

Expanding Access to Nasoalveolar Molding in Cleft Care by Identifying Barriers and Demystifying Burden of Care

2020 Grants

Dr. Pradip Shetye

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FollowUp Form

Award Information

In an attempt to make things a little easier for the reviewer who will read this report, please consider these two questions before this is sent for review:

- Is this an example of your very best work, in that it provides sufficient explanation and justification, and is something otherwise worthy of publication? (We do publish the Final Report on our website, so this does need to be complete and polished.)*
- Does this Final Report provide the level of detail, etc. that you would expect, if you were the reviewer?*

Title of Project*

Expanding Access to Nasoalveolar Molding in Cleft Care by Identifying Barriers and Demystifying Burden of Care

Award Type

Biomedical Research Award (BRA)

Period of AAOF Support

July 1, 2020 through June 30, 2023

Institution

NYU Grossman School of Medicine

Names of principal advisor(s) / mentor(s), co-investigator(s) and consultant(s)

Dr. Barry Grayson

Amount of Funding

\$30,000.00

Abstract

(add specific directions for each type here)

Respond to the following questions:

Detailed results and inferences:*

If the work has been published, please attach a pdf of manuscript below by clicking "Upload a file".

OR

Use the text box below to describe in detail the results of your study. The intent is to share the knowledge you have generated with the AAOF and orthodontic community specifically and other who may benefit from your study. Table, Figures, Statistical Analysis, and interpretation of results should also be attached by clicking "Upload a file".

Shetye, Pradip final report BRA 2020.pdf

Were the original, specific aims of the proposal realized?*

Yes

Were the results published?*

Yes

Have the results of this proposal been presented?*

Yes

To what extent have you used, or how do you intend to use, AAOF funding to further your career?*

The award and the research have helped in my recent promotion from the title of Assistant Professor to Associate Professor.

Comment: Thank you for sharing this positive outcome. We appreciate knowing the impact of AAOF awards on orthodontic career development.

Accounting: Were there any leftover funds?

\$0.00

Published

Citations*

You indicated results have been published. Please list the cited reference/s for publication/s including titles, dates, author or co-authors, journal, issue and page numbers

One manuscript was published in the Cleft Palate and Craniofacial Journal, and the second one is under review with Journal of Craniofacial Surgery. Park JJ, Alfonso AR, Kalra A, Staffenberg DA, Flores RL, Shetye PR. Defining the Treatment Gap in Nasoalveolar Molding: Factors Affecting the Utilization of NAM in an Urban Cleft Center. Cleft Palate Craniofac J. 2022 Dec 22

Comment: *Your efforts are significant and impressive. We encourage you to continue pursuing publication of the work from this grant.*

Was AAOF support acknowledged?

If so, please describe:

n/a

Comment: *We appreciate that your answer of n/a may refer to the fact that you are still working on papers, but our question is to determine if your publication or posters acknowledge the AAOF support (under acknowledgements).*

Presented

Please list titles, author or co-authors of these presentation/s, year and locations:*

see attachment

Was AAOF support acknowledged?

If so, please describe:

Internal Review

Reviewer Comments

Reviewer Status*

Approved

File Attachment Summary

Applicant File Uploads

- Shetye, Pradip final report BRA 2020.pdf



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AAO Foundation Final Report Form (a/o 5/30/2023)

Please prepare a report that addresses the following:

Type of Award: American Association of Orthodontic Foundation, Robert L. Boyd Biomedical Research Award 2020-2021.

Name(s) of Principal Investigator(s): **Pradip R. Shetye DDS, BDS, MDS**

Institution: Hansjörg Wyss Department of Plastic Surgery, New York University School of Medicine, New York, NY, United States of America.

Title of Project: Expanding Access to Nasoalveolar Molding in Cleft Care by Identifying Barriers and Demystifying Burden of Care

Period of AAOF Support: 07-01-2020 to 06-30-2023

Amount of Funding: \$30,000 USD

Summary/Abstract: The project was completed and submitted for publication in two parts. Below are the abstracts

The Burden of Care of Nasoalveolar Molding: Assessment of an Institutional Experience

Allyson R. **Alfonso**, MD¹; Jenn J. **Park**, BS¹; Aneesh **Kalra**, BDS, MOrth¹; Evellyn M. **DeMitchell-Rodriguez**, MD¹; Hudson C. **Kussie**¹; Chen **Shen**, MD¹; David A. **Staffenberg**, MD¹; Roberto L. **Flores**, MD¹; Pradip R. **Shetye**, DDS¹

Abstract

Background: Nasoalveolar molding (NAM) is an early pre-surgical intervention to facilitate primary cleft lip repair by reducing cleft severity and improving labial and nasal form. However, it continues to be associated with the burden of care that influences access and completion of therapy. The authors, therefore, aim to determine the burden of care of NAM therapy for families seeking treatment at a high-volume urban cleft center.

Methods: A retrospective study of all patients undergoing primary cleft repair between 2012-2020 was performed. Patients were grouped based on whether or not NAM therapy was offered. Variables including physical, psychosocial and financial factors were assessed.

Results: Two hundred and thirty-seven patients underwent primary cleft repair between 2012-2020. Of these, 176 patients were indicated for NAM, with 4% discontinuing, and 61 patients did not undergo NAM. The 169 patients who completed NAM had a mean duration of treatment of 13.6 ± 8.8 weeks consisting of 15 ± 6 scheduled NAM adjustment visits and 1 ± 1 unscheduled visit made urgently to assess caregiver concerns. Mean travel distance was 28.6 ± 37.1 miles. Eighty-four percent of caregivers were married and 16% did not have English as a primary language. Though 57% had private insurance, 43% of patients received charity support for their treatment.

Conclusions: NAM is a finite pre-surgical intervention that requires caregivers to participate in patient care for approximately three months of their early life. The decision to pursue NAM should be considered alongside the burden of care for caregivers to complete treatment.

This research was virtually presented at the 78th American Cleft Palate-Craniofacial Association Annual Meeting, April 28 - May 1, 2021, Portland, Oregon, and in person presented at the 14th International Cleft Congress, 11-15 July 2022, Edinburg, Scotland, UK, and the final manuscript has been submitted to Journal of Craniofacial Surgery and is under review.

Defining the Treatment Gap in Nasoalveolar Molding: Factors Affecting the Utilization of NAM in an Urban Cleft Center

Jenn J. Park¹, Allyson R. Alfonso¹, Aneesh Kalra¹, David A Staffenberg¹, Roberto L. Flores¹, Pradip R. Shetye¹

Abstract

Background

A majority of cleft centers incorporate nasoalveolar molding (NAM), a presurgical intervention to align the cleft alveolus, into treatment protocols. However, there are limited data on patients who may be eligible for but do not receive NAM. Here, we characterize the reasons for the non-utilization of NAM and identify associated demographic factors.

Methods

A single-institution retrospective review was performed of all patients with cleft lip and alveolus undergoing primary unilateral and bilateral cleft lip repair from 2012-2020. Patients were grouped based on NAM status. Demographic and treatment data were collected, including the documented reasons for not pursuing NAM.

Results

Of 230 eligible patients, there were 61 patients who did not undergo NAM (no-NAM) and 169 patients who underwent NAM (NAM). In the no-NAM group, 37 (60.7%) received no presurgical intervention, 12 (19.7%) received presurgical nostril retainers, 3 (4.9%) received lip taping, 1 (1.6%) received a combination of taping/nostril retainers, and 7 (11.5%) discontinued NAM. The most common reasons for not receiving NAM were a cleft alveolus with sufficient

alignment (21.3%), medically complex patient (16.4%), late presentation (16.4%), and alveolar notching (18%). Compared to the NAM group, the no-NAM group had a significantly higher proportion of non-married caregivers and caregivers whose primary language was not English. There was no significant difference in the distance of family from the treatment center or insurance coverage between groups.

Conclusions

Common reasons for non-utilization of NAM include well-aligned cleft alveolus, medical complexity, and late presentation. Socioeconomic factors including caregiver marital status and primary language may affect rates of NAM utilization.

This research was presented at The Northeastern Society of Plastic Surgery meeting on Sept 30th 2022 and the manuscript has been published in Cleft Palate Craniofacial Journal.

Respond to the following questions:

1. Were the original, specific aims of the proposal realized?
 - a. Yes
2. Were the results published?
 - a. If so, cite reference/s for publication/s including titles, dates, author or co-authors, journal, issue, and page numbers
 - a. One manuscript was published in the Cleft Palate and Craniofacial Journal, and the second one is under review with Journal of Craniofacial Surgery.

Park JJ, Alfonso AR, Kalra A, Staffenberg DA, Flores RL, Shetye PR. Defining the Treatment Gap in Nasoalveolar Molding: Factors Affecting the Utilization of NAM in an Urban Cleft Center. Cleft Palate Craniofac J. 2022 Dec 22

- b. Was AAOF support acknowledged?
 - a. Yes, AAOF has been acknowledged in the presentation and publication.
 - c. If not, are there plans to publish? If not, why not?
 - a. n/a
 3. Have the results of this proposal been presented?
 - a. If so, list titles, author or co-authors of these presentation/s, year and locations
 - a. Please see above
 - b. Was AAOF support acknowledged?
 - a. AAOF was acknowledged
 - c. If not, are there plans to do so? If not, why not?
 - a. n/a
 4. To what extent have you used, or how do you intend to use, AAOF funding to further your career?

The award and the research have helped in my recent promotion from the title of Assistant Professor to Associate Professor.

Accounting for Project:

Funding has been fully exhausted and there is no remaining balance at the time of the project end date