ORIGINAL ARTICLE

The Impact of Pre-surgical Orthopedics Appliances (PSOAs) in Bilateral Cleft Lip and Palate (BCLP) Patients

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ABSTRACT

INTRODUCTION: Acceptable maxillary growth in bilateral cleft lip and palate (BCLP) is difficult to achieve. Pre-surgical orthopedic treatment aims at the reduction of cleft size by guiding growth and functional rehabilitation. The objective of this study was to evaluate the impact of Pre-surgical Orthopedics Appliances (PSOAs) on facial growth in BCLP. **MATERIALS AND METHODS:** Consented subjects were patients who were treated in Hospital Universiti Sains, Malaysia, and Hospital Raja Perempuan Zainab II. Ages of patients ranged from 7 to 21 years of age with non-syndromic cleft and no associated anomalies. A lateral cephalogram was taken and data collected was analyzed to compare the facial growth of BCLP with and without PSOA and between active and passive PSOA. **RESULTS:** The study sample comprised of 52 BCLP patients with 26 having PSOA and 26 did not having PSOA. Among these patients, those who had PSOA had significant shorter length of PNS-ANS (3.69 mm; p= 0.04) and Co-A (8.38 mm; p=0.04) compared to those who did not have PSOA. However, there were no significant difference in the length measurements between passive and active PSOA users. **CONCLUSION:** The usage of PSOA gives a shorter maxillary length in the facial growth of bilateral cleft patients. This study proved the effectiveness of PSOA on facial growth of cleft patients in local population.

INTRODUCTION

Cleft lip and palate (CLP) is one of the most common birth defects worldwide.[1] It is caused by two main factors namely, genetic and environmental factors.[2] CLP involves deformity of multiple structures around the oral cavity and the face.[1,3,4] In addition, it causes various impacts to the patients as well as the family such as self-esteem, especially among girls, psychology and social burden.[5] Generally, males are more affected by CLP than females with a ratio of about 3: 2. Meanwhile females prone to have ~~a~~ cleft palate only.[4–6]

Deficient columella and ectopic premaxilla are the primary reconstructive challenges in repairing bilateral cleft lip and palate (BCLP).[7,8] In addition, the excessive forward-thrusting in the development of the isolated premaxilla is a result of influences of the vomer and septum.[9] By four years of age, the size of maxillary skeleton has almost reached 80% of the size of an adult.[10] Previously, premaxilla was amputated in order to facilitate lip closure and to avoid tension on the lateral lip components. However, amputation that was carried out at an early age may cause severe disturbances on the development and gross facial abnormalities. Therefore, an innovation of a treatment, Pre-surgical Orthopedics Appliances (PSOAs) is beneficial as it provides a better solution to overcome reconstructive challenges of the salvage of the premaxilla.

PSOAs is a general term used to describe the use of appliances for a treatment of an infant's cleft deformity is by repositioning the cleft maxillary segments and the premaxilla before the reconstruction is done.[11,12] The main aim of PSOAs is to reduce the cleft width and to decrease tension between maxillary segments. It is suggested to be used for children with ≤ 10 mm clefts. There are two different types PSOAs available, that are called active and

passive appliances. Active appliance comes with mechanical means such as elastic chains, screws and plates meanwhile passive appliance applies external force to induce arch alignment during growth.[13–15]

Nasoalveolar moulding is a technique that has been adopted as part of the treatment protocol. It has been proven to help in reducing soft-tissue and cartilaginous deformity. It facilitates soft-tissue repair in an optimal condition and minimize tension thus reducing scar formation. This technique has successfully improved the surgical outcome.[13,16] However, previous studies have contradictory reports, that several adverse effects in facial growth had been identified when using orthodontic treatment.[17,18] Therefore, this study aims to evaluate the impact of PSOAs on facial growth in BCLP and to differentiate the effectiveness between active and passive PSOA. To the best of our knowledge, this is the first study conducted on the effectiveness of PSOA in Malaysian population.

MATERIALS AND METHODS

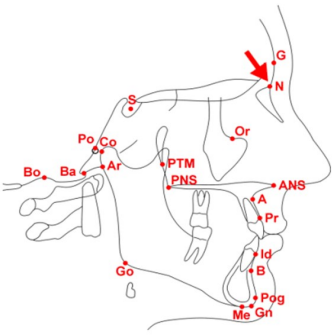
Study design

This study was approved by Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/17010004) and Medical Research and Ethics Committee, Ministry of Health of Malaysia (NMR-17-461-33882) and permission granted for data collection. We adhered to best practice standards and ethical procedures which included voluntary participation, informed consent, privacy and confidentiality, publication policy, and anonymity in the management of data and reporting of study findings.

Fifty-two consenting patients, aged between 7 to 21 years old with orofacial clefts were recruited from Reconstructive Sciences Unit, Hospital Universiti Sains Malaysia (HUSM) Kubang Kerian, Kelantan and Orthodontic Department, Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan. The sampling frame was a list of patients who fulfilled the inclusion and exclusion criteria. Cleft patients with good quality and well-oriented lateral cephalometric radiographs as well as having no previous orthognathic or facial cosmetic surgery were included in this study. While those patients with syndromic and vitamin deficiency disorder were excluded from the study. Written assent and informed consent was obtained from all selected patients. Patients were divided according to their respective groups (BCLP with and without PSOA). Patients were subjected to undergo a lateral cephalogram imaging and all data were documented.

Cephalometric and statistical analysis

The anthropometric measurement was performed and analyzed using Dental Imaging Software System version 6.14.7. Cephalometry was the method used to define maxillary morphology and spatial position, using lateral head films obtained by conventional methods. The reference points and clinical interpretation of normal lateral cephalogram as in Figure 1 and Table I. By using the cephalometric points: S (sella); N (nasion); ANS (anterior nasal spine); A (A point); Ptm' (posterior nasal spine) and Co (condylion), angular and linear measurements were obtained, permitting a morphological evaluation of maxilla (Co-A, ANS-Ptm') and its spatial position in relation to the anterior cranial base (SNA, SN.ANS, SN. Ptm'ANS, SN-ANS, SNPtm', N-ANS) (Figure 2). All collected data was analysed with an independent t-test using SPSS software version 22.



Abbreviation	Landmark	Definition
S	Sella	Center of the pituitary fossa of the sphenoid bone determined by inspection (In 3D measurements, midpoint of floor of pituitary fossa in the median plane)
Na	Nasion	Junction of the frontonasal suture
Ba	Basion	Most anterior point of the foramen magnum
ANS	Anterior Nasal Spine	Most anterior midpoint of the anterior nasal spine of the maxilla
PNS	Posterior Nasal Spine	Most posterior midpoint of the posterior nasal spine of the palatine bone
A	A-Point	Point of maximum concavity in the midline of the alveolar process of the maxilla viewed sagittally
B	B-Point	Point of maximum concavity in the midline of the alveolar process of the mandible viewed sagittally
Me	Menton	Most inferior midpoint of the chin on the outline of the mandibular symphysis viewed sagittally
Pog	Pogonion	Most anterior midsagittal point along convexity of chin of mandibular body viewed sagittally
Go	Gonion	Point midway along curvature of angle of mandible between inferior border of body and posterior border of ramus of mandible viewed sagittally
Co	(Superior) Condylion	Most superior point of the mandibular condyle (viewed sagittally and antero-posteriorly)
Gn	Gnathion	Most antero-inferior point on mental symphysis
Or	Orbitale	Most inferior point on the infraorbital rim
Po	Porion	Most superior point of the external acoustic meatus

Figure 1 Reference points for normal lateral cephalogram

Table I The clinical interpretation of the lateral cephalogram

Cephalometric Measure	Caucasian Norm	Interpretation
SNA	81° ± 3°	> Prognathic maxilla Orthognathic maxilla < Retrognathic maxilla
SNB	78° ± 3°	> Prognathic mandible Orthognathic mandible < Retrognathic mandible
ANB	3° ± 2°	> Skeletal Class II Skeletal Class I < Skeletal Class III
SN to MxPl	8° ± 3°	> Posteriorly inclined maxilla Normally inclined maxilla < Anteriorly inclined maxilla
MMPA	27° ± 4°	> Open basal configuration Normal vertical relationship < Deep basal configuration
Facial Proportion	55% ± 2%	> Increased facial proportion Normal facial proportion < Decreased facial proportion

RESULTS

The demographics data of all patients with and without PSOA were documented (Table II). Out of 52 patients, 26 patients were treated with PSOA and another 26 patients were not treated with PSOA. From 26 patients treated with PSOA, twenty (76.9%) of them were aged between 7-14 years old and 6 (23.1%) patients aged between 15-21 years old. Similarly, from 26 patients who were not treated with PSOA, eighteen (69.2%) patients were aged between 7-14 years old meanwhile 8 (30.8%) patients were aged between 15-21 years old.

Distribution of patients by gender showed that 34 were males and 18 were females. All patients were Malays. Number of patients with PSOA and without PSOA was similar which were 26 patients each group respectively. Based on types of PSOA used; 15 (57.7%) patients were passive PSOA users, meanwhile 11 (42.3%) patients were active PSOA users. There was no significant association between the distribution of age and gender with the two groups of with and without PSOA (p>0.05).

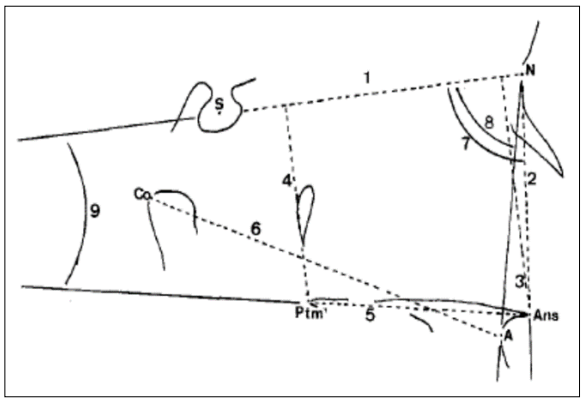


Figure 2 The cephalometric points, angles, and dimensions. (1) S-N, (2) N-ANS, (3) SN-ANS, (4) SN-PNS', (5) PNS'-ANS, (6) Co-A, (7) SN. ANS, (8) SNA, (9) NAFH.

Table II Demographics data for subjects with and without PSOA (n=52)

Variables	With PSOA (n=26)	Without PSOA (n=26)	p-value[a]
Age category			
7-14 years old	20 (76.9)	18 (69.2)	0.532
15-21 years old	6 (23.1)	8 (30.8)	
Gender			
Female	11 (42.3)	7 (26.9)	0.244
Male	15 (57.7)	19 (73.1)	
Race			
Malay	26 (100.0)	26 (100.0)	-
Types of PSOA			
Active	11 (42.3)	-	-
Passive	15 (57.7)		

[a]Chi-square tests were used for comparing age and gender between the two groups

PSOA treatment was analysed by independent t-test according to different age groups as shown in Table III. Nine different variables were included: SN, N-ANS, SN-ANS, SN-PNS, PNS-ANS, Co-A, SN-ANS (degree), SNA, and NA-FH. It was found that the cephalometric variables were not significantly different between groups of with PSOA and without PSOA in both age category except for variables PNS-ANS and Co-A. In the age group of 7-14 years old, the mean length of PNS-ANS in patients with PSOA (40.75 ±6.66 mm) showed significantly shorter than patients without PSOA (44.44±4.02 mm), p=0.049. Meanwhile, in the age group of 15-21 years old, mean length of Co-A showed a significantly shorter in patients with PSOA (73.50±4.46 mm) compared to patients without PSOA (81.88±5.79 mm). A prominent reduction of SNA angle was shown in the 7-14 years age group (3.67 degrees) and in the 15-21 years age group (2.38 degrees) in patients with PSOA compared to patients without PSOA.

Table IV depicts the effects of passive and active PSOA treatment in those with BCLP. There were no significant differences in all variables measured between passive and active PSOA in the treatment of BCLP (p>0.10). Therefore, this result indicated that both appliances were similarly effective, worked well, incomparable, and suitable to be used for patients before underwent for palate surgery.

Table III Lateral Cephalometric measurement between two groups of with and without PSOA according to different age groups (n=52).

Variables	With PSOA[a]	Without PSOA[a]	p-value
7-14 years old [n=38: with PSOA (n=20), without PSOA (n=18)]			
SN (mm)	59.10 (3.82)	58.72 (3.01)	0.739
N-ANS (mm)	41.15 (5.36)	40.78 (3.77)	0.808
SN-ANS (mm)	41.95 (5.15)	41.44 (4.98)	0.761
SN-PNS (mm)	32.70 (5.80)	33.06 (4.98)	0.841
PNS-ANS (mm)	40.75 (6.66)	44.44 (4.02)	**0.049 b**
Co-A (mm)	71.15 (9.08)	75.00 (6.18)	0.140
SN-ANS (degree)	89.50 (5.80)	92.17 (5.26)	0.148
SNA (degree)	86.05 (5.41)	89.72 (6.02)	0.055
NA-FH (mm)	86.35 (5.23)	83.33 (6.62)	0.310
15-21 years old [n=14: with PSOA (n=6), without PSOA (n=8)]			
SN (mm)	60.33 (3.88)	63.75 (4.46)	0.161
N-ANS (mm)	43.83 (4.54)	43.25 (6.11)	0.848
SN-ANS (mm)	44.67 (4.46)	44.38 (6.21)	0.924
SN-PNS (mm)	41.33 (11.50)	38.38 (6.67)	0.554
PNS-ANS (mm)	46.50 (7.84)	48.75 (7.78)	0.603
Co-A (mm)	73.50 (4.46)	81.88 (5.79)	**0.012 b**
SN-ANS (degree)	93.33 (5.43)	94.38 (5.60)	0.733
SNA (degree)	89.00 (8.46)	91.38 (6.74)	0.569
NA-FH (mm)	86.00 (5.87)	86.88 (4.73)	0.762

Independent T-Test
a Mean (SD), SD = standard deviation
b p-value <0.05
mm = milimetre

Table IV Facial growth of BCLP between two groups; active and passive PSOA

Variable	Passive PSOA Mean (SD)	Active PSOA Mean(SD)	p value
SN (mm)	59.20(4.30)	59.64(3.17)	0.779
N-ANS (mm)	41.67(6.25)	41.91(3.67)	0.910
SN-ANS (mm)	42.27(6.04)	43.00(3.49)	0.722
SN-PNS (mm)	34.40(7.81)	35.09(8.88)	0.835
PNS-ANS (mm)	40.80(6.98)	43.82(7.49)	0.301
Co-A (mm)	70.93(9.50)	72.73(6.39)	0.593
SN-ANS (degrees)	89.73(6.91)	91.27(4.13)	0.518
SNA (mm)	85.93(6.87)	87.82(5.21)	0.454
NA-FH (mm)	85.67(5.67)	87.09(4.78)	0.507

p-value <0.05
Independent T-Test, SD= standard deviation
mm = milimetre

DISCUSSION

There are 3 directions of maxilla growth which are anteroposterior, vertical and transverse.[4] It is important to understand them because each of them require different methods. Previously, it has been found that the common following lip repair was anteroposterior growth disturbance.[4] Previous studies found maxillary length was decreased, incidence of anterior open bite (disturbance of vertical growth) and anterior crossbite (disturbance of horizontal growth) was increased in patients with CLP treated with the Latham appliance.[17,19]

Cephalometric studies revealed inconsistent findings at age 12 and 17 years, with ratings at the age of 9 years.[15] Hence, it was suggested that at the age 9–10 years was an optimal age for the facial growth assessment based on guideline of the Euro Cleft Project.[20] In our study, from 9 variables measurement taken, only PNS-ANS and Co-A showed significant difference in mean length among those with and without PSOA based on different age categories. The anteroposterior relationship can be highlighted from the cephalometric variable PNS-ANS. Significant shorter maxillary length was identified among the patients with PSOA compared to patients without PSOA in age group of 7-14 years old, but it was not significant in the age group of 15-21 years old. The shorter maxillary length in 7-14 years of age patients, treated with PSOA proved that lip tension and scar tissue considered to be the major factors affecting growth.[17]

Despite technically excellent operation of cleft repair, the well-known growth-inhibiting impact of surgery could not be avoided.[21] A previous study found almost similar findings for BCLP patients either with or without PSOA.[17] Contradictory finding were discovered in UCLP patients treated with PSOA whereas they had decreased in maxillary length.

In our study, Co-A also showed significant mean difference among patients aged 15-21 years old between with and without PSOA groups, but no significant mean difference in the 7-14 years old age group. This may be due to anatomic aberrancy or various positions of point A. Lip repair is also associated with remodeling in the maxillary anterior alveolar region causing a significant retrusion of point A, without changes in other areas of the maxilla.[22] The next cephalometric variable which shows anteroposterior relationship is SNA angle showed a

prominent reduction of 3.67 degrees in the 7-14 years age group and 2.38 degrees in the 15-21 years age group with PSOA compared to patients without PSOA. This is confirmed by the decrease in the SN-ANS angle, 2.67 degrees, and 1.05 degree, respectively. The reduction in these angles revealed the disturbance was caused by PSOA and surgical procedures caused anterior midface displacement. Therefore, the clinical aspect seen in operated cleft patients was confirmed.

The most controversial part in the treatment of cleft lip and palate was the usage of PSOA treatment. Previously, it has been shown that controlling the oronasal complex, narrowing cleft width, improving the anatomical position of the maxillary segment and the angulation of the palatal shelves to more horizontal position was plausible.[23] Previous findings on the evolution of BCLP postnatal facial development has generated important knowledge. PSOA is an effective and reliable intervention which improves the shape of alveolar cleft, lip and nose. In addition, using PSOA to align protruded premaxilla permits the reconstruction of orbicularis oris.

However, lip pressure could cause negative feedback on the maxillary growth. The aligned premaxilla would push back lingually. This matter could be resolved by avoiding using PSOA to align the protruded premaxilla on an alveolar arch. It was also more superior for palatal expansion compared to NAM.[24] However, it could result in improper oral care and mucosal edema. Hence, the NAM has been used since then.[24]

Regarding vertical relationship, the usage of PSOA has caused the SN-ANS maxillary downward trend with the centre of rotation near the posterior nasal spine for both age group. Maxillary rotation caused an increased in anterior midface height (N-ANS, SN- ANS). This rotating effect correlates with surgery to improve the vertical facial growth. Unfortunately, it influenced the displacement of the anterior maxillary due to the backward spatial repositioning.

The active device used in this study was the intraoral appliance which was applied during infancy whereas the passive device used is the 'lip tape therapy'. This study showed similar effectiveness between the usage of active and passive devices. Previous study in UCLP found no difference between patients with passive plates or not.[25] It was found that additional NAM was helpful in reducing the severity of the initial cleft deformity.[26] In the short term, NAM is beneficial to align tissues prior to surgery. It facilitates in performing better outcome especially in reducing scar formation. Nevertheless, the long term usage of NAM would have stable change in nasal shape and better lip form.[26] This appliance was also carried out by consultant orthodontist in treating cleft patients to decompensate the labial segments, align and coordinate the dental arches for a stable occlusal outcome.[27]

To date, current active device used is the Presurgical Nasoalveolar Molding (PNAM).[28] The major benefit of this device was to increase the columella skin and the prolabium length prior to surgery, therefore produce adequate skin to reconstruct the central lip length. It has allowed improvement in nasal symmetry and aesthetics.[29] Additional benefit was improved feeding ability, psychosocial health and family support.[30]

Several studies found that cleft patients were able to attain normal maxilla growth, but some studies reported to the contrary.[31–34] These may be due to limitations in the study and different variables such as age groups, time of operation being carried out which was either late, partial or unoperated, type of surgical technique used, experience of the surgeons and different racial groups.[34,35] In addition, although the chances in studying maxillary growth among the unoperated clefts was limited, it provides indispensable knowledge for a better understanding of the influence of surgery on growth. Hence, this could be helpful in improving the cleft treatment protocol.[32]

CONCLUSION

Our findings suggested that patients with BCLP who had PSOA treatment at early teens (7-14 years old) had significant shorter maxillary lengths but were insignificant at late teens (15-21 years old) when compared with the control group. In addition, both passive and active PSOA were effective in reducing cleft width. This study provides

value added knowledge regarding cleft and the effectiveness of PSOA on facial growth of cleft patients in Malaysian population. Therefore, it is beneficial to improve medical care, treatment, and prevention of problems in the future.

CONFLICT OF INTEREST

The authors declare there is no competing interests.

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