

Bone-anchored maxillary protraction in patients with unilateral cleft lip and palate: *Is maxillary expansion mandatory?*

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ABSTRACT

Objectives: To assess the effectiveness of bone-anchored maxillary protraction (BAMP) in patients with unilateral cleft lip and palate (UCLP) and whether it was enhanced when preceded by maxillary expansion.

Materials and Methods: The sample consisted of 28 growing children (9–13 years old) with UCLP and Class III malocclusion. They were divided into two equal groups. In group I, patients were treated with BAMP not preceded by maxillary expansion. In group II, patients were treated with BAMP preceded by maxillary expansion. To assess treatment changes in three dimensions, Cone-beam computed tomography images were taken 1 week after surgical placement of the miniplates (T1) and after 9 months of treatment (T2).

Results: BAMP produced forward movement of the maxilla in both groups (3.17 mm) and (3.37 mm) respectively, without significant differences between the two groups except for clockwise rotation of the palatal plane in group I (1.6°).

Conclusions: BAMP is an effective treatment modality for correcting midface deficiency in patients with UCLP whether or not maxillary expansion was carried out. (*Angle Orthod.* 2020;90:539–547.)

KEY WORDS: Bone-anchored maxillary protraction; Cleft lip and palate; Maxillary expansion

INTRODUCTION

Clefts of the lip and/or palate are one of the most common congenital craniofacial deformities.¹ Patients with surgically repaired cleft lip and palate (CLP) are characterized by midface deficiency that may or may not be combined with mandibular excess. The resulting stretch of muscular forces alter future maxillary growth

leading to inhibition of growth and development of the nasomaxillary complex and a severe three-dimensional (3D) maxillary collapse.²

Protraction facemask therapy is the most common approach for early treatment of these patients.³ It has many drawbacks, including unwanted dentoalveolar effects and the excellent compliance needed with a troublesome extraoral appliance for satisfactory outcomes.

Some recent studies have reported the use of modified surgical miniplates in conjunction with facemask therapy, providing a sort of skeletal anchorage and thus maximizing the orthopedic effects.^{4–6} More recently, the bone-anchored maxillary protraction (BAMP) protocol was introduced by De Clerck et al.⁷ and Nguyen et al.⁸ that involved placing modified surgical miniplates in both the maxilla and the mandible connected by Class III intermaxillary elastics. It offers the possibility to apply pure bone-borne orthopedic forces for 24 hours per day, avoiding any dentoalveolar compensations and improving patient compliance. This treatment approach did not include maxillary expansion to open the circummaxillary sutures and facilitate maxillary protraction as in the contemporary protocol. This was justified by the

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existing controversy about the effect of expansion on maxillary protraction by facemask as described by Vaughn et al.,⁹ who found no difference between maxillary protraction with and without rapid maxillary expansion (RME). Additionally, 3D evaluation of the effects of RME on the circummaxillary sutures reported opening of the intermaxillary, internasal, maxillonasal, frontomaxillary, and frontonasal sutures but no changes in the frontozygomatic, zygomaticomaxillary, and zygomaticotemporal sutures.¹⁰ On the other hand, those sutures unaffected by RME are the ones most affected by BAMP as reported by Nguyen et al.,⁸ who found opening of these sutures using BAMP without RME. These observations suggest that perhaps the direct and continuous force application to the maxillary and zygomatic bones produces distraction of the circummaxillary sutures.

The BAMP protocol was previously evaluated for the correction of midface deficiency in skeletal Class III patients and proved to be an effective treatment modality.^{7,8} However, the presence of the limiting postsurgical scar tissue in patients with surgically repaired CLP might affect the efficiency of this approach. This was examined in only a few recent studies^{11,12} and therefore needs further investigation. Additionally, these studies did not examine the effect of expansion on that protraction protocol.

MATERIALS AND METHODS

This prospective study included a sample of 28 growing children with complete unilateral CLP (UCLP) ranging in age from 9 to 13 years (mean = 10.8, SD = 1.2). The participants were selected from the outpatient clinic of the Orthodontic Department and Cleft-Care-Center affiliated with the Oral and Maxillofacial Surgery Department, Ain Shams University. Patients were selected according to the following inclusion criteria: nonsyndromic surgically repaired complete unilateral cleft of the lip, alveolar process, and secondary palate; skeletal Class III malocclusion primarily due to maxillary deficiency (determined by clinical examination and confirmed by measuring SNA <78°); prepubertal stage of skeletal maturity according to cervical vertebral maturation method (CS1–CS3)¹³; mixed dentition or full permanent dentition stages; anterior crossbite; or edge-to-edge incisor relationship. None of the patients had previous orthopedic or orthodontic treatment, and they were all medically healthy except for the CLP deformity.

The research protocol was approved by the research ethics committee of the Faculty of Dentistry, Ain Shams University. Before the start of treatment, informed consent and assent were signed by the parents and patients, respectively.

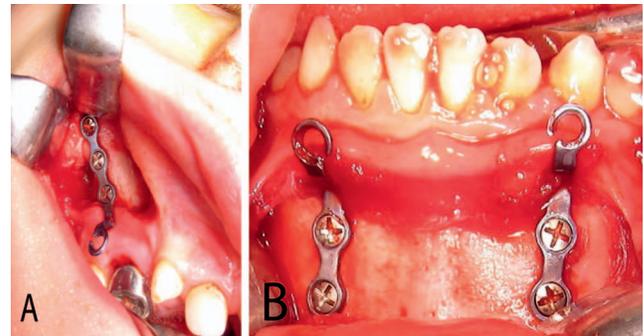


Figure 1. Miniplates fixed intraorally. (A) Maxillary miniplate fixed in the infrazygomatic buttress; (B) Mandibular miniplate fixed in the anterior mandible.

The patients were divided according to the amount of the maxillary constriction present to one of the two study groups:

1. Group I (n = 14; 10 boys, 4 girls; mean age 10.3 ± 0.9 years) was treated with BAMP not preceded by maxillary expansion.
2. Group II: (n = 14; 6 boys, 8 girls; mean age 11.3 ± 1.4 years) was treated with BAMP preceded by maxillary expansion.

Four custom-made modified surgical titanium miniplates (Modern Techniques Center, Cairo, Egypt) that were accepted by the research ethics committee of the Faculty of Dentistry, Ain Shams University, were manufactured for this research from the biocompatible titanium alloy Grade 2. The surgical procedure was performed under general anesthesia. For every patient, four miniplates were inserted on the left and right infrazygomatic buttress of the maxilla, and between and inferior to the right and left permanent lateral incisor and canine. Mucoperiosteal flaps were elevated, and the modified miniplates were secured to bone by three maxillary (diameter = 2.3 mm; length = 6 mm) and two mandibular (diameter = 2.3 mm; length = 5 mm) monocortical self-drilling miniscrews. The attachment hook of each miniplate perforated the attached gingiva near the mucogingival junction (Figure 1). Postoperative medications were prescribed for every patient: antibiotics and nonsteroidal anti-inflammatory drugs for 5 days. Soft diet and oral hygiene instructions were given.

For patients in group I, the miniplates were loaded to start orthopedic protraction 3 weeks after surgery using Class III intermaxillary elastics providing an initial force of approximately 150 g per side, increased to 200 g after 1 month of traction and to 250 g after 2 months.⁷

For patients in group II, 2 weeks before surgical insertion of the miniplates, a banded fan-shaped



Figure 2. Fan expander cemented intraorally.

maxillary expander (Rango screw-Leone Ortodonzia, Firenze, Italy) was prepared for every patient. It was cemented 2 weeks after surgical insertion of the miniplates (Figure 2). Activation of the palatal expander started by RME for 7 days to disarticulate the circummaxillary sutures. After 1 week of activation, orthopedic protraction of the maxilla started using Class III intermaxillary elastics in the same way as patients in group I.

The patients in both groups were instructed to wear the elastics 24 hours per day. For all patients, after 2–3 months of intermaxillary traction, a removable posterior bite-plane was placed in the mandibular arch to eliminate occlusal interference in the incisor region. (Figure 3).

To visualize the treatment changes in 3D, cone-beam computed tomography (CBCT) scans were taken for every patient 1 week after placement of the miniplates (T1) and after 9 months (T2). All images were acquired using an i-CAT machine (Imaging Sciences International, Hatfield, Pa). The projection data were reconstructed with i-CAT software and saved in DICOM (Digital Imaging and Communications in Medicine) file format, which were then downloaded and reconstructed into volumetric images using InVivo 5 software (version 5.2; Anatomage, San Jose, Calif). To exclude any effect of growth during the investigation



Figure 3. Intermaxillary traction with removable bite-plane in the mandibular arch.

period, a customized 3D craniofacial analysis was developed that depended on stable cranial base structures that do not undergo remodeling after the age of 4 to 5 years.^{14,15} The analysis consisted of the following (Table 1):

1. A new coordinate reference system including 3 reference planes (Figure 4): modified midsagittal plane,^{16,17} interspinous plane (ISP), and T perpendicular plane (TPP).
2. Angular measurements (TA/TPP, TB/TPP, ATB, TOr/TPP, PP/TPP, MP/TPP, PP/MP, U1/PP, L1/MP) (Figure 5).
3. Linear measurements (A-ISP, Co-A, JR-JL, Or-ISP, KR-ISP, B-ISP, Co-Gn, overjet) (Figure 6).

All measurements were done by the same investigator. To assess the reliability of the measurements, four randomly selected CBCT scans were remeasured by the same investigator 1 week after the initial measurement and by another investigator. Cronbach alpha reliability coefficient results showed very good intraobserver and interobserver agreement with Cronbach alpha value not less than 0.800 for all the variables.

Statistical Analysis

Statistical analysis was performed utilizing SPSS software (version 20.0; IBM, Armonk, NY). Numerical data were explored for normality by checking the data distribution and using Kolmogorov-Smirnov and Shapiro-Wilk tests for further choice of appropriate parametric and nonparametric tests. Descriptive statistics were computed for all the variables. The significance level was set at $P \leq .05$. Within each group, most of the data showed parametric distribution where paired *t*-tests were used to test the significant differences between T1 and T2 measurements, while Wilcoxon signed-rank tests were used for nonparametric data (PP/TPP-overjet). Mann-Whitney *U*-tests were used to compare changes between the two groups.

RESULTS

There were no statistically significant differences between the two groups at T1 for age, gender, and the analyzed parameters (Table 2 and 3). The changes between T1 and T2 are shown in Table 4 and Figures 7 through 10, which showed significant active treatment effects in both groups with no statistically significant differences between the two groups except for the increase in the interjugale width in group II ($P \leq .05$), and the clockwise rotation of the palatal plane, which was statistically significant in group I. For both groups; there was significant forward movement of the maxilla

Table 1. Description of Landmarks, Planes, and Lines Used in the Three-Dimensional Craniofacial Analysis

	Abbreviation	Definition
Landmark		
Orbitale	Or (R & L)	Most inferior point on the infraorbital rim of the maxilla
Point-T ¹⁶	T	The most superior point of the anterior wall of sella turcica at the junction with tuberculum sellae
Basion	Ba	Midpoint of the anterior-inferior border of foramen magnum
Foramen spinosum ¹⁷	Fs (R & L)	The most inferior point on the foramen spinosum
Point ELSA ¹⁷	ELSA	Computer-generated medial (mean) point between the right and left foramen spinosum
Anterior nasal spine	ANS	Most anterior midpoint of the anterior nasal spine
Posterior nasal spine	PNS	Most posterior midpoint of the posterior nasal spine
Point A	A	Midpoint of the anterior limits of the apical base of the maxilla
Condylon	Co (R & L)	Uppermost midpoint of the condyle
Gonion	Go (R & L)	Most lateral-inferior point on the mandibular angle
Point B	B	Midpoint of the anterior limits of the apical base of the mandible
Menton	Me	Midpoint of the lowest point on the mandibular symphysis
Gnathion	Gn	The most anterior-inferior point on the mandibular symphysis
Jugale	J (R & L)	The most superior aspect of the concavity of the maxillary bone as it joins the zygomatic process
Key ridge	KR (R & L)	The lower most point on the contour of the shadow of the anterior wall of the infratemporal fossa
Upper central incisor (incisal edge)	U1CR	Midpoint of the incisal edge of the maxillary right central incisor
Upper central incisor (Apex)	U1RR	Maxillary right central incisor root tip
Lower central incisor (incisal edge)	L1CR	Midpoint of the incisal edge of the mandibular right central incisor
Lower central incisor (Apex)	L1RR	Mandibular right central incisor root tip
Reference plane/line		
Modified midsagittal plane	MSP	A plane connecting points (T), point ELSA and Basion (Ba).
Interspinosal plane	ISP	A plane connecting right and left foramen spinosum perpendicular to the modified MSP.
T-perpendicular plane	TPP	A plane drawn from point (T) perpendicular to the modified MSP and ISP.
Palatal plane	PP	A plane connecting points anterior nasal spine (ANS) and posterior nasal spine (PNS), perpendicular to the modified MSP.
Mandibular plane	MP	A plane connecting points right gonion (GoR), left gonion (GoL), and menton (Me).
TOr line	TOr	A line connecting point T and right orbital (Or)
TA line	TA	A line connecting point T and point A.
TB line	TB	A line connecting point T and point B.
Long axis of upper central incisor	U1	A line connecting the incisal edge of the upper right central incisor (U1CR) and the upper right central incisor root apex (U1RR).
Long axis of lower central incisor	L1	A line connecting the incisal edge of the lower right central incisor (L1CR) and the lower right central incisor root apex (L1RR).

with no significant difference between the two groups. The midface, represented by points orbitale and key ridge, was significantly displaced forward. Mandibular growth was restrained. The intermaxillary relationship

represented by the ATB angle showed statistically significant improvement. Significant improvement in the overjet was observed. No significant changes were found in the incisor inclination.



Figure 4. Coordinate reference system used in the study: (A) Frontal view. (B) Sagittal view. (C) Axial view.

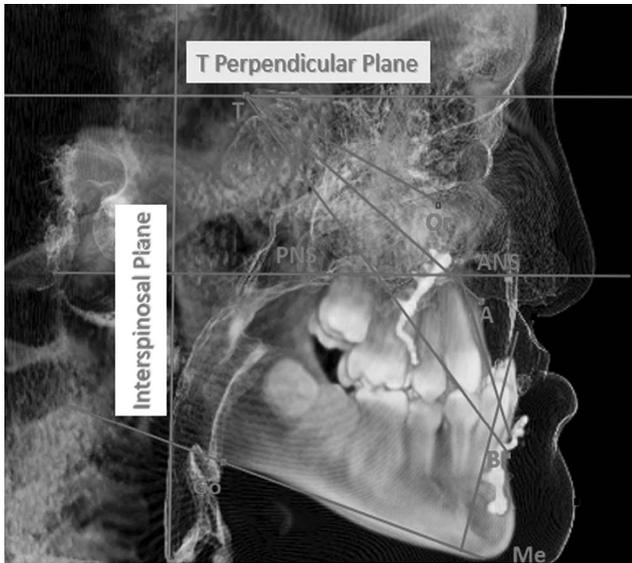


Figure 5. Angular measurements.

DISCUSSION

Midface deficiency is one of the most characteristic features of patients with CLP.² It has been estimated that 25% to 60% of patients born with UCLP will require maxillary advancement to correct maxillary hypoplasia and improve facial esthetics.¹⁸ Other skeletal characteristics for those patients include more flattening of the cranial base, smaller mandibles, impaired jaw relation with prevalence of skeletal Class III, and larger anterior facial height.^{2,19} Compared with noncleft Class III patients, maxillary growth in patients with CLP is under negative influence from the fibrous scar tissue resulting from early surgical palatal repair, which also results in variable amounts of transverse maxillary deficiency

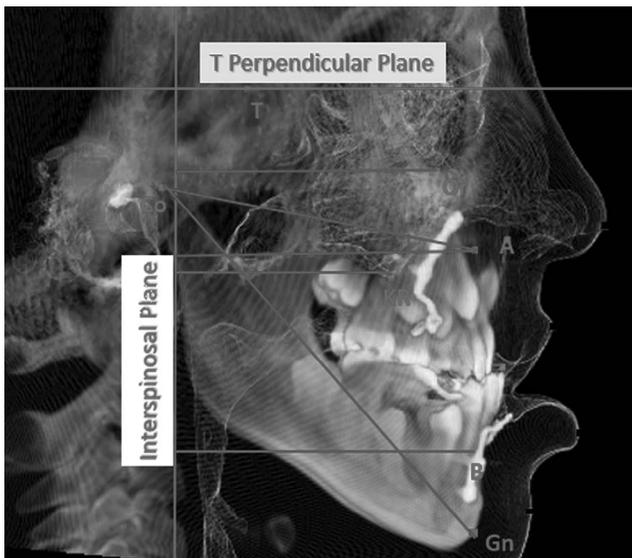


Figure 6. Linear measurements.

Table 2. Descriptive Statistics of Baseline Characteristics at T1

Baseline Characteristics	Group I	Group II	P Value*
Age in years, mean (SD)	10.3 (0.9)	11.3 (1.4)	.207
Gender, n (%)			
Male	10 (71.4)	6 (42.9)	.12663
Female	4 (28.6)	8 (57.1)	

* Significant at $P \leq .05$.

and posterior crossbites. Treatment often includes maxillary expansion to achieve good posterior occlusion.¹²

The BAMP protocol produced significant forward movement of the maxilla in both groups. This was evident by a significant decrease ($P \leq .05$) in the angle between the TA line and TP plane representing the anterior cranial base and acting as the horizontal reference plane (Table 4). This angle is equivalent to the SNA angle used in traditional cephalometric analysis in which increase means forward movement of the maxilla. However, in this customized analysis using the new coordinate reference system, the decrease of this angle indicated forward movement of the maxilla. This was confirmed by the increase in the effective maxillary length (Co-A), and by the increase in the linear distance between point A and the ISP representing the vertical reference plane (Table 4). However, other studies^{7,20,21} have reported a greater amount of forward movement of point A using the BAMP protocol. This difference might be related to the stretching of the lip and palatal scar of patients with cleft that might have represented a restriction to the forward movement or might have been due to a longer investigation period in those studies. Furthermore, measurements were taken on lateral cephalograms created from CBCTs with a 7.5% magnification factor in the studies carried out by De Clerck et al.⁷ and Cevitanes et al.,²⁰ while Elnagar et al.²¹ used two-dimensional lateral cephalometry, which reflected the changes of midline landmarks.

Regarding previous studies of BAMP in patients with cleft, the amount of forward movement of point A in the study carried out by Jahanbin et al.¹¹ was greater, which might have been due to the longer treatment duration. Additionally, that study was analyzed using lateral cephalometric radiographs that reflected the changes in midline landmarks. On the other hand, in the study carried by Yatabe et al.,¹² the amount of anterior maxillary displacement for the patients with cleft was less than in the current study.

Since there was no statistically significant difference in the amount of maxillary protraction between the two groups, the hypothesis proposed by previous studies was confirmed.^{7,8,20-25} In those studies, maxillary expansion was not undertaken before the BAMP protocol because of the belief that the direct and

Table 3. Descriptive Statistics at T1^a

Parameter	Group I (BAMP Not Preceded by Maxillary Expansion)		Group II (BAMP Preceded by Maxillary Expansion)		P Value*
	Mean	SD	Mean	SD	
Maxillary AP measurements					
TA/TPP °	41.42	2.03	42.18	2.79	.5708
Co-A (mm)	84.00	1.80	85.01	1.89	.3261
A-ISP (mm)	62.14	2.52	60.48	3.28	.3092
Maxillary transverse measurements					
JR-JL (mm)	60.56	3.48	60.03	3.00	.7654
Midfacial measurements					
TOr/TPP °	28.13	2.09	28.86	2.84	.5939
Or-ISP (mm)	51.01	3.35	49.96	4.03	.6057
KR-ISP (mm)	36.76	2.35	35.20	3.83	.3764
Mandibular AP measurements					
TB/TPP °	54.08	2.80	54.20	0.78	.9148
Co-Gn (mm)	107.42	1.99	107.47	3.09	.9719
B-ISP (mm)	67.77	1.52	67.37	0.63	.5322
Maxillomandibular measurements					
ATB°	12.66	1.96	12.02	2.71	.6281
Vertical measurements					
PP/TPP °	0.02	3.38	1.18	3.12	.658
MP/TPP°	24.70	4.95	28.20	1.80	.1042
PP/MP °	22.14	4.58	22.68	2.80	.7946
Dentoalveolar measurements					
Overjet (mm)	-7.40	1.43	-8.17	5.08	.841
U1/PP °	107.26	4.05	105.42	6.09	.5182
L1/MP °	80.74	3.74	83.53	2.00	.1073

^a BAMP indicates bone anchored maxillary protraction.

* Significant at $P \leq .05$.

Table 4. Descriptive Statistics for T2–T1 Changes and Comparison

Parameter	Within Groups						Between Groups P
	Group I (BAMP Not Preceded by Maxillary Expansion)			Group II (BAMP Preceded by Maxillary Expansion)			
	Mean	SD	P	Mean	SD	P	
Maxillary AP measurements							
TA/TPP °	-1.82	1.07	.019*	-1.80	1.08	.020*	.841
Co-A (mm)	2.70	1.37	.012*	2.80	0.92	.002*	1.000
A-ISP (mm)	3.17	1.37	.007*	3.37	1.57	.009*	1.000
Maxillary transverse measurements							
JR-JL (mm)	0.20	0.32	.234	1.76	0.20	<.001*	.008*
Midfacial measurements							
TOr/TPP °	-1.45	0.94	.026*	-1.32	0.84	.024*	.690
Or-ISP (mm)	2.77	1.55	.016*	3.03	1.57	.013*	.690
KR-ISP (mm)	1.72	1.05	.021*	2.16	1.08	.011*	.548
Mandibular AP measurements							
TB/TPP °	0.60	0.99	.248	1.00	1.28	.158	.690
Co-Gn (mm)	0.79	1.13	.195	0.91	1.14	.149	.841
B-ISP (mm)	-0.19	0.42	.374	-0.29	0.34	.132	.690
Maxillomandibular measurements							
ATB°	2.42	1.68	.032*	2.80	1.60	.017*	.548
Vertical measurements							
PP/TPP °	1.64	0.65	.043*	-0.30	2.64	.686	.421
MP/TPP°	0.64	2.25	.559	1.30	2.01	.220	.548
PP/MP °	0.22	1.70	.783	0.16	3.03	.912	1.000
Dentoalveolar measurements							
Overjet (mm)	2.66	2.06	.043*	2.54	0.41	.043*	.548
U1/PP °	-0.46	2.05	.642	0.06	2.75	.963	.841
L1/MP °	1.67	4.68	.470	1.29	2.42	.299	.841

^a BAMP indicates bone anchored maxillary protraction.

* Significant at $P \leq .05$.



Figure 7. Extraoral views for a patient in group I: (A) before and (B) after BAMP not preceded by maxillary expansion.

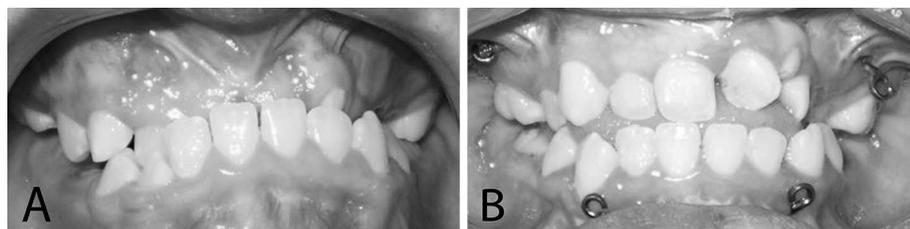


Figure 8. Intraoral views for a patient in group I: (A) before and (B) after BAMP not preceded by maxillary expansion.



Figure 9. Extraoral views for a patient in group II: (A) before and (B) after BAMP preceded by maxillary expansion.

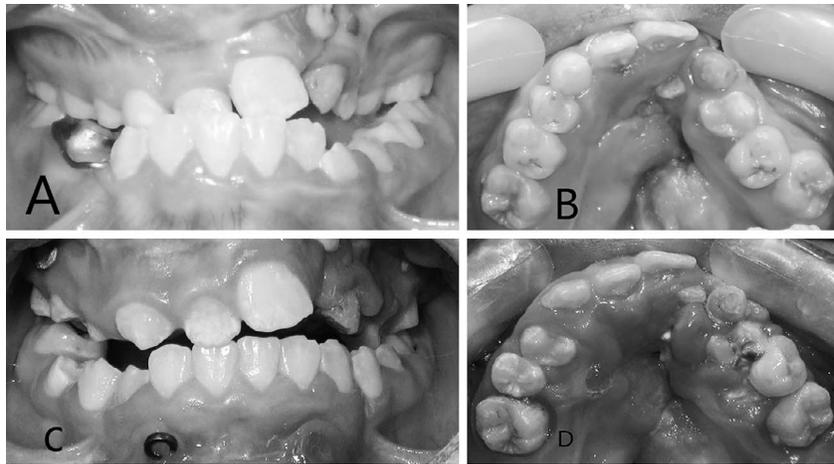


Figure 10. Intraoral views for a patient in group II: (A and B) before and (C and D) after BAMP preceded by maxillary expansion.

continuous protraction force applied to the maxilla was enough to disarticulate the surrounding circummaxillary sutures. Therefore, expansion may be performed only when needed, but not for the purpose of enhancing the protraction protocol.

The increase in the interjugale width in group II, in which RME was carried out, confirmed that maxillary expansion had occurred at the skeletal level in order to investigate its effect on the BAMP protocol.

The significant forward movement of the infraorbital and zygomatic regions in both groups was consistent with findings of other studies using BAMP.^{7,12,21} These findings suggested that the effect of BAMP was limited not only to the maxilla but also extended superiorly to the level of the midface. This effect was evident clinically where the characteristic deficiency in the zygomatic region and the malar prominence, represented by the obvious paranasal concavity commonly seen in patients with cleft,¹⁹ was greatly improved in the studied sample after treatment.

No significant change was found in the sagittal position of the mandible within either group during treatment and between the treatment groups.

The intermaxillary relationships within each group were significantly improved with no significant difference between the two groups. This was mainly due to forward movement of the maxilla together with restraint of mandibular growth as evidenced by the results.

The clockwise rotation of the palatal plane in group I (Table 4) was in agreement with Nguyen et al.⁸ On the other hand, the palatal plane in patients in group II showed variable responses. The maxillary expansion that was carried out in group II might have triggered variable responses of the palatal plane to the applied protraction force in different patients who were previously subjected to different surgical techniques

and timing of surgical palatal closure during early childhood.

Most of the dental changes were not statistically significant except for the decrease in the overjet, which reflected the improvement of the anterior crossbite. The stable position of the incisors indicated a pure skeletal effect without any dentoalveolar side effects. Other studies reported flaring of the lower incisors with the BAMP protocol.^{7,21,22} As patients in this study were instructed to wear the lower removable bite plane full time, except during meals, this might have sealed the effect of the tongue and kept it away from the lower incisors.

Limitations

In addition to the increased number of surgeries, this protocol relied completely on excellent hygiene, which is often compromised in patients with CLP, to prevent failure of the miniplates. Additionally, lack of enough space for the insertion of three miniscrews in the maxilla, along with the difficulty of accessibility caused by stretching and scarring of the soft tissue, was one of the major difficulties. Furthermore, the results of this study were limited to a short-term observation period, just long enough to investigate the effect of expansion on the BAMP protocol. Long-term studies with a larger sample size are needed after active treatment is completed.

CONCLUSIONS

- The BAMP protocol was an effective treatment modality for correcting midface deficiency in patients with UCLP. Maxillary expansion should only be carried out when there is a transverse maxillary deficiency; otherwise, it is not needed to precede BAMP for effective maxillary protraction.

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