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Determinants of Caregiver Completion and Perceived Outcomes: PLANA vs. NAM

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INTRODUCTION

- Nasoalveolar molding (NAM) is widely used in presurgical infant orthopedics (PSIO), however its requires caregiver compliance both with weekly in-office adjustments and maintenance of the appliance in order to be successful[1-4]

- Appointment frequency, feeding difficulties, intraoral sores, and emergency visits have been associated with reduced NAM compliance[5-7]

- Presurgical Lip, Alveolus, and Nose Approximation (PLANA) is a PSIO technique that utilizes silicone nasal stents in combination with lip-taping to achieve similar nasolabial results as NAM in just four to five office visits[8]

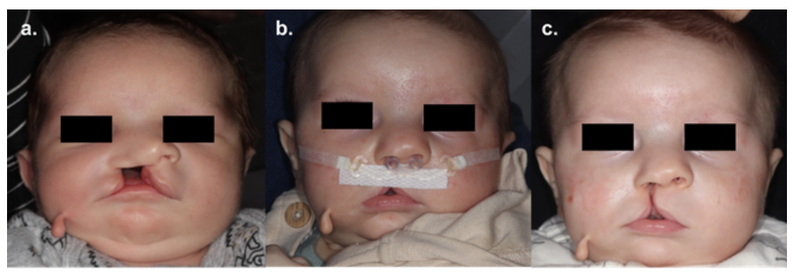


Fig 1. Patient before, during, and after PLANA therapy

- **The purposed of this study was to investigate factors affecting caregiver completion and perceived treatment outcomes of PLANA versus NAM**

MATERIALS & METHODS

- A single-center combined retrospective-prospective study was conducted using a 27-item questionnaire comprised of multiple choice or free response items split into three sections: (1) demographic information; (2) treatment metrics; and (3) subjective caregiver experience

- The questionnaire was distributed to caregivers of patients with cleft lip with or without cleft palate (CL/P) who sought care at Columbia University Irving Medical Center Division of Plastic Surgery between December 2016 and March 2026 and who underwent either PLANA or NAM prior to primary cheiloplasty

- Statistical analysis was conducted with R studio software
  - Mann-Whitney U tests were performed for ordinal and non-normal continuous outcomes while Fisher's exact test was used for categorical outcomes (with Freeman-Halton extension for multi-category variables)
  - Statistical significance was defined as $P < 0.05$

RESULTS

- Thirty caregivers (17 PLANA, 13 NAM) included
- 100% of PLANA completed therapy compared to 84.6% of NAM (P = 0.179)
- No significant differences in demographics

Variables	PLANA (%)	NAM (%)	P value
Caregiver Characteristics			
Gender (n)			
Female	14 (82.4%)	11 (84.6%)	1.000
Male	3 (17.6%)	2 (15.4%)	
Age (years) at time of Child's Birth			
<35 years	5 (31.2%)	5 (41.7%)	0.698
≥35 years	11 (68.8%)	7 (58.3%)	
Race/Ethnicity			
Asian	3 (17.6%)	1 (7.7%)	0.947
Hispanic	4 (23.5%)	3 (23.1%)	
Non-Hispanic Black	3 (17.6%)	2 (15.4%)	
Non-Hispanic White	7 (41.2%)	7 (53.8%)	
Education			
No college degree	6 (35.3%)	5 (38.5%)	1.000
College degree	11 (64.7%)	8 (61.5%)	
Household Characteristics			
Caregivers in Household during PLANA/NAM			
1	0 (0.0%)	1 (7.7%)	0.433
2+	17 (100.0%)	12 (92.3%)	
Family Income			
≤$50,000	4 (23.5%)	1 (7.7%)	0.355
>$50,000	13 (76.5%)	12 (92.3%)	
Caregiver Working Full-Time During PSIO			
Not working full-time	15 (88.2%)	8 (61.5%)	0.190
Working full-time	2 (11.8%)	5 (38.5%)	
Reason for Not Working Full-Time			
Maternity or Family Leave	11 (73.3%)	3 (37.5%)	0.172
Unemployed	4 (26.7%)	4 (50.0%)	
Unknown	0 (0.0%)	1 (12.5%)	
Access to Care			
Distance to Treatment Center			
≤30 miles	11 (68.8%)	8 (61.5%)	0.714
>30 miles	5 (31.2%)	5 (38.5%)	
Travel Time to Treatment Center			
≤60 min	11 (64.7%)	7 (53.8%)	0.711
>60 min	6 (35.3%)	6 (46.2%)	
Took Public Transportation to Treatment Center			
No	14 (82.4%)	11 (84.6%)	1.000
Yes	3 (17.6%)	2 (15.4%)	
Insurance			
Insurance Type			
Private	9 (52.9%)	8 (61.5%)	0.721
Public (Medicaid)	8 (47.1%)	5 (38.5%)	
Did Insurance Cover PLANA/NAM Therapy?			
No insurance coverage	1 (5.9%)	1 (7.7%)	1.000
Insurance coverage	16 (94.1%)	12 (92.3%)	

Table 1. Demographics of PLANA/NAM caregivers

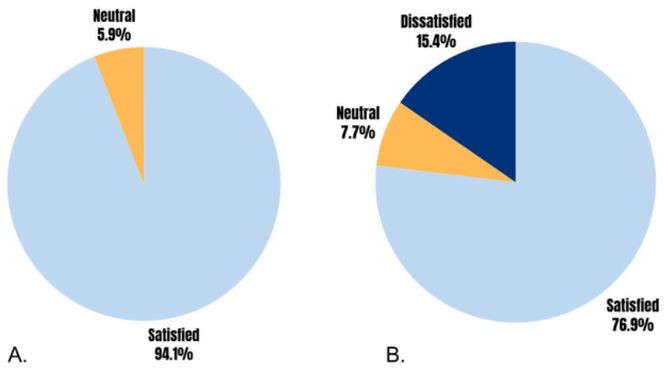


Fig 2. Caregiver satisfaction with PLANA vs. NAM

Variables	PLANA (%) n = 17	NAM (%) n = 13	P value
Skin Reactions or Allergies to Device			
None/Mild	9 (52.9%)	9 (69.2%)	0.465
Moderate/Severe	8 (47.1%)	4 (30.8%)	
Ulcerations on the Lips			
None/Mild	13 (100%)	17 (100%)	1.00
Moderate/Severe	0 (0.0%)	0 (0.0%)	
Ulcerations on the Nose			
None/Mild	13 (100%)	17 (100%)	1.00
Moderate/Severe	0 (0.0%)	0 (0.0%)	
Ulcerations on the Gum Ridges			
None/Mild	17 (100%)	12 (92.3%)	0.433
Moderate/Severe	0 (0.0%)	1 (7.7%)	
Feeding Difficulties			
None/Mild	17 (100%)	9 (69.2%)	**0.026**
Moderate/Severe	0 (0.0%)	4 (30.8%)	
Breathing Difficulties			
None/Mild	16 (94.1%)	13 (100%)	1.00
Moderate/Severe	1 (5.9%)	0 (0.0%)	

Table 2. PLANA/NAM-Related Clinical Complications

- Zero PLANA caregivers indicated dissatisfaction with the treatment outcome compared to two NAM caregivers (P = 0.167)
- More caregivers perceived moderate-to-significant facial change after PLANA compared to NAM (88.2% vs. 66.7%, P = 0.198)
- PLANA caregivers reported significantly less feeding difficulty during therapy (0% PLANA, 30.8% NAM, P = 0.026)
- NAM caregivers reported less skin reactions or allergies to the device (30.8% NAM, 47.1% PLANA, P = 0.465)

CONCLUSIONS

- This study observed no significant differences in social, financial, or geographic access to care across PLANA and NAM caregivers

- PLANA caregivers reported less feeding difficulty and more skin irritation than NAM caregivers

- Despite more skin irritation, PLANA caregivers reported greater rates of treatment completion, more perceived facial change, and higher satisfaction following treatment

- PLANA's simplified design and treatment protocol may be associated with a more favorable caregiver experience and perceived patient outcomes

CLINICAL SIGNIFICANCE

- PLANA should be considered an integral PSIO option for craniofacial teams seeking to reduce treatment burden while supporting caregiver satisfaction and treatment completion

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