

# Comparison of different feeding methods for babies with unilateral cleft lip and palate: a clinical randomized controlled trial

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## ABSTRACT

**Objective:** To compare the effect of a rigid feeding plate, a flexible feeding plate, and a special feeding teat on feeding babies with unilateral cleft lip and palate. **Materials and methods:** This randomized controlled trial aimed to compare the feeding efficiency and comfort of three management strategies—rigid acrylic plates, flexible vacuum-formed plates, and specialized cleft teats—in neonates with unilateral cleft lip and palate prior to surgical repair. The study enrolled 30 full-term infants within two weeks of birth, randomly assigned to three groups: acrylic plates (A), flexible plates (F), and no plates with a special silicone teat (T). Feeding efficiency was measured, alongside the number of appliance adjustment visits. **Results:** Results demonstrated that infants using acrylic plates exhibited significantly higher feeding efficiency compared to those with flexible plates or no plates with specialized teats, with no significant difference between the latter two. The flexible plate group required more adjustment visits, indicating lower stability. **Conclusion:** The study concludes that rigid acrylic feeding appliances provide superior feeding performance in neonates with unilateral cleft lip and palate, whereas flexible plates are associated with increased adjustments. These findings support the use of acrylic plates as the preferred pre-surgical feeding aid in this population.

**Key Words :** Cleft lip and palate, Feeding appliance, Vinyl-Feeding appliance

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## INTRODUCTION

Cleft palate is defined as an opening in the hard and/or soft palate as a result of improper union of the maxillary process and the median nasal process during intrauterine development<sup>[1]</sup>. The risk of developing orofacial clefts have a multifactorial origin, whereby involving a combination of genetic and environmental factors<sup>[2]</sup>. The condition impacts many functions and systems: It affects feeding, interferes with speech, and creates social and mental stresses for both the child and the parents. Feeding difficulties in babies with cleft lip and/or palate are well documented<sup>[3]</sup>. The feeding challenges include insufficient suction, excessive air intake, choking, nasal regurgitation, fatigue,

inadequate milk intake and weight gain, and prolonged feeding duration. <sup>[4-8]</sup>. The feeding obturator is a prosthetic aid that is designed to restore the separation between the oral and nasal cavities<sup>[1]</sup>. This study aimed to compare the feeding efficiency and comfort of three feeding aids—rigid acrylic plate, flexible vacuum-formed plate, and specialized feeding teat—in newborns with unilateral cleft lip and palate. The null hypothesis of this research was there is no statistically significant difference in feeding efficiency and comfort among neonates with complete unilateral cleft lip ± palate who are managed with (A) conventional rigid acrylic obturators, (F) flexible vacuum-formed thermoplastic obturators,

or (T) specialized cleft teats without an obturator, rmoplastic obturators, or (T) specialized cleft teats without an obturator, during the pre-surgical feeding period.

### Materials and Methods

This randomized clinical trial was conducted at the Outpatient Prosthodontic Clinic of the Faculty of Dentistry, Tanta University, Egypt. The study was carried out after approval by the Research Ethical Committee at the Faculty of Dentistry, Tanta University (Registration #R-RP-7-23-2) and ClinicalTrials.gov (Identifier: NCT06103162). Before treatment, all Parents of the babies signed an informed consent to participate in the study. Power analysis was performed, and the sample size calculation was based on the feeding efficiency with a power of 0.8 and a confidence level (alpha) of 0.05. The assumed means and standard deviation were derived from a previously published study<sup>19</sup>

<sup>1</sup> Forty-eight cleft lip and palate babies were screened and examined by an experienced clinician. Out of the 48 babies examined, thirty (15 males, 15 females) fulfilled the inclusion criteria and were enrolled in the study. The inclusion criteria for the trial were as follows: Babies with a complete unilateral cleft lip and palate, born at full term, aged within 2 weeks of birth [Figure 1],



[Figure 1]. Cleft palate neonate

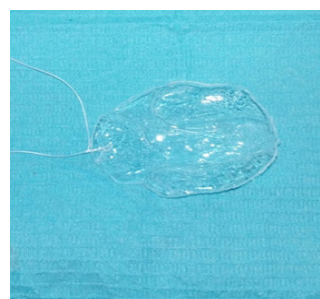
and the mother's agreement to record feeding period and milk amount for each feeding session over the trial period. The exclusion criteria included babies with cleft lip only or syndromic infants. All selected babies were randomly and equally divided into three groups—10 babies (five males and five females) for each group. First group (A) received rigid acrylic plates, second group (F) received flexible plates, and third group (T) did not wear any plate but used a special silicone teat for cleft palate babies. For groups A and F, a preliminary impression was made with Putty viscosity elastomeric impression material (Zhermack SpA – Badia Polesine, Italy) for each baby. A cast was poured on the preliminary impression obtained. With

the help of the custom tray, a secondary impression was made using putty viscosity elastomeric impression material [Figure 2].



[Figure 2]. Final impression in acrylic custom tray

The Final cast was obtained, and all the undercuts were blocked. For group A, clear heat-cure polymerising acrylic resin ( Acrostone, Egypt) was used to fabricate the acrylic plate. Floss was attached to the acrylic feeding appliance. For group F, a 1.5 mm-thick transparent thermoplastic sheet ( Bio-Art, Brazil) was adapted over the cast using a vacuum-forming machine. Once the sheet was adapted, it was removed from the cast and trimmed. Floss was attached to the flexible feeding appliance [Figure3].



[Figure3]. Flexible feeding plate appliance

The appliances were adjusted for a better fit. All babies wore it until lip repair. For group III, the babies' parents were instructed to feed their babies using a special teat bottle for children with cleft palate [Fig. 4 ].



[Figure 4]. Special teat

The feeding duration and amount per feeding were used in order to calculate the outcome measure ,feeding efficiency(mL/min).Feeding efficiency was calculated by the investigator for each appliance. The measure was defined as the volume of fluid transferred per unit time, in milliliters per minute (mL/min).

#### Evaluation:-

The feeding efficiency(mL/min)was calculated for each baby. Babies' visits due to discomfort necessitating adjustments to their feeding appliances were counted.These adjustments were essential to relieve pain caused by the appliance.

#### Results

The Acrylic feeding plate demonstrates significantly higher feeding efficiency compared to both the Flexible feeding plate and the Special feeding bottle. There is no statistically significant difference in feeding efficiency between the Flexible feeding plate and the Special feeding bottle (Table 1-2) The Flexible feeding appliance was associated with a significantly higher number of adjustment visits compared to both the acrylic feeding plate and the Special feeding bottle. There is no significant difference between the acrylic feeding plate and the Special feeding bottle in terms of adjustment visits (Table 1-2)

**Table1:** Comparisons of Feeding Methods for Feeding Efficiency and Adjustment Visits

The mean difference is significant at the 0.05 level.

		N	Mean	Std. Deviation	Minimum	Maximum	Median	F	Sig.
feeding efficiency	Acrylic feeding plate	10	9.4300	1.6031	7.32	12.03	9.5	57.4	.001*
	flexible	10	5.2930	0.79720	4.28	6.54	5.3		
	Special feeding bottle	10	4.0390	0.86861	2.94	5.40	4.1		
adjustment visit	Acrylic feeding plate	10	1.6000	0.69921	1.00	3.00	1	39.1	.001*
	flexible	10	3.4000	0.51640	3.00	4.00	3		
	Special feeding bottle	10	1.3000	0.48305	1.00	2.00	1.5		

**Table 2:** Mean Differences and Significance from Post-Hoc Comparisons of Prosthetic Appliance Types on Feeding Efficiency and Adjustment Visits

The mean difference is significant at the 0.05 level.

			Mean Difference (I-J)	Std. Error	Sig.
Feeding efficiency	Acrylic feeding plate	Flexible feeding plate	4.13700*	0.52631	0.000*
	Acrylic feeding plate	Special feeding bottle	5.39100*	0.52631	0.000*
	Flexible feeding plate	Special feeding bottle	1.25400	0.52631	0.073
Adjustment visit	Acrylic feeding plate	Flexible feeding plate	-1.80000*	0.25676	0.000*
	Acrylic feeding plate	Special feeding bottle	0.30000	0.25676	0.759
	Flexible feeding plate	Special feeding bottle	2.10000*	0.25676	0.000*

#### Discussion

The present randomized clinical trial evaluated the feeding efficiency of three management strategies for neonates with complete unilateral cleft lip and palate:(A) acrylic rigid heat-cured polymethyl-methacrylate (PMMA) feeding plates,(F) vacuum-formed 1.5 mm thermoplastic feeding plates,and (T) no plate but a specialized silicone cleft teat. The primary outcomes were feeding efficiency and the number of adjustment visits.Acrylic feeding appliances offer superior pre-surgical feeding performance for these infants. The Flexible feeding appliance is associated with a significantly higher number of adjustment visits compared to both the acrylic feeding plate and the Special feeding bottle. Feeding plate aim to obturate the palatal defect to create negative intra-oral pressure, shield sensitive tissues from teat trauma, and guide tongue posture to facilitate suck–swallow–breath coordination [2]. Heat-cured PMMA remains the clinical gold standard because of its rigidity and dimensional stability. Vacuum-formed the rmoplastic sheets are increasingly advocated because they are resilient and can be fabricated rapidly without polymerization monomer exposure<sup>[9,10]</sup>. The present study corroborated these advantages. Consistent with the observational study<sup>[9]</sup>, the PMMA feeding plate significantly improved feeding efficiency relative to the no-plate special teat group.By sealing the oronasal communication, the feeding plate permits generation of intraoral suction pressures comparable to non-cleft neonates<sup>[8]</sup>.

Notably, the acrylic plate delivered higher mean milk transfer rates than the flexible appliance. The rigid plate supplies a firm, stable surface that lets the infant draw milk efficiently<sup>[12-14]</sup>, whereas the flexible vinyl plate can flex, warp, or press into palatal undercuts, causing shifts and flexible tissue injuries that lead to more adjustment visits. The maintenance of the flexible vinyl appliance is particularly sensitive, as the use of warm or hot water during cleaning can result in distortion. This distortion may lead to increased flexible tissue injuries and necessitate more frequent adjustment visits. There are few clinical studies that have directly compared flexible vacuum-formed feeding plates with conventional rigid acrylic feeding plates in infants with cleft lip and palate; the published evidence on flexible plates usually consists of isolated case reports and tiny case series.<sup>[6,11,10]</sup> underscoring the need for the present randomized trial.

## Conclusion

Babies generated better levels of feeding when they used an acrylic feeding appliance in comparison to the flexible appliance and specialized feeding teats.

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