

MOLDING THERAPY OF A COMPLETE BILATERAL CLEFT INFANT USING RING PLATE WITH MODIFIED WIRE NASAL STENTS

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INTRODUCTION

Cleft lip and palate (CLP) deformity is reported in the literature as having a varied incidence.¹ As per report of the International Perinatal Data Base of Typical Oral Clefts (IPDTC) working group, the overall prevalence of cleft lip with or without cleft palate was 9.92 per 10,000. The prevalence of cleft lip was 3.28 per 10,000, and that of cleft lip and palate was 6.64 per 10,000.² The bilateral CLP deformity typically presents with a procumbent or rotated premaxilla. The alar base width is significantly increased, and the lip segments are widely separated.³ The flattened nasal tip is tethered directly to the prolabium by a severely deficient or absent columella. The lower lateral alar cartilages are flared where they should be convex. The greatest challenge for aesthetic reconstruction is the absent or deficient columella.

Presurgical infant orthopaedics has been used in the treatment of cleft lip and palate patients for centuries. The early techniques were focused on elastic retraction of the protruding premaxilla followed by stabilization after surgical repair.⁴

Hoffman described the use of a head cap with arms extended to the face to retract the premaxilla and narrow the cleft. There have been many improvements in this method of using the head as extra oral anchorage, and it is still used today to retract the premaxilla.³

Berkowitz has demonstrated the use of head bonnet two weeks before surgery and compared this technique with lip adhesion.⁵

McNeil first described the use of an intraoral appliance to reposition bony cleft segments. Since then, a variety of approaches have been proposed to mould the intraoral alveolar segments closer together (Pruzanski S, Jacobson BN, Rosenstein SW, Georgiade and Latham, Latham, Kusy and Georgiade, Peat).⁶ Hotz and Knoinski described the use of a passive orthopaedic plate to align the cleft segments slowly.⁴

All of these appliances were designed to correct the alveolar cleft only, despite the fact that the cleft nasal deformity remains the greatest aesthetic challenge.³

Grayson and colleagues⁶ proposed the first combined approach for primary Unilateral and bilateral cleft lip, nose and alveolus repair using a pre-surgical Nasoalveolar moulding (NAM) device followed by a one-stage surgical repair. As per their report, the NAM appliance non-surgically shaped the developing alveolar process as well as the nasal structures and specifically addressed elongating the columella and nasal tip projection for the bilateral cleft repair.

These appliances however comprised mostly of an intra-oral palatal plate and extra-oral attachments like straps, tapes and springs etc. A custom made self-retentive appliance with anterior acrylic ring that surrounds the premaxillary segment was introduced by the author¹ for PNAM of neonates born with bilateral cleft of the lip and palate. Philosophy of this innovative device with anterior acrylic ring was to retract and align the protruded and rotated pre-maxillary segment without using extraoral forces such as head caps, bonnet, elastics or adhesive tapes.

A novel modification of the original ring plate appliance is introduced as addition of nasal stents, fabricated from 0.7mm stainless steel wire having terminal acrylic bulbs.

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This article reports on a case regarding appliance design, clinical management, biomechanics of Naso-alveolar molding, data analysis and the actual outcomes of PNAM therapy using modified nasal stents on the original ring plate used in BCLP treatment.

METHODOLOGY

Consent was taken from the parents and a detailed history proforma was prepared for the patient. The chair side clinical pre treatment records were attained as extra oral/intra oral photographs (Fig. 1a, b and c), anthropometric measurements of the columella and prolabium followed by an initial impression. The initial impression was recorded as described in the earlier article¹, to make an accurate cast (Fig. 1k).

Appliance Fabrication

The design and method of the ring plate was the same as described previously. The plate was made up of hard, clear self-cure acrylic (Fig. 1e). Taking care of the air passage, the plate was made self retentive by the addition of soft acrylic (GC Corporation Tokyo, Japan) on its palatal surface, filling the cleft area (Fig. 1d).

The protruding premaxillary segment was retracted, aligned and repositioned to desired position between the lateral alveolar segments (Fig. 1f). The palatal plate was adjusted every two weeks.

The nasal stents were added to the ring plate at the third week of moulding therapy. The wire stents were bent from 0.7 mm stainless steel wire in the form of spring that terminated in a tear drop loop. The lower end of the spring was embedded in acrylic ring on both sides at its junction with anterior margin of the palatal plate. The retentive end of the spring was bent in undulated manner for retention. The nasal stent on each side was fabricated on terminal loop from hard

acrylic and then soft acrylic was added on the top surface. The wire stent was adjustable so as to place acrylic bulb underneath the nasal tip. The stents were activated on weekly basis. The advancement of the alar cartilages into the nasal tip and restoration of nostril anatomy was accomplished by adding acrylic to the nasal stents. Columellar lengthening was achieved by the force directed to the nasal stents and probably the distalizing force from the horizontal premaxillary acrylic ring. The parents were instructed on how to insert and remove the PNAM appliance, which was worn at all times except for routine cleaning (Fig. i, Fig. j). The endpoint of treatment with PNAM, for this patient was by the end of three months when the columella was sufficiently lengthened, the prolabium was adequately increased in width and length, and it was brought back into the maxillary arch. The premaxilla was retracted and aligned with the lateral alveolar segments.

Data Collection & Analysis

Measurements were recorded from the actual casts (Fig. k, Fig. l), the cast photocopies and on the infant's skin.

Photocopies were taken of both pre and post moulding casts for recording linear and angular measurements (Fig. m, Fig. n). In this study, a total of 7 variables were used comprising 6 linear measurements and 1 angular measurement (Table 1). The linear and angular measurements from the cast photocopies comprised of Retraction of premaxilla, Rotation of premaxilla, Inter canine width and Inter molar width. The linear measurement from the cast: Downward movement of premaxilla (with the help of soft vinyl scale) Anthropometric measurements: (Directly from the skin with the help of soft vinyl scale) included Columellar length and Prolabium length.

TABLE 1: TABULAR REPRESENTATION OF THE LINEAR /ANGULAR MEASUREMENTS

Measurements	Pretreatment	Post treatment	Difference
Retraction of the premaxillary segment (mm)	33	30	3
Rotation of the premaxillary segment(degrees)	26°	11°	15°
Downward movement of the premaxilla (mm)	5	8	3
Inter canine width (in mm)	26	27	1
Intermolar width (mm)	33	34	1
Columellar length (mm)	R 0.0L 0.5	R 3.0L 3.0	R 3.0L 2.5
Prolabium Length (mm)	7	10	3



a



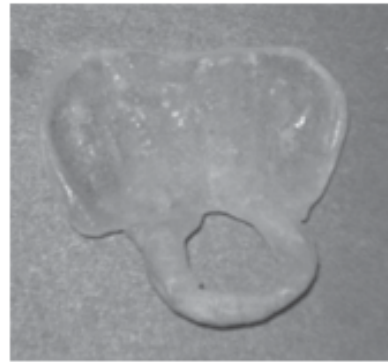
b



c



d



e



f



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h



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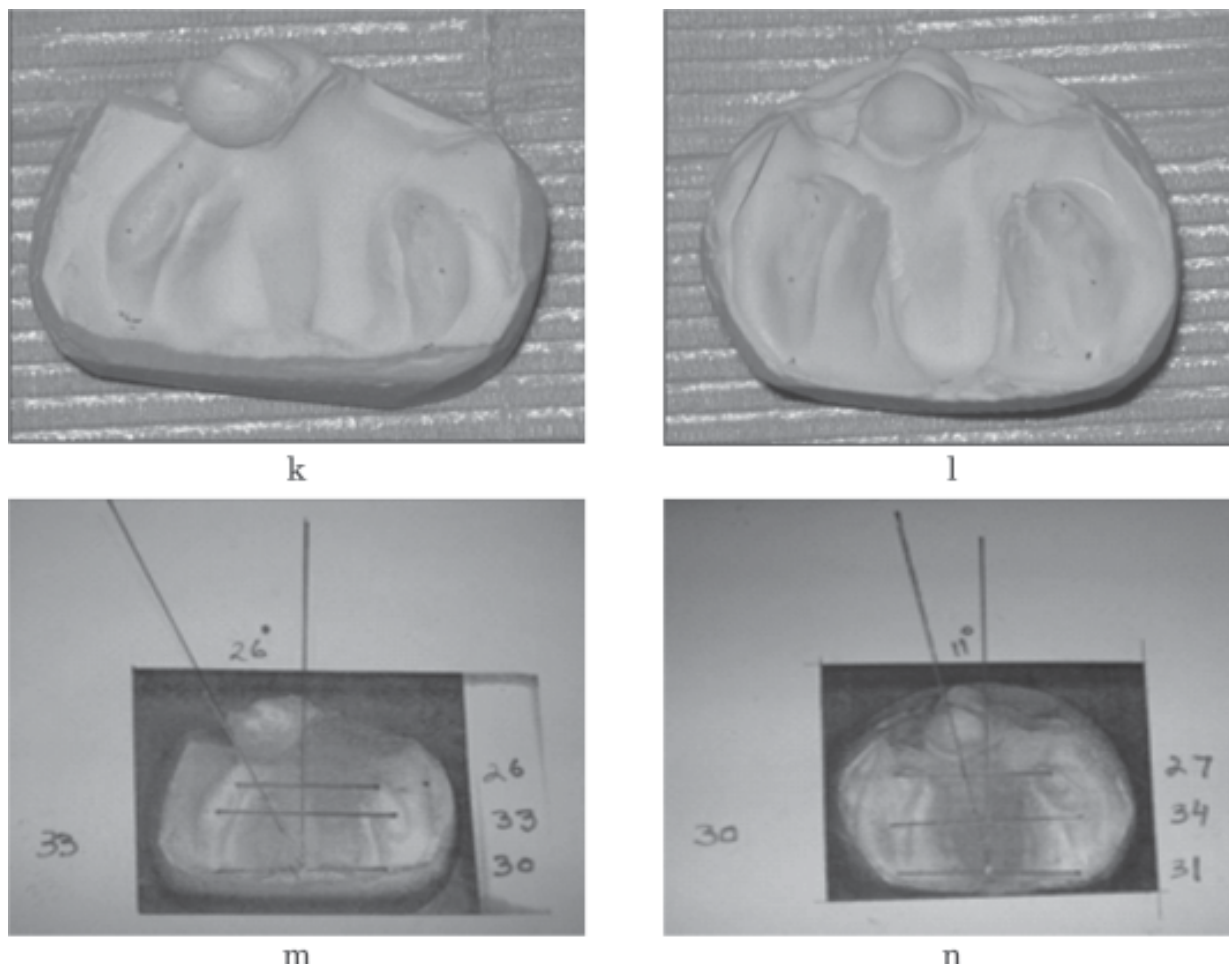


Fig 1: (a)Pre treatment front view, (b)Pre treatment profile, (c)Pre treatment Intra oral view, (d)Treatment initiation: Appliance in situ, (e)PSIOP with anterior ring, (f)Post moulding front view, (g)Post moulding profile, (h)Post moulding intraoral view, (i)Ring plate with wire nasal stents, (j)Treatment completion: Post moulding appliance in situ, (k)Pre treatment cast, (l)Post moulding cast, (m)Pre treatment Cast photocopy analysis, (n)Post treatment cast photocopy analysis.

RESULTS

Results were based on the measurements from pre and post moulding records and tabulated (Table 1).

DISCUSSION

The treatment of patients with CLP remains a subject of considerable controversy. At present, there are two competing philosophies. One involves surgical correction alone, whereas the other involves surgical correction in conjunction with presurgical moulding of the cleft segments.⁷

Matsuo et al reported that the use of a stent in the deformed neonate auricular cartilage reduced the need for otoplasty. Also, later, Matsuo et al suggested the use of nasal conformers (a pair of silicone tubes to

mould the nostrils) before and after cleft lip surgery to improve nasal form.⁸

Persistent problems with associated nasal deformities have given rise to the use of Presurgical Nasoalveolar Moulding (PNAM) in cleft-treatment protocols.⁶ Over the last two decades, various devices and techniques of PNAM therapy have been introduced by the researchers for the treatment of BCLP, namely Grayson^{4,10,11,12,13,14}, Bennun⁸, Santiago⁹, Cutting¹⁵, Fang¹⁶, Mishima¹⁷ et al, Da Silveira¹⁸ et al and Delgado¹⁹ et al.

A number of studies have documented the technique of PNAM therapy for the treatment of BCLP patients. However, only a few studies have documented the actual changes seen in patients treated with PNAM therapy namely Spengler⁷, Fang¹⁶,

Mishima¹⁷ and Delgado¹⁹ etc. Spengler and co-workers quantified the effectiveness of applying PNAM therapy in the treatment of BCLP patients and concluded that combination of columellar lengthening and dome elevation helped to improve the nasal symmetry and finally, both nostril heights were significantly increased, improving tip projection.⁷

In our documented experience we quantified, that simple and cost effective intra-oral ring plate achieved significant retraction and alignment of the deviated pre-maxilla. We are using this molding technique for over ten years. Recent incorporation of wire nasal stents to this ring plate enhanced nasolabial molding by inducing nonsurgical elongation of the columella and prolabium and nasal dome elevation, leading to aesthetic surgical outcome.

Ma, Zemnick and Giacona⁶ have emphasized that the NAM device can provide satisfying results, yet a major determinant of this success is dependent on the parents' motivation, compliance and cooperative efforts of a craniofacial team. In our experience with modified nasal stent ring plate, the parents were counselled and educated about how to insert and remove the PNAM appliance, which was worn all the time except for routine cleaning. The parents were also demonstrated to administer antifungal drops over palatal surface before inserting the plate into baby's mouth, in order to prevent infection of middle ear and oral cavity.

Bennun⁸ and Figueroa modified the nasal extension, to improve the original presurgical dynamic nasal remodeling appliance (DPNR). The palatal plate was left loose in the mouth. The DPNR is reported to differ from NAM because DPNR takes advantage of the dynamic force originating during suction and swallowing, to produce the remodeling effects on the nasal structures. The DPNR technique does not rely on the relatively static force exerted by the orthopedic plate held in place by means of tape or adhesives. On comparison of our custom made ring plate with Bennun's appliance, the ring plate utilizes both static as well as dynamic force. The static force becomes active on insertion of the appliance, being self retentive and this force is continuous in nature with the appliance wear. Whereas dynamic force is synergistically added during functional activity of the orofacial musculature like suction and swallowing.

Unlike other active appliances mentioned in the literature¹, our custom made ring plate does not rely on

irritant or elaborate means of retention. The soft acrylic is used to fill the cleft gap for retention. The retraction or molding of the premaxillary cleft segment becomes easier due to the moldability of the tissues, due to raised levels of hyaluronic acid³ and maternal estrogen circulating in the neonates.¹⁴ We achieved significant retraction and alignment of the deviated pre-maxilla using this molding therapy. The palatal adjustment was done to follow growth of the alveolar segments as well as to ensure retention of the device. Recent incorporation of wire nasal stents to the ring plate enhanced nasolabial molding by improving nostril anatomy, nasal symmetry, columellar elongation and nasal tip projection. Our experience shows a positive effect of molding therapy on the soft and alveolar tissues and is supported by the research studies of the above mentioned investigators.³⁻¹⁹ Improvement of the deviated nasal septum was also observed besides marked alignment of the premaxillary segment with this appliance.

Suri, Disthaporn, Atenafu and Fisher²⁰ conducted a study to evaluate quantitative differences in presurgical alveolar alignment, nostril anatomy and columellar elongation of infants with BCLP treated with nasoalveolar molding (NAM) from those treated with maxillary infant orthopedics only (IO). They concluded that infants who received NAM had longer columellae and better aligned alveolar segments than those who received only IO. Other nostril dimensions were not reported as significantly different. Our findings with modified ring plate incorporating wire nasal stents are supported by Suri's study.

Grayson and Maull³ reported a few serious complications associated with NAM, the most common being irritation of the oral mucosal or gingival tissue. Common areas of breakdown reported are the frenum attachments, the anterior premaxilla, and the posterior fauces as the moulding plate is retracted. The area under the horizontal prolabium elastic band can reportedly become ulcerated if the band is too tight. The most common area of soft tissue irritation is the cheeks. Bennun⁸ and Figueroa have reported complication as irritation and ulceration of the nasal mucosa in their original design. Our modified ring plate does not need any kind of extra oral adhesives. It uses soft acrylic on the top surface in the defect area for retention and on the nasal stents, underlying the nostrils. Moreover, we prescribe antifungal drops to the patients before every placement. Perhaps these precautionary measures can be ascribed for the near zero incidence of related complications.

Grayson and Shetye⁴ reported that the cleft deformity is significantly reduced in size with the NAM therapy before surgery, making primary repair of the lip, alveolus and the nose an effortless procedure. The approximation of the alveolar processes before surgery also enables the surgeon to perform gingivoperiosteoplasty successfully. They emphasized that with the alveolar segments in a better position and increased bony bridges across the cleft, the permanent teeth have a better chance of eruption in a good position with adequate periodontal support. Studies have also demonstrated that 60% of patients who underwent NAM and gingivoperiosteoplasty did not require secondary bone grafting. The remaining 40% who did need bone grafts showed more bone remaining in the graft site compared to patients who have had no gingivoperiosteoplasty. In our modified ring plate, further modification is suggested by incorporating weekly activations on the palatal plate to minimise cleft gap for approximation of the cleft alveolar segments.

CONCLUSION

It has been quantitatively shown that orthopaedic self retentive ring plate with wire nasal stents produces significant retraction of the premaxillary segment without applying extra oral forces.

It improves nostril anatomy and thus enhances nasal symmetry and nasal tip projection.

Maxillary growth is accommodated and the function is facilitated with this appliance.

The primary nasolabial repair after NAM becomes precise and effortless with minimal scarring, and improved nasolabial anatomy. It is a low cost appliance, simple fabrication and comfortable for the infant. PNAM therapy is a useful adjunctive treatment and it should be considered a routine procedure in the treatment protocol for BCLP infants.

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