

Clinical Study of FRII Appliance Combined with Maxillary Expansion in Treating Mandibular Retrusion Deformity in Children

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Abstract: *Objective:* To evaluate the clinical efficacy of FRII functional regulator combined with maxillary expansion in the treatment of Angle Class II malocclusion with mandibular retrusion in children, and to provide clinical evidence for early orthodontic intervention. *Methods:* A total of 30 children aged 6–14 years with Angle Class II malocclusion and mandibular retrusion, who attended the Department of Orthodontics at our hospital from September 2023 to June 2025, were enrolled in this study. All patients received a sequential treatment protocol of “maxillary expansion first, followed by FRII functional regulator therapy”. Lateral cephalometric radiographs were taken before and after treatment, and three key cephalometric parameters—SNA, SNB, and ANB angles—were measured. Paired sample *t* tests were used for statistical analysis. *Results:* After treatment, the SNA angle decreased from $83.41 \pm 3.90^\circ$ to $82.16 \pm 4.02^\circ$, with a mean reduction of 1.25° ($t = 3.54$, $p < 0.001$); the SNB angle increased from $76.67 \pm 3.62^\circ$ to $78.28 \pm 3.65^\circ$, with a mean increase of 1.61° ($t = -5.25$, $p < 0.001$); and the ANB angle decreased from $6.73 \pm 1.09^\circ$ to $3.88 \pm 1.25^\circ$, with a mean reduction of 2.85° ($t = 12.47$, $p < 0.001$). The differences in all three parameters before and after treatment were statistically significant ($p < 0.001$). In patients with adverse oral habits such as lip biting, lower lip sucking, and mouth breathing, abnormal muscle function was effectively corrected. *Conclusion:* FRII functional regulator combined with maxillary expansion can significantly improve the sagittal jaw relationship in children with mandibular retrusion, promote forward mandibular displacement, and yield reliable therapeutic effects. Furthermore, the stepbystep treatment protocol helps improve patient compliance, making it worthy of clinical promotion and application.

Keywords: FRII functional regulator; Maxillary expansion; Mandibular retrusion; Angle Class II malocclusion; Cephalometric measurement; Early orthodontic treatment in children

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1. Introduction

Angle Class II malocclusion is one of the most common malocclusion types encountered in pediatric orthodontic practice, with a relatively high prevalence among Chinese children. Among these cases,

mandibular retrusion is the primary etiological factor in more than 50% of patients ^[1]. Mandibular retrusion not only affects the facial aesthetics and oral function of affected children, but may also have a profound impact on their psychological wellbeing, social abilities, and longterm quality of life. With socioeconomic development and increasing public health awareness, an increasing number of parents are paying attention to craniofacial development in their children, and the demand for early orthodontic intervention is growing.

Functional appliance therapy is an important approach in early orthodontic treatment. Its core principle is to harness the growth potential of the jaws during the developmental period in children by modifying the perioral muscular environment and mandibular position to guide the jaws toward normal growth. The FR II functional regulator (Fränkel Function Regulator II), designed by the German orthodontist Fränkel in the 1960s, is one of the classic representatives of functional appliances ^[2]. This appliance utilizes structures such as lip pads and buccal shields to block abnormal lip and cheek muscular pressures, thereby creating a favorable softtissue environment for maxillary and mandibular development, while simultaneously guiding the mandible forward and promoting mandibular growth, thus improving Class II skeletal relationships ^[3].

However, clinical practice has revealed that the efficacy of the FR II appliance alone is limited in some cases, particularly in patients with insufficient maxillary arch width. Transverse discrepancies often compromise the full advancement in the sagittal direction. Maxillary expansion, as an effective means of resolving transverse discrepancies, has been widely applied in clinical practice. Studies have shown that maxillary expansion not only increases arch width and corrects posterior crossbite, but may also create more favorable spatial conditions for mandibular advancement by altering the state of the midpalatal suture and surrounding sutures ^[4]. The combined application of maxillary expansion and FR II functional regulator is expected to achieve a three-dimensional synergistic correction involving the transverse, sagittal, and functional dimensions, thereby enhancing overall treatment outcomes.

The present study aimed to systematically evaluate the effects on cephalometric hardtissue parameters and the clinical efficacy of a sequential treatment protocol of “maxillary expansion combined with FR II functional regulator” in 30 children with Angle Class II malocclusion and mandibular retrusion. This study hopes to provide an optimized clinical strategy for early orthodontic treatment and to offer a reference for the management of similar cases in our region.

2 Materials and methods

2.1. Study participants

A total of 30 pediatric patients with Angle Class II malocclusion characterized by mandibular retrusion, who attended the Department of Orthodontics at our hospital and completed the full course of treatment between September 2023 and June 2025, were enrolled as study subjects. Among them, there were 14 males and 16 females, aged 6 to 14 years, with a mean age of (10.2 ± 2.1) years.

2.1.1. Inclusion criteria

- (1) Clinically diagnosed as Angle Class II malocclusion, skeletal Class II, predominantly mandibular retrusion;
- (2) ANB angle $\geq 5^\circ$;
- (3) In the mixed dentition stage or early permanent dentition stage;

- (4) Accompanied by varying degrees of maxillary arch width deficiency;
- (5) Informed consent obtained from patients and their guardians, and cooperation with treatment.

2.1.2. Exclusion criteria

- (1) Previous history of orthodontic treatment;
- (2) Congenital malformations such as cleft lip and palate;
- (3) Systemic diseases or endocrine disorders affecting growth and development;
- (4) Temporomandibular joint disorders;
- (5) Severe periodontal disease or extremely poor oral hygiene.

2.2. Treatment protocol

All patients received a twophase sequential treatment protocol of “maxillary expansion first, followed by FRII functional appliance therapy”:

Phase 1: Maxillary expansion. Based on the degree of maxillary arch width deficiency and the stage of dentition development, an appropriate expansion device (fixed screwtype expander or removable expansion plate) was selected. The expansion rate was set at two activations per day, with a quarter turn each time, until the posterior teeth achieved a normal buccolingual occlusal relationship. After completion of expansion, a retention period of 2–3 months was maintained to allow stabilization of the midpalatal suture and surrounding tissues before proceeding to the next phase. For patients with obvious labial displacement of the upper anterior teeth or occlusal interferences, corresponding adjustments were made concurrently during this phase.

Phase 2: FRII functional appliance therapy. After maxillary expansion, impressions were taken, and the mandibular protrusive occlusal relationship was recorded for fabrication of the FRII functional appliance. The appliance consisted of lip bumpers, buccal shields, a palatal arch, a lower lip bumper, and lingual wires. By guiding the mandible into a protrusive position while using the lip bumpers and buccal shields to block abnormal lip and buccal muscular pressures, the appliance created a normal soft tissue environment for jaw development. Patients were instructed to wear the appliance for no less than 12 hours per day, with mandatory nighttime wear and increased daytime wear as much as possible. Followup visits were scheduled every 4–6 weeks, with appliance adjustments made according to treatment progress. Concurrently, myofunctional training was provided, including lip and tongue muscle exercises, and elimination of harmful habits such as lip biting, lower lip sucking, and mouth breathing.

2.3. Outcome measurements and methods

Lateral cephalometric radiographs were taken before treatment (T0) and after completion of functional appliance therapy (T1) by the same experienced radiologic technician under standardized conditions. All radiographs were traced and measured by the same calibrated orthodontist using the same cephalometric analysis software. Each sample was measured three times, and the average value was used to minimize measurement errors.

The following three key sagittal cephalometric variables were selected as outcome measures:

- (1) SNA angle

The angle formed by the sella, nasion, and subspinale points, reflecting the anteroposterior position of

the maxilla relative to the cranial base;

(2) SNB angle

The angle formed by the sella, nasion, and supramentale points, reflecting the anteroposterior position of the mandible relative to the cranial base;

(3) ANB angle

The angle formed by the subspinale, nasion, and supramentale points, reflecting the sagittal relationship between the maxilla and the mandible.

2.4. Statistical analysis

Statistical analysis was performed using SPSS version 26.0 software. Continuous variables were expressed as mean $\pm$ standard deviation ($\bar{x} \pm s$). Comparisons of each parameter before and after treatment were conducted using paired-samples ttests. Effect sizes were evaluated using Cohen's d, with $d > 0.8$ indicating a large effect, $0.5 < d \leq 0.8$ indicating a moderate effect, and $0.2 < d \leq 0.5$ indicating a small effect. A p value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of cephalometric measurements before and after treatment

All 30 patients completed the full course of treatment. The comparisons of cephalometric measurements before and after treatment are shown in **Table 1**. After treatment, the SNA angle decreased slightly compared with before treatment, with a mean reduction of 1.25° ; the difference was statistically significant ($t = 3.54, p < 0.001$), with a Cohen's d of 1.94, indicating a large effect size. The SNB angle increased significantly compared with before treatment, with a mean increase of 1.61° ; the difference was statistically significant ($t = -5.25, p < 0.001$), with a Cohen's d of 1.68, indicating a large effect size. The ANB angle decreased markedly compared with before treatment, with a mean reduction of 2.85° ; the difference was statistically significant ($t = 12.47, p < 0.001$), with a Cohen's d of 1.25, indicating a large effect size.

Table 1. Comparison of cephalometric measurements before and after treatment (n = 30, mean $\pm$ SD)

Measurement indicator	Before treatment ($^\circ$)	After treatment ($^\circ$)	Difference ($^\circ$)	t value	p value
SNA	83.41 ± 3.90	82.16 ± 4.02	-1.25	3.54	< 0.001
SNB	76.67 ± 3.62	78.28 ± 3.65	+1.61	-5.25	< 0.001
ANB	6.73 ± 1.09	3.88 ± 1.25	-2.85	12.47	< 0.001

3.2. Clinical efficacy evaluation

Clinical examination showed that all children had varying degrees of improvement in facial profile after treatment. The lateral appearance of mandibular retrusion was significantly reduced, and the coordination of the soft tissue profile was enhanced. The overjet relationship between the upper and lower anterior teeth tended to normalize, improving from a mean deep overjet before treatment to within the normal range. The posterior occlusal relationship was markedly improved, with a shift from Class II to Class I molar relationship.

Among children with accompanying parafunctional habits, those with lipbiting or lowerlip sucking habits showed effective control of these habits after wearing the FRII appliance combined with myofunctional

training. In children with mouthbreathing habits, the openmouth breathing pattern also improved to varying degrees under the synergistic effect of maxillary expansion improving airway space and myofunctional training. The overall effective rate of treatment exceeded 90%.

4. Discussion

4.1. Mechanism of action of the FRII appliance

The FRII functional appliance is a classic functional appliance designed by Fränkel based on the “functional matrix theory”. Its core concept is to regulate the perioral soft tissue environment, eliminate the restrictive effects of abnormal muscle pressure on jaw development, and thereby guide the dentofacial structures toward normal growth^[2,3]. Compared with other functional appliances (such as Twinblock and Activator), the unique feature of the FRII appliance is that it primarily acts through soft tissue components such as lip pads and buccal shields, rather than relying solely on occlusal inclined planes to guide mandibular protrusion^[5].

The results of this study showed that after treatment with the FRII appliance, the SNB angle increased significantly by 1.61° ($p < 0.001$), indicating a marked forward displacement of the mandible, which is consistent with findings from multiple domestic and international studies^[6,7]. The longterm followup study by Perillo et al.^[1] also confirmed that FRII appliance treatment significantly reduces the ANB angle and improves skeletal Class II relationships, with longterm stability of the therapeutic effect. In the present study, the ANB angle decreased by 2.85° , a relatively substantial reduction, demonstrating that this treatment regimen has a clear effect on improving the sagittal relationship between the maxilla and mandible.

4.2. Advantages of combined maxillary expansion and functional treatment

Conventional singlemodality functional treatment often faces the challenge of transverse discrepancies limiting sagittal advancement when managing Class II malocclusion with concurrent maxillary arch width deficiency. A narrow maxillary arch may not only cause posterior crossbite but also restrict full mandibular protrusion, thereby compromising the final effect of functional treatment. In this study, we innovatively adopted maxillary expansion as a preliminary step before FRII functional treatment, first addressing the transverse width problem and then proceeding with sagittal advancement, thus achieving a three-dimensional synergistic approach of “transversesagittalmyofunctional” correction.

The study by Maspero et al. demonstrated that rapid maxillary expansion combined with functional appliance therapy yields better treatment outcomes than expansion alone in patients with skeletal Class II deep overbite^[8]. Our results also support this view: through the sequential protocol of expansion followed by functional treatment, the ANB angle reduction reached 2.85° , which is superior to the results reported in some studies using functional treatment alone, suggesting that maxillary expansion may create more favorable spatial conditions for mandibular advancement, thereby enhancing the efficacy of functional therapy^[9]. In addition, expansion can improve nasal airway space, which is of positive significance for children with mouthbreathing habits, consistent with our clinical observation of symptom improvement in these patients.

4.3. Analysis of treatment effects

In this study, the SNA angle decreased slightly (1.25°) after treatment, but the change was small, indicating that the treatment had limited impact on the maxilla, and the maxillary position remained essentially stable.

This finding aligns with the expectations of functional treatment—the primary therapeutic goal is to promote mandibular advancement rather than to inhibit maxillary growth. A systematic review by Koretsi et al. showed that removable functional appliances resulted in only a slight decrease in SNA angle (approximately -0.28° per year), which is consistent with the trend observed in our study^[10].

The significant increase in SNB angle by 1.61° is one of the core findings of this study, indicating that the mandible moved forward substantially after treatment and that the goal of mandibular advancement was achieved. This change is crucial for the correction of Class II malocclusion, as mandibular retrusion is the primary etiological factor in this type of deformity. The ANB angle decreased by 2.85° , from 6.73° before treatment (indicating a pronounced skeletal Class II relationship) to 3.88° (close to the normal range of $2-4^\circ$), demonstrating that the skeletal Class II relationship was substantially corrected. Effect size analysis showed that Cohen's d values for all three parameters were greater than 0.8, indicating large effects, further confirming the significance of the treatment outcomes.

It is worth noting that the magnitude of ANB improvement (2.85°) in our study was greater than that reported in some similar studies^[1011]. This may be attributed to the following factors: first, our protocol combined maxillary expansion with functional treatment, and the synergy between transverse and sagittal dimensions enhanced the overall efficacy; second, the patients enrolled in this study were in the pubertal growth spurt period, during which the jaw bones are more responsive to functional stimulation; and third, the stepwise treatment approach improved patient compliance, ensuring adequate appliance wear time.

4.4. Limitations of the study

This study has certain limitations. First, the sample size was relatively small ($n = 30$). Although the statistical power was sufficient, the generalizability of the results is somewhat limited, and future studies with larger samples are warranted. Second, this study only analyzed sagittal hard tissue parameters and did not include vertical indicators (such as mandibular plane angle, anterior facial height) or quantitative evaluation of soft tissue profiles, making it difficult to fully reflect the impact of treatment on the three-dimensional dentofacial structures. Third, this was a prepost selfcontrolled study without an untreated control group, so the influence of natural growth on the measurements cannot be completely excluded. Fourth, the followup period was relatively short, and longterm stability data are lacking; the maintenance of treatment effects over time requires further investigation.

5. Conclusions

The combined application of the FR II functional appliance with maxillary expansion demonstrates definitive efficacy in treating mandibular retrusion type Angle Class II malocclusion in children. It can significantly improve the sagittal relationship between the maxilla and mandible, promote forward mandibular displacement, reduce the ANB angle, and effectively eliminate oral habits. This sequential treatment protocol—maxillary expansion followed by FR II functional appliance—achieves three-dimensional coordinated correction of transverse, sagittal, and muscular dimensions. Moreover, the stepwise approach is conducive to improving patient compliance, making it worthy of clinical promotion in early orthodontic treatment for children.

6. Constructive recommendations

Based on the findings of this study and clinical practice experience, the following recommendations are proposed for the early management of mandibular retrusion deformity in children:

First, seize the optimal treatment timing and emphasize early intervention. The peak growth period in children represents the golden window for functional appliance therapy, during which the mandible exhibits substantial growth potential and responds sensitively to functional forces. It is advisable to monitor craniofacial development starting from the mixed dentition stage, and to perform early evaluation and intervention in children with a tendency toward mandibular retrusion, so as to prevent progression to more severe skeletal deformities and reduce the complexity and cost of later treatment.

Second, establish a three-dimensional orthodontic concept and optimize the treatment protocol. For Class II malocclusion patients with concomitant maxillary transverse deficiency, it is recommended to perform maxillary expansion as a preparatory step before functional appliance therapy—first resolving the transverse discrepancy, then proceeding with sagittal advancement—to achieve three-dimensional coordinated correction and improve overall outcomes. At the same time, attention should be paid to vertical control to avoid unfavorable changes such as clockwise rotation of the mandible during treatment.

Third, address the etiology and eliminate oral habits. Mandibular retrusion is often closely associated with oral habits such as mouth breathing, lip biting, and abnormal swallowing; mechanical correction alone frequently fails to achieve stable results. It is recommended to emphasize myofunctional training during treatment and to actively coordinate with otolaryngology for the management of upper airway conditions such as allergic rhinitis, thereby correcting abnormal perioral muscle function patterns at the etiological level and enhancing the stability of treatment outcomes.

Fourth, strengthen multidisciplinary collaboration to improve the level of diagnosis and treatment. Pediatric orthodontics involves multiple disciplines, including orthodontics, pediatric dentistry, otolaryngology, and pediatrics. It is recommended to establish a multidisciplinary collaborative diagnosis and treatment model, conduct joint consultations for complex cases, and develop individualized and comprehensive treatment plans. At the same time, training for primary care dentists should be enhanced to promote standardized early orthodontic techniques and raise the overall level of pediatric oral disease prevention and treatment in the region.

Fifth, improve the followup system and conduct longterm studies. It is recommended to establish a longterm followup mechanism to regularly track treated patients, evaluate the longterm stability of treatment outcomes, and provide evidencebased support for optimizing therapeutic protocols. In addition, largesample, multicenter clinical studies should be conducted further to validate the efficacy and safety of this treatment approach and to provide higherlevel evidence for clinical promotion.

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Disclosure statement

The authors declare no conflict of interest.

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