



Protocols in Presurgical Infant Orthopaedic Treatment - An Evidence Based Review

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Abstract

Presurgical infant orthopaedic (PSIO) protocol is applied prior to cleft Lip and/ cleft palate surgical intervention to facilitate the repair by restoring the alar base and maintaining the skeletal, soft tissue harmony. The objective of this review is to assess the literature on the presurgical infant orthopaedic protocol most widely used and accepted. Searches were made in PubMed, Cochrane and Google Scholar on cleft lip and/palate. A large number of articles documented approaching PSIO for cleft treatment with the intent to provide a satisfactory treatment for cleft patients, requiring far more than just correctional surgery and its ability to do so is unique. Craniofacial Orthodontists can choose from a wide array of treatment options for their patients and can learn from the outcomes attained by applying a combination of outcomes at various other centers.

Keywords: Systematic Review; Cleft Lip; Cleft Palate; Presurgical; Infant Orthopaedics; PSIO

Introduction

Pre-Surgical Infant Orthopaedic (PSIO) protocol indisputably has a valuable impact in the management of cleft lip and palate infants, showing approximation and alignment of alveolar segments and narrowing the gap between lip components, with the intent of separating oral cavity from nasal and maintaining the tongue position. However, nasal cartilage symmetry and increase in the columella length results remain distinctive [1], with long term benefits still under speculations. Although the popularity of NAM has grown by leaps and bounds in the last one decade, it has become essential to annotate the outcome of both NAM and other PSIO protocols. Studies regarding NAM have been either case studies or single center retrospective comparisons of before-and-after clinical features on small samples with no control non-NAM cases.

An evidence-based approach to cleft lip and palate management in the last two decades has led many craniofacial orthodontists to show great enthusiasm for presurgical infant orthopaedics

(PSIO). Patients with unilateral and bilateral complete cleft lip and/ palate demand far more than just correctional surgeries. Any manipulations of the infant's orofacial complex prior to nasal and lip surgical repair is conducted under the aegis of term presurgical infant orthopaedics (PSIO).

An inevitable manifestation of cleft lip and palate remains to be primary nasal deformity, presenting a significant surgical challenge requiring patients to undergo multiple surgical procedures.

Advocates of PSIO have stated, besides improving arch form and facilitating arch closure, its main objective is improving nasal symmetry and lip aesthetics. In order to make cleft lip and/or palate care cardinal for these patients, it's essential to understand these protocols and develop a more centralized approach. The aim of the present review is to provide scientific literature on most current PSIO appliances in patients with CLP and to analyse the current state of PSIO.

Timing	Procedure
After 16 weeks of pregnancy	cleft lip diagnosis by ultrasound images (Palate is more difficult to acquire)
Prenatal	Discussion with craniofacial surgeon, consultation with a geneticist/dysmorphologist
Neonatal	If the child has cleft palate, specialized nipples and bottles are necessary to improve feeding after birth
6-12 months of age	12 weeks of age cleft lip repair; cleft palate one-stage repair with intravelar veloplasty
5 years	secondary rhinoplasty

Table 1: Treatment modalities in the management of unilateral cleft lip and palate which are often based on chronological age.

Materials and Methods

This evidence-based review is registered at the international prospective register of systematic reviews, PROSPERO, with the following registration number CRD42021280979. The report followed the preferred Reporting items for Evidence based reviews and Meta-Analyses (PRISMA) 2020 edition. Three electronic Databases namely PubMed, Cochrane and Google Scholar Library on Cleft-Lip and/Palate were searched and used in the current study. Studies that were conducted between the years 2011 and 2021 with the primary keywords were searched. We used search strategies involving the MeSH descriptors and 61 studies met the inclusion criteria.

The main descriptors used were as follows

- **MeSH:** “Presurgical infant orthopaedics” OR “pre surgical orthopaedics”OR “infant orthopaedics” AND (“Cleft Palate”[Mesh] OR “Cleft Lip”[Mesh] OR “infant” OR “neonatal” OR “unilateral cleft lip and palate”
- **Pub-Med:** The searches in this database were made in “Search Details.”
- **Cochrane:** The searches in this database were made in “search History”, and the search strategy was assembled in “search for”.
- **Google Scholar:** The searches in this database were made in “Google search”.

All abstracts provided by the databases in the searches were collected resulting in a total of 136 articles. From these abstracts,

studies that clearly did not include presurgical infant orthopaedics were excluded. After meticulous reading of the full text articles, 21 articles were included for the analysis of the obtained conclusion (Figure 1). Further assessment of the literature for inclusion in this review was performed by evaluating the full text based on the selection criteria. Literatures that were not in line with the selection criteria were then excluded from the study. Quality assessment and data synthesis were completed independently by two investigators (NK and AF) and any discrepancies were resolved by consultation with the third author (MZ).

The following inclusion criteria were used for the evidence-based review.

- Study types: RCTs and observational study
- Study assessed an outcome related to the use of pre-surgical infant orthopaedic
- Studies done after 2010
- Studies reported in English language.

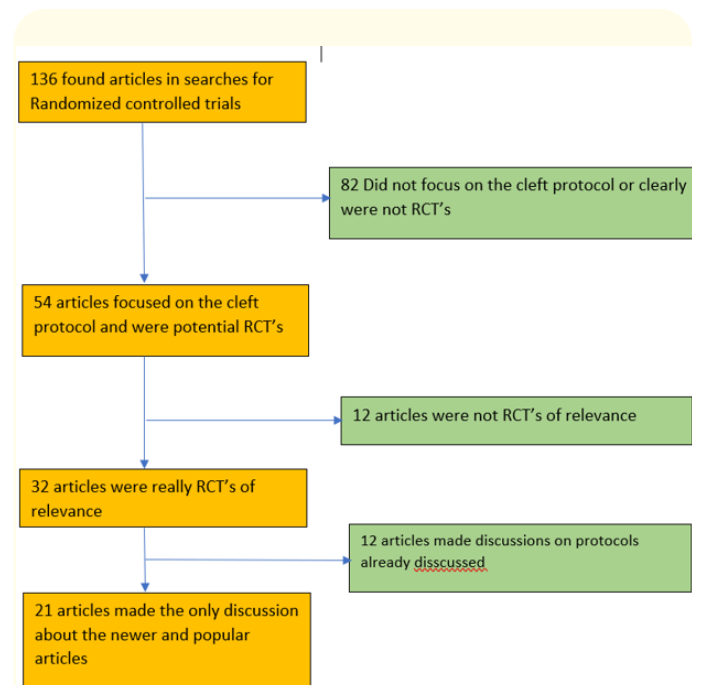


Figure 1: The flow chart above outlines the selection process of articles.

Results

The protocols enlisted in the 21 articles are as follows:

- Naso-alveolar Moulding: 7/21 = 33.33%
- Modified Latham Appliance: 2/21 = 9.52%
- Lip Taping: 4/21 = 19.04%
- McNeil: 1/21 = 4.76%
- Nasal Elevator Device- Dyna Cleft: 1/21 = 4.76%
- SAC-PP-MR Technique: 1/21 = 4.76%
- Aligner NAM: 1/21 = 4.76%
- 3-D Vomer Plate: 2/21 = 9.52%
- Lip taping w/ prefabricated nasal stent: 1/21 = 4.76%
- Vacuum formed NAM: 1/21 = 4.76%

Discussion

In order to conduct a successful clinical practice with PSIO protocols, the systematic reviews and RCTs are considered the most appropriate evidence. The main search engine proposed by World Health Organization i.e., PubMed and Cochrane Library, along with google scholar were used to find the RCTs to formulate a study for evidence based medicine. A total of 136 articles were found, and we reached 21 articles that proposed PSIO protocols on cleft patients.

PSIO came into existence with McNeil in 1950 using buccal plates to manipulate the alveolar segments. Beginning with Grayson and Colleagues [2] in 1993, has inspired many orthodontists over the last few decades to develop a protocol that not only shapes the nasal cartilage, but also mould's the alveolar process. Two of the most favored PSIO protocols employed are Nasoalveolar molding and Latham-Millard technique [3] with the later potentiating a successful GPP and obligating nasolabial fistula prior to secondary bone graft [4], while the former aims at reducing the severity of cleft defect in both UCLP and BCLP infants [2]. In UCLP infants the cleft defect between the alveolar segments is approximated, the lip elements are brought close together and the deviated columella is repositioned. For BCLP infants, the Grayson NAM technique successfully retracts the Premaxilla and the alveolar segments are widened for alignment. The columella is elongated non-surgically [2]. The direct benefit of using the Latham device as part of pre-surgical infant dentofacial orthopaedic is ease of gingivoperiosteoplasty. Millards, an acclaimed plastic surgeon, modified the Latham's fixed appliance such that it amalgamated with his surgical protocol reporting a significantly reduced number of fistulas post-operative [14]. However, the Latham dento-maxillary orthopaedic appliance used screws to approximate the alveolar segments in unilateral

complete cleft patients. A "Modified Latham " appliance designed by Stephen Ruso and Ernest Ruas at John Hopkins Hospital, Florida claims that the use of elastic power chain instead of screws to approximate the alveolar segments reduces the treatment time to 2 weeks [15].

Lip tapping alone has been labelled as a tyrannised PSIO protocol in spite of it being a simple and inexpensive procedure, which is even more pressing when dealing with a lifelong condition such as cleft lip and palate. The dearth of impression making and appliance fabrication permits the early start of treatment exhibiting good maxillary arch dimensions and lip approximation [13].

Inspired by the technique employed by Berggren and Berggren., *et al*, in 2002 a simple nasal elevator composed of plastic, with an elastic band pasted on the forehead was used to approximate the cleft edges [5]. A new and simpler way of providing PSIO gave rise to Dynacleft, where the maxillary segments are approximated indirectly aided by force factors coming from lip muscle traction [6]. Due to the dentoalveolar growth and simultaneous cleft reduction, the need for fabricating new plates demands the nasal stents to be re-mounted, adding to the visiting appointments. This leads to a quick-lock system for nasal stent transfer, minimising the wire adaptations. The addition of CAD/CAM technology has not only saved the chair side time, but significantly increased the cleft side nasal height and improved the nasal symmetry [7]. It's use is on ever increasing rise for recording details in cleft-Lip and Palate patients and is relatively less risk averse and more precise when compared to the primitive impression making procedure [8]. A series of case results documenting PSIO cases treated with CAT has opened a window to a new and exciting future [9].

A modified, yet simpler and cheaper technique called "The SAC-PP-MR " technique recently came into existence with the intent to target all, to not only facilitate cheiloplasty and ensure positive aesthetic outcome. It successfully documented reducing the cleft size to zero [9].

Presurgical Infant Orthopaedic Treatment (PSIO) has been accepted and acknowledged into practice by the majority of multidisciplinary cleft teams around the world attributing the cleft defect repair and primary nose surgery [10-12]. An inter center comparison study using Asher-McDade scale demonstrated a significantly favorable outcome in nasolabial appearance scores Vs outcomes resulting from primary surgical repair only [17].

Craniofacial Orthodontists can choose from a wide array of treatment options for their patients and can learn from the outcomes attained by applying a combination of outcomes at various other centers. However, attempts have been made by craniofacial orthodontists to modify PNAM device with the intent to simplify

the fabrication and reduce the frequency of recall visits [18]. Distance as a factor has been obsolete from many discussions advocating the use of PSIO or eliciting the need for newer PSIO techniques, however it has been revealed to cause a significant difference in the delivery of cleft care (Table2).

Experimental Group	Conclusion	Explanation for Conclusion
Naso-Alveolar Moulding (NAM)	NAM helps to approximate the segments of cleft maxilla and reduce inter-segment space [2]	For Unilateral cleft cases the NAM Device helps to approximate the greater and lesser segment, simultaneous elevating lateral cartilage and straightening the deviated columella [2]
Modified Latham Appliance	Shorter treatment duration compared to traditional Latham appliance and NAM, making operative placement at an older age feasible [15].	The power chain provides a continuous force application on the palatal segments, bringing the two together in a span of 2 weeks of active therapy without impacting the future growth of facial sutures [15].
Lip Taping	Lip taping alone can change the maxillary arch dimensions before surgical lip repair in UCLP infants; A simple and inexpensive type of PSIO [13]	Eliminated the need to make an impression, allowing the treatment to start early and making it inexpensive with a significant change in maxillary arch dimensions
Muscle Activated NAM	Helps better alveolar position along with improvement in nasal symmetry, alignment of nasal septum and nasal tip projection [16].	The Device guides the placement of tongue tip thereby preventing the cleft widening effect of tongue allowing the facial musculature movements to act as a guide.
Nasal Elevator Device - Dyna Cleft	significantly reduce the cleft width and improve the nasal asymmetry	The device acts indirectly on the cleft alveolar segments with force vector generated from traction of lip muscles, keeping the nostril airway less restricted and overall technique being less invasive. It is less expensive and easier for parents to manage.
Aligner -NAM	significant increase in the columella length with near-complete approximation of maxillary alveolar segment [21].	Intraoral scanner for recording intraoral impressions is less hazardous and more accurate. Downside of acrylic plate such as ulceration is eliminated ²¹ .
SAC-PP-MR Technique	a modified, economical, comparatively easier and faster technique reducing the defect to zero [9].	a passive appliance stimulates the involved tissues during physiological functions like swallowing and feeding resulting in overcorrection of alar cartilage; the technique derives its basis from functional matrix theory
Latham Appliance	significant reduction in alveolar cleft width allowing for minimal dissection gingivoperiosteoplasty [14]	achieved favourable nasolabial aesthetics with midface growth sometimes affected (GOSLON Score 4 or 5) making orthognathic surgery inevitable
Vacuum formed NAM	significantly reduced alveolar and palatal cleft width along with reduction in midline deviation [22]	a sequential appliance fabrication eliminates the burden of presurgical therapy [22]
Surgical Nasoalveolar Moulding	Pre-surgical Naso-Alveolar Moulding followed by primary surgical repair still lacks sufficient scientific evidence when compared to primary cheilorrhinoplasty in closing the alveolar gap and improving nasal appearance, therefore NAM is still not considered gold standard [20]	Primary nasal and palatal repair surgery in unilateral cleft lip palate patients, based on a literature review [20]

Table 2: Conclusion of Articles that used various Presurgical Infant Orthopaedic (PSIO) techniques.

Conclusion

In Conclusion, Craniofacial Orthodontists can choose from a wide array of treatment options for their patients and can learn from the outcomes attained by applying a combination of outcomes at various other centres. Distance as a factor has been obsolete from many discussions advocating the use of PSIO or eliciting the need for newer PSIO techniques, however it has been revealed to cause a significant difference in the delivery of cleft care.

Conflict of Interests

The authors declare that there is no conflict of interest.

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Authors' Contributions

NK: Methodology, data collection, writing manuscript. AF: Methodology, data collection, visualisation, review and editing. MZ: Conceptualisation, data collection, Supervision, Review and editing.

Bibliography

- Hitesh Kapadia and Douglas Olson. "Nasoalveolar Moulding for unilateral and Bilateral cleft lip repair". *Oral and Maxillofacial Surgery Clinics of North America* 32 (2020): 197-204.
- Grayson BH and Garfinkle JS. "Early cleft Management: the case for nasopalveolar moulding". *American Journal of Orthodontics and Dentofacial Orthopedics* 145.2 (2014): 134-124.
- Diana S., et al. "Clinical Outcomes Utilizing a "Modified Latham" Appliance for Presurgical Infant Orthopedics in Patients with Unilateral Complete Cleft Lip and Palate". *The Cleft Palate-Craniofacial Journal* 56.7 (2019): 929-935.
- Santiago PE and Grayson BH. "Reduced need for alveolar bone grafting by presurgical orthopedics and primary gingivoperiosteoplasty". *Cleft Palate Craniofacial Journal* 35.1 (1998): 77-80.
- Monasterio L., et al. "Tratamiento Interdisciplinario de la Fisuras Labio-Palatinas". *Santiago: Luis Monasterio Aljaro* (2008): 133-164.
- Luis Monasterio and Alison Ford. "Comparative Study of Nasopalveolar Molding Methods: Nasal Elevator Plus Dyna Cleft Versus NAM-Grayson in Patients with Complete Unilateral Cleft Lip and Palate". *The Cleft Palate-Craniofacial Journal* 50.5 (2013): 548-554.
- Florian D., et al. "Facilitating CAD/CAM nasopalveolar molding therapy with a novel click-in system for nasal stents ensuring a quick and user-friendly chairside nasal stent exchange". *Scientific Reports* 8 (2018): 12084.
- Chalmers EV, et al. "Intraoral 3D scanning or dental impressions for the assessment of dental arch relationships in cleft care: which is superior?" *The Cleft Palate-Craniofacial Journal* 53.5 (2016): 568-577.
- Ricardo Elizondo, et al. "Presurgical Preparation of Infants with Unilateral Cleft Lip and Palate: The SAC-PP-MR Innovative Technique". *The Cleft Palate-Craniofacial Journal* 56.3 (2019): 408-414.
- Bennun R., et al. "Non-Surgical correction of nasal deformity in unilateral complete cleft lip: a 6 year follow-up". *Plastic Reconstructive Surgery* 104 (1999): 616.
- Grayson B and Shetya P. "Pre-surgical Naso-Alveolar Moulding treatment in CLP Patients". *Indian Journal of Plastic Surgery Supplement* 42 (2009): S56-S61.
- Liou E., et al. "The progressive changes of Nasal symmetry and grow after Naso-alveolar moulding: a three year follow-up study". *Plastic and Reconstructive Surgery* (2004): 114.
- Mohamed Ael-G., et al. "Is Taping alone an efficient pre-surgical infant orthopedic approach in infants with unilateral cleft lip and palate? A randomized control trial". *The Cleft-Palate Craniofacial Journal* 57.12 (2020).
- Latham RA. "Orthopedic advancement of the cleft maxillary segment: A preliminary report". *The Cleft-Palate Journal* (1980).
- Diana SJ, et al. "Clinical Outcomes Utilising a "Modified Latham" Appliance for Presurgical Infant Orthopedics in Patients with Unilateral Complete Cleft Lip and Palate". *The Cleft-Palate Craniofacial Journal* 56.7 (2019).
- Sanjay Suri and Bryan Thompson. "A Modified Muscle-Activated Maxillary Orthopaedic Appliance for Presurgical Nasopalveolar Moulding in Infants with Unilateral Cleft Lip and Palate". *Cleft Palate-Craniofacial Journal* 41.3 (2004).
- Supakit Peanchitlertkajorn, et al. "An intercentre comparison of nasolabial appearance including a centre using Naso-Alveolar Moulding". *The Cleft Palate-Craniofacial Journal* (2018).

18. Ajay Bajaj, *et al.* "Modified Presurgical Naso-Alveolar Moulding in the infants with complete unilateral cleft Lip and Palate - A stepwise approach". *Journal of Maxillofacial and Oral Surgery* (2011).
19. P Priyanka Niranjane, *et al.* "Current status of presurgical infant orthopaedic treatment for cleft lip and palate patients: A critical review". *Indian Journal of Plastic Surgery* 47.3 (2014).
20. Chitravelu Siva Subramanian NKK, *et al.* "A modified Pre-surgical Orthopaedic (Nasoalveolar Moulding) device in the treatment of unilateral cleft lip and palate". *European Journal of Dentistry* (2016).
21. Percy Rossell-Perry. "The Surgical Nasoalveolar Moulding: A Rational Treatment for Unilateral Cleft Lip Nose Deformity and Literature Review". *PRS Global Open* (2020).
22. Puneet Batra, *et al.* "OrthoAligner NAM: A case series of pre-surgical infant orthopedics (PSIO) using clear Aligners". *The Cleft Palate-Craniofacial Journal* 57.5 (2020): 646-655.
23. Khadega Ali Al Khateeb, *et al.* "Short term efficacy of pre-surgical vacuum formed Naso-Alveolar Moulding Aligners on Nose, Lip and Maxillary Arch Morphology in Infants with Unilateral cleft lip and palate: A prospective clinical trial". *The Cleft-Palate Craniofacial Journal* 58.7 (2020): 815-823.