

Modified Presurgical NAM: A Comparative Clinical Evaluation in Complete Unilateral Cleft Lip and Palate Management

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Abstract

Original Research Article

Background: Cleft lip and palate deformity presents one, of the most complex surgical challenges. Although surgical correction remains the cornerstone of treating this deformity, some inadequacies still remains. Presurgical-Nasoalveolar molding (PNAM) is used as an adjunct to reduce and reshaping the alveolar and nasal defect. In the original Grayson's technique has some limitations such as frequent appointment and recall, and ulcerations so Figueroa modified PNAM technique (less researched) was selected for PNAM in the present study as it allows nasal and alveolar moulding at the same time thereby reducing the requirement of appointments for adjustments. **Aim:** To evaluate the effectiveness of Figueroa modified PNAM as a method of improving nasal symmetry and alveolar cleft in patients with UCLP (Unilateral Cleft Lip and Palate). **Materials and Methods:** Total number of Thirty (n=30) children of less than one year of age, with cleft lip and palate were selected for the study. These were equally divided into 2 groups, group I treated with PNAM appliance, using Figueroa modified PNAM technique & followed by surgical lip repair and group II (control group) where primary cheiloplasty was carried out without PNAM. These patients were evaluated at various intervals and compared for various alveolar and nasal parameters, (nostril height, nostril width, columellar height, Bi-alar width and Intersegment distance). Data obtained from comparison of the groups were analyzed using-t-test. **Results:** A significant improvement of nasal symmetry and reduction of alveolar cleft gap on the cleft side in the PNAM group was observed in the PNAM group as compared to the control group. **Conclusion:** The Figueroa modified PNAM technique is efficient, cost effective and less tedious, that can reduce the number of future secondary surgeries. Studies with wider patient base, randomization and longer follow-ups are needed for definitive results.

Keywords: Cleft, Pre Surgical Orthopedics, Nasoalveolar, Molding.

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INTRODUCTION

Cleft of the lip, and palate (CLAP) are the most common congenital deformity of the head and neck. The pre-surgical nasoalveolar moulding (NAM) as a method of pre-surgical orthopaedics is gaining popularity in the cleft treatment protocols [1]. Previously used methods and techniques for CLAP management were limited to the correction of the alveolar cleft gap only, despite the fact that the cleft nasal deformity remains the major aesthetic challenge [2]. Nasal deformity in unilateral cleft lip and palate patients increases with time leading to abnormal growth pattern which causes a great deal of personal, social,

and psychological morbidity [2]. Before the introduction of the concept of PNAM, repair of a wide cleft involved several surgeries from birth to adolescence, setting the child at risk for emotional and social adjustment stigmas. Alar cartilage, which is elastic like auricular cartilage, is correctable in the early neonatal period [3]. Considering this Grayson and Cutting combined the concept of pre-surgical orthopaedics in the cleft lip nasal deformity, and developed the concepts of Pre-surgical Nasoalveolar Moulding (PNAM), which combined a nasal moulding stent with a passive, pre-surgical moulding appliance in treating cleft lip and palate infants [7].

In the original Grayson's technique adjustments in the appliance are made weekly and nasal stents are added when the alveolar gap is reduced to 5 mm [7]. It makes this procedure more tedious, bothersome for the parents and patients in term of multiple adjustments and visits [9-11].

In Figueroa modified PNAM technique, nasal and alveolar moulding are done at the same time to reduce the number of adjustments till cheiloplasty [10]. This procedure is less commonly researched, with few investigations on its efficacy [11]. Therefore the purpose of this study was to evaluate the effect of Figueroa modified PNAM technique on nasal symmetry and alveolar cleft deformity, in the patients with complete unilateral CLAP.

MATERIAL AND METHOD

This Prospective study was conducted at Himachal Pradesh Govt. Dental College and Hospital after receiving the institutional ethical approval. The study included thirty (n=30) non-syndromic infants with unilateral cleft lip and palate (UCLP) after obtaining written informed consent from their parents. The subjects were divided into two groups, Group I, the study group (N=15), with unilateral cleft lip and palate (0-6 months), underwent the PNAM (Modified Figueroa technique), fig. Group II, control group (N=15) with unilateral cleft lip and palate, treated surgically without any pre-surgical intervention.

In group I, the PNAM was started as early in 10 to 15- day- old infant, and the average duration of the therapy was 6 months. On completion of PNAM, the study group was subjected to conventional surgical repair of CLAP. The surgical repair in both the groups was carried out by the same plastic surgeon. All the nasal parameters were recorded over the face with the help of Vernier calliper and alveolar parameter (inter-segmental distance) was recorded over study cast models. Pre-treatment records in both the groups, post PNAM records (Post-Surgical in Group II) were taken by a single Pedodontist.

The PNAM appliance fabrication and steps involved the impression making using elastomeric impression material, (Addition silicone- 3M) in putty consistency. A dental stone cast was obtained and wax- up of the cast was done according to the contour and topography of the intact arch as per the Figueroa's PNAM technique, before the fabrication of the moulding plate. The moulding plate was fabricated using self- cure clear acrylic on the waxed up cast. A nasal stent was added at the same time of fabrication of moulding plate (Fig 1-6). The complete appliance was delivered and the patients were recalled initially after 24 hr to check for problem due to appliance and later every 3-4 weeks for adjustments till primary cheiloplasty. Adjustments in the appliance was done using selective grinding and addition of soft denture liner.



Fig-1: Preoperative Frontal View



Fig-2: NAM Appliance



Fig 3: Lip Taping and Appliance Insertion



Fig-4: Post-Operative Frontal View



Fig-5: Pre-Operative Cast Model



Fig-6: Post-Operative Cast Model

Assessment of the Study Models and Facial Photographs

Photographic Analysis

Nasal parameters were measured over the patient's face (using vernier calliper with .01 mm

precision) and photographs respectively. Standard photographic views, pictures and their measurements were done using the aid of the computer. Intersegmental distance was measured over the dental stone models (Fig 5 & 6). Nasal symmetry was quantified by the following linear anthropometric measurements such as nostril height, nostril width, bi-alar width, and columellar height. Primary lip repair was done on completion of PNAM depending on the improvement of nasal and alveolar parameters. All measurements in both the groups were recorded twice, once just before any intervention and then, one week post completion of PNAM in group I and the primary lip repair in the control group.

All the data obtained from the two groups was subjected to statistical analysis. All statistical analyses were performed using SPSS version 26.0 (SPSS Inc. South Wacker Drive, Chicago, United States). Comparison was done using a two-tailed sample t-test or a Chi-square test when indicated. For significance p value of < 0.05 was considered to be significant.

RESULTS

Among all the subjects 71.9% were boys and 29.1% were girls.

Post NAM Outcomes in Group 1 Subjects

On comparison of pre and post PNAM Outcomes (nasal and alveolar parameters) this modified PNAM had been proved an effective pre-surgical intervention for the improvement of nasal symmetry and reduction of alveolar gap in complete unilateral cleft lip and palate patients (Table-1).

Table-1: Pre and Post-NAM Outcome Comparison in Group I

Parameters		Pre treatment		Post treatment		p value
		Mean	SD	Mean	SD	
NH	C	2.00	0.63	4.58	0.49	<0.001
	NC	5.33	0.51	5.83	0.75	2.09
NW	C	15.16	2.78	9.33	2.87	<0.001
	NC	7.41	2.76	7.75	3.25	1.85
CH		1.33	0.51	4.5	0.54	<0.001
BAW		25.5	1.04	20.83	0.75	<0.05
ISD		9.16	2.92	2.33	1.50	<0.001

Measurements in mm, C=cleft side, NC=non-cleft side, NH=nostril height, NW=nostril width, CH=columellar height, BAW=bi-alar width, ISD=Intersegment distance. *p<0.05 significant

In group I, on comparison of pre-treatment vs post PNAM results on the cleft side, increase in nostril height was observed (2 ± 0.63 vs 4.58 ± 0.49) ($p < .001$). There was no significant change on the non cleft side. Nostril width was found to be reduced on cleft side (15.16 ± 2.78 vs 9.33 ± 2.87 ; $p < 0.001$). As a positive outcome of PNAM in group I subjects, increase in the columellar height (1.33 ± 0.51 vs 4.5 ± 0.54 ; $p < .001$)

was observed on the cleft side. Decrease in the bi-alar width (25.5 ± 1.04 vs 20.83 ± 0.75); $p < 0.05$ was also recorded. Intersegment distance was observed to decrease post PNAM (9.16 ± 2.92 vs 2.33 ± 1.50 ; $p < 0.001$). Overall results showed a significant improvement in nasal symmetry and reduction of intersegmental cleft distance.

Table-2: Pre and Post treatment (within one week of Post Surgery) comparison of nasal and intraoral parameters in group II subjects

Parameters	Side of the face	Pre-treatment		Post treatment		p value
		Mean	SD	Mean	SD	
NH	C	2.01	0.62	3.05	0.58	<0.05
	NC	4.32	0.51	4.83	0.75	0.18
NW	C	15.18	2.79	11.91	2.61	<0.05
	NC	6.91	2.50	7.08	3.09	=0.85
CH		1.28	0.20	2.86	0.21	<0.001
BAW		25.3	1.03	23.51	0.89	2.12
ISD		9.14	2.90	8.09	2.78	0.31

*p<0.05 significant

In group II, control group, on comparison of pre-treatment vs post surgical results (1 week of surgery) on the cleft side showed increase in nostril height, (2.01 ± 0.62 vs 3.05 ± 0.58 ; $p < 0.05$). Nostril width was found to be reduced post surgery on cleft side (15.18 ± 2.79 vs 11.91 ± 2.61 ; $p < 0.05$). Increase in the columellar height (1.28 ± 0.20 vs 2.86 ± 0.21) ($p < 0.001$) was observed on the cleft side. Decrease in the bi-alar width (25.3 ± 1.03 vs 23.51 ± 0.89 ; $p = 2.12$) was observed. Intersegment distance was also observed to decrease (9.14 ± 2.90 vs 8.09 ± 2.78 ; $p = 0.31$). Overall

results showed a significant improvement in nasal symmetry and reduction of intersegmental cleft distance but the difference in improvement was less as compared to Group I i.e. treatment with PNAM group (Table-3).

Post Treatment Outcome (Change) Comparison between the Groups

Post treatment outcomes for nasal and alveolar parameters was compared on the basis of change in various measurements pre and post operatively (Table-3).

Table-3: Post Treatment Change In Various Parameters between the Groups on the Cleft Side

S.no	Parameter measured	Group- I		Group- II	
1	Nostril Height	2.58	0.15	1.04	0.12
2	Nostril Width	- 5.83	0.98	-3.27	2.61
3	Columellar Height	3.17	0.25	1.58	0.19
4	Bi-alar width	-4.67	-1.13	- 1.79	0.21
5	Inter-segmental distance	-6.83	-1.72	- 1.05	0.49

Nostril Height

The nostril height on cleft side increased in both the groups post intervention but the change was more significant in the PNAM group as compared to surgery only group (2.58 ± 0.15 vs 1.04 ± 0.12) (Table-3).

Nostril Width

Nostril width on cleft side decreased in both the groups but the difference was more in PNAM group as compared to the control group (-5.83 ± 0.98 vs -3.27 ± 2.61 mm) (Table-3).

Columellar Height and Bi-Alar Width

Post intervention, in both the groups columellar height on the cleft side was observed to increase. This difference was remarkable in Group I as compared to Group II (3.17 ± 0.25 vs 1.58 ± 0.19) (Table-3).

The post procedural reduction of bialar width was more in group I vs group II where minimal reduction was observed (-4.67 ± 1.13 vs $- 1.79 \pm 0.21$) (Table-3).

Inter-Segmental Distance (ISD)

Decrease in the Intersegmental distance is considered as a positive outcome of treatment. It was observed to decrease in both the groups but by a much higher margin in group I vs group II. (-6.83 ± 1.72 vs $- 1.05 \pm 0.49$) (Table-3).

DISCUSSION

If cleft patients are treated without any pre-surgical interventions, then nasal deformity increases with the time, and remain the greatest aesthetic challenge [2]. Any form of the nonsurgical treatment to reduce the nasal deformity early in the life is therefore highly desirable.

First attempt at the pre-surgical nasal correction was made by Matsuo et al. who highlighted the role of preoperative moulding in changing the cartilage memory of deformed nasal cartilage [3]. As these cartilages have higher amount of hyaluronic acid, which gradually diminishes after few months of birth it is desirable to start the PNAM procedures as early as possible [2].

The PNAM technique offers both the advantages of not only improving the soft tissue but also the bony segments approximation thereby improving the overall function and aesthetics before the primary lip repair [4, 5].

The PNAM was begun at New York university medical centre in 1992-93 by Dr. Berry H. Grayson, an orthodontist [7]. The average age to start PNAM therapy is the 26th day after birth and the average treatment period of PNAM is 110 days [6].

Literature on Grayson's nasoalveolar moulding technique, as an effective method to treat cleft nose deformity is abundant [7, 8]. It has its limitations such as facial irritation, mucosal ulceration and the requirement of frequent appointments for appliance adjustments [9-11]. The parents' socioeconomic status, climatic condition and topography of Himachal Pradesh were limitations for the parents for weekly appointments for follow up and adjustments as required in the Grayson's technique.

So, Figueroa modified PNAM technique was chosen in the present study as it allowed performance of nasal and alveolar moulding at the same time minimizing frequent follow-up visits from weekly to once every 3-4 weeks for moulding [10]. It led to a significant improvement in the nasal shape and symmetry both in the vertical (nostril height and columellar length) as well as horizontal dimensions (nostril width and bi-alar width) before primary cheiloplasty (Table 1 & 2). The results are in consonance with the studies done by Suri *et al.*, Clarke *et al.*, Panga *et al.*, and Thakur *et al.*, [1, 12, 13, 22]. Authors such as Williams *et al.*, Mishra *et al.*, and LI SN *et al.*, did not report any significant difference in nostril width and alar perimeter [14-16].

The alveolar cleft width reduction (intersegmental distance) were accomplished using adhesive tape tractions applied across the cleft lip as proposed by Grayson *et al.*, [7]. In the present study, the intersegmental distance (maxillary cast measurement) was reduced by 6.83 mm after 4 months of PNAM procedure in the group I as compared to only 1.05 in the surgery only group (Table-3). Most of the study have reported reduction in the intersegmental distance have used Grayson's method of PNAM. Ezzat *et al.*, Baek *et al.*, Pai *et al.*, also reported a similar reduction of 5.8 mm after 3-4 months of PNAM treatment [6, 17, 18]. Few studies Bongaarts *et al.*, and Isogawa have reported no significant effects of PNAM on the width of alveolar gap [19, 20]. Literature is scarce on the assessment of alveolar changes using Figueroa's PNAM technique. A significant reduction in the alveolar gap was reported by Singh A *et al.*, using Figueroa's PNAM technique [21].

The reduced alveolar cleft gap (intersegmental distance) after NAM may lead to avoidance of surgery in future like secondary alveolar bone grafting and rhinoplasties. This technique had proven to be beneficial for the surgeon and patient both alike.

In present study nasal symmetry was significantly improved, including positive changes in all the nasal and alveolar parameters. Limitations of present study can be considered in terms of small sample size, smaller follow-up period and treating control group subjects without PNAM.

CONCLUSION

In terms of reduction of appliance adjustments, parents visits, improvement of nasal anatomy and reduction of alveolar cleft gap, Figueroa modified technique has been an efficient and effective technique, to treat complete unilateral cleft lip and palate patients. PNAM therapy is a useful adjunctive treatment and it should be considered as a routine procedure in treatment protocol for cleft infants before primary cheiloplasty. Emphasis is laid on the need for large sample size studies with randomization to confirm the findings of this study.

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