SLOW MAXILLARY EXPANSION IN CLEFT LIP AND PALATE PATIENTS USING EXPANDER WITH DIFFERENTIAL OPENING: A CBCT CLINICAL STUDY

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Abstract

Objectives The purpose of this clinical study was to evaluate the orthopaedic and dentoalveolar treatment outcomes of slow maxillary expansion (SME) using the expander with differential opening (EDO) in patients with cleft lip and palate (CLP). ***Material and methods*** Eight children with maxillary arch constriction and CLP in the mixed dentition were selected. The patients were treated with EDO. Cone-beam computed tomography (CBCT) scans were done prior to expansion and six months after the expansion. Alveolar crest width, maxillary alveolar width, buccal and palatal alveolar bone thickness of molars were assessed. Interphase comparisons were performed using paired t-tests ($p<0.05$). ***Results*** SME using EDO promoted significant increases in alveolar crest width, maxillary alveolar width, and palatal alveolar bone thickness of molars. Additionally, SME promoted a slight reduction of buccal alveolar bone thickness of molars. ***Conclusions*** In children with CLP, SME using EDO caused orthopaedic and dentoalveolar changes. ***Clinical relevance*** SME can be recommended to treat individuals with CLP who have a constricted maxillary arch in the mixed dentition. ***Trial registration*** The trial was registered at Clinicaltrials.gov under the identifier NCT04997083.

Keywords Maxillary expansion . Slow expansion . Expander with differential opening . Cone-beam computed tomography . Cleft lip . Cleft palate

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INTRODUCTION

Cleft lip and palate (CLP) represents the most common human birth deformity, affecting about one in 700 infants [1]. The majority of CLP patients will have a constricted V-shaped maxillary dental arch owing to a lack of bony growth and scar tissue from previous lip and palate repair surgery [2]. Before getting an alveolar bone grafting, expanding the segments in the late mixed dentition may be necessary to enhance surgical access and provide maximal bone infill [2].

Several appliances, such as the Hyrax expander and the Quad-helix appliance, have been employed for maxillary expansion in CLP patients [3]. Conventional expanders increase the space between the maxillary molars and canines by opening the expander screw in parallel [4]. CLP causes a triangular-shaped dental arch because of transverse maxillary constriction. Because of this, the expander with a differential opening (EDO) was developed to allow for variable levels of anterior and posterior expansion in CLP [5]. The EDO has two palatal screws, and the variable activation protocol encourages varying degrees of expansion in the anterior and posterior parts of the maxillary arch [4]. In a recent clinical trial comparing Hyrax with EDO, the anterior region of the mid-palatal suture showed a larger degree of separation and the inter-canine distance showed a greater increase with EDO [4].

The literature describes three different maxillary expansion protocols: semi-rapid, rapid (RME), and slow (SME) maxillary expansions [6]. Heavy and continuous stresses are transferred to the maxilla in a short period of time during RME, causing an instantaneous increase in maxillary transverse widths. SME, on the other hand, takes place with lesser forces spread over longer times [7]. SME improves bone development in the inter-maxillary suture by producing less tissue resistance all around circum-maxillary structures [8].

Cone beam computed tomography (CBCT) was only recently made available in head and neck procedures [9]. The examination of the craniofacial structures is enabled by the use of CBCT, which effectively prevents anatomic superimpositions and issues that have come on by magnification [10]. A CBCT study of the dental, orthopaedic, and alveolar bone plate alterations following SME is required for a deeper understanding of the orthopaedic consequences of this expansion procedure in children with CLP [3].

This study aimed to use CBCT to assess the treatment results brought by SME protocol employing EDO in the maxillary dental arch in children with cleft lip and palate.

MATERIALS AND METHODS

- **Trial design**

This clinical trial study was registered at ClinicalTrials.gov (NCT04997083) and adhered to the Consolidated Standards of Reporting Trials (CONSORT) statement and recommendations [11]. All patients and their parents or legal guardians gave their agreement after being informed of the procedure, which was ethically approved by the Faculty of Dental Medicine for Girls' Research Ethics Committee at Al-Azhar University in Cairo, Egypt (approval no: REC-OR-23-02).

- **Participants, eligibility criteria, and settings**

Patients were recruited between July 2021 and March 2022 at the Al-Azhar Cleft Lip and Palate Treatment Center and the Orthodontic Clinic of Faculty of Dental Medicine for Girls at Al-Azhar University in Cairo, Egypt. The following were the selection criteria: children with cleft lip and palate, children of both sexes between the ages of 8 and 12, children with maxillary constriction and posterior crossbites. The exclusion criteria included the lack of permanent maxillary first molars, a maxillary dentition that was not suitable for bonding the expander (fewer than one dental unit alongside each permanent first molar), and a history of previous maxillary expansion or fixed orthodontic treatment.

- **Interventions**

The patients were treated with the EDO. All patients were treated by the same orthodontist (AE) during the period from August 2021 to October 2022. Orthodontic bands were fitted to maxillary permanent first molars, and bonded acrylic plates were placed, covering all posterior maxillary teeth. Red acrylic was used to mark the palatal cusp tips of posterior maxillary teeth. The EDO screws, which are placed in the middle of the arch, were soldered to palatal side of molar bands that were cemented to the permanent first molars. A wire extension with hooks near to canine area on both sides was soldered on the buccal aspect of the first permanent molars for facemask elastics attachment **(Fig. 1b).**

The anterior and posterior screws of EDO (*Great Lakes Orthodontics*, *Tonawanda*, *NY*, *USA*) were activated with a slow expansion protocol of one 1/4 turn every two days (three times weekly) until a minor overcorrection at the molar and canine areas is reached. In the region of the molars, the palatal cusp tips of the posterior maxillary teeth must touch the buccal cusp tips of the posterior mandibular teeth (the red acrylic line of EDO should contact the buccal cusp tips of the posterior mandibular teeth), while at the anterior teeth, a slight overcorrection of 2 millimeters should be accomplished in the inter-canine distance.

The active phase of expansion ranged from two to six months, based on the extent of the maxillary arch constriction. The degree of expansion was established individually and varied from patient to patient. After this stage, the expander screws were secured with ligature wire **(Fig. 1c)** and kept in the oral cavity as a retainer for six months. The expander was removed at the end of the retention phase **(Fig. 1d),** and a fixed retainer was put in its place. The retainer has a trans-palatal arch between the maxillary permanent first molars with an extended palatal arm resting on the palatal surfaces of the permanent maxillary premolars/deciduous molars and anterior teeth **(Fig. 1e).** The retainer also has hooks in the canine area on both sides as the treatment was then continued with facemask appliance.

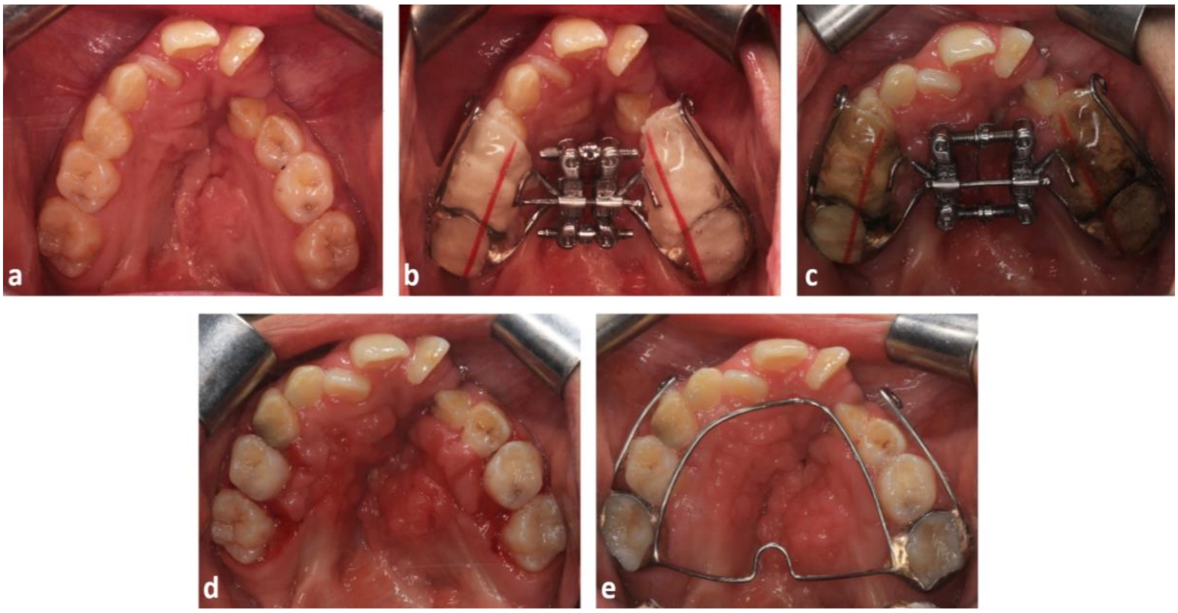

Figure 1. Pre-treatment (**a**), expander with differential opening (**b**), ligation of expander screws (**c**), after expander removal (**d**), and retainer (**e**)

Registration method

Each patient had two CBCT scans taken using the Planmeca ProMax 3D Mid-CBCT scanner (*Planmeca Oy, Helsinki, Finland*). The first scan was done just before the expansion (T1), and the other scan was done from the first to the sixth month following the active phase of the expansion when the expander was removed at the end of the retention phase (T2). DICOM format was used to store the images. The technical specifications for image acquisition were 90 kVp, 12 mA, 6.2 s scanning time, a FOV of 10×10 cm, and 0.2 mm voxel size.

Outcomes

The analysis was done using Invivo dental software, version 5.2 (Anatomage Inc., San Jose, CA), to perform the linear measurements after each patient's superimposition of pre- and post-expansion CBCT scans. Prior to measurement, the 3D model from each participant at T1 was placed in a fixed position that was standardized in both the frontal and lateral views. The infraorbital line in the frontal view and Frankfort horizontal plane in the lateral view were parallel to the horizontal plane. The T2 scan was adjusted to achieve the optimal superimposition of the cranial base concerning the oriented T1 scan **(Fig. 2).**

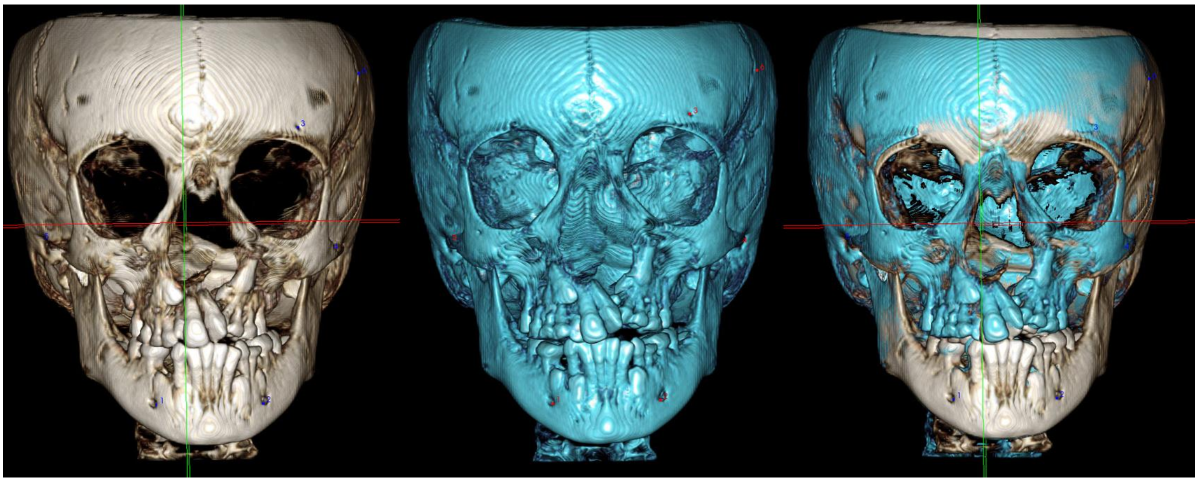

Figure 2. Cranial base superimposition of the pre- (white) and post- (blue) expansion three-dimensional surface models in an anterior view of a patient treated using the expander with differential opening

The outcomes of this research were changes in the maxillary alveolar width (MAW) at both the molar and premolar areas, as well as changes in the alveolar crest width (ACW), buccal (BBPT) and palatal (PBPT) bone plate thickness only at the molar region. The linear variables measured in the axial and coronal images both before and after expansion are shown in **Figures 3 and 4.**

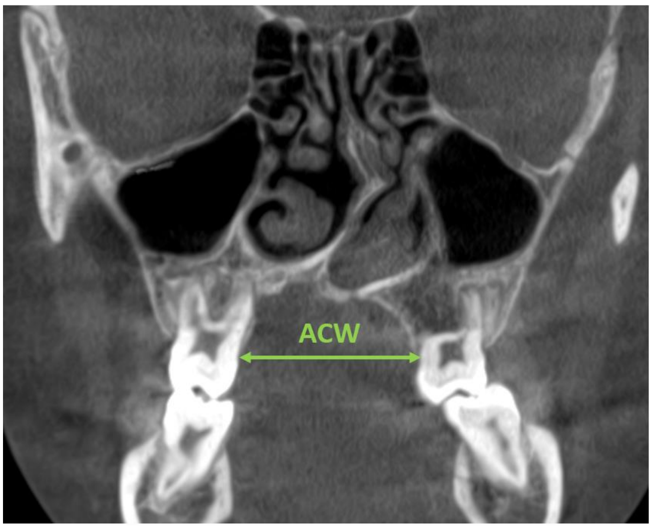

Figure 3. CBCT transversal dimensions at the first molar region. The meaning of each abbreviation is described below: *ACW*—alveolar crest width—measured from the right palatal alveolar crest to the left palatal alveolar crest

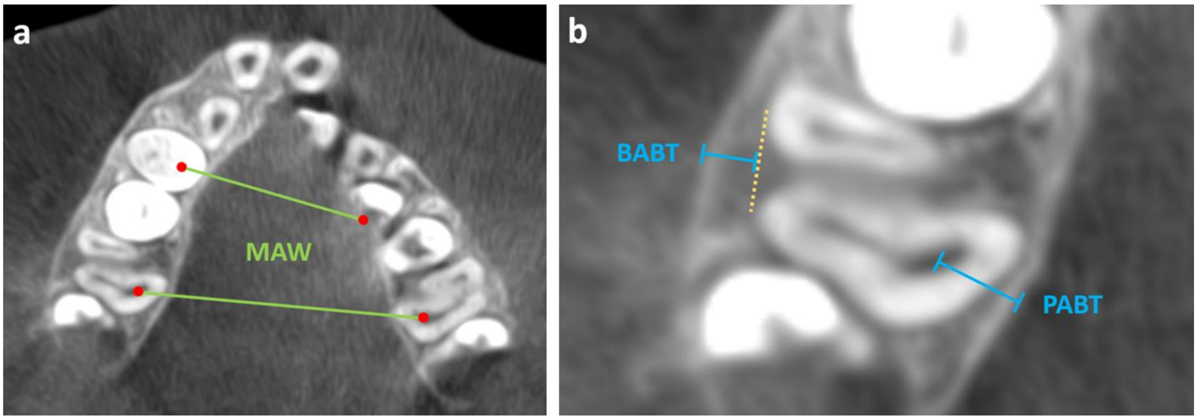

Figure 4. Alveolar bone measurements performed on axial section (**a**, **b**). *MAW*—maxillary alveolar width—measured from the center of palatal root canal of the right permanent maxillary first molar to the center of palatal root canal of the left permanent maxillary first molar at the level of root separation. The same procedure was done at the most anterior appliance-supporting teeth. *BABT*—buccal alveolar bone thickness—buccal bone plate thickness measured from the external border of the buccal cortical plate to the center of buccal aspect of mesiobuccal and distobuccal roots of the first permanent molar. *PABT*—Palatal alveolar bone thickness—palatal bone plate thickness measured from the external border of the palatal cortical plate to the center of palatal root of the first permanent molar

- **Sample size calculation**

The sample size was estimated using a significance level of 5% and a statistical power of 80% to detect the amount of palatal expansion in children with cleft lip and palate using expander with differential opening and a slow protocol. The needed sample size was ten patients, with a 15% dropout rate. Considering possible losses, eight patients were chosen (four boys and four girls).

STATISTICAL ANALYSIS

In order to evaluate intraobserver agreement, the same operator assessed all measurements twice in 16 CBCT scans randomly selected in a 2-week interval. For comparing samples that were related, the paired sample t-test was used. The related 95% confidence intervals (CI) were generated at the 5% level of significance ($P < 0.05$). P-values lower than 0.05 were deemed significant. In terms of the quantitative data, mean, and standard deviation were shown. The statistical package for social sciences, version 23.0 (*SPSS Inc., Chicago, Illinois, USA*) was used to conduct all statistical analyses.

RESULTS

- **Participant flow**

Two (33%) of the 12 people whose eligibility was assessed were excluded because they did not match the eligibility criteria, and two patients discontinued the intervention. All of the remaining eight patients who were recruited in the trial completed it. The trial ended when the sample size permitted a 15% dropout rate.

- **Baseline data**

The initial ages of the patients, who made up the whole research sample, ranged from 8 to 12 years, with a mean ± SD of 10.57±1.21. As regards gender distribution, there were equal numbers of male and female subjects of each type (50%) (Table 1).

Table 1. Patients' baseline characteristics table

Baseline characteristics	Total (n=8)
Gender	
Female (%)	4 (50%)
Male (%)	4 (50%)
Initial age (years)	
Range	8-12
[Mean±SD]	10.57±1.21

- **Numbers analyzed for each outcome**

SME was performed in 8 patients treated with the EDO (four female and four male; mean initial age of 10.57 years ± 1.21).

Comparing pre-treatment and post-treatment results in the coronal view of the molar region showed that EDO promoted significant increases in the alveolar crest width ($p < 0.05$). In the axial view of the molar region, there were significant increases in palatal alveolar bone thickness of molars and maxillary alveolar width posterior ($p < 0.05$). Moreover, a significant decrease in buccal alveolar bone thickness was observed ($p < 0.05$) **(Table 2).**

Table 2. Comparison between pre-treatment and post-treatment expansion changes in molar region

Variable	Pre-treatment	Post-treatment	Paired sample t-test		
			Mean±SD	t-test	p-value
Coronal					
Alveolar crest width (mm)	31.99±3.93	36.15±4.00	4.16±0.33	12.451	<0.001*
Axial					
Buccal alveolar bone thickness 16 at CEJ (mm)	2.64±1.00	1.65±0.82	-0.99±0.23	-4.378	0.003*
Palatal alveolar bone thickness 16 at CEJ (mm)	3.48±1.19	5.16±1.32	1.69±0.26	6.54	<0.001*
Buccal alveolar bone thickness 26 at CEJ (mm)	2.31±0.60	1.49±0.38	-0.83±0.17	-4.828	0.002*
Palatal alveolar bone thickness 26 at CEJ (mm)	4.15±1.43	5.65±1.62	1.50±0.24	6.295	<0.001*
Maxillary alveolar width posterior (mm)	36.25±4.13	40.16±4.03	3.91±0.31	12.543	<0.001*

*Statistically significant at p < 0.05

Comparison between pre-treatment and post-treatment results in the axial view of the premolar region showed that EDO promoted a significant increase in maxillary alveolar width anterior ($p < 0.05$) **(Table 3).**

Table 3. Comparison between pre-treatment and post-treatment expansion changes in premolar region

Variable	Pre-treatment	Post-treatment	Paired sample t-test		
			Mean±SD	t-test	p-value
Axial					
Maxillary alveolar width anterior (mm)	27.04±2.97	29.08±2.86	2.04±0.18	11.432	<0.001*

*Statistically significant at p < 0.05

- **Harms**

Participants in this trial had no serious harms other than temporary mild pain or discomfort in the palate and nasal cavity areas during the active expansion period and difficulty in speech and swallowing during a few weeks after appliance installation. Gingival enlargement was observed upon expander removal, but it regresses in 1 to 2 weeks. Two CBCT scans were obtained from each research subject. To reduce the radiation dose to the patient and surroundings as little as practically possible, the acquisition process was adjusted in accordance with radiology's ALADA (As Low As Diagnostically Acceptable) principles [12].

DISCUSSION

In growing children without oral clefts, the dentoalveolar effects of SME are well described in the literature [4, 13–16]. Nevertheless, there aren't enough clinical studies that specifically use CBCT to explore the dentoalveolar impact of SME in individuals with cleft lip and palate. In the current study, pre- and post-expansion CBCT exams were employed for orthodontic treatment planning and secondary alveolar bone graft planning, respectively. Moreover, both American and European CBCT guidelines [17, 18] identify CLP rehabilitation as one of the indications.

Increasing the width of the arch by moving a few or several teeth at a rate of 0.5 to 1 millimetre per week is known as SME, which is a form of dentoalveolar expansion. In this study, the slow expansion active phase ranged from 2 to 6 months; this may be less than reported in other slow expansion studies (4 to 21 months) due to differences in the type of appliance used [3, 4, 19].

SME can be a viable substitute for RME in CLP patients, according to clinical trials that identified no significant differences between the dentoalveolar effcts of SME and RME [3, 19, 20]. Due to the decreased pain and discomfort, SME may be chosen over RME [21]. SME also improves bone development in the intermaxillary suture since there is less tissue resistance around the circum-maxillary structures [22]. The long-term outcomes produced by SME and RME were comparable [23]. According to several studies, SME generates more post-expansion stability [24, 25] when given an acceptable retention period.

In noncleft patients, a previous study observed that slow expansion produced an orthopaedic effect [13]. A little more than half of the total transverse expansion was caused by this orthopaedic impact in conjunction with growth [13]. Another research found that SME had a 34.2% orthopaedic impact [3]. Prior investigations claimed that the lack of the mid-palatal suture in CLP could increase orthopaedic movement by lowering the resistance to maxillary lateral movements [26, 27].

Maxillary constriction must be evaluated before treatment to ascertain the severity of transverse deficiency in canine compared to molar regions. The EDO resulted in differential expansions between both the anterior and posterior maxillary arch widths [4, 28-30].

The results of our investigation show that, after SME procedure, the EDO could provide orthopaedic and dentoalveolar effects **(Fig. 1, Tables 2, 3).** The EDO promoted significant increases in all maxillary transverse dimensions at molar and premolar regions **(Tables 2, 3).** There were a significant increase in the alveolar crest width (4.16±0.33). In a previous clinical trial on CLP patients, there was an increase in alveolar crest width with EDO [5]. Another study on CLP patients showed a significant increase in alveolar crest width after SME [3].

A decrease in the buccal alveolar bone thickness (0.91) and an increase in palatal alveolar bone thickness (1.59) were observed in our study. These changes are consistent with other CBCT investigations in non-cleft individuals [4, 13] and may have resulted from the expander's dental effects. Despite statistical significance, the buccal alveolar bone change was less than 1 mm and hence not clinically significant **(Table 2).** In non-cleft patients, a previous study observed a higher drop in buccal bone thickness and a comparable gain in palatal bone thickness following SME; the authors speculate that this may be because the buccal root torque was activated before cementation [13]. In cleft patients, a recent CBCT study observed that SME produced a significant decrease in buccal bone thickness and an increase in palatal bone thickness [3]. A previous study indicates that SME causes buccal bone loss in varying degrees [13]. This must be considered a palatal expansion constituent [31, 32]. The lateral rotation of maxillary halves, with the fulcrum located near the fronto-maxillary suture exhibiting a triangular expansion pattern, may be the cause of the buccal inclination of the posterior teeth [33, 34]. Another possible cause is the lateral bending of the alveolar crests, which may result in the molars inclining towards the buccal segment [13, 35, 36].

A recent study on CLP patients showed significant increases in posterior and anterior alveolar width dimensions [37]. In the present study, there were significant increases in posterior maxillary alveolar width (3.91±0.31) and anterior maxillary alveolar width (2.04±0.18) in molar and premolar regions, respectively. A previous study on noncleft patients found significant increases in alveolar width in molar and canine regions after SME [38]. Another study on noncleft patients found an increase in alveolar width after SME [13]. When greater anterior expansion is necessary, such as in situations of crossbites involving molars and canines, the EDO is a simple alternative.

LIMITATIONS

One limitation of the study is the lack of a conventional expander group to compare the results. Further studied should assess the changes seen after SME and compare the orthopaedic and dentoalveolar effects of the EDO with the conventional expander.

GENERALIZABILITY

The findings of this research may be generalized to non-cleft patients receiving identical expander and activation protocol in mixed dentition. With patients of different age range, while using various expander types or when using the same expander with different activation protocols, different outcomes might be seen.

CONCLUSIONS

- Slow maxillary expansion using the expander with differential opening caused orthopaedic and dentoalveolar changes in cleft lip and palate patients.
- CBCT is useful at every treatment stage of CLP patients as it provides detailed information about bone morphology.
- The maxillary alveolar width increased in both molar and premolar regions after SME using EDO. The palatal alveolar bone thickness of molars also increased, producing a decrease in the buccal alveolar bone thickness.
- Slow expansion with EDO increased the alveolar crest width in molar region.

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Declarations

- **Ethics approval**

In this article, all procedures involving human participants were in accordance with the ethical standards of the Research Ethics Committee of Faculty of Dental Medicine for Girls, Al-Azhar University in Cairo, Egypt (approval no: REC-OR-23-02).

- **Informed consent**

Informed consent was obtained from all individual participants included in the study.

- **Conflict of interest**

The authors declare that they have no conflict of interest.

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