Evaluation of The Treatment Outcome of Cleft Palate Patients Treated with Differential Opening Expander with Alt-RAMEC Protocol and Facemask: A cohort clinical study Section A -Research paper



Evaluation of The Treatment Outcome of Cleft Palate Patients Treated with Differential Opening Expander with Alt-RAMEC Protocol and Facemask: A cohort clinical study

Sarah S. Khalil¹, Ahmed E. Salama², Maiada M. Awad³, Maha M. Mohmed⁴

Article History: Received: 05.06.2023	Revised: 06.07.2023	Accepted: 10.07.2023
---------------------------------------	---------------------	----------------------

Objectives: The purpose of this study was to assess the effectiveness of the expander with differential opening (EDO) with alternate rapid maxillary expansion and contraction (Alt-RAMEC), and Facemask Protraction in patients with cleft lip and palate using cone beam computed tomography (CBCT) records. Material and methods: Eight cleft lip and palate patients, ages 8 to 12, were selected. All patients had maxillary permanent first molars and displayed a constricted maxillary arch. Primary lip adhesion and palatal closure were done in early childhood. All patients treated with the Alt-RAMEC protocol used EDO and a protraction facemask. CBCT scans were taken both before and six months after treatment. Maxillary transverse dimensions were measured, including the nasal cavity width, maxillary width, alveolar crest width, arch width, inclination of the molar teeth, alveolar width, alveolar crest level, and buccal and palatal bone plate thickness. A paired-sample ttest for significance was used when comparing related samples. The Pearson's correlation coefficient (r) test was used to assess the degree of association between two sets of variables. Results: All maxillary transverse measurements increased significantly at the molar and premolar regions (p<0.05). Alveolar crest level and buccal bone plate thickness were slightly decreased (0.57mm) and 0.5 mm, respectively (p<0.05). The molar teeth showed a significant increase in buccal inclination (6.36°) (P<0.001). Forward movement of the maxilla was seen in the lateral cephalometric extract from CBCT. Conclusion: Significant maxillary expansion and advancement were achieved while using the EDO with Alt-RAMEC and facemask protraction, while there was a slight decrease in buccal bone thickness and height and a significant increase in buccal molar inclination. Registration: This trial was registered at ClinicalTrials.gov with the identifier NCT04970095, and the date of registration was July 16, 2021. Clinical Relevance: This innovative treatment approach corrects anterior and posterior crossbite in patients with cleft lip and palate who have dentoskeletal anomalies.

Key words: Expansion, Cleft lip and palate, Alt-RAMEC, Facemask, EDO

- 1. Researcher, Orthodontic Department, BDS (2016), Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt, Dentist at The Egyptian Ministry of Health. Corresponding author E-mail: <u>sarahlala83@gmail.com</u>.
- 2. Professor of Orthodontics, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt. E-mail: drsalama007@gmail.com.
- 3. Lecture of Oral and Maxillofacial Surgery Department, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt. E-mail: <u>mmawadd@yahoo.com</u>.
- 4. Assistant professor of Orthodontics, Faculty of Dental Medicine for Girls, Al-Azhar University, Cairo, Egypt. E-mail: <u>mahaorthodontist2014@gmail.com</u>.

INTRODUCTION

Cleft lip and palate (CLP) anomalies are the most prevalent among all craniofacial anomalies, affecting one in every 700 births and disturbing the quality of life of more than 7 million people around the world [1].

Cleft patients usually have orofacial problems such as missing or unerupted permanent teeth, an alveolar bone defect, speech difficulty, severe transverse maxillary constriction, and anteroposterior deficiency class III malocclusion [2]. The goals of early treatment for cleft patients generally include enhancing forward and transverse maxillary growth. A treatment protocol including a combined face mask and maxillary expansion [3]. Transverse maxillary constriction can be improved by various appliances and treatment protocol such as Hass, Fan-shaped, or Hyrax, with rapid maxillary expansion, slow maxillary expansion, or alternate rapid maxillary expansion and constriction (ALT-RAMEC) [4].

Conventional rapid maxillary expansion (RME) with Hyrax or Hass produces similar transversal increases in the anterior and posterior

Evaluation of The Treatment Outcome of Cleft Palate Patients Treated with Differential Opening Expander with Alt-RAMEC Protocol and Facemask: A cohort clinical study Section A -Research paper

regions of the maxillary dental arch, risking over expansion of the intermolar distance to correct the intercanine distance. On the other hand, The Fantype expanders have a posterior hinge that concentrates the expansion effect in the intercanine region, with mild effects in the intermolar distance [5-7].

So, when maxillary constriction is more evident in the anterior region of the arch, the fantype expander (FE) or the expander with differential opening (EDO) can be indicated [7,8]. An expander with differential opening (EDO) has two parallel-opening screws, one anteriorly and one posteriorly positioned in the palate. They were designed especially for achieving different amounts of expansion in the anterior and posterior regions of the maxillary dental arch in patients with cleft lip and palate [8,9].

Studies comparing the Hyrax expander and the EDO in cleft patients showed that the EDO promoted greater expansion in the anterior region of the maxillary dental arch than the hyrax [10]. Other comparisons between the EDO and the FE showed that the EDO showed greater transverse skeletal expansion compared to the FE, with similar vertical and anteroposterior effects and greater dentoalveolar expansion in the molar region, while the FE produced a greater increase in intercanine distance [11,12]. To enhance forward maxillary movement, a protraction face mask was used.

In 1982, the concept of maxillary expansion (ME) was introduced to be used in conjunction with the protraction face mask [13]. It worked on the principle of disarticulating the maxilla from the neighbouring bones, which are connected by circum-maxillary sutures, thus making bringing it forward using a protraction face mask easier. Different articles published the amount of expansion required to disarticulate the maxilla. Hass suggested that 5 mm of expansion was enough [14], but Alcan suggested that a minimum of 12 to 15 mm was required [15]. Expanding the maxilla beyond 15 mm is not accepted clinically or practical.

So Liou (2005) introduced the Alternate Rapid Maxillary Expansion and Constriction (Alt-RAMEC) technique to loosen the circummaxillary sutures and help to advance the maxilla in patients with cleft lip and palate [16]. It enables sutural mobilization with the opening and closing of the rapid maxillary expansion RME screw for seven consecutive weeks. It is like a simple tooth extraction in which we repeatedly rock the tooth buccally and lingually until the tooth is "disarticulated" out of the alveolar socket. With the advent of cone-beam computed tomography (CBCT) in dentistry, this study was performed to assess and evaluate the effect of the expander with differential opening and facemask therapy with the Alternate Rapid Maxillary Expansion and Constriction Alt-RAMEC protocol to achieve maxillary expansion and protraction in cleft lip and palate patients.

MATERIAL AND METHOD

Study design:

Prospective clinical trial.

Ethical consideration

Ethical approval was obtained by the Research Ethical Committee at the Faculty of Dental Medicine for Girls, Al-Azhar University in Cairo, Egypt (*Protocol number: REC-OR-23-01*). The study was registered in the Clinical Trials Registry of Egypt (*NCT04970095*).

The objectives of the study were discussed with the parents, and a written informed consent form was signed by the participants' parents or legal guardians before the orthodontic treatment.

Patient selection:

A randomly selected sample of 8 patients with cleft lip and palate (4 males and 4 females) was taken from the Orthodontic clinic in the Faculty of Dental Medicine for Girls and the 'Al-Azhar Cleft Lip and Palate Treatment Centre, at Al-Azhar University in Cairo Egypt.

Sample size estimation and statistical power

The calculation was estimated using the CDC Epi Info program version 7.2.0.1 (Atlanta, USA), assuming a power of 80% and alpha=0.05 to detect the amount of expansion of the palate using a differential opening expander and an alternative rapid maxillary expansion and contraction protocol among cleft lip and palate patients.

A total sample of 8 consecutive patients is needed based on an estimated 85.7% obtained improvement in occlusal index according to Terumi Ozawa et al. et al 2020 ⁽¹⁶⁾.

Inclusion criteria

- Patients of both sexes.
- Cleft lip and palate patients.
- All patients' ages range from 8 to 12 years.
- All cases showed maxillary arch constriction and deficiency.

- All patients had maxillary permanent first molars.
- Primary lip adhesion and palatal closure were done in early childhood.

Exclusion criteria:

- 1. Patients have never received any surgically assisted expansion, maxillary protraction, or fixed orthodontics before.
- 2. Maxillary dentition unsuitable to bond the expander (less than two dental units' bedside the first permanent molar).
- 3. Absent maxillary permanent first molars.
- 4. Uncooperative patients/parents

<u>Fabrication of Expander with Differential</u> <u>Opening (EDO) appliance</u>

After Separation and band selection impressions were made and the cast was poured, the tooth-borne, banded, and bonded Maxillary Expander with Differential Opening (EDO) appliance was fabricated for each patient (Fig. 1, A) (10). The body of the appliance was placed flush against the palate, with a clearance of about 1-2mm between the appliance and the palate. The anterior screw of EDO was placed anteriorly as much as possible, and the posterior screw of EDO was placed mesial to the maxillary first molar. The posterior two arms were contoured, adapted, and cut to be in contact with the two bands on the upper first permanent molar bilaterally on the working model, then soldered from the palatal side of the molar bands with silver solder. The anterior two arms were contoured, adapted, and embedded in an acrylic plate.

The occlusal surfaces of the teeth were coated with acrylic resin (1-2 mm thickness) to enlarge the surface area of the appliance for improved cement adhesion and to eliminate occlusal interferences in the anterior region. A red mark was drawn on the acrylic occlusal surface of the palatal cusp of maxillary teeth to facilitate the identification of overcorrection when the palatal cusp of maxillary teeth occludes with the buccal cusp of mandibular teeth. A facemask hook was added in the region of the maxillary canine area, and the facemask hooks were positioned vertically around the canines and as superior as possible.

Alt-RAMEC protocol

- The Patients were treated for 7 weeks⁽¹⁸⁾.
- The Expansion or constriction rate was 4 times per day (1mm per day, 1/4 turn) for both screws: two 1/4

turns in the morning and two $^{1}\!\!/_{4}$ turns in the evening.

- The sequences were: (first week: 7 days of expansion); (second week: 7 days of constriction); (third week: 7 days of expansion); (fourth week: 7 days of constriction); (fifth week: 7 days of expansion); (sixth week: 7 days of constriction); (seventh week: 7 days of expansion).
- The patient was seen every week to ensure a correct operation.
- The width between the arms of the expander was measured during every weekly visit.
- Then expansion continued until the red mark on the acrylic occlusal surface occluded opposite the buccal cusp tips of the mandibular posterior ones.
- If the anterior cross bite was still present, the anterior screw would only be activated four times a day until the anterior cross bite was corrected.
- After completion of expansion, the appliance was fixed using flowable composite (Fig. 1, B).

Face mask protocol

- After a phase of expansion, the patient was treated by petit facemask maxillary protraction (Figs. 2, 3).
- A facemask has a horizontal bar for elastic (ORMCO Z-pak elastics (3/8), 14 oz.).
- Adjust the horizontal bar of the facemask according to the growth pattern of each patient. If we require downward and forward movement of the maxilla, adjust the horizontal bar a little in the downward direction against the lower lip (20–40 degrees to the occlusal plane). If we require only forward movement of the maxilla, adjust the horizontal bar more superiorly against the upper lip (less than 20 degrees to the occlusal plane).
- The delivering force was 400 to 500 grammes per side.
- The patient wore the facemask for 16 hours a day.
- The protraction facemask therapy continued until a 2 mm overjet was achieved.

After the expansion active phase, the screw was fixed with acrylic resin, the appliances were kept in the dental arch, and the facemask was worn during sleep for 6 months as retainers. Cone beam computed tomography (CBCT) was obtained before expansion and 6 months post-expansion, after appliance removal.

Images were obtained with a Planmeca machine, and the technical parameters for image acquisition were 90 kV, 12 mA, image size 20×20 cm, and voxel size of 200 µm for each patient. For image acquisition, the patients were sitting, the 2010

Frankfort horizontal plane was parallel to the ground, and the median sagittal plane was perpendicular to the ground.

<u>Superimposition of the CBCT 3D surface</u> models

The Digital Imaging and Communications in Medicine (DICOM) data resulting from each CBCT scan were exported to specialized software, **Invivo dental software version 5.2 (Anatomage Inc., San Jose, CA)**, for a three-dimensional superimposition. For superimposition, the anterior cranial base and the occipital area posterior of the foramen magnum were selected as the stable structures.

Changes in liner and angular measurement were analyzed with **Invivo dental software** version 5.2 (Anatomage Inc., San Jose, CA).

CBCT measurement

The Alt-RAMEC expansion protocol and face mask effects were examined to compare the measurements made at T0 and T1 in all three planes of space.

- 1. The changes in the liner and angular transverse dimension were evaluated with coronal and axial cuts. The transverse posterior maxillary measurements were registered on the permanent first molars (Fig. 4,5), and the transverse anterior measurements were recorded at the level of the most anterior appliance-supporting teeth (Fig. 6).
- 2. The changes in the anteroposterior plane were assessed using the SNA angle, SNB angle, and ANB angle measured in the lateral cephalograms obtained from the CBCT scans (Fig. 7).

Statistical analysis

Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean \pm standard deviation, and ranges. Also, qualitative variables were presented as numbers and percentages.

The following tests were done:

- A paired-sample t-test of significance was used when comparing related samples.
- Pearson's correlation coefficient (r) test was used to assess the degree of association between two sets of variables. The paired t test was also used to evaluate differences in transverse changes between the anterior and posterior regions.

Positive = Increase in the independent variable leads to an increase in the dependent variable.

Negative= Increase in the independent variable leads to a decrease in the dependent variable.

- The confidence interval was set to 95%, and the margin of error accepted was set to 5%. So, the p-value was considered significant for the following:
- Probability (P-value)
- P-value ≤ 05 was considered significant.
- P-value <001 was considered highly significant.
- P-value >0.05 was considered insignificant.

RESULTS

This study included 8 cleft lip and palate patients. The patient's age ranged from 8 to 12 years, with a mean (\pm) SD of 10.88 \pm 1.36. As regards sex distribution, there were matched female and male (50%) of each type (Table. 1).

EDO promoted statistically significant (p<0.05) increases in Maxillary width in the molar and premolar regions, with a mean difference of 1.73mm and 3.08 mm, respectively, which show greater expansion in the premolar region than the intermolar region. EDO demonstrated similar changes in Nasal cavity width in the molar and premolar regions, with a mean difference of 1.75 mm (p<0.05). Greater increase in Alveolar crest width and Arch width in the molar region, the mean difference being 4.79 mm and 4.35 mm, respectively (p<0.05) (Table.2).

As the EDO was a tooth-borne expander, there was an effect on the dentoalveolar apparatus; there was a statistically significant increase (P<0.05) of approximately 0.5 mm in bone dehiscence at the alveolar crest level after treatment. The thickness of the buccal bone plate showed a statistically significant decrease (mean difference of -0.57 mm) with a significant increase in the thickness of the palatal alveolar bone (mean difference of 1.33 mm). Both were measured on the permanent first molar anchor tooth at the level of the CEJ. And there was a statistically significant increase in buccal molar inclination mean difference between 2.25° and 6.36° (Table. 2).

There was a statistically significant smaller increase in anterior alveolar width (AWA) of 4.18 mm than in posterior alveolar width (AWP) of 4.11mm. For changes in cephalometric reading in the sagittal direction, in the maxilla, a significant difference (P < .05) was seen in the following parameters: SNA with a mean increase of 0.76° and ANB with a mean increase of 2. 10°. In the mandible, there was a significant difference (P < .05) in SNB with a mean reduction of -1.35° (Table 3).

There was no significant correlation between posterior and anterior according to

maxillary width (mm), nasal cavity width, and maxillary alveolar width posterior in pre-treatment and post-treatment (p-value >0.05). (Table 3)



Figure (1): Photographic showing the tooth borne- banded and bonded Maxillary Expander with Differential Opening (EDO) appliance (A) pre-expansion (B) post expansion.



Figure (2): Photographic showing (A) pre protraction (B) post protraction

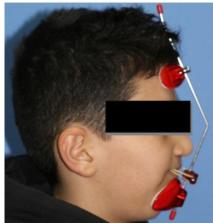


Figure (3): Photographic showing the patient wearing petit face mack with elastic

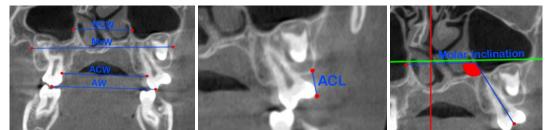


Figure (4): Cone beam computed tomography (CBCT) coronal slice at the first molar region transversal dimensions. The meaning of each abbreviation is described below: NCW—nasal cavity width—width of the nasal cavity measured at the level of the intersection between nasal cavity and maxillary sinus floor. MxW— maxillary width—maxillary width at the level of the hard palate. ACW—alveolar crest width—maxillary width at the level of the interpalatal alveolar crests. AW—arch width—dental arch width measured at the level of the palatal cusp tips. ACL—alveolar crest level—the buccal alveolar bone crest level was measured as the distance between the mesiobuccal cusp tip of the first permanent molar and the buccal alveolar bone crest.

inclination—angle between long axis of the first permanent molar and line parallel to axial plane passing through the tip of palatal root

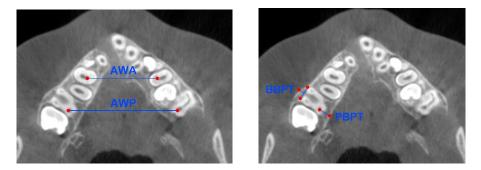


Figure (5). Cone beam computed tomography (CBCT) axial slice. AWA —Alveolar Width Anterior — measured from the center of the palatal root canal at the level of the root furcation from right premolar to left premolar. AWP—Alveolar Width Posterior measured from the center of the palatal root canal at the level of the root furcation from right first molar to left molar — BBPT—buccal bone plate thickness— measured from the external border of the buccal alveolar bone plate to the center of line connected the buccal aspect of mesiobuccal and distobuccal roots of the first molar . PBPT—palatal bone plate thickness— measured from the external limit of the palatal alveolar bone plate to the most palatal midpoint of the palatal root of the first permanent molars.

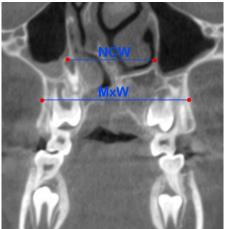


Figure (6) CBCT transverse dimensions at the first premolar region. The meaning of each abbreviation is described below: NCW—nasal cavity width—width of the nasal cavity measured at the level of the intersection between nasal cavity and maxillary sinus floor. MxW—maxillary width—maxillary width at the level of the hard palate.

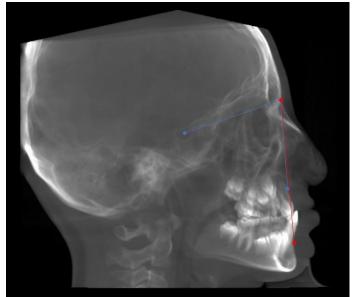


Figure (7): lateral cephalograms obtained from the CBCT scans to measurement SNA (blue) ,SNB (red) and ANB angles.

Table 1: Baseline	characteristics	distribution	among	study grou	n (n=8).
Lable I. Dusenne	ciluluctoribules	ansuroution	uniong	Study Stou	p(n=0)

Baseline characteristics	Total (n=8)
Gender	
Female	4 (50.0%)
Male	4 (50.0%)
Age (years)	
Range	8-12
[Mean±SD]	10.88±1.36

Table 2: Intergroup comparisons of the expansion changes (Paired Sample t-test)

	Pre-	Paired Sample t-test			
	Treatment	Treatment	MD±SE	t-test	p-value
Molar region					
Coronal					
Maxillary width (MxW)(mm)	60.20±4.24	61.93±3.93	1.73±0.56	3.093	0.017*
Alveolar crest width (ACW)(mm)	33.01±3.18	37.80±3.22	4.79±0.66	7.257	< 0.001**
Arch width (AW)(mm)	41.11±4.37	45.46±4.16	4.35±0.72	6.018	< 0.001**
Nasal cavity width (NCW)(mm)	28.53±2.76	30.28±2.53	1.75±0.46	3.812	0.007*
Tooth inclination URPFM (degree)	111.08±6.07	113.33±5.00	2.25±0.68	3.308	0.013*
Tooth inclination ULPFM (degree)	109.40±6.98	115.76±3.50	6.36±2.08	3.058	0.018*
Alveolar crest level URPFM(ACL) (mm)	7.08±1.05	7.58±1.21	0.50±0.40	1.250	0.251
Alveolar crest level ULPFM (ACL) (mm)	7.28±1.19	7.76±1.18	0.49±0.19	2.536	0.039*
Axial				•	
Buccal alveolar bone thickness URPFM at CEJ (mm)	1.82±0.43	1.25±0.72	-0.57±0.13	4.309	0.004*
BABT					
Palatal alveolar bone thickness URPFM (mm) PABT	3.71±0.69	5.04±0.65	1.33±0.27	5.011	0.002*
Buccal alveolar bone thickness ULPFM at CEJ (mm)	1.47 ± 0.71	1.06 ± 0.68	0.41 ± 0.20	2.046	0.080
Palatal alveolar bone thickness ULPFM at CEJ (mm)	3.39±0.94	4.55±1.17	1.16 ± 0.27	4.383	0.003*
Maxillary alveolar width posterior (MAWP) (MM)	37.06±3.18	41.18±2.62	4.11±0.46	9.017	<0.001**
Premolar region				I	1
Coronal					

Nasal cavity width (NCW)(mm)	26.99±2.40	28.74±2.47	1.75±0.70	2.499	0.041*
Maxillary width (MxW)(mm)	41.23±6.17	44.30±5.30	3.08±0.41	7.413	<0.001**
Axial		1			
Maxillary alveolar width anterior (MAWA) (mm)	26.60±2.87	30.78±4.01	4.18±0.59	7.054	<0.001**
URPFM: upper right permanent first molar, ULPFMP: upper left permanent first molar, CEJ: cementoenamel junction					
<i>p-value</i> >0.05 <i>is insignificant;</i> * <i>p</i> <0.05 <i>is significant;</i> **	*p-value <0.001 is	highly significan	nt		

Table 3: Intergroup	comparisons of	protraction	changes (Paired Sample t-test)
Table 5. Intergroup	comparisons or	production	changes (i anca bampic i test)

	Pre-Treatment	Post-Treatment	Paired Sa	ample t-t	est
	rie-freatment	rost-rreatment	MD±SE	t-test	p-value
SNA (degree)	78.33±4.53	79.11±4.43	-0.79±0.25	3.137	0.016*
SNB (degree)	75.54±4.50	74.19±4.26	-1.35±0.51	2.624	0.034*
ANB (degree)	2.79±2.48	4.89±2.85	2.10±0.44	4.743	0.002*
<i>p-value</i> >0.05 is insignificant; * <i>p</i> <0.05 is significant; ** <i>p-value</i> <0.001 is highly significant					

Table 4: Correlation among the following variable using Pearson Correlation Coefficient

Correlated outcome	Person correlation (r-value)	p-value
Before treatment		
Anterior and posterior nasal cavity width	0.693	0.057
Anterior and post Maxillary width	0.404	0.321
Anterior and posterior Maxillary alveolar width	0.605	0.112
After treatment		
Anterior and posterior nasal cavity width	0.642	0.086
Anterior and post Maxillary width	0.665	0.072
Anterior and posterior Maxillary alveolar width	0.153	0.718
<i>p-value</i> >0.05 <i>is insignificant;</i> * <i>p</i> <0.05 <i>is sig</i>	nificant; **p-value <0.001 is highly s	ignificant

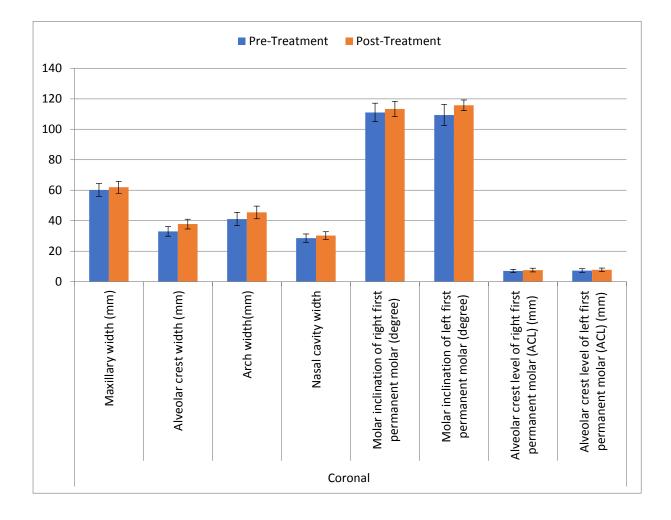


Figure (8): A clustered column chart compares pre- and post-treatment measurements at the coronal plane of the first permanent molar region.

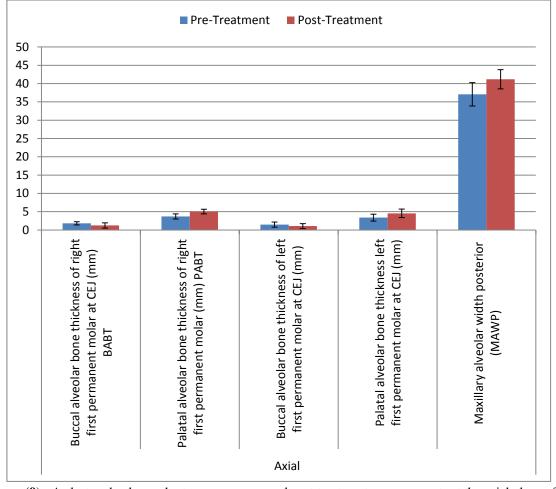


Figure (9): A clustered column chart compares pre- and post-treatment measurements at the axial plane of the first permanent molar region.

DISCUSSION

In this study, the EDO appliance was used to promote differential expansions in the anterior and posterior regions of the maxillary arch. The need for differential expansions is justified because, when using conventional RME expanders in patients with CLP, there is the risk of overexpanding the intermolar distance to correct the extreme constriction in the intercanine distance.

Over the past few years, many investigators have reported different studies to compare the effects of EDO with conventional expander hyrax and fan-shaped expanders.

For cleft patients, Garib compared EDO and hyrax using RME, and the rate of expansion was 0.8 mm per day for one week. The EDO promoted significantly greater increases in the nasal cavity width (1.99 mm), maxillary width (1.31mm), alveolar crest width (4.79 mm), and arch width (5.91mm) at the molar region, an increase in intercanine width (difference, 3.63 mm), and smaller increases in canine buccal tipping than the conventional hyrax expander.

A different protocol was used in this study. Seven weeks of expansion and constriction with a protocol of 1 mm per day were used to ensure an effective Alt-RAMEC in a reasonable treatment time. This study demonstrated significant increases in nasal cavity width (1.75mm), maxillary width (1.73mm), alveolar crest width (4.79 mm), and arch width (4.35mm) at the molar region.

In our study, the mean maxillary width at the premolar region was 3.08mm, which was bigger than the maxillary width of 1.44mm in Garib's study.

For non-cleft patients, de Medeiros Alves reported a randomized clinical trial comparing the Hyrax expander and the EDO using dental models and occlusal radiographs that showed the EDO promoted a greater split of the anterior region of the midpalatal suture and a greater increase of the intercanine distance than the Hyrax expander. Camila Massaro and Daniela Garib reposted two studies that compare the EDO and the FE. One study using digital dental models and the other using CBCT showed distinct maxillary arch width and shape changes after RME. The EDO showed greater dentoalveolar expansion in the molar region, while the FE produced a greater intercanine distance increase.

Since the expander used in the study is a tooth-borne appliance, it was also mandatory that the effect of Alt-RAMEC on the dentoalveolar apparatus be taken into consideration, especially those surrounding the anchor teeth.

The effect of tooth and tissue-borne expanders under the Alt-RAMEC protocol on buccal and palatal alveolar bone has been studied for cleft and non-cleft patients. Gandedkar and Liou (2018) published a study for non-cleft patients on changes in BABT and PABT in patients undergoing the Alt-RAMEC protocol in 4 transverse sections, where they found a significant reduction in the BABT in the cervical region and an increase in the PABT of the anchor teeth ⁽¹⁹⁾. Also, Singh (2021) reported the same result for a cleft patient after completion of Alt-RAMEC and protraction by a face mask, where the measurement was at three transverse sections. Similarly, in this study, there was a reduction in BABT (mean difference: -0.57±0.13) and an increase in PABT (mean difference: 1.33 ± 0.27)⁽²⁰⁾.

The vertical alveolar crest bone level after expansion has been reported in many studies. Studies that used Hyrax expanders conceded vertical alveolar bone loss, which ranges from 0.65 mm to 4.6 mm in the first molar region ^(23,24,25). In this study, the mean vertical alveolar crest bone loss was 0.5 mm, which is similar to that used in the Hyrax study.

The face mask appliance is the most popular appliance to move the maxilla forward. Many investigators used RME before face mask treatment to disarticulate the circummaxillary sutures and facilitate maxillary protraction. Few reviews in the literature used the Alt-RAMEC protocol with face mask maxillary protraction ⁽¹⁸⁾. For cleft patients, Liou and Tsai reported greater maxillary forward movement in the Alt-RAMEC group (5.8 mm) ⁽¹⁶⁾. Yen ⁽²¹⁾ introduced a modification of the techniques introduced by Liou and Tsai: a combination of Alt-RAMEC, 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. ⁽²²⁾ found no significant difference in the maxillary sagittal movement after facemask treatment with ALT-RAMEC or RPE in cleft patients.

This study demonstrated significant differences in maxillary forward movement (SNA mean difference -0.79 ± 0.25)

The EDO with Alt-RAMEC protocol promoted a significant buccal inclination of the maxillary permanent first molars with a mean increase of 6.36 degrees (Table 2). These results are in accordance with previous studies in individuals with and without oral clefts [4, 26]. The lateral rotation of the maxillary segments, which is accompanied by a greater lateral displacement of the anchorage tooth crown than the movement of the tooth apex, causes the posterior teeth's buccal inclination [27].

The comparison between the anterior and posterior regions showed no significant differences between maxillary width, nasal cavity width, and alveolar width in pre-treatment and post-treatment p-value >0.05. However, there was a virtually smaller increase in the MxW and AWA (Tables 2, 4). A prospective clinical trial study also suggested no significant differences between the posterior and anterior regions when using EDO [10].

The results showed greater expansion in the anterior and posterior regions and forward movement of the maxilla after using EDO with the Alt-RAMEC protocol and facemask in a cleft lip and palate patient. The EDO may be used as an alternative to conventional expanders when a greater amount of expansion is required in the maxillary dental arch's anterior region. **CONCLUSION**

- The EDO showed greater expansion in the anterior region than the posterior region.
- 2. Alternate rapid maxillary expansion and constriction can effectively protract the maxilla when used with EDO.
- 3. A greater frequency of anterior crossbite correction was observed in the study group.
- 4. A decrease in the height and thickness of the buccal bone plate is expected given the effects of Alt-RMEC on the supporting tissues of patients with clefts.

REFERENCES

- Wehby GL, Murray JC. Folic acid and orofacial clefts: a review of the evidence. Oral diseases. 2010 Jan;16(1):11-9.
- 2) Dixon MJ, Marazita ML, Beaty TH, Murray JC. Cleft lip and palate: understanding genetic and

environmental influences. Nature Reviews Genetics. 2011 Mar;12(3):167-78.

- 3) Zhang Z, Zhang P, Li S, Cheng J, Yuan H, Jiang H. Skeletal, dental and facial aesthetic changes following anterior maxillary segmental distraction by tooth-borne device in patients with cleft lip and palate. International Journal of Oral and Maxillofacial Surgery. 2021 Jun 1;50(6):774-81.
- 4) Figueiredo DS, Bartolomeo FU, Romualdo CR, Palomo JM, Horta MC, Andrade Jr I, Oliveira DD. Dentoskeletal effects of 3 maxillary expanders in patients with clefts: a cone-beam computed tomography study. American Journal of Orthodontics and Dentofacial Orthopedics. 2014 Jul 1;146(1):73-81.
- 5) Doruk C, Bicakci AA, Basciftci FA, Agar U, Babacan H. A comparison of the effects of rapid maxillary expansion and fan-type rapid maxillary expansion on dentofacial structures. The Angle Orthodontist. 2004 Apr;74(2):184-94.
- Çörekçi B, Göyenç YB. Dentofacial changes from fan-type rapid maxillary expansion vs traditional rapid maxillary expansion in early mixed dentition: a prospective clinical trial. The Angle orthodontist. 2013 Sep;83(5):842-50.
- 7) Cozza P, De Toffol L, Mucedero M, Ballanti F. Use of a modified butterfly expander to increase anterior arch length. Journal of Clinical Orthodontics: JCO. 2003 Sep 1;37(9):490-5.
- Garib DG, Garcia LC, Pereira V, Lauris RC, Yen S. A rapid maxillary expander with differential opening. Journal of Clinical Orthodontics: JCO. 2014 Jul 1;48(7):430-5.
- 9) de Medeiros Alves AC, Janson G, Mcnamara Jr JA, Lauris JR, Garib DG. Maxillary expander with differential opening vs Hyrax expander: a randomized clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics. 2020 Jan 1;157(1):7-18.
- 10) Garib D, Lauris RD, Calil LR, Alves AC, Janson G, De Almeida AM, Cevidanes LH, Lauris JR. Dentoskeletal outcomes of a rapid maxillary expander with differential opening in patients with bilateral cleft lip and palate: A prospective clinical trial. American Journal of Orthodontics and Dentofacial Orthopedics. 2016 Oct 1;150(4):564-74.
- 11) Massaro C, Janson G, Miranda F, Aliaga-Del Castillo A, Pugliese F, Lauris JR, Garib D. Dental arch changes comparison between expander with differential opening and fan-type expander: a

randomized controlled trial. European journal of orthodontics. 2021 Jun;43(3):265-73.

- 12) Massaro C, Garib D, Cevidanes L, Janson G, Yatabe M, Lauris JRP, Ruellas AC. Maxillary dentoskeletal outcomes of the expander with differential opening and the fan-type expander: a randomized controlled trial. Clin Oral Investig. 2021 Sep;25(9):5247-5256. doi: 10.1007/s00784-021-03832-9. Epub 2021 Feb 12. PMID: 33580351; PMCID: PMC8357852.
- 13) Bell RA. A review of maxillary expansion in relation to rate of expansion and patient's age. American journal of orthodontics. 1982 Jan 1;81(1):32-7.
- 14) Haas AJ. Long-term posttreatment evaluation of rapid palatal expansion. The Angle Orthodontist. 1980 Jul;50(3):189-217.
- 15) Alcan T, Keles A, Erverdi N. The effects of a modified protraction headgear on maxilla. American Journal of Orthodontics and Dentofacial Orthopedics. 2000 Jan 1;117(1):27-38.
- 16) Liou EJ, Tsai WC. A new protocol for maxillary protraction in cleft patients: repetitive weekly protocol of alternate rapid maxillary expansions and constrictions. The Cleft palate-craniofacial journal. 2005 Mar;42(2):121-7
- 17) Terumi Ozawa O, Daniela Salzedas C, Beatriz Oliveira DL, Sathler R, Baessa G, Garib D. Efficacy of Rapid Maxillary Expansion Associated with Maxillary Protraction in Patients With Unilateral Complete Cleft Lip and Palate. The Cleft Palate-Craniofacial Journal. 2020 Jul;57(7):872-6.
- 18) Liu W, Zhou Y, Wang X, Liu D, Zhou S. Effect of maxillary protraction with alternating rapid palatal expansion and constriction vs expansion alone in maxillary retrusive patients: a single-center, randomized controlled trial. American Journal of Orthodontics and Dentofacial Orthopedics. 2015 Oct 1;148(4):641-51.
- 19) Gandedkar NH, Liou EJ. The immediate effect of alternate rapid maxillary expansions and constrictions on the alveolus: a retrospective cone beam computed tomography study. Progress in orthodontics. 2018 Dec;19(1):1-7.
- 20) Singh S, Batra P, Raghavan S, Sharma K, Srivastava A. Evaluation of Alt-RAMEC With Facemask in Patients With Unilateral Cleft lip and Palate (UCLP) Using Cone Beam Computed Tomography (CBCT) and Finite Element Modeling—A Clinical Prospective Study. The Cleft Palate-Craniofacial Journal. 2022 Feb;59(2):166-76.

Evaluation of The Treatment Outcome of Cleft Palate Patients Treated with Differential Opening Expander with Alt-RAMEC Protocol and Facemask: A cohort clinical study Section A -Research paper

- 21) Yen SL. Protocols for late maxillary protraction in cleft lip and palate patients at Childrens Hospital, Los Angeles. InSeminars in orthodontics 2011 Jun 1 (Vol. 17, No. 2, pp. 138-148). WB Saunders.
- 22) Vieira GL, de Menezes LM, de Lima EM, Rizzatto S. Dentoskeletal effects of maxillary protraction in cleft patients with repetitive weekly protocol of alternate rapid maxillary expansions and constrictions. The Cleft palate-craniofacial journal. 2009 Jul;46(4):391-8.
- 23) Cardinal L, da Rosa Zimermann G, Mendes FM, Andrade Jr I, Oliveira DD, Dominguez GC. Dehiscence and buccal bone thickness after rapid maxillary expansion in young patients with unilateral cleft lip and palate. American Journal of Orthodontics and Dentofacial Orthopedics. 2022 Feb 10.
- 24) Pangrazio-Kulbersh V, Jezdimir B, de Deus Haughey M, Kulbersh R, Wine P, Kaczynski R. CBCT assessment of alveolar buccal bone level

after RME. The Angle Orthodontist. 2013 Jan;83(1):110-6.

- 25) Rungcharassaeng K, Caruso JM, Kan JY, Kim J, Taylor G. Factors affecting buccal bone changes of maxillary posterior teeth after rapid maxillary expansion. American Journal of Orthodontics and Dentofacial Orthopedics. 2007 Oct 1;132(4):428e1.
- 26) Garib DG, Henriques JF, Janson G, Freitas MR, Coelho RA. Rapid maxillary expansion—tooth tissue-borne versus tooth-borne expanders: a computed tomography evaluation of dentoskeletal effects. The Angle Orthodontist. 2005 Jul;75(4):548-57.
- 27) de Almeida AM, Ozawa TO, Alves AC, Janson G, Lauris JR, Ioshida MS, Garib DG. Slow versus rapid maxillary expansion in bilateral cleft lip and palate: a CBCT randomized clinical trial. Clinical oral investigations. 2017 Jun;21(5):1789-99.