different studies conducted on fixed functional appliance.⁷⁻¹³

SOFT TISSUE

An increased facial angle, decreased upper lip curvature, H-line angle, Upper sulcus depth and upper lip signifies that mandible has become more protrusive after usage of appliance and a reduction in lip strain is observed according to significant values of upper lip curvature, upper sulcus depth.^{7,8} The position of the upper lip had become more retrusive, similarly evidenced by the work of Sabine Ruf.¹⁰

Conclusion

Result of this study led to the following conclusions: -

1. There are statistically significant variations in skeletal, dento-alveolar, and soft-tissue parameters after use of AdvanSync™2.
2. Time taken to complete the treatment is much lesser than any other fixed appliance as this allows the orthodontists to brace the teeth simultaneously for individual tooth correction.
3. SNA has decreased from pre-treatment due to usage of appliance, an increase in SNB shows that mandible has moved forward.
4. Upper incisors proclination has reduced but lower incisor has proclined as compared to pre-treatment. This had overall effect on upper lip with reduced lip strain and lower lips are moved forward.

5. Due to mandibular advancement lower airway have been improved, this may benefit the patient from developing obstructive sleep apnoea later in their life.

From the study this can be concluded that AdvanSync™2, is quite proficient for correcting skeletal Class II malocclusion, this could be attributed to restraint on maxilla along with simultaneous mandibular advancement.

Here case selection is vital for the successful treatment outcome, as skeletal Class II malocclusion due to combination of maxillary prognathism and mandibular retrognathism could be best treated.

Limitation of this study could be, as it is a 2 dimensional study conducted on lateral cephalogram, for a better treatment outcome evaluation a CBCT could be best. Study with increased number of sample size would give better result as bias will be reduced.

Declaration of conflicting interests

The Author(s) declare(s) that there is no conflict of interest.

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