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MTH herbst appliance, class II elastics and Paolone-Kaitsas functional appliance in mixed dentition class II patients: a retrospective cohort study

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Abstract

Background It is generally accepted that the ideal time to benefit from functional therapy in Class II patients is during the circumpubertal growth period (CVM 3–4). However, in severe cases, early intervention during the mixed dentition phase may be indicated, particularly to reduce the risk of dental trauma and to protect the child from potential bullying. The aim of this study was to evaluate the effects of the Manni Telescopic Herbst (MTH) appliance in young patients with mixed dentition, comparing the outcomes with two control groups: one treated with Class II elastics and a Wilson arch, and the other with a removable functional appliance (Paolone-Kaitsas, PK).

Methods Following statistical matching for age, sex and pre-treatment overjet, lateral cephalograms taken at beginning (T0) and at appliance removal (T1) from 30 patients treated with the MTH appliance were compared with those of 15 patients treated with Class II elastics and 15 treated with the PK appliance.

Results Regarding skeletal parameters, significant differences were observed in the mandibular sagittal position (SNB (T1-T0), $p = 0.01$) and in the relationships between skeletal bases (ANB (T1-T0), $p = 0.03$; Wits (T1-T0), $p < 0.01$), when comparing MTH and PK groups to the Class II elastics group. The Herbst group exhibited the most substantial skeletal changes. For dental variables, better incisor control was achieved with the removable PK appliance (Ii/GoGn T1-T0 1.513 ± 5.739, and Is/PP (T1-T0) 2.507 ± 6.482). No statistically significant difference was found regarding skeletal divergence (SN/GoGn (T1-T0), $p = 0.38$) when focusing on younger patients in mixed dentition phase.

Conclusion Both the fixed MTH appliance and the removable PK appliance produced greater skeletal effects compared to Class II intermaxillary elastics, even when applied during the mixed dentition phase. Although the PK group demonstrated better dentoalveolar control, when significant skeletal modifications are required in young patients with mixed dentition, the use of a fixed functional appliance - such as the Herbst - is preferable.

Keywords Class II malocclusion, Mixed dentition, Functional appliances

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Introduction

According to Angle's classification, Class II malocclusion is defined as the dental condition where the mandibular first molar is distally positioned to the maxillary one [1]. Nowadays, more attention is focused not only on teeth, but also on bones, soft tissues and facial appearance [2], and taken as a whole, the feature that mainly characterizes patients with class II malocclusion is mandibular retrognatia [3, 4].

Therefore, a popular strategy adopted by orthodontists through the years has been the achievement of mandibular advancement by the use of functional appliances, which keep the mandible in protrusive position, changing its posture, in order to solve the skeletal and dental class II [5]. Among the functional devices, the Herbst appliance has recently shown the most promising results [6], confirming to have skeletal and dental effects, such as mandibular advancement together with distal movements of upper teeth and mesial movements of lower ones [7].

A lot of studies have proven the efficacy of treatment of class II malocclusions with Herbst appliance, but the attention has mainly been focused on group of individuals with permanent dentition. To our knowledge, only few data are available at the moment specifically on the use of Herbst appliance in mixed dentition [8–14].

One reason for the lack of studies in children is that there is a consensus that the ideal time to benefit from functional therapy in Class II patients is the circumpubertal growth period (CVM 3–4), rather than in cervical maturation stages 1–2 [15].

However, in some severe cases, therapy may be initiated early in the mixed dentition period, especially to protect the child from the risk of trauma to which they are exposed [16] and from the possibility of being victim of bullying [17].

In addition, the novelty of the present article resides in the adoption of a specific type of Herbst appliance—the Manni Telescopic Herbst appliance—characterized by an acrylic splint on the lower teeth to prevent undesirable anchorage loss and achieve better vertical control.

Since the literature does not provide extensive evidence on Class II therapy with an acrylic splint Herbst appliance during cervical maturation stages 1–2, the aim of our study was to assess the effects of the Manni Telescopic Herbst (MTH) appliance in young patients in mixed dentition.

To evaluate the effectiveness of the MTH appliance, lateral cephalograms of a group of patients treated with the Herbst appliance were compared with two control groups: one treated with Class II elastics and a lingual arch, and the other with a removable functional appliance (Paolone-Kaitsas, PK). The null hypothesis stated that there were no significant differences in skeletal and dentoalveolar variables among the groups.

Materials and methods

study design

In this retrospective controlled cohort study young skeletal class II growing patients with mandibular retrusion were recruited, according to the following inclusion criteria: (1) mixed dentition; (2) class II malocclusion (≥ 1/2 cusp width); (3) treatment with Herbst or class II elastics or PK appliance; (4) complete pre and post treatment cephalometric records. Instead, the exclusion criteria were: (1) incomplete diagnostic records; (2) tooth agenesis; (3) presence of systemic disease; (4) bone pathology; (5) previous orthodontic treatments.

The patients were treated at three separate private practices in Italy by three different clinicians between January 2018 and December 2024. Each practice treated a distinct group of patients—one with the MTH appliance, one with Class II elastics, and one with the PK appliance—and the cephalometric analysis of the collected X-rays was subsequently performed by a single operator.

Therefore, the PICO framework guiding the present study was as follows:

- Population (P): Young patients with Class II malocclusion in the mixed dentition stage.
- Intervention (I): Treatment with the Manni Telescopic Herbst (MTH) appliance.
- Comparison (C): Two control approaches—(1) Class II elastics in combination with a Wilson arch, and (2) a removable functional appliance (Paolone-Kaitsas, PK).
- Outcome (O): Evaluation of treatment effects, focusing on dental and skeletal changes, as well as indirect benefits such as trauma prevention and psychosocial well-being. Specifically, the primary outcome of the study was the change in ANB angle (T1-T0). The selected secondary outcomes included the position of the maxillary and mandibular incisors (Is/PP (T1-T0) and Ii/GoGn (T1-T0), respectively), as well as skeletal divergence (SN/GoGn (T1-T0)).

The study was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans and was approved by the Ethics Committee of Vita-Salute San Raffaele University (approval code DIG-RETRO-1/2021).

The sample size calculation was performed based on the data published by Manni et al. [18], setting up the study as a three-arm case-control (3 groups) with a Type I error probability (alpha: 0.05), a power of 0.80, and an effect size of 0.5 (using the ANB angle difference (T1-T0)

Fig. 1 (**a-c**). The MTH appliance

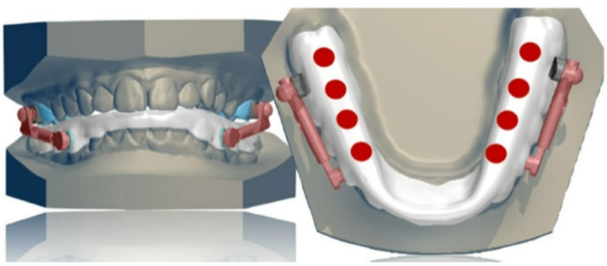

Fig. 2 The digitally created splint

as the primary outcome measure). The sample size estimation suggests a group size of 15 subjects for analysis [19]. Group Herbst consisted of a data frame of 58 subjects altogether but in order to reduce possible selection bias of cases, a matching method was adopted according to a "nearest neighbor" approach using age, sex, overjet (T0) and treatment time as model regressors. This process allowed matching of subjects with a final data frame of 60 subjects overall (30 Herbst, 15 Elastics and 15 PK).

Treatment protocols

Group 1 Herbst (H) was treated with an acrylic splint Herbst appliance, specifically the MTH appliance, which included a fixed transpalatal bar cemented to the first upper molars. A bilateral telescospe mechanism connected the maxillary first molars to the lower splint, maintaining the mandible in anterior position, as illustrated in Fig. 1.

The splint is fabricated by applying resin using a 3D printer (Fig. 2). Occlusal contacts are first verified using a virtual articulator and subsequently refined intraorally to achieve balanced posterior contacts. The splint is partially removable, allowing for oral hygiene procedures, but it cannot be completely removed from the mouth [20].

No fixed appliances were used prior to functional therapy, and no skeletal anchorage was adopted.

Group 2 Elastics (E) was treated with class II intermaxillary elastics from lingual arch and a 2 × 4 round 0.018 wire; bands were cemented onto deciduous molars in both the maxillary and mandibular arch [21], while Begg brackets were inserted in maxillary incisors (Fig. 3) [22].

The elastics prescribed to patients in this group had a force level of 2 oz and were to be worn full-time, except during meals and home oral hygiene procedures.

Group 3 (PK) used a removable functional appliance. This device consists of two acrylic plates (upper and lower), connected laterally by two three-helix springs, which can be progressively activated to regulate both posterior and anterior facial height, with a greater activation in the posterior region. To control the occlusal plane, the plates fully cover the dental occlusal surfaces. Additionally, an expansion screw is incorporated into the upper plate (Figs. 4 and 5) [23, 24].

Patients in Group 3 were instructed to wear the PK appliance for a total of 10 h per day, including 2 h in the afternoon and overnight during sleep.

Variables and data collection

The lateral cephalograms taken at the beginning of treatment (T0) and immediately after the removal of the respective appliances (T1), depending on the group, were analyzed by the same examiner. All images were standardized and scaled before analysis, using the ruler present on the lateral cephalograms. When the ruler was not available, the known dimensions of the craniostat were used for scaling.

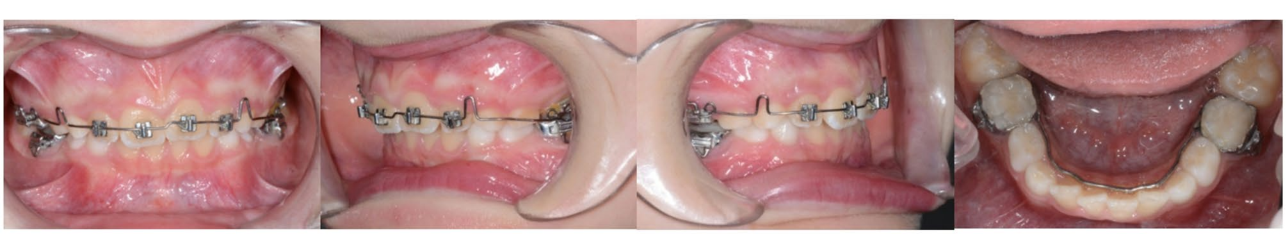

Fig. 3 (**a-d**) Class II intermaxillary elastics and lingual arch

Fig. 4 (**a-d**) The PK appliance

Fig. 5 The plates separated

Cephalometric analysis was performed to evaluate dentofacial changes, considering the following parameters: maxillary and mandibular sagittal positions (SNA° and SNB°, respectively), skeletal divergence (SN/GoGn°) and skeletal relationship (ANB° and WITS in mm) for skeletal variables; maxillary and mandibular incisor inclination (Is/PP° and Ii/GoGn°, respectively) and overjet (OJ in mm) for dental variables.

The data obtained from the analyses were combined, and the changes induced by the three treatments were calculated as the differences between T0 and T1 values for each parameter.

To assess the reliability of the results, average random raters' intraclass correlation coefficients (ICCs) were calculated for both linear and angular measurements using six randomly selected cephalograms. The same operator performed all tracings in a single session after a 12-week interval (Table 3).

Statistical analysis

The entire sample was described as mean ± SD, median (IQR) for continuous variables, and as n (%) for categorical variables. The assumption of normality of distributions was verified using the Shapiro-Wilk test, while homoscedasticity was assessed using Bartlett's test. A No parametric approach was adopted according to variables distributions. Group differences were evaluated using the Kruskal-Wallis for independent samples. A p-value equal to or less than 0.05 was considered statistically significant, with an alpha value of 0.05. The association between primary outcomes and treatment was assessed using nested Rank Based linear regression models. Four Rank Based linear regression models were built on ANB (T1-T0), II GoGn (T1-T0), IS/PP (T1-T0) and Wits (T1-T0) as dependent variables, respectively. For each outcome three nested regression models were performed. Model 1 was unadjusted model built on each dependent variable and type of treatment while model 2 was adjusted for age and Sn/GoGn (T0) and model 3 was adjusted for model 2 regressors plus IS/PP (T0), II/GoGn (T0) and lenght of treatment.

Results

Considering all groups, the total study sample included 60 patients: Group H comprised 30 patients, while Group E and Group PK included 15 patients each. Baseline data are presented in Table 1.

A statistically significant difference was observed in patients' ages: while Group E and Group PK showed almost identical values (8.133 ± 1.125 and 8.133 ± 0.516 years, respectively), patients in Group H were, on average, older (9.467 ± 1.833 years).

A statistically significant difference was also found in the mean treatment duration across the three groups, with Group E undergoing the longest therapy duration (20.467 ± 7.15 months) compared to Group H (13.2 ± 2.941 months) and Group PK (13.6 ± 1.502 months).

In addition to age, sex, and treatment duration, Table 2 presents pre- and post-treatment measurements, as well as the differences between them for each group. The last column reports the intergroup differences in each measurement.

Regarding skeletal parameters, significant differences were observed in the mandibular sagittal position (SNB (T1-T0), $p = 0.01$) and in the relationships between skeletal bases (ANB (T1-T0), $p = 0.03$; Wits (T1-T0), $p < 0.01$).

For dental variables, both maxillary and mandibular incisor inclinations showed significant differences (Ii/GoGn (T1-T0), $p < 0.01$; Is/PP (T1-T0), $p < 0.01$). However, these indices were significantly different among the three groups at T0 (Ii/GoGn (T0), $p < 0.01$; Is/PP (T0), $p < 0.01$).

Table 1 Description of the whole sample according to type of treatment at baseline (T0)

	Group herbst		Group elastics		Group Paolone-Kaitsas		
	Mean ± SD	**Median (iqr)**	**Mean ± SD**	**Median (iqr)**	**Mean ± SD**	**Median(iqr)**	**P***
Proportions	30 (50.00)		15 (25.00)		15 (25.00)		
Age (years)	9.467 ± 1.833	10 (3)	8.133 ± 1.125	8 (1.5)	8.133 ± 0.516	8 (0)	**< 0.01**
Sex							
Female	14 (46.70)		6 (40.00)		8 (53.30)		0.76
Male	16 (53.30)		9 (60.00)		7 (46.70)		
SNA (T0)	81.02 ± 2.407	81.05 (3.575)	81.787 ± 3.62	81.2 (3.9)	80.273 ± 2.83	79.5 (4)	0.61
SNB (T0)	75.17 ± 3.093	75.4 (4.5)	76.547 ± 3.806	76.2 (5)	73.56 ± 2.732	74.2 (2.75)	0.08
ANB (T0)	5.843 ± 1.565	6.15 (2.125)	5.26 ± 1.562	4.9 (1.7)	6.693 ± 2.132	6.2 (3.35)	0.07
Wits (T0)	3.3 ± 2.535	4 (3)	1.6 ± 2.028	1 (3)	3.067 ± 3.195	3 (3.5)	0.06
SN/GoGn (T0)	32.617 ± 4.384	32.8 (6.375)	30.493 ± 7.288	30.3 (6.85)	36.947 ± 3.723	37.4 (4.15)	< 0.01
Is/PP (T0)	114.193 ± 3.865	114.75 (5.425)	109.033 ± 6.468	107.6 (4)	106.933 ± 11.839	107 (15.9)	< 0.01
II/GoGn (T0)	97.377 ± 4.748	97.05 (5.675)	92.667 ± 9.013	91.6 (8.6)	93.747 ± 6.175	94 (6.45)	< 0.01
OJ (T0)	8.31 ± 1.934	7.8 (2.2)	7.44 ± 2.445	6.6 (3.65)	7.18 ± 2.536	6.9 (2.8)	0.21
CVM							
CS1	4 (80.00)		15 (100.00)		15 (100.00)		0.15
CS2	1 (20.00)		--		--		

*Wilcoxon sum rank test for continuous variables and Chi squared test for categorical ones

N:60. *All data are continuous and shown as mean ± sd, median (iqr) for continuous variables and n (%) for categorical ones*

No significant differences were observed in overjet measurements among the three groups.

The following table (Table 3) shows the Average Random Raters Interclass Correlation Index for all continuous collected variables.

To identify statistically significant differences between the groups, a pairwise analysis with Bonferroni correction was performed (shown in Table 4). Differences were considered significant when the adjusted p value was lower than 0.05.

The comparison between Group H and Group E revealed significant differences in SNB and ANB changes ($p = 0.0098$ and $p = 0.0095$, respectively). Regarding dental variables, significant differences were observed in the maxillary incisors' inclination (before and after treatment, $p = 0.0036$ and $p = 0.0064$, respectively) and in the mandibular incisors position at T1 ($p = 0.0056$). Treatment duration also differed significantly between the two groups ($p = 0.00085$).

In the comparison between Group PK and Group H, significant differences were found only in dental variables, specifically mandibular incisors inclination after treatment ($p = 0.0035$) and in the change in Is/PP values ($p = 0.0015$).

No significant differences were observed between Group E and Group PK.

The following tables present the nested Rank Based linear regression models.

Table 5 reports the model using Wits (T1-T0) as the dependent variable and treatment type as the regressor, adjusted for age, SN/GoGn (T0), Is/PP (T0), II/GoGn (T0) and treatment duration. Treatment was found to be statistically significantly associated with changes in Wits (T1-T0). The H group showed a coefficient of − 3 (− 4.68 to − 1.32, $p < 0.01$) in a crude model (model 1), this relationship is maintained statistically significant in models 2 and 3 assuming coefficient value of − 3.00, (4.87 to − 1.13, $p < 0.01$) and − 2.59, (− 4.82 to − 0.36, p:0.02), respectively. No statistically significant difference was observed between Group PK and Group E, in all regression models.

Table 6 indicates that treatment type (specifically with Herbst appliance) is also statistically significantly associated with ANB (T1-T0), showing a coefficient of − 0.46 (− 2.2 to − 0.4, $p > 0.01$). This relation was maintained statistically significant also in model 2 and model 3 assuming coefficients values of − 1.41 (− 2.37 to − 0.46, $p < 0.01$) and − 1.70 (− 3.08 to − 0.31, p:0.02), respectively.

Regarding dental variables, no statistically significant associations were found when the model was built using Ii/GoGn (T1-T0) as dependent variable (Table 7) while a statistically significant association was found between Is/PP (T1-T0) and type of treatment. Table 8 shows a positive statistically significant association between IS/PP (T1-T0) and PK treatment with a coefficient 6.3 (2.05 to 10.54, $p < 0.01$) (model 1). This relationship is maintained statistically significant in models 2 and 3 assuming coefficient value of 5.31, (0.46 to 10.17, p:0.03) and 5.53, (1.18 to 9.88, p:0.01), respectively. The relation between IS/PP (T1-T0) was found statistically significant for treatment type H when adjusted for whole regressors (model 3) assuming a coefficient value of 4.04 (0.03 to 8.05, p:0.05).

Table 2 Description of the whole sample according to type of treatment

	Group herbst		**Group elastics**		**Group Paolone-Kaitsas**		
	Mean ± SD	**Median (iqr)**	**Mean ± SD**	**Median (iqr)**	**Mean ± SD**	**Median (iqr)**	**p**
Proportions	30 (50.00)		15 (25.00)		15 (25.00)		
Age (years)	9.467 ± 1.833	10 (3)	8.133 ± 1.125	8 (1.5)	8.133 ± 0.516	8 (0)	**< 0.01**
Sex							
Female	14 (46.70)		6 (40.00)		8 (53.30)		0.76
Male	16 (53.30)		9 (60.00)		7 (46.70)		
SNA (T0)	81.02 ± 2.407	81.05 (3.575)	81.787 ± 3.62	81.2 (3.9)	80.273 ± 2.83	79.5 (4)	0.61
SNA (T1)	80.88 ± 2.964	80.7 (3.85)	80.933 ± 3.627	81.3 (4.4)	80.387 ± 2.947	80.7 (3.25)	0.76
SNA (T1-T0)	− 0.14 ± 1.407	− 0.05 (1.675)	− 0.853 ± 2.563	− 0.5 (2.7)	0.113 ± 3.363	− 0.6 (4.4)	0.73
SNB (T0)	75.17 ± 3.093	75.4 (4.5)	76.547 ± 3.806	76.2 (5)	73.56 ± 2.732	74.2 (2.75)	0.07
SNB (T1)	76.787 ± 3.048	76.55 (3.45)	76.32 ± 3.679	75.8 (4.2)	75.04 ± 3.26	75.1 (2.9)	0.10
SNB (T1-T0)	1.617 ± 1.154	1.7 (1.225)	− 0.227 ± 2.424	− 0.1 (2.45)	1.48 ± 2.479	1.3 (3.15)	**0.01**
ANB (T0)	5.843 ± 1.565	6.15 (2.125)	5.26 ± 1.562	4.9 (1.7)	6.693 ± 2.132	6.2 (3.35)	0.12
ANB (T1)	4.093 ± 1.479	4 (2.15)	4.613 ± 1.582	4 (2.15)	5.353 ± 1.828	5.6 (2.05)	0.76
ANB (T1-T0)	− 1.75 ± 1.151	− 1.7 (1.475)	-0.647 ± 1.578	− 0.7 (1.6)	− 1.34 ± 1.906	− 0.7 (3.2)	**0.03**
Wits (T0)	3.3 ± 2.535	4 (3)	1.6 ± 2.028	1 (3)	3.067 ± 3.195	3 (3.5)	0.06
Wits (T1)	− 0.267 ± 1.68	0 (3)	0.933 ± 1.438	1 (2)	1 ± 2.035	1 (2)	**0.02**
Wits (T1-T0)	− 3.567 ± 2.487	− 4 (3)	− 0.667 ± 2.289	− 1 (3.5)	− 2.067 ± 2.89	− 1 (3)	**< 0.01**
SN/GoGn (T0)	32.617 ± 4.384	32.8 (6.375)	30.493 ± 7.288	30.3 (6.85)	36.947 ± 3.723	37.4 (4.15)	**< 0.01**
SN/GoGn (T1)	32.563 ± 4.642	32.15 (5.05)	31.073 ± 6.726	32.5 (7.1)	36.813 ± 4.147	37.3 (6.85)	**< 0.01**
SN/GoGn (T1-T0)	− 0.053 ± 1.651	-0.2 (2.275)	0.58 ± 3.108	1.7 (3.25)	− 0.133 ± 2.561	− 0.4 (3.95)	0.38
Is/PP (T0)	114.193 ± 3.865	114.75 (5.425)	109.033 ± 6.468	107.6 (4)	106.933 ± 11.839	107 (15.9)	**< 0.01**
Is/PP (T1)	110.213 ± 4.16	110.85 (4.025)	104.62 ± 6.576	104.9 (6.3)	109.44 ± 0.068	107.3 (14.4)	**0.02**
Is/PP (T1-T0)	− 3.98 ± 5.18	− 4.65 (6.4)	− 4.413 ± 9.469	− 4.7 (12.35)	2.507 ± 6.482	1.9 (4.65)	**< 0.01**
II/GoGn (T0)	97.377 ± 4.748	97.05 (5.675)	92.667 ± 9.013	91.6 (8.6)	93.747 ± 6.175	94 (6.45)	**< 0.01**
Ii/GoGn (T1)	103.75 ± 6.1	104.05 (7.85)	96.853 ± 10.132	95.3 (6.05)	95.26 ± 7.899	94.5 (11.45)	**< 0.01**
Ii/GoGn (T1-T0)	6.373 ± 5.224	6.45 (7.3)	4.187 ± 4.809	3.4 (7.6)	1.513 ± 5.739	− 0.3 (6.65)	**< 0.01**
OJ (T0)	8.31 ± 1.934	7.8 (2.2)	7.44 ± 2.445	6.6 (3.65)	7.18 ± 2.536	6.9 (2.8)	0.21
OJ (T1)	3.117 ± 1.089	3.25 (1.6)	4.253 ± 1.634	4.6 (2.05)	3.667 ± 1.334	3.3 (2.35)	0.06
OJ (T1-T0)	− 5.193 ± 2.128	− 4.9 (2.25)	− 3.187 ± 3.407	− 4 (5.55)	− 3.513 ± 2.66	− 3.6 (3.05)	0.06
T1-T0 (months)	13.2 ± 2.941	12.5 (2)	20.467 ± 7.15	20 (12)	13.6 ± 1.502	13 (1.5)	**< 0.01**

**Kruskal Wallis sum rank test for continuous variable and chi squared test for categorical ones*

N:60 All data are shown as mean ± sd, median (iqr) as continuous variables and n (%) for categorical ones

Table 3 Average random raters interclass correlation index for continuous collected variables

Variable	**Average Random Raters ICC**
SNA T0	0.94 (0.91 to 0.96), $p < 0.05$
SNA T1	0.96 (0.93 to 0.97), $p < 0.05$
SNB T0	0.96 (0.94 to 0.98), $p < 0.05$
SNB T1	0.96 (0.93 to 0.97), $p < 0.05$
Wits T0	0.95 (0.93 to 0.97), $p < 0.05$
Wits T1	0.96 (0.93 to 0.97), $p < 0.05$
SN GOGN T0	0.98 (0.97 to 0.99), $p < 0.05$
SN GOGN T1	0.98 (0.97 to 0.99), $p < 0.05$
Is PP T0	0.98 (0.97 to 0.99), $p < 0.05$
Is PP T1	0.98 (0.97 to 0.99), $p < 0.05$
II GOGN T0	0.95 (0.92 to 0.99), $p < 0.05$
II GOGN T1	0.98 (0.97 to 0.99), $p < 0.05$
OJ T0	0.85 (0.77 to 0.90), $p < 0.05$
OJ T1	0.82 (0.72 to 0.88), $p < 0.05$

Table 4 P values of pairwise analysis with "Bonferroni" correction for significant variables

	Group E	**Group H**	**Group E**	**Group H**
	SNB (T1-T0)		ANB (T1-T0)	
Group H	0.0098	--	0.0095	--
Group PK	0.2424	1.00	1.000	1.000
	Is/PP (T0)		Is/PP (T1)	
Group H	0.0036	--	0.0064	--
Group PK	1.00	0.0730	1.00	0.7883
	II/GoGn (T1-T0)		II/GoGn (T1)	
Group H	0.498	--	0.0056	--
Group PK	0.169	0.015	1.00	0.0035
	Wits (T1)		T1-T0 (months)	
Group H	0.106	--	0.00085	--
Group PK	1.00	0.074	0.01494	0.43238
	Is/PP (T1-T0)		II/GoGn (T0)	
Group H	1.00	--	0.012	--
Group PK	0.1102	0.0015	1.00	0.126

*p values with "Bonferroni Correction"

Table 5 Rank based linear regression on wits difference (T1-T0) as dependent variable and regressors

	Model 1				Model 2				Model 3			
	Coef	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**
Treatment (H)	− 3.00	0.86	− 4.68 to − 1.32	**< 0.01**	− 3.00	0.95	− 4.87 to − 1.13	**< 0.01**	− 2.59	1.14	− 4.82 to − 0.36	**0.02**
Treatment (PK)	− 1.00	0.99	− 2.94 to 0.94	0.31	− 1.00	1.11	− 3.17 to 1.17	0.37	− 0.82	1.23	− 3.24 to 1.60	0.51
Age (years)					0.10	0.25	− 0.5 to 0.5	0.99	0.15	0.24	− 0.31 to 0.62	0.52
SN/GoGn (T0)					− 0.10	0.07	− 0.14 to 0.14	0.99	0.01	0.09	− 0.16 to 0.18	0.92
IS/PP (T0)									− 0.04	0.05	− 0.13 to 0.05	0.41
II/GoGn (T0)									0.05	0.07	− 0.09 to 0.19	0.48
Time of treatment									0.08	0.08	− 0.08 to 0.25	0.34

Discussion

The timing of orthodontic treatment is crucial, and its initiation should be tailored to the specific type of malocclusion being addressed. While there is consensus on the importance of interceptive therapy in childhood for Class III malocclusion [25], determining the optimal timing for treating Class II patients remains a critical issue.

Several studies have demonstrated that the most effective period for initiating Class II malocclusion therapy with functional appliances is during the circumpubertal growth phase (CVM 3–4). Indeed, Mcnamara [26], Petrovic [27], and Franchi and Baccetti [28] are among the many researchers who have shown that functional therapy administered during this period enhances mandibular growth.

However, in severe class II malocclusion cases, the use of functional appliances during the mixed dentition phase may be preferable. This decision may be influenced by esthetic concerns and the risk of bullying [17], the increased likelihood of trauma due to excessively proclined upper incisors [16, 29–31], and the need to restore proper oral functioning [32]. Moreover, given that the daily wear time has been found to decrease with patient age [29–31], removable appliance should work better in mixed dentition phase.

Few studies have investigated the early use of Herbst appliance in mixed dentition phase ([]), and these studies generally compare treated patients to an untreated control group. In the present study, all patients received treatment – either with the Herbst appliance (specifically the MTH appliance), a removable functional appliance, or class II intermaxillary elastics in combination with the Wilson Arch. The distribution of CVM stages among the included patients was comparable across the groups, with no statistically significant differences observed between the CS1 and CS2 stages.

The primary objective of functional appliances is to correct the skeletal class II malocclusion by.

guiding skeletal growth and facilitating neuromuscular adaptation to the new mandibular posture. These skeletal effects have been well documented in the literature ([27, 33, 34]). Additionally, it has been established that Class II elastics primarily induce dentoalveolar changes, with less significant skeletal modifications ([35, 36]). Consistently, the present study found that functional appliances produced more pronounced skeletal effects, with statistically significant differences observed for both ANB (p = 0.03) and Wits (p < 0.01), when comparing the Herbst and PK appliances to elastics. Furthermore, pairwise analysis revealed a statistically significant difference between Group H and Group E, while no significant difference

Table 6 Rank based linear regression on ANB difference (T1-T0) as dependent variable and regressors

	Model 1				Model 2				Model 3			
	Coef	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**
Treatment (H)	0.46	0.46	− 2.22 to − 0.40	**< 0.01**	− 1.41	0.49	− 2.37 to − 0.46	**< 0.01**	− 1.7	0.71	− 3.08 to − 0.31	**0.02**
Treatment (PK)	0.53	0.53	− 1.83 to 0.23	0.13	− 0.71	0.57	− 1.82 to 0.40	0.21	− 0.97	0.77	− 2.48 to 0.53	0.23
Age (years)					0.11	0.13	− 0.14 to 0.37	0.38	0.11	0.15	− 0.18 to 0.4	0.47
SN/GoGn (T0)					− 0.02	0.04	− 0.09 to 0.05	0.59	0.01	0.05	− 0.09 to 0.12	0.83
IS/PP (T0)									0.02	0.03	− 0.04 to 0.08	0.45
II/GoGn (T0)									0.04	0.04	− 0.05 to 0.12	0.44
Time of treatment									− 0.07	0.05	− 0.1 to 0.1	0.99

was observed between Group H and Group PK. Nonetheless, the Herbst group exhibited the most substantial skeletal changes (ANB (T1-T0) − 1.75 ± 1.151 and Wits (T1-T0) − 3.567 ± 2.487). This finding suggests that the Herbst appliance can be effective even before the pubertal peak, though long-term stability should be carefully evaluated.

Regarding skeletal divergence (SN/GoGn), previous studies have shown that elastics tend to result in a greater increase in lower facial height and in mandibular plane angle compared to functional appliances [35]. However, in the present study, no statistically significant difference was found when focusing on younger patients with mixed dentition phase (p = 0.38).

With respect to dental variables, the study found that better incisor control was achieved with the removable PK appliance. The difference between groups was statistically significant for both mandibular incisor inclination relative to the mandibular plane and upper incisor inclination relative to the palatal plane (Is/PP (T1-T0) $p<0.01$ and II/GoGn (T1-T0) $p>0.01$). Specifically, Group PK demonstrated the most effective control over both upper (Is/PP(T1-T0) 2.507 ± 6.482) and lower incisors (II/GoGn (T1-T0) 1.513 ± 5.739). Furthermore, the variation in the latter parameter was also statistically significant in pairwise analysis when comparing Group H and Group PK (p:0.015).

The superior dentoalveolar stabilization achieved with the PK appliance can be attributed to its structural design (Fig. 3). Specifically, the resin plate allows for activation not only in the transverse direction for expansion, but also in the sagittal direction, promoting upper incisor proclination, which counteracts the effects of anchorage loss. Additionally, the improved control over lower incisor inclination may be explained by the activation of the inferior vestibular arch.

Despite providing superior incisal control and greater patient comfort, the PK appliance does not induce significant skeletal effects due to its removable nature. Moreover, since it is not a fixed appliance, patient compliance is a crucial factor [37]. Thus, initiating treatment with this appliance should be carefully considered based on the patient's ability to adhere to treatment [38].

Similar compliance-related concerns apply to Class II elastics, which rely heavily on patient collaboration. Beyond remembering to wear or replace them, factors such as difficulties during eating or social concerns may hinder their consistent use.

Consequently, patient compliance represents a major imitation in studies comparing fixed functional appliances to removable devices or elastics, as reduced adherence may compromise treatment efficacy and alter study outcomes.

Table 7 Rank based linear regression on II Go/Gn difference (T1-T0) as dependent variable and regressors

	Model 1				Model 2				Model 3			
	Coef	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**
Treatment (H)	2.4	1.67	− 0.87 to 5.67	0.15	1.16	1.81	− 2.39 to 4.7	0.52	2.24	− 0.20	− 4.85 to 3.94	0.84
Treatment (PK)	− 3.4	1.92	− 7.17 to 0.37	0.08	− 3.74	2.11	− 7.83 to 0.43	0.08	2.43	− 1.91	− 9.41 to 0.12	0.06
Age (years)					0.79	0.48	− 0.15 to 1.74	0.10	0.47	1.85	− 0.05 to 1.79	0.06
SN/GoGn (T0)					0.06	0.14	− 0.21 to 0.33	0.66	0.17	− 0.02	− 0.33 to 0.33	0.98
IS/PP (T0)									0.10	1.37	− 0.06 to 0.32	0.17
II/GoGn (T0)									0.14	− 1.37	− 0.46 to 0.08	0.17
Time of treatment									0.17	− 1.73	− 0.61 to 0.04	0.08

Table 8 Rank based linear regression on II IS/PP difference (T1-T0) as dependent variable and regressors

	Model 1				Model 2				Model 3			
	Coef	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**	**Beta**	**Stand. Err.**	**CI 95%**	**p**
Treatment (H)	− 0.33	1.87	− 3.98 to 3.37	0.87	0.17	2.13	− 3.99 to 4.34	0.94	4.04	1.97	0.03 to 8.05	**0.05**
Treatment (PK)	6.3	2.16	2.05 to 10.54	**< 0.01**	5.31	2.48	0.46 to 10.17	**0.03**	5.53	2.49	1.18 to 9.88	**0.01**
Age (years)					− 0.41	0.57	− 1.52 to 0.7	0.47	− 0.03	− 0.07	− 0.87 to 0.81	0.95
SN/GoGn (T0)					0.29	0.16	− 0.02 to 0.61	0.07	0.39	2.5	0.08 to 0.69	0.01
IS/PP (T0)									− 0.49	− 5.65	− 0.66 to − 0.32	< 0.01
II/GoGn (T0)									0.21	1.71	− 0.03 to 0.46	0.09
Time of treatment									0.41	2.73	0.12 to 0.71	0.01

Limitations

The first limitation of the present study lies in its retrospective design: patients were not randomized, and the data quality relies on the existing cephalometric X-rays. Secondly, although statistical matching was performed at the beginning, the process was fully effective only for sex and overjet (T0), but not for age. Consequently, to account for potential confounding factors, the variables that significantly differed at T0 - namely age (T0), SN/GoGn (T0), Is/PP (T0), II/GoGn (T0) and treatment duration - were included in the regression models. These models support the primary findings, as the results remain statistically significant after adjusting for confounders, regardless of treatment type, age, skeletal divergence (SN/GoGn T0), inclination on incisors (II/GoGn and Is/PP at T0) and treatment duration.

Conclusions

Based on the results obtained, the following conclusions can be drawn:

- The functional appliances used in this study – both the fixed MTH appliance and the removable PK appliance - produced greater skeletal effects compared to Class II intermaxillary elastics, even applied during the mixed dentition phase. Notably, the group treated with the Herbst appliance achieved the most favorable outcomes, primarily due to the fixed nature of the device, which ensure greater effectiveness than the removable PK appliance.
- Although the best dentoalveolar control was observed in the PK group, when significant skeletal modifications are required in young patients with mixed dentition, the use of a fixed functional appliance - such as the Herbst - is preferable.

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Author contributions
G.G., M.C. and A.M: conceptualization and methodology, supervision; A.M, M.C., M.P. and R.K.: collection of the data; E.G. and A.B.: analysis of the data and writing the original draft; F.C.: statistical analysis; M.C.: review and editing. All authors read and approved the final manuscript.

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Data availability
The datasets used and/or analyzed during the current study are available fromthe corresponding author on reasonable request **.**.

Declarations

Ethics approval and consent to particicpate
The study was conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans and was approved by the Ethics Committee of Vita-Salute San Raffaele University (approval code DIG-RETRO-1/2021).

Consent for publication
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Competing interests
The authors declare no competing interests.

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