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CASE REPORT

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Preserving early presurgical access for infants with cleft lip and palate when nasoalveolar molding is inaccessible, a case series of six infants

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Abstract

Background: Cleft lip with or without cleft palate has a narrow neonatal window during which presurgical infant orthopedics can improve cleft segment alignment and nasal form. Nasoalveolar molding (NAM) is the reference technique but is frequently inaccessible because of cost, distance, and specialist availability. **Cases**: We describe six consecutive infants with unilateral cleft lip with or without cleft palate treated with DynaCleft® at a single university based pediatric dental clinic. The device was used in three distinct clinical roles, as a standalone therapy in three infants, as a bridge to NAM in two infants, and as an adjunct to NAM in one infant. Alveolar cleft width was measured with a calibrated caliper. Change in nasal form was recorded on a non validated categorical scale without blinding, and was reported as a subjective clinical impression rather than as a measured outcome. A measurable alveolar gap was present in four infants. Reductions of 11 mm and 5 mm were recorded in the two bridge infants, 11 mm in the adjunct infant, and 3 mm in the one standalone infant with a measurable gap, who had a Simonart's band. Referral timing and clinical role were completely confounded, so the series does not support a simple timing effect. The only adverse event attributed to DynaCleft® was mild skin irritation. **Conclusions**: In this small case series, DynaCleft® was feasible in three separate presurgical roles and may help preserve an early presurgical pathway when NAM cannot be started promptly. Because this series' design is descriptive, the grading subjective, and follow up short, these observations are limited to short term presurgical findings in six infants. No comparative or causal conclusion can be drawn, and prospective controlled studies with validated and blinded outcome measures are needed.

Keywords

Cleft lip and palate; Nasoalveolar molding; Presurgical infant orthopedics; DynaCleft®; Early intervention; Cartilage plasticity; Health equity; Early referral

1. Introduction

Cleft lip with or without cleft palate affects approximately 1 in 700 live births and is among the most common congenital craniofacial anomalies worldwide [1, 2]. Beyond its well-recognized effects on feeding, growth, speech, hearing, and psychosocial development, cleft lip with or without cleft palate is characterized by a narrow early treatment window during which presurgical infant orthopedics may substantially improve cleft segment alignment and nasal form before primary surgical repair.

The biological basis for this window is well established. Maternally transferred estrogen stimulates hyaluronic acid synthesis within the neonatal cartilage matrix, disrupting collagen and elastin crosslinking and reducing cartilage rigidity [3, 4]. This transient increase in tissue malleability is greatest during the first weeks of life and then declines. As maternal estrogen clears, cartilage stiffness increases progressively over roughly the first six to eight weeks [3, 4]. It is important to emphasize that this decline is graded rather than a discrete closure. Peak responsiveness passes early, but a measurable capacity for correction can persist beyond the neonatal period, so clinical response attenuates gradually rather than ending abruptly. Because the therapeutic window is governed by tissue biology rather than by the device employed, this graded time dependence is expected on mechanistic grounds to apply across presurgical infant orthopedic modalities.

Nasoalveolar molding (NAM) is the most established presurgical infant orthopedic technique and uses a custom intraoral acrylic appliance combined with nasal stents to reshape the alveolar segments and nasal cartilage simultaneously. It has been associated with improvements in alveolar alignment, nasal symmetry, and surgical outcomes in multiple studies [3, 5, 6]. Conventional NAM nevertheless

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contains an inherent temporal limitation. Nasal stenting is typically deferred until the interalveolar gap narrows to approximately 5 mm, because premature stenting risks a meganostril deformity from excessive lateral soft tissue tension [7, 8]. Reaching this threshold through intraoral molding alone often requires four to eight weeks [9, 10], which consumes precisely the window of greatest neonatal cartilage plasticity. Earlier nasal correction may also carry functional significance, because neonates are obligate nasal breathers and may benefit from improved airway patency, more effective feeding, and more stable sleep during the first weeks of life. NAM also places substantial demands on families and on the treating center. It requires specialized expertise, custom appliance fabrication, and frequent follow up visits, often weekly, together with substantial caregiver commitment over several months [11, 12].

When NAM is not immediately accessible, the practical clinical question is not whether NAM is ideal, but whether any presurgical intervention can be started within the neonatal period so that the biologic window is not lost. DynaCleft® (Southmedic, Barrie, Ontario, Canada) is one such option. It combines elastic adhesive taping with an external nasal elevator to approximate lip segments and lift collapsed alar cartilage. It requires no minimum alveolar gap and no custom appliance fabrication, and it can be applied by caregivers at home after initial training, so treatment can begin within days of birth [13, 14]. Other prefabricated presurgical systems have also been described [15, 16].

Only DynaCleft® was used in the present series. No infant was treated with any other prefabricated system, and this report makes no claim about a device that was not used here. For the same reason, no comparison is drawn between DynaCleft® and NAM or DynaCleft® and any other prefabricated appliance, because a single arm case series cannot support a comparative statement.

Prefabricated systems have already been described as accessible alternatives [13–16], but published accounts of how a single prefabricated device is deployed across distinct clinical roles within one practice remain limited. The specific contribution of this report is therefore descriptive and practical. To our knowledge it is the first consecutive series to document the use of one prefabricated system in three separate roles within a single practice, namely as a standalone therapy, as a bridge to a custom NAM appliance, and as an adjunct that maintains treatment continuity when a medically complex infant cannot wear NAM. We describe six consecutive infants with unilateral cleft lip with or without cleft palate managed in this way. The report is not a demonstration of efficacy and is not comparative. It is intended to show how an accessible presurgical approach can be positioned in practice when NAM is delayed or unavailable, and to generate hypotheses for prospective investigations.

2. Case presentation

2.1 Setting, participants, and ethics

This CARE compliant retrospective case series describes six consecutive infants with unilateral cleft lip with or without cleft palate treated with DynaCleft® as part of presurgical infant orthopedics at a single University based pediatric dental clinic. Institutional Review Board approval (IRB202600320) and written parental consent for publication of deidentified clinical information were obtained. Infants evaluated between 01 January 2025, and 28 February 2026, were included if they received DynaCleft® as part of presurgical infant orthopedics and their caregivers provided informed consent, regardless of medical complexity. The series was not designed to compare modalities or to establish efficacy, and it does not include a control group.

2.2 Definitions and criteria for treatment allocation

Two terms are used throughout this report and are defined here. Noninvasive presurgical approximation refers to any method that narrows the labial and alveolar gap and reshapes the nasal cartilage using external taping, elastic tension, or a removable appliance, without an incision. This category includes simple lip taping, DynaCleft®, and conventional NAM. Invasive presurgical approximation refers to a surgical procedure carried out before definitive lip repair in order to narrow the cleft, and at our center this means surgical lip adhesion, which is performed by the cleft surgical team rather than in the pediatric dental clinic.

The choice between the two categories is made in the multidisciplinary cleft clinic. Noninvasive approximation is the default pathway and was used in all six infants reported here. Lip adhesion is considered only when the infant cannot tolerate a molding appliance or sustained home taping for medical or social reasons. No infant in this series met these criteria, so no invasive approximation was performed in this cohort and no surgical approximation outcomes are reported.

2.3 Intervention and follow up

At the initial visit, caregivers underwent standardized instruction in device application, including taping technique, proper positioning of the nasal elevator, skin preparation, and recognition of adverse effects. Caregivers then performed daily home application. Adherence and application technique were assessed at each follow up visit through caregiver report and photographic documentation, with corrective guidance provided when necessary. Follow up visits were scheduled every two to four weeks based on clinical need and caregiver comfort, which reduced visit frequency compared with traditional NAM protocols that typically require weekly visits.

Depending on cleft severity and treatment goals, DynaCleft® was used in three distinct clinical roles. It was used as standalone therapy, following initial lip taping, for infants with less complex anatomy or where NAM was not indicated or not accessible. It was used as bridge therapy before NAM for wider or more complex clefts, where early DynaCleft® use was intended to reduce initial cleft dimensions and improve nasal contour before custom appliance fabrication. It was used as adjunctive therapy for medically complex infants during unavoidable periods when NAM could not be worn, helping to maintain previously achieved outcomes and to support continued alveolar molding and nasal correction until primary lip surgery. In the two bridge infants, DynaCleft® and a custom

intraoral appliance were not started together at the first visit for two practical reasons. First, a custom NAM appliance requires a caregiver decision followed by impression and laboratory fabrication, and no intraoral appliance is available during that interval, so external approximation was the only treatment that could begin immediately. Second, introducing two devices simultaneously in the first days of life adds considerably to caregiver burden at the point when families are least prepared, and a staged start was judged more likely to be tolerated. Once the appliance was delivered, DynaCleft® was continued alongside NAM in both infants rather than being withdrawn.

2.4 Outcome assessment

Two outcomes were recorded before primary lip repair. Both are descriptive rather than confirmatory, and neither should be read as a validated endpoint. The first was change in alveolar cleft width, defined as the difference in the widest transverse dimension of the alveolar cleft between the initial visit and the final presurgical visit, measured directly with a calibrated caliper. The term alveolar cleft width is used consistently throughout this report, and no other measure of arch dimension is reported. The second was change in nasal form, recorded on serial clinical photographs. No validated instrument was applied. Change in nasal form was recorded on a predefined categorical scale of none, mild, moderate, or marked, based on the composite appearance of four features, namely nostril symmetry between the cleft and non-cleft sides, judged from the shape and the size of the nostril on each side, columella deviation, alar dome projection on the cleft side, and nasal tip position relative to the facial midline. Grading was performed by the treating clinician alone and was not blinded, with no second independent rater, no interobserver reliability analysis, and no validated esthetic outcome measure. This grading therefore carries a substantial risk of observer bias and is reported throughout as a clinical impression rather than as a measured result. Secondary observations included age at treatment initiation, caregiver adherence, weight change, and adverse effects.

2.5 Photographic documentation

Clinical photographs were obtained at each visit for routine care and not as a pre-determined research imaging protocol. Head position and camera angulation were not standardized across visits, standardized basal views were not consistently obtained, and intraoral occlusal photographs were not systematically recorded. The photographic record therefore serves only as qualitative illustration. It does not permit calibrated photogrammetric evaluation, and it cannot independently corroborate either the caliper measurements or the nasal form grading reported below. The visual evidence for treatment effect in this report is consequently limited, and the images should be read as documentation of clinical course rather than as measurement. A standardized imaging protocol for future work is proposed in Section 3.1.

2.6 Case descriptions

Six infants with unilateral cleft lip with or without cleft palate, four female and two male, were managed across the three clinical roles (**Supplementary Table 1**). Because the three roles describe different clinical situations, the cases are presented and interpreted separately by role and are not pooled. The components of the device and their application *in vivo* are shown in Fig. 1. Treatment course of each infant, including age at referral, duration of DynaCleft® use, the point of transition to a custom NAM appliance where applicable, and age at primary lip repair, is summarized in Fig. 2.

Mean patient age at treatment initiation was 5.8 weeks, ranging from the first week of life to 21 weeks. Treatment began within the first three weeks of life in four infants. Individual cases are described below and grouped by clinical role. Representative photographs of all six patients before treatment, after presurgical infant orthopedics, and following primary lip repair are presented in Fig. 3.

2.6.1 Standalone therapy (cases 1, 2, and 6)

Case 1: an infant with unilateral incomplete cleft lip and alveolus in whom DynaCleft® was started at the second week of life. Because the diagnosis involved the alveolus without an associated palatal cleft, no measurable alveolar gap was present, and alveolar molding was not included in their treatment. Change in nasal form was recorded as marked. The only device related adverse event was mild skin irritation at the taping site.

Case 2: an infant with unilateral complete cleft lip and alveolus. A financial barrier delayed initiation until approximately

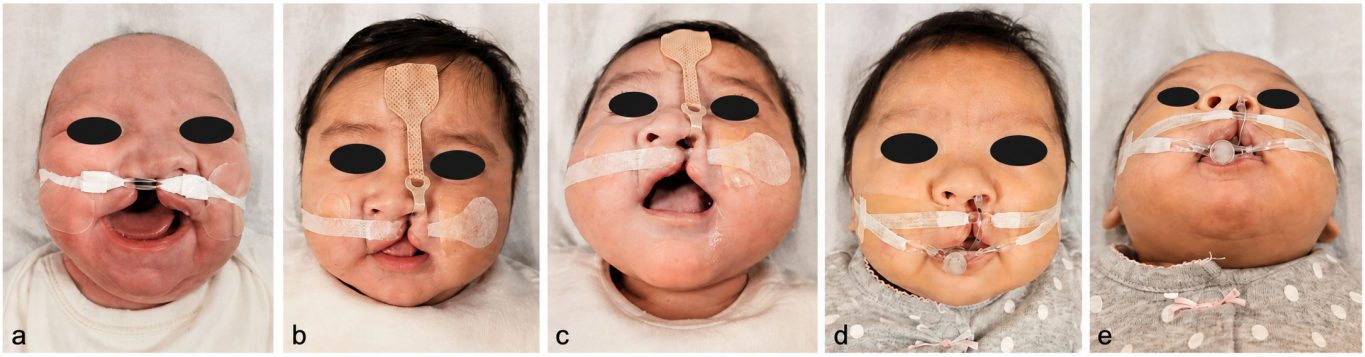


FIGURE 1. Representative clinical photographs illustrating different presurgical approaches used in infants with cleft lip and palate. (a) Lip taping. (b,c) DynaCleft® therapy. (d,e) Nasoalveolar molding (NAM) appliance therapy.

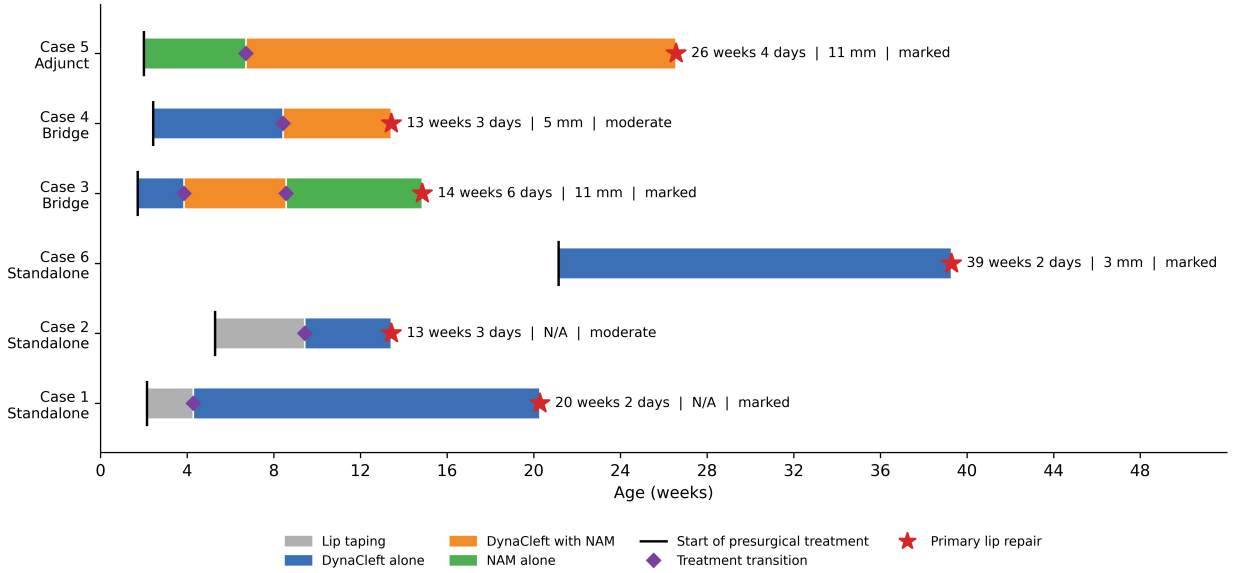


FIGURE 2. Treatment course of each infant. Labels to the right of each bar give treatment duration, cleft width reduction, and change in nasal form. NAM, Nasoalveolar molding.



FIGURE 3. Clinical photographs obtained at three time points: before initiation of presurgical treatment, at the completion of presurgical treatment before primary lip repair, and after primary lip repair. Photographs were not obtained using a standardized imaging protocol.

5 weeks of age. As in Case 1, the diagnosis involved the alveolus without an associated palatal cleft. Change in nasal form was recorded as moderate, and no device related adverse event was reported.

Case 6: an infant with unilateral cleft lip and palate in whom referral was delayed, so treatment did not begin until 21 weeks of age. Despite this late start, an alveolar cleft width reduction of 3 mm was recorded and change in nasal form was recorded as marked. Mild skin irritation was the only device related adverse event. Two features of this case require explicit statement. First, no intraoral appliance was used, so the reduction in the alveolar gap cannot be attributed to intraoral molding. The external elastic strips applied approximating tension across the lip segments, and in the presence of a Simonart's band that tension is transmitted through the soft tissue bridge to the underlying alveolar segments, which is the most plausible mechanism for the narrowing observed here. Second, the Simonart's band is itself a favorable prognostic feature. Infants with a Simonart's band generally present with a narrower cleft and a less severe nasal deformity at baseline, so the marked nasal result recorded in this infant cannot be separated from that anatomical advantage. This case is therefore presented as a late referral in a favorable anatomical subtype, and it is not offered as evidence about the effect of initiation timing.

2.6.2 Bridge to NAM (cases 3 and 4)

Case 3: an infant with unilateral cleft lip and palate treated with DynaCleft® from the first week of life to reduce initial cleft dimensions before custom NAM appliance fabrication. An alveolar cleft width reduction of 11 mm was recorded and change in nasal form was recorded as marked. Mild skin irritation was the only device related adverse event, and no adverse event was attributed to the subsequent NAM appliance.

Case 4: an infant with unilateral cleft lip and palate started treatment in the second week of life as a bridge to NAM and following the same staged sequence as Case 3. An alveolar cleft width reduction of 5 mm was recorded and change in nasal form was recorded as moderate. Mild skin irritation was the only device related adverse event, and no adverse event was attributed to the subsequent NAM appliance. In both bridge cases, DynaCleft® provided active treatment during the interval between the first visit and delivery of the custom appliance. The reasons why an intraoral appliance was not started simultaneously in these two infants are set out in Section 2.3.

2.6.3 Adjunct to NAM (case 5)

Case 5: a medically complex infant with unilateral cleft lip and palate who required gastrostomy tube placement. DynaCleft® was used alongside NAM from the second week of life during periods when treatment continuity had to be maintained. An alveolar cleft width reduction of 11 mm was recorded and change in nasal form was recorded as marked. Mild skin irritation was attributed to DynaCleft®. After initiation of NAM the infant repeatedly presented with intraoral ulceration at the sites of plate contact and required frequent rest periods from the appliance. These events were attributed to the NAM plate. This case demonstrates feasibility of adjunctive use in the setting of significant medical comorbidity.

2.7 Confounding of timing and clinical role

Referral timing and clinical role were completely confounded in this series, and this must be stated before any pattern is described. Both delayed cases were standalone cases. Case 2 started at about 5 weeks because of a financial barrier, and Case 6 started at 21 weeks because of delayed referral. Both bridge cases, Cases 3 and 4, were early starters. Any apparent gradient across the series therefore reflects timing and clinical role together and cannot be attributed to timing alone. Results are reported separately by clinical role, because the three roles describe different clinical situations with different comparators and should not be interpreted collectively. In the standalone group, a measurable alveolar gap was present only in Case 6, in which a reduction of 3 mm was recorded in the presence of a Simonart's band. Cases 1 and 2 involved the alveolus without an associated palatal cleft, so no measurable alveolar gap was present, and alveolar molding was not included in their treatment. In the bridge group, reductions of 11 mm and 5 mm were recorded in Cases 3 and 4. In the adjunct group, a reduction of 11 mm was recorded in Case 5. These values are deliberately not averaged across the three groups, because a pooled mean drawn from three different clinical strategies would not describe any one of them. Using the predefined categorical scale, change in nasal form was graded as moderate to marked in all six infants. As stated in Section 2.4, this grading was qualitative and unblinded, was performed by the treating clinician alone, used no validated instrument, and had no interobserver reliability analysis, so it should be interpreted as a subjective clinical impression susceptible to observer bias rather than an objective measurement.

2.8 Weight trajectories and adverse events

Weight gain during treatment varied across cases and appeared to reflect intercurrent illness rather than treatment related factors, based on the temporal association between weight changes and documented clinical events. Cases 1, 3, and 4, all initiating treatment within the first three weeks of life without significant intercurrent illness, maintained stable or improved daily weight gain throughout treatment. Cases 2, 5, and 6 experienced periods of attenuated weight gain associated with intercurrent illness, which included fever, feeding difficulties requiring gastrostomy tube placement, and diarrhea respectively, or with delayed initiation, or with both. Weight trajectories remained acceptable during these periods and improved and stabilized as the underlying issues resolved.

Adverse events are reported separately by attribution to avoid ambiguity, and are listed infant by infant in **Supplementary Table 1**. The only event attributed to DynaCleft® was mild skin irritation at the taping site, which is consistent with previously reported tolerability profiles for external taping systems in this population. In Case 5, frequent alveolar and palatal ulceration occurred, and this was attributed to the concurrent custom NAM appliance rather than to DynaCleft®. Each episode resolved with a pause in taping of three to four hours and with hydrocolloid tape placed beneath the lip strips or beneath the forehead anchor of the nasal elevator, and no infant discontinued treatment. No major device related adverse events were attributed to DynaCleft® in any infant.

Several theoretical risks of the DynaCleft® device warrant consideration. The nasal elevator component may pose a potential aspiration hazard if accessed by the infant during application, removal, or repositioning, although no such adverse events have been reported in the literature to date. Prolonged placement of the nasal elevator at a single site may lead to localized skin indentation, which requires periodic repositioning. Inadequate tensioning may yield suboptimal nasal correction, whereas excessive force carries a risk of soft tissue injury, including tearing at the nasal base. To mitigate these risks, caregivers were encouraged to photograph the treated area at regular intervals and to share the images with the provider so that skin integrity, taping tension, and progress could be assessed remotely.

3. Discussion

This series described how one accessible prefabricated device functioned in three separate clinical roles when NAM was delayed or unavailable. The design is a consecutive case series without a control group, so the observations below are exploratory and are offered to shape future prospective work rather than as evidence of efficacy. Because the three roles describe different clinical situations, they are discussed separately and are not treated as a single intervention. Observations are presented case by case within each role, no pooled effect is claimed, and the constraints of the design are stated here and in the limitations rather than being restated at each point below.

A tempting reading of the series is that earlier initiation produced better outcomes. We do not make that claim. Early initiation is biologically desirable, but nothing in these data can isolate an independent effect of timing. As the effects of maternally transferred estrogen on cartilage malleability wane over the first six to eight weeks of life, morphologic responsiveness declines progressively rather than ending abruptly. Case 6 began at 21 weeks and still showed measurable change, but we no longer present this case as evidence that late initiation attenuates rather than abolishes the response. That reading is confounded, because this infant had a Simonart's band, and infants with a Simonart's band typically present with a narrower cleft and more favorable nasal morphology at baseline. A comparable result in a late referral without a Simonart's band would be required before any statement about residual responsiveness could be supported. Case 6 is therefore retained as a descriptive late referral in a favorable anatomical subtype and carries no inference about timing.

The practical relevance of this time dependence for infants who lack access to NAM is not device specific. The therapeutic window is governed by tissue biology, so what matters is that an appropriate presurgical intervention begins early. In this series that intervention was DynaCleft®, which requires no minimum alveolar gap and can be started within days of birth. Because no other prefabricated system was used here, this report offers no evidence about any other device, and mechanistic argument about systems that were not applied has been removed from this discussion. In Cases 1, 2, and 6, infants with less complex cleft anatomy, it was used as a standalone approach, and clinically observed presurgical improvement was recorded while the logistical and financial demands of NAM were avoided. In Cases 3 and 4, infants with wider clefts and greater alveolar discrepancy, early DynaCleft® use preceded transition to NAM and was intended to improve initial alveolar alignment and nasal form before the custom appliance was fabricated, converting what would otherwise have been a passive waiting period into an active treatment phase while the biological window remained open. In Case 5, a medically complex infant requiring gastrostomy tube placement, DynaCleft® was used alongside NAM with observed improvement, which shows feasibility in the setting of significant medical comorbidity.

These observations can be set alongside the small published literature on prefabricated presurgical systems. Tanikawa described nasal elevator and lip taping as an accessible presurgical option in low resource settings and emphasized reduced visit frequency and caregiver administered application [13]. Bahaa and colleagues compared a conventional NAM protocol with application of the DynaCleft® nasal elevator in infants with unilateral cleft lip and palate and reported reduction in cleft width and improvement in nasal appearance in both groups [14]. The alveolar reductions and the direction of nasal change recorded here are broadly consistent with those accounts. Two differences deserve mention. First, the published reports describe the device in a single role, whereas the present series describes the same device in standalone, bridge, and adjunct roles within one practice. Second, those reports used comparative or protocol driven designs with defined comparators, whereas the present report is uncontrolled and unblinded, so the agreement in direction of change should be read as consistency of clinical impression and not as confirmation of effect.

Several service level factors bear on early access. Many families learn of the diagnosis through prenatal screening and can prepare in advance, cleft lip is usually identified at birth even when prenatal ultrasonography misses it, and isolated cleft palate may go undetected until feeding difficulties arise, which underscores the importance of careful oral examination during the newborn assessment. Variable awareness among frontline providers about available presurgical interventions and their time sensitive window may also contribute to delayed referral [17–19]. Traditional NAM protocols often require frequent visits to specialized centers, sustained caregiver time, and financial resources that may disproportionately limit access for families in rural, underserved, or resource constrained settings [11, 12, 20, 21]. Prefabricated systems, with their reduced visit frequency and caregiver administered home application, may in principle serve as practical entry points into early cleft care in such settings, as illustrated in the bridge cases. This series was conducted at a single university based academic clinic, a comparatively well-resourced environment, so these access considerations are conceptual and hypothesis generating rather than demonstrated benefits, and they require testing in the settings they describe.

These observations also sit within a wider literature on comprehensive cleft care that extends well beyond the presurgical period. Contemporary multidisciplinary pathways coordinate surgical, orthodontic, speech, and psychosocial care from birth to skeletal maturity, and reviews of comprehensive management describe the interdisciplinary framework within

which presurgical preparation takes place [22]. The choice and execution of primary surgery continue to shape outcome long after the presurgical phase, as shown in comparative analyses of primary palatoplasty techniques and their postoperative complications [23]. Long term cohort data further show that many patients require several secondary procedures on the lip, nose, and alveolus into late adolescence, and that greater baseline severity is associated with a greater cumulative surgical burden [24]. This longer view matters here in two ways. It underlines that any presurgical benefit must eventually be judged against long term functional, orthodontic, speech, and esthetic outcomes, none of which were assessed in this series. It also indicates that the most informative future evaluation of accessible presurgical approaches will be one that follows infants well past primary repair rather than one that stops at the final presurgical visit.

Within these limits, the series offers a clinically grounded illustration of how an accessible presurgical approach can be used when resource intensive NAM is delayed or unavailable. Three practical steps follow. The first is early identification of cleft lip with or without cleft palate. The second is referral to a multidisciplinary cleft team, ideally within the first week of life. The third is documentation of social, geographic, or financial barriers at the point of referral, which allows the receiving team to select a feasible presurgical pathway. None of these steps requires specialized presurgical infant orthopedic training.

This study has several important limitations, which together define it as a descriptive and hypothesis generating report rather than a comparative or confirmatory one. The sample was small, with only six infants. The design was retrospective, there was no control group, and the experience was limited to a single center. The three clinical roles represent fundamentally different clinical situations. They are reported separately for that reason, but this heterogeneity also means that referral timing and clinical role are completely confounded, which prevents attribution of any difference in outcome to a single variable including referral timing. In addition, differences in treatment duration, baseline cleft anatomy and severity, comorbidities, concurrent NAM use, and other case specific factors further limit direct comparison of outcomes across these six infants. Only DynaCleft® was used, so this report supports no statement about any other prefabricated system.

Measurement and documentation were also limited. Alveolar cleft width could not be measured in two infants because the alveolus was notched without separation of the alveolar segments, so no gap was present to measure. Alveolar cleft width was obtained by indirect measurement with a paper strip and caliper by a single unbinded clinician, without assessment of reproducibility. Change in nasal form was graded qualitatively by the treating clinician alone, without blinding, without a second independent rater, without interobserver reliability analysis, and without a validated esthetic outcome instrument. This introduces substantial observer bias and is the single largest threat to the internal validity of the report. Photographic documentation was not standardized. Head position and camera angulation varied across visits, standardized basal views were not consistently obtained, and intraoral occlusal photographs were not systematically recorded, so the images cannot objectively substantiate the reported millimeter reductions.

Follow up was short. Outcome assessment was confined to the presurgical period and the immediate period after primary lip repair. Functional, orthodontic, speech, and postoperative esthetic outcomes were not evaluated, and no infant has been followed to alveolar bone grafting or to skeletal maturity. Every conclusion drawn from this series is therefore restricted to short term presurgical observation. Nothing reported here speaks to long term outcome, to long term burden of care, or to the durability of any change recorded before surgery.

Future work should therefore be prospective and multicenter, and should enroll a larger number of infants within the recommended initiation window while also including a comparison or control condition. It should apply standardized and blinded quantitative outcome measures, including calibrated photogrammetry or three dimensional imaging for nasal form and cast based or digital measurement for alveolar width. It should also adopt a fixed imaging protocol that specifies standardized frontal, basal, and worm eye views with controlled head position and an in image scale reference, together with routine intraoral occlusal records. Such a design would allow the relationship between referral timing, modality selection, and presurgical outcomes to be characterized across diverse clinical and socioeconomic contexts.

4. Conclusions

In this small retrospective case series, DynaCleft® was feasible in three separate presurgical roles, namely as a standalone intervention, as a bridge to NAM, and as an adjunct in a medically complex infant. The observations are descriptive and case specific, and the series supports no comparative or causal statement. Their practical implication is that early identification of cleft lip with or without cleft palate and prompt referral to a multidisciplinary cleft team allow an accessible presurgical option to be started while a family waits for definitive care, a possibility that now requires prospective controlled evaluation with standardized and blinded outcome measures and follow up extending beyond primary repair.

AVAILABILITY OF DATA AND MATERIALS

The data supporting the findings of this study are contained within the article and its **Supplementary materials**. Additional de-identified data may be available from the corresponding author upon reasonable request, subject to patient privacy and ethical restrictions.

AUTHOR CONTRIBUTIONS

MSL and MG—conceived and designed the study; analyzed and interpreted the data. MSL—provided clinical care, collected the clinical data, and performed the measurements; drafted the manuscript. MG—revised it critically for important intellectual content. Both authors read and approved the final manuscript and agree to be accountable for all aspects of the work.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Institutional Review Board of Florida (approval number IRB202600320). Written informed parental consent for publication of deidentified clinical information was obtained for all participants.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Marcio Guelmann is serving as one of the Editorial Board members of this journal. We declare that Marcio Guelmann had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to CMK.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.jocpd.com/files/article/2117538280503164928/attachment/Supplementary%20material.docx.

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