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ORIGINAL RESEARCH

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A comparative evaluation of Angle Class II Division 1 malocclusion treatment effects using an activator versus an EF Line® preformed appliance in the Vietnamese population: a randomized controlled trial

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Abstract

Background: The study aimed to evaluate skeletal, dental, and soft tissue changes in patients with Class II Division 1 malocclusion after 6 months of treatment with a conventional functional appliance (the Activator) versus a prefabricated myofunctional appliance (PMA). **Methods**: A randomized clinical trial was conducted on 60 patients diagnosed with Angle Class II Division 1 malocclusion (ANB $\geq$4°, normal maxillary position) and an overjet $\geq$6 mm. All participants were in the cervical vertebral maturation (CVM) stages 1–3 (CS1–CS3). The sample included 29 girls and 31 boys with a mean age of 9.7 $\pm$ 1.31 years. Patients were randomly allocated by lottery to receive either an Activator or a PMA, with 30 subjects in each group. Skeletal, dental, and soft tissue parameters were recorded at baseline and after 6 months of treatment. Blinding was not performed. **Results**: Both appliances produced significant skeletal improvements. In the Activator group, ANB angle and Wits appraisal were reduced by −1.03° and −2.09 mm, respectively ($p < 0.001$). Comparable reductions were observed in the PMA group (0.73° and 1.68 mm; $p < 0.001$). Mandibular length, as well as anterior and posterior facial heights, increased significantly in both groups ($p < 0.001$). The Activator demonstrated greater increases in mandibular length and posterior facial height ($p = 0.034$ and $p = 0.035$), whereas the PMA resulted in significantly larger increases in Pg–Pg′ distance and total chin thickness ($p = 0.039$ and $p = 0.037$). **Conclusions**: Both the Activator and PMA were effective in reducing overjet and improving skeletal and dental relationships in growing patients with Class II Division 1 malocclusion. The Activator produced slightly greater skeletal effects on mandibular growth, while the PMA showed more pronounced soft tissue changes, supporting its role as a functional and habit-modifying appliance. **Clinical Trial Registration**: ClinicalTrials.gov, ID: NCT06566027 (Retrospective registration).

Keywords

Angle Class II Division 1 malocclusion; Activator; EF Line® appliance; Myofunctional appliance; Functional appliance; Severe overjet; Vietnamese population

1. Introduction

Class II Division 1 malocclusion with large overjet (>6 mm) is common in Vietnamese children, affecting approximately 31% of primary school students in the north of the country. Such excessive overjet increases the risk of traumatic injury to the maxillary incisors and can negatively affect self-esteem and social interactions [1–3]. Early functional-appliance therapy is, therefore, recommended to reduce overjet and to encourage forward mandibular growth, improving both occlusion and facial profile [4, 5].

The Activator, a custom-made removable functional appliance, advances the mandible to a forward position and has been shown to produce favorable skeletal and dental effects in growing patients [6–8]. Prefabricated myofunctional appliances (PMAs), such as the EF Line® appliance (Éducation Fonctionnelle, Orthoplus, Igny, France), offer a simplified alternative. Designed to correct oral dysfunctions, guide eruption, and promote balanced facial development, these appliances can improve mandibular posture and muscle function [9]. Previous studies have reported improvements in overjet, overbite, and sagittal jaw relationships following treatment with prefabricated myofunctional systems [10, 11].

Idris *et al.* [12] (2019) compared the Activator and a prefabricated trainer in children with Class II Division 1 malocclusion and found significant skeletal and dental improvements in both

groups, with greater skeletal effects in the Activator group. Similarly, Cozza *et al.* [13] and Perinetti *et al.* [14] observed clinically relevant mandibular advancement with prefabricated appliances, although results varied depending on patient compliance and growth pattern.

Although several studies have reported favorable outcomes with both the Activator and various PMAs in Class II malocclusion, most of the evidence has been derived from European or Australian populations [2, 15]. These populations differ markedly from Asian cohorts in craniofacial morphology, dietary habits, and growth characteristics, which may affect treatment response. Moreover, few studies have directly compared the skeletal, dental, and soft-tissue effects of prefabricated functional appliances with those of conventional functional appliances, and previous reports were mostly retrospective or lacked standardized cephalometric evaluation [16, 17].

Therefore, a randomized clinical trial in a Vietnamese pediatric population is warranted to evaluate skeletal, dental, and soft tissue changes in patients with Class II Division 1 malocclusion after 6 months of treatment with a conventional functional appliance (the Activator) versus a PMA.

2. Materials and methods

2.1 Study participants

Inclusion criteria included Vietnamese children between the ages of 8 and 12 years with central incisors erupted, Angle Class II division 1 malocclusion (ANB angle $\geq 4°$, basic normal maxillary status), and severe overjet ≥ 6 mm in the developmental stage (CS1–CS3), no previous orthodontic treatment, and agreeing to engage in the study. Excluded criteria: The young (below 8 years) with crossbite and severe crowding were excluded.

2.2 Study methods

A randomized clinical trial was conducted on a total of 60 patients with an Angle Class II, division 1 malocclusion, and an overjet of ≥ 6 mm who were eligible for the study. The study was performed between June 2023 and May 2024. Thus, the sample consisted of 60 subjects (29 girls and 31 boys) with a mean age of 9.7 $\pm$ 1.31 years. We designed the study to treat patients, randomly assigning them by lottery to receive either an activator or the PMA. The activator versus the PMA group consisted of 30 subjects (17 girls, 13 boys) and 30 subjects (12 girls, 18 boys), respectively. The changes in skeletal, dental, and soft tissue were recorded before and at 6 months of treatment. Blinding was not performed. After six months of treatment, the study's endpoint was reached, and then selected those who achieved the standards for sampling at Can Tho University of Medicine and Pharmacy. The study was approved by the Research Ethics Committee of the Can Tho University of Medicine and Pharmacy (Biomedical Research No. 23.340.HV/PCT-H signed the study on 12 April 2023). This trial is registered with ClinicalTrials.gov Identifier (Registration Number): NCT06566027.

2.3 Sample size estimation

With an alpha of 0.05 and a power of 90%, and based on the mean of 0.63 and the standard deviation of 1.4 for the change in the ANB angle in the study by Alouini *et al.* [18], and the mean of 1.89 and the standard deviation of 1.12 for the change in the ANB angle in the study by Idris *et al.* [12], the sample size calculator offered by ClinCalc (https://clincalc.com/stats/samplesize.aspx) indicated that a sample size of n = 26 for each group was adequate. Assuming a dropout rate, 30 patients were selected for each group. Thus, the total sample size for both groups was 60 patients.

The baseline data (T0) used in this study were partially derived from the same patient cohort described in our previous publication: "Clinical and Radiographic Characteristics of Class II Division 1 Malocclusion Patients Treated with Functional Appliances at Ho Chi Minh City Dental Hospital" (Can Tho Journal of Medicine and Pharmacy, 2024; Issue 80) [19]. In the present study, these data were further analyzed in the context of a randomized controlled trial comparing both appliances. No duplicate text or results have been reproduced from the earlier publication, and the current manuscript focuses on treatment outcomes and comparative analysis. This overlap has been transparently declared in accordance with Committee on Publication Ethics (COPE) and International Committee of Medical Journal Editors (ICMJE) guidelines [9].

2.4 Study procedure

Randomization followed a simple 1:1 allocation procedure with concealed assignment using sealed, opaque envelopes. Thirty slips labeled "Activator" and thirty slips labeled "PMA" were prepared, folded, and thoroughly mixed. Each slip was placed into an identical opaque envelope, which was then sealed and returned to a common box. The envelopes were reshuffled, and each participant selected one envelope, which determined group assignment. The allocation was recorded by an investigator who was independent of both the treatment procedures and data analysis (Fig. 1).

2.4.1 Appliances

The Activator appliance was custom-made in a standardized manner. The acrylic in the lateral segments was removed to allow the eruption of the posterior teeth. A passive maxillary labial bow was used to aid anterior retention and retrocline the maxillary incisors if they were proclined. The construction bite was often taken in the edge-to-edge position of the incisors. All Activator appliances were made at the same orthodontic dental lab according to a given prototype (Fig. 2).

2.4.2 PMA

The PMA used in this study was EF Line® appliances (Éducation Fonctionnelle, Orthoplus, Igny, France): included the EF Class II Standard, EF Class II 2 Steps, EF Class II Large, and EF Guide Evolution models. Appliance type for each patient was selected according to the manufacturer's recommendations, and all devices were supplied by the same manufacturer (Fig. 2).

The participants were instructed to wear the appliance 14–18 hours per day and to maintain good compliance during

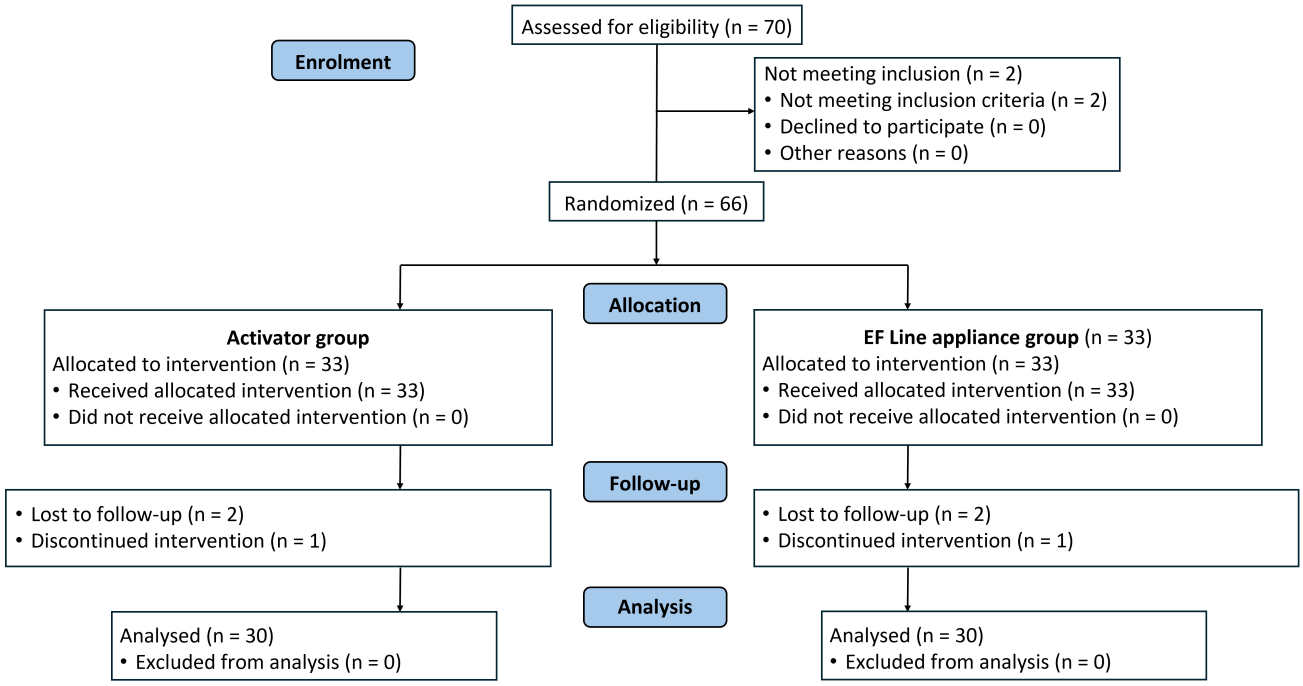

FIGURE 1. CONSORT flow diagram of the study.

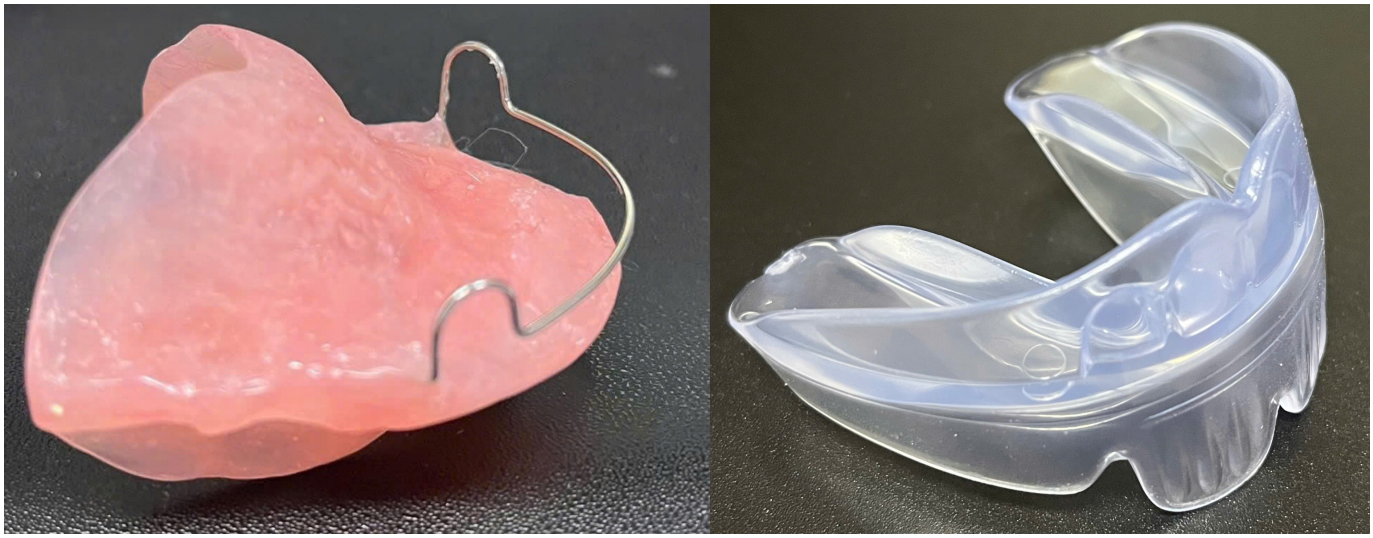

FIGURE 2. Activator appliance and EF Line® appliance.

the treatment period [2, 12, 20, 21]. Daytime wear could be divided into separate periods of at least 30 minutes. Monthly follow-up visits were performed. Lateral cephalograms were taken before treatment (T0) and after 6 months of treatment (T1) (Fig. 3).

2.5 Cephalometric analysis

All patients underwent lateral cephalometric radiography performed by an experienced X-ray technician using a Planmeca ProMax® 2D digital unit (Planmeca, Helsinki, Finland). Each image was imported into AudaxCeph software (version 6.0.50.3887, AUDAX d.o.o., Ljubljana, Slovenia) and standardized to life-size according to the calibration ruler on the radiograph (**Supplementary Fig. 1**).

Because cephalometric analysis can be affected by radiographic distortion, magnification, and landmark identification errors, several measures were taken to ensure accuracy. All radiographs were acquired by the same technician, and digital images were corrected for magnification using the software's internal scale. A single orthodontist performed all landmark identification and measurements. To assess intra-examiner reliability, 10 randomly selected radiographs were retraced and remeasured two weeks later. The intraclass correlation coefficient (ICC) exceeded 0.85, confirming the high reproducibility and reliability of the measurements.

2.6 Statistics

Statistical analyses were performed using SPSS (version 18.0, IBM Corp., Armonk, NY, USA). For categorical variables, the frequency (n) and proportion (%) were calculated. For

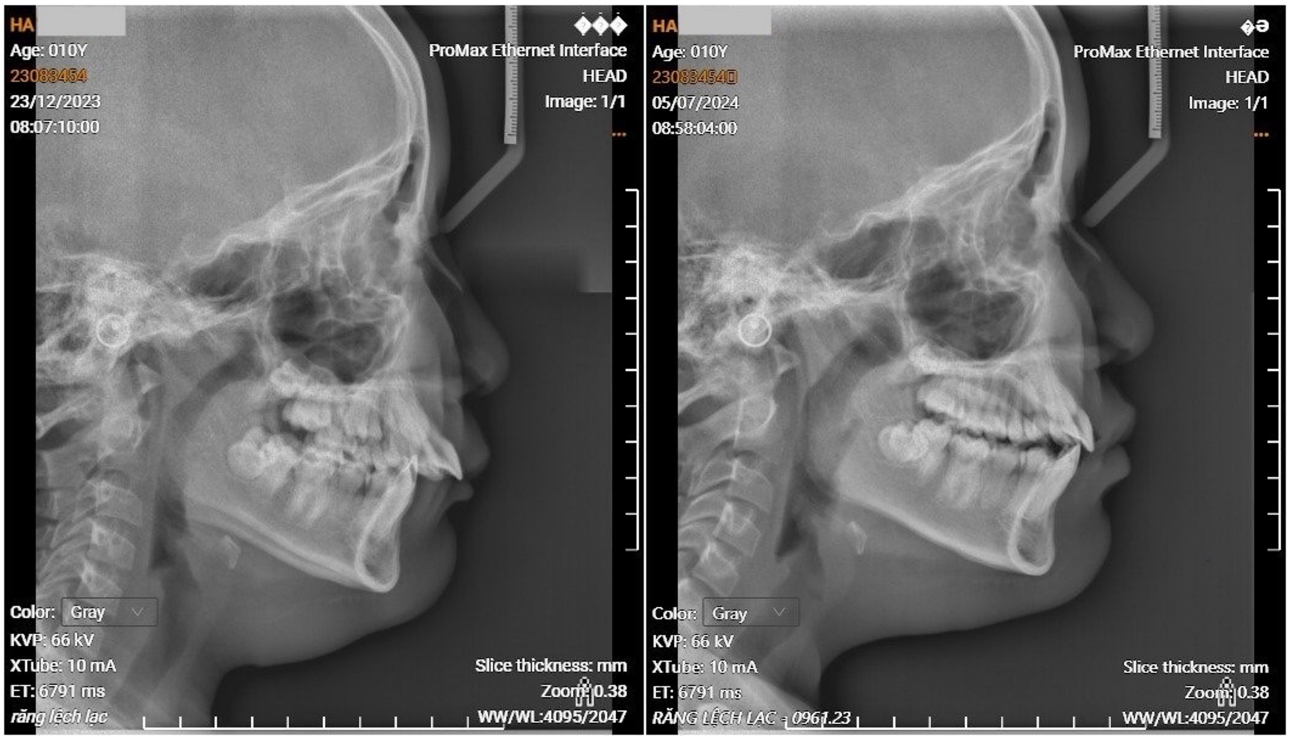

FIGURE 3. Lateral cephalograms at T0 (before treatment) and T1 after treatment (6 months later).

continuous variables, the mean and median were calculated. Treatment outcomes were assessed utilizing Fisher's exact test for categorical data, paired samples *t*-test and independent samples *t*-test for normally distributed continuous data, and the Wilcoxon test and Mann-Whitney U-test for non-ideal symmetric distributions of data. The skewness and kurtosis tests were used to assess the normality of continuous variables and select the most appropriate tests. *p*-values less than 0.05 were considered statistically significant.

3. Results

The Activator group included 13 boys and 17 girls, and the PMA group included 18 boys and 12 girls; the male-to-female ratios did not differ significantly between or within groups ($p > 0.05$).

The overall mean age of the 60 participants was 9.7 ± 1.31 years. Mean ages were 9.93 ± 1.20 years in the Activator group and 9.47 ± 1.38 years in the PMA group, with no significant age difference between groups ($p > 0.05$).

3.1 Pre- and post-treatment skeletal changes

In the Activator group, the SNB angle increased by 0.75 ± 1.23° ($p < 0.01$), while the ANB angle (−1.03 ± 0.92°) and Wits appraisal (−2.09 ± 1.16 mm) both decreased significantly ($p < 0.001$). Mandibular length increased by 3.0 ± 2.02 mm, posterior facial height by 2.34 ± 1.78 mm, and anterior facial height by 2.76 ± 1.97 mm (all $p < 0.001$). Maxillary length, the lower anterior facial ratio, and the SL (Sella–Line length) and SE (Soft tissue Esthetic measurement) measurements also increased ($p < 0.05$). Vertical relationships remained stable, with no significant changes in SN–GoGn or FH–MP angles ($p > 0.05$), indicating that mandibular growth direction was not altered.

In the PMA group, the SNB angle rose by 0.61 ± 1.36° ($p < 0.05$), the ANB angle decreased by −0.73 ± 0.91°, and the Wits appraisal decreased by −1.68 ± 1.35 mm ($p < 0.001$). Mandibular length increased by 1.98 ± 1.61 mm, posterior facial height by 1.47 ± 1.5 mm, and anterior facial height by 2.1 ± 1.94 mm (all $p < 0.001$). Maxillary length, the lower anterior facial ratio, and SL and SE measurements also increased significantly ($p < 0.05$), with no significant change in SN–GoGn or FH–MP angles ($p > 0.05$).

Between-group comparison showed significantly greater gains in mandibular length (Co–Gn) and posterior facial height (S–Go) in the Activator group than in the PMA group ($p < 0.05$) (Table 1).

3.2 Pre- and post-treatment dental changes

In the Activator group, significant dental changes were observed: the U1–SN angle decreased by −5.84 ± 3.72°, the U1–NA angle by −5.61 ± 4.0°, and the U1–NA distance by −1.36 ± 1.45 mm (all $p < 0.001$). The interincisal angle increased by 3.93 ± 4.9° and overjet decreased by −2.93 ± 1.93 mm ($p < 0.001$), while overbite decreased by −0.85 ± 1.13 mm ($p < 0.01$). The L1–MP and L1–NB angles also showed significant increases ($p < 0.05$).

TABLE 1. Skeletal index changes before and after treatment in the Activator group and PMA group.

	Activator group (mean ± SD)				PMA group (mean ± SD)				*p* (Δ Change)
	T0	T1	Δ Change	*p*	T0	T1	Δ Change	*p*	
SNA (°)	84.47 ± 2.99	84.18 ± 3.26	−0.29 ± 0.79	0.056*	83.6 ± 3.83	83.48 ± 3.56	−0.12 ± 1.60	0.683*	0.549[b]
SNB (°)	79.47 ± 3.16	80.22 ± 3.40	0.75 ± 1.23	0.002*	78.53 ± 3.18	79.15 ± 3.04	0.61 ± 1.36	0.019*	0.670[a]
ANB (°)	4.99 ± 1.60	3.96 ± 1.73	−1.03 ± 0.92	<0.001*	5.07 ± 1.72	4.34 ± 1.71	−0.73 ± 0.91	<0.001*	0.208[a]
FH–Npog (°)	85.00 ± 3.30	85.20 ± 3.40	0.16 ± 1.94	0.641*	83.89 ± 2.98	84.04 ± 2.56	0.16 ± 1.64	0.605*	0.446[b]
Wits (mm)	2.60 ± 1.94	0.50 ± 2.09	−2.09 ± 1.16	<0.001*	2.13 ± 2.21	0.45 ± 2.22	−1.68 ± 1.35	<0.001*	0.208[a]
Co–A (mm)	79.55 ± 4.72	80.70 ± 4.68	1.15 ± 1.88	0.002*	78.51 ± 4.55	79.32 ± 4.62	0.81 ± 1.98	0.033*	0.493[a]
Co–Gn (mm)	97.54 ± 4.82	100.54 ± 5.08	3.00 ± 2.02	<0.001*	95.95 ± 5.83	97.93 ± 6.28	1.98 ± 1.61	<0.001*	0.034[a]
(Co–Gn)–(Co–A) (mm)	17.99 ± 2.78	19.84 ± 3.24	1.85 ± 1.47	<0.001*	17.44 ± 3.35	18.62 ± 3.73	1.17 ± 1.27	<0.001*	0.061[a]
SN–GoGn (°)	29.79 ± 4.79	29.87 ± 4.86	0.08 ± 1.57	0.791*	30.06 ± 3.75	30.22 ± 4.01	0.17 ± 1.61	0.574*	0.827[a]
SN–OP (°)	14.01 ± 3.45	15.14 ± 3.43	1.13 ± 1.59	<0.001*	15.87 ± 3.16	16.87 ± 2.96	1.00 ± 2.04	0.011*	0.795[a]
FH–MP (°)	25.28 ± 5.71	25.71 ± 5.37	0.42 ± 2.32	0.326*	26.62 ± 4.07	27.07 ± 3.93	0.46 ± 2.35	0.295*	0.956[a]
S–Go (mm) (PFH)	68.51 ± 4.78	70.86 ± 4.85	2.34 ± 1.78	<0.001*	67.82 ± 4.28	69.29 ± 4.33	1.47 ± 1.50	<0.001*	0.035[b]
N–Me (mm) (AFH)	100.60 ± 4.40	103.4 ± 4.80	2.76 ± 1.97	<0.001*	100.37 ± 6.82	102.47 ± 7.29	2.10 ± 1.94	<0.001*	0.191[a]
ANS–Me (mm)	56.03 ± 3.15	57.95 ± 3.58	1.92 ± 1.59	<0.001*	56.44 ± 4.24	57.74 ± 4.59	1.30 ± 1.68	<0.001*	0.148[a]
LAFH/AFH (%)	52.97 ± 1.84	53.50 ± 1.75	0.53 ± 1.11	0.014*	53.10 ± 1.75	53.53 ± 1.80	0.40 ± 0.96	0.028*	0.637[a]
PFH/AFH (%)	68.14 ± 4.48	68.59 ± 4.45	0.46 ± 1.84	0.184*	67.61 ± 3.04	67.76 ± 2.97	0.15 ± 1.53	0.596*	0.485[a]
SL (mm)	45.04 ± 5.59	46.14 ± 6.26	1.10 ± 2.09	0.007*	43.42 ± 4.59	44.26 ± 4.79	0.84 ± 1.87	0.020*	0.614[a]
SE (mm)	18.45 ± 2.55	18.81 ± 2.61	0.36 ± 0.87	0.030*	18.05 ± 2.46	18.46 ± 2.43	0.41 ± 0.83	0.010*	0.821[a]

**Paired samples t-test; [a]Independent samples t-test; [b]Mann-Whitney U-test.*

SD: Standard Deviation; PMA: prefabricated myofunctional appliance; AFH: anterior facial height; LAFH: lower anterior facial height; PFH: posterior facial height; SL: Sella–Line length; SE: Soft tissue Esthetic measurement.

Similarly, the PMA group exhibited a decrease in U1–SN (−4.03 ± 5.28°), U1–NA (−3.92 ± 5.13°), and overjet (−2.43 ± 2.39 mm) (all $p < 0.001$). The U1–NA distance and overbite decreased by −0.99 ± 1.74 mm and −0.88 ± 1.34 mm, respectively (both $p < 0.01$). The interincisal angle increased by 2.83 ± 6.56° ($p < 0.05$), and the L1–MP angle, L1–NB angle, and L1–NB distance all rose significantly ($p < 0.05$).

Intergroup analysis revealed no significant differences in dental changes between the two appliances (Table 2).

3.3 Pre- and post-treatment soft tissue changes

In the Activator group, the Ls–E line distance increased by 0.84 ± 1.05 mm ($p < 0.001$), indicating reduced upper-lip protrusion relative to the E line. The nasolabial angle, facial convexity angle (Gl′–Sn–Pg′), and upper-lip height also increased significantly ($p < 0.05$). In the PMA group, the Ls–E line distance increased by 0.83 ± 1.23 mm ($p < 0.01$), likewise reflecting decreased upper-lip protrusion. Between groups, the PMA produced a significantly greater increase in Pg–Pg′ and total chin thickness than the Activator ($p < 0.05$) (Table 3).

4. Discussion

According to Baccetti *et al.* [22], the peak of mandibular growth occurs before the CS4 stage. Our sample selection criteria included patients aged 8 to 12 years, meaning that these patients still had significant potential for mandibular growth. Even if, at this skeletal stage, growth is not provided, a recent Cochrane systematic review showed that children and young adolescents would benefit from interceptive orthodontics because of a significant reduction in incisal trauma risk, as large overjet increases the possibility of incisor injury in these patients [23].

In this study, the evaluation was performed after 6 months of treatment. Bilgiç *et al.* [24] also conducted a study comparing the effectiveness of the Forsus and Activator appliances in treating Class II Division 1 malocclusion after 6 months of intervention. Madian *et al.* [15] studied cephalometric changes after functional treatment with twin block versus myobrace appliances in developing skeletal class II patients after 6 months of treatment. ShanthiniPriya *et al.* [25] also studied and compared the temporomandibular joint (TMJ) and skeletal changes three-dimensionally in growing patients with Class II malocclusion treated with the Twin block and Advansync appliance after the functional phase (6–8 months). Additionally, the goal of early orthodontic intervention is to achieve a Class I skeletal relationship as early as possible. Furthermore, no patients were recorded as dropping out.

4.1 Pre- and post-treatment skeletal changes

The results of this study showed that the activator appliance and the PMA did not produce significant between-group skeletal differences among people with Class II Angle 1 malocclusion (p (T0–T1) > 0.05), except for changes in the length of the mandible (Co–Gn) and the height of the back of the face (S–Go index). This suggests that the skeletal effects were almost identical between the two groups of patients treated with the activator appliance and the PMA.

However, the length of the mandible (Co–Gn) and height of the posterior facial level (S–Go) increased more in the activator group than in the PMA group ($p < 0.05$). The hard plastic construction of the activator appliance, in contrast to the soft plastic PMA, explains why it held the mandible firmly and didn't pull it back when the mandible advanced [26, 27]. The influence on the skeletal system was almost the same between the both appliance groups. Many studies have indicated that prefabricated functional appliances may impact mandibular length when compared to untreated children in the mixed dentition stage [23, 28]. Studies employing historical controls found that pre-fabricated functional appliances enhanced mandibular length by 2–4 mm compared with no treatment [21, 29]. A study by Idris *et al.* [12] compared how well activator and trainer appliances (ready-made functional appliances) worked for treating class II malocclusion Division 1. The SNB angle went up significantly more in the activator group than in the trainer group ($p < 0.05$), while the ANB angle went down significantly more in the activator group. Idris *et al.* [12] found that the Trainer appliance had a statistically significant influence on changes in SNB angle, Wits index, mandibular length (Co–Gn), anterior facial height (N–Me), and frontal mandibular facial height (ANS–Me) ($p > 0.05$). The Trainer appliance significantly affected SNA, ANB, and FH–MP angles ($p < 0.05$) [12]. In contrast, in Oshang *et al.* [30], there was no significant change in mandible size after Multi-P appliance treatment. Based on a previous study on prefabricated appliances, Das and Reddy found that there were no significant differences in Co–Gn distance between patients who were treated with prefabricated functional appliances and patients who were not treated [31]. Idris *et al.* [12] showed no significant increase in mandibular length in the prefabricated appliance group.

The findings indicate a stronger skeletal effect of the Activator specifically on mandibular elongation and vertical posterior facial growth. A plausible explanation is the Activator's rigid acrylic construction, which maintains a stable forward mandibular position and counteracts the natural tendency of the mandible to retract under muscular tension. In contrast, the PMA, fabricated from more flexible material, may allow slight mandibular recoil during function, leading to a less pronounced skeletal response in these dimensions [26, 27].

Studies employing historical controls found that prefabricated functional appliances enhanced mandibular length by 2–4 mm compared with no treatment [12, 29]. In the present study, the skeletal effects were nearly equivalent between the groups treated with both appliances. This may be partially explained by the fact that our sample had a mild Class II skeletal discrepancy, as indicated by the ANB angle of 5.03 ± 1.65°. According to Bollhalder *et al.*'s [32] study, children with mild malocclusion have a higher proportion of cases with an ANB angle <7°.

TABLE 2. Dental index changes before and after treatment in the Activator group and PMA group.

	Activator group (mean ± SD)				PMA group (mean ± SD)				*p* (Δ Change)
	T0	T1	Δ Change	*p*	T0	T1	Δ Change	*p*	
U1–SN (°)	119.81 ± 8.53	113.97 ± 8.01	−5.84 ± 3.72	<0.001*	113.40 ± 9.64	109.37 ± 9.33	−4.03 ± 5.28	<0.001*	0.130[a]
U1–NA (°)	35.37 ± 7.22	29.76 ± 7.32	−5.61 ± 4.00	<0.001*	29.82 ± 9.62	25.89 ± 8.96	−3.92 ± 5.13	<0.001*	0.159[a]
U1–NA (mm)	8.15 ± 1.96	6.79 ± 2.19	−1.36 ± 1.45	<0.001*	5.97 ± 2.99	4.98 ± 2.57	−0.99 ± 1.74	0.0041*	0.384[a]
L1–MP (°)	98.94 ± 7.05	100.63 ± 7.42	1.68 ± 4.07	0.030*	94.82 ± 6.31	96.21 ± 5.57	1.38 ± 3.67	0.047*	0.760[a]
L1–NB (°)	30.09 ± 5.15	32.58 ± 5.14	2.48 ± 3.89	0.003**	25.79 ± 7.72	27.82 ± 6.27	2.02 ± 4.47	0.019*	0.672[a]
L1–NB (mm)	6.02 ± 1.82	6.50 ± 1.99	0.48 ± 1.32	0.055*	4.90 ± 2.58	5.61 ± 2.63	0.71 ± 1.24	0.003*	0.490[a]
U1–L1 (°)	109.77 ± 9.50	113.72 ± 8.76	3.93 ± 4.90	<0.001**	119.32 ± 14.15	122.14 ± 13.17	2.83 ± 6.56	0.013**	0.363[b]
Overjet (mm)	8.58 ± 2.06	5.65 ± 2.22	−2.93 ± 1.93	<0.001*	7.73 ± 2.48	5.30 ± 2.12	−2.43 ± 2.39	<0.001**	0.169[b]
Overbite (mm)	3.83 ± 1.19	2.98 ± 1.01	−0.85 ± 1.13	0.001**	4.12 ± 1.41	3.24 ± 1.30	−0.88 ± 1.34	0.001*	0.925[a]

**Paired samples t-test; **Wilcoxon test; [a]Independent samples t-test; [b]Mann-Whitney U-test.*
SD: Standard Deviation; PMA: prefabricated myofunctional appliance.

TABLE 3. Soft tissue index changes before and after treatment in the Activator group and PMA group.

	Activator group (mean ± SD)				PMA group (mean ± SD)				*p* (Δ Change)
	T0	T1	Δ Change	*p*	T0	T1	Δ Change	*p*	
Nasolabial angle (°)	94.98 ± 12.28	97.45 ± 11.47	2.47 ± 6.50	0.045*	94.40 ± 9.59	96.75 ± 8.54	2.34 ± 7.08	0.079*	0.941[a]
Ls–E line (mm)	−2.08 ± 1.86	−1.25 ± 1.77	0.84 ± 1.05	<0.001*	−2.65 ± 1.49	−1.82 ± 1.93	0.83 ± 1.23	0.001**	0.973[a]
Li–E line (mm)	−2.88 ± 2.22	−3.02 ± 2.25	−0.14 ± 1.05	0.472*	−2.69 ± 2.61	−2.65 ± 2.09	0.04 ± 1.88	0.900*	0.642[a]
Pg–Pg′ (mm)	12.24 ± 2.42	11.94 ± 2.13	−0.29 ± 1.30	0.144**	11.71 ± 2.28	12.04 ± 2.28	0.33 ± 0.97	0.115**	0.039[a]
Gl′–Sn–Pg′ (°)	164.08 ± 5.64	164.99 ± 5.81	0.91 ± 1.87	0.012*	165.13 ± 5.21	165.72 ± 5.12	0.59 ± 1.80	0.084*	0.494[a]
Upper lip thickness (mm)	11.04 ± 1.49	10.93 ± 1.55	−0.11 ± 1.16	0.608*	11.35 ± 1.88	11.72 ± 1.90	0.38 ± 1.42	0.156*	0.150[a]
Total chin thickness (mm)	14.98 ± 2.13	14.75 ± 1.99	−0.23 ± 1.16	0.182**	14.54 ± 2.20	14.88 ± 2.14	0.34 ± 0.86	0.109**	0.037[a]
Upper lip height (mm)	22.15 ± 2.29	22.94 ± 1.80	0.79 ± 1.61	0.011*	22.43 ± 1.95	22.84 ± 2.43	0.41 ± 1.31	0.098*	0.314[a]

**Paired samples t-test; **Wilcoxon test; [a]Independent samples t-test.*
SD: Standard Deviation; PMA: prefabricated myofunctional appliance.

The magnitude of skeletal response is closely related to both the amount and direction of mandibular advancement as well as to the rigidity of the appliance. A more rigid appliance, such as the Activator, provides continuous forward posturing of the mandible, promoting remodeling at the condylar cartilage and glenoid fossa through increased functional loading. In contrast, flexible prefabricated appliances like the EF Line® may dissipate part of this force through material deformation, resulting in a smaller skeletal effect. This explanation aligns with previous experimental findings that mechanical stability and sustained mandibular advancement are critical determinants of condylar adaptation and mandibular lengthening [33, 34].

4.2 Pre- and post-treatment dental changes

The results of reducing overbite and having the mandibular incisors protrude more than the mandibular jaw were identical in both appliance groups. The changes in the other dental indices were not significantly different between the two appliance groups (p (T0–T1) > 0.05), which means that the both appliance groups had the same effect on the teeth. Idris *et al*. [12] did a study that compared how well the Activator and Trainer appliances (ready-made functional appliances) treated class II division 1. The overjet index (overbite) went down a lot more in the Activator group than in the Trainer group ($p < 0.05$). Idris *et al*. [12] found that the Trainer appliance tilted maxilla incisors backward, resulting in a significant decrease in the U1–SN angle index ($p < 0.05$) and overjet index (overbite) ($p < 0.001$). The L1–MP, U1–L1 angles, and overbite index did not alter significantly with the Trainer appliance ($p > 0.05$) [12]. Thus, the activator appliance and the PMA both have the effect of tilting the maxilla incisors backward, reducing the protrusion of the maxilla incisors compared to the maxilla jaw as shown by the decreased U1–SN, U1–NA, and U1–NA (mm) indexes, tilting the mandibular incisors forward as shown by the increased L1–MP and L1–NB indexes, straightening the maxilla incisor axis as shown by the increased U1–L1 index, reducing overbite and overbite as shown by the decreased overjet. Comparing the changes in dental indices after 6 months of treatment on the lateral cephalometric radiographs between the activator group and the PMA group, the results of this study showed that the changes in teeth when treating class II division 1 angle with the activator appliance and the PMA were not statistically different, with p (T0–T1) > 0.05 in all dental indices. The similar influence on teeth between the two groups was most clearly seen in the reduction of overjet and overbite, and in making the mandibular incisors protrude more than the mandibular jaw (L1–NB mm).

The dental changes observed in both appliance groups, including proclination of the lower incisors and retroclination of the upper incisors, are typical compensatory mechanisms in functional treatment. These occur as the neuromuscular balance between the lips, cheeks, and tongue is altered during mandibular advancement, leading to modified pressure on the anterior teeth. Similar trends have been reported in studies using Twin Block and Trainer appliances, supporting the notion that dentoalveolar adaptation complements skeletal correction in Class II treatment [35].

4.3 Pre- and post-treatment soft tissue changes

Before and after 6 months of treatment, there wasn't a big difference in soft tissue indices between the two groups (the activator group and the PMA group), with p (T0–T1) > 0.05. The only ones that were different were the Pg–Pg′ index and the total chin thickness index, which had p (T0–T1) < 0.05. Relief from lip tension often leads to an increase in lip thickness [36]. Thus, the EF Line® appliance may contribute to a measurable reduction in upper-lip tension. This effect is consistent with its design as a functional educational appliance (Éducation Fonctionnelle), which aims not only to advance the mandible but also to retrain perioral musculature. By encouraging proper lip seal and balanced activity of the lips, cheeks, and tongue, the PMA helps eliminate deleterious oral habits, such as chronic mouth breathing, tongue thrusting, or incompetent lip posture, that can perpetuate a Class II malocclusion. Improved neuromuscular coordination around the oral cavity may, therefore, support more stable occlusal relationships and harmonious facial growth, even when skeletal changes are modest compared with a rigid custom appliance like the Activator. In contrast to the research results of Idris *et al*. [12], which compared the effectiveness of treating class II malocclusion with the Activator appliance and the Trainer appliance, the Trainer appliance did not significantly affect the changes in soft tissue indices ($p > 0.05$). Specifically, the nasolabial angle index, the distance between the maxilla and mandibular lips to the E line (Ls–E and Li–E), and the Gl′–Sn′–Pg′ angle did not statistically change in the Trainer group. Idris *et al*. [12] found that the activator group significantly improved the Gl′–Sn–Pg′ angle compared with the trainer group ($p < 0.01$) [2]. However, Maetevorakul *et al.* [37] found that morphological features of soft tissue, age, gender, and type of therapy all had an impact on soft tissue alterations. Alhumadi *et al.* [38] found that gender influences the thickness of soft tissue, whereas Tentolouri *et al.* [39] discovered that when muscle thickness is thin, the incisors lean forward more.

Both appliances effectively corrected Class II Division 1 malocclusion, but their strengths differ. Activator: Because it produced a significantly greater increase in mandibular length and posterior facial height, the Activator is preferable when the primary treatment goal is to stimulate forward mandibular growth and enhance lower facial height. PMA: With its myofunctional training design and ease of use, the EF Line® appliance is particularly suitable for patients who need improvement in oral functional habits, such as lip seal, tongue posture, and muscle coordination, or when a ready-made appliance is desired to simplify clinical delivery.

The soft-tissue adaptations observed with the PMA appliance may stem from its influence on muscle tone and habitual posture. By promoting nasal breathing and balanced perioral activity, the appliance reduces hyperactivity of the mentalis and orbicularis oris muscles, allowing improved lower lip competence and enhanced chin projection. These neuromuscular changes can occur independently of skeletal modification, explaining why soft-tissue improvement was detected even when skeletal differences between appliances were minimal [18, 40].

Taken together, these findings suggest that the differences in skeletal and soft-tissue effects between the Activator and PMA are primarily attributable to appliance design, rigidity, and the pattern of neuromuscular adaptation they induce. Understanding these mechanisms provides a biological rationale for the comparable treatment outcomes observed across studies using various functional appliance systems.

Both Activator and PMA are effective in treating malocclusions and skeletal discrepancies. However, this study has several limitations. The six-month follow-up may not capture long-term skeletal growth or treatment stability. Cephalometric measurements were performed by a single, non-blinded examiner, which could introduce measurement bias despite high intra-examiner reliability. The sample size was relatively small and drawn from a single center, limiting generalizability. Multiple EF Line® subtypes were used according to manufacturer guidelines, and subtle design differences may have contributed to outcome variability. Finally, patient compliance was based on self- and parent reports rather than objective monitoring, making the true effect of wear time difficult to assess. Larger, multicenter studies with longer follow-up, objective compliance tracking, and blinded assessments are needed to validate these findings.

5. Conclusions

In the domains of skeletal, dental, and soft tissue, an effective comparison might be made between the Activator and the PMA. Both appliances contribute to the treatment's effectiveness rate. The EF Line® appliance, on one hand, reduces lip tension and serves as a functional educational tool (Éducation Fonctionnelle). It functions as a guide to correct undesirable habits of the lips, cheeks, and tongue. On the other hand, the activator appliance has a greater impact on skeletal changes compared with the PMA.

AVAILABILITY OF DATA AND MATERIALS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

AUTHOR CONTRIBUTIONS

LNL, NNKL, and BTCL—collected and analyzed the data. KNT—contributed to data interpretation and statistical analysis. KPVL—contributed to study supervision and critical revision of the manuscript. All authors reviewed and edited the manuscript. All authors designed the study and wrote the manuscript. All authors read and approved the final version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This retrospective study was conducted according to the guidelines of the Declaration of Helsinki, and all procedures were performed following the requirements of the Ethics Committee of the University of Medicine and Pharmacy. The Can Tho University of Medicine and Pharmacy Ethics Council in Biomedical Research (No. 23.340.HV/PCT-H) signed the study on 12 April 2023. Written informed consent was obtained from all participants and from the parents or legal guardians of minor participants prior to enrollment. All data were anonymized before analysis.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest. The product names cited in the manuscript were included only for identification purposes and do not imply any financial or commercial relationships.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.jocpd.com/files/article/2028753204760461312/attachment/Supplementary%20material.docx.

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