



## Pre-Surgical Infant Orthopedics: An Up-To-Date Review of Techniques and Clinical Implications

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### Abstract

**Background:** Pre-surgical infant orthopedics (PSIO) has evolved significantly since the mid-20th century and is a critical component in the early management of cleft lip and/or palate (CL/P).

**Objective:** To provide a comprehensive review of PSIO techniques, including traditional methods and recent innovations such as nasoalveolar molding (NAM) and 3D printing.

**Methods:** A literature-based review highlighting the evolution, clinical applications, protocols, materials, complications, and emerging trends in PSIO.

**Results:** Techniques vary in complexity and outcomes, with NAM and digital workflows offering enhanced customization. Complications are manageable with interdisciplinary collaboration.

**Conclusion:** Technological advances are reshaping PSIO, yet debates remain regarding efficacy and accessibility. A multidisciplinary, patient-centered approach remains essential.

**Keywords:** Pre-Surgical Infant Orthopedics (PSIO); Cleft Lip and Palate; Nasoalveolar Molding (NAM); Passive Orthopedic Appliances; Active Orthopedic Appliances; 3D-Printed Orthopedic Appliances

### Introduction

Cleft lip and/or palate (CL/P) represents one of the most common congenital craniofacial anomalies worldwide, with significant implications for feeding, speech, dentofacial development, and psychosocial well-being [2]. In recent decades, advances in pre-surgical infant orthopedics (PSIO) have played a pivotal role in the early management of CL/P, aiming to improve surgical outcomes, support facial growth, and facilitate feeding and bonding in the neonatal period [1,3,4].

First introduced in the 1950s, PSIO techniques have evolved significantly in response to both technological innovation and deeper clinical insight. Traditional methods, such as passive plates and active appliances, have been supplemented by more sophisticated approaches like nasoalveolar molding (NAM) and, more recently, digitally fabricated devices using additive manufacturing (3D printing) [1,6,20,34]. These interventions aim to align alveolar segments, mold nasal cartilages, and establish a more favorable anatomical foundation for primary lip and palate repair [6,8,9].

Despite widespread clinical adoption, the use of PSIO remains a subject of ongoing debate, with conflicting evidence regarding its long-term benefits, potential complications, and impact on facial growth [12,14,23,33,35]. Furthermore, ethical and logistical challenges—particularly in low-resource settings—continue to influence access and implementation [16,17,38]. As such, a comprehensive understanding of the history, techniques, materials, and clinical implications of PSIO is essential for informed decision-making and future innovation.

This review aims to provide an examination of the evolution and current landscape of PSIO, including traditional and modern appliance types, clinical protocols, materials science considerations, ethical aspects, and future directions. By synthesizing existing literature and identifying areas for further research, this paper seeks to inform both clinical practice and the development of more equitable, effective treatment paradigms for infants born with cleft lip and/or palate.

### Historical background

The origins of pre-surgical infant orthopedics (PSIO) trace back to the mid-20th century, when early efforts were made to improve surgical outcomes in infants born with cleft lip and/or palate by manipulating maxillary and nasal structures prior to primary repair [1]. In 1950, McNeil introduced an active orthopedic plate intended to reduce the cleft width by guiding alveolar segments into alignment [1]. This marked the beginning of structured pre-surgical interventions in cleft care. Following McNeil's work, Hotz and colleagues in the 1960s developed a passive orthopedic plate, aimed primarily at facilitating feeding and guiding natural growth rather than actively applying forces to the maxillary segments [1,2].

These passive devices were simpler to fabricate and more comfortable for infants, leading to widespread adoption, particularly in European cleft centers [1,2].

The 1990s saw a significant advancement in PSIO with the introduction of nasoalveolar molding (NAM) by Grayson and Cut-

ting [6]. NAM combined alveolar molding with nasal cartilage reshaping using nasal stents, offering a comprehensive approach to presurgical correction of cleft deformities [6,8,9].

This innovation was driven by a better understanding of neonatal cartilage plasticity and the therapeutic window provided by elevated maternal estrogen levels postpartum [6]. NAM soon gained popularity, particularly in North America and parts of Asia, where early intervention was becoming a standard component of multidisciplinary cleft care [6,18,19].

In recent years, digital technology has further transformed the field. The integration of intraoral scanning, CAD/CAM design, and 3D printing has made possible the rapid fabrication of customized appliances with improved precision and reduced reliance on physical impressions [20,34]. These advancements have the potential to enhance workflow efficiency in cleft teams.

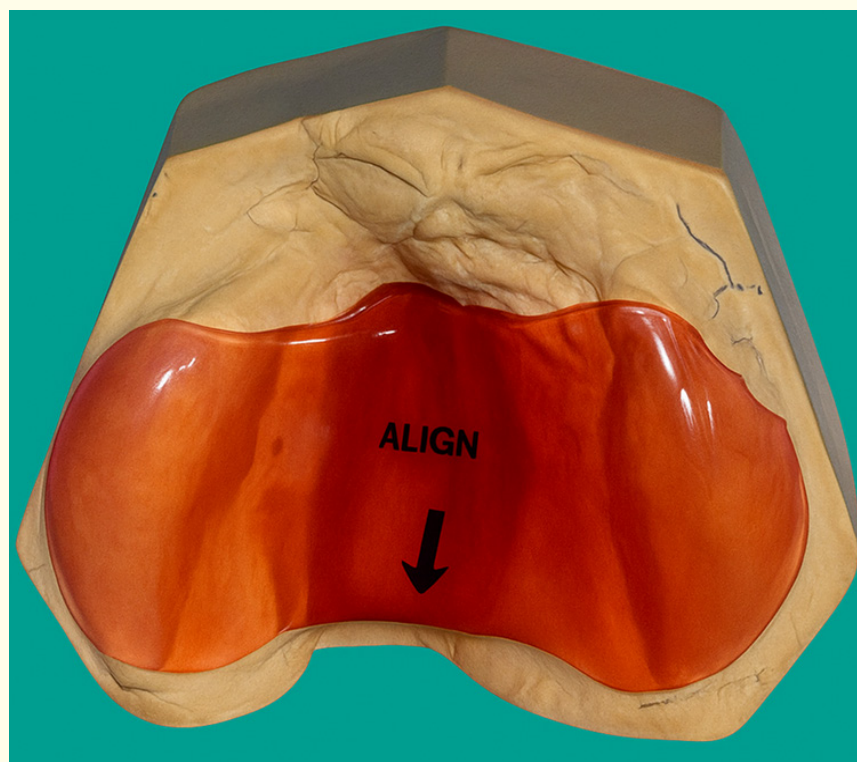
Through decades of innovation, PSIO has evolved from rudimentary appliances to highly customized, digitally-fabricated devices. Each historical phase reflects a broader shift in clinical philosophy—from passive guidance to active correction, and now toward personalization and customization. Understanding this historical trajectory is essential to appreciating the rationale behind current practices and the ongoing debates surrounding PSIO's role in cleft care [4,23,33,34].

### Techniques

#### Passive appliances

Passive appliances (Figure 1) represent the earliest form of pre-surgical infant orthopedics, first popularized in the mid-20th century by practitioners such as McNeil and Burston [1]. Unlike NAM, passive appliances exert no active force; instead, they function as space-occupying molds that passively guide the growth of the alveolar segments and assist in feeding by improving intraoral seal [2,13].

The typical passive appliance is a custom-molded acrylic plate that conforms to the infant's maxillary arch, with a flange extend-



**Figure 1:** Passive PSIO Appliance. A passive orthopedic appliance used to maintain maxillary arch form and support feeding without applying active force.

ing into the cleft to prevent the tongue from entering the cleft space [2,13]. This helps maintain the separation of the oral and nasal cavities, facilitating feeding and reducing the risk of aspiration [2,13,30].

These appliances do not include nasal stents or alveolar molding features, and thus are primarily focused on palatal protection, feeding support, and potentially simplifying surgical closure by gently maintaining or narrowing the cleft width through tissue adaptation [13,30].

Passive appliances are relatively low-maintenance compared to NAM, requiring less frequent clinical adjustments and imposing a lighter burden on caregivers [13]. As such, they have remained popular in resource-limited settings and among teams that prioritize minimal intervention during the pre-surgical period [15,33].

Clinical evidence for passive appliances is mixed. While some studies suggest benefits in feeding, weight gain, and parental satisfaction [13,30], others indicate that passive plates do not significantly impact surgical outcomes or long-term maxillofacial development [14,22,33].

### Active appliances

Active appliances (Figure 2) in pre-surgical infant orthopedics are appliances designed to apply directed forces to the maxillary segments, promoting controlled movement and alignment prior to surgical repair [1,3]. One of the earliest and most well-known active appliances is the Latham appliance, introduced in the late 20th century [1].

Clinical outcomes associated with active appliances remain a topic of debate. Some studies have reported improved alignment of the alveolar ridges, reduced cleft width, and enhanced nasal symmetry [4,27,28], while others have found no substantial long-term advantage over passive methods or NAM [14,23,32].

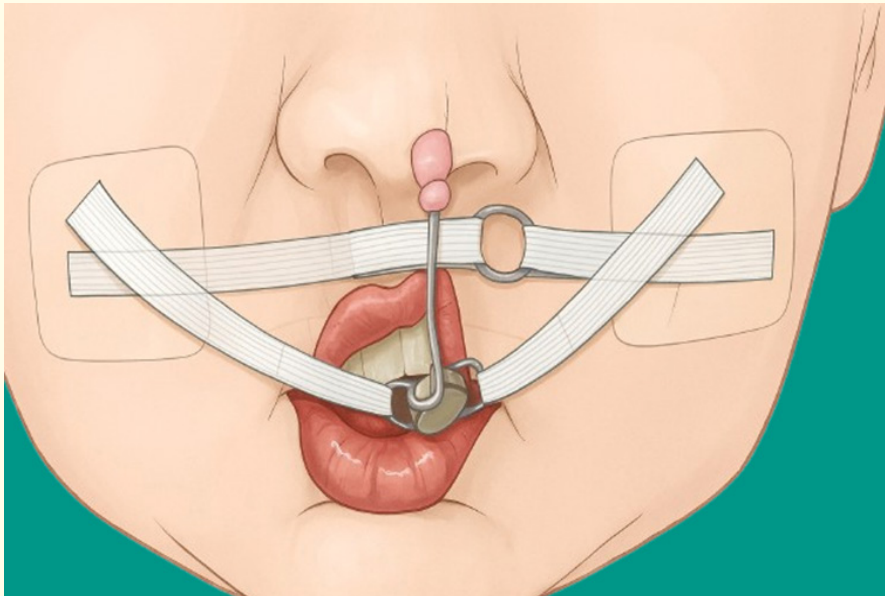


**Figure 2:** Active PSIO – Latham Appliance. An active orthopedic appliance fixed to the maxilla to reposition cleft segments using mechanical force.

### Nasoalveolar Molding (NAM)

Nasoalveolar molding (NAM)(Figure 3) is one of the most widely recognized and studied pre-surgical infant orthopedic techniques [6,8,9]. NAM leverages the plasticity of neonatal cartilage, particularly within the first six to eight weeks of life when maternal estrogen levels are still elevated [6,7].

The NAM appliance typically consists of two components: an intraoral molding plate and external nasal stents [6,8,9]. Studies have demonstrated significant improvements in nasal symmetry, columellar length, alveolar gap reduction, and soft tissue approximation [8,9,11,18,19,21]. However, NAM is not without controversy. Critics have raised concerns about the intensive nature of treatment, the psychological burden on families, and the lack of high-level evidence demonstrating long-term benefits in facial growth or functional outcomes [12,14,33,35].



**Figure 3:** NAM Appliance, A nasoalveolar molding appliance combining an intraoral plate and nasal stents to align alveolar segments and improve nasal shape.

Despite these debates, NAM remains a cornerstone of PSIO in many cleft centers worldwide [6,9,18,19].

More recently, PLANA-a simplified, non-invasive technique employing adhesive taping and external nasal conformers-has been introduced [34]. Early studies report favorable outcomes in nasal symmetry and caregiver adherence. However, further clinical trials

are needed to validate its long-term efficacy and optimize protocols [34].

3D-printed appliances

The integration of 3D printing technologies into pre-surgical infant orthopedics (PSIO) represents a significant advancement in both the precision and accessibility of treatment [20,34]. These ap-

Technique	Type of Force Applied	Customization Required	Duration of Use	Reported Clinical Outcomes
NAM (Nasoalveolar Molding)	Active + Passive (taped traction + intraoral plate)	High (weekly adjustments)	Typically 3-6 months (until primary lip repair)	Improved nasal symmetry, alveolar alignment, reduced cleft width
Passive Appliance	Passive (guidance without external force)	Moderate (initial impression, occasional adjustment)	Typically 3-6 months	Maintains arch form, may reduce cleft width moderately
Active Appliance	Active (mechanically applied force via springs/screws)	High (frequent monitoring and activation)	Varies; often until surgical repair	Promotes maxillary segment alignment, higher risk of mucosal irritation

**Table 1:** Summary of Pre-surgical Infant Orthopedic Techniques.

**Note:** NAM: Nasoalveolar Molding; Duration of use may vary depending on clinical protocol and surgeon preference.



pliances are designed and fabricated using digital workflows that allow for highly customized, reproducible, and rapidly producible devices [20,34].

Both passive plates and NAM devices can be 3D-printed, incorporating retention arms, nasal stents, and other functional features [20,34]. Furthermore, aligner NAM has been researched upon to potentially replace the molding plates and nasal stents with a series of digitally designed, 3D-printed removable appliances [34].

### Digital platforms for pre-surgical infant orthopedics

Among the emerging tools, Cleft Align demonstrates strong potential with its AI-driven segmentation and automated alignment workflow, enabling remote planning and 3D-printed appliance fabrication [34]. In contrast, 3D-NAM, a digital adaptation of traditional NAM, allows for custom nasal molding plates derived from intraoral scans, although it remains technically demanding and time-intensive [34]. RapidNAM simplifies the NAM process using a template-based semi-automated design [34].

### Clinical protocols

#### Timing of initiation

PSIO typically begins within the first few weeks of life, often between 7 to 14 days postpartum, once the infant is medically stable and feeding has been reasonably established. Early initiation capitalizes on the plasticity of neonatal cartilage and the rapid growth of craniofacial structures during this period.

#### Initial evaluation

Before appliance fabrication, infants undergo a comprehensive evaluation that includes:

Detailed history taking and clinical examination (including cleft morphology and nasal assessment)

#### Feeding assessment

Family counseling regarding treatment objectives, process, and expected outcomes.

Intraoral and extraoral photographs and intraoral impressions (digital or conventional) to capture baseline anatomy.

This stage may also include genetic counseling or a multidisciplinary team consultation to evaluate any associated syndromes or comorbidities.

### Appliance fitting and adjustment

NAM devices require weekly to biweekly visits for adjustments of the intraoral plate and nasal stents. Tapes and elastics are typically changed at home by caregivers under provider guidance, emphasizing the importance of caregiver training and compliance. Passive plates require fewer adjustments, typically every 2 to 4 weeks, unless growth or fit necessitates earlier revision. 3D-printed appliances can be rapidly redesigned and reprinted for sequential stages, with turnaround times dependent on the clinic's digital workflow and in-house printing capability. Regular follow-up is essential to monitor growth and anatomical changes, skin and mucosal health (e.g., ulcerations, pressure spots), nasal symmetry and projection (in NAM), parental compliance and technique with taping or stent management, and feeding progress.

### Duration of therapy and endpoint

PSIO typically continues until primary lip repair, which occurs between 3 to 6 months of age, depending on the institution's surgical protocol and the infant's readiness. The timing of appliance discontinuation coincides with the preoperative phase, during which the infant undergoes final surgical planning and pre-anesthetic evaluation.

### Interdisciplinary collaboration

Effective PSIO implementation requires close coordination among pediatric dentists, orthodontists, plastic or oral and maxillofacial surgeons, speech and feeding therapists, nursing staff, case coordinators, and, critically, parents and caregivers, whose active participation is essential for treatment success.

### Materials and biocompatibility

The materials used in pre-surgical infant orthopedic (PSIO) appliances must fulfill a set of stringent requirements, including biocompatibility, durability, ease of modification, and patient comfort. Given the sensitive anatomy and rapid growth of the neonatal oral cavity and nasal structures, the selection and handling of materials are critical to minimizing adverse reactions and ensuring treatment efficacy [1,20,34].

#### Commonly Used Materials

- Acrylic Resins/Polymethyl methacrylate (PMMA) is the most widely used material for conventional NAM and passive plates. It is chosen for its durability, rigidity, and ease of modification during adjustment visits. Typically used with stainless steel wires and soft resin nasal stents [6,8,20].
- Silicone Elastomers are used for nasal stents or soft-lining materials in contact with mucosal surfaces. They offer flexibility and improved patient comfort, but can degrade over time with cleaning or exposure to oral fluids [6,34].
- Thermoplastic materials like ethylene vinyl acetate (EVA) or polycaprolactone (PCL) are used in some passive or digitally fabricated appliances. These are moldable at low temperatures, making them suitable for rapid chairside adaptation [20,34].
- 3D Printing Resins in digitally designed PSIO systems are bio-compatible photopolymers used for stereolithography (SLA) or digital light processing (DLP). These include materials such as Dental LT Clear Resin or BioMed Clear Resin, which meet ISO 10993 standards for prolonged mucosal contact [20,34].

Biocompatibility in PSIO appliances is essential to prevent allergic reactions, mucosal irritation, or cytotoxicity. Key factors influencing biocompatibility include good surface finish, as rough or unpolished surfaces can irritate delicate mucosa and harbor microbial biofilm [1,20]. Appliances are typically polished or coated to reduce these risks. Residual monomer content in improperly cured acrylics may release unreacted monomers, which are cytotoxic. Proper fabrication techniques and post-curing are essential. Hygiene and maintenance, with frequent removal and cleaning by caregivers, are necessary to maintain biocompatibility over time. Instructions typically include mild soap rinsing and periodic inspections [20,34].

#### Complications and management

While PSIO has revolutionized pre-surgical management of cleft lip and palate patients, it is not without potential complications. Early identification and appropriate management of these issues are essential to ensure safe, effective outcomes and parental satisfaction [6,9,12,14,23,33,35].

- Skin Irritation and Pressure Sores are caused by continuous pressure from tapes or poorly fitted appliances and inadequate skin preparation or hypersensitivity to adhesives. These can be managed by using hypoallergenic tapes (e.g., Tegaderm™, Hypafix®) and applying skin barrier films before taping. Adjusting pressure points by selectively relieving the appliance and temporarily discontinuing NAM may be needed in severe cases [6,12,14].
- Oral Ulceration and Mucosal Injury may result from excessive pressure from the molding plate or nasal stents, or from sharp or rough edges on the appliance. These complications can be managed by regularly inspecting the oral mucosa, smoothing appliance edges using dental burs or polishers, modifying appliance design to distribute forces evenly, and using soft lining materials to cushion sensitive areas [6,14].
- Feeding Difficulties can occur when the appliance interferes with the sucking reflex or tongue movement. Management includes adjusting appliance thickness-especially in the palatal region-providing feeding counseling to caregivers, and temporarily removing the appliance during feeding. The use of specialized cleft feeding bottles (e.g., Haberman, Pigeon) is recommended [2,3,13,30].
- Nasal Stent Displacement or Overcorrection may be caused by improper stent design, inadequate fixation, or overly aggressive nasal molding forces. It can be managed by adjusting stent size and position incrementally while monitoring nasal symmetry during follow-ups to prevent overcorrection [8,9,19,21].
- Appliance dislodgement and aspiration risk may occur due to poor appliance retention or lack of caregiver vigilance. This can be mitigated by ensuring a precise fit, educating caregivers on supervision, and advising against use during sleep if retention is unreliable [8,9,33].
- Parental noncompliance or burnout can result from frequent clinic visits, the burden of appliance maintenance, or unrealistic expectations. Educating parents thoroughly before initiating NAM, providing counseling during follow-ups, offering digital NAM or aligner-type appliances, and creating peer support groups can enhance compliance [6,8,34].

- Tooth eruption of neonatal teeth can be seen erupting through the cleft anytime during the course of NAM treatment. These can erupt at varied angulations and positions. The situation can be managed either by leaving the tooth in place, if it isn't too far from a primary tooth location, or considered for extraction. The extraction can be done beforehand as a separate procedure or at the time of lip repair [14].
- Fungal infections and stomatitis can rarely develop under the plate. A referral to the infant's paediatrician should be made in such cases. It's recommended to keep the plate off till the condition is completely cured [14].
- Delayed Surgical Timeline may result from complications or compliance issues that hinder adequate progress. Early multidisciplinary coordination with surgeons is essential to adjust surgical timelines and consider alternative pre-surgical strategies if NAM proves ineffective [14,23].
- **Biomaterials and smart devices:** New biocompatible polymers with antimicrobial properties, flexibility, and self-adaptive features are being explored for PSIO devices. These materials promise greater infant comfort and safety, lower infection risk, and enhanced appliance durability [20,34].
- **Sensor-embedded appliances:** Sensors integrated into PSIO devices are being developed to monitor intraoral pressure, fit, and usage in real-time. These innovations can inform timely clinical decisions and improve treatment outcomes [34].
- **Telehealth for remote monitoring:** The integration of secure video consultations allows cleft care teams to remotely evaluate appliance fit and provide real-time guidance for minor modifications to caregivers, significantly improving access in rural or underserved areas [34].

#### Future directions and innovations

The field of pre-surgical infant orthopedics (PSIO) continues to evolve rapidly, driven by advances in materials science, digital technology, and a deeper understanding of craniofacial development [20,34].

- **Advances in 3D printing and digital workflow integration:** Three-dimensional (3D) printing has revolutionized the fabrication of patient-specific PSIO appliances, enabling higher precision, reproducibility, and faster turnaround. Integration with intraoral scanning and digital planning platforms has significantly reduced manual modeling errors and enhanced interdisciplinary collaboration [20,34].
- **Artificial intelligence-supported predictive growth modelling:** AI-based predictive modeling tools are now being developed to simulate craniofacial growth, which may help tailor interventions to individual infants by forecasting how cleft morphology may respond to specific PSIO strategies [34].
- **Automated design pipelines:** Machine learning algorithms are being trained to automate the design of NAM or other PSIO appliances from digital scans, allowing clinicians to generate optimized designs quickly and consistently, which reduces variability and speeds up the learning curve [34].

#### Gene therapy

Although not yet part of clinical protocols for cleft lip and palate (CLP) or pre-surgical infant orthopedics (PSIO), gene therapy shows possible future applications. Advances in gene-editing tools such as CRISPR-Cas9 may enable correction of mutations in genes like *IRF6* and *MSX1*, which are associated with CLP development [34]. Additionally, gene therapy could enhance tissue regeneration by upregulating osteogenic and soft tissue growth factors such as BMPs and TGF- $\beta$ , potentially improving alveolar molding outcomes. It may also help reduce post-surgical scarring by targeting genes involved in inflammation and fibrosis. However, significant challenges remain, including safety risks-particularly in neonates-like inadequate delivery methods for targeting craniofacial tissues, and unresolved ethical concerns surrounding genetic manipulation in infants [34].

#### Conclusion

Pre-surgical infant orthopedics (PSIO) plays a critical role in the early management of cleft lip and palate, aiming to improve surgical outcomes and support optimal craniofacial development. Over the decades, PSIO techniques have evolved from passive appliances to advanced digitally designed interventions. Emerging technologies-such as AI-driven design, smart biomaterials, and telehealth integration-promise to further enhance the precision, accessibility,



and effectiveness of care. As innovation continues to reshape this field, a multidisciplinary, patient-centered approach remains essential to maximizing both functional and aesthetic outcomes for affected infants.

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