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Original Research Article

Feeding effectiveness of nasoalveolar molding appliances made with polymethyl methacrylate vs. polyamide in newborns with unilateral cleft lip and palate: A randomized controlled trial

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Abstract

Background: Infants with cleft lip and palate face feeding challenges due to anatomical disruptions, leading to complications like nasal regurgitation, choking, and poor nutrition. Nasoalveolar molding (NAM) appliances, traditionally made from polymethyl methacrylate (PMMA), reduce the severity of cleft before surgery, help seal the oronasal opening and improve feeding. PMMA's rigidity limits adaptability, potentially reducing feeding efficiency. Polyamide, a crystalline polymer with higher flexibility and reduced thickness may provide a better anatomical adaptation, enhancing feeding performance.
Aim: To evaluate the feeding effectiveness of NAM appliances made from PMMA versus polyamide in newborns with unilateral cleft lip and palate.
Materials and Methods: A clinical trial (2020–2024) at two Indian hospitals enrolled 76 infants, randomized into Group A (PMMA) and Group B (polyamide). After attrition, 58 infants remained. NAM appliances were activated biweekly. Bottle-feeding volumes were measured three days before and after NAM placement and at weeks 4 and 8. Weight was recorded at baseline (T0), Day 3 (T1), Weeks 4 (T2), 8 (T3), and 12 (T4) respectively.
Results: Group B had significantly higher feeding volumes on Day 3 (662 ml and 627.87 ml, $p = 0.001$) and over the three-day average (627.12 ml and 608.5 ml, $p = 0.040$). No significant difference was noted at Week 4 ($p = 0.103$), but Week 8 showed improvement in Group B (1141.25 ml and 1110 ml, $p = 0.045$). Weight gain was significantly higher in Group B at T1 (0.16 kg, $p = 0.047$), T3 (0.32 kg, $p = 0.0003$), and T4 (0.35 kg, $p = 0.0482$).
Conclusion: Polyamide NAM appliances demonstrated superior feeding effectiveness and weight gain, supporting their use when feasible.

Keywords: Cleft lip and palate, Feeding, Naso alveolar molding, Polymethyl methacrylate, Polyamide, Randomized controlled trial

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1. Introduction

Feeding difficulties are a frequent concern among infants, particularly within the first six months of life. These challenges tend to be more significant in babies born prematurely or those with congenital conditions like cleft lip and palate (CL/P). Such infants are at a higher risk of suboptimal nutrition, which can contribute to infection risk, prolonged hospitalizations, and, in severe cases, mortality. Beyond the physical complications, such as nasal regurgitation, choking, and aspiration, feeding difficulties in early infancy can disrupt the social dynamics of mealtime, potentially straining the parent-child relationship and affecting the emotional well-being of both the caregiver and the infant.[1] These children are more prone to having a lower birth weight.[2,3] Prolonged feeding times, increased fatigue, and insufficient nutritional intake, often leading to delayed weight.[4,5] These issues can also contribute to developmental delays.[6,7] The inability to establish effective feeding can negatively impact parent-infant bonding, leading to maternal feelings of inadequacy and a heightened risk of depression.[7,8] These complexities highlight the need for tailored feeding interventions, including assistive feeding devices and comprehensive, objective assessments.

An obturator, a specialized feeding prosthesis, plays a critical role in establishing a functional seal between the oral and nasal cavities, thereby optimizing oropharyngeal coordination during feeding.[4,9] Presurgical orthopaedic appliances, designed primarily to approximate cleft segments

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and minimize the extent of the cleft deformity, inherently function as obturators.[10,11] Clinical evidence supports the efficacy of obturators in improving feeding outcomes [12-14] though some studies present heterogeneous findings.[7,15] In the early 1990s, Grayson and Cutting, expanding upon Matsuo's foundational work, pioneered the NAM technique.[16,17] NAM helps reduce cleft size by approximating the cleft segments, contour the nasal framework, and elongate the columella, thereby optimizing nasal symmetry and establishing a more favourable anatomical configuration for primary cheiloplasty and rhinoplasty in CL/P.[18] This technique has significantly enhanced surgical outcomes in CL/P repairs and has gained widespread acceptance as an effective intervention.[14] Beyond its physical benefits, NAM promotes early parent-infant bonding, fostering emotional well-being and positively influencing the child's mental development. These advantages underscore the importance of initiating NAM therapy as early as possible after birth.

Traditionally, polymethyl methacrylate (PMMA) has been the material of choice for NAM appliances due to its cost-effectiveness and ease of manipulation. However, PMMA's rigidity, bulkiness, and limited adaptability to changing oral structures may result in less effective obturation, leading to suboptimal feeding outcomes and reduced patient comfort. These challenges have necessitated the exploration of alternative materials. Polyamide thermoplastic materials have emerged as a superior alternative to PMMA in Denture fabrication. Polyamide, a crystalline polymer, boasts high flexural and impact strength, excellent flexibility, aesthetic appeal, and comfort, making it ideal for denture bases. It exhibits higher elasticity compared to traditional heat-polymerizing resins, greater heat resistance, and better ductility. Moreover, polyamide offers toxicological safety for patients with resin monomer or metal allergies.[19-21]

As effective feeding relies on achieving adequate intraoral negative sucking pressure, an appliance that closely adapts to the cleft anatomy is essential. It is hypothesized that the higher elasticity and reduced thickness of polyamide, compared to PMMA, allow for superior anatomical adaptation, ensuring a more effective seal between the nasal and oral cavities. This, in turn, may enhance feeding performance and improve patient comfort, particularly for the delicate anatomy of neonates. Based on this premise, this study was conducted with the aim of evaluating the feeding effectiveness of nasoalveolar molding appliances made from polymethyl methacrylate versus polyamide in newborns with unilateral cleft lip and palate.

1.1. Hypotheses

1. **Null hypothesis (H_0):** There is no significant difference in feeding effectiveness between Nasoalveolar Molding appliances made with polymethyl methacrylate and those made with polyamide in newborns with unilateral cleft lip and palate.
2. **Alternative hypothesis (H_1):** There is a significant difference in feeding effectiveness between Nasoalveolar Molding appliances made with polymethyl methacrylate and those made with polyamide in newborns with unilateral cleft lip and palate.

2. Materials and Methods

2.1. Study design and setting

This study was conducted as a randomized controlled trial between Jan 2020 and June 2024 at two institution-based hospitals in South India. Institutional ethics committee approved the study (IRB/2018/No.104). The trial was registered in CTRI Reg.no.CTRI/2020/01/022796.

2.2. Sample size and randomization method

The sample size for the study was determined to be 56, for a power of 80% and a 95% confidence interval.**Error! Reference source not found.** To account for potential dropouts and loss to follow-up, a total of 76 participants were enrolled from an initial screening of 90.

2.3. Inclusion criteria

Infants aged 1 week to 8 weeks diagnosed with unilateral CL/P.

2.4. Exclusion criteria

Infants with Syndromic CL/P, Infants older than 2 months, Infants who had undergone lip surgery, Infants with other medical conditions such as severe respiratory or cardiac conditions, hearing loss. Parents /Caregivers of all the infants consented to participate in the study. Simple randomization was employed to allocate participants into two study arms: Group A – Regular NAM appliance (PMMA), and Group B – Modified NAM appliance (polyamide).Randomization software was used to generate random sequences (www.sealedenvelope.com). Allocation sequence was concealed to prevent selection bias. Unique randomization code was assigned to the Participants upon enrollment. Attrition Management: Of the initial 76 participants, 18 were excluded from the study due to a combination of reasons: missed follow-up visits (n=5), commuting difficulties (n=4), severe respiratory infections requiring hospitalization (n=2), and mucosal irritation leading to discontinuation of the appliance (n=7). Data from the remaining 58 participants were included in the final analysis,with 30 in GroupA and 28 in Group B.group). The remaining dataset ensured robust statistical power and validity. Investigators and data collectors were blinded to the allocation sequence.

NAM Appliance Protocol - Impressions were taken using putty silicone (Dentsply Aquasil, Dentsply Sirona Inc., Noida, U.P, India), and models were prepared with type IV

Die stone (GC Fuji Rock, GC India Dental Pvt. Ltd., Telangana). Group A NAM appliance was fabricated using cold-cure acrylic material (DPI RR, Dentsply Sirona Inc., Noida, U.P., India) following Grayson's method.[17] Group B NAM appliance was made with polyamide with injection molding technique. Activation of the appliance for palatal molding was done every two weeks. Group A activation was done with soft liners (GC India Pvt Ltd, Isnapur, Telangana, India) added preferentially while group B activation was done using soft-liners with primers (Avue, Dental Avenue Pvt Ltd, Palghar, India).[22,24] Feeding bottle used for both the groups were Haberman's (Medela AG, Switzerland) or Pigeon, long (Pigeon India Pvt Ltd, Uttar Pradesh, India)

2.5. Data collection

1. **Feeding assessment:** The amount of feeding from bottles was measured for three days before and three days after the delivery of the NAM appliance. The mean of these values were taken as T0 and T1 respectively. Follow up was recorded at week 4(T2) and at week 8(T3)
2. **Weight measurements:** Infants were weighed using a digital weighing scale (Easycare, German Tech, Mumbai, Maharashtra, India) three days before and three days after receiving the NAM appliance. The mean of these measurements was recorded as T0 and T1 respectively. Additional weight measurements were taken at four weeks (T2), eight weeks (T3)and twelve weeks(T4)

2.6 Outcome Measures

Primary outcome measure: The total volume of milk consumed in 24 hours was measured for three consecutive days both before and after the delivery of the NAM appliance and at the end of 4 and 8 weeks.

Secondary Outcome Measures

Mean change in the weight at the end of 3 days, immediately before and after the appliance delivery, and at 4,8 and 12 weeks.

2.7. Statistical analysis

IBM SPSS Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp. Released 2019 was used to analyze the data, with a significance level set at 5% (P- 0.05) and Metrics: Mean, Count, Maximum, Minimum, Standard Deviation (S.D), and Coefficient of Variation (CV). For analysis of feeding measurements, Levene's Test was conducted to assess the equality of variances, ensuring that the assumptions for parametric tests (such as the t-test) were met. As the data appeared to follow a normal distribution with equal variances, t-tests for Equality of Means were applied to determine if the observed differences in performance metrics (mean values) between the two systems were statistically significant, rather than due to random variation. These tests help draw reliable inferences about the effectiveness and consistency of the modifications under different conditions and over time. For assessing the weight changes during the study period, Paired t-tests within each group were conducted while independent t-tests between Groups A and B at each time point to compare group differences.

3. Results

Out of 58 participants, group A had 17 boys and 13 girls while group B had 18 boys and 10 girls with an overall 35 boys and 23 girls. Infant's mean age was 2.1 weeks and mean weight at presentation was 2.56kg (**Table 1** and **Figure 1**)

3.1. Feeding metrics

Group statistics convey the mean of before and after the appliance delivery at different points of time (**Table 2**). Equality of Variances (Levene's Test): Across all metrics and time points, the significance values were above 0.05, confirming that the assumption of equal variances was valid. Hence, the results from the row "Equal variances assumed" were used for inference (**Table 3**).

3.2. Day-level analysis

Day-Level Analysis: Pre- intervention- The t-tests for these days yielded 0.756 for Day1, 0.919 for Day2, and 0.789 for Day3 at T0, showing no statistically significant difference between the groups. Post-intervention- The results from Day 1 and Day 2 showed p-values of 0.319 and 0.155, respectively, suggesting no statistically significant differences between the groups. On Day3, a significant difference in the mean was observed 34.125 ml ($p = 0.001$), Average of days 1-3 showed a significant result ($p = 0.040$), with a mean difference of 18.625 ml. At week 4, the group B had a higher mean, but the difference was not statistically significant ($p = 0.103$). At week 8, a significant difference was observed ($p = 0.045$), with a mean difference of 31.250ml (**Table 3**). Mean Co-variance (cv) values for the pre intervention days in group A was 7.59 and in group B, it was 5.65. Post-intervention average cv values showed lower variability in group B (5.08) compared to group A (7.51). At weeks 4 and 8, group B continued to show a reduced CV (8.02 and 5.72) compared to group A (8.98 and 6.44) respectively (**Table 4**).

3.3. Weight changes

At T0, no significant difference was observed between the groups ($p = 0.735$). By T1, a significant difference was noted (0.16 kg, $p = 0.047$). At T2, a marginal difference was observed 0.13 kg ($p = 0.1$). At T3, a highly significant difference was identified (0.32kg, $p = 0.0003$) while at T4, a borderline significant difference was observed (0.35 kg, $p=0.0482$) (**Table 5**, **Figure 2**).

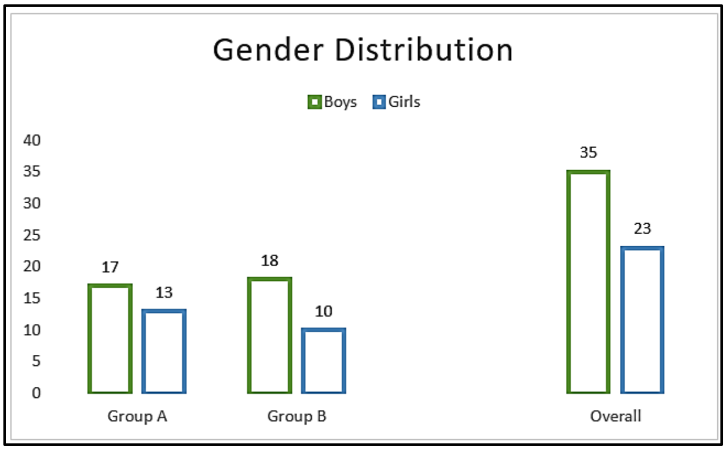

Figure 1: Descriptive statistics -Gender distribution of the participants

Table 1: Descriptive statistics -Mother's age and the infant's age and weight

.	N	Mean	Std. Dev
Mother’s Age (years)	58	31.2	5.17
Infant age (weeks)	58	2.1	.74
Weight of the baby (kgs)	58	2.56	.42

N-number of samples, Std. Dev.-standard deviation

Table 2: Mean value of feeding measurements on Day,1,2,3, week 4 and week 8

Group Statistics					
Group		**N**	**Mean**	**Std. Deviation**	**Std. Error Mean**
Day1_Before	Group A	30	509.7500	39.18971	6.19644
	Group B	28	507.2500	32.00461	5.06037
Day2_Before	Group A	30	522.8750	44.22970	6.99333
	Group B	28	523.7500	31.51617	4.98314
Day3_Before	Group A	30	546.7425	41.71996	6.59650
	Group B	28	549.0000	33.03456	5.22322
Before Average	Group A	30	526.4565	39.96894	6.31964
	Group B	28	526.6668	29.75380	4.70449
Day1_After	Group A	30	596.1250	45.74858	7.23349
	Group B	28	587.3750	30.94635	4.89305
Day2_After	Group A	30	623.2500	47.19776	7.46262
	Group B	28	610.2500	32.38293	5.12019
Day3_After	Group A	30	627.8750	52.34011	8.27570
	Group B	28	662.0000	35.53416	5.61844
After Average	Group A	30	608.5003	47.10899	7.44858
	Group B	28	627.1253	30.90259	4.88613
Week4	Group A	30	896.8750	83.07241	13.13490
	Group B	28	925.5000	71.88566	11.36612
Week8	Group A	30	1110.0000	65.32709	10.32912
	Group B	28	1141.2500	71.46812	11.30010

Table 3: Comparison of mean feeding measurements between Group A and Group B

	Levene's Test for Equality of Variances		**t-test for Equality of Means**						
	F	**Sig.**	**t**	**df**	**Sig. (2-tailed)**	**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**	
								Lower	**Upper**

Day1_Before	Equal variances assumed	0.002	0.968	0.312	78	0.756	2.50000	8.00020	-13.42718	18.42718
	Equal variances not assumed			0.312	75.005	0.756	2.50000	8.00020	-13.43720	18.43720
Day2_Before	Equal variances assumed	0.356	0.552	-0.102	78	0.919	-0.87500	8.58711	-17.97061	16.22061
	Equal variances not assumed			-0.102	70.486	0.919	-0.87500	8.58711	-17.99936	16.24936
Day3_Before	Equal variances assumed	0.151	0.698	-0.268	78	0.789	-2.25750	8.41403	-19.00855	14.49355
	Equal variances not assumed			-0.268	74.105	0.789	-2.25750	8.41403	-19.02243	14.50743
Before Average	Equal variances assumed	0.058	0.810	-0.027	78	0.979	-0.21025	7.87846	-15.89506	15.47456
	Equal variances not assumed			-0.027	72.069	0.979	-0.21025	7.87846	-15.91541	15.49491
Day1_ After	Equal variances assumed	1.244	0.268	1.002	78	0.319	8.75000	8.73300	-8.63606	26.13606
	Equal variances not assumed			1.002	68.512	0.320	8.75000	8.73300	-8.67407	26.17407
Day2_ After	Equal variances assumed	1.703	0.196	1.436	78	0.155	13.00000	9.05025	-5.01767	31.01767
	Equal variances not assumed			1.436	69.058	0.155	13.00000	9.05025	-5.05449	31.05449
Day3_ After	Equal variances assumed	1.435	0.235	3.412	78	0.001	34.12500	10.00270	14.21115	54.03885
	Equal variances not assumed			3.412	68.652	0.001	34.12500	10.00270	14.16835	54.08165
After Average	Equal variances assumed	1.799	0.184	2.091	78	0.040	18.62500	8.90818	0.89018	36.35982
	Equal variances not assumed			2.091	67.320	0.040	18.62500	8.90818	0.84575	36.40425
Week 4	Equal variances assumed	1.253	0.266	1.648	78	0.103	28.62500	17.36993	-5.95587	63.20587
	Equal variances not assumed			1.648	76.423	0.103	28.62500	17.36993	-5.96711	63.21711
Week 8	Equal variances assumed	0.064	0.801	2.041	78	0.045	31.25000	15.30957	0.77098	61.72902
	Equal variances not assumed			2.041	77.379	0.045	31.25000	15.30957	0.76713	61.73287

Table 4: Co-variance determination between group A and B with respect to feeding metrics

	Group A						Group B					
	Mean	**Count**	**Maximum**	**Minimum**	**S. D**	**CV**	**Mean**	**Count**	**Maximum**	**Minimum**	**S. D**	**CV**
Day1_Before	509.75	30	650.00	430.00	39.19	7.69	507.25	28	580.00	450.00	32.00	6.31
Day2_Before	522.88	30	680.00	430.00	44.23	8.46	523.75	28	600.00	460.00	31.52	6.02
Day3_Before	546.74	30	700.00	480.00	41.72	7.63	549.00	28	620.00	490.00	33.03	6.02
Before Average	526.46	30	676.67	446.67	39.97	7.59	526.67	28	596.67	470.00	29.75	5.65
Day1_After	587.38	30	750.00	520.00	45.75	7.67	596.13	28	650.00	540.00	30.95	5.27
Day2_After	610.25	30	780.00	520.00	47.20	7.57	623.25	28	680.00	540.00	32.38	5.31
Day3_After	627.88	30	830.00	560.00	52.34	7.91	662.00	28	700.00	550.00	35.53	5.66
After Average	608.50	30	786.67	533.33	47.11	7.51	627.13	28	676.67	546.67	30.90	5.08
Week4	896.88	30	1100.00	750.00	83.07	8.98	925.50	28	1100.00	750.00	71.89	8.02
Week8	1110.00	30	1250.00	1000.00	65.33	6.44	1141.25	28	1255.00	1050.00	71.47	5.72

Table 5: Comparison of weight changes at different intervals between Group A and Group B

Weight in KGS n-40	**T0**			**T1**			**T2**			**T3**			**T4**		
	mean	**SD**	**P value**	**mean**	**SD**	**P value**	**mean**	**SD**	**P value**	**Mean**	**SD**	**P value**	**mean**	**SD**	**P value**
Group A	2.703	0.422	0.7425	2.358	0.317	0.0471*	3.418	0.348	0.1063	4.518	0.348	0.0003*	5.020	0.380	0.0482*
Group B	2.67	0.459		2.51	0.337		3.54	0.293		4.83	0.380		5.370	0.390	

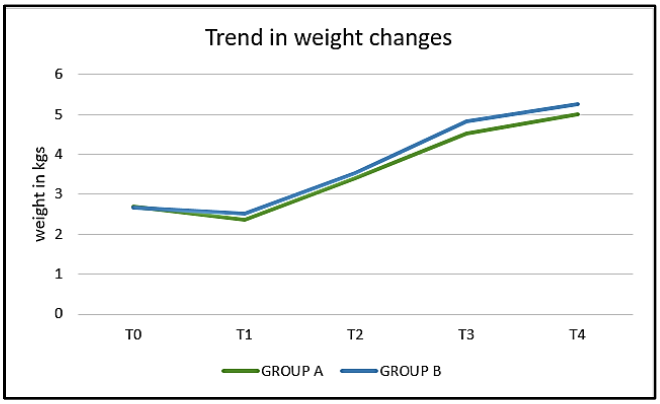

Figure 2: Trend in weight changes at different intervals of time between the groups

4. Discussion

Infants with CL/P often exhibit shorter sucking bursts, faster sucking rates, and shorter individual sucks compared to non-cleft infants.[8] Breastfeeding rates in this population are notably low. Danner et al. reported that, in their study 88.2% of mothers attempted breastfeeding, only 40% were successful.[25] Similarly, Pathumwiwatana et al. found 80% of the infants in their study were breastfed for 3–4 months, 10% were exclusively breastfed for six months. They concluded that exclusive breastfeeding was achievable in CL/P infants when a supportive relationship is established between the infant, parents, and extended family.[26] In the current study, although all mothers were advised to attempt direct breastfeeding, only 50% managed to initiate it effectively. Instead, most preferred expressed breast milk feeding via a bottle, highlighting the challenges of breastfeeding in CL/P infants.

Feeding interventions, including palatal obturators, specialized feeding bottles, and lactation education, have shown promise in addressing these challenges[13-15]. Turner et al. demonstrated that combining a palatal obturator with lactation education led to a reduction in feeding times, increased milk intake, and improved flow rates.[13] Similarly, Prahl et al., observed better feeding outcomes in infants with obturators, although Choi et al. noted no significant differences in intraoral negative pressure generation with or without intraoral orthopedic plates.[15,5]

The type of appliance used has also been shown to influence feeding efficiency. Britton et al. assessed feeding practices in 20 CL/P infants and found that 70% of parents who used pre-surgical appliances rated them as highly effective in facilitating feeding.[27] Modified appliances, such as the Hotz-type plate studied by Kogo et al., were particularly beneficial. Their study reported that four infants with CL/P successfully breastfed while wearing the plate, consuming approximately 22 g per feeding trial. [12] These findings underscore the potential of properly adapted appliances to improve feeding outcomes. In terms of materials, a study by Khateeb et al. evaluated vacuum-formed nasoalveolar molding (VF-NAM) plates and found that they were effective in correcting the alveolar morphology and improving the nasal symmetry.[28] Oday et al., studied NAM plates made from different materials and found that polyethylene terephthalate modified with glycol (PET-G) demonstrated better fit and retention compared to polyethylene terephthalate modified with glycol and ethylene vinyl acetate (PET-G/EVA) and PMMA, emphasizing the importance of material properties in achieving optimal outcomes.[28] Alansari et al., incorporated chlorhexidine-loaded halloysite nanotubes (CHX-HNTs) fillers into PMMA-based appliances to reduce microbial infections.[29]

The current study builds on the hypothesis that Polyamide's lightweight, flexible, and biocompatible properties may enhance anatomical adaptation and intraoral negative pressure generation, critical for effective feeding. The improved feeding outcomes in Group B (polyamide NAM) align with Kogo et al.'s findings on the importance of a well-adapted appliance in facilitating breastfeeding and milk intake.[12] Additionally, the statistically significant improvements observed in Group B after Day 3 reflect the adaptation period necessary for polyamide NAMs to optimize their functional benefits. This adaptation likely contributed to improved tongue-palate-teat contact during bottle feeding, reduced nasal regurgitation and feeding-related aspiration risks, increased milk intake, and maternal confidence over time. At Week 4, improvements were observed in Group B but did not reach statistical significance. By Week 8, group B exhibited substantial and statistically significant performance gains, highlighting its long-term effectiveness. Additionally, a lower coefficient of variation (CV) in feeding outcomes for the polyamide NAM group suggested more consistent feeding responses over time. While both groups demonstrated feeding improvements, Group B showed greater stability at later time points (Weeks 4 and 8), likely due to better palatal adaptation, improved tongue-palate-teat contact, and enhanced negative intraoral pressure generation(Table 4). Additionally, polyamide's thermoplastic nature allowed for easy modifications as the infant's oral cavity developed, ensuring continued effectiveness. In contrast, PMMA NAMs, while durable, were more rigid, limiting their adaptability to the dynamic intraoral environment and potentially reducing feeding efficiency. Both appliances effectively sealed the anterior cleft alveolus, and mothers were instructed on proper bottle-feeding techniques, including covering the cleft lip with the teat to ensure a lip seal. Similar to Turner et al.'s findings, both methods reduced nasal aspiration and spillage.[13] No significant gender-related differences in feeding outcomes were observed. Importantly, maternal confidence improved in both groups, suggesting that NAM use regardless of material positively influenced parental feeding experiences (**Table 3** and **Table 4**).

Weight gain is a critical indicator of feeding success in CLP infants. Martin et al. found that cleft type significantly impacts weight gain, with infants with isolated clefts of the hard and soft palate experiencing the most severe feeding difficulties and associated weight loss. The study also highlighted maternal factors, such as self-perception and mental health, as significant contributors to feeding success[31]. Woods et al. found no significant differences in weight gain between NAM and non-NAM groups during their evaluated timeframes.[32] Shaw et al., found beneficial effect on the head circumference and the weight of squeezable bottle-feeding group as against rigid bottle.[33] Although, Prahl et al., found an increase in Feeding velocity in the passive maxillary plate group against no plate group, their results did not show statistically significance for weight- for- age[15]. Goldberg reported a case where weight gain was observed after the obturator was delivered to assist feeding.[9] Since the current study compared two NAM groups, comparing with similar studies was found challenging as the studies discussed above involved comparison between NAM vs no NAM groups. The results are discussed as observed in the study.

In the current study, while both groups showed significant improvements in weight gain over time, the differences became more pronounced in the long term. At T1, Group B showed significantly better weight outcomes than Group A, suggesting that polyamide NAMs provided improved feeding support early on potentially due to its better adaptability and comfort. By T2, Group B maintained a slight edge in weight gain. This trend may reflect the sustained benefits of the Polyamide NAM. At T3, the difference in weight gain became significant again, with Group B showing greater gains than Group A. Weight changes recorded at 12 weeks continued to exhibit a similar trend (Fig. 2).

4.1. Limitations

Study limitations include exclusion of potential direct breastfeeding which could have influenced total weight gain, unmeasured milk spillage, possibly overestimating intake, a short duration of the study.

Recommendations for Future Studies -Capture data on breastfeeding sessions to provide a holistic understanding of feeding effectiveness, using Objective Measurement Tools such as electronic feeding monitors or precise measurement systems . Conduct follow-ups over a longer period to assess sustained feeding effectiveness and growth outcomes.

5. Conclusion

This study adds to the growing body of evidence supporting the use of advanced materials, such as polyamide, in NAM appliances to improve feeding outcomes in CL/P infants. The flexibility, biocompatibility, and superior adaptability of polyamide NAMs provide significant advantages over traditional PMMA NAMs, particularly in long-term feeding efficiency and weight gain. These findings suggest that material innovation in NAM design has the potential to significantly enhance the quality of care for CLP infants and their families.

6. Source of Funding

The authors declare that the study was self-funded.

7. Conflict of Interest

The authors declare no conflict of interest.

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