

# Oral Orthopedics for Bilateral Cleft Palate Infants

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Running Title: Oral orthopedics for BCLP infants

## **Abstract**

**BACKGROUND:** It is difficult to obtain a good lip repair if a cleft in the lip and alveolus is very wide, or if there is a protruding pre-maxilla as in bilateral clefts. The lip and alveolar segments can be brought closer together or the pre-maxilla moved to a more normal position through an intervention called pre-surgical orthopedics. Pre-surgical infant maxillary orthopedics (PSIO) has been employed since the 1950's as an adjunctive neonatal therapy for correction of protruded pre-maxilla in bilateral cleft lip and palate. Though there is variation in the types of pre-surgical orthopedic plate and the surgical techniques used, the main objectives remain the same.

**AIMS:** The aim of this study was to investigate the efficacy of pre-surgical infant orthopedic plate in the management of infants born with bilateral cleft lip and palate; and to compare them with those infants born with bilateral cleft lip and palate who did not undergo pre-surgical orthopedic at the age of one year.

**METHODOLOGY:** Study models of 20 bilateral cleft infants with maxillary constriction and were treated with pre-surgical orthopedic plate group 'A', and 20 bilateral cleft infants with no maxillary constriction and were not treated with pre-surgical orthopedic plate group 'B' were reviewed at the combined cleft palate and craniofacial clinic (KCCDC). Direct measurements of the critical dimensions including inter- canine width, inter-tuberosity width and palatal length were done on the model using a digital caliper. The results between the two groups of infants were compared at the age of 3-4 weeks and at the age of one year.

**RESULTS:** Results showed significant increase in inter- canine width and inter-tuberosity width and significant decrease in palatal length in group 'A' after the intervention. There was no significant difference in the end result at one year old in group 'A' compared with group 'B'.

**CONCLUSION:** This study showed that pre-surgical orthopedics expand the palatal width and create a room to retract the protruded pre-maxilla, hence it offers some improvement in the morphology of the palate in the bilateral cleft infants although the end results at one year old are still not ideal.

**KEY WORDS:** oral orthopedics, bilateral cleft lip and palate, protruded pre-maxilla, arch expansion, pre- surgical orthopedic plate.

## **INTRODUCTION:**

In bilateral cleft lip and palate patients (BCLP), it is difficult to obtain a good lip repair if the cleft in the lip and alveolus is very wide, or if there is a protruding pre-maxilla as in bilateral clefts. The lip and alveolar segments can be brought closer together or the pre-maxilla moved to a more normal position through an intervention called pre-surgical infant maxillary orthopedics (Stellzig *et al.*, 1999). This can involve the application of external taping across the cleft by means of an elastic strap attached to a head bonnet before unifying the cleft lip, a surgically applied internal device, or an acrylic molding device taped in place.

The contemporary use of pre-surgical orthopedic plates in the rehabilitation of protruded pre-maxilla in infants born with bilateral cleft lip and palate has been a controversial issue for many researchers. Some observations claimed that; this type of treatment inhibits maxillary growth (Pruzansky, 1964) and increase incidence of dental caries (Bokhout *et al.*, 1996). Others believed that this appliance helps in correcting segmental displacement, narrowing the cleft and so produced a somehow well-aligned alveolar arch (McNeil, 1956), improves speech (Stuffins, 1981), and facilitates surgical closure of cleft and enhance esthetics upshot.

Pre-surgical maxillary orthopedics in infants has been utilized as an adjunctive neonatal therapy for the correction of protruded pre-maxilla in bilateral cleft lip and palate. Pre-surgical treatment that usually was carried out up to the time of lip operation, started to be abandoned in many centers throughout the world; this was particularly so in countries where there was no kind of insurance to cover the high cost of treating cleft lip and palate patient and the disbelief of the optimistic outcome of these appliances. However, many other centers still continue the treatment in a modified and more cost effective form, judging the benefits to outweigh the disadvantages. By means of pre-surgical appliances, an attempt is made to correct the segmental displacement, narrowing the cleft and so produce a well-aligned alveolar arch (Romero *et al.*, 2003; Prasad *et al.*,

2000; McNeil, 1956), facilitating surgical closure of cleft leading to enhanced esthetics and improved speech (Stuffins, 1981).

The aim of this study was to investigate the efficacy of pre-surgical orthopedic plate in the management of infants born with bilateral cleft lip and palate; and to compare them with those infants born with bilateral cleft lip and palate who did not undergo pre-surgical orthopedics at the age of one year.

### ***Objectives***

The aim of this study was to investigate the efficacy of pre-surgical infant orthopedic plate in the management of infants born with bilateral cleft lip and palate; and to compare them with those infants born with bilateral cleft lip and palate and did not undergo pre-surgical orthopedic at period of one year of age.

### **MATERIALS AND METHODS**

This was a comparative study involving two groups of bilateral cleft lip and palate infants attending the combined cleft palate and craniofacial clinic (KCCDC); Kota Bahru; Malaysia. Group 'A' consisted of 20 BCLP infants (8 males and 12 females) who had maxillary constriction with protruded pre-maxilla and underwent pre-surgical orthopedics intervention (Fig.1 and Fig .2). Study models of these infants were taken at the age of 3-4 weeks of birth before pre-surgical infants' orthopaedics (PSIO) intervention and at the age of one year after PSIO intervention.

Group 'B' consisted of 20 BCLP infants (7 males and 13 females) that had no maxillary constriction or protruded pre-maxilla and had not undergone pre-surgical orthopedics treatment. Study models of these infants were taken at the age of 3-4 weeks and at one year old. Certain identified points were digitized on the casts of both the groups and measurements of the anatomical points were made using fowler-sliding digital caliper (Fowler Ultra – Gold, USA).

The maxillary constrictions or protruded pre-maxilla assessment and the preference of PSIO intervention need were defined and determined by clinician's estimation and judgment who are responsible for patient's care.

### ***Inclusion criteria***

**Group A:**

Infants with nonsyndromic bilateral cleft lip and palate, who had maxillary constriction and protruded pre-maxilla and underwent pre-surgical orthopaedic treatment.

Infants attended the Combined Cleft Lip and Palate and Craniofacial Deformities Clinic.

Pre-treatment study casts at age of 3-4 weeks and post-treatment study casts at the age of one year were taken.

Parents consented to the treatment.

**Group B:**

Infants with nonsyndromic bilateral cleft lip and palate, who had no maxillary constriction or protruded pre-maxilla and had not undergone pre-surgical orthopaedic treatment.

Infants attended the Combined Cleft Lip and Palate and Craniofacial Deformities Clinic.

Study casts at age of 3-4 weeks and at one year old were taken.

**Exclusion criteria****Group A:**

Infants who did not complete PSIO treatment at the Combined Cleft Lip and Palate and Craniofacial Deformities Clinic.

Pretreatment and/or post-treatment study casts were not taken or not complete.

**Group B:**

Study casts at age of 3-4 weeks and at one year old were not taken or not completed.

**Group A & Group B:**

Subjects with medical conditions likely to affect their normal growth and development, such as Down's syndrome, Pierre Robin syndrome or Crouzon's syndrome.

Four subjects with BCLP were excluded from the study: one subject was excluded because his parents failed to activate the screw as instructed, and three patients continued treatment at hospitals closer to their residences.

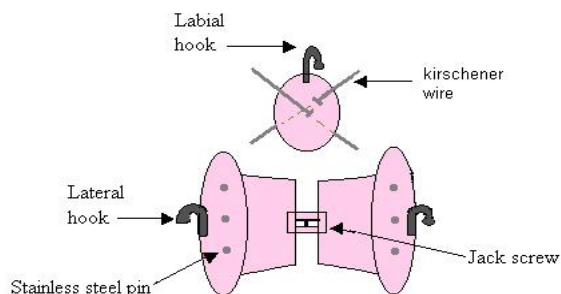
**Description of the appliance:**

Pre-surgical infant orthopedic appliances normally consist of a layer of hard acrylic incorporating a small screw, which allows differential expansion. The palatal surface is covered with soft acrylic, which extends up through the cleft into the nasal cavity (Kehrer *et al.*, 1981).

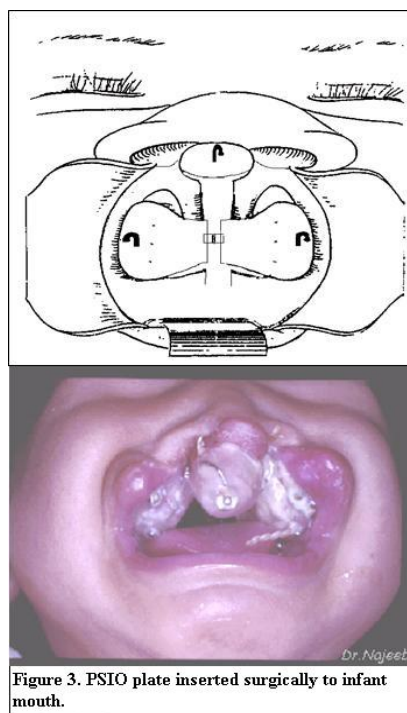
Although there is a variation in the design of pre-surgical infant orthopedic appliances used, the main objectives remain the same. The technique described below for the fabrication, design, placement, and activation of pre surgical orthopedic plate is the standard technique used at KCCCCDC. An alginate impression of the maxillary arch is taken 3 or 4 weeks after birth. The tray used is constructed of acrylic and is perforated to allow escape of impression material. Clear orthodontic resin is added to form a normal palatal vault and to construct the appliance. The appliance consists of two separated parts that fit in the cast. The first part is a cap that is fitted in the pre-maxilla portion with a small hook in its labial surface, and the second part is fitted in the palate surface of the cast with a jack screw in the separated mid line of the appliance. A small hook is incorporated in each bucco-occlusal surface of the lateral alveolar side of the appliance (Fig. 1). The appliance is then fitted on the cast, polished and put in warm water (approximately 37 °C) to be ready for insertion (Fig. 2). The PSIO appliance is surgically fixed in the patient's mouth under general anesthesia (Fig. 3). The labial cap was fixed to the pre-maxillary fragment via holes drilled in the labial acrylic cap and two crossed Kirschner wires passing through the pre-maxillary fragment. Three stainless steel pins were also passed through each palatal process and acrylic cap. The pins fixed the appliance to the underlying processes. Each pin was 2 mm in diameter and approximately 11-13 mm in length (Figures. 1 and 3).



Figure 1. Pre-surgical infant orthopedics (PSIO) plate cast.



**Figure 2. Components of the appliance.**



**Figure 3. PSIO plate inserted surgically to infant mouth.**

Two days after insertion of the appliance; two lengths of power chain were placed and adjusted from the labial hook to both the lateral hooks to retract the pre-maxillary fragment. The parents were also instructed to activate the midline screw once a day for two weeks. Each turn of the midline screw provide approximately 0.25 mm of expansion

per day. The subjects were reviewed weekly and the chain replaced if necessary. When the desired expansion, retraction of the pre-maxilla and arch form had been achieved; activation was stopped, and the appliance was used as a retainer until lip surgery time at approximately 3–6 months of age (The standard time CLP infants received a surgical lip-closure). The end of expansion and the time of lip surgery (the end of retention) were determined by the clinicians' judgments that were responsible for the patients' care.

**Points digitized on dental casts:**

- Point I (Incisal point): point on the top of the alveolar crest where the incisive papilla and labial frenum meet, or the tip of the interdental papilla between the central incisors.
- Point C (Cuspid point): where the lateral sulcus crosses the crest of the alveolar ridge, or the distal anatomical contact point of the deciduous canine.
- Point T (Tuberosity point): the posterior limit of the tuber maxillary in the sulcus where the raphe pterygo-mandibular is adheres, or the distal point of second deciduous molar.

**Calculated distances:**

- C – C': Inter-canine's width, or anterior palatal arch width.
- T – T': Inter-tuberosities width, or posterior palatal arch width
- I – H: Palatal length

Points digitized on dental casts and measurement of the anatomical points was determined according to (Sillman, 1964) and (Robertson *et.al.*, 1977) as described in Fig. 4.

Fowler sliding caliper was used to obtain the measurements (Fig. 5).

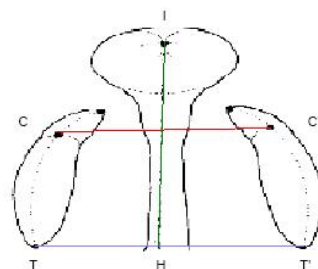


Figure 4. Points and Measurements digitized on the dental cast.



Figure 5. Digital caliper

### ***Reproducibility of the measurements:***

To test the reproducibility of the measurements in Group 'A' and Group 'B' casts, all measurements; inter-canines width (C-C), inter-tuberosity width (T-T) and palatal length (I-H), were completed twice on 20 dental casts (5 from group 'A' pre treatment dental casts, 5 from group 'A' post treatment dental casts, 5 from group 'B' casts taken at the age of 3-4 weeks and 5 from group 'B' dental casts taken at the age of one year) with two weeks interval between repeated measurements. The differences between repeated measurements were tested for significance using a paired t -test. Paired t-tests showed no significant differences ( $p > 0.05$ ) between any of the repeated measurements (Table.1). The degree of reproducibility of measurements, i.e. intra class correlation coefficient (ICC) was calculated (Table.1) and suggest that the measurements were almost identical or with negligible errors of measurements.

**Table.1.** Maxillary arch dimensions and Palatal changes in Group 'A' [PSOP group]

<b>Measuremen t In (mm)</b>	<b>Pre treatment Median (IQR)</b>	<b>Post treatment Median (IQR)</b>	<b>Difference Median (IQR)</b>	<b>Z statistic <sup>a</sup></b>	<b>p value</b>
C-C Width	22.475 (3.220)	26.660 (1.840)	4.240 (1.812)	-2.197	.028
T-T Width	33.805 (3.872)	39.500 (3.370)	4.690 (6.495)	-2.981	.003

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I-H Length	30.880 (2.170)	28.055 (2.872)	-2.740 (5.505)	-2.746	.006
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a : *Wilcoxon signed ranks.*

### **Data analysis**

The data was analyzed using Statistical Package for the Social Sciences (SPSS) version 11.0. Changes in the amount of inter-canine width, inter-tuberosity width and palatal length in pre and post treatments models or models taken at the age of 3-4 weeks and at one year old of the same group were evaluated using Two-related sample analysis and Wilcoxon signed ranks test in each group. Comparisons between group 'A' and group 'B' at the age of 3-4 weeks, and comparisons of group 'A' after intervention and group 'B' at the age of one year in the variables mentioned above were tested using nonparametric test; Mann Whitney test.

Principles outlined in the Declaration of Helsinki were followed in the results of experimental studies on humans.

## **RESULTS**

### **Group A**

Group 'A' consists of 20 BCLP patients who had maxillary constriction and protruded pre-maxilla and underwent PSIO intervention. The results of this group before and after intervention show that there was significant increase of inter-canine width and inter-tuberosity width of (4.185 mm and 5.695 mm), respectively. In the other hand, there was significant decrease in the palatal length (I- H) of (2.825 mm). As shown in Table 1.

### **Group B**

This group consists of 20 BCLP infants who had not undergone pre-surgical orthopedics and does not had apparent protruded pre-maxilla. There were no significant differences in the measurements taken at the age of 3-4 weeks and at the age of one year. As shown in Table 2.

**Table.2.** Maxillary arch dimensions and Palatal changes in Group 'B'

Measurement In (mm)	Group B at the age of 3-4 weeks Median (IQR)	Group B at the age of one year Median (IQR)	Difference Median (IQR)	Z statistic <sup>a</sup>	p value
C-C Width	24.100 (1.650)	26.500 (1.60)	2.340 (1.812)	-2.066	.078
T-T Width	35.460 (3.640)	37.430 (1.20)	1.090 (6.495)	-2.082	.083
I-H Length	28.583 (2.247)	28.900 (2.170)	0.460 (1.505)	-1.016	.660

*a* : Wilcoxon signed ranks.

**Comparisons between group 'A' and group 'B'.**

The results of comparisons between group 'A' and group 'B' at the age of 3-4 weeks show that there were significant differences in the measurements between the groups as shown in Table.3. While the results of comparisons between group 'A' after intervention and group 'B' at the age of one year show that there were no significant differences in the measurements between the groups as shown in Table.4.

**Table.3.** Comparisons between group ‘A’ (before intervention) and group ‘B’ at the age of 3-4 weeks.

Measurement In (mm)	Group A (at age of 3-4 weeks) Pre treatment Median (IQR)	Group B (at age of 3-4 weeks) Median (IQR)	Z statistic <sup>a</sup>	p value
C-C Width	22.475 (3.220)	24.100 (1.650)	-1.674	.046
T-T Width	33.805 (3.872)	35.460 (3.640)	-1.952	.030
I-H Length	30.880 (2.170)	28.583 (2.247)	-1.855	.017

*a: Mann whitney test*

**Table.4.** Comparisons between group ‘A’ (after intervention) and group ‘B’ at the age of one year

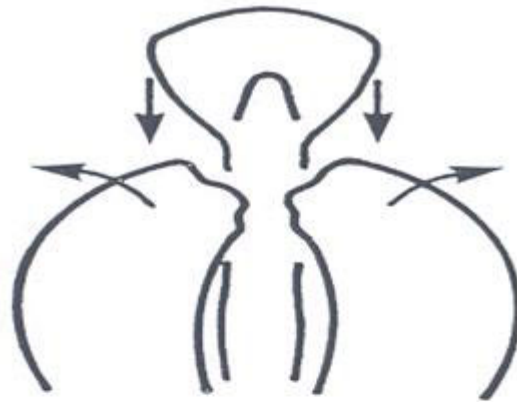
Measurement In (mm)	Median (IQR) Group A (Post treatment)	Median (IQR) Group B	Z statistic <sup>a</sup>	P value
C-C Width	26.660 (1.840)	26.500 (1.60)	-0.402	0.760
T-T Width	39.500 (3.370)	37.430 (1.20)	-2.602	0.054
I-H Length	28.055 (2.872)	28.900 (2.170)	-0.833	0.531

*a: Mann whitney test*

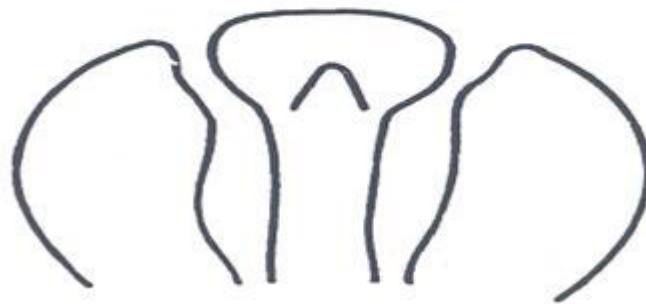
## DISCUSSION

It was determined that approximately 40% of the BCLP infants exhibited collapse of maxillary arch (Pruzansky & Aduss, 1967). The number of dental crossbites evaluated variation in the extent of arch collapse. The absence of variable amount of lip tissue and division in the alveolus and palate in BCLP infants results in outward displacement of the pre-maxilla, an attempt to correct these displacements and to facilitate lip surgery by surgically fixed pre-surgical orthopedics is put into practice. This procedure will reduce lip tension at the surgical site allowing for better cosmetic results (Stellzig *et al.*, 1999; Ross RB & MacNamara MC, 1994). Consequently PSIO intervention reduces the size of the clefts thereby aiding in surgery, and assure parents at a crucial time (Hatzioannou, 1989). It has also been alleged that this form of treatment results in improved speech and facial aesthetics (Stuffins, 1981). However, other researchers preserve that pre-surgical orthopaedics may inhibit maxillary growth (Pruzansky, 1964), and lead to an increase in dental caries if the teeth have emerged (Bokhout, *et al.*, 1996).

The results of this study suggest that there is an improvement and significant increase in inter-canine and inter-tuberosity width occurs after PSIO intervention but of no significant difference comparing with the inter-canine and inter-tuberosity widths of the group 'B' which had no maxillary constriction and without intervention at the age of one year (table.1 and 4). Undoubtedly, the activation of midline expansion screw in PSIO plate in these BCCLP patients would explain the increase in palatal width (inter-canine and inter-tuberosity widths) that was necessary to accommodate the retracted pre-maxilla (Fig. 6). The possibility of more expansion need at a later date would be debatable; this proclamation is in agreement with other investigators (Romero *et al.*, 2003; Prasad *et al.*, 2000).



**Orthopaedic  
allignment**



**Figure. 6. Orthopaedic alignment mechanism by  
dentoalveolar expansion and pre-maxillary  
retraction.**

PSIO intervention had shown a significant decrease in palatal length, which is the consequence of the retraction of the protruded pre-maxilla by using elastic chain in PSIO appliance, and when compared with the group without intervention it had shown more ideal result which is significant (table.1 and 4). Hence decreasing the palatal length and alignment of the alveolar segments is beneficial not only for lip and nose reconstruction but also for establishing a more favorable occlusion (Bitter, 1992; Millard and Latham, 1999; Chan *et al.*, 2003). What's more; the use of power chain which was replaced at the weekly visits when necessary to retract the pre-maxilla was convenient for both parents and clinician.

Moreover, Infants with pre-surgical orthopedics become more similar to no maxillary constriction contemporaries. Therefore, the morphological characteristics of the upper part of the mouth change to more normalized form (Graf-Pinthus and Bettex, 1974). Millard and colleagues in 1999 compared the results obtained using pre-surgical orthopedics followed by periosteoplasty and lip adhesion with those using lip adhesion alone for cases of unilateral and bilateral clefts, and they concluded that pre-surgical orthopedics followed by periosteoplasty and lip adhesion approach achieves the main goal of moving the palate into a normal position and stabilizing the arch with a bony bridge that attracts teeth. It avoids the difficult anterior fistulae and presents a more symmetrical platform upon which the lip can be united and the nose can be corrected early.

On the contrary, Ross and MacNamara in 1994; studied the effect pre-surgical orthopedics on facial aesthetics on two groups of teenagers with repaired BCLP. There was no significant difference in facial aesthetics between the treated and non-treated groups and no difference was found in revisionary surgical procedures required to the lip and nose. Berkowitz and colleagues in 2004; studied the dental occlusion at 3,6,9 and 12 years of age for BCLP patients who have used the Latham fixed appliance for pre-surgical orthopedics treatment and compared them with a control group. The patients who received pre-surgical orthopedic treatment had more anterior and buccal crossbites. Another study of infant orthopedics in patients with unilateral cleft and palate investigating many variables such as feeding, parent satisfaction, speech, nasolabial appearance and dental arch development until age 5 years, as for arch dimensions they

found no significant difference between pre-surgical infant orthopedics and non pre-surgical infant orthopedics group (Bongaarts *et al.*, 2004). From these studies it seems that it is possible that active pre-surgical orthopedic treatment might be, in some cases, unpromising to further dentofacial development in patients with BCLP.

## **CONCLUSION**

This study showed that pre-surgical orthopedics offers some improvement in the morphology of the palate in cleft infants although the end results at one year old are still not ideal. It has been widely accepted that pre-surgical orthopedic plates are able to expand the palate to create a space for the retracted pre-maxilla. In addition; it is agreed that pre-surgical orthopedic plates are able to control the growth of the cleft maxillary segments to facilitate the lip repair as well as to achieve a more balanced oro-facial growth. On the other hand, one of the drawbacks of this procedure is the surgical insertion of the appliance by using the metal pins, thus it could impair the teeth buds and interfere with the developing teeth. Additional inconvenience against this is the supplementary costs associated with use of an operating theatre and surgeon. More studies are required for evaluating the fixed pre-surgical orthopedic appliances.

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