

## ABSTRACT

**Purpose:** The aim of this pilot study was to determine the accuracy of digital fabrication compared to conventional fabrication of nasoalveolar molding (NAM) appliances to treat infants born with cleft lip and palate.

**Methods:** Conventional and digital impressions were obtained on 5 infants born with cleft lip and palate. Custom impressions were taken using a custom tray and Aluwax. Digital impressions were obtained using the TRIOS 3Shape scanner. Conventional and digital NAMs were fabricated. Both models and NAMs were compared digitally using Romexis software, which compared the mm difference between the 2.

**Results:** Average differences between the 2 copies of each case cast was -0.372mm and for the NAMs was -0.408mm. Tolerance level of 0.200mm and confidence interval of 95.0% was used. Traditionally fabricated NAMs fit on all 3D printed casts.

**Conclusions:** Although variations exist between the stone and 3D printed casts, the ability of traditionally fabricated NAMs to fit on 3D printed casts demonstrated that these differences were not clinically significant.

## BACKGROUND

- Cleft lip and/or cleft palate (Figure 1) represent the most common orofacial birth defects in humans.
- Presurgical Infant Orthopedics (PSIOs) were first introduced in the 16<sup>th</sup> century and has been updated throughout the years.
- NAM (Figure 2), introduced by Grayson in 1993, corrects the alveolus, lip and nose in one stage in infants with CL/P.
- An impression of the cleft site is required for NAM therapy; there is no standard impression technique or material.
- Digitization of impressions and appliance fabrication is emerging as technologies improve.
- The goal of this projects is to compare digital impression, design, and 3D print of NAM appliances to conventional methods.**



Figure 1: Complete right unilateral CLP in a 3-month-old prior to NAM treatment.



Figure 2: Traditionally fabricated NAM with nasal stent addition.

## METHODS

### Conventional NAM Fabrication Protocol:

- This portion is standard of care following traditional methods.
- Impression made using an elastomeric material in an infant acrylic impression tray, in a medical setting
- Stone impression is poured
- NAM will be fabricated on the stone model using PMMA acrylic resin

### Study NAM Fabrication Protocol:

- This portion is the study component.
- Digital impression will be obtained using either the TRIOS scanner
- Digital impression will be sent to the dental team to convert into a format compatible with 3D software
- NAM will be digitally fabricated, and 3D printed using Formlabs Dental LT Clear 3D printed resin and COE Soft reline material

- Conventional and study models and NAMs were digitally compared using Romexis software. Tolerance level of 0.200mm and confidence interval of 95.0% was used.

## RESULTS

- Five infants with cleft lip and palate were recruited for this study (Figure 3)
- Conventional casts and NAMs were fabricated (Figure 4A).
- Digital casts and NAMs were 3D printed (Figure 4B).
- Conventional casts and NAMs were superimposed on the study casts and NAMs (Figure 5).
  - Mean average difference for casts: -0.372mm.
  - Mean average difference for NAMs: -0.408mm
- Traditionally fabricated NAMs fit on 3D printed casts
- No significant difference between the conventional and study casts.
- Significant difference between the conventional and study NAM's.

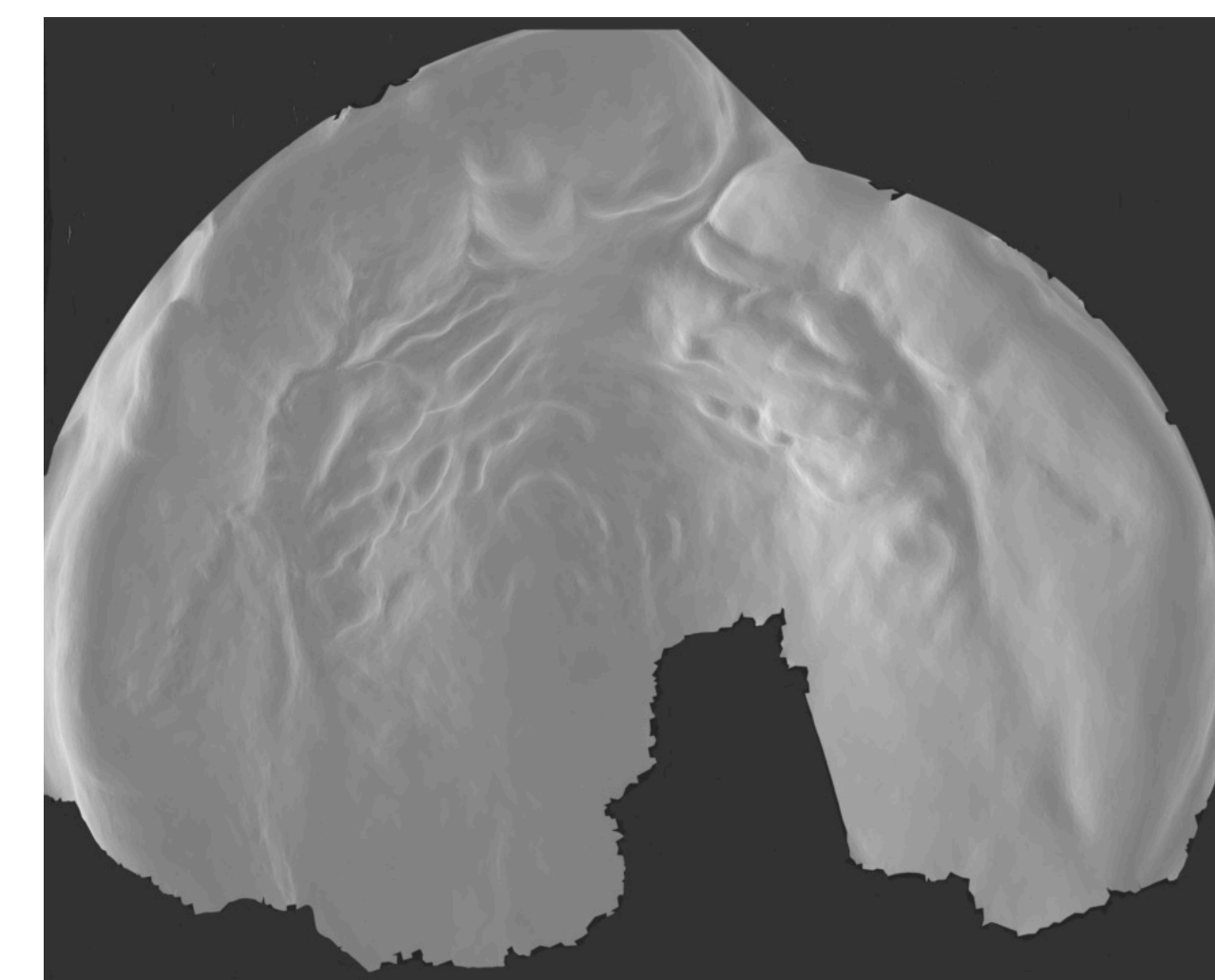


Figure 3: Intraoral scan- 1-month-old with unilateral left CL/P- jpg format



Figure 3: (A) Traditional casts and NAMS and (B) Digital impression casts and digitally fabricated NAMS



Figure 5: Superimposition of scanned traditional cast and digital impression cast on Romexis.

## DISCUSSION

- The riskiest part of PSIO therapy is the impression, therefore it is recommended by the AAPD that impressions be performed in a clinical setting such as a hospital, where medical or dental personnel are prepared to handle infant airway emergencies.**
- This study showed that accurate digital impressions can be obtained on infants with CL/P.**
- 3D printed NAMs were not as accurate as those fabricated manually specifically in the cleft region.**

### Limitations:

- Small sample size
- Lack of intraoral comparison between convention and study NAMs.

### Further research:

- Increase sample size
- Comparison between convention and study NAMs intraorally
- Alteration to the digital fabrication of NAMs is required, cleft areas need to be blocked out prior to fabrication.

## CONCLUSION

**Digitization of impression and appliance fabrication have a promising future for NAM therapy**

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## REFERENCES

