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# Conventional Pre-Surgical Naso-Alveolar Molding (PNAM) Device versus CAD/CAM PNAM Conjugated with Surgical Anatomical Nasal Stent for the Treatment of Unilateral Cleft Lip and Palate

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**ABSTRACT**

Objectives: comparing the effect of conventional PNAM and CAD/CAM-PNAM devices for the presurgical preparation of unilateral cleft lip and palate and also using a new surgical nostril retainer based on anatomy which facilitate repair of nose during unilateral cleft lip. **Design**: randomized controlled clinical trials with double blind evaluation as a part of a research work conducted on 20 children. **Setting**: prosthodontics department, faculty of dentistry Mansoura University and its related hospital's **Patients**: all patients were selected with the same criteria of non-syndrome associated unilateral cleft lip reaching nostril. **Interventions**: patients were randomly divided in two equal groups each patient receives NAM device according to each group criteria. **Results**: cleft gap was measured pre/post NAM and there were a significant difference between before and after for each group and there was no significant difference between both groups. Better symmetry was achieved in cases using the surgical custom nostril retainer. **Conclusions**: PNAM contributed effectively for reduction of cleft gap and subsequently, in lip repair surgery, the use of anatomical nasal retainer is helpful, best fits, cheaper, saves time and facilitates surgical reconstruction with better results.

## INTRODUCTION

Cleft lip and palate is reported to occur in approximately 1 in 700 live births, with the prevalence in Egypt to be 0.3/1000.(1) About half of the oral clefts involve lip and palate (46%), a third of the clefts involve only the palate (33%), and clefts of lip alone account for 21%. CL/ P are more often unilateral than bilateral and more common in males than females. The unilateral defects occur more often on the left side than the right side.(2)

The principal objective of presurgical nasoalveolar molding (NAM) is to reduce the severity of the initial cleft deformity. This enables the surgeon and the patient to enjoy the benefits associated with repair of cleft deformity that is of minimal severity.(3) The aim of NAM is to reduce the severity of the cleft (e.g., nasal deformity, cleft size), thereby improving future surgical results, reducing the need for lip and nose revisions, and minimizing scarring. NAM has been shown to significantly improve nasal symmetry in both the short (3 months to 1 year) and long term (3 to 12 years).(4)

The integration of CAD/CAM technology for serial NAM plate production in the treatment of cleft patients represents a special field with high potential but is, as yet, in its fledgling stages. The production of purely virtually designed NAM plates is currently possible, but nevertheless, the final plate adaptation has to be performed within the mouth of the infant.. In particular, the integration of the nasal stent remains difficult and needs more research in the programming steps.

Ritschl *et al* (2016) found that NAM plates can be produced virtually by using CAD/CAM technology. The CAD/CAM NAM results show no significant differences from the conventional technique.(5)

Yu *et al* found that CAD-NAM effectively reduced the cleft gap, corrected the maxilla midline, and improved the sagittal length of the maxilla. The alveolar height decreased significantly after the treatment, which indicated that the traction force of the appliance may have obstructive effects on the vertical growth of the alveolar bone.(6)

Postoperative maintenance of the corrected nostrils is a must for achieving a symmetric and well-proportioned nose in patients with cleft nasal deformity.(7) The use of a nasal retainer that sustains the corrected nasal cavity for several months after surgical repair of cleft lip-nose deformity have great effect and was shown by Yeow et al.(8)

Due to controversy between published researches regarding the efficacy of CAD NAM versus conventional NAM, so the aim of this study was to compare the effect of conventional NAM and the CAD/NAM in conjugation with surgical nasal retainer.

## PATIENTS AND METHODS

Twenty infants with non-syndrome associated unilateral cleft lip and palate were referred from the Outpatient Clinic of Mansoura Children Hospital and Plastic Surgery Department at Mansoura University to Prosthodontics department at Faculty of Dentistry Mansoura University. All parents were thoroughly informed about the full details of the PNAM procedures. They approved written consents for inclusion in the study. All steps were done after approved from the Ethical Committee of Faculty of Dentistry, Mansoura University. Study was designed to be randomized controlled clinical trials with double blind evaluation.

All infants were randomly grouped into two different groups; each group consisted of 10 infants (I and II) using block randomization sealed envelope method. Preoperative images were taken according to the following method: A series of standard basilar view photographs in 1:1 ratio were taken for each patient at resting posture by tilting the infant's head back to bring the alar domes to a level below the eyebrows but above the canthi. (9)

Impressions were taken by the prosthodontist using a special tray with heavy body rubber base material according to Grayson 2005 (10). For group I The molding plate is fabricated according to (11) on the dental stone model. For group II the cast was digitally scanned and using 3shape® dental software, special tray in appliances module in dental designer CAD NAM was designed according to Ritschel *et al* (5) . Plates were printed using frozen 3D printer using biocompatible denture resin from NextDent. Figure 3

NAM devices were inserted and parents were informed about using the devices. Follow up were made weekly (group I) and biweekly (group II).

After 3 months (group I) children were sent for lip repair surgery. A customized nasal surgical retainer was constructed for group II children. Cotton buds were placed into nasal openings. Light body Silicon impression was injected into both nostril openings and then heavy body was adapted over it. The impression was 3D scanned and nostril outline was copied and mirrored using Meshmixer software. Finally, the nostril retainer was construed from PEEK material in order to be sterilized before surgery.

The surgical closure was done using Millard repair (12) For group II the nostril retained was fixated to the nose using suture. (See Figure 1) After surgery, indirect anthropometric measurements (nostril height, nasal basal height, columellar height, nostril width, and nasal basal width) were made on the digital photographs with the help of IMAGE ANALYSIS software. (See Figure 2) The casts were 3d scanned at the time of initiation of PNAM and then on completion of PNAM before cheiloplasty. The present study confirmed the landmarks and reference lines (see Figure 4) using the methods described by Mazaheri *et al* (13).

The data were analyzed using SPSS® software version 22 (SPSS Inc., Chicago, IL, USA). One-Sample Kolmogorov-Smirnov and Shapiro Wilk tests were used to diagnose normality of data distribution of all variables. The data were parametric and presented as mean±SD for comparisons. Between-group comparisons of nasal and cast measurements was performed using independent t-test. To detect significant differences intact and cleft side nasal measurements and between before and after cast measurements, paired samples t-test was used. P-values <0.05 were considered to be significant.

**Figure 1 showing the nasal stent in place with surgical correction**

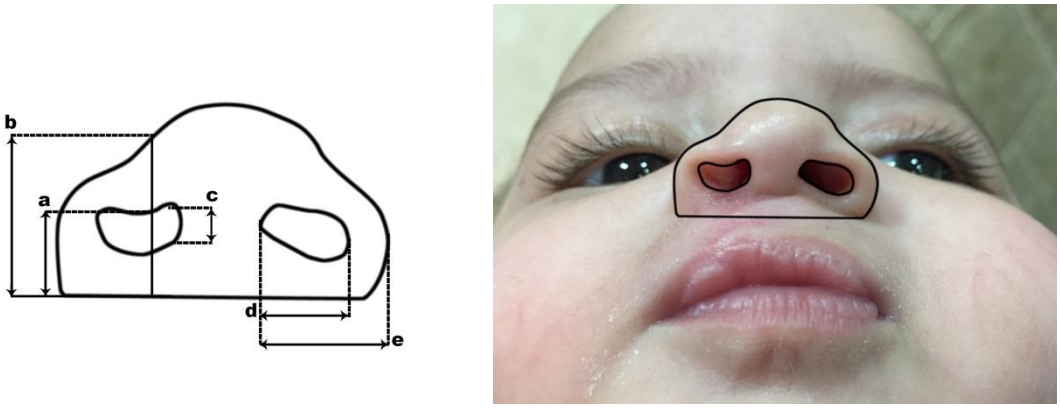


**Figure 2 showing final result and landmarks for measurements**

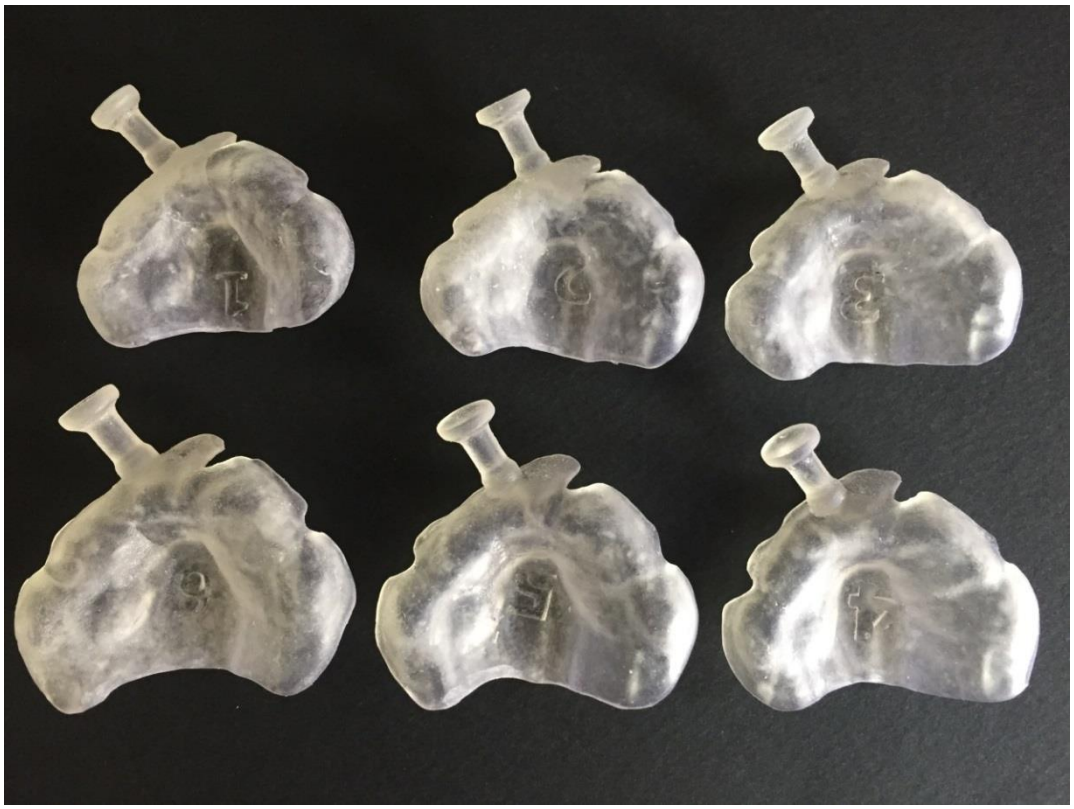

**Figure 3 CAD NAM plates with different sizes**

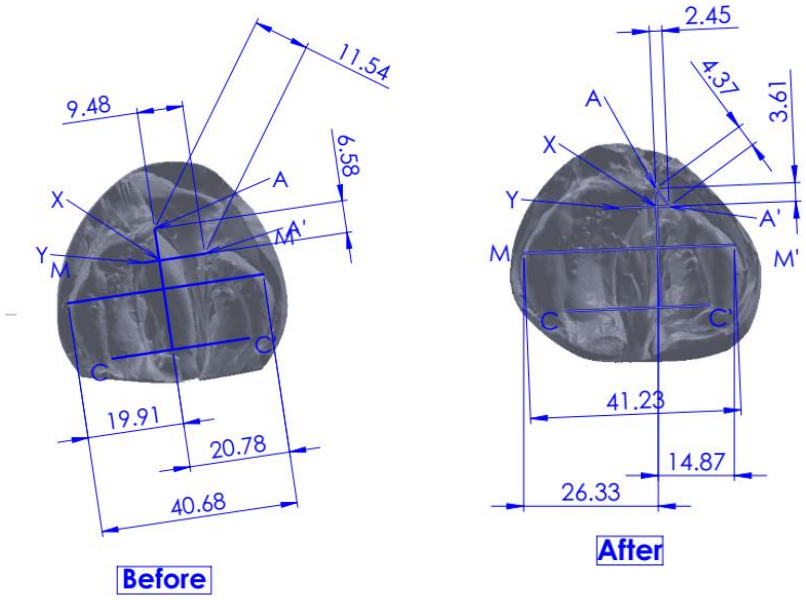


**Figure 4 showing before and after result of cast measurements**

## RESULTS

**Nasal measures (**Table 1**)**

There was no significant difference in all nasal measurements between groups except c_(CS). For c_(CS), group II showed significant higher values than group I (p=.027). No significant difference (in difference in nasal measurements between (IS) and (CS) side between groups or landmarks was noted.

**Table 1 Difference in nasal measurements between intact and cleft side**

| | | a_(CS) | a_(IS) | b_(CS) | b_(IS) | c_(CS) | c_(IS) | d_(CS) | d_(IS) | e_(CS) | e_(IS) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Gp I conv NAM** | ***X*** | .797 | .993 | 1.799 | 1.817 | .317 | .405 | .887 | 1.256 | 1.473 | 1.811 |
| | ***SD*** | .196 | .245 | .218 | .282 | .124 | .128 | .237 | .213 | .283 | .272 |
| **Gp II CAD NAM** | ***X*** | .932 | 1.158 | 1.914 | 1.898 | .486 | .480 | 1.018 | 1.105 | 1.580 | 1.646 |
| | ***SD*** | .233 | .370 | .238 | .413 | .184 | .189 | .187 | .231 | .204 | .221 |
| **Indep t-test(p value)** | | .17 | .25 | .27 | .61 | .027* | .30 | .18 | .14 | .34 | .15 |

**Cast measures** (Table 2)

For difference between before and after measurements A'_X, A_A' and M'_X group II showed more significance than group I. For other cast measurements no significant differences between groups were noted.

**Table 2 difference in cast measurements between before and after PNAM for both groups**

| | | A'_X before | A'_X after | Difference of *X* | A_X_before | A_X_after | A_A' before | A_A' after | Difference of *X* | M_M' before | M_M after | M'_X before | M'_X after | Difference of *X* | M_X_before | M_X_after | Difference of *X* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Group I** | ***X*** | 6.614 | 2.692 | **3.922** | 8.181 | 3.653 | 7.120 | 2.818 | **4.302** | 39.713 | 41.754 | 17.657 | 16.405 | **1.252** | 21.807 | 25.151 | -3.344 |
| | ***SD*** | 3.711 | 3.046 | | 4.354 | 3.079 | 3.595 | 1.377 | | 2.391 | 3.269 | 4.353 | 3.843 | | 3.293 | 2.457 | |
| **Group II** | ***X*** | 11.004 | 3.710 | **7.294** | 7.837 | 4.062 | 11.378 | 4.965 | **6.413** | 41.018 | 42.667 | 22.048 | 19.805 | **2.243** | 18.868 | 22.719 | -3.851 |
| | ***SD*** | 4.652 | 2.414 | | 4.738 | 2.052 | 4.970 | 2.579 | | 4.599 | 4.074 | 3.196 | 4.349 | | 2.087 | 4.602 | |
| **p val** | | .031* | .41 | | .86 | .73 | .042* | .032* | | .43 | .58 | .019* | .049* | | .028* | .15 | |

## DISCUSSION

The efficacy of both techniques, i.e. Grayson's PNAM and CAD-CAM PNAM comparing the maxillary cast analysis preoperatively and postoperatively showed a significant decrease in the distance between major and minor segments and increase in the arch width postoperatively in both Group I and II,

Yu *et al* found that CAD-NAM effectively reduced the cleft gap, corrected the maxilla midline, and improved the sagittal length of the maxilla. The alveolar height decreased significantly after the treatment, which indicated that the traction force of the appliance may have obstructive effects on the vertical growth of the alveolar bone. (6)

Ritschl *et al* found that NAM plates can be produced virtually by using CAD/CAM technology. The CAD/CAM NAM results show no significant differences from the conventional technique. (5)

## CONCLUSION

Both NAM techniques similarly improved nasal deformities and reduced alveolar gaps, but the CAD NAM was more efficient and reduces visits and treatment time.

CAD NAM significantly decrease the cleft gab height than the conventional NAM.

Using nostril retainer makes surgical repair easier for surgeon and assures support of nostril.

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