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Case Study

A Case Study Utilizing the Removable Osseo-Restoration Appliance™ for Early Treatment of a Class 3 Malocclusion in the Mixed Dentition

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Abstract

Introduction: This case study demonstrates the skeletal and dental changes achieved using the Removable Osseo-Restore Appliance™ (RORA) in an 8-year-old male with an early Class III malocclusion.

Aim: To evaluate the effectiveness of the RORA appliance in correcting the Class III malocclusion.

Methods: The RORA appliance is a removable maxillary device worn full time, including while eating. The device features two sagittal screws that are turned twice a week until 5 - 7 mm of separation is achieved. The patient undergoes evaluation appointments every four weeks. Cephalometric tracings were taken before and after treatment and compared to assess positive skeletal changes, facial growth, and anterior crossbite correction.

Results: The cephalometric comparisons revealed positive skeletal changes and correction of the anterior crossbite. Furthermore, the treatment produced different effects than those typically achieved with facemask treatment.

Conclusion: The RORA appliance was effective in the early treatment of a Class III malocclusion.

Keywords: *Class III Malocclusion; Interceptive Orthodontic Treatment; Jaw Orthopedics; Removable Orthopedic Appliances; Mixed Dentition; Sagittal Removable Appliances*

Introduction

Class III malocclusion in the mixed dentition affects approximately 4% [0.7 - 13%] of the global population [1]. Historically, facemask treatment, rapid palatal expansion, and fixed appliances during the mixed dentition have been considered effective and stable for correcting skeletal Class III malocclusion [2]. However, a recent systematic analysis and meta-analysis indicate that while early facemask treatment may provide some short-term benefits, there is a lack of evidence on long-term benefits. The review found moderate evidence supporting using the facemask treatment, while other appliances had weak evidence [3]. Additionally, evidence suggests that rapid palatal expansion and facemask treatment together are no more effective than facemask treatment alone [4]. Despite this, facemask treatment for early correction of skeletal Class III malocclusion is still considered the treatment with the best evidence and is widely accepted.

The etiology of Class III malocclusion is considered to be multifactorial, with genetics and hereditary patterns playing a significant role. However, environmental factors also contribute to this form of malocclusion, such as mouth breathing with concomitant low rest-

ing tongue posture, nasal airway obstruction, and atypical swallowing. These factors are recognized to contribute to the development of Class III malocclusion [5]. Additionally, it is interesting that tongue-tied patients tend to develop this form of malocclusion [6]. Therefore, clinicians must conduct a thorough myofunctional evaluation and understand if the patient has habitual or obligatory mouth breathing tendencies before early treatment of a Class III case. This is particularly important since studies have shown that Class III patients more commonly exhibit low tongue posture and a retruded position at rest compared to other sagittal skeletal classes I and II [7].

In adult non-growers, Class III malocclusion is not purely a result of skeletal mandibular prognathism, as the components of Class III malocclusion can vary. Skeletal mandibular prognathism accounts for about 75% of presentations, while retrognathic maxilla alone accounts for roughly 20%. About 8% of cases exhibit disharmony in both the maxilla and mandible. Differential diagnosis is necessary to determine the nature of Class III malocclusion during growth. For example, a functional shift of the mandible from abnormal tooth contact can force the mandible forward into a "pseudo" Class III while the profile remains Class I skeletal. Treatment that removes the abnormal forward shift is necessary in such cases.

Additionally, a hypodivergent pattern with abnormal over-closure of the mandible rotating forward and up, resulting in an anterior crossbite, can be treated effectively by dentoalveolar compensations. A compensated Class III may have a positive overjet or end-to-end incisor relation but reclined lower incisors, which may require maxillary sagittal forward development, camouflage, or surgical correction [8]. Witt's appraisal is a proposed formula for accurately triaging Class III into surgical, camouflage, and non-surgical treatment. A range of 0 to -5 mm suggests treatment with a reverse pull facemask, while a range of -4 to -12 mm requires more robust growth-directed treatment, followed by subsequent imaging to determine growth treatment vector response and decide if non-surgical camouflage or surgery is necessary [9].

Facemask therapy is the most common early intervention treatment for Class III malocclusion, with long-term data to support its efficacy. Therefore, it is important to analyze the effects of this approach as a reference point to compare the treatment outcomes with the Removable Osseo-Restoration Appliance™. About 40 - 60% of skeletal Class III patients exhibit some form of maxillary retrusion [10] which can be treated early with maxillary protraction between the ages of 8 - 10 years to enhance treatment effects [11]. The success of maxillary protraction is increased with early mixed dentition treatment, as studies have shown that the maximum velocity of maxillary growth occurs between ages 6 - 8 years [12,13].

Facemask therapy has several combined effects, including both skeletal and dental changes. The maxilla will move forward and downward, along with a counterclockwise rotation of the maxillary plane, resulting in some increased proclination of the maxillary anteriors in response to mesial migration of the posterior teeth under traction. The counterclockwise rotation of the maxillary plane induces a mandibular clockwise rotation (downward and backward) as compensation for the maxillary changes. This mandibular effect is partly responsible for improving the sagittal relationship of both jaws and establishing a positive overjet. There is also an increase in facial height due to the mandibular changes. The common clinical protocol is to place hooks forward in the cuspid region and apply a 30-degree downward angle from the plane of occlusion pull on elastics to partially offset the counterclockwise direction of the maxillary plane rotation. The duration of facemask application ranges from 12 - 24h per day using a force of 300 to 600g per side for 9 - 12 months, with an average of 2 mm in maxillary advancement [14]. However, compliance with facemask therapy can be a real problem, as electronic monitoring revealed that although patients reported wearing the facemask for 13 - 14h per day, the recording device only reported 6 - 7h of actual wear [15]. Additionally, prolonged contact with the chin cup portion of the facemask can irritate the skin and limit wear time.

In a summary of the effects of facemask application in a pre-pubertal group of 34 patients, corrections of sagittal Class III discrepancies were 80.1% skeletal and 19.9% dentoalveolar [16]. Another study of 20 patients treated with a facemask demonstrated a combination of effects to diminish the Class III problem, including maxillary forward development, backward mandibular movement, proclination of

upper incisors, and retroclination of lower incisors. After a 4-year observation period, 15 of the 20 patients maintained a positive overjet or end-to-end incisal pattern [17].

Materials and Methods

The Removable Osseo-Restore Appliance™ (RORA) is a sagittal appliance used for many years and was developed by Dr. Steve Galella in Tennessee, USA (Figure 1). The current modifications to the appliance are as follows:

1. The size and angulation of the two active screws have been modified.
2. The force delivered to the acrylic components by screw activation has been modified.
3. The anterior palatal acrylic does not touch the maxillary incisors.
4. The labial bow is a double-loop style between the lateral incisors and cuspids.
5. The occlusal pads are uniformly 4 mm thick, measured from the depth of the maxillary first molar fossa to the occlusal surface of the occlusal pads.
6. The occlusal pads are flat with no indexes or indentations.
7. A 3 mm ½ spherical divot is placed in the acrylic over the posterior 1/3 of the incisal papilla for tongue-tip placement.
8. Delta clasps are placed on the first molars, and arrowhead clasps are placed between the first and second deciduous molars for retention.

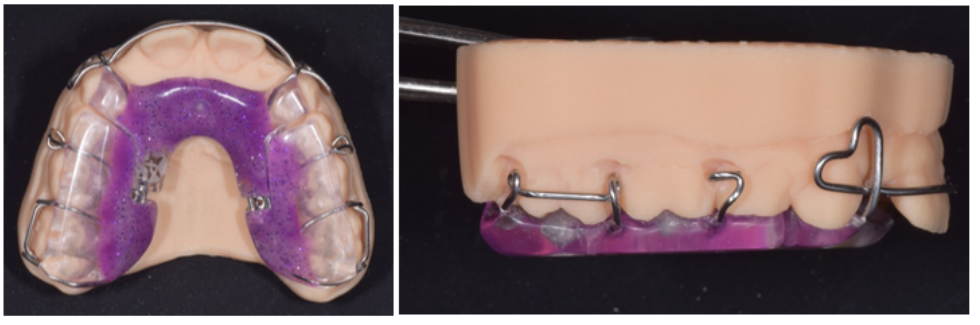

Figure 1: *The removable osseo-restore appliance™.*

According to a white paper [18] and Dr. Steve Galella, the developer, the RORA is ideally used in patients aged 6 - 9 years in CVM growth stage 3 - 4. It is typically placed after the eruption of the upper permanent central incisors, but in more severe cases, it can be used in the primary dentition, primarily after the eruption of the permanent upper and lower first molars. The appliance takes advantage of the displacement and remodeling occurring in the facial region during this time. It is worn 24/7, including during eating, to provide additional growth stimulation, and it is removed only for oral hygiene. The usual treatment time is 8 - 12 months, and the patient is seen every 4 weeks for evaluation and adjustment.

The occlusal pads are 4 mm thick, as measured from the first molar fossa's depth to the pads' occlusal surface. At delivery, only the first molars are in contact. After 1 month, Ramus Uprighting, an Enlow concept, allows all posterior teeth to come into contact. An example of

this phenomenon is shown in figure 2 (not the case study patient). This observed effect is evidence of the mandible actively remodeling. The indents created during chewing are removed at each follow-up visit to keep the occlusal surfaces smooth, allowing de-proprioception of the mandible.

Figure 2: *Example delivery of RORA Example one month after delivery RORA.*

There are several steps to achieve maximum benefit from the RORA appliance, including 24/7 wear, adapting to eating with the appliance, nasal breathing at all times (especially during sleep), and tongue-to-palate placement. Usually, after 1 month of wearing the appliance 24/7 and successfully eating with it, the screws can be turned on both sides twice a week, usually on Wednesday and Sunday before bed. Each turn is 0.2 mm, yielding approximately 1.6 mm of forward sagittal separation per month. When approximately 6 mm of screw opening has been achieved, the screws are fixated, allowing 3 months of additional wear time with no turns.

At the end of this orthopedic phase, a transverse appliance may be utilized to optimize transverse development, if needed.

The patient was an 8-year-old healthy male with no medical or systemic conditions. He was referred to our clinic by a speech therapist due to a confirmed skeletal Class III malocclusion with an anterior crossbite. During sleep, mild mouth breathing was noted. The pediatric sleep questionnaire [19] scores was 3, indicating a low risk for sleep-disordered breathing, so a sleep test was not considered. Upon examination, mild resistance in the right nasal passage during nasal breathing was observed, and the nares were static upon inspiration. The lip seal at rest was competent, and low tongue posture was confirmed. Nasal breathing demonstrated a mixed upper chest and diaphragmatic pattern.

The myofunctional evaluation revealed that the tongue-to-spot (TTS) tongue range of motion ratio (TRMR) was 80%, and the linguopalatal seal (LPS) TRMR was also 80% [20], indicating no tongue tie was present. A swallowing test was conducted, observing the patient sipping water and holding it for three seconds, followed by a swallow, which did not reveal any perioral compensations, indicating a normal swallow [21]. The patient's development was normal for his age, and his dentition was intact. Oral hygiene was fair, and the caries risk was moderate. The patient was receiving speech therapy at the time of the initial presentation, and the first phase of treatment utilizing the RORA was presented. Observation of the patient during the entire clinical visit demonstrated no open-mouth breathing habit, indicating that he was a competent nasal breather.

RORA therapy began on August 25, 2022. The patient followed all instructions and continued active turns until March 28, 2023, at which point the screws were fixated, and records were taken, including photographs, model scans, and progress CBCT. At month 3, the labial wire can be removed as it does not serve any purpose other than to help parents know the child is wearing the appliance (Figure 3).

Pre-treatment composite: 06/03/2022

Post-treatment composite: 03/28/2023

Pre-treat panoramic image

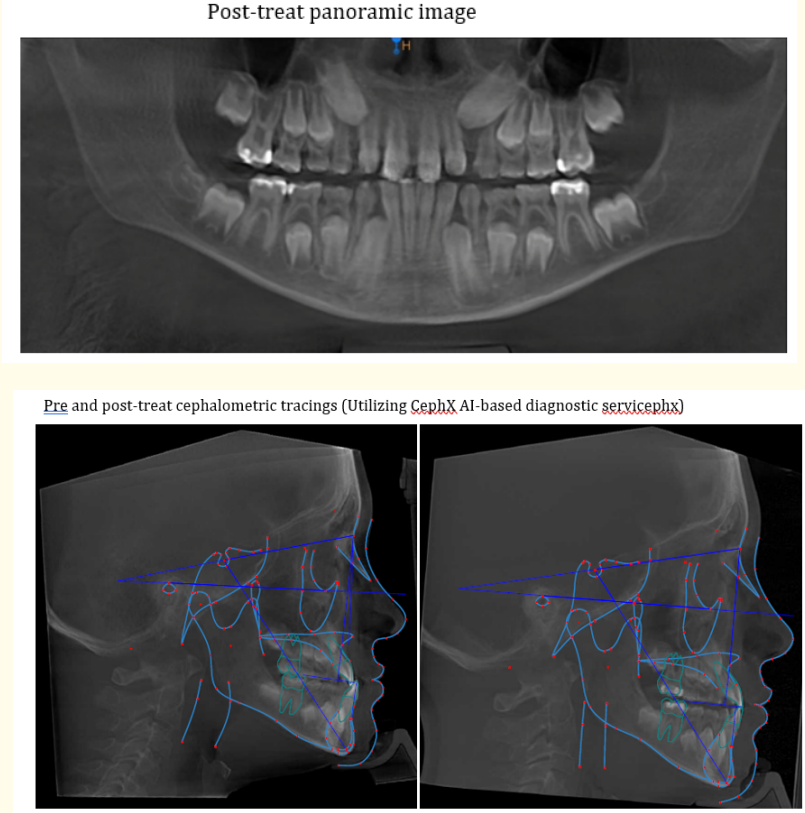

Figure 3: *Patient in RORA at time of fixation (7 months active treatment) and starting 3-month holding pattern (removal of labial wire in month 3.*

Results and Discussion

Based on the author's experience, this appliance has a high compliance rate among patients. Eating while wearing the appliance is easily achievable, and its comfort is remarkable. The appliance also has a TMJ splint effect, often making patients feel better wearing it. It does not cause speech impediment and has little discomfort during wear. This contrasts the compliance difficulties experienced by patients undergoing the widely accepted early Class III treatment, reverse pull face mask therapy.

In this case study, the patient's Class III relationship and maxillary sagittal deficiency persisted even after seven months of treatment. This is mainly due to the post-treatment Witt's appraisal being -5.42 mm. As a result, the patient will be fitted with a second RORA, which is often necessary for a skeletal Class III patient to achieve a more complete skeletal correction. This appliance is also suitable for treating Class I and II malocclusions as it promotes growth in both jaws.

The arch length changes after the treatment demonstrate a substantial increase in arch length post treatment, which would translate into more arch perimeter room for eruption of permanent teeth resulting in less potential crowding in the permanent dentition (Figure 4).

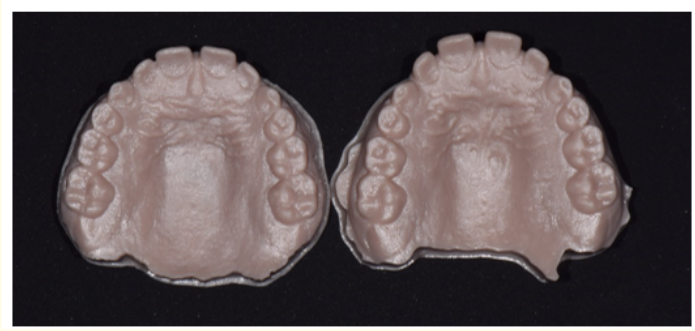

Figure 4: *Arch length comparison.*

It is widely known that Class II malocclusion is the most common type, accounting for 60% of cases. In rare cases, the maxilla may be prognathic together with a Class II Mandible [22]. Therefore, the RORA is a suitable orthopedic jaw treatment option for children.

Upon comparing the cephalometric data, it becomes apparent that the RORA appliance produced highly favorable skeletal corrections with minimal dentoalveolar compensations (As shown in figure 5):

Descriptor	Meas.	Type	Mean	Sd	Patient	Type	Mean	Sd	Patient	Graph	Comment
pre and post treatment analysis											post treat analysis
SN TO PALATAL PLANE		Deg	3.0	5.0	10.73	Deg	3.0	5.0	6.53	-(*)+	
SN-Occ. Plane		Deg	16.0	3.0	18.47	Deg	16.0	3.0	14.36	-(*)+	
SNA		Deg	82.0	2.0	73.17	Deg	82.0	2.0	76.89	-(* |)+	Maxilla retruded
SNB		Deg	80.0	2.0	78.4	Deg	80.0	2.0	79.67	-(*)+	
UI to SN		Deg	103.0	4.0	106.6	Deg	103.0	4.0	112.77	-(| *)+	Upper incisor too protruded
Wits Appraisal		mm	0.0	2.0	-9.44	mm	0.0	2.0	-5.42	-(* |)+	Class III Skeletal problem
Y-AXIS(JARABAK)		Deg	67.0	3.0	67.82	Deg	67.0	3.0	66.27	-(*)+	
A Pt to Nasion Vertical	A to Na Perp	mm	1.0	2.0	-3.11	mm	1.0	2.0	-0.4	-(*)+	
ANB		Deg	2.0	2.0	-5.23	Deg	2.0	2.0	-2.78	-(* |)+	Class III relatioship
ANS to the Anterior Arc		mm			-10.85	mm			-9.41	-( )+	
FMA		Deg	28.0	3.0	22.95	Deg	28.0	3.0	24.86	-(*|)+	Low Mandibular Plane
Anterior facial height		mm	0.0	2.0	7.62	mm	0.0	2.0	8.47	-(| *)+	Long Anterior Lower Face Height
L1-MP		Deg	92.0	3.4	82.17	Deg	92.0	3.4	83.72	-(* |)+	

Figure 5: *Cephalometric comparisons.*

- A point to Nasion-Vertical shifted from -3.11 mm pre-treatment to -0.4 mm post-treatment, resulting in a total of 2.71 mm forward maxillary skeletal growth. This is superior to the average of 2mm forward maxillary growth achieved through face mask treatment lasting 9 - 12 months. The RORA achieved 2.71 mm of forward maxillary growth in just 7 months.
- SNA also confirms the maxillary skeletal change, shifting from 73.17' to 76.89'.

- Unlike reverse pull face mask treatment, the mandible did not undergo the usual downward and backward rotation in this RORA case. Instead, the mandible moved forward, as indicated by the shift from SNB pre-treat 78.4' to post-treat 79.67'.
- There was a slight increase in anterior face height, but the Y-axis angle decreased from 67.82' to 66.27', indicating a reduction in the tendency for vertical growth. This is in contrast to facemask therapy, which results in the mandible's expected downward and backward rotation, contributing to increased face height.
- The maxillary incisors showed increased proclination (U1-SN pre-treat 106.6' to post-treat 112.77'), but the usual lingual compensation seen with face mask treatment was absent after RORA treatment (L1-MP 82.17' to 83.72'). This amounts to less dentoalveolar compensation with the RORA than with facemask treatment.
- Finally, the maxillary occlusal plane had a counterclockwise rotation (SN-occl. plane pre-treat 18.47' to post-treat 14.3'), but the maxillary basal bone also had a counterclockwise rotation, as indicated by SN-Palatal plane pre-treat 10.73' to post-treat 6.53'. This reflects a natural growth phenomenon rather than a dentoalveolar compensation produced by face mask therapy.

Limitations of the Study

It should be noted that this study is limited to a single case, and a larger sample size with controls is necessary to validate the efficacy of the RORA as an effective option for early Class III interceptive treatment. Additionally, the subject in this study had a relatively normal mandibular position (SNB pre-treat 78.4') and a retrognathic maxilla, which is one subtype of Class III cases. Further research is needed with more prognathic mandible Class III subjects to understand the potential of the RORA in Class III treatment. To the author's knowledge, there is little published research on the RORA, and hopefully, future investigations will be conducted to gain more insight into its effectiveness.

Conclusion

Compared to the known difficulties associated with face mask treatment and the compromises often made with its use, the Removable Osseo-Restore Appliance™ has demonstrated, in this case, study, the ability to correct a Class III malocclusion in a pre-pubertal patient. It produced measurable skeletal changes in just 7 months, rather than relying solely on dentoalveolar compensations. This treatment's ease of use and high compliance rate make it a viable option for interceptive jaw orthopedics in early mixed dentition patients.

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