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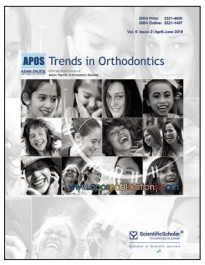

Original Article

Bonded maxillary expander in growing patients with or without unilateral cleft lip and palate: How does it influence transversal and vertical dentoskeletal changes?

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ABSTRACT

Objectives: Growing patients with unilateral cleft lip and palate (UCLP) usually show maxillary retrusion with constricted upper arch. Thus, orthodontic treatment with maxillary expansion is often needed. This study aimed to evaluate transversal and vertical changes in patients with or without UCLP after maxillary expansion.

Material and Methods: This observational retrospective study included patients aged between 7 and 14 years, with UCLP (test group) or without cleft lip and palate (controls), constricted upper arch and normodivergent growth pattern treated with a bonded maxillary expander. Patients with craniofacial syndromes, previous orthodontic treatment, or incomplete records were excluded. The digital dental casts and lateral radiographs of the head before (T0) and after treatment (T1) were collected and digitized by scanning with the 3ShapeTRIOS®. Statistical analysis was performed with STATA software. The Chi-square test was used for sex data in the two groups, and evaluation of the differences between the two groups was performed with the independent samples. $P < 0.05$ was considered statistically significant.

Results: The study sample included 51 patients (10.0 ± 2.5 years), 21 patients with UCLP, and 30 patients as the control group. Before treatment, all the transversal values measured on the maxillary arch at the occlusal and gingival level, as well as the length of the arch, presented statistically significant differences between the two groups with $P < 0.05$. The comparison at T1 did not show significant differences between the two groups for the transversal values, except for the value measured between the second premolars at the gingival level ($P < 0.05$). The cephalometric values measured in the analysis in the two groups did not show a statistically significant difference, except for the I-SN who showed significant differences both at T0 and T1 due to the presence of previous scars in UCLP patients.

Conclusion: The UCLP group showed an improvement in all transverse diameters after treatment with the bonded maxillary expander without affecting the mandibular divergence and incisor inclination.

Keywords: Bonded maxillary expander, Cephalometry, Constricted upper arch, Digital dental casts, Unilateral cleft lip and palate

INTRODUCTION

The cleft lip and palate (CLP) is the most frequently encountered malformation of the facial region with a multifaceted etiology involving environmental, genetic, and epigenetic factors interacting among them, i.e., smoking, bad habits, air pollution during pregnancy, specific genes, and microRNA mutations.[1-4] Many orofacial structures, including the lips and the palate, derive

from the first pharyngeal arches. The pathogenic processes occur between the 4th and 12th week of gestation when the medial nasal and maxillary processes in the primary palate or the palatal units in the secondary palate fail to fusion.[5,6] Oral cleft can be unilateral or bilateral if one or both sides are interested, and patients with CLP show different malformations, including aesthetical defects of the face[7] and of the smile with a higher prevalence of dental anomalies.[8-10] Moreover, these subjects may have difficulty in speaking and uttering a lot of phonetic sounds due to the possible presence of velopharyngeal defects,[11-13] conductive hearing loss due to elevated air conduction,[14] reduced upper airway dimensions and sleeping disorders.[15]

Thus, these malformations need interdisciplinary treatment from birth until adulthood.[8,16,17]

The treatment of children with CLP consists of a first surgery performed at around 4 or 6 months of age for functional reconstruction of the nasolabial area, following the functional cheilorhinoplastic technique of Markus *et al*.[18] Soft palate surgery is usually performed at 12 months, while hard palate surgery at around 18 months. A secondary alveolar bone graft is usually planned when the patient is 9–12 years old.[19-21]

A significant decrease in vertical and sagittal facial dimensions in surgically treated patients with unilateral CLP (UCLP) was detected during mixed dentition in comparison to noncleft children.[22] Recent research also showed that the occlusion was more affected when the surgery for the hard palate closure was delayed.[21]

In any case, to improve the growth of the maxilla in width and length, it is necessary to monitor the occlusion and intervene with an early orthodontic treatment.[8] Specifically, the orthopedic treatment of maxillary expansion aims to improve both dentoskeletal occlusions, although not reaching the size of the upper arch as in healthy patients,[23,24] as well as the hearing of the middle ear, breathing, and other oral functions.[14,15,25,26]

Another usual skeletal problem of patients affected by CLP and constricted upper arch is maxillary retrusion due to the cleft and the scars due to the surgical treatment of the hard palate in childhood, often resulting in a Class III malocclusion. In these cases, the early orthopedic treatment should also include therapies aimed at increasing maxillary diameters and controlling mandibular protrusion[27-30] also improving the soft tissues.[31-33]

There are many types of expansion devices and protocols based on different activation modes. The Haas and Hyrax expanders were both efficient for the correction of dentoskeletal crossbite and did not show significant differences in the size increase of the upper dental arch in patients with CLP. [34,35]

Pugliese *et al*. 2020 used three different devices in patients with full bilateral cleft lip and palate: Hyrax, quad-helix, and differential opening expander. The data showed similar changes in the size of the maxillary dental arch with the three appliances and only with hyrax, the arch morphology was not changed.[36]

There are different activation protocols, i.e., rapid maxillary expansion (RME), slow maxillary expansion, and mixed maxillary expansion.[23,25,37] The expansion of the maxilla was found to be efficient, with no statistically significant differences both in terms of width and perimeter of the upper arch and in the three-dimensional morphology of the palate in patients with bilateral CLP treated with slow or rapid activation.[25,38,39]

The hybrid activation of the expander has shown good results in increasing the transverse tooth and skeletal dimensions, causing fewer dental side effects than magnetic resonance imaging[37,40-42] and in a recent publication carried out at the Orthodontic Program of the University of Campania *Luigi Vanvitelli*, a sample of patients with CLP were treated in mixed dentition with a McNamara bonded maxillary expander, using hybrid activation.[43] The changes in the upper arch after the treatment were detected on three-dimensional digital models by a laser scanner, demonstrated as an even more effective and reliable method than measurements made directly on the plaster models.[44]

The main purpose of this observational retrospective study is to evaluate changes in the diameters of the upper arch after treatment with a bonded maxillary expander and mixed activation protocol on digital dental models in growing patients with and without UCLP. The secondary objective will be the comparison before and after the treatment of cephalometric variables in the same sample to investigate the sagittal dentoskeletal effects of this type of expansion.

MATERIAL AND METHODS

The sample data were collected from the database of the Orthodontic Program of the University of Campania *Luigi Vanvitelli*, Naples, Italy, from March 2020 to April 2023. The study was made by the Declaration of Helsinki and approved by the Ethical Committee of the University of Campania *Luigi Vanvitelli*, Naples, Italy (Prot. N°147). The parents of each child involved in the study signed an informed consent for the use of personal data. The inclusion criteria were patients with non-syndromic UCLP, age range between 7 and 14 years, a constricted upper arch, a cervical vertebral maturation stage between CS1 and CS4, and treatment protocol including a bonded maxillary expander with mixed activation.[37,42,43] Patients with other craniofacial syndromes, with previous orthodontic treatment, or incomplete documentation were excluded. All patients had been previously treated in the Maxillofacial Surgery and Oral Units at the University

of Campania *Luigi Vanvitelli*, Naples, Italy, by the same surgical protocol: A first lip surgery performed between 4 and 6 months, soft palate surgery is usually performed at 12 months while hard palate surgery at around 18 months.

All included patients had undergone an initial orthodontic checkup in mixed dentition [Figure 1] and were treated with a McNamara bonded palatal expander extended from the anteriorly deciduous canines and the first permanent molars,[8,43] an acrylic resin shower in the lower arch, class III elastics and chin cup.[45,46] The expansion protocol envisaged a hybrid activation with a first phase of chairside activation (four laps, two laps after 20–30 min, and a last lap after 10–15 min) and a second phase at home with one lap every 3 days.[40,42] The subjects underwent a follow-up every 2 weeks, and the therapy ended when an overcorrection of about 2 mm was obtained. After the active expansion period, the screw of the appliance was blocked with acrylic composite, and the expander was used as retention for about 8 months [Figure 2].[43] Patients with UCLP were considered the sample group, while subjects without UCLP were as controls.

The initial (T0) and after maxillary expansion (T1) plaster models of each patient were collected and digitized by scanning with the 3ShapeTRIOS® with a manufacturing inaccuracy of <20 microns (www.3shape.com).[44] The digital models were exported in STL format and imported into the Viewbox 4 software (dHal Software, Kifissia, Greece) to carry out the measurements by the expert operators themselves [Figure 3].[43,47] Supplementary Tables 1 and 2 described the reference points and measurements, respectively, used to perform the analysis of digital dental models.

The Viewbox software was used to carry out the cephalometric analysis, establishing standard parameters to be adopted for the measurements and eliminating the operator-dependent error of measurement. The collection of cephalometric data was carried out before expansion (T0) and after expansion (T1) in both groups of patients.

The following values were measured: The sella-nasion with mandibular plane angle (SNGoMe), the Frankfort-mandibular plane angle (FMA), the incisor mandibular plane angle (IMPA), the Frankfort-mandibular incisor angle (FMIA), and the maxillary incisor with sella-nasion angle (I^SN).

Data analysis

Continuous variables were reported as means and standard deviations if the data distribution was normal or as medians and interquartile ranges if the data showed a skewed distribution. The Shapiro–Wilk test was used to evaluate normality assumption. Analysis of continuous variables and comparison between groups (two categorical variables) was performed using Student's *t*-test.

Linear regression models were performed to evaluate the association between T1 evaluation (as dependent variable) and groups, adjusting for information at baseline (diff at T1 = groups + diff at baseline). Beta coefficients and 95% confidence intervals (β) have been calculated for all models.

Figure 1: Initial intraoral photographs of a patient in mixed dentition with unilateral cleft lip and palate (T0).

Figure 2: Intraoral photographs and panoramic X-ray after treatment (T1).

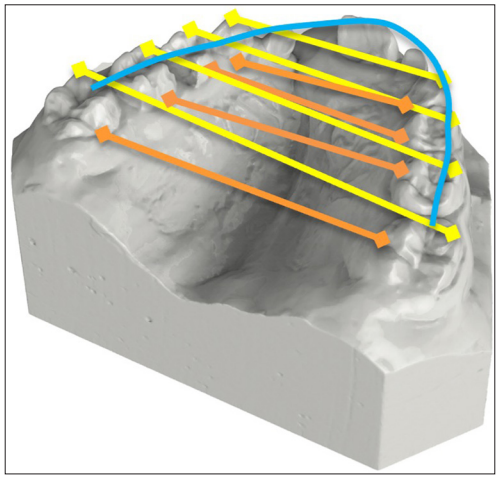

Figure 3: Digital dental casts of the upper arch with transverse diameters and arch length (yellow: occlusal plane, orange: gingival plane, blue: arch length at occlusal plane).

$P < 0.05$ was considered statistically significant. All analyses were performed using statistical software STATA v18 (StataCorp. 2023. College Station, TX: StataCorp LLC).

RESULTS

The total study sample included 51 patients (mean age: 10.0 ± 2.5 years). Of these, 21 patients from the UCLP group, including 11 females and 10 males, and 30 patients from the control group, including 19 females and 11 males. The initial mean age of the UCLP group was 10.8 ± 3.2 years, while the mean initial age of the control group was 9.4 ± 1.8 years with a $P = 0.061$, therefore, with a non-significant difference between the two groups at T0. The total phase of expansion treatment (T0 - T1) lasted 1.8 ± 0.8 years in the UCLP group and 1.1 ± 0.34 years in the control group.

Table 1: Measurements of maxillary expansion before treatment (T0).

Variables	OverSall	UCLP	Control	*P*
	Mean (SD)	Mean (SD)	Mean (SD)	
Year	10.0 (2.5)	10.8 (3.2)	9.4 (1.8)	0.061
3–3 OC	29.0 (5.8)	25.6 (7.4)	31.3 (2.5)	<0.001**
3–3 G	23.4 (5.2)	20.5 (6.4)	25.5 (2.6)	<0.001**
4–4 OC	35.8 (8.4)	30.5 (10.7)	39.5 (2.8)	<0.001**
4–4 G	24.3 (6.5)	20.2 (7.9)	27.1 (3.1)	<0.001**
5–5 OC	42.3 (4.3)	39.5 (4.0)	44.3 (3.3)	<0.001**
5–5 G	28.3 (4.0)	26.1 (3.5)	29.9 (3.6)	<0.001**
6–6 OC	50.4 (8.3)	46.8 (11.3)	52.9 (3.9)	0.008*
6–6 G	32.0 (5.9)	29.8 (7.8)	33.6 (3.3)	0.022*
AL OC	86.9 (19.3)	75.5 (25.9)	94.8 (4.7)	<0.001**

UCLP: Unilateral cleft lip and palate, SD: Standard deviation, OC: Occlusal plane, G: Gingival plane, AL OC: Arch length at the occlusal plane. * and ** mean the level of statistical significance. *P<0.05; **P<0.001 are statistically significant.

Table 2: Differences between pre and post maxillary expansion measurements (T1–T0).

Variables	UCLP			Non-UCLP			Group difference	
	Pre	Post	Difference	Pre	Post	Difference	b (95% CI)	*P*
	mean (SD)	mean (SD)		mean (SD)	mean (SD)			
3–3 OC	25.6 (7.4)	30.8 (8.6)	5.3 (3.0)	31.3 (2.5)	35.6 (2.1)	4.3 (2.5)	0.94 (−0.84; 2.72)	0.29
3–3 G	20.5 (6.4)	25.2 (8.0)	4.7 (3.1)	25.5(2.6)	29.8 (2.5)	4.2 (3.0)	0.33 (−1.70; 2.37)	0.75
4–4 OC	30.5 (10.7)	36.4 (12.9)	5.9 (3.4)	39.5 (2.8)	46.1 (3.2)	6.6 (2.9)	0.48 (−1.54; 2.50)	0.64
4–4 G	20.2 (7.9)	25.7 (10.0)	5.5 (3.3)	27.1 (3.1)	33.3 (2.9)	6.2 (3.1)	−0.19 (−2.34; 1.96)	0.86
5–5 OC	39.5 (4.0)	46.9 (4.6)	7.4 (2.1)	44.3 (3.3)	51.6 (3.3)	7.3 (2.6)	−0.62 (−2.27; 1.04)	0.46
5–5 G	26.1 (3.5)	32.9 (4.5)	6.8 (2.5)	29.9 (3.6)	37.5 (3.0)	7.6 (2.7)	−1.68 (−3.33; −0.03)	**0.046***
6–6 OC	46.8 (11.3)	52.5 (13.1)	5.8 (3.5)	52.9 (3.9)	60.3 (4.0)	7.4 (3.3)	−1.26 (−3.32; 0.80)	0.23
6–6 G	29.8 (7.8)	35.6 (9.7)	5.8 (3.6)	33.6 (3.3)	41.1 (3.7)	7.5 (3.2)	−1.53 (−3.58; 0.52)	0.14
AL OC	75.5 (25.9)	78.5 (26.3)	2.9 (5.5)	94.8 (4.7)	99.7 (6.4)	4.9 (4.5)	−2.05 (−5.35; 1.25)	0.22

b: Difference between groups, CI: Confidence interval, UCLP: Unilateral cleft lip and palate, SD: Standard deviation, OC: Occlusal plane, G: Gingival plane, AL OC: Arch Lenght at the occlusal plane. * means level of statistical significance.

Before treatment (T0), all the transversal values measured on the maxillary arch at the occlusal and gingival level, as well as the length of the arch, presented statistically significant differences between the two groups with $P < 0.05$ [Table 1], in particular in the anterolateral areas.

The comparison between T0 and T1 did not show statistically significant differences between the two groups at the diameters of the arches, both at the level of the cusp tips and at the gingival level, except for the value measured between the second premolars at the gingival level ($P < 0.05$) [Table 2].

The cephalometric values measured before and after treatment in the two groups did not show any statical significance, except for the I-SN value that showed significant differences both at T0 and T1 due to the previous scar tissue both at T0 and T1 in patients with UCLP [Table 3].

Table 3: Cephalometric data before treatment (T0).

Variables	UCLP		Non-UCLP	*P*
	mean (SD)		mean (SD)	
SNGoMe	37.6 (3.7)		35.1 (4.7)	**0.046**
FMA	26.6 (4.0)		24.3 (5.0)	0.082
IMPA	87.4 (4.0)		86.8 (7.1)	0.72
FMIA	66.3 (5.6)		68.9 (7.2)	0.18
I-SN	91.2 (9.8)		108.6 (7.3)	**<0.001**

UCLP: Unilateral cleft lip and palate, SD: Standard deviation, SNGoMe: The sella-nasion with mandibular plane angle, FMA: the Frankfort-mandibular plane angle, IMPA: the Incisor mandibular plane angle, FMIA: the Frankfort-mandibular incisor angle, I^SN: the Maxillary incisor with sella-nasion angle.

DISCUSSION

Several studies in the literature have highlighted the maxillary morphogenetic varieties, in mixed or permanent dentition, in patients with cleft lip and palate compared to control groups before different types of orthopedic/orthodontic treatment.[47,48] In particular, the distances between the upper canines were found to be significantly reduced in some studies both at the coronal and gingival level; thus, the expansion of the upper jaw in patients with cleft lip and palate is often requested treatment in subjects during the maxillary growth phase.[22,49,50]

The expansion of the maxilla produces various positive effects in patients with UCLP, including not only the improvement of occlusion with an increase in the transverse diameters and the correction of the cross-bite, where present[21,51] but also the resolution of other breathing, hearing, and language issues often associated with the UCLP, thanks to the enlargement of the nasal airways, the improvement of hearing in the middle ear,[14,15,26] and of speech by facilitating movements of the tongue in the increased oral cavity space.[13,48,52] Furthermore, the improvement in facial esthetics that results from the enlargement of the middle third of the face should not be underestimated.[52]

Most patients with CLP have a diagnosis of constricted and retruded maxilla due to scar residues, resulting from previous surgery to close the lip and palate, that negatively affect the growth of the maxilla concerning the mandible. Therefore, the orthopedic/orthodontic treatment before the pubertal peak is indicated to reduce the discrepancies between the mandible and maxilla.[53] Many studies have evaluated dental and alveolar changes in patients with uni or bilateral cleft lip and palate using different devices and expansion protocols. In the study of Ayub *et al.*, the RME produced similar effects

in both groups, except arch length and palate depth which were less developed in patients with CLP.[23]

In our study, patients with constricted and retruded maxillary arch with and without UCLP were included to compare the post-maxillary expansion data, all presenting similar maxillary retrusion and contraction associated with mandibular protrusion. Other authors in previous studies have used other types of maxillary expansion with different types of expanders and activation protocols.[23,25,35,36] In this study, a bonded maxillary expander (McNamara type) with hybrid activation of the expansion screw was used for the 1st time in association with early therapy for class III malocclusion, which also includes lower Splint, Class III intermaxillary elastics and Chincup, protocol defined with the acronym of SEC III modified due to the presence of the expansion screw in the upper splint[45,46] to treat transverse, sagittal, and vertical problems simultaneously. Hoefert *et al*. also included class III patients treated with Delaire expansion and facial mask, and this showed clear improvements in facial esthetics with an improvement in soft tissues in a three-dimensional analysis.[33] Our results showed improvements in all transversal dimensions of the upper arch and the total arch length. The bonded expander eliminates possible interference with the lower arch thanks to the presence of smooth acrylic splints that cover the occlusal surface. This implies that the expander bonded together with the hybrid activation protocol should be adopted in UCLP as a procedure between the slow and rapid protocol to obtain an efficient maxillary expansion.[43] This also leads to avoiding buccal tipping of premolars and molars, ensuring adequate activation.[25,38]

This study, of course, showed some limitations such as the retrospective nature of the study design and short-term collected results. The stability of orthodontic–orthopedic treatment over time can be threatened by the presence of scar residues due to primary surgery, the lack of palatal support bone, abnormal muscle forces, and highly representative orthodontic tooth movements. In recent years, several studies have been performed on the stability of the transverse dimension after treatment in patients with CLP. Li and Lin have demonstrated how the use of retention spans to maintain the results obtained in long-term re-evaluations.[54] Patients with CLP, 1 year after the expansion and implant-prosthetic treatment in adulthood, had less stability and less volume and surface of the palate than healthy patients.[55]

A new perspective for diagnosis, treatment planning, and monitoring could be the use of intraoral scanners during clinical routines in offices and hospitals in assessing dentofacial and nasolabial morphology in cleft patients; also useful to better communicate with the affected patients and their families.[56] Therefore, future aims could be the evaluation of the airway volumes and the influence of tongue position and movement before and after treatment in a wide sample, as performed in previous studies using a different oral appliance in patients with CLP.[57,58]

Moreover, it could be relevant to evaluate the long-term stability during adulthood of the treatments performed in mixed dentition with the palatal expander in comparison to matched control groups without CLP.

CONCLUSION

The results of this study showed that growing subjects with UCLP show an improvement in all transverse diameters and the length of the upper arch after treatment with a bonded expander and hybrid activation measured on digital dental models. No statistically significant differences were revealed in the mandibular divergence before and after treatment in both groups. The comparison of treatment outcomes in the two groups did not show relevant differences except for upper central incisor inclination, which resulted in more retroclined in patients with UCLP due to previous surgery for treating the cleft during the 1st year of age.

Ethical approval: The research/study approved by the Institutional Review Board at the University of Campania Luigi Vanvitelli, number Protocol N° 147, dated 2021.
Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.
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