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Influence of conventional and skeletal anchorage system supported fixed functional appliance on maxillo-mandibular complex and temporomandibular joint: A preliminary comparative cone beam computed tomography study

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Keywords
Skeletal anchorage system
Class II malocclusion
Fixed functional appliance
Temporomandibular joint
CBCT

Summary

Aim > Fixed functional appliance (FFA) used in the treatment of Class II malocclusion, lead to mandibular anterior teeth proclination, thus limiting the skeletal effects of the appliance. To counter this side effect, FFA is anchored in the lower anterior region of the mandible using the skeletal anchorage system. This pilot study was done to evaluate treatment and one-year post-treatment maxillo-mandibular, and temporomandibular joint (TMJ) effects of conventional fixed functional appliance (FFA) and skeletal anchorage system supported fixed functional appliance (SAS-FFA) using cone beam computed tomography (CBCT) images.
Material and method > Sixteen Class II individuals were equally divided into Group I (FFA) (mean age 13.11 ± 0.38 years) and Group II (SAS-FFA) (mean age 12.96 ± 0.38 years). CBCT scans taken, before treatment (T0), at the end of comprehensive treatment (T1), and after one-year post-treatment (T2), were evaluated for changes in maxillo-mandibular complex and TMJ. Intraclass correlation coefficient and independent "*t*" test were used for repeated measures, and inter-group (mean) changes respectively.

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Results > After one-year post-comprehensive treatment, SAS-FFA showed significant maxillary restriction (SNA, −1.93°, $P < 0.05$) with significant increase in mandibular length (Go-Pog, 3.25 mm, $P < 0.001$) (Co-Gn, 7.87 mm, $P < 0.001$). SAS-FFA groups showed significant upward and backward increase in condylar volume (571 mm^3, $P < 0.001$) with anterior translation of glenoid fossa. FFA group showed significant lower dentition and vertical relationship relapse, along with non-significant changes at TMJ.
Conclusion > SAS-FFA is an effective combination, which brings favourable changes on maxillo-mandibular complex and temporomandibular joint with non-significant relapse in comparison to FFA at one-year post-treatment.

Mots clés
Ancrage squelettique
Malocclusion de Classe II
Appareil fonctionnel fixe
Articulation temporo-mandibulaire
CBCT

Résumé

Influence des appareils fonctionnels fixes conventionnels et à ancrage squelettique sur le complexe maxillo-mandibulaire et l'articulation temporo-mandibulaire : étude préliminaire comparative par tomographie à faisceau conique assistée par ordinateur

Objectif > *L'appareil fonctionnel fixe (FFA) utilisé dans le traitement des malocclusions de classe II, conduit à une vestibuloversion des incisives mandibulaires, limitant ainsi l'effet squelettique de l'appareil. Pour contrer cet effet secondaire, le FFA est appuyé dans la région antérieure mandibulaire sur un système d'ancrage osseux. Cette étude pilote avait pour objectif de comparer les effets d'un appareil fonctionnel fixe conventionnel (FFA) et ceux d'un appareil fonctionnel fixe à ancrage osseux (SAS-FFA) sur le complexe maxillo-mandibulaire et l'articulation temporo-mandibulaire, à la fin du traitement et un an après, à l'aide de coupes tomographiques volumiques à faisceau conique (CBCT).*
Matériel et méthode > *Seize individus de classe II ont été répartis en deux groupes de même taille : le groupe I (FFA) (âge moyen 13,11 ± 0,38 ans) et le groupe II (SAS-FFA) (âge moyen 12,96 ± 0,38 ans). Les coupes de CBCT effectuées avant le traitement (T0), en toute fin de traitement (T1), et un an après la fin du traitement (T2), ont été évaluées pour déceler des changements dans le complexe maxillo-mandibulaire et l'ATM. Le coefficient de corrélation intraclasse et le test « t » indépendant ont été utilisés respectivement pour les mesures répétées et les changements intergroupes (moyens).*
Résultats > *Un an après la fin du traitement, le SAS-FFA a montré un recul maxillaire significatif, (SNA, −1,93°, $p < 0{,}05$) avec une augmentation significative de la longueur mandibulaire (Go-Pog, 3,25 mm, $p < 0{,}001$) (Co-Gn, 7,87 mm, $p < 0{,}001$). Le groupe SAS-FFA a montré une augmentation significative vers le haut et vers l'arrière du volume condylien (571 mm^3, $p < 0{,}001$) avec translation antérieure de la cavité glénoïde. Le groupe FFA a montré une récidive significative des dents mandibulaires et de relation verticale, ainsi que des changements non significatifs au niveau de l'articulation temporo-mandibulaire.*
Conclusion > *Le SAS-FFA est une combinaison efficace, qui apporte des changements favorables sur le complexe maxillo-mandibulaire et l'articulation temporo-mandibulaire avec une récidive non significative par rapport au FFA un an après le traitement.*

Introduction

Temporary anchorage devices (TAD) and skeletal anchorage system (SAS) have gained a profound application in orthodontics. TAD or SAS expand the horizons of orthodontic treatment as they eliminate the dental component, and use bone as an anchoring unit [1]. Fixed functional appliance (FFA) like Jasper Jumper and Forsus Fatigue Resistance Device® (FRD) have been used routinely in the treatment of Class II skeletal relationship, but as they are directly anchored on lower arch-wire, they invariably aid in mandibular anterior teeth proclination, thus

TABLE I
Patient inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Females: age of patient: 12–16 years	Presence of any primary teeth
Skeletal Class II division 1 defined by an SNA, $84 \pm 2°$; SNB $76 \pm 2°$; ANB $\geq 4 \pm 1°$	Absence of permanent teeth except third molars
Bilateral Angle's Class II molar relationship	Prosthetic restorations on teeth
Anterior overjet of ≥ 6 mm and 100% deep bite	Periodontal disease
Minimal or no crowding or spacing (≤ 2.5 mm) of the upper and lower dental arches	Previous orthodontic treatment
Non-extraction treatment plan	Temporomandibular joint disorder

limiting the appliances skeletal effect [2–4]. In order to counter the aforementioned side effect, FFA is anchored in the lower anterior region of the mandible [5,6].

Studies have evaluated skeletal, dental, and soft-tissue effects of conventional and skeletal anchorage supported fixed functional appliance, however, the shortcomings of these studies were; 2D-lateral cephalograph studies, studies with historical control group, and animal studies of which the results are difficult to extrapolate in human being [7–11]. Studies conducted on human beings have used CBCT to evaluate the effect of fixed functional appliance [12–14], however, no previous studies have evaluated the effect of skeletal anchorage supported FFA on maxillo-mandibular complex and temporomandibular joint, and at one year post-treatment. Hence, this pilot study was conducted with aims to evaluate the effect of fixed functional appliance (Forsus-FRD®) on maxilla and mandible, on temporomandibular joint, and its effect one-year post-treatment in individuals treated with conventional anchorage of fixed functional appliance and SAS supported fixed functional appliance. The following hypotheses were tested:

- significant growth modulation of maxillo-mandibular complex (maxillary restriction and mandibular advancement) and TMJ remodelling occurs when fixed functional appliance is anchored on to SAS in comparison to conventional (non-SAS) anchored fixed functional appliance;
- non-significant relapse occurs over one-year period in SAS supported fixed functional appliance in comparison to conventional fixed functional appliance.

Materials and methods

This prospective study was conducted after ethical approval of this study was obtained from the hospitals institutional review board, and parents of the patients signed an informed consent before participating in the study. Sixteen growing individuals (females only) with eight subjects in each group formed the study sample (*tables I and II*).

Individuals satisfying criteria (*table I*) were divided into two groups:

- group I: Conventional fixed functional appliance (FFA), and;
- group II: Skeletal anchorage system supported fixed functional appliance (SAS-FFA).

In both groups, all teeth were bonded with 0.022×0.025 inch slot brackets and maxillary first molars were banded with triple buccal tube having a headgear tube. Initially, 0.014 inch NiTi

TABLE II
Table showing subjects mean age at the beginning of treatment along with time (days) taken for each treatment phase.

	Group I (FFA)	Group II (SAS-FFA)	Mean difference	*P*-value	Significance
Mean age before treatment, (years)	13.11 ± 0.38	12.96 ± 0.38	0.15 ± 0.19	0.446	NS
Pre-functional phase, (months)	2.99 ± 0.11	0.42 ± 0.13	2.54 ± 0.14	0.000	S
Functional phase, (months)	7.59 ± 0.32	10.45 ± 0.16	2.86 ± 0.13	0.000	S
Post-functional phase, (months)	3.02 ± 0.23	2.95 ± 0.26	0.06 ± 0.13	0.637	NS
Total treatment time, (months)	13.61 ± 0.49	13.80 ± 0.29	0.24 ± 0.21	0.262	NS

FFA: fixed functional appliance; SAS-FFA: skeletal anchorage system-fixed functional appliance; NS: non-significant; S: significant.

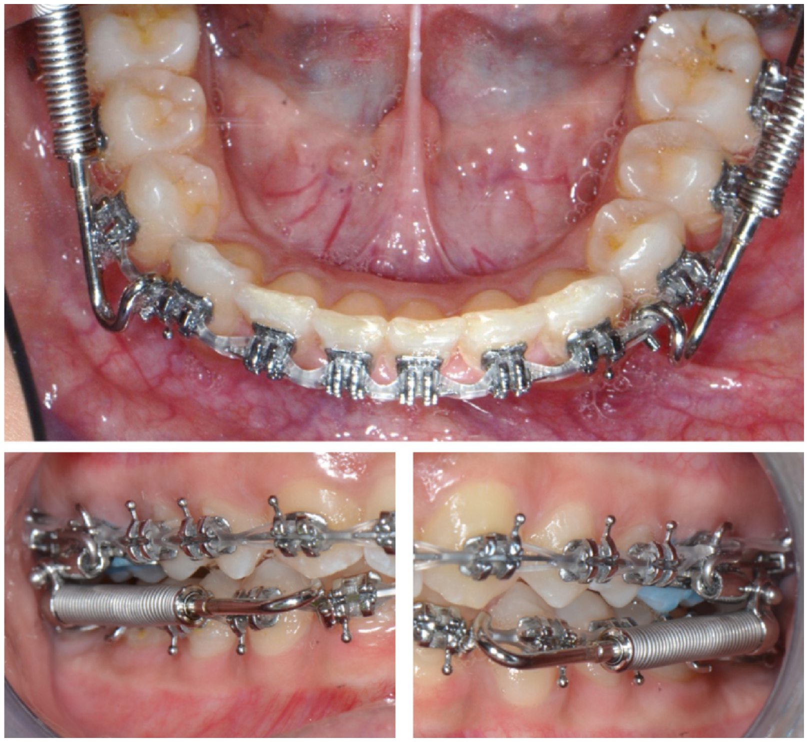

FIGURE 1
Forsus-FRD® hooked on the lower arch-wire in Group I (FFA group)

arch-wires were placed in the upper and lower dental arches and a 0.032-inch stainless steel transpalatal arch with buccal root torque was placed on maxillary first molars.
For Group I, Forsus-FRD® (3 M Unitek, Monrovia, California, USA) was placed after insertion of 0.021 × 0.025 inch stainless steel upper and lower arch-wires (*figure 1*). The total time taken to reach the aforementioned wire was 2.99 ± 0.11 months, and functional phase lasted for 7.59 ± 0.32 months (*table II*).
For Group II, two SAS plates (S.K Surgicals®, Pune, Maharashtra, India) (*figure 2*) were placed bilaterally in the anterior region of the mandible immediately after placement of 0.014 inch NiTi wires as described (*figure 3*) and loaded after five to seven days of soft-tissue healing period (*figure 4*). The functional phase lasted for 10.45 ± 0.16 months (*table II*).
In both groups, follow-up was carried-out at every four-week interval for activation of push rod by crimps supplied by the manufacturer. Additionally, in Group II, power chains were replaced in the upper and lower arches. FFA was removed when a Class I molar relationship was achieved in both groups. After the functional phase, the treatment continued for 3.02 ± 0.23 months in Group I and 2.95 ± 0.26 months in Group II for occlusion settling with light settling elastics, and final finishing and detailing. The total treatment time taken was 13.61 ± 0.49 months for Group I and 13.80 ± 0.29 months for Group II (*table II*).
The retention protocol consisted of one year full-time wear of upper and lower Hawley's removable retainers, and also, fixed retention was planned by bonding wires from canine to canine in both arches.

CBCT image acquisition

Individuals were subjected to CBCT imaging with i-CAT equipment (Imaging Sciences International Inc, Hatfield, PA) at 120 kV and 3–8 mA, with a scanning time of 10 seconds having field of view of 16 × 22 cm, at a 12-bit gray scale. CBCT recordings were undertaken at pre-treatment (T0), immediately after removal of FFA (T1), and at one-year post-treatment (T2) by seating the individual in erect sitting position with teeth in centric occlusion, after adjusting chin rest and camper's plane parallel to the ground. The machine's laser light beam standardized the head position with longitudinal light beam passing through the centre of glabella and philtrum, and transverse light beam passing through lateral eye canthus. Scan data was reconstructed with 0.20 mm slice thickness, and converted to DICOM images, and were evaluated with "Invivo 5.1'' (Anatomage Inc, San Jose, CA) software.
As assessed by cervical vertebral maturation method, at T0 all individuals were in the circumpubertal phase of skeletal development (15% pre-pubertal, 70% pubertal, 15% post-pubertal),

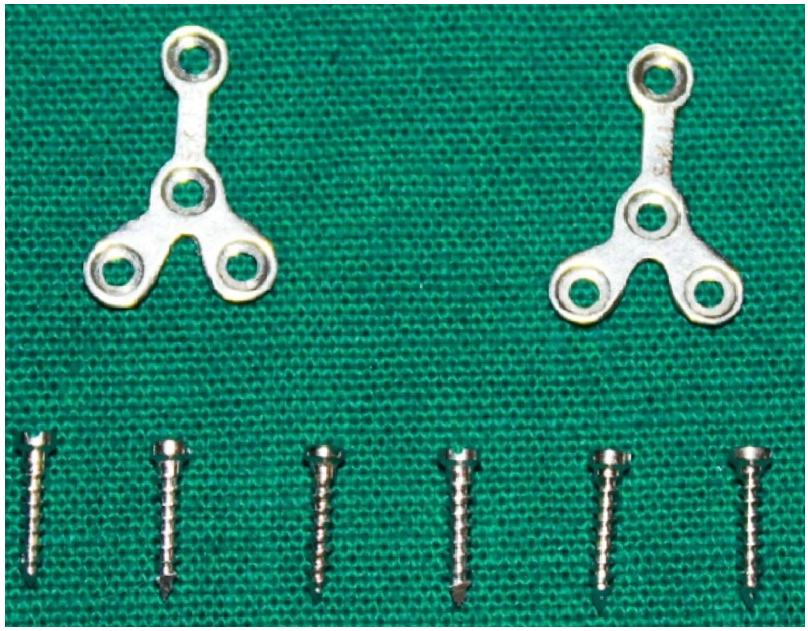

Figure 2
Skeletal anchorage system comprising "triangular design" plates and screws (8 mm length)

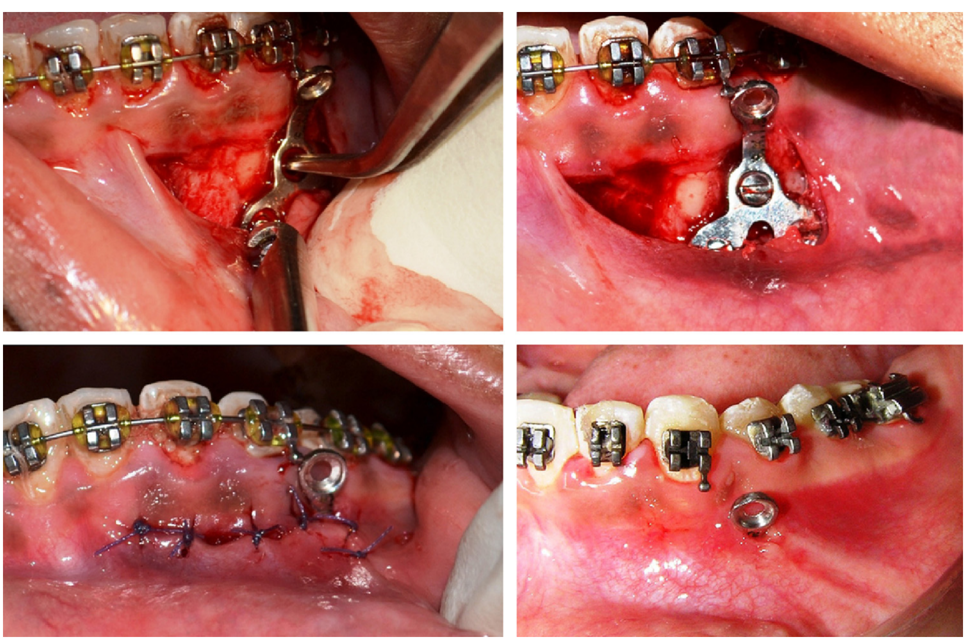

Figure 3
A horizontal incision is made for skeletal plate insertion. Enough clearance is provided between the fixation screws of the plates and adjacent teeth roots

and the mean chronological age was 13.11 ± 0.38 years for Group I and 12.96 ± 0.38 years for Group II.
Corresponding images were superimposed with "point registration'' tool of "Invivo software'' by selecting certain stable skeletal structural landmarks of anterior cranial base [15] (*figure 5*).

The reference lines and angles used in this study were also used in previous studies [16,17]. Tempormandibular joint spaces (anterior, superior and posterior) linear measurements were done according to the methods used by Vitral et al. [18] and Vitral and Telles [19] and volumetric assessment according to

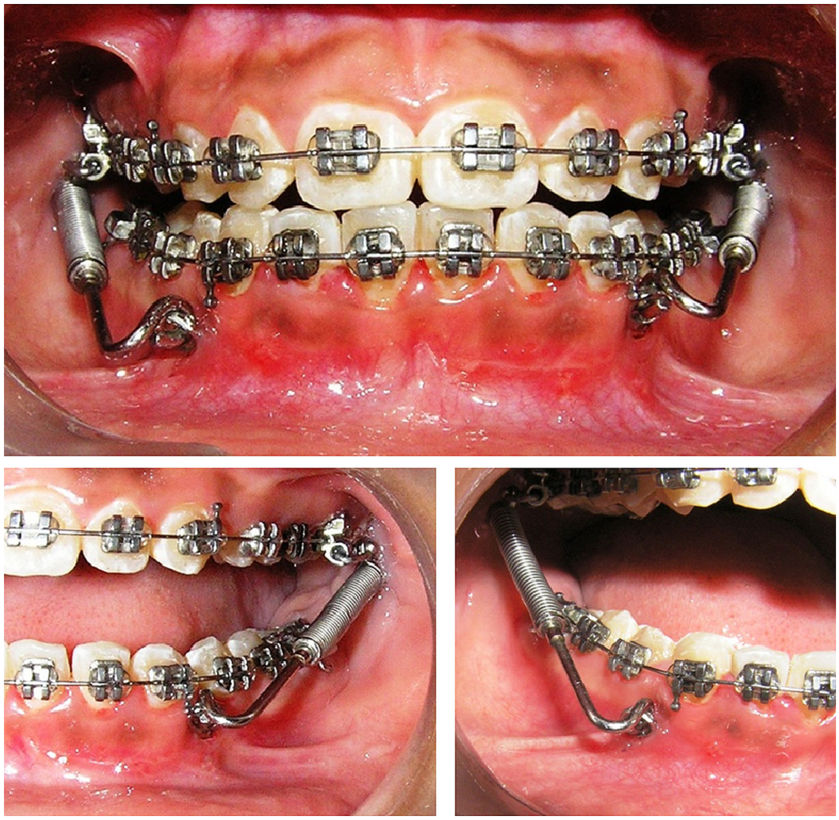

FIGURE 4
The Forsus-FRD® is hooked on the plates

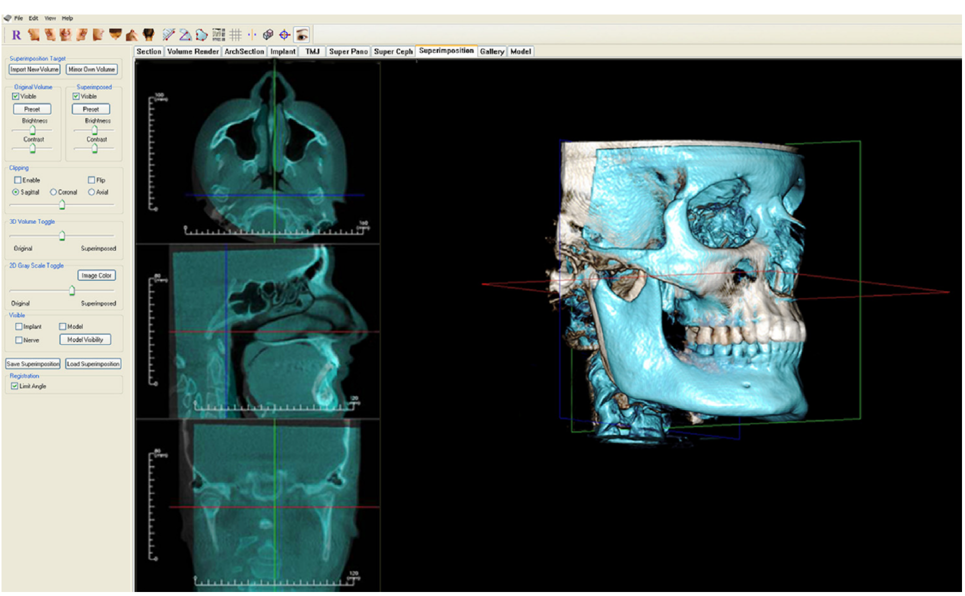

FIGURE 5
The "superimposition tool" of "Invivo 5.1" used to assess maxillary and mandibular changes by superimposing two images

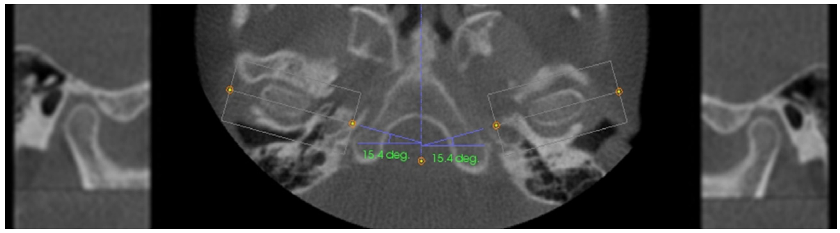

Figure 6

Anterior, posterior and superior joint spaces were evaluated along with volumetric evaluation of mandibular condyle

the methodology described by Yidirium et al. [14] and Bayram et al. [20], (*figure 6*).

Statistical analysis

A single operator carried-out all measurements. Descriptive statistics (SPSS Version 19.0, SPSS Inc, Chicago, Ill) of all measurements of both groups were calculated. Data was checked for normality with Shapiro-Wilks test. For intra-observer variance, ten randomly selected CBCT scans were measured twice at 2 weeks apart by the same observer. The method error was assessed by intraclass correlation coefficient (ICC), and ICC ranged from 0.94 to 0.98 for linear measurements, from 0.96 to 0.99 for angular measurements, and 0.95 to 0.99 for volumetric measurements. Simple linear scatter plot showed consistency of first and second measurements with R^2 linear 0.999, 0.979 and 0.998 for angular, linear and volumetric measurements respectively. Independent "*t*" test was applied to test the inter-group variations at different phases of treatment (T0-T1, T1-T2, T0-T2) at significance level of $P < 0.05$.

Results

The results are shown as mean changes of FFA and SAS-FFA groups from T0-T1, T1-T2, and T0-T2 (*tables III–V*).

During the T0-T1 interval

Sagittal skeletal positions exhibited significantly greater decrease in SAS-FFA group compared to FFA group (FFA vs. SAS-FA [ANB, −1.81° vs. −5.00°, $P < 0.001$] [$A^{\perp}B$, −1.63 mm vs. −3.00 mm, $P < 0.001$] [NA-Pog, −2.30° vs. −2.94°, $P < 0.01$]). The maxilla exhibited significant decrease in skeletal position in SAS-FFA group compared to FFA group (FFA vs. SAS-FFA [SNA, −0.93° vs. −1.68°, $P < 0.05$] [$A^{\perp}N^{\perp}$, −0.10 vs. −1.16 mm, $P < 0.001$] [$A^{\perp}$Ptm, −0.56 vs. −1.76 mm, $P < 0.01$] [$S^{\perp}$Ptm, −0.31 mm vs. −1.62 mm, $P < 0.001$]). Mandible skeletal relation showed significant increase in SAS-FFA group than FFA (FFA vs. SAS-FFA [SNB, 0.87° vs. 3.43°, $P < 0.0001$] [Go-Pog, 1.31° vs. 2.75°, $P < 0.05$] [Co-Gn, 3.12 vs. 5.50 mm, $P < 0.001$]).

Mandibular dentoalveolar relationships showed significant increase in FFA group in comparison to SAS-FFA group (FFA vs. SAS-FFA [L1-MP, 4.75 mm vs. 0.75 mm, $P < 0.001$] [L1-NB, 4.00° vs. 0.12° mm, $P < 0.001$] [L1-NB, 2.82 vs. 0.03 mm, $P < 0.001$]).

In temporomandibular joint spaces, anterior joint space showed significant increase in SAS-FFA in comparison to FFA (FFA vs. SAS-FFA [AJS, 0.07 vs. 0.38 mm, $P < 0.001$]). Superior joint space and posterior joint space showed significant decrease in SAS-FFA than FFA group (FFA vs. SAS-FFA [SJS, −0.04 vs. −0.55 mm, $P < 0.001$] [PJS, −0.37 vs. −0.92, $P < 0.001$]). Condylar volume increased in SAS-FFA than FFA (FFA vs. SAS-FFA [SJS, 322 vs. 494 mm, $P < 0.05$]).

During the T1-T2 interval

Sagittal skeletal relationships showed non-significant differences in both groups. Significant decrease of vertical skeletal relationship was shown in FFA group in comparison to SAS-FFA group (FFA vs. SAS-FFA [SN-GoGn, −2.06° vs. 1.56°, $P < 0.05$] [FH-GoMe, −2.93° vs. 0.18°, $P < 0.05$] [MM-plane, −2.87° vs. 0.08°, $P < 0.05$] [Y-axis, −3.18° vs. 0.50°, $P < 0.05$]). In mandible, Go-Pog showed increase in SAS-FA in comparison to FFA group (FFA vs. SAS-FFA [Go-Pog, 0.00 vs. 0.50 mm, $P < 0.05$]). Temporomandibular joint spaces and volume showed non-significant difference in both groups.

During T0-T2

Significant decrease in sagittal relationship was noted in SAS-FFA compared to FFA group (FFA vs. SAS-FFA [ANB, −1.56° vs. −5.18°, $P < 0.001$] [$A^{\perp}B$, −1.33° vs. −2.97°, $P < 0.001$] [NA-Pog, −2.16° vs. −2.91°, $P < 0.001$]). In vertical skeletal relation, SAS-FFA showed significant increase in comparison to FFA (FFA vs. SAS-FFA [SN-Go Gn, 1.25° vs. 3.43°, $P < 0.001$] [FH-Go Me, 0.12° vs. 2.56°, $P < 0.001$] [MM-Plane, 1.63° vs. 3.56°, $P < 0.001$] [Y-axis, 0.25° vs. 2.75°, $P < 0.001$]). Mandible skeletal relation showed significant increase in SAS-FFA group than FFA (FFA vs. SAS-FFA [SNB, 0.75° vs. 3.25°, $P < 0.05$] [Go-Pog, 1.31 vs. 3.25 mm, $P < 0.05$] [Co-Gn, 4.62 vs. 7.87 mm, $P < 0.001$]).

Temporomandibular joint spaces; anterior joint space showed significant increase in SAS-FFA in comparison to FFA (FFA vs. SAS-FFA [AJS, 0.15 vs. 0.45 mm, $P < 0.05$]). Superior joint space and posterior joint space showed significant decrease in SAS-FA than

TABLE III
Comparison of mean changes during T0-T1 period in Group I (FFA) and Group II (SAS-FFA).

Variables	T0-T1				
	Group I (FFA)	Group II (SAS-FFA)	Difference	*P*-value	Significance
Sagittal					
ANB, (deg)	−1.81 ± 0.75	−5.00 ± 0.59	−3.18 ± 0.33	0.000	S
$A^{\perp}B^{\perp}$, (mm)	−1.63 ± 0.63	−3.00 ± 0.34	−1.36 ± 0.25	0.000	S
NA-Pog, (deg)	−2.30 ± 0.44	−2.94 ± 0.25	−0.63 ± 0.17	0.003	S
Vertical					
SN-GoGn, (deg)	3.31 ± 0.65	3.56 ± 0.90	0.25 ± 0.39	0.536	NS
FH-GoMe, (deg)	3.06 ± 1.01	2.75 ± 1.03	0.31 ± 0.51	0.552	NS
MM-Plane, (deg)	4.50 ± 0.75	3.65 ± 1.00	0.85 ± 0.44	0.078	NS
Y-axis, (deg)	3.43 ± 0.90	3.25 ± 1.03	0.18 ± 0.48	0.705	NS
Maxilla					
SNA, (deg)	−0.93 ± 0.49	−1.68 ± 0.75	−0.75 ± 0.31	0.036	S
$A^{\perp}N$, (mm)	−0.10 ± 0.12	−1.16 ± 0.23	1.06 ± 0.09	0.000	S
$A^{\perp}Ptm$, (mm)	−0.56 ± 0.17	−1.76 ± 0.62	−1.09 ± 0.26	0.001	S
$S^{\perp}Ptm$, (mm)	−0.31 ± 0.37	−1.62 ± 0.51	1.31 ± 0.22	0.000	S
Mandible					
SNB, (deg)	0.87 ± 0.69	3.43 ± 0.67	2.56 ± 0.34	0.000	S
Go-Pog, (mm)	1.31 ± 0.37	2.75 ± 1.10	1.43 ± 0.41	0.011	S
Co-Gn, (mm)	3.12 ± 0.64	5.50 ± 1.06	2.37 ± 0.44	0.000	S
Dentoalveolar					
U1-SN, (deg)	−5.13 ± ±1.80	−6.50 ± 0.88	−1.37 ± 0.69	0.067	S
U1-NA, (deg)	−1.43 ± 0.67	−4.06 ± 0.86	−2.62 ± 0.38	0.000	S
U1-NA, (mm)	−0.94 ± 0.41	−2.26 ± 0.96	−1.32 ± 0.37	0.012	S
L1-MP, (deg)	4.75 ± 1.16	0.75 ± 0.53	4.00 ± 0.45	0.000	S
L1-NB, (deg)	4.00 ± 0.88	0.12 ± 0.23	3.87 ± 0.32	0.000	S
L1-NB, (mm)	2.82 ± 0.39	0.03 ± 0.45	2.86 ± 0.21	0.000	S
Overjet, (mm)	−4.45 ± 0.25	−4.53 ± 0.25	−0.08 ± 0.12	0.519	NS
Overbite, (mm)	−3.68 ± 0.11	−3.81 ± 0.24	−0.13 ± 0.09	0.198	NS
TMJ					
Anterior joint space, (mm)	0.07 ± 0.09	0.38 ± 0.04	0.31 ± 0.36	0.000	S
Superior joint space, (mm)	−0.04 ± 0.02	−0.55 ± 0.15	−0.50 ± 0.05	0.000	S
Posterior joint space, (mm)	−0.37 ± 0.10	−0.92 ± 0.23	−0.55 ± 0.09	0.000	S
Condyle volume, (mm^3)	322 ± 32	494 ± 74	172.50 ± 28	0.000	S

FFA: fixed functional appliance; SAS-FFA: skeletal anchorage system-fixed functional appliance; TMJ: temporomandibular joint; NS: non-significant; S: significant.

Table IV
Comparison of mean changes during T1-T2 period in Group I (FFA) and Group II (SAS-FFA).

Variables	T1-T2				
	Group I (FFA)	Group II (SAS-FFA)	Difference	*P*-value	Significance
Sagittal					
ANB, (deg)	0.25 ± 0.96	0.18 ± 0.79	0.43 ± 0.44	0.340	NS
$A^{\perp}B^{\perp}$, (mm)	0.22 ± 0.42	0.02 ± 0.04	0.20 ± 0.14	0.202	NS
NA-Pog, (deg)	0.13 ± 0.36	0.02 ± 0.03	0.11 ± 0.12	0.411	NS
Vertical					
SN-GoGn, (deg)	−2.06 ± 0.86	−0.12 ± 0.23	−1.93 ± 0.31	0.000	S
FH-GoMe, (deg)	−2.93 ± 1.01	−0.18 ± 0.25	−2.75 ± 0.37	0.000	S
MM-Plane, (deg)	−2.87 ± 0.74	−0.08 ± 0.18	−2.78 ± 0.27	0.000	S
Y-axis, (deg)	−3.18 ± 0.96	−0.50 ± 0.59	−2.68 ± 0.40	0.000	S
Maxilla					
SNA, (deg)	0.12 ± 0.44	0.25 ± 0.53	0.12 ± 0.24	0.619	NS
$A^{\perp}N^{\perp}$, (mm)	0.00 ± 0.00	0.02 ± 0.07	0.02 ± 0.02	0.304	NS
$A^{\perp}$Ptm, (mm)	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	1.000	NS
$S^{\perp}$Ptm, (mm)	0.00 ± 0.00	0.25 ± 0.46	0.25 ± 0.16	0.170	NS
Mandible					
SNB, (deg)	0.12 ± 0.23	0.18 ± 0.25	0.06 ± 0.12	0.619	NS
Go-Pog, (mm)	0.00 ± 0.00	0.00 ± 0.26	0.50 ± 0.09	0.001	S
Co-Gn, (mm)	1.50 ± 0.75	2.37 ± 0.74	0.87 ± 0.37	0.035	S
Dentoalveolar					
U1-SN, (deg)	0.38 ± 0.51	0.25 ± 0.46	0.12 ± 0.24	0.619	NS
U1-NA, (deg)	0.25 ± 0.26	0.06 ± 0.67	0.18 ± 0.25	0.479	NS
U1-NA, (mm)	0.25 ± 0.26	0.13 ± 0.23	0.37 ± 0.12	0.010	S
L1-MP, (deg)	−2.87 ± 1.30	−0.12 ± 0.23	−2.75 ± 0.46	0.000	S
L1-NB, (deg)	−2.56 ± 1.29	−0.18 ± 0.25	−2.75 ± 0.46	0.000	S
L1-NB, (mm)	−2.37 ± 0.41	−0.26 ± 0.31	−2.63 ± 0.18	0.000	S
Overjet, (mm)	2.97 ± 0.24	0.03 ± 0.05	3.00 ± 0.09	0.001	S
Overbite, (mm)	1.98 ± 0.38	0.02 ± 0.07	2.01 ± 0.13	0.000	S
TMJ					
Anterior joint space, (mm)	0.07 ± 0.10	0.06 ± 0.04	0.00 ± 0.03	0.877	S
Superior joint space, (mm)	−0.04 ± 0.07	−0.09 ± 0.62	−0.02 ± 0.02	0.339	S
Posterior joint space, (mm)	−0.10 ± 0.07	−0.08 ± 0.04	−0.02 ± 0.03	0.431	S
Condyle volume, (mm^3)	90 ± 62	76 ± 20	14 ± 23	0.547	S

FFA: fixed functional appliance; SAS-FFA: skeletal anchorage system-fixed functional appliance; TMJ: temporomandibular joint; NS: non-significant; S: significant.

Table V
Comparison of mean changes during T0-T2 period in Group I (FFA) and Group II (SAS-FFA).

Variables	T0-T2				
	Group I (FFA)	Group II (SAS-FFA)	Difference	*P*-value	Sig
Sagittal					
ANB, (deg)	−1.56 ± 1.08	−5.18 ± 0.75	−3.75 ± 0.46	0.000	S
$A^{\perp}B^{\perp}$, (mm)	−1.33 ± 0.69	−2.97 ± 0.36	−1.63 ± 0.27	0.000	S
NA-Pog, (deg)	−2.16 ± 0.35	−2.91 ± 0.26	−0.75 ± 0.15	0.000	S
Vertical					
SN-GoGn, (deg)	1.25 ± 0.65	3.43 ± 0.77	2.1 ± 0.35	0.000	S
FH-GoMe, (deg)	0.12 ± 0.23	2.56 ± 0.77	2.43 ± 0.28	0.000	S
MM-Plane, (deg)	1.63 ± 0.51	3.56 ± 1.11	1.93 ± 0.43	0.000	S
Y-axis, (deg)	0.25 ± 0.37	2.75 ± 0.75	2.50 ± 0.29	0.000	S
Maxilla					
SNA, (deg)	−1.06 ± 0.32	−1.93 ± 0.72	0.87 ± 0.28	0.008	S
$A^{\perp}N$, (mm)	−0.10 ± 0.12	−1.19 ± 0.255	−1.20 ± 0.238	0.001	S
$A^{\perp}Ptm$, (mm)	−0.56 ± 0.17	−1.76 ± 0.62	−1.25 ± 0.32	0.003	S
$S^{\perp}Ptm$, (mm)	−0.31 ± 0.37	−1.87 ± 0.83	1.56 ± 0.32	0.001	S
Mandible					
SNB, (deg)	0.75 ± 0.75	3.25 ± 0.84	2.50 ± 0.40	0.000	S
Go-Pog, (mm)	1.31 ± 0.37	3.25 ± 1.13	1.93 ± 0.42	0.002	S
Co-Gn, (mm)	4.62 ± 1.30	7.87 ± 1.12	3.25 ± 0.60	0.000	S
Dentoalveolar					
U1-SN, (deg)	−4.75 ± 1.66	−6.25 ± 0.88	−1.50 ± 0.66	0.041	S
U1-NA, (deg)	−1.18 ± 0.45	−4.00 ± 0.88	−2.81 ± 0.35	0.000	S
U1-NA, (mm)	−1.19 ± 0.53	−2.14 ± 0.87	−0.95 ± 0.36	0.023	S
L1-MP, (deg)	1.87 ± 1.50	0.62 ± 0.69	1.25 ± 0.58	0.000	S
L1-NB, (deg)	1.43 ± 1.08	0.31 ± 0.25	1.12 ± 0.39	0.013	S
L1-NB, (mm)	0.45 ± 0.42	0.22 ± 0.39	0.22 ± 0.20	0.289	NS
Overjet, (mm)	−1.47 ± 0.27	−4.56 ± 0.27	−3.09 ± 0.13	0.000	S
Overbite, (mm)	−1.68 ± 0.42	−3.83 ± 0.22	−2.14 ± 0.17	0.000	S
TMJ					
Anterior joint space, (mm)	0.15 ± 0.03	0.45 ± 0.03	0.30 ± 0.01	0.000	S
Superior joint space, (mm)	−0.09 ± 0.03	−0.62 ± 0.15	0.53 ± 0.05	0.000	S
Posterior joint space, (mm)	−0.48 ± 0.12	−1.00 ± 0.24	0.52 ± 0.09	0.000	S
Condyle volume, (mm^3)	413 ± 83	571 ± 74	158 ± 39.56	0.001	S

FFA: fixed functional appliance; SAS-FFA: skeletal anchorage system-fixed functional appliance; TMJ: temporomandibular joint; NS: non-significant; S: significant.

FFA group. Condylar volume increased in SAS-FFA than FFA (FFA vs. SAS-FA [SJS, 413 vs. 571 mm, $P < 0.05$]).

Discussion

The greatest effect of the SAS anchored Forsus-FRD® was on mandible with a significant increase of mandibular length (Go-Pog, 3.25 mm) (Co-Gn, 7.87 mm), and also significant increase of sagittal positioning of mandible (SNB, 3.25°). In SAS-FFA (Group II), no proclination of mandibular anterior teeth was noted, which is in great contrast to significant mandibular teeth proclination experienced by tooth-borne fixed functional appliance (Group I). This can be attributed to the fact that Forsus-FRD® was anchored onto SAS, which completely eliminated the dependency of teeth as anchorage unit. Unal et al. found similar skeletal changes with mandible significantly moving forward ($P < 0.001$), and overjet corrections mainly due to skeletal changes [11].

During the post-functional follow-up period (T1-T2), significant relapse was noted in the lower dentition of the FFA group (L1-MP, −2.87°; L1-NB, −2.56°; L1− NB, −2.37 mm). The study's findings of lower dentition, overjet and overbite are similar to findings noted in other studies [9,21]. However, studies done by Siara-Olds et al. [22], and Ghislanzoni et al. [23] did not find any significant difference in any measurements. Sagittal relation showed significant decrease in SAS-FFA in comparison to FFA group. Specifically, the significant T0-T1 increase in vertical relation of FFA was lost in the one-year follow-up period; hence, overall (T0-T2) significant vertical relapse was noted in FFA group.

Significant increase in anterior joint space was noted along with significant decrease of superior and posterior joint space in SAS-FFA indicating bony resorption of anterior wall with deposition of superior and posterior wall, which corresponded to downward and forward remodelling of glenoid fossa. Also, condylar volume showed significant increase in SAS-FA indicating upward and backward growth of condyle. No human study has used CBCT to evaluate condylar response to functional appliance therapy in Class II malocclusion, except studies done by Yildirim et al. [14], Elkrody et al. [12], LeCornu et al. [13] and Souki et al. [24]. Yildirim et al. [14] evaluated condylar volumetric changes, as condyle is a growth site that plays an important role in mandibular growth, in patients treated with twin-block appliance, and concluded that condylar volume significantly increased in post-treatment images when compared to pre-functional therapy images. LeCornu et al. [13] studied Herbst appliance effect on Class II malocclusion and compared changes with Class II controls treated with elastics, and concluded that Class II patients treated with the Herbst appliance demonstrated anterior displacement of the condyles and glenoid fossae. The findings of our study of glenoid fossa's anterior wall resorption and posterior and superior wall deposition are similar to the findings of aforementioned study. Souki et al. [24] studied the skeletal mandibular changes associated with Herbst appliance treatment by comparing individuals that did not receive Herbst appliance treatment, and found that a significant mandibular forward displacement was achieved due to increased condylar bone remodelling in Herbst appliance subjects. In comparison to our study findings the findings of Souki et al. showed a larger change in the condyle, possibly, because of the Herbst appliance being a rigid fixed functional appliance in comparison to forsus being a flexible fixed appliance. Nonetheless, the current study corroborates the findings of the aforementioned studies with regards to SAS-FFA groups favourable changes in the TMJ.

In our study, although both FFA and SAS-FFA groups showed increase in condylar volume, SAS-FA (494 ± 74 mm^3) showed significantly greater condylar response than FFA group (322 ± 32 mm^3). Also, at one-year post-treatment evaluation period, SAS-FFA (571 ± 74 mm^3, $P < 0.001$) showed greater condylar response than FFA (413 ± 83 mm^3) group, indicating a continued stimulated growth response of condyles in SAS-FFA group. Baume and Derichsweiler [25] showed, in Macaca mulatta, by vital-staining and histologic analyses that condylar cartilage with its endochondral growth apparatus responded most actively to functional therapy, and at post-treatment, the condylar head assumed a prolonged, bilobed shape as part of a growth response that tended to compensate for the induced mandibular displacement. The findings of our study are similar to the above-mentioned study.

Treatment duration with fixed functional appliances also plays a vital role. Recently, Elkordy et al. [12] studied 3D (CBCT) skeletal and dental effects of mini-implant anchorage supported FRD with conventional FRD in 11 to 14-year-old individuals, and concluded that FRD with mini-implant anchorage effectively reduced mandibular incisors unfavourable proclination and intrusion, but did not produce additional skeletal effects. The duration of functional appliance wear in their study ranged from 4 to 6 months. The duration of functional phase in our study was 7.59 ± 0.32 months for Group I (FFA) and 10.45 ± 0.16 months for Group II (SAS-FFA), which lasted significantly longer than Group I (FFA) and, also longer than most of the previously mentioned studies with fixed functional appliances (average six months) [11,16,17]. In Group I, the shorter duration of functional phase was due to early correction of overjet by rapid proclination of lower incisors, which was significantly earlier than Group II, thus limiting the amount of skeletal correction in Group I, whereas, in Group II, overjet correction was by gradual increase in mandibular length. Hence, the longer duration of functional phase in Group II explains the significant orthopaedic response (maxillary restriction and mandibular advancement), which allowed the mandible to exhibit its full growth potential in Group II than in Group I. Moreover, histological evidence shows that additional growth occurs with longer treatment time, and if adequate time is allowed, mineralization and adaptation of muscle attachments is a distinct possibility

[26]. Also, animal study suggests that prolonged retention phase allows conversion of type III to type I collagen leading to adequate bone maturation and stability [27].

Although, our study has evaluated the effect of fixed functional appliance at one-year post-treatment, perhaps it would be interesting to evaluate the temporomandibular joint adaptation long-term. Feres et al. consider that although functional appliances enhance condylar and mandibular growth, long-term stability needs further investigation [28]. Moreover, Feres et al. hypothetically proposed that mandibular growth may be enhanced through the use of adjunctive methods such as low-intensity pulsed ultrasound (LIPUS), light emitting diode (LED), Low-level laser (LLL), growth hormone, and gene therapy, in conjunction with functional appliances, and needs further investigation at morphologic and histomorphometric analysis [28].

Post-treatment stability is ensured through stable cuspal interdigitation of the maxillary and mandibular dentition [3,16]. Relapse of overjet and overbite were common findings at one year post-treatment, solely due to relapse in lower incisor inclination [22]. In our study, no relapse was noted at one-year retention period in Group II, due to maintenance of pre-functional incisor inclination, as a result of fixed functional appliance being anchored directly on bone. However, significant amount of relapse was noted in Group I.

The limitations of the present study are the need of additional surgical procedure for the insertion and removal of SAS, additional costs incurred due to SAS, and also, no untreated Class II group was used as a control group. It is unethical however to deliberately delay treatment in Class II growing individuals, as there is suggestive evidence of significant mandibular growth occurring when functional appliance is used at pubertal peak [10].

The general findings of this pilot study show that combination of SAS with fixed functional appliance induces mandibular advancement and condylar remodelling significantly more than tooth-borne fixed functional appliance, and the conventional fixed functional appliances main effects were dentoalveolar in nature with relapse of overjet and vertical corrections at one-year post-treatment. The study results suggest that application of Forsus-FRD with SAS (Group II), the growing mandible was completely freed from labial flaring of mandibular anterior teeth, thus allowing mandible to express its full growth potential. Hence, this observation classically explains why mandible growth is expressed significantly more in Group II than Group I. However, future studies with larger sample size are essential in order to compare the findings of this study, and also to evaluate long-term outcomes.

Conclusion

Hypothesis accepted; significant maxillo-mandibular complex growth modulation and TMJ remodelling occurs when the fixed functional appliance is anchored on to SAS as compared to conventional anchored fixed functional appliance.

Non-significant relapse occurs over one-year post-treatment in SAS supported fixed functional appliance treatment as compared to conventional anchored fixed functional appliance in the treatment of Class II division 1 malocclusion in growing individuals.

Disclosure of interest: the authors declare that they have no competing interest.

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