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Randomised Controlled Trial
Cleft lip and palate

Long-term effect of presurgical nasoalveolar molding on growth of maxillary arch in unilateral cleft lip and palate: randomized controlled trial

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Abstract. The objective of this study was to investigate the long-term effect of presurgical nasoalveolar molding (PNAM) on growth of the maxillary arch through early childhood until 6 years of age in complete unilateral cleft lip and palate (UCLP) patients presenting for PNAM at different ages. Complete UCLP patients who were treated at our centre were divided into two groups. The study group underwent PNAM and was further subdivided into three subgroups (PNAM initiated within 1 month, between 1 and 6 months, and between 6 and 12 months of age in subgroup I, II, and III, respectively). The control group did not undergo PNAM and was further subdivided into three subgroups. Patients were evaluated at T1 (first visit), T2 (before cheiloplasty), and T3 (at 6 years). Between T1and T2, the intersegment distance (ISD) reduced significantly in the study group but increased in the control group, whereas the intercanine width (ICW) in both the study and control groups did not show significant change. Between T2 and T3, ISD and ICW were reduced significantly in the control group due to arch collapse, whereas in the study group, ISD reduced slightly with ICW remaining almost similar to noncleft norms. We conclude that reduced ISD following PNAM improves arch symmetry and stability, and thus may prevent arch collapse in the long term.

Key words: unilateral cleft lip and palate; presurgical infant orthopedics; presurgical nasoalveolar molding; maxillary growth.

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Introduction

Presurgical nasoalveolar molding (PNAM) has been included in the comprehensive treatment plan for patients with complete unilateral cleft lip and palate (UCLP) in many cleft centres. However, the effects of PNAM on maxillary arch formation in complete UCLP patients remain controversial.

Proponents of PNAM state that it guides the growth of the maxilla and corrects the deviation of maxillary segments[1–5]. Hotz's plate is a passive appliance that was developed by Hotz and Gnoinski[1,2]

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and has been reported to guide the alveolar arch into an ideal form in infants with UCLP[1,3].

Conversely, it has been reported that PNAM is not always necessary for correct alveolar growth[6–8]. Kramer et al.[9] reported that maxillary growth is artificially restricted by orthopedic appliances. Prahl et al.[10] and Bongaarts et al.[11] reported that PNAM has a temporary effect on maxillary arch dimensions that does not persist beyond surgical soft palate closure.

A fine scar forms when a surgical incision heals under less rather than more tension. The principal objectives of the treatment were to remove the tongue action from the cleft area, to promote the anterior growth of the lesser segment, and to reduce the severity of the initial cleft deformity. This enables the surgeon and the patient to enjoy the benefits associated with repair of the cleft deformity that is of minimal severity.

McNeil[12] in 1950 first introduced the concept of modern presurgical infant orthopedics (PSIO), which consists of an intraoral device to actively mold the cleft alveolar segments into the desired position through a series of acrylic plates. According to him, the segments of the upper jaw in UCLP newborns are too far apart and must be moved closer to each other by PSIO.

Grayson et al.[13] in 1999 described the first treatment protocol for PNAM. According to them, a PNAM appliance is inserted as early as possible after birth. A nonsurgical lip adhesion is also performed by placing tape across the upper lip, which aids in the closure of the cleft, decreases the width of the base of the nose, and helps to approximate the lip. However, a review of the literature reveals the positive effect of PNAM on alveolar morphology even in older infants who present late for treatment[14,15].

The maxillary arch form in complete UCLP patients changes substantially during infancy as a result of treatment and growth. The anterior alveolar arch width narrows with time, accelerated by surgical closure of the lip and palate. Unfortunately, the arch form narrows in many cases to the extent that the alveolar segments overlap with each other in transverse direction (that is, collapse) to a greater degree than would be considered ideal[6]. The major concern with the collapsed arch form is the development of crossbite in the deciduous and permanent dentition.

Kramer et al.[16] in 1992 showed that UCLP patients initially demonstrated larger anterior and posterior arch width dimensions than noncleft populations. These differences were reversed when compared with noncleft individuals at 18 months. In general, treated patients with UCLP have a smaller maxillary arch width and a higher prevalence of lateral and anterior crossbites compared with the noncleft populations. This is one of the objectives leading to the inclusion of PNAM in to their treatment protocols, to prevent the occurrence and severity of collapsed arch forms.

The short term-benefits of PNAM are widely accepted, but the long-term effects are still controversial. Any treatment protocol can only be fully assessed in prospective, well-controlled, randomized studies with long-term follow-up.

The objective of this study was to investigate the long-term effect of PNAM on the growth of maxillary arch through early childhood until 6 years of age in complete UCLP patients presenting for PNAM at different ages.

Materials and Methods

This prospective study was carried out after obtaining approval from the central ethical committee of Nitte University, Mangalore, India. Written informed consent was obtained from the patients' parents before their inclusion in the study. This study included two groups: a study group and a control group.

The study group included 60 nonsyndromic complete UCLP patients who presented up to 1 year of age in whom PNAM was performed. They were subdivided into three subgroups of 20 patients each. In subgroup I, PNAM was initiated before 1 month of age. In subgroup II, PNAM was initiated at 1 to 6 months of age. In subgroup III, PNAM was initiated at 6 months to 1 year of age. The average age at initiation of PNAM was 11 days (range 1–28 days) in subgroup I, 94 days (range 33–180 days) in subgroup II, and 235 days (range 180–365 days) in subgroup III.

The control group included 60 nonsyndromic complete UCLP patients up to 1 year of age in whom PNAM was not performed. They were subdivided into three subgroups of 20 patients each. Subgroup I patients underwent operation at 6 months of age, subgroup II patients between 6 and 9 months of age, and subgroup III patients between 9 and 15 months of age.

Nasoalveolar molding

PNAM was performed in the study group in accordance with patient-centric PNAM protocol followed in the author's unit[14]. PNAM was continued until 6 months of age in subgroup I and for a minimum of 3 months in subgroups II and III, thereby delaying surgery up to a maximum of 15 months of age in some cases, depending on the age at presentation. Upper arch impressions were recorded at the time of initiation of PNAM (T1), on completion of PNAM (T2), and at 6 years of age (T3). To maintain uniformity, upper arch impressions were recorded in control group patients at the time of their corresponding study subgroups. As part of the protocol, the alveolus adjacent to the cleft was actively molded by a combination of selective trimming of the appliance and the addition of a layer of soft liner as needed to promote alveolar growth in the antero-medial direction. Once relative approximation of the alveolar segment was noted, passive molding was undertaken to retain the alveolar segments in the new, improved position while forward growth of the lesser segment was stimulated. Care was taken to prevent collapse of the arch by the addition of a soft liner over the palatal shelves and by applying lateral pressure on the arch. All impressions, casts, and PNAM appliances were made by the same investigator (R.K.A.).

Anthropometric measurements

Linear anthropometric measurements for the maxillary arch as indicated by Ezzat et al.[17] and Wada et al.[18] were used for this study (Table 1 and Fig. 1), including the intersegment distance (ISD), intercanine width (ICW), and posterior arch width (PAW). All the measurements were obtained twice by an independent examiner using a sliding caliper with 0.01-mm precision. To blind the examiner to the

Table 1. Maxillary arch linear anthropometric measurements.

Intersegment distance (ISD)	Measurements between the tangents to the most medial curvature at the center of the ridges
Intercanine width (ICW)	Distance between the canine grooves or lateral sulcus points (the point at which the lateral sulcus crosses the crest of the alveolar ridge)
Posterior arch width (PAW)	Distance between the retromolar points (posterior limit of tuberosity)