










Cephalometric changes of pushing splints 3 compared to rapid maxillary expansion and facemask therapy on the airway space in class III growing patients: A randomized clinical trial

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Abstract

Background: Early orthopaedic treatment with rapid maxillary expansion (RME) associated with facemask (FM) has been shown to be effective in correcting Class III malocclusions in children. Treatment with pushing splints 3 (PS3) has shown to correct skeletal discrepancies in Class III growing patients. However, the effects of orthopaedic treatment on the upper airways in children with Class III malocclusion is controversial.

Objectives: The aim of this study was to evaluate the cephalometric changes in the airways of PS3 compared to the RME/FM protocol.

Materials and Methods: In this study, 48 patients with Class III malocclusion (age range 5.5–8.5 years old) were selected for this study, and 24 were treated with PS3 appliance and 24 with RME/FM therapy. Lateral cephalograms before (T0) and at the end of the treatment (T1) were analysed to compare pharyngeal spaces. Paired and unpaired t tests were used for data analysis ($P < .05$).

Results: A total of 41 patients (21 patients for the PS3 group, 11 males and 10 females, mean age 7.0 ± 1.2 years; 20 patients for the RME/FM group, 10 males and 10 females, mean age 7.2 ± 1.3 years) were included. The results showed a statistically significant ($P < .05$) increase in the nasopharyngeal space after both therapies. However, the effects were similar considering that there were no differences between groups for the assessed variables at T0–T1.

Conclusions: Early treatment of Class III malocclusion with PS3 does not induce a statistically significant increase in the sagittal airway space compared to RME/FM. The absence of untreated group could not define the role of growth in the increase of space.

KEYWORDS

airway, class III, facemask, pushing splints 3, RME

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1 | INTRODUCTION

Airway obstruction is a common disorder that may involve upper, lower, or entire airway. It is reported that airway volume changes related to dento-skeletal patterns and orthopaedic treatments may have effects on the airway space in children.¹

A recent systematic review and meta-analysis has confirmed the beneficial effects on the respiratory pattern of orthodontic treatment in patients with OSA. However, orthodontic treatment, performed by monitoring the improvement of respiratory parameters, should be limited to patients who have an orthodontic indication, without considering it elective in all children with OSA.²

Orthopaedic therapy with rapid maxillary expansion (RME) and functional Class II device seems to be associated with an increase of upper airway space both in the short and in the long term in growing patients.³⁻⁵ This effect results in a benefit also in children with obstructive sleep apnoea (OSA).^{6,7}

Furthermore, many studies concerning the association between Class III malocclusion and respiratory disorders have been performed.⁸

The prevalence of Class III malocclusion varies from 0% to 26% and the different features include mandibular prognathism or macrogathia, maxillary retrognathism or micrognathia, or a combination of these features.⁹⁻¹¹ Hereditary factors could also be involved in the development of this type of malocclusion. These factors can influence the long-term stability of early orthopaedic treatment of Class III malocclusion.¹⁰

Early treatment of Class III malocclusions allows the clinician to achieve a better result and reduce the risk of maxillofacial surgery.⁸

The treatment of choice in Class III growing patients is RME associated with FM.^{7,10,12} Recently, the use of Pushing Splints 3 (PS3) has been introduced.^{10,13}

A recent randomized controlled trial (RCT) study assessed the dento-skeletal effects produced by PS3 in Class III children. The effects on the airways induced by PS3, however, have not been studied yet.¹³

Studies in two-dimensional (2D) and three-dimensional (3D) images have demonstrated the improvement of the upper airway spaces after palatal expansion therapy in children.¹⁴

A systematic review and meta-analysis of Class III patients reported an increase in nasopharyngeal dimension in patients treated with maxillary protraction appliances compared to the control group, but no effects were reported on the lower pharynx dimension.⁸

A meta-analysis conducted on Class III patients demonstrated that the RME/FM protocol has no different effects on the upper airway width compared to the treatment using only FM. Both treatment approaches failed to demonstrate a significant effect on the lower pharynx width.¹⁵ Therefore, the effects of orthopaedic treatment on the upper airways in children with Class III malocclusion are still controversial.

The study performed in 2021 by Galeotti et al¹³ comparing RME/FM and PS3 showed that both therapies are effective for the early correction of Class III malocclusion but the FM therapy allows

obtaining more favourable effects in the control of mandibular position.

Therefore, the aim of this study is to evaluate if RME/FM therapy also has a more positive effect on the airways, compared to PS3 which does not involve palatal expansion.

The null hypothesis of the present study is that there is a significant difference between the use of PS3 and RME/FM on the airway dimensions in growing Class III patients.

2 | MATERIALS AND METHODS

2.1 | Subjects

The study was designed as an RCT and followed the consort checklist for RCT studies.¹⁶

The study protocol was approved by the Ethics Committee of Bambino Gesù Children's Hospital (479_OPBG_2012) and included Class III patients collected at the Dentistry Unit of Bambino Gesù Children's Hospital, IRCCS (Rome, Italy) from February 2012 to June 2018. All patients were treated after parental consent.

In this study, 48 patients were divided (24 males and 24 females) into two groups: the first one was treated with PS3 appliance and the second group was treated with RME/FM therapy. The patients age range was 5.5–8.5 years old.

The patients were allocated to the two groups, with stratification according to gender. Two randomization lists were elaborated, one for males and one for females, and the patients were randomly allocated by a balanced block randomization into the two groups.

A single operator allocated the patients by means of a custom-made Java script and was responsible for the allocation concealment. The allocation was disclosed only when a new patient was enrolled in the trial.

The following baseline conditions were considered for inclusion criteria:

- Caucasian ethnicity;
- deciduous, early or late mixed dentition;
- mesial step deciduous molar relationship or Class III permanent molar relationship;
- pre-treatment Wits appraisal of -2.0 mm or less.

The following baseline conditions were considered for exclusion criteria:

- craniofacial anomalies;
- systemic disease affecting normal growth patterns;
- clinically evident (more than 5%) facial and/or mandibular asymmetry;
- previous orthodontic treatment;
- anomalies in number of teeth or dental morphology;
- periodontal disease;

- signs and/or symptoms of temporomandibular disorders.
- adenoidectomy and/or adenotonsillectomy performed during orthodontic treatment.

2.1.1 | Group 1: PS3 Group

The PS3 appliance is manufactured by making impressions of both dental arches.

It consists of two acrylic sticks and two connection modules (one on each side) with Forsus™ L-pins. The two splints are removable and cover all the crowns of the teeth (Figure 1A).

The mandibular incisors (if they are too retroclined) should not be covered with resin on the buccal surface. Tests to close the mouth with articulating paper must be carried out in order to remove any premature contact. The force applied by Forsus™ modules is approximately 200 g per side. The hours of use of the PS3 should be at least 14 hours/day.

The result of the applied force by Forsus™ L-pin produces an intrusive movement on both the lower molar and the upper canine, but with a mesialization vector on the upper arch, and a distalization vector on the lower arch.

The device is reactivated at each appointment by compressing the coil springs through thicknesses of 1–2 mm and, when it is required, adapted with orthodontic resin.

2.1.2 | Group 2: RME/FM

In order to manufacture the bonded maxillary expander with resin splints, impressions of both arches and the registration of a raised intra-arch wax are required.

The expander is cemented with a self-cured resin-reinforced glass ionomeric cement. Activation of $\frac{1}{4}$ of the screw once a day is required. The expansion ends until the palatal cusps of the upper molars are in contact with the buccal cusps of the mandibular molars.



FIGURE 1 Illustration of PS3 (A) and RME/FM (B).

The use of the facial mask is requested for 14 hours a day. Light elastics were used initially (150g per side), then they were transitioned to higher forces (300g per side) when the patient got used to it (Figure 1B).

2.2 | Cephalometric analysis

Lateral standardized cephalograms were taken before (T0) and at the end of the treatment (T1) and were performed in natural head position, with standardized settings. The patient was required to maintain the same position during cephalogram acquisition, avoiding breathing and swallowing movements.

The active phase of treatment ended when an overjet between 2 and 4 mm and an overcorrection towards Class II molar relationship was achieved. After this active phase, a T1 lateral cephalogram was taken.

Dolphin Imaging 11.0 software was used to obtain cephalometric analysis (Dolphin Imaging, Chatsworth, CA, USA). The cephalometric analysis was an adaptation of the analysis introduced by Kirjavainen and Kirjavainen¹⁷ and it consisted of nine linear measurements. These measurements are described and illustrated in Figure 2.

2.3 | Blinding

The operators who executed the cephalometric analysis and those who performed the statistical analysis were blinded to the treatment.

2.4 | Method Error

The method error was calculated on 10 randomly selected patients at both T0 and T1. The same examiner digitized twice the same set of landmarks after a washout period of at least 6 weeks. The method error for all measurements was calculated using Dahlberg's formula.¹⁸ Systematic differences between duplicated measurements were tested using a paired Student's *t*-test with the type I error set at $P < .05$.

The method error ranged from 0.4 to 1.3 mm for linear measurements and from 0.5° to 1.0° for angular measurements. There was no systematic error for any of the 11 measurements (Student's *t* test; $P > .05$).

2.5 | Statistical analysis

Descriptive statistics included the mean and standard deviation (SD) of cephalometric measurements at T0 and T1 and for the T0–T1 interval. Unpaired samples *t*-test was applied to compare the cephalometric variables at baseline (T0) and to assess if there were significant differences in the changes during the T0–T1 interval between the two groups. Furthermore, paired sample *t*-test was used

to compare the cephalometric changes between T0 and T1 within each group. Statistical significance was tested at $P < .05$.

3 | RESULTS

Forty-eight patients, 24 males and 24 females, were included in the study (mean age \pm SD = 7.1 ± 1.3 years). However, six patients (three of the PS3 group and three of the RME/FM group) dropped out of the study because they did not perform the documentation at T1 and one patient of the RME/FM group was excluded because she underwent adenotonsillectomy during orthodontic treatment. Therefore, a total of 41 patients (21 patients for the PS3 group, 11 males and 10 females, mean age 7.0 ± 1.2 years; 20 patients for the RME/FM group, 10 males and 10 females, mean age 7.2 ± 1.3 years) were available for the statistical analysis (Figure 3). The mean treatment duration was 1.4 ± 0.4 years for the PS3 group and 1.6 ± 0.4 for the RME/FM group.

Analysis of the cephalometric measurements in the RME/FM group and in the PS3 group at T0 showed no significant differences between the two groups, indicating that the two groups presented similar characteristics at baseline (Table 1).

The comparison between pre-treatment (T0) and post-treatment (T1) values in the RME/FM group showed statistically significant increase for the following values: AD1-PNS, PNS-Ba, AD2-PNS, AD2-H, PNS-H, SPAS, H-H' and a statistically significant reduction of AD1-Ba in the RME/FM group (Table 2).

The comparison between T0 and T1 values in the PS3 group showed a statistically significant increase for the following values: AD1-PNS, AD1-Ba, PNS-Ba, AD2-PNS, AD2-H, PNS-H, SPAS, p-pp, Pas-ppas. A statistically significant reduction of the AD1-Ba value also was observed (Table 3).

The between-group comparisons for the T1–T0 changes showed no statistically significant differences between the two groups for any of the variables examined (Table 4).

4 | DISCUSSION

The purpose of this cephalometric study was to evaluate the effects of PS3 on sagittal airway dimension compared to RME/FM.

It can be thought that the use of the facial mask and the PS3 can have a retrusive effect on the jaw and reduce the hypopharyngeal region. Moreover, as previously demonstrated, the application of RME can increase the space at the level of the nasal cavities^{3,5} and this may suggest that the RME/FM protocol can increase the airway space more compared to the PS3. So it can be supposed that the two therapies have different effects on airway space and different cephalometric results.

The literature reports conflicting evidence regarding the changes in the airway before and after the treatment of Class III malocclusion with RME/FM.^{19,20} No studies were performed to evaluate the effects of PS3 on airway dimensions.

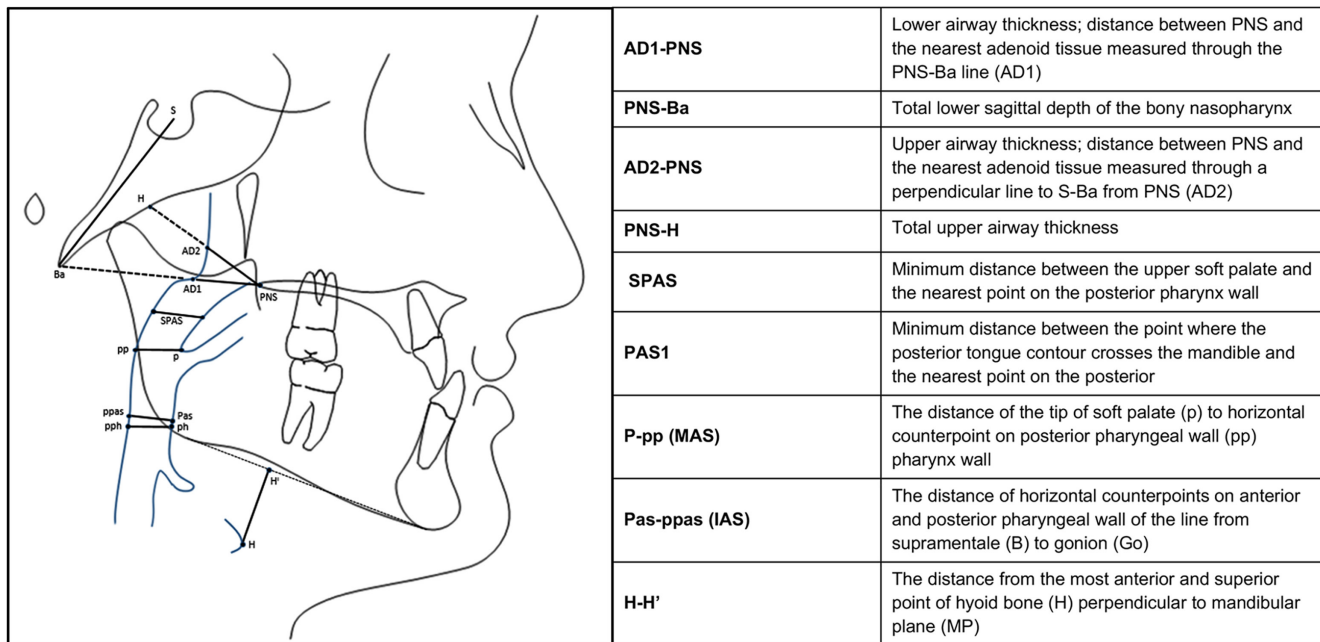
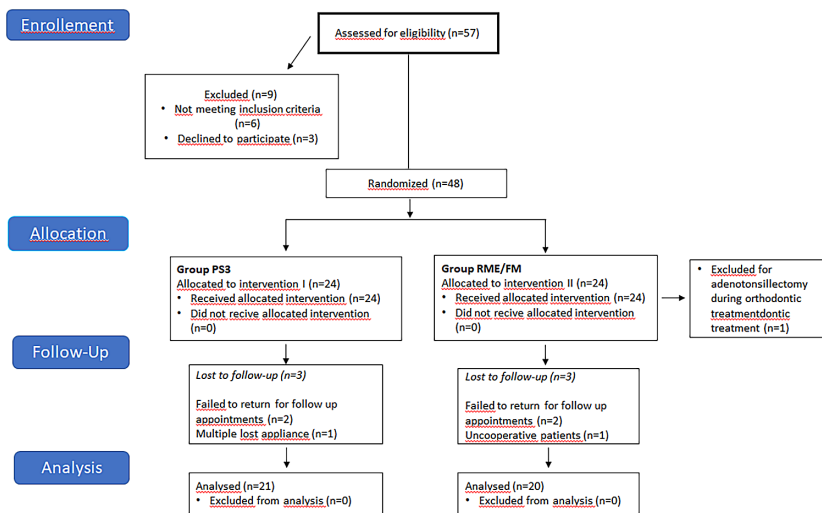


FIGURE 2 Description and illustration of cephalometric measurements.

FIGURE 3 The CONSORT flow diagram.



The analysis of the results of the present study showed statistically significant increases in the sagittal dimension of nasopharyngeal region in both groups.

The increases evidenced in each group were similar and, therefore, no statistically significant differences were found between PS3 and RME/FM groups on the T1-T0 changes in the sagittal airway dimensions.

The sample examined in this study is similar in mean age at the start of treatment (7.01 ± 0.43 years) and treatment protocol to the RME/FM group evaluated by Mucedero et al. (7.1 ± 1.8 years) that evaluated Class III patients compared to a control group of untreated Class III subjects.²⁰ It might be hypothesized, therefore, that also PS3 therapy has no significant effects on the sagittal

airway dimension if compared to a control group of untreated Class III subjects.

A recent systematic review, which included six papers and comprised the aforementioned studies, concluded that maxillary protraction appliances increase post-palatal and nasopharyngeal airway dimensions in growing skeletal Class III patients compared to controls. On the contrary, no effects were reported on the lower pharynx dimension.⁷

The main difference between our study and this meta-analysis is the mean age of the children, which is reported as 10.5 years old. This difference in age might justify the differences: at the age of 7 years, children have a physiological hypertrophy of adenoidal and tonsillar tissue²¹ which largely influences the airway evaluation.

TABLE 1 Descriptive statistics and comparison at T0 between the two treated groups.

	RME/FM		PS3		Δ	P
	Mean	SD	Mean	SD		
AD1-PNS	15.42	4.99	15.69	5.63	0.27	.42
AD1-Ba	22.41	4.20	21.72	5.37	-0.69	.34
PNS-Ba	37.83	2.34	37.42	3.06	-0.41	.35
AD2-PNS	10.69	3.22	11.73	4.18	1.04	.25
AD2-H	17.85	2.84	15.38	3.45	-2.47	.60
PNS-H	28.54	2.56	27.11	2.36	-1.43	.89
SPAS	6.30	2.70	6.56	3.21	0.26	.22
ph-pph	9.86	2.80	9.97	2.87	0.11	.99
p-pp	9.79	2.20	9.56	2.30	-0.23	.69
Pas-ppas	11.56	2.67	11.00	2.94	-0.56	.8
H-H'	11.68	5.30	9.81	4.19	-1.87	.67

Note: Significance level was set at $P < .05$. Data are reported as mean \pm SD and their 95% confidence interval (95% CI).

TABLE 2 Descriptive statistics and comparison of pre-treatment (T0) and post-treatment (T1) values in the group treated with RME/FM.

	T0		T1		P
	Mean	SD	Mean	SD	
AD1-PNS	15.42	4.99	18.09	5.27	.00
AD1-Ba	22.41	4.20	21.74	3.79	.00
PNS-Ba	37.83	2.34	40.48	2.42	.00
AD2-PNS	10.69	3.22	13.19	3.37	.00
AD2-H	17.85	2.84	18.45	2.25	.01
PNS-H	28.54	2.56	31.77	1.49	.00
SPAS	6.30	2.70	6.96	3.17	.00
ph-pph	9.86	2.80	10.00	2.94	.13
p-pp	9.79	2.20	10.21	2.23	.26
Pas-ppas	11.56	2.67	11.8	3.02	.05
H-H'	11.68	5.30	11.45	4.52	.01

Note: Significance level was set at $P < .05$. Data are reported as mean \pm standard deviation (SD) and their 95% confidence interval (95%CI). Bold characters indicate a statistically significant difference.

Due to the absence of a control group of untreated Class III subjects in our study, we may not confirm if these differences were due to the effects of the orthopaedic therapies or if the space increase could be due to growth.

Our results confirm previous evidence that early treatment of Class III malocclusion does not reduce the airway space.⁸ Both orthodontic therapies (PS3 and RME/FM protocol) show similar dentoalveolar and skeletal effects as previously demonstrated.¹³ In addition, our results showed that the cephalometric measures of upper airway space were similar in both therapies, demonstrating that there is no difference in upper airway effect between the two devices.

TABLE 3 Descriptive statistics and comparison of pre-treatment (T0) and post-treatment (T1) values in the group treated with PS3.

	T0		T1		P
	Mean	SD	Mean	SD	
AD1-PNS	15.69	5.63	19.59	5.02	.00
AD1-Ba	21.72	5.37	20.69	4.83	.00
PNS-Ba	37.42	3.06	40.28	2.89	.00
AD2-PNS	11.73	4.18	14.11	3.54	.00
AD2-H	15.38	3.45	15.51	3.72	.00
PNS-H	27.11	2.36	29.62	2.82	.00
SPAS	6.56	3.21	7.92	3.19	.00
ph-pph	9.97	2.87	10.02	2.48	.06
p-pp	9.56	2.30	10.75	2.22	.03
Pas-ppas	11.00	2.94	11.89	3.33	.01
H-H'	9.81	4.19	12.02	5.90	.18

Note: Significance level was set at $P < .05$. Data are reported as mean \pm SD and their 95% confidence interval (95% CI). Bold characters indicate a statistically significant difference.

TABLE 4 Descriptive statistics and comparisons of the T1-T0 changes between the two treated groups.

	RME/FM		PS3		Δ	P
	Mean	SD	Mean	SD		
AD1-PNS	2.67	3.69	3.89	3.68	1.22	.89
AD1-Ba	-0.67	3.61	-1.03	3.26	-0.36	.50
PNS-Ba	2.65	2.18	2.85	1.80	0.2	.21
AD2-PNS	2.50	1.86	2.38	2.17	-0.12	.45
AD2-H	0.59	2.53	0.13	2.54	-0.46	.78
PNS-H	3.22	1.84	2.51	1.52	-0.71	.48
SPAS	0.66	1.7	1.36	2.60	0.70	.12
ph-pph	0.13	3.30	0.05	2.93	-0.08	.91
p-pp	0.41	2.69	1.19	2.32	0.78	.64
Pas-ppas	0.24	3.04	0.88	3.12	0.64	.82
H-H'	3.06	16.43	3.63	8.80	0.57	.69

Note: Significance level was set at $P < .05$. Data are reported as mean \pm SD and their 95% confidence interval (95% CI).

Therefore, it can be hypothesized that skeletal correction with both therapies is associated with an increase in nasopharyngeal spaces and therefore an improvement in nasal breathing function.

This study presents with the following limitations:

1. use of lateral cephalograms, a 2D image, to measure airways that are 3D complex anatomical structures. In the OSA patient, adenotonsillar hypertrophy can influence the cephalometric investigation due to the encumbrance of the lymphoid tissues in the airway space. This problem could be solved through the use of 3D images. On the other hand, the use of CBCT presents high biological costs because patients are exposed

- to a massive radiation dose before and after treatment with consequent ethical implications;
- lack of long-term data, which would be desirable to assess whether the effects are stable in the long term.

Further studies are needed to verify the response to orthopaedic therapy in patients with sleep disorders.

5 | CONCLUSIONS

Early treatment of Class III malocclusion with PS3 does not induce a statistically significant increase in the sagittal airway space compared to RME/FM.

AUTHOR CONTRIBUTIONS

AG and PF involved in conceptualization; PF, RR, SM and VV involved in methodology; RU, VV and VD involved in formal analysis; VV, FA, RU and RR involved in investigation; VV, PA and PF involved in resources; VV involved in data curation; VV, AG and PF wrote the original draft preparation; PF, LF and AG involved in writing, reviewing and editing; PF and VD involved in supervision; AG and VV involved in project administration.

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CONFLICT OF INTEREST STATEMENT

None to declare.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Bambino Gesù Children's Hospital (ethical approval # 479_OPBG_2012).

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