

# Early Weight Gain in Infants With Cleft Lip and Palate Treated With and Without Nasoalveolar Molding: A Retrospective Study

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## Abstract

**Objective:** To assess weight gain of infants with cleft lip and/or palate (CL ± P) treated with nasoalveolar molding (NAM).

**Design:** Retrospective, case–control chart review.

**Setting:** Doernbecher Children’s Hospital, Oregon Health & Science University, Portland, Oregon.

**Patients, Participants:** Infants with nonsyndromic CL ± P and noncleft controls.

**Interventions:** Prior to primary lip surgery, NAM was either included (+NAM) or not included (–NAM) in the cleft treatment protocol.

**Main Outcome Measure(s):** Weight gain and percentage weight gain relative to initial weight were compared among +NAM, –NAM, and control groups from birth to 7 months and from birth to 36 months.

**Results:** Comparing +NAM and –NAM groups, no significant difference in weight or percentage weight gain was found in either time window. Compared to controls, from birth to 7 months, both CL ± P groups weighed less ( $P < .001$ ), while percentage weight gain was greater for the +NAM ( $P < .001$ ) and did not differ for –NAM. From birth to 36 months relative to controls, weight for +NAM showed no significant difference and –NAM weighed less ( $P < .01$ ), while percentage weight gain was greater for both CL ± P groups ( $P < .001$ ).

**Conclusions:** Comparisons of CL ± P infants treated with and without NAM showed that with the NAM appliance, despite its added complexity, there was no adverse impact on weight gain. Comparisons to noncleft, control infants suggests that NAM treatment may have a beneficial impact on weight gain.

## Keywords

cleft lip and/or cleft palate (CL ± P), unilateral cleft lip and/or palate (UCL ± P), bilateral cleft lip and/or palate (BCL ± P), nasoalveolar molding (NAM).

## Introduction

One of the earliest observed comorbidities in infants with a unilateral cleft lip and/or palate or bilateral cleft lip and/or palate is a low birth weight and delayed weight gain (Avedian and Ruberg, 1980; Choi et al., 1991; Brine et al., 1994; Lee et al., 1997; Gopinath and Muda, 2005; Bessell et al., 2011; Miranda et al., 2016). Nyarko and associates (2013) concluded that infants born with a cleft lip and/or palate (CL ± P) have twice the risk for low birth weight compared to noncleft infants. In noncleft infants, nutritive sucking is achieved through negative intraoral pressure created by sealing the lips

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and velopharynx while expanding the intraoral cavity either through contraction of the tongue or movement of the mandible, whereas infants with CL  $\pm$  P are unable to seal their oral cavity and therefore cannot create sufficient negative pressure (Clarren et al., 1987; Choi et al., 1991; Brine et al., 1994; Masarei et al., 2007; Zarate et al., 2010; Miller, 2011; Kaye et al., 2016; Miranda et al., 2016). Delayed weight gain has been attributed to the abnormal exchange between nasal and oral cavities, resulting in prolonged feeding times, nasal regurgitation, increased risk of choking, and aspiration, where the infant often fatigues before reaching a full feeding (Jones, 1988; Choi et al., 1991; Brine et al., 1994; Gopinath and Muda, 2005; Masarei et al., 2007; Miller, 2011; Kaye et al., 2016; Miranda et al., 2016).

A proposed benefit of presurgical infant orthopedics, such as alveolar molding, has been to facilitate feeding (Brine et al., 1994; Uzel and Alparlan, 2011). Published in 2005, the Dutch-cleft study examined the efficacy of alveolar molding appliances in achieving weight gain and found the appliances had no positive effect on feeding (Prahl et al., 2005). Because of this, investigators concluded that “infant orthopedics with the aim of improving feeding and consequent nutritional status in infants with unilateral cleft lip and palate can be abandoned” (Prahl et al., 2005).

The nasoalveolar molding (NAM) appliance was introduced in the early 1990s aimed at improving the aesthetic outcome of the primary lip and nose surgery by reducing the severity of the cleft deformity prior to surgery (Cutting et al., 1998). Since the method’s introduction, the treatment approach has shown increasingly wider use (Hansen et al., 2016). The appliance is similar to the alveolar molding appliance mentioned above, with the addition of nasal stents aimed at shaping the nasal cartilages (Cutting et al., 1998; Barillas et al., 2009; Garfinkle et al., 2011; Grayson and Garfinkle, 2014). Due to the appliance’s more complex design on account of the nasal stents and increased physical contact with facial soft tissues relative to the alveolar molding appliance, it should be determined whether treatment involving the NAM appliance poses a burden on weight gain in infants with CL  $\pm$  P.

At the Doernbecher Children’s Hospital (DCH) Craniofacial Clinic (Portland, Oregon), when clinically indicated for treatment of CL  $\pm$  P infants, caregivers are given the choice of using the NAM appliance (+NAM) or not using the appliance (–NAM) where approximately 85% select NAM treatment. With +NAM treatment, on average the NAM appliance is delivered at 4 weeks and adjusted weekly or biweekly until the infant reaches 4 to 5 months of age when the primary lip surgery is performed. Using +NAM, –NAM, and unaffected (non-CL  $\pm$  P) patient cohorts, this study examines infant weight gain from birth to 7 months to assess impact while the NAM appliance was in use and from birth to 3 years to evaluate longer term patterns in weight gain. The null hypothesis tested is that the use of the NAM appliance does not adversely impact weight gain relative to CL  $\pm$  P infants who did not receive NAM therapy.

## Methods

This study was performed with the approval of the institutional review board, Oregon Health & Science University (OHSU). Records were retrospectively and consecutively reviewed from 2014 and earlier for infants with CL  $\pm$  P in the database of DCH Craniofacial Clinic. Records from noncleft control participants were similarly reviewed from the Pediatric Medicine Clinic at DCH. Written consent to participate in research was obtained from each caregiver at the first appointment, and each patient was assigned an anonymous identifier for purposes of data collection.

Minimum sample size was based on a power calculation using 0.2 kg as the average initial weight difference between CL  $\pm$  P and control groups, with a standard deviation of 0.3 kg. To achieve an  $\alpha$  level of .05 and a power of 0.8, each group required at least 38 participants. Inclusion criteria were CL  $\pm$  P infants who were fed orally and had a minimum of 5 weight measurements during the 3-year study period, +NAM patients completed NAM therapy, and –NAM patients did not initiate NAM therapy. Exclusion criteria were premature birth (child-birth occurring earlier than 37 completed weeks of gestation), the presence of a syndrome, supplemental feeding through a G-tube, or records with incomplete weight measurements. Control participants were infants born at OHSU Hospital with no complications and having no medical conditions or use of medications. Records were reviewed consecutively from 2014 to 2008 in order to obtain 40 participants in each group.

All +NAM participants had NAM treatment by a single provider (J.S.G.) at the DCH Craniofacial Clinic. Naked weight measurements were recorded in kilograms (Scale-Tronix Pediatric Scale 4800; Welch Allyn, Skaneateles Falls, New York), and age was recorded in days at each appointment with the craniofacial team. Weights for control patients were from recordings obtained during pediatric checkup appointments.

In order to evaluate changes in weight during time prior to and through primary lip surgery, as well as longer term, +NAM, –NAM, and control groups were evaluated over 2 overlapping time windows: (1) birth to 7 months and (2) birth to 36 months. To assess parity of the 3 groups in terms of data collection time points, means and standard deviations were determined for age at first weight entry, weight at first entry, number of weight entries from birth to 7 months, age at last entry from birth to 7 months, number of entries from birth to 36 months, and age at last entry from birth to 36 months. Weight gain as measured as well as calculated based on percentage of initial weight was compared among the 3 groups using a generalized linear regression with repeated measurements. In order to portray the trend between age and weight gain more clearly, smooth splines were fitted. Post hoc pairwise comparisons were made using a Tukey adjustment. SAS 9.3 (SAS Institute Inc, Cary, North Carolina) and R 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria) were used for the analyses. Statistical significance was set to  $P < .05$ .

**Table 1.** Mean Age, Initial Weight, and Number of Data Entry Points for Each Participant Group.

Group	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
	Weight (kg) at 1st Entry	Age (days) of 1st Entry	No. Entries <7M	Age (M) of Last Entry <7M	No. Entries <36M	Age (M) of Last Entry <36M
+NAM	3.3 (0.4)	11.0 (12.9) <sup>a</sup>	7.3 (3.2) <sup>a,b</sup>	6.2 (0.8)	15.4 (5.8) <sup>a,b</sup>	29.5 (6.5) <sup>a</sup>
-NAM	3.5 (0.6)	17.9 (27.0) <sup>a</sup>	5.4 (2.7)	5.6 (1.3) <sup>a</sup>	12.4 (5.9)	27.9 (7.3) <sup>a</sup>
Control	3.4 (0.4)	0.0 (0.0)	5.5 (1.1)	6.5 (0.5)	10.8 (3.2)	23.0 (8.4)

Abbreviation: M, months; NAM, nasopalveolar molding.

<sup>a</sup>Significant versus control group.

<sup>b</sup>Significant versus -NAM group.

**Table 2.** Comparison of Groups: Weight Measurements Versus Age.

Comparison	Weight Difference (kg)	Standard Error	Adjusted P Value
<b>Birth to 7 months</b>			
+NAM vs -NAM	0.052	0.144	.9299
Control vs +NAM	0.546	0.143	.0006 <sup>a</sup>
Control vs -NAM	0.598	0.144	.0002 <sup>a</sup>
<b>Birth to 36 months</b>			
+NAM vs -NAM	0.217	0.192	.4949
Control vs +NAM	0.396	0.193	.1036
Control vs -NAM	0.613	0.193	.0052 <sup>a</sup>

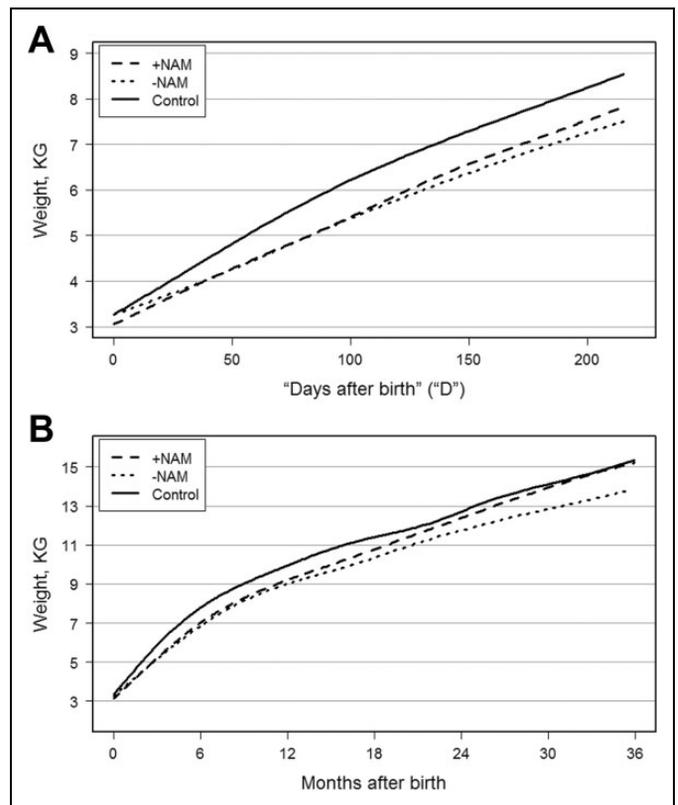
Abbreviation: NAM, nasopalveolar molding.

<sup>a</sup>Statistically significant.

**Results**

Characteristics of the data collection for the +NAM, -NAM, and control groups are shown in Table 1. Mean weight at the first entry was similar among groups, ranging from 3.3 to 3.5 kg. The mean age for the first entry varied among groups, where all control participants had records at birth (day 0), whereas on average the age at first recording available from the DCH Craniofacial Clinic was 11 days for +NAM and 18 days for -NAM cohorts. In the birth to 7-month time window, the number of weigh entries was greater for the +NAM group than either the -NAM or control group (mean 7.4 vs 5.4 and 5.5, respectively), and the age at last entry was lowest for the -NAM group relative to the +NAM and control groups. In the birth to 36-month window, the mean number of weigh entries was also greater for the +NAM group than -NAM or control group (15.4 vs 12.4 and 10.8, respectively), whereas the mean age at last entry was lowest for the control group.

Comparing weight measurements (Table 2), no statistically significant difference was found between +NAM and -NAM groups in the 7-month (Figure 1A) and 36-month (Figure 1B) time windows. During the first 7 months when the CL ± P groups were compared to the control group, both the +NAM and -NAM groups showed lower weights (both *P* < .001). During the 36-month time window when compared to the control group, the -NAM group showed statistically significant lower weight (*P* < .01), whereas there was no significant difference between the +NAM and control groups.



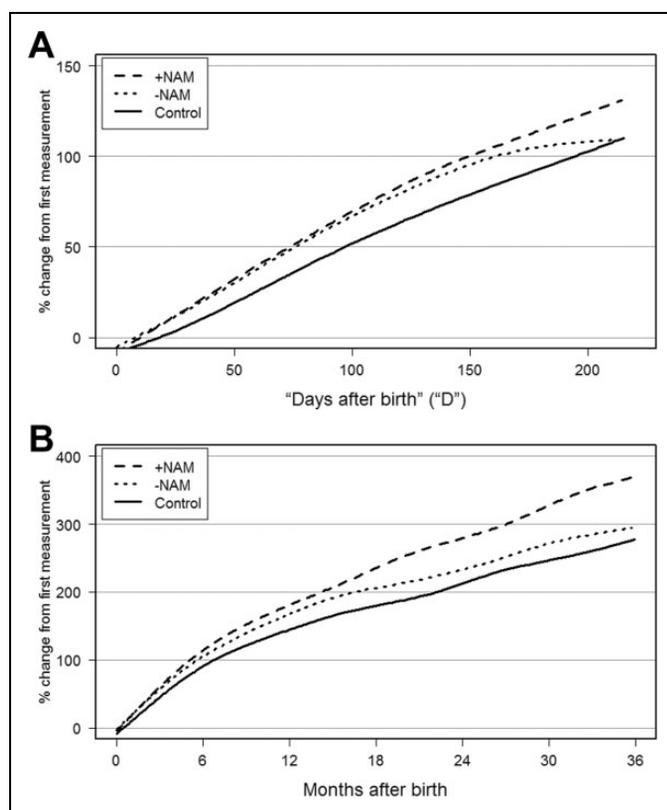
**Figure 1.** Plots of weight (kg) versus age (days) for the +NAM, -NAM, and control groups from birth to 7 months (A) and birth to 3 years (B). Lines were created using a smoothing spline fitted in R software. Statistical assessment (Table 2) showed no significant difference between +NAM and -NAM groups for either time window. From birth to 7 months (A), the control group had greater weight gain compared to either of the CL/P groups. From birth to 3 years (B), there was no significant difference between +NAM and -NAM groups or between +NAM and control groups, whereas weight for the -NAM group was significantly less than for the control group. NAM indicates nasopalveolar molding.

Comparing percentage weight gain from initial weight measurement (Table 3), no difference was found between the +NAM and -NAM groups in either the 7-month (Figure 2A) or 36-month (Figure 2B) time window. Compared to the control group, in the birth to 7-month window, the +NAM group had statistically significant greater percentage weight

**Table 3.** Group Comparisons: Percentage Weight Gain Versus Age.

Comparison	% Weight Difference	Standard Error	Adjusted <i>P</i> Value
<b>Birth to 7 months</b>			
+NAM vs -NAM	6.31	4.07	.2711
Control vs +NAM	-14.47	4.04	.0014 <sup>a</sup>
Control vs -NAM	-8.16	4.07	.1147
<b>Birth to 36 months</b>			
+NAM vs -NAM	13.04	7.47	.1913
Control vs +NAM	-35.17	7.51	<.0001 <sup>a</sup>
Control vs -NAM	-22.12	7.51	.0103 <sup>a</sup>

Abbreviation: NAM, nasoalveolar molding.

<sup>a</sup>Statistically significant.

**Figure 2.** Plots of weight gain as percentage of initial weight for the +NAM, -NAM, and control groups from birth to 7 months (A) and birth to 3 years (B). Lines were created using a smoothing spline fitted in R software. Statistical assessment (Table 3) showed no significant difference between +NAM and -NAM groups for either time window. From birth to 7 months (A), no significant difference was found between -NAM and control groups, whereas percentage weight gain was significantly greater for the +NAM compared to the control groups. From birth to 3 years (B), the percentage weight gain for both the +NAM and -NAM groups was significantly greater than for the control group. NAM indicates nasoalveolar molding.

gain ( $P = .001$ ), whereas the -NAM group showed no difference. In the birth to 36-month window, relative to the control group, both the +NAM and -NAM groups showed significantly greater weight gain ( $P < .001$  and  $P = .01$ , respectively).

## Discussion

This study to our knowledge is the first to examine the association of NAM treatment with weight gain in a cleft population and to compare weights of infants treated by NAM to a noncleft control group. Although benefits of NAM treatment have been reported related to outcomes of primary lip surgery, for example, improved nasal cartilage symmetry, increased length of the columella, and decreased need for revision surgery (Garfinkle et al., 2011; Grayson and Garfinkle, 2014), it is important to rule out that due to the potential intrusiveness of the appliance, NAM therapy could negatively impact infant weight gain. Beyond use as an indicator of an infant's ability to thrive, preoperative weight gain is a primary factor used by surgeons to evaluate when an infant is ready for primary cheiloplasty (Hansen et al., 2016).

During the birth to 7-month time window, the finding of no statistically significant difference in weight gain between -NAM and +NAM groups supports the null hypothesis that the presence of the NAM appliance does not adversely impact weight gain in infants affected by CL  $\pm$  P. During this period, both +NAM and -NAM groups showed reduced weight relative to infants in the control group. This finding is consistent with previous investigations where deficiencies in weight as well as height have been noted within the first year of life before primary palatoplasty has occurred (Hotz and Gnoinski, 1976; Avedian and Ruberg, 1980; Marques et al., 2009; Kaye et al., 2016; Miranda et al., 2016). Delayed weight gain from infancy to 2 years has been attributed to environmental factors such as difficulty feeding and recurrent infectious diseases, whereas at older ages poor weight gain is more often related to biologic factors such as reduced growth hormone production (Marques et al., 2009). In the current study, when comparing weight measurements among groups from birth to 3 years, we found the -NAM group had lower weight compared to the control group, confirming that infants with CL  $\pm$  P continue into childhood weighing less than infants not affected by clefts. Similarly, Kaye and associates (2016) reported that within the first 2 years of life there was an overall trend toward lower average weights for infants with clefts compared to unaffected infants. A unique finding of the current study is that no statistically significant difference was found between +NAM and control infants within the birth to 3-year time window, whereas a weight deficiency persisted with the -NAM group. These indirect comparisons suggest a potential benefit in weight gain related to NAM treatment.

When assessing percentage weight gain relative to initial weight measurement, during the birth to 7-month time window, the +NAM and -NAM groups showed no significant difference. During this time when compared to the control group, the +NAM group showed a greater percentage weight gain and the -NAM showed no significant difference. These results relative to the control group suggest that NAM treatment may enhance increases in weight that occurs with rebound growth. The finding of reduced weight in early infancy for the CL  $\pm$  P groups is consistent with previous reports, such as from Avedian and

Ruberg (1980) who found patients with CL  $\pm$  P generally remained below normal weight until at least 6 months of age and from Cunningham and associates (1997) where infants with CL  $\pm$  P displayed an intrinsic growth pattern that was below the mean for the general population.

During the birth to 36-month time window, the current study found both the +NAM and -NAM groups had significant increases in weight percentage relative to the control group. This finding is consistent with cleft participants experiencing increased rate of weight gain, or rebound growth, as described in previous investigations following repair of CL  $\pm$  P (Hotz and Gnoinski, 1976; Avedian and Ruberg, 1980; Ball et al., 1995; Lee et al., 1997; Marques et al., 2009; Zarate et al., 2010; Miranda et al., 2016). Miranda and colleagues (2016), for example, reported that in children with CL  $\pm$  P, growth impairment was found in early infancy, whereas after the age of 5 months, children with clefts began to demonstrate catch-up growth. Similarly, Lee and colleagues (1997) report that despite a significant reduction in growth early on for CL  $\pm$  P infants, rapid recovery takes place following surgical repair, resulting in no long-term residual growth deficit. Zarate and associates (2010) also found that despite an initial lag in weight gain, typically recovery of the weight gain occurs between 6 months and 3 years.

Although in the current study there was no statistically significant difference in weight between +NAM and -NAM groups, there were differences when the 2 CL  $\pm$  P groups were compared to the control group. In both time windows, the -NAM group showed a reduction in weight gain of 0.5 to 0.6 kg compared to the control group, meanwhile the +NAM group had less weight gain compared to the control group only in the birth to 7-month window. In the birth to 36-month time window, there was no statistical difference between +NAM and control groups, suggesting somewhat stronger rebound growth in the +NAM group. Although weight measurements for the -NAM group showed deficiencies in weight relative to controls, results of percentage weight gain in the birth to 36-month window showing that the -NAM group had a greater increase in weight percentage than controls suggest that with additional time weights of the -NAM and control groups will become more similar, patterns of weight gain consistent with previous studies (Avedian and Ruberg, 1980; Lee et al., 1997; Zarate et al., 2010; Miranda et al., 2016).

There are limitations to the current study. As a retrospective study, there was no control over the timing and frequency of recall visits and this likely contributed to wider variability when making comparisons among the groups than if weights had been obtained at standardized time points for all groups. This difference among groups was demonstrated by variations in number of entries and age of last entry in each of the 2 time windows. Differences were also found regarding mean age when initial weight was recorded (+NAM group: 11.0 days; -NAM group: 17.9; control group: 0.0; Table 1). The older age when initial weight measurements were obtained for the +NAM and -NAM groups likely accounts for why when initial weights were compared (Table 1); no difference was found

among the groups, while other investigators have found that infants with CL  $\pm$  P typically have lower birth weights (Choi et al., 1991; Brine et al., 1994; Lee et al., 1997; Gopinath and Muda, 2005; Bessell et al., 2011; Miranda et al., 2016). Assuming there would be continual weight gain following birth, differences in initial age for the first weight measurement likely impacted comparisons of percentage weight gain as the values were calculated based on the first weight recorded. For the control group with weight recordings at birth, the percentage weight gain was possibly biased toward a higher percentage weight gain relative to the +NAM and -NAM groups. Thus, in reality the rebound growth found for the CL  $\pm$  P groups based on percentage weight gain may have been stronger than what was indicated in the current results.

The possibility should also be noted that factors beyond the NAM appliance itself may contribute to the differences found when the CL  $\pm$  P groups were compared to the control group, such as the amount of support in home environment or attention from the craniofacial team. The -NAM group showed reduced weight gain relative to controls in both time periods, whereas +NAM differed from controls only in the birth to 7-month time window. This may relate to differences found in the number of visits to the craniofacial clinic by the +NAM group relative to -NAM group during the 7-month time window (mean 7.3 vs 5.4 visits, respectively) and 36-month window (mean 15.4 vs 12.4). In a recent study by Sischo and colleagues (2016), when psychosocial characteristics of caregivers of infants affected by CL  $\pm$  P treated either by NAM or traditional care were compared, caregivers of infants receiving NAM showed better outcomes, such as more rapid declines in depressive symptoms and anxiety. Improved coping was thought to relate to increased contact with other affected families and with craniofacial team members during NAM treatment visits (Sischo et al., 2016). Future investigation would be of value in further assessing psychosocial and other potential resource disparities such as socioeconomic status of caregivers who opt for NAM therapy for their CL  $\pm$  P infants relative to caregivers who use traditional care.

## Conclusions

When comparing infants with CL  $\pm$  P in +NAM and -NAM groups, no statistically significant differences were found in the weight measurements or percentage weight gain from initial measurement. These results demonstrate that treatment with the NAM appliance does not adversely impact weight gain despite the appliance's added complexity. When assessing percentage weight gain, from birth to 7 months, the +NAM group showed greater weight gain than controls, and from birth to 36 months, both the +NAM and -NAM groups showed greater weight gain than controls. These findings demonstrate rebound growth and suggest that such growth may be enhanced by treatment involving NAM.

## Declaration of Conflicting Interests

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