

# Effect of maxillary protraction with alternating rapid palatal expansion and constriction vs expansion alone in maxillary retrusive patients: A single-center, randomized controlled trial

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**Introduction:** The objective of this randomized controlled trial was to investigate the effects of facemask protraction combined with alternating rapid palatal expansion and constriction (RPE/C) vs rapid palatal expansion (RPE) alone in the early treatment of maxillary retrusive patients. **Methods:** Patients with a midface deficiency were recruited and randomly allocated into either the control group (RPE) or the intervention group (RPE/C). Eligibility criteria included the following: age 7 to 13 years old, Class III malocclusion, anterior crossbite, ANB less than 0°, Wits appraisal less than -2 mm, A-Np less than 0 mm, and no cleft of lip or palate. The primary outcome was the degree of maxillary forward movement after treatment. The secondary outcomes were the changes of the other cephalometric variables after treatment and the treatment time. Simple randomization was carried out using a random number table at the beginning of the study. Envelopes containing the grouping information were used to ensure allocation concealment from the researchers. Blinding was applicable for cephalometric analysis only. Hyrax palatal expanders and facemask maxillary protraction were used in all patients. Patients in the RPE group were treated with rapid palatal expansion for 1 week. Patients in the RPE/C group were treated with RPE/C for 7 weeks. The expansion or constriction rate was 1 mm per day. Cephalometric analysis with traditional cephalometric measurements and an x-y coordinate system were used to compare the pre-treatment and posttreatment cephalometric radiographs. Independent *t* tests were used to compare the data between the 2 groups. **Results:** A total of 44 patients were randomized to either the RPE group or the RPE/C group in a 1:1 ratio. One subject in the RPE group was lost to follow-up during the treatment. Per-protocol analysis was used. All the other 43 patients reached the treatment completion criteria and were analyzed (RPE group: *n* = 21; RPE/C group: *n* = 22). The average protraction time was 10.84 months in the RPE group, which was significantly longer than that in the RPE/C group (9.06 months) (effect size [ES], 1.78 [95% CI, 0.15, 3.42; *P* = 0.033]). Maxillary forward movement increased by 3.04 mm in the RPE/C group, which was significantly greater than that in the RPE group (2.11 mm) (ES, -0.93 [95% CI, -1.65, -0.20; *P* = 0.013]). The counterclockwise rotation of the palatal plane was 1.73° in the RPE/C group, which was significantly greater than that in the RPE group (0.83°) (ES, 0.90 [95% CI, 0.08, 1.73; *P* = 0.033]). The degree of mandibular downward and backward rotation was significantly smaller in the RPE/C group (*P* < 0.05). No serious harm was observed during treatment and research. **Conclusions:** Facemask maxillary protraction with RPE/C might positively affect the forward movement of the maxilla compared with facemask protraction with RPE alone in the early treatment of maxillary retrusive patients. Although the differences between the groups were statistically significant for forward movement of the maxilla and rotation of the palatal and mandibular planes, these may not be clinically relevant, since the differences were less than 1 mm and 1°, respectively. **Registration:** This trial was not registered. **Protocol:** The protocol was not published before trial commencement. **Funding:** This research was supported by Peking University Research Fund. No conflict of interest is declared. (Am J Orthod Dentofacial Orthop 2015;148:641-51)

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The nature of Class III skeletal malocclusion is related to maxillary retrusion, mandibular protrusion, or both, with most patients characterized by maxillary retrusion.<sup>1–3</sup> Class III skeletal discrepancies are difficult to correct because of the complexity of treatment and unpredictable skeletal growth, development, and treatment outcome for these young patients.<sup>4,5</sup> For years, orthodontists have used dentofacial orthopedics on such discrepancies with varying success. The application of protraction forces to the maxilla is common in the early management of patients with maxillary retrusion.<sup>6–9</sup>

In previous studies, improvements of midface deficiency with facemask protraction without rapid palatal expansion (RPE) were reported.<sup>10,11</sup> However, RPE is commonly carried out before protraction to rectify any transverse discrepancy and, theoretically, to potentiate anteroposterior correction by the release of the circummaxillary sutures.<sup>8,12</sup>

In the last decade, Liou<sup>13,14</sup> introduced an alternating rapid maxillary expansion and constriction (RPE/C) methodology using a 2-hinged expander. In a controlled clinical trial, he used RPE/C (1 mm per day) for 9 weeks, followed by intraoral maxillary protraction in 10 patients with clefts.<sup>15</sup> The study demonstrated superior achievement of maxillary forward movement in the RPE/C group relative to the comparison group of cleft patients whose maxillary protraction was preceded by expansion alone. He speculated that the alternating method of maxillary expansion and constriction, compared with an expansion approach alone, produced greater disarticulation at the circummaxillary sutures; this was later supported in an animal study.<sup>16</sup> Another clinical investigation yielded conflicting results. Da Luz Vieira et al<sup>17</sup> found no significant difference between 2 groups of 10 patients with cleft lip and palate who were treated with facemask maxillary protraction after receiving either RPE/C, or solely RPE with a modified Haas-type palatal expander.

The RPE/C method has also been examined in non-cleft Class III patients planned for subsequent maxillary protraction.<sup>18</sup> A clinical study published by Isci et al<sup>18</sup> in 2010 described findings similar to those of Liou,<sup>15</sup> despite notable methodologic differences in their study, which included the use of a hyrax expander, different expansion and constriction rates (0.4 mm per day), and a facemask.

A major limitation of the previous studies was the lack of randomization. To our knowledge, no randomized controlled study has been conducted on the application of RPE/C.

## Specific objectives or hypotheses

The aim of this study was to investigate the effects of facemask protraction combined with hyrax RPE/C vs hyrax RPE alone in noncleft maxillary retrusive patients. We examined differences of treatment time along with skeletal, dental, and soft tissue changes.

## MATERIAL AND METHODS

### Trial design and any changes after trial commencement

The study was a parallel-group, randomized, active-control trial with a 1:1 allocation ratio. There were no changes after trial commencement.

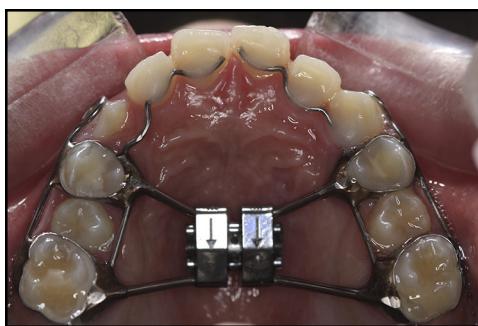
### Participants, eligibility criteria, and setting

Approval for this randomized clinical trial was obtained from Peking University Medical Science Research Ethics Committee (IRB00001052-07094). Participants were recruited from the Department of Orthodontics at Peking University, based on the following inclusion criteria: (1) 7 to 13 years old before treatment with a midface soft tissue deficiency; (2) fully erupted maxillary first molars, Class III malocclusion, and anterior crossbite; and (3) ANB less than 0°, Wits appraisal less than -2 mm<sup>19</sup> (corrected cephalometric tracing technique was applied for patients with a functional shift<sup>20</sup>), and distance from Point A to nasion perpendicular<sup>21</sup> less than 0 mm. The exclusion criteria were (1) previous orthodontic treatment; (2) other craniofacial anomalies, such as cleft lip and palate; and (3) maxillary dentition unsuitable to bond a hyrax expander. Consent was obtained from the parents or guardians of the patients before their recruitment.

### Interventions

Banded and soldered hyrax palatal expanders were used for the patients in both groups (Fig 1). Two maxillary first molars and 2 deciduous molars were banded. For the patients whose maxillary first premolars had fully erupted, 2 maxillary first molars and 2 maxillary first premolars were banded. The anterior extension arms were bonded to the lingual surfaces of the maxillary anterior teeth to help palatal expansion. The protraction hooks were designed around the maxillary canine area. All expanders were manufactured by the same orthodontic technician.

After the expanders were banded, the parents or guardians of the patients were taught how to activate and deactivate the expanders. Patients in the control group (RPE) were treated with RPE for 1 week. The expander was activated 4 times per day (1 mm per day)



**Fig 1.** Hyrax expander.



**Fig 2.** One-piece facemask.

for 7 days. Patients in the intervention group (RPE/C) were treated with RPE/C for 7 weeks. Both the expansion and the constriction rates were 4 times per day (1 mm per day). The sequence was 7 days of expansion, 7 days of constriction, 7 days of expansion, 7 days of constriction, 7 days of expansion, 7 days of constriction, and then a final 7 days of expansion. The patients were instructed to come to the office for follow-up every week to ensure correct operation. The width of the expanders was measured during the weekly visits. Sometimes, inadequate expansion or constriction was found. Then the parents or guardians would be tested on their skill of activation or deactivation, and further guidance would be provided at the same time. Any damaged expander was required to be repaired (or replaced) and rebanded within 2 days.

After RPE or RPE/C, the patients in both groups were treated with facemask maxillary protraction. A 1-piece facemask with an adjustable anterior wire and hooks for elastics was used (Fig 2). The elastic direction was 15° to 30° downward from the occlusal plane, delivering a force between 400 and 500 g per side. The patients were instructed to wear the facemask for at least 14 hours a day. The patients' records of hours showed that facemask wearing time was about 11.5 hours on average in both groups. The patients were instructed to follow up every month. There were no purposive differences between the 2 groups during follow-ups, such as instructions. The protraction force was tested each time and adjusted if needed, as was the protraction direction. Any damaged facemask was replaced immediately. Any damaged expander was required to be repaired (or replaced) and rebanded within 2 days. The patients who did not wear their facemasks for enough time were educated by one of the authors (W.L.) during their monthly follow-ups. The same cooperation and education process was used for these patients and their parents or guardians, including an explanation of

the importance of wearing the facemask and guidance about living normally with the facemask.

The treatment completion criterion was a positive overjet with a Class II or a Class I molar relationship. No retention appliances were used after treatment. All clinical treatments were performed by the team of W.L. and Y.Z.

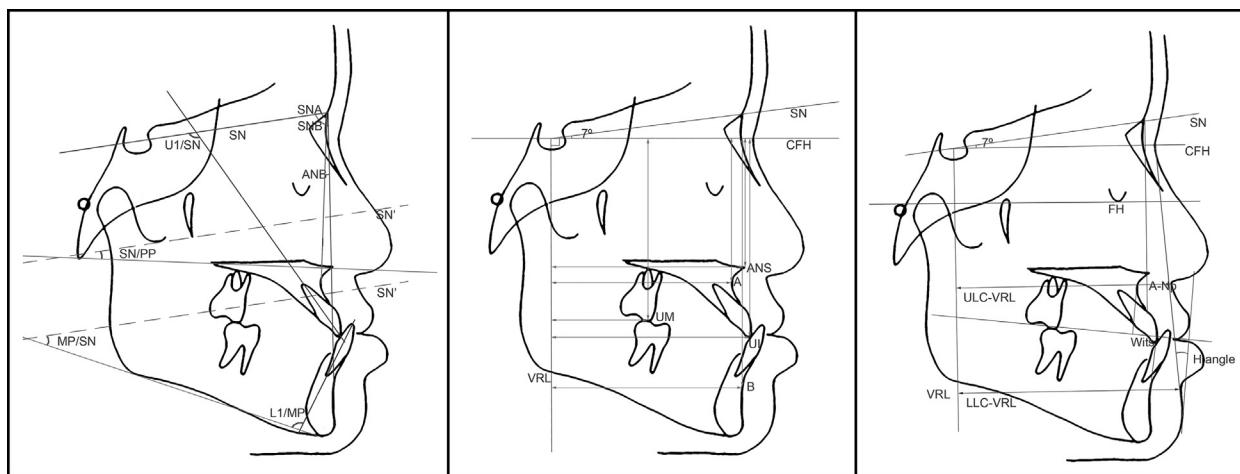
#### Outcomes (primary and secondary) and any changes after trial commencement

The primary outcome was the degree of maxillary forward movement after treatment (A-VRL). The secondary outcomes were the changes of the other cephalometric variables and the treatment time.

Lateral cephalometric radiographs were taken at the beginning and end of treatment. These radiographs were hand-traced and measured by an investigator (W.L.). Traditional cephalometric measurements were used to describe changes before and after treatment. An x-y coordinate system was also set up.<sup>22-24</sup> The horizontal axis (CFH) was the sella-nasion line rotated 7° downward, whereas the vertical axis (VRL) was constructed by passing a line perpendicular to the horizontal axis through sella. The distances from several landmarks to the horizontal and vertical axes were measured. A total of 22 cephalometric variables were used to evaluate the craniofacial, dental, and soft tissue changes (Fig 3). There were no outcome changes after trial commencement.

#### Sample size calculation

Because no studies in orthodontic literature used the same protocol as we did in this study, the sample size was estimated by G\*Power (version 3.0.8)<sup>25</sup> according to the previous study on the 2-hinged expander RPE/C and intraoral maxillary protraction (95% power; 5% significance level; 2-tailed).<sup>15</sup> The sagittal movements of Point A were  $2.6 \pm 1.5$  mm in the RPE group and



**Fig 3.** Cephalometric measurements.

$5.8 \pm 2.3$  mm in the RPE/C group. A minimum sample size of 11 in each group was required to detect a significant difference between the groups. The sagittal movements of ANS were  $2.1 \pm 1.3$  mm in the RPE group and  $4.8 \pm 2.5$  mm in the RPE/C group. A minimum sample size of 16 in each group was required to detect a significant difference between the groups. Therefore, 16 was the minimum sample size of each group. The sample size was increased by 40%, resulting in 22 patients in each group, to account for dropouts and the use of a different protocol from the previous study.

#### Interim analyses and stopping guidelines

The study would stop if serious harm was observed during the treatment and research.

#### Randomization (random number generation, allocation concealment, implementation)

Patients were recruited and allocated to either the control group (RPE) or the intervention group (RPE/C) according to their participation sequence. Simple randomization was applied. Randomization was carried out using a random number table from a medical statistics textbook. Starting from the fourth line, first number of the table, a series of random numbers was obtained from left to right and up to down. The randomized numbers were divided by 4, and the remainder was taken. The remainder numbers 1 and 2 were allocated to the RPE and RPE/C groups, respectively, ignoring the other numbers. After all 44 numbers were obtained, there might be a size imbalance between the 2 groups. The following randomized number would be divided by 4 and the remainder ( $n$ ) would be taken (if divided exactly,  $n = 4$ ). For example, if  $n = 3$ , we would move the third subject of the larger

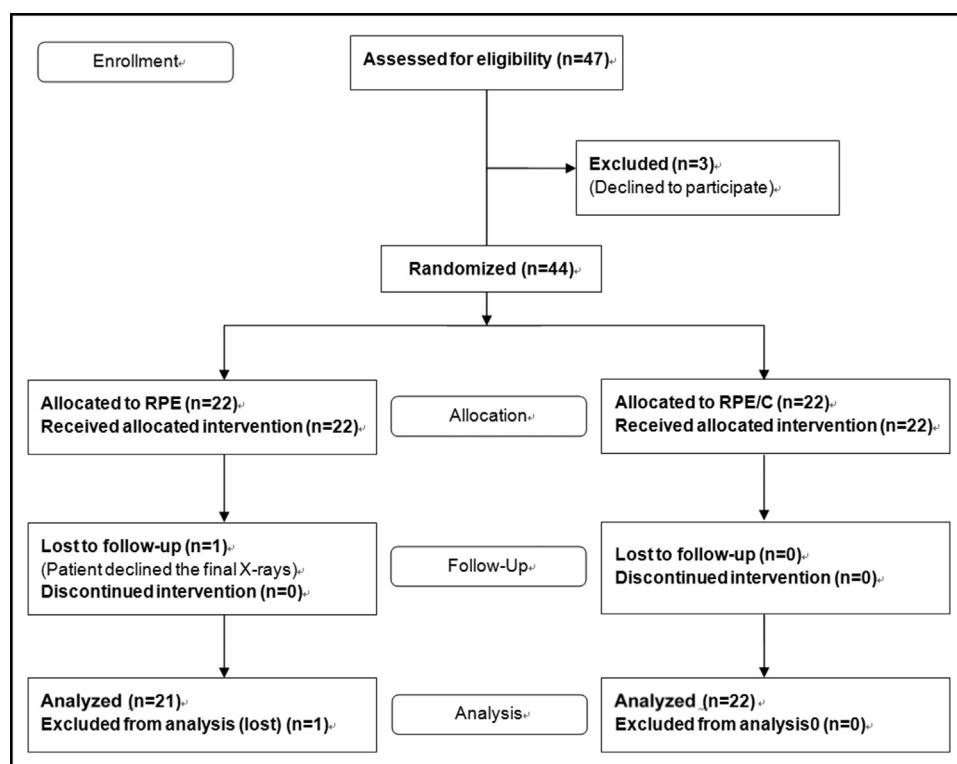
group to the other group. We would repeat this process until the 2 groups were balanced. In this study, adjustment was not needed, since the 44 patients were assigned to the 2 groups with a 1:1 ratio. A table with recruitment sequential numbers, paired selected randomized numbers, and group numbers was prepared. Forty-four envelopes containing the subjects' information were used to ensure allocation concealment from the researchers. Sequential numbers were written on the envelopes. One investigator (W.L.) was responsible for generating and implementing the random allocation process, enrolling participants, and opening the envelopes in sequence.

#### Blinding

Blinding of either orthodontists or participants was not possible because the treatment protocols in 2 groups were different. Operators and patients would easily know which group the patients were in. However, blinding was used during the cephalometric analysis. All cephalometric films were deidentified by opaque tape and replaced by research numbers, and then disarranged before tracing. The investigator who was responsible for measuring (W.L.) did not know the grouping of the cephalometric radiographs, which looked similar.

#### Statistical analysis (primary and secondary outcomes, subgroup analyses)

All statistical analyses were performed using software (version 18.0; PASW Statistics, Chicago, Ill). Descriptive statistics included the means and standard deviations of age, total treatment time, protraction time, cephalometric values, and changes of values in each group. The 1-sample Kolmogorov-Smirnov test was used to test the



**Fig 4.** CONSORT flow chart showing the flow of patients through the trial.

normality of the distributions for all times and differences of the cephalometric values. Independent *t* tests were used to compare the 2 groups, including total treatment time, protraction time, and changes of cephalometric values; *t'* tests were used for the values that showed "equality of variances not assumed" between the groups (SNA and UI-VRL). The level of significance was 0.05, with a 2-tailed test.

#### Error of the method

All point locations and measurements were double-checked carefully at the end of the initial tracing and measuring. Not all radiographs were traced twice. However, to evaluate the errors of tracing, 10 radiographs were chosen at random. Tracing, locating, and measuring were done twice, 2 weeks apart, and then subjected to Dahlberg's formula.<sup>5,24,26,27</sup> The method error was determined using Dahlberg's formula, where *n* = 10, and *d* was the difference between the measurements of cephalometric values at 2 time points. The method error did not exceed 0.59° for any angular measurement or 0.66 mm for any linear measurement. The values indicate that this analysis was reliable compared with other estimations of technical error.

## RESULTS

#### Participant flow

A total of 44 Chinese patients were recruited and randomized in a 1:1 ratio to either RPE (*n* = 22) or RPE/C (*n* = 22). One subject in the RPE group was lost to follow-up during treatment because the patient declined to have the final x-rays (Fig 4). All other 43 patients achieved a positive overjet with a Class II or a Class I molar relationship. In anticipation of relapse, most of them were overcorrected to an overjet of 2 to 3 mm. Patient recruitment was from January 2008 to December 2009. The follow-up period lasted to the end of treatment for each patient. The research was finished after treatment was completed for all patients in February 2011. Per-protocol analysis was used. The patient lost to follow-up was excluded.

#### Baseline data

The ages and sexes at baseline are shown in Table I. The average ages of the patients were 9.81 years in the RPE group and 10.11 years in the RPE/C group. Some important cephalometric values before treatment are also listed (Table I).

**Table I.** Mean ages, sexes, and main cephalometric values at baseline

	RPE group (n = 21)		RPE/C group (n = 22)		
	Mean	SD	Mean	SD	
Age (y)	9.81	1.72	10.11	1.44	
Sex					
Male (n = 10)	10.04	1.83	Male (n = 10)	10.39	1.49
Female (n = 11)	9.61	1.66	Female (n = 12)	9.88	1.41
SNA (°)	79.49	3.07	78.19	3.29	
SNB (°)	82.63	3.21	81.19	3.46	
ANB (°)	-3.14	2.17	-3.00	1.84	
SN/PP (°)	8.33	2.58	9.84	3.39	
MP/SN (°)	33.11	5.97	35.14	5.53	
A-NP (mm)	-3.97	2.20	-4.46	2.52	
A-CFH (mm)	46.97	2.69	47.32	2.85	
A-VRL (mm)	56.81	2.98	55.43	3.93	
ANS-CFH (mm)	40.87	2.37	41.43	2.92	
ANS-VRL (mm)	61.98	3.26	60.50	3.64	

#### Numbers analyzed for each outcome, estimation and precision, subgroup analyses

The outcomes of the 43 patients were analyzed in the RPE group (n = 21) and the RPE/C group (n = 22). All quantitative data were normally distributed (Table II). The average total treatment times (from the beginning of expansion to the end of protraction) were  $11.19 \pm 2.75$  months in the RPE group and  $10.95 \pm 2.73$  months in the RPE/C group. No significant difference was found between the groups (effect size [ES], 0.24 [95% CI, -1.45, 1.92; P = 0.779]). The average protraction time (from the beginning to the end of protraction) was  $10.84 \pm 2.76$  months in the RPE group, which was significantly longer than in the RPE/C group ( $9.06 \pm 2.55$  months) (ES, 1.78 [95% CI, 0.15, 3.42; P = 0.033]).

Table II shows the means and standard deviations of the cephalometric values before and after treatment, the means and standard deviations of differences before and after treatment, and the comparisons of the changes after treatment between the 2 groups. The RPE/C group showed statistically significant advancements of the maxilla (A-VRL, A-Np, SNA, and ANS-VRL) compared with the RPE group (P <0.05). The increases in the RPE and RPE/C groups were A-VRL, 2.11 and 3.04 mm (ES, -0.93 [95% CI, -1.65, -0.20; P = 0.013]); A-Np, 1.78 and 2.48 mm (ES, -0.70 [95% CI, -1.30, -0.09; P = 0.025]); SNA, 1.93° and 2.67° (ES, -0.73 [95% CI, -1.40, -0.07; P = 0.031]); ANS-VRL, 1.89 and 2.87 mm (ES, -0.98 [95% CI, -1.75, -0.22; P = 0.013]), respectively. Significant differences were also shown in changes of SN/PP, which decreased by 0.83° in the RPE group and 1.73° in the RPE/C group

(ES, 0.90 [95% CI, 0.08, 1.73; P = 0.033]). The results indicate that the counterclockwise rotation of the palatal plane was greater in the RPE/C group.

The mandibular and soft tissue cephalometric analysis results showed statistically significant changes between the 2 groups in SNB, MP/SN, B-VRL, and LLC-VRL (P <0.05). SNB decreased by 2.35° and 1.49° (ES, -0.87 [95% CI, -1.52, -0.21; P = 0.010]); MP/SN increased by 3.32° and 2.00° (ES, 1.32 [95% CI, 0.24, 2.40; P = 0.017]); B-VRL decreased by 3.31 and 1.90 mm (ES, -1.41 [95% CI, -2.64, -0.18; P = 0.025]); LLC-VRL decreased by 2.82 and 1.27 mm (ES, -1.55 [95% CI, -2.51, -0.60; P = 0.002]) in the RPE and the RPE/C groups, respectively. The results in the mandibular skeletal and soft tissue indicate that the downward and backward rotations of the mandible were less in the RPE/C group after treatment.

No significant difference in the changes of maxillary dental and intermaxillary skeletal and dental variables was found between the 2 groups (P >0.05).

#### Harms

No serious harms or unintended effects were observed during the treatment and research.

#### DISCUSSION

##### Main findings in the context of the existing evidence, interpretation

Maxillary advancement is the most important aim of maxillary protraction. Facemask treatment could move the maxilla forward (SNA increased an average of 2.10°).<sup>9</sup> RPE was believed to be a favorable method in maxillary protraction for many years. RPE may disrupt the circummaxillary suture system and facilitate maxillary forward movement.<sup>28-32</sup> Over the past few years, several investigators have reported different results that showed no significant differences between the expansion and nonexpansion patients in facemask maxillary protraction.<sup>6,9,22</sup> Different opinions also arise about the use of RPE/C in maxillary protraction. Most investigators consider the RPE/C protocol to be a better expansion method that can prevent unnecessary excessive maxillary expansion and may better disarticulate the circummaxillary sutures.<sup>14-16,18,23</sup> For cleft patients, Liou and Tsai<sup>15</sup> reported greater maxillary forward movement in the RPE/C group (5.8 mm) relative to the RPE group (2.6 mm); intraoral maxillary protraction was used in both groups. Yen<sup>33</sup> introduced a modification of the techniques introduced by Liou and Tsai: a combination of RPE/C, Class III elastics, and facemask protraction. Good clinical outcomes were obtained in adolescent patients with cleft lip and palate. However,

da Luz Vieira et al<sup>17</sup> found no significant difference in the maxillary sagittal movement after facemask treatment with RPE/C or RPE in cleft patients.

For noncleft patients, only 1 controlled clinical trial on the use of RPE/C and facemask is available. Isci et al<sup>18</sup> compared the RPE and RPE/C protocols using hyrax expanders in maxillary protraction. The rate of expansion and constriction was 0.4 mm per day. Two rounds of RPE/C were used in the RPE/C group, and the expanders were closed at the end of RPE/C. Point A moved forward by 4.13 mm along the SN direction after treatment in the RPE/C group; this was significantly greater than the movement in the RPE group (2.33 mm). A different RPE/C protocol was used in our study. Seven weeks of expansion and constriction with a protocol of 1 mm per day was used to ensure an effective RPE/C in a reasonable treatment time. This study demonstrated significant differences in maxillary forward movement between the RPE/C and the RPE groups with similar treatment times. On average, Point A moved 3.04 mm forward along the horizontal axis in the RPE/C group; this was about 1.4 times greater than in the RPE group (2.11 mm). The changes of A-Np, SNA, and ANS-VRL in the RPE/C group were also significantly greater than in the RPE group. The results suggest that circummaxillary sutures can be better loosened or weakened by RPE/C than RPE alone. The difference of maxillary forward movement (A-VRL) was 0.93 mm between the 2 groups in our study; this was smaller than the amounts in the studies of Liou and Tsai<sup>15</sup> and Isci et al.<sup>18</sup> Because of the different protocols, patient ages, and populations, comparing the maxillary movements in the previous reports with our study is difficult. Despite this, the same trend was observed: the RPE/C protocol might allow greater forward maxillary movement during treatment.

Although the maxilla had greater forward movement in the RPE/C group, no significant difference was found in the maxillary dental changes between the RPE and RPE/C groups. When orthopedic vs orthodontic effects were evaluated, the ratio of Point A movement (average changes of A-VRL) to UM movement (the average changes of UM-VRL) was 1:1.78 in the RPE/C group, compared with 1:2.13 in the RPE group. Meanwhile, the total treatment time was similar between the 2 groups. Therefore, RPE/C and facemask protraction might result in a greater orthopedic-orthodontic ratio in maxillary movement with similar treatment times.

Obviously, patient cooperation is a key factor in the treatment effects.<sup>33</sup> Great efforts were made for patient education in this study. However, the average wearing time was 11.5 hours per day in both groups. Several patients had a longer protraction time (>15 months)

and barely reached a positive overjet because of their poor cooperation.

Clockwise rotation of the palatal plane was greater in the RPE/C group. Numerous studies have reported decreases in the palatal plane angle after RPE and protraction,<sup>7,9,17,24,34</sup> and some studies have reported no significant changes.<sup>19,35</sup> Maxillary rotation has various causes, including the elastic protraction direction and intraoral point of force application. Theoretically, palatal rotation will occur if the elastic force is not in line with the maxillary center of resistance,<sup>36</sup> which is located between the root apices of the first and second premolars.<sup>37</sup> Moreover, dry human skull studies have demonstrated that different protraction heights, different force directions, and different points of force application can produce different maxillary rotation directions.<sup>36,38</sup> Based on findings from previous studies, we adjusted the elastic direction to 15° to 30° downward from the occlusal plane to reduce maxillary rotation.<sup>7,11,34,36,39</sup> However, SN/PP in the RPE/C group rotated more clockwise than in the RPE group in our study. We inferred that the maxillary component and the palatal plane might be more easily rotated by protraction force because of looser circummaxillary sutures after RPE/C. Further mechanical research is needed to investigate the exact changes of the maxillary component and the circummaxillary sutures after RPE/C.

Many researchers have shown downward and backward rotation of the mandible after RPE and facemask protraction.<sup>19,24,35,39,40</sup> In our study, the mandible rotated downward and backward less in the RPE/C group than in the RPE group. By contrast, Isci et al<sup>18</sup> found no significant difference in the changes of the mandibular plane angle between the RPE/C and RPE groups. Da Luz Vieira et al<sup>17</sup> found no statistically significant differences between the groups for the mandibular plane angle changes, either. Our findings can be attributed to 3 reasons: (1) SN/PP rotated clockwise more, and the maxillary molars did not extrude more in the RPE/C group; these changes might decrease mandibular downward and backward rotation; (2) the chin can be pushed backward during facemask therapy<sup>11</sup>; in this study, the facemask protraction time in the RPE/C group was significantly shorter than in the RPE group, perhaps causing less backward movement of the chin; and (3) the proportion and degree mandibular functional shift before treatment might have been different between the 2 groups, and between our study and previous studies. This might also have influenced the results. It is believed that the facemask methodology ideally should be used in patients with Class III

**Table II.** Comparisons of the changes after treatment between the 2 groups

	RPE group									
	Pretreatment		I-sample K-S test		Posttreatment		I-sample K-S test		Changes	
	Mean	SD	P	Mean	SD	P	Mean	SD	P	
<b>Maxillary skeletal</b>										
SNA (°)	79.49	3.07	0.896	81.42	3.15	0.928	1.93	0.79	0.769	
SN/PP (°)	8.33	2.58	0.574	7.50	2.85	0.935	-0.83	1.17	0.557	
A-NP (mm)	-3.97	2.20	0.902	-2.18	2.23	0.681	1.78	0.77	0.989	
A-CFH (mm)	46.97	2.69	0.985	49.29	3.08	0.801	2.32	1.54	0.962	
A-VRL (mm)	56.81	2.98	0.938	58.92	2.90	0.917	2.11	0.95	0.991	
ANS-CFH (mm)	40.87	2.37	0.873	43.55	2.42	0.951	2.69	1.38	0.841	
ANS-VRL (mm)	61.98	3.26	0.954	63.87	3.26	1.000	1.89	1.28	0.770	
<b>Maxillary dental</b>										
U1/SN (°)	107.43	6.01	0.852	113.39	6.57	0.903	5.96	5.56	0.600	
UI-CFH (mm)	65.80	3.85	0.976	69.37	4.31	0.781	3.57	1.88	0.778	
UI-VRL (mm)	60.22	4.17	0.653	64.79	4.37	0.932	4.56	1.45	0.964	
UM-CFH (mm)	58.91	3.47	0.892	63.00	4.67	0.908	4.09	2.23	1.000	
UM-VRL (mm)	31.78	4.17	0.390	36.27	4.22	0.370	4.50	2.69	0.524	
<b>Mandibular skeletal and dental</b>										
SNB (°)	82.63	3.21	0.823	80.28	3.03	0.996	-2.35	1.21	0.711	
MP/SN (°)	33.11	5.97	1.000	36.43	6.06	0.971	3.32	1.91	0.979	
B-CFH (mm)	82.44	4.92	0.870	88.46	6.38	0.903	6.02	2.57	0.984	
B-VRL (mm)	59.56	5.82	0.994	56.25	5.55	0.971	-3.31	2.26	0.999	
L1/MP (°)	85.20	7.51	0.606	81.62	7.94	0.992	-3.58	4.41	0.912	
<b>Intermaxillary skeletal and dental</b>										
ANB (°)	-3.14	2.17	0.783	1.14	2.21	0.712	4.29	1.54	0.907	
Wits (mm)	-10.20	3.06	0.757	-6.92	4.08	0.594	3.28	2.63	0.942	
<b>Soft tissue</b>										
H angle (°)	9.80	4.45	0.776	16.75	4.60	0.948	6.95	3.86	0.889	
ULC-VRL (mm)	69.99	3.98	0.988	72.20	3.89	0.965	2.22	1.15	0.981	
LLC-VRL (mm)	72.20	5.20	0.874	69.38	5.28	0.974	-2.82	1.57	0.948	

K-S, Kolmogorov-Smirnov.

\*P <0.05; †P <0.01; NS, not significant.

malocclusion combined with lower mandibular plane angulation because it would rotate the mandibular plane clockwise.<sup>9</sup> From our results, the RPE/C and facemask methodology might be more suitable for a Class III malocclusion combined with a high mandibular plane angle, open bite, or a tendency of open bite compared with the RPE protocol.

Although some statistically significant differences were found in this study, these differences were so small that they might not influence the real clinical outcomes. Facemask treatment with or without RPE has been demonstrated to be effective.<sup>9,40,41</sup> In this study, patients in the RPE group also had similar clinical effects and satisfaction with their treatment as those in the RPE/C group. Therefore, the RPE/C protocol should be selected carefully.

### Limitations

One limitation of this study was that we did not divide the patients into several groups according to

age and sex. Although it has been reported that changes caused by facemask and expansion therapy in younger children are not significantly different from changes in older children,<sup>28</sup> some other investigators have found that facemask therapy is more effective in patients who are younger than 10 years of age.<sup>6</sup> In this study, we did not include subgroups because of the difficulty of obtaining a larger sample. A confounding factor might have been introduced, and the clinical heterogeneity might have been affected. Another limitation of this study was that blinding was implemented only on cephalometric tracing, and no blinding was used during patient treatment. Also, there was no supervision during implementing the random allocation process and opening the envelopes. Operating bias may have been introduced in this study. Moreover, our sample size was small. The subjects in the 2 groups might not have been balanced. Additionally, a long period of observation is needed to investigate the long-term effects.

**Table II.** *Continued.*

RPE/C group										Between the groups			
Pretreatment		1-sample K-S test		Posttreatment		1-sample K-S test		Changes		1-sample K-S test		Mean difference of the changes (95% CI)	Independent t test P
Mean	SD	P	Mean	SD	P	Mean	SD	Mean	SD	P			
78.19	3.29	0.474	80.86	3.87	0.592	2.67	1.31	0.878	-0.73 (-1.40, -0.07)	0.031*			
9.84	3.39	0.428	8.11	3.35	0.686	-1.73	1.48	0.967	0.90 (0.08, 1.73)	0.033*			
-4.46	2.52	0.415	-1.98	2.96	0.520	2.48	1.15	0.840	-0.70 (-1.30, -0.09)	0.025*			
47.32	2.85	0.995	49.23	3.13	0.873	1.91	1.26	0.789	0.42 (-0.45, 1.28)	0.338 NS			
55.43	3.93	0.916	58.46	4.33	0.975	3.04	1.35	0.859	-0.93 (-1.65, -0.20)	0.013*			
41.43	2.92	0.735	43.25	3.14	0.998	1.82	1.28	0.943	0.87 (0.05, 1.69)	0.038*			
60.50	3.64	0.890	63.38	3.98	0.949	2.87	1.20	0.757	-0.98 (-1.75, -0.22)	0.013*			
108.07	7.21	0.991	113.81	6.23	0.899	5.75	4.56	0.884	0.21 (-2.91, 3.34)	0.892 NS			
66.22	3.73	0.783	68.91	4.25	0.709	2.70	1.63	0.983	0.88 (-0.20, 1.96)	0.108 NS			
59.25	5.72	0.969	64.16	5.91	0.844	4.91	2.30	0.997	-0.35 (-1.54, 0.83)	0.551 NS			
58.79	4.15	0.934	62.95	4.83	0.603	4.16	1.51	0.931	-0.07 (-1.24, 1.10)	0.906 NS			
30.93	4.28	0.997	36.33	5.50	0.868	5.40	2.80	0.815	-0.91 (-2.60, 0.79)	0.286 NS			
81.19	3.46	0.947	79.70	3.72	0.997	-1.49	0.89	0.855	-0.87 (-1.52, -0.21)	0.010*			
35.14	5.53	0.793	37.14	5.91	0.991	2.00	1.59	0.964	1.32 (0.24, 2.40)	0.017*			
83.38	4.64	0.872	88.38	4.97	0.418	5.00	2.63	0.905	1.02 (-0.59, 2.62)	0.208 NS			
57.12	6.23	0.854	55.22	6.67	0.878	-1.90	1.71	0.449	-1.41 (-2.64, -0.18)	0.025*			
87.10	5.14	0.200	82.80	5.37	0.867	-4.30	3.54	0.269	0.73 (-1.73, 3.19)	0.553 NS			
-3.00	1.84	0.504	1.15	2.50	0.433	4.15	1.41	0.448	0.13 (-0.78, 1.04)	0.772 NS			
-10.02	2.50	0.298	-6.37	3.43	0.750	3.65	1.89	0.569	-0.37 (-1.78, 1.03)	0.594 NS			
10.10	3.08	0.918	18.18	3.86	0.855	8.08	3.69	0.989	-1.13 (-3.45, 1.19)	0.332 NS			
68.62	4.94	0.922	71.40	5.20	0.954	2.78	1.53	0.980	-0.56 (-1.40, 0.27)	0.181 NS			
69.24	6.45	0.914	67.97	6.65	0.685	-1.27	1.53	0.373	-1.55 (-2.51, -0.60)	0.002†			

## Generalizability

Since patients of both sexes and a wide age range were included in this study, the results might be representative to a certain degree. The RPE/C protocol could be effective for those who meet our inclusion criteria. For all maxillary retrusive children, the generalizability of these results might be limited. There are several reasons. On the one hand, this research was performed in 1 center by an orthodontic treatment group. On the other hand, our inclusion criteria were limited and strict, so the entire population might not have been represented. For example, younger or older patients may have different growing and developing characteristics and may have various reactions to our treatment protocol. Patients with clefts or other craniofacial anomalies may also obtain different treatment outcomes. Although some statistically significant differences were found, the applicability of this study was fair because these differences were all smaller than 1 mm or 1°, and patients in the 2 groups did not have any obvious clinical

differences after treatment. Similar clinical results and similar patient satisfaction were achieved in both groups.

## CONCLUSIONS

The following conclusions may be drawn from this study.

1. The protocol of hyrax RPE/C and facemask maxillary protraction might positively affect the forward movement of the maxilla compared with RPE alone in the early treatment of maxillary retrusive patients.
2. Greater palatal plane counterclockwise rotation and less mandibular downward and backward rotation were observed in the RPE/C group.
3. Although the differences between the groups were statistically significant for forward movement of maxilla and rotation of palatal and mandibular plane, they may not be clinically relevant because they were less than 1 mm and 1°, respectively.

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