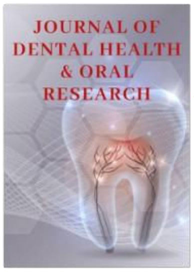

e-ISSN 3050-9432
Journal of Dental Health and Oral Research

ATHENAEUM SCIENTIFIC PUBLISHERS

Research Article

Effectiveness of the Activator in Overjet Reduction: Impact of Wear Time and Cephalometric Features in Class II/1 Patients

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Citation: Goch NBV, et al. Effectiveness of the Activator in Overjet Reduction: Impact of Wear Time and Cephalometric Features in Class II/1 Patients. J Dental Health Oral Res. 2025;6(2):1-10.

https://doi.org/10.46889/JDHOR.2025.6221

Received Date: 17-06-2025

Accepted Date: 30-06-2025

Published Date: 08-07-2025

Abstract

Introduction: The success of Angle Class II malocclusion correction using functional appliances is highly variable. This study aimed to investigate the relationship between overjet reduction, activator wear time measured by a microsensor and the patient's skeletal and dental cephalometric features.

Methodology: The study included 96 patients with moderate to severe Class II/1 malocclusion treated with activators. Overjet reduction was measured in millimeters and also given as a percentage change. Wear time was recorded using a Theramon® microsensor. Lateral cephalometric radiographs taken before treatment were analyzed. Multivariable analysis was used to assess whether wear time and cephalometric features predicted overjet reduction. Results: The initial median overjet was 8.0 mm, which declined to 2.0 mm after activator use. Overjet reduction was moderately correlated with activator wear time (R = 0.31; P = 0.0019). Mean activator wear time per day was positively predictive of overjet reduction (estimate = 2.418; P = 0.0009), whereas the Sella-Nasion-Point A (SNA) angle had a negative predictive value (estimate = -1.992; P = 0.0134).

Conclusion: Activator wear time partially predicts overjet reduction, but skeletal features also play a role. A significant reduction in overjet is associated with a smaller SNA angle. In patients with maxillary protrusion, the effectiveness of the activator may be reduced.

Keywords: Orthodontics; Angle Class II/1; Functional Appliance; Microsensor; Cephalometrics

Abbreviations

CE: Conformité Européenne (European Conformity); CI: Confidence Interval; CVM: Cervical Vertebral Maturation (growth stage index); mm: Millimeters; P: P-value (statistical significance); R: Pearson correlation coefficient; SD: Standard Deviation; 2D: Two-Dimensional; %: Percent / Percentage; ®: Registered Trademark

Introduction

Activators are frequently used for Angle Class II correction in growing patients. These types of functional appliances position the jaw forward, modifying the existing balance among the dentition, soft orofacial structures and musculature. Patient cooperation is considered a key determinant of successful treatment with functional appliances. Cassut, et al., concluded that cooperation is the only factor that significantly influences treatment success, basing their assessment of patient cooperation on oral hygiene, number of missed appointments and reports of poor activator fit [1]. Of note, the study did not include wearing time of the activator as a measure of cooperation.

Actual wearing time of a functional appliance is reported to be lower than the orthodontist's recommendation [2-4], averaging only about 50% of the prescribed duration [5]. In addition, wearing time correlates positively with the reduction in overjet [2]. Self-report can diverge from actual wearing time, but objective measures are possible using a Theramon® microsensor. The use of microsensors in activators allows for the identification of patients who, despite adhering to the recommended daily wearing time, have not experienced full sagittal skeletal and dental Class II corrections. Insufficient correction suggests the involvement of dental and/or skeletal factors in treatment success. Research already has addressed whether cephalometric values can be predictors of treatment success with functional appliances. Ahn, et al., identified four cephalometric predictors of a favorable treatment outcome with the Bionator: a horizontal growth pattern, a near-normal anteroposterior relationship between the maxilla and the mandible, retrusive mandibular incisors and a retrusive lower lip [6].

To the best of our knowledge, few studies have focused on the relationship among microsensor- measured activator wear time, overjet reduction and skeletal and dental cephalometric features. The aim of this study was to investigate the relationship among these three components using a Theramon® microsensor to determine which factors predict the success or failure of activator treatment in patients with Class II Division I malocclusion.

Methodology

Study Design

Patients were selected from 375 children with Angle Class II malocclusion who started orthodontic functional appliance treatment with an activator during 2014 to 2019, when all activators were equipped with a microsensor at our university clinic. For this retrospective study, only patients with moderate to severe Class II/1 malocclusions were included.

Participants/Subjects

The following inclusion criteria were applied: molar relationship of at least half a cusp Class II on one side, with normal or proclined maxillary incisors (Class II Division 1 malocclusion) and an overjet of at least 6 mm. Patients with syndromes, systemic diseases or congenital craniofacial or dental anomalies were excluded, as were patients with missing or incomplete microsensor data or early discontinuation of activator treatment and those requiring extractions or receiving fixed functional appliances for Class II correction (Fig. 1).

The study group ultimately consisted of 96 patients with moderate to severe Class II/1 malocclusion treated with an activator. Of the 96 patients, 68 were treated with a T appliance, 19 with a Twin-block, 4 with a Monoblock, 3 with a semi-open activator, 1 with a Bionator and 1 with a van Beek activator.

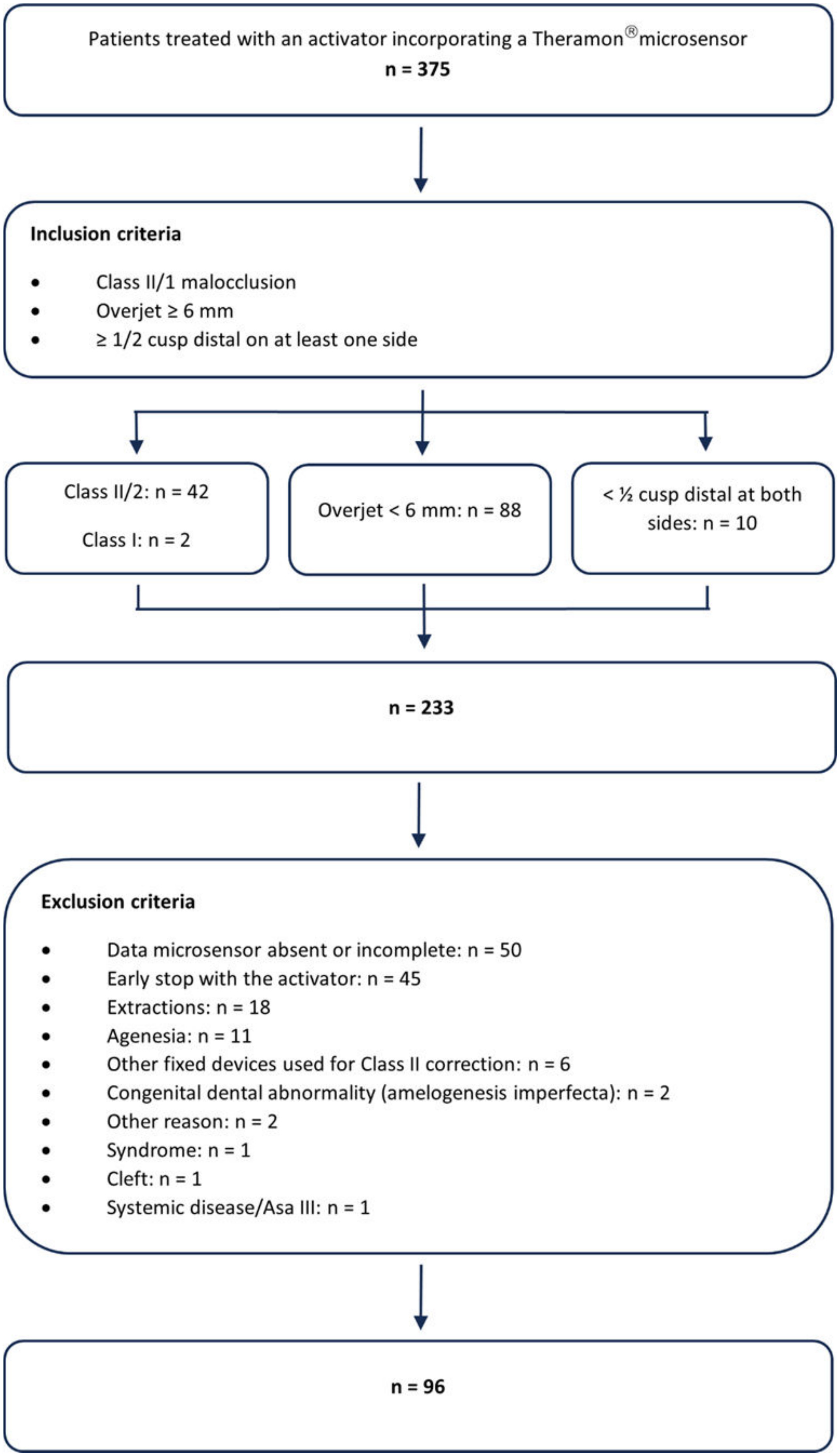

Figure 1: Flow chart of patient selection.

Data Collection
To measure wearing time objectively, all activators were equipped with a Theramon® microsensor (Gschladt Company, Hargelsberg, Austria). Patients and parents were informed about the presence of the microsensor in the activator before treatment. The microsensor, measuring 12.8 × 8.7 × 4.2 mm (width × height × depth), was inserted into the polymer material of the functional appliance by a dental technician and activated according to the manufacturer's instructions. Its function is to record the time that the activator reaches a temperature of more than 35°C as the wearing time. The Theramon® reading station reads the microsensor and creates a diagram with the daily activator wearing time and the average wearing time over the last treatment period. Check-up appointments during activator treatment were scheduled every 6 to 8 weeks. Each patient was informed about the importance of wearing the activator correctly, with the recommended wearing time of the activator being from 16 to 22 hours per day. The Theramon® microsensor data were read at each visit.

To assess overjet reduction, the overjet was measured at each activator check-up appointment. The distance between the buccal surfaces of the maxillary and mandibular central incisors was recorded using a dental probe. This measurement procedure is part of the standard treatment protocol at our university clinic and was therefore performed routinely for all activator patients.

Data Analysis
As part of the diagnosis and treatment plan, a lateral cephalometric radiograph (Planmeca® ProMax 2D, Helsinki, Finland) was taken for each patient for subsequent cephalometric analysis. Viewbox® (version 3.1.1.9; dHAL, Kifissia, Greece), a CE-certified computerized cephalometric analysis program widely used in orthodontic research, was used to analyze the cephalometric data. Point placement was carried out with an on-screen cursor and linear and angular values were calculated (Table 1) and the Radboud analysis applied. Values and variables used in this analysis have been previously described [7,8]. All images were evaluated by two investigators: twice by one investigator for assessing intra- observer reliability and once by the second investigator for evaluating interobserver reliability.

Measurement	Description	Purpose
Skeletal		
SNA (°)	The angle between the sella/nasion plane and the nasion/A plane	The anteroposterior position of the maxilla in relation to the anterior cranial base
SNB (°)	The angle between the sella/nasion plane and the nasion/B plane	The anteroposterior position of the mandible in relation to the anterior cranial base
NL/ML (°)	The angle between the nasal line and the mandibular line	The vertical skeletal jaw relation
Dental		
ILs/NL (°)	The maxillary incisor inclination angle to the nasal line	The inclination of the upper incisors relative to the palatal plane
Is/APog (mm)	The maxillary incisor to A-pogonion line	The position of the upper incisors relative to the A-pogonion line
ILi/ML (°)	The mandibular incisor inclination angle to the mandibular line	The inclination of the lower incisors relative to the mandibular plane
Ii/Apog (mm)	The mandibular incisor to the A-pogonion line	The position of the lower incisors relative to the A-pogonion line

Table 1: Description of the analyzed linear and angular cephalometric skeletal and dental measurements.

Age at the start of treatment, total activator treatment period and percentage overjet reduction showed a normal distribution for boys and for girls, as evaluated by the Kolmogorov-Smirnov test. The independent-samples t-test was applied to compare differences between genders in age, total activator treatment period and percentage overjet reduction.

The Kolmogorov-Smirnov test identified a non-normal distribution for mean activator wear time per day for all patients and by gender, overjet in millimeters before and after activator treatment and overjet reduction in millimeters. The non-parametric Mann-Whitney test thus was used to compare between-gender differences in mean activator wear time per day and overjet reduction in millimeters, along with overjet (in millimeters) before and after activator treatment.

Pearson's r correlation coefficient was used to determine correlations between age at the start of activator treatment and mean activator wear time per day, total activator treatment period and mean activator wear time, overjet reduction in millimeters and mean activator wear time and percentage overjet reduction and mean activator wear time. Intra- and interobserver agreement for cephalometric measurements also was assessed using Pearson's r correlation coefficient.

Multiple linear regression was used to determine the correlation between cephalometric measurements and percentage overjet reduction after activator treatment and the correlation among cephalometric measurements, mean activator wear time per day and percentage overjet reduction after activator treatment. All statistical analyses were performed using GraphPad Prism software, version 9.00 for Windows (GraphPad Software).

Results Participants

The study group consisted of 50 boys and 46 girls. At the start of activator treatment, the mean age for all patients was 11.9 (range: 8.7-14.3) years. Boys and girls differed significantly in mean age at the start of activator treatment (P = 0.0019; boys, 12.2 [range: 10.3-14.1] years; girls, 11.6 [range: 8.7-14.3] years). The median CVM index for all patients was stage II, with a range from stage I to stage IV.

Activator Treatment

The median of the mean activator wear time per day for all patients was 10.57 hours (range: 3.32- 18.02 hours; interquartile range: 9.47-12.31 hours) and in the gender comparison, it was 10.67 hours for boys and 10.57 hours for girls (P = 0.71). Patient age at the start of activator treatment was negatively correlated with mean activator wear time per day (P = 0.0062; R = -0.28). The mean total activator treatment period was 38.60 weeks (range: 16.14-86.86 weeks). The mean total activator treatment time was 38.50 weeks for boys and 38.71 weeks for girls, which was not significantly different (P = 0.9402). Total activator treatment period (in weeks) negatively correlated with mean activator wear time per day (P = 0.0009; R = - 0.33).

Overjet Outcomes

Median overjet before activator treatment (8.0 mm) differed significantly from median overjet after treatment (2.0 mm; P < 0.0001; Fig. 2), for a median overjet reduction of 6.0 mm (Fig. 2) or 75% (Fig. 2). In the between-gender comparison, the median overjet reduction after activator treatment was 6.0 mm for boys and 5.8 for girls, which was not a significant difference (P = 0.3626). The percentage reduction also did not differ significantly between genders (76.52% for boys and 70.35% for girls; P = 0.0848).

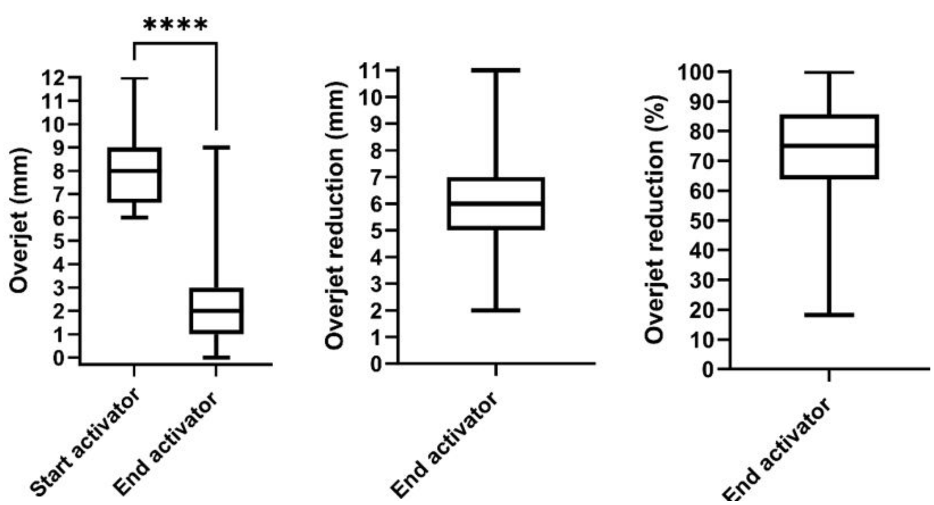

Figure 2: Overjet reduction after activator treatment. A) Overjet in millimeters, compared before and after activator treatment. The pre-treatment median was 8.0 (range: 6.0-12.0; interquartile range: 6.63-9.0) mm and the post-treatment median was 2.0 (range: 0.0-9.0; interquartile range: 1.0-3.0) mm (P < 0.0001. B) Median post-treatment reduction. Median post-treatment reduction after activator treatment was 6.0 (range: 2.0-9.0; interquartile range: 5.0-7.0) mm. C) Percentage overjet reduction. The median percentage overjet reduction was 75% (range: 18.8%-100.0%; interquartile range: 63.64%-85.71%).

Overjet reduction (in millimeters) after activator treatment correlated with mean activator wear time per day (P = 0.0016; R = 0.32; Fig. 3). The percentage overjet reduction after activator treatment also correlated with the mean activator wear time per day (P = 0.0019; R = 0.31; Fig. 3).

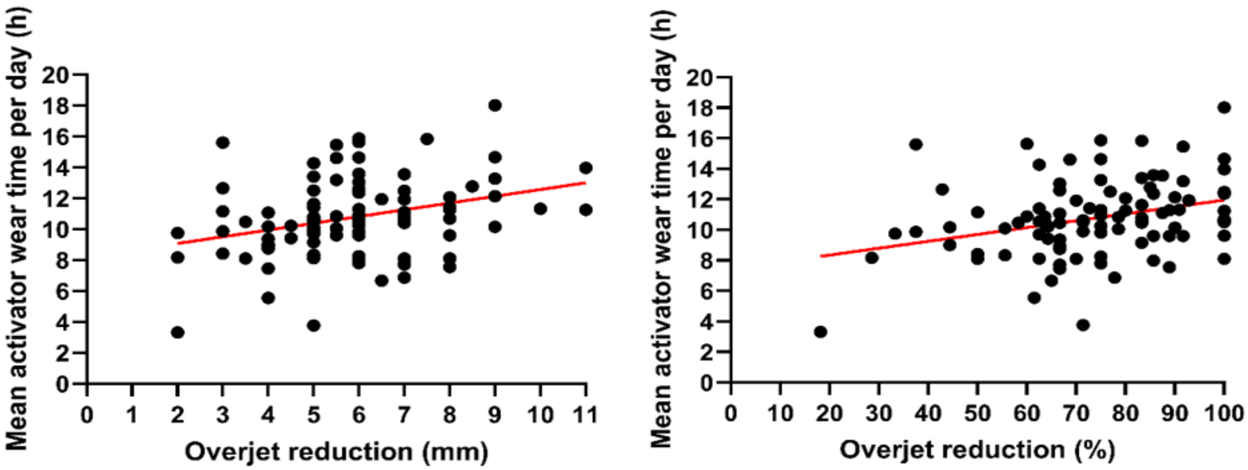

Figure 3: Correlation between overjet reduction after activator treatment and mean activator wear time per day. A) Scatterplot of overjet reduction (in mm) after activator treatment and mean activator wear time per day (P = 0.0016; Red line: R = 0.32). B) Scatterplot of percentage overjet reduction with activator treatment and mean activator wear time per day (P = 0.0019; Red line: R = 0.31).

Post-treatment overjet reduction correlated with pre-treatment overjet values (P < 0.0001; R = 0.6209; Fig. 4). The percentage overjet reduction, however, did not correlate with overjet measures at the start of activator treatment (P = 0.5774; R = -0.05758; Fig. 4). Compared with the length-length comparison in millimeters, the calculation of overjet reduction as a percentage offers the better representation and a fairer comparison of the magnitude of reduction relative to the initial overjet.

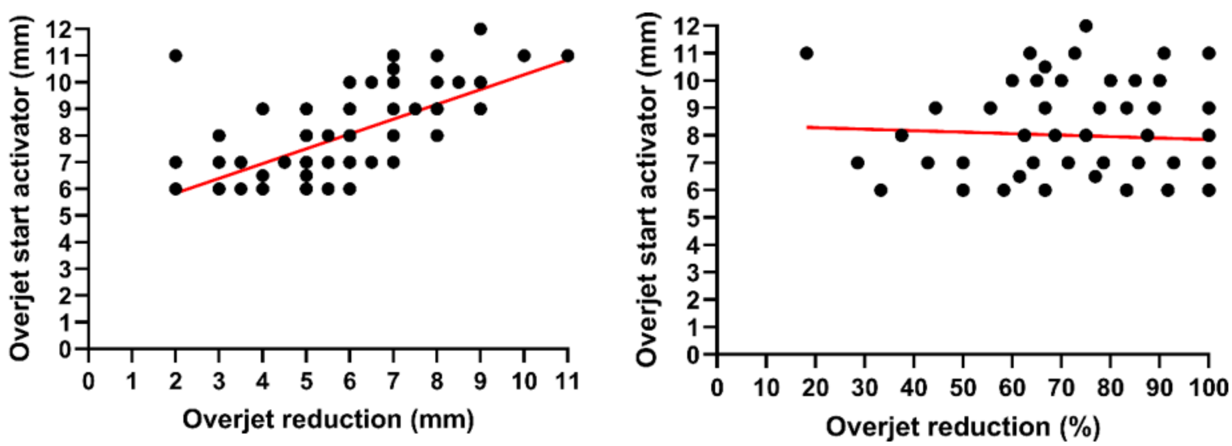

Figure 4: Correlation of pre- and post-treatment overjet reduction. A) Values in millimeters. Post-treatment overjet reduction correlated with pre-treatment overjet (P < 0.0001; Red line: R = 0.6209). B) Percentage change. The percentage change in overjet after treatment did not correlate with pre-treatment values in millimeters (P = 0.5774; Red line: R = -0.05758).

Cephalometric Measurements and Correlation Analyses

Pearson's correlation coefficient was used to determine intra-observer and interobserver agreement for cephalometric measurements. All values were >0.81, indicating very good intra- and interobserver agreement for all skeletal and dental cephalometric measurements. The cephalometric measurements showed a relatively wide range in both the angular and distance measurements (Table 2), indicating substantial variability in the values.

Measurement	Mean	SD	Minimum	Maximum
Skeletal				
SNA (°)	79.09	3.734	69.70	90.75
SNB (°)	76.01	3.367	68.00	84.45
NL/ML (°)	28.69	4.587	17.80	43.60
Dental				
ILs/NL (°)	112.7	5.980	100.4	129.2
Is/APog (mm)	10.07	2.170	4.900	15.45
ILi/ML (°)	98.44	6.343	82.90	119.4
Ii/Apog (mm)	2.478	1.967	-2.000	6.550

Table 2: Skeletal and dental cephalometric measurements at the start of activator treatment. Mean values calculated from cephalometric measurements 1 and 2 by the first observer (NBG); SD: Standard Deviation.

Multiple linear regression was used to examine correlations between cephalometric measurements and percentage overjet reduction and showed a negative association of SNA with the percentage overjet reduction (estimate = -2.092; $P < 0.05$; Table 3).

Measurement Intercept	Estimate	Standard Error	95% CI	/t/	P
Overjet reduction %	257.5	118.7	21.58 to 493.5	2.169	0.0328*
Skeletal					
SNA (°)	-2.092	0.8357	-3.753 to -0.4318	2.504	0.0141*
SNB (°)	1.436	1.023	-0.5976 to 3.470	1.403	0.1640
NL/ML (°)	-0.5393	0.7642	-2.058 to 0.9793	0.7058	0.4822
Dental					
ILs/NL (°)	-0.7580	0.5808	-1.912 to 0.3961	1.305	0.1952
Is/APog (mm)	0.9852	1.735	-2.462 to 4.432	0.5680	0.5715
ILi/ML (°)	-0.3860	0.4986	-1.377 to 0.6048	0.7742	0.4409
Ii/Apog (mm)	0.5225	1.531	-2.520 to 3.565	0.3413	0.7337

Table 3: Results of multiple linear regression on percentage overjet reduction and skeletal and dental cephalometric values. CI, confidence interval.

Multiple linear regression analysis with percentage overjet reduction also showed a negative association with SNA (estimate = -1.992; $P < 0.05$) and a positive association with mean activator wear time per day (estimate = 2.418; $P < 0.001$; Table 4). These findings indicate a correlation among a greater percentage overjet reduction, a small SNA angle and a higher mean activator wear time (Fig. 5).

Measurement Intercept	Estimate	Standard Error	95% CI	/t/	P
Overjet reduction %	216.8	112.7	-7.186 to 440.8	1.924	0.0576
Adherence					
Mean activator wear time per day (h)	2.418	0.7047	1.018 to 3.819	3.432	0.0009***
Skeletal					
SNA (°)	-1.992	0.7893	-3.561 to -0.4233	2.524	0.0134*
SNB (°)	1.695	0.9689	-0.2314 to 3.620	1.749	0.0838
NL/ML (°)	-0.5043	0.7214	-1.938 to 0.9294	0.6992	0.4863
Dental					
ILs/NL (°)	-0.6950	0.5485	-1.785 to 0.3951	1.267	0.2085

Is/APog (mm)	0.2819	1.650	-2.998 to 3.562	0.1709	0.8647
ILi/ML (°)	-0.5407	0.4727	-1.480 to 0.3989	1.144	0.2558
Ii/Apog (mm)	1.062	1.454	-1.827 to 3.951	0.7305	0.4671

Table 4: Results of multiple linear regression on percentage overjet reduction, activator wear time and skeletal and dental cephalometric values.

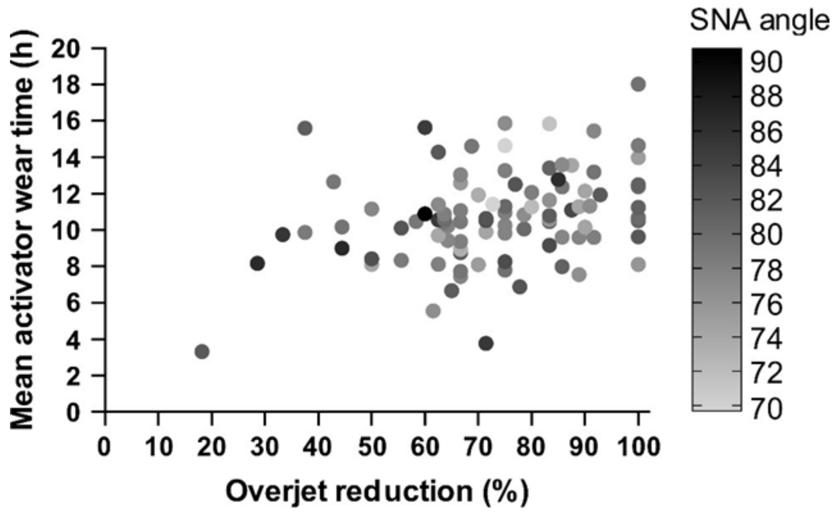

Figure 5: Results of multiple linear regression of percentage overjet reduction, mean activator wear time and SNA angle (in degrees).

Discussion

The reasons for the significant variability in treatment response to functional appliances for correcting Class II malocclusion in growing patients are not fully understood. The aim of this study was to examine the relationship between overjet reduction and objective activator wear time and to evaluate cephalometric dental and skeletal factors that may predict the effectiveness of functional appliances. To objectively measure the wear time, the activators used in this study were equipped with Theramon® microsensors.

Our findings indicate a positive correlation between overjet reduction and the daily activator wearing time. Treatment with functional appliances resulted in a median percentage reduction of 75% from the initial overjet and median length reduction of 6 mm. Additionally, the SNA point emerged as predictive of overjet correction. Specifically, patients with a lower SNA angle were more likely to experience a higher percentage of overjet reduction. This pattern suggests that in patients whose Class II malocclusion is primarily the result of maxillary protrusion, activator effectiveness may be reduced.

The mean age at the start of treatment was 11.90 years, with a statistically significant difference between boys (mean = 12.23 years) and girls (mean= 11.55 years). This difference was expected, as boys generally experience a later growth spurt than girls. Furthermore, patients who began treatment at a younger age were more adherent and wore the device for longer periods each day ($R = -0.28$), a finding consistent with previous studies [3]. The mean total treatment time with functional appliances was 38.60 weeks for all patients. In line with the findings of Arponen, et al., we also identified a negative correlation between total activator treatment duration and daily objective wear time [5]. Longer daily wear was associated with a shorter overall treatment duration with the functional appliance.

Although patients were instructed to wear the activator for 16 to 22 hours per day, the median wear time across all patients was 10.57 hours, with no significant differences between boys and girls. This result is consistent with previous findings that patients generally do not wear the functional appliance for the prescribed hours [5]. Various studies using the Theramon® microsensor to measure adherence have reported median wear times ranging from 6.77 to 9.7 hours per day, suggesting a substantial gap between actual use and the recommended 12 to 15 hours daily [4,9,10]. Our participants had a slightly better median wear time, possibly because the prescribed hours were higher, but still much lower than the recommended time. The correlation between percentage overjet reduction and daily wear time was moderate ($R = 0.31$), indicating that wear time is not the only determinant of treatment success. Even patients with good adherence did not always experience the expected results. Patel, et al., analyzing cephalometric differences between patients with favorable and less favorable responses to treatment with functional appliances, identified specific skeletal characteristics that could predict treatment success. Notably, patients with a more favorable outcome tended to have a smaller, more retrusive mandible and reduced anterior and posterior facial heights [11].

We also evaluated cephalometric factors that could influence overjet correction, analyzing diagnostic cephalometric radiographs from 96 patients, with good inter-rater reliability. The analysis revealed significant skeletal and dental variability among the study group at the start of treatment. A negative correlation was found between the SNA variable and the percentage overjet reduction after treatment with the activator. Clinically, in patients with a lower SNA angle, an increased percentage of overjet reduction can be expected. The predictive value of the SNA angle complements other cephalometric predictors previously described in the literature. Lombardo, et al., found that the smaller the mandibular angle at the beginning of treatment, the greater the expected chin soft tissue advancement [12]. Franchi, et al., reported that patients with Co-Go-Me angle values below 125.5° would respond favorably to treatment with functional appliances [13]. Caldwell, et al., concluded that patients with a deep bite combined with a small SNB angle at the start of treatment will experience a greater reduction in overjet [14]. Contrary to these reports. However, Fleming, et al., found no cephalometric values that could potentially predict Class II correction [15]. Based on our findings, we conclude that treatment success with functional appliances depends not only on wearing time and patient adherence but also on the anteroposterior position of the maxilla in relation to the anterior cranial base. The percentage overjet reduction after treatment with functional appliances can be predicted by the cephalometric variable SNA in combination with mean activator wear time per day. The use of Theramon® microsensors to objectively measure wear time, combined with the assessment of patient-specific skeletal features that may negatively impact overjet reduction, can enable a more personalized treatment plan and follow-up, increasing the likelihood of treatment success.

This study has several limitations. It is retrospective and thus subject to inherent constraints. Different types of activators were used, with the choice of activator type based on individual patient needs and possibly influenced by clinician preference, potentially affecting treatment outcomes. The involvement of multiple practitioners in patient care at the university clinic introduced variability into treatment approaches and motivational strategies and the latter are critical for treatment success. Finally, the median CVM index of II suggests that some portion of the study group was likely treated before the start of the growth spurt, which may have influenced the results.

Conclusion

There was a positive correlation between the reduction in overjet and the daily wearing time of the activator. There was a negative correlation between the SNA variable and the percentage overjet after treatment with the activator. Multiple factors influence the magnitude of overjet reduction, including patient adherence and maxillary protrusion, which collectively determine the effectiveness of the activator. For future studies, we recommend conducting a prospective clinical trial using a single type of activator equipped with a microsensor. This approach would minimize variability in treatment outcomes caused by different activator types.

Acknowledgments

Thank any individuals or organizations that contributed to the study but do not meet the criteria for authorship. Include funding sources, if applicable.

Conflict of Interest Statement

All authors declare that there are no conflicts of interest.

Informed Consent Statement

Informed consent was obtained from each participant involved in this study

Authors' Contributions

All authors contributed equally to this work and approved the final version of the manuscript for publication.

Financial Disclosure

The authors received no external financial support for this study.

Ethical Statement

Not applicable.

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