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Changes in nose symmetry in unilateral cleft lip and palate treated by differing pre-surgical assistance: An objective assessment of primary repair[☆]

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ABSTRACT

Background: Residual deformity of the nose, not lip, continues to be the greater challenge in UCCLP rehabilitation. Platform distortions often re-emerge following primary reconstruction revealing the stereotypical cleft-nose. Nasal alveolar molding reduces nose asymmetry. However, this study applies directional mechanics to the underlying platform distortions and soft tissue nose, introducing a novel device addressing the distorted septo-premaxillary junction.

Methods: Retrospective assessment of 47 UCCLP patients by 2-dimensional photographic analysis with 24 subjects treated by dento-maxillary advancement (DMA) and nasal septum button-head pin (NSBP), 17 having nasal molding (NM), compared to 23 subjects without nose treatment, 16 with DMA and 7 with passive plates. Measurements were assessed by *t* tests, ≤ 0.05 confidence.

Results: Frontal view: nose-treatment sample achieved ideal ala-bases vertical symmetry ($p = 0.00065$ & 0.00073); significantly improved ala-rims “slump” angle ($p = 0.0071$). Both samples had nose positioning within the facial frame like non-cleft population. Sub-nasal view: significant differences were for columella angle ($p = 0.0015$), nares “offset” ($p = 0.002$), and columella symmetry ($p = 0.022$) with nose-treatment achieving near ideal columella symmetry score (0.92) vs. (0.81).

Conclusions: NM and the novel NSBP procedures integrated with the platform correction effect of the DMA successfully treated at three distorted anatomic-levels native to UCCLP to improve nasal aesthetics.

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1. Introduction

Facial esthetics plays a key role in social attractiveness (Shaw et al., 1985; Asher-McDade et al., 1992); nasal form and function are of great concern to patients with unilateral complete cleft lip palate UCLP (Asher-McDade et al., 1992; Mani et al., 2013). UCLP

nasal platform has a stereotypic pattern of distortions with deviation of nasal septum with height foreshortening, reverse bending of the pre-maxilla, and asymmetry in antero-posterior, vertical, and lateral positions of the piriform rims at prenatal age (Latham, 1990), at postnatal age 3 month (Zemann et al., 2002), and at adult age 20 years (Wu et al., 2013).

Although innovative primary repair (Miyamoto et al., 2007) and bone grafting for nasal support are advocated (Nagasai et al., 2009; Kau et al., 2011), they are without long-term effect for piriform symmetry, nasal morphology, or nostril shape (Sander et al., 2011; Tai et al., 2000; Feichtinger et al., 2006; Wu et al., 2008). Obscured by unstable reconstructive procedures, the

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platform distortions re-emerge and sustain the discernible stigmata of the cleft nasal deformity residing in three-dimensions and three tissue layers (Wu et al., 2013; Bardach and Cutting, 1990; Cohen et al., 2003).

The Hotz plate (Hotz and Gnoinski, 1976), commonly used in Europe does not improve nose aesthetics (Yamada et al., 2003). Marginal improvements on nasal aesthetics reported by Matsuo et al. (1989) use isolated nose stents, and more recently more effective results by others (Berggren, 2001; Monasterio et al., 2008) employ isolated nasal elevators. Attached to classical alveolar molding plates (McNeil, 1950, 1954; Burston, 1958), nasal molding devices evolved between 1991 and 2001 (Dogliotti et al., 1991; Grayson et al., 1993; Grayson and Santiago, 1997; Grayson et al., 1999; Grayson and Cutting, 2001) as “Naso-alveolar molding” intended to align cleft defect margins, reduce columella, nasal tip, and ala rim asymmetries; beneficial and stable effects on nasal form are claimed and stable long-term (Maul et al., 1999; Lee et al., 2008; Barillas et al., 2009).

Consistent cleft-side ala base support is established for cleft lip and nasal reconstruction using *dentomaxillary advancement* (DMA) appliance therapy according to Latham (Millard, 1990; Latham, 1980; Spolyar et al., 1992, 1993), however, without reasonable improvement in the stubbornly abnormal nasal septum and pre-maxilla native positions (Spolyar et al., 1992). This equally crucial anatomic area of the cleft maxilla, considering nose aesthetics, is constantly deformed. There is no pre-surgical means described that yet approaches the cleft deformity at that level. Although, primary surgical correction of nasal septal deviation for anterior centering has been described (Janiszewska-Olszowska et al., 2014).

The aim of the present study is to evaluate nose symmetry in UCLP postoperatively after incorporating two novel pre-surgical devices that attempt to correct septo-premaxillary and nasal distortions assessed by 2D-photography like other studies (Brusse et al., 1999; Gotfredsen et al., 1999; Russell and Tompson, 2009; Kim et al., 2009; Pigott and Pigott, 2010) without need for subjective rating (Asher-McDade et al., 1991; Lo et al., 2002; Iliopoulos et al., 2014), or specialized equipment (Fisher et al., 1999; Ferrario et al., 2003; Nkenke et al., 2006).

2. Material and methods

This retrospective study assesses the effect of those presurgical devices on nose symmetry compared with a patient collective treated by Latham appliance or a passive orthopedic plate.

2.1. The nasal devices

Introduced by the first author (JLS), the *nasal septum buttonhead pin* (NSBP) is a tool to reduce septum deviation (Fig. 1); it is placed through the non-cleft naris and tether-chained to the Latham DMA (Fig. 2). *Nasal molding* (NM), designed by first author (JLS), is intended to improve nasal distortions and, like NSBP, adding another level of treatment to presurgical therapy (Fig. 3).

Early-on, an unpublished NSBP pilot study of frontal serial cephalographs ($n = 4$) showed the nasal septum deflection angle was reduced by mean 22° from 57° to 35° that would increase nasal height by 3 mm with estimated 11 mm septum length. This finding was consistent with the cross sectional cast study ($n = 4$, treatment and $n = 8$, control) findings from direct measurements for anterior premaxillary descent (3.0 mm) related to the greater segment medial incline angle reduction (6°). This study gave substance for photographic analysis of clinically detectable nasal feature changes.

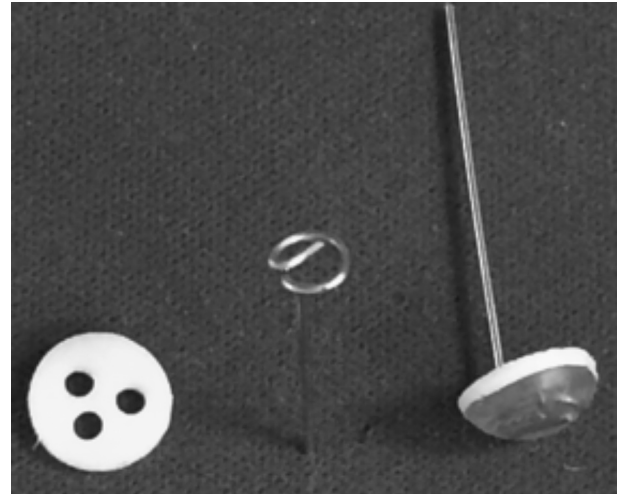


Fig. 1. View of nasal septum button-head pin (NSBP). The button is made with 1 mm Teflon sheet material using 7 mm leather punch and three (3) holes added. A 0.022 (0.58 mm) ss wire is bent to form a flat-end helix with the length of the shaft passing through one hole, the other two used to secure the button-head to the helix using .014 (0.37 mm) ligature wire. Light cured acrylic “gel” is added to the button-head making it more secure. The pin is trimmed to 25 mm length and end sharpened. The NSBP materials withstand all methods of sterilization.

2.2. Patients and cohorts

The patients of first author (JLS) had primary surgical repair at Children's Hospital of Michigan, Detroit; Providence Hospital, Southfield & St John/Providence Park, Novi and William Beaumont Hospital, Royal Oak, Michigan, USA.

Cases were excluded with associated syndromes, incomplete clefts, Simonart's band, secondary nose surgery beyond the primary repair, prior orthodontic treatment, and photos or images of poor quality or view.

Cases included were Caucasian or Non-Caucasian subjects with isolated complete UCLP with or without primary or secondary

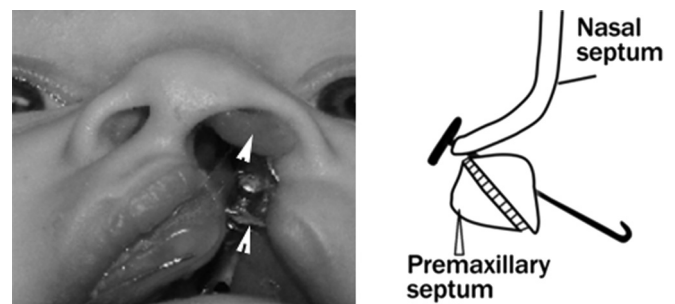


Fig. 2. Application of the NSBP: (left) infant UCLP, age 10 weeks shows nasal molder (NM) (top arrow) and NSBP properly positioned behind premaxilla (bottom arrow) with elastic chain attached. Gentle initial tensioning is used, since force strain exceeding growth adaptation can lead to excoriation, dehiscence, or focal distortion of the septum. Light continuous force is sufficient. (right) Frontal schematic shows NSBP positioning to nasal septum (NS) and premaxilla. Pin enters through non-cleft naris placed dorsal and beyond about 7 mm (depth of premaxillary alveolus) and oriented about 60° to caudal exiting intraoral at side opposite and behind alveolar premaxilla. In placing NSBP it is important to engage the premaxillary septum bone where the sharpened pin cannot push through; a 0.9 mm dia. hand drill is used to then make a pin-hole for the NSBP. When the button-head is drawn against the septum, the pin is trimmed to 10-mm length with end turned to form a hook. Elastic chain (Rocky Mountain® Orthodontics, Denver CO, USA) attaches from hook to a button-cleat on appliance lesser segment (LS). Tensional force is not more than 50 g with one-link activation after three weeks, as natural tensioning occurs by LS growth descent exceeding NS descent.

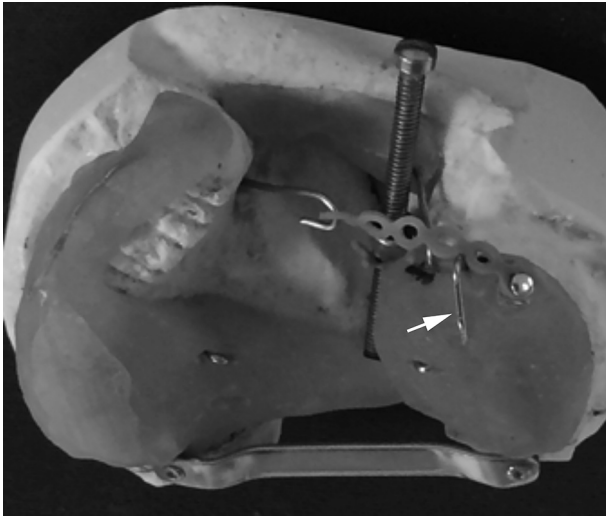


Fig. 3. The model image reflects the patient arrangement and shows DMA base appliance with NSBP and chain® only minimally distorted for light tensioning force of 25–50 g, and NM filling the nasal-side dome on the model. The NM is secured into the device and held by spring-clip action (arrow), easily removed by wedging action with a sharp instrument. It is pre-adjusted to apply dilation stress on columella, relined for nasal tip influence, and adjusted for ala rim support. Parents are free from any direct involvement to advance treatment. Patients are monitored weekly-biweekly like with DMA treatment with removal at primary reconstruction.

alveolar bone grafting or periosteoplasty, had received all primary surgery by encoded surgeons, and were consecutively treated patients to the extent possible.

Forty-seven ($n = 47$) patients represented four cohort groups (Group-1, DMA, $n = 16$; Group-2 DMA + NSBP, $n = 8$; Group-3 DMA + NSBP + NM, $n = 16$; Group-4, Passive orthopedic plate, $n = 7$), (Table 1). Based on presurgical nose treatment or not, Groups (1 + 4) were combined to form a *No Auxiliary Directed Assistance Treatment Group-5* (NADA-TG5), and groups (2 + 3) combined to form a *Nose And Septum Auxiliary Treatment Group-6* (NASA-TG6), Table 2. Variables considered are: gender; cleft side; alveolar management (cancellous bone graft, gingivoperiosteoplasty, no surgery); age in months for: primary repair, device delivery, photographic record, presurgical treatment duration; and compliance.

2.3. Photographic protocol

Frontal photographs were taken in natural head position and sub-nasal views aligned along nasal bridge. Pictures and slides were converted to digital images by the principal investigator (JLS). Images were adjusted similar to Asher-McDade et al. (1991) before digitizing. Cropping and numbers for de-identified images and descriptive data were consistent with “Exemption from Notice” (HIC#E2013-031), category 45CFR46.101(4) approval for this study by human investigation committee (HIC) William Beaumont Hospital, Royal Oak, MI, USA. All right side cleft patient images were flipped horizontally.

Eleven (11) points in frontal view and (21) in sub-nasal view were digitized (Table 3) using the Numonics AccuGrid digitizer (Numonics Corporation, Montgomeryville, PA, USA), resolution 0.0127 mm and accuracy 0.127 mm to provide measurements, (Table 4). The digitizing scheme and measurements were designed prior to data collection by principal investigator (JLS) with some landmarks similar to other studies (Barillas et al., 2009; Russell and Tompson, 2009; Kim et al., 2009; Pigott and Pigott, 2010; Russell et al., 2014).

2.4. Statistics

Statistics were derived from Triola (1995). In non-study UCLP test sample, landmark identification and measurements were done by the same examiner and repeated after two months; a two-tailed t test indicated any significant repeated paired measurement differences. Spearman's rank correlation coefficient tested confidence of measurement repeatability. The level of significance was assigned at ($p \leq 0.05$) for all test claims. For null and alternative hypotheses, if treatment pointed to the direction of outcome, then a claim 1 “left” or 2 “right” one-tailed t test was used and, if not, then two-tailed t -test was used to compare NADA-TG5 and NASA-TG6 mean scores. F-test for variance equivalence was carried out for all parameters.

3. Results

Statistical studies comparing four cohort groups in six combinations found no evidence to support a difference between Group-1 and Group-4 for subnasal parameters, and for frontal parameters save for ala base vertical asymmetry in frontal view ($p = 0.039$ and 0.045) significantly less, but still asymmetric in Group-1. No evidence to support a difference between Group-2 and Group-3 in all parameters was found, but indirectly a difference was found for columella symmetry when compared to Group-1 for Group-3 ($p = 0.027$) but not for Group-2. With minor intra-group differences the creation of NADA-TG5 and NASA-TG6, the *Analytical Assessment Groups* (AAGs) is reasonable differing by having nose treatment or not.

No variance non-equivalence was found for studied parameters. In the test sample, no statistical significant difference was found between initial and repeated measurements performed by examiner. As a test for reproducibility, correlation coefficient studies were significant at $p \leq 0.05$ confidence level for all paired measurements, save two small angle parameters, ala base and ala rim angles. The r -values ranged from 0.64 to 0.96 indicating good agreement for measurement accuracy.

NADA-TG5 mean image age was 43 months; NASA-TG6, 15 months. 16 of 23 subjects in NADA-TG5 and 12 of 24 in NASA-TG6 were male. Predominant ethnicity was Caucasian with two Asian in NADA-TG5; two Black and one Hispanic in NASA-TG6. From Table 1, NADA-TG5, mean DMA delivery age was 2.3 months with 2.5 months mean duration, and NASA-TG6 mean DMA + NSBP + NM devices delivery age was 3.6 months with 2.3 months mean duration. Seven subjects in NADA-TG5 had passive orthopedic plate peri-surgical assistance used from just prior to primary repair until HP repair. NADA-TG5 represents a random sample, and photographic documentation likely occurred because of positive esthetics, which could affect outcome with more difficulty rejecting the null hypotheses. NASA-TG6 with consecutive sampling rate of (24/37) had photographs taken in a clinical routine. Consecutive sampling was eroded by family relocation, unavailable follow-up, or inadequate or failed documentation.

3.1. Patients and surgical variables

The 47 patients had 10 different surgeons, (Table 2) with NADA-TG5 having seven and NASA-TG6 with five. Two surgeons had a total of 21 patients equally divided between AAGs. Seven of the NADA-TG5 cases had no primary alveolar procedures, seven periosteoplasty and nine primary cancellous bone grafts. Four NASA-TG6 cases had no primary alveolar procedures, one periosteoplasty and 19 primary cancellous bone grafts. All patients had Millard type lip repairs and primary nasal procedures using suspension sutures, cartilage manipulation, and subperiosteal release.

Table 1
Data collection for sample population with header legend below.

Grp	ID#	Sex	Ethn	Side	Graft	BGAg	Device	PAge	Dur	CmplyPin	CmplyNM	ImAge
1	1	M	C	L	CH	3	LD	0.49	2.92			41
1	2	M	C	L	CH	3	LD	1.12	2.00			4
1	3	M	C	L	GP	14	LD	10.58	3.55			52
1	4	M	C	L	GP	9	LD	1.61	7.92			39
1	5	M	C	L	CH	4	LD	2.27	1.68			15
1	6	M	A	L	GP	3	LD	1.45	1.87			4
1	7	F	C	L	CH	4	LD	1.48	2.79			7
1	9	F	C	R	CH	3	LD	2.56	1.18			120
1	12	M	C	L	CH	4	LD	1.84	2.04			9
1	13	M	C	R	CH	6	LD	4.14	2.04			39
1	14	M	C	L	CH	3	LD	1.48	1.64			156
1	15	M	C	L	GP	4	LD	1.25	2.76			99
1	17	F	C	R	CH	4	LD	1.97	2.10			95
1	44	M	C	R	GP	3	LD	0.85	1.68			7
1	47	F	C	L	GP	4	LD	2.0	2.00			7
1	48	F	C	R	GP	4	LD	1.48	2.04			6
N = 16 (Mean, Group-1, DMA subjects) N = 16								(2.34)	(2.53)			(44)
4	34	M	C	L	N	1	PO					51
4	35	M	C	L	N	1	PO					15
4	36	F	C	L	N	1	PO					3
4	37	M	C	L	N	1	PO					6
4	38	M	C	L	N	1	PO					6
4	39	M	C	L	N	1	PO					48
4	42	F	A	L	N	4	PO					83
N = 7 (Mean, Group-4, Plate subjects) [Mean Group-1 + 4]												(30) [43]
2	10	M	C	R	CH	5	LD + SP	1.48	3.68	G		9
2	16	M	C	L	CH	4	LD + SP	2.17	2.10	G		27
2	18	M	C	R	CH	9	LD + SP	6.77	2.27	G		11
2	19	M	C	L	CH	3	LD + SP	1.58	1.81	F		5
2	20	F	C	L	CH	4	LD + SP	2.23	1.64	G		17
2	23	M	C	R	CH	7	LD + SP + NM	4.50	2.60	G	P	10
2	43	M	C	R	CH	4	LD + SP	2.14	1.61	G		61
2	46	M	C	R	CH	3	LD + SP	1.48	2.04	F		6
N = 8 Mean, Group-2, DMA + NSBP subjects)								(2.80)	(2.22)			(18)
3	8	M	C	L	CH	4	LD + SP + NM	2.83	1.61	F	G	5
3	11	M	C	L	CH	3	LD + SP + NM	1.74	1.31	G	G	7
3	21	M	C	L	N	5	LD + SP + NM	2.40	2.33	G	F	9
3	22	F	B	R	N	6	LD + SP + NM	4.04	1.61	G	G	6
3	24	M	H	L	CH	8	LD + SP + NM	4.50	3.45	G	G	26
3	25	F	C	L	CH	4	LD + SP + NM	2.10	1.58	G	G	18
3	26	F	C	R	CH	4	LD + SP + NM	2.33	1.22	G	G	24
3	27	F	C	L	CH	7	LD + SP + NM	4.47	2.14	G	F	12
3	28	F	C	R	CH	5	LD + SP + NM	2.50	2.27	G	F	18
3	29	F	C	R	CH	11	LD + SP + NM	8.38	2.30	G	F	17
3	30	F	C	R	N	6	LD + SP + NM	3.71	2.27	G	G	7
3	31	F	C	L	CH	5	LD + SP + NM	2.66	2.27	G	G	9
3	32	M	C	L	CH	4	LD + SP + NM	2.33	1.93	G	G	9
3	33	F	C	R	GP	5	LD + SP + NM	2.20	3.06	G	P	6
3	40	F	B	L	N	11	LD + SP + NM	5.22	5.78	G	F	16
3	45	F	C	R	CH	4	LD + SP + NM	6.31	1.58	G	G	31
N = 16 (Mean, Group-3, DMA + NSBP + NM) [Means Group2 + 3]								(3.60)	(2.30)			(14) [15]

Grp – Treatment groups: (1: DMA & 4: Prosthesis) = (5: Control) (2: DMA + NSBP & 3: DMA + NSBP+NM) = (6: Test)

ID – Coded number for each case anonymous existence used for file management.

Sex – M = Male and F = Female.

Ethn – Ethnicity: C = Caucasian, B = Black, H = Hispanic.

Side – Side of UCLP cleft: R = right and L = left.

Graft – Status of alveolar surgery: CH = Cancellous hip, GP = Gingivoperiosteoplasty, N = No alveolar primary repair.

BGAg – Age in months for primary repair, alveolar repair and/or lip repair.

Device – Grp Devices: LD = Latham DMA, SP = nasal septum buttonhead pin, NM = Nasal molder, PO = Passive plate.

PAge – Age in months at delivery and placement of the presurgical devices. Does not include prosthesis cases.

Dur – Duration of active phase of DMA treatment in all cases, save prosthesis treatment cases.

CmplyPin – NSBP compliance: G = Good used 100%, F = Fair used > 50%, P = Poor used < 50% or ineffectively.

CmplyNM – NM compliance: G = Good used 100%, F = Fair used > 50%, P = Poor used < 50% or ineffectively.

ImAge – Photographic mage: Age in months.

Nine NADA-TG5 and ten NASA-TG6 subjects had midline nasal septum relocation by one surgeon as in cases reported (Janiszewska-Olszowska et al., 2014). Any outcome differences between AAGs should reflect differences in presurgical management, surgical opportunity, and procedural cascade independent of the multiple treating surgeons.

Compliance for the NSBP procedure was good for 22/24 cases without interruption during the presurgical phase. Two cases were judged fair with effective treatment during about half the time due to button detachment and another to excess tension with dehiscence. Nasal molding compliance was good in 10 of 17 cases, fair in 5, and poor in 2 cases, one outsourced with appliance use

Table 2

Study groups with header legend below.

Group	Type	N	Age	Surg#	Code:	A	B	C	D	E	F	G	H	I	J
1	DMA	16	44	5				2	3	1	1				9
2	DMA + NSBP	8	18	3								1		2	5
3	DMA + NSBP + NM	16	14	4							1	1	4	5	5
4	Prosthesis	7	30	2		5	2								
5	NADA-TG5	23	43	7		5	2	2	3	1	1				9
6	NASA-TG6	24	15	5							1	2	4	7	10
Total		47													

Group: A group representing a type of treatment.

Type: Treatment represented by the Group.

N: Number of subjects in sample group.

Age: Mean image age in months.

Surg#: Number of different treating surgeons.

Code: Code for each surgeon relates to number of patients treated.

1: Sample treated by Latham dentomaxillary advancement (DMA) appliance.

2: Sample treated by DMA and nasal septum buttonhead pin (NSBP).

3: Sample treated by DMA, NSBP, and nasal molder (NM) appliance.

4: Sample treated using oral plate.

5: Groups 1 & 4 treated without NSBP & NM combined into Group 5 (NADA-TG5).

6: Groups 2 & 3 treated with NM and/or NSBP combined into Group 6 (NASA-TG6).

ineffective and the other used less than half the presurgical duration, one related to device disturbance and another to device mechanics and low parental interest.

Parents are well counseled and advised regarding the infant patient's response, need for direct supervision throughout the orthopedic phase of treatment, burdens of infant agitation after device placement, possible temporary feeding difficulties, and any daily device adjustments performed by them. The acceptance of the presurgical treatment by the parents is rarely a problem with the most troubling period two to four days post-operatively when infants are agitated and out of their "optimal state" from general anesthesia, routine PE tube placement, and pinning of fixed orthopedic devices, and adapting to different feeding mechanics, not unlike the reported initial adjustment period in nasoalveolar molding (Li et al., 2014). Psychological benefit and confidence comes with necessary parental involvement in

treatment, and in observing improvement in facial form of the infant as correction occurs and in knowing the surgeon's intentions will be facilitated. In the first author's experience, parents overwhelmingly embrace presurgical therapies in spite of apparent burdens in care.

3.2. Frontal photographic assessment












Considering positional symmetry within the facial frame, the nose was characterized by normal medial symmetry without difference between nose and no-nose therapy; however, in the group without nose assistance asymmetry was observed, when considering bilateral ala base vertical position within the facial frame, the nose was characterized by shortening on the non-cleft side and downward positioning of the cleft side ala base; observations are supported by the following measurements (Table 5, Frontal view):

Table 3

Definition of digitized measurement points.

Frontal photograph digitized points
1: Right canthus and 2: Left canthus defines intercanthi horizontal plane.
3: Midpoint of intercanthi plane locates midsagittal vertical plane.
4: Midpoint nasal bridge determined by visual judgment.
5: Nasal tip, midpoint of alar cartilage apices determined by visual judgment.
6: Right alar base and 7: Left alar base points defined by midpoint between most lateral and inferior outline of base attachment.
8: Centroid of interalar line locates midpoint of nasal base plane.
9: Most inferior midpoint of columellar outline by visual judgment.
10: Right alar rim and 11: Left alar rim defined by most superior outline of each rim judged with near equal para-sagittal offset.
Sub-nasal photograph digitized points
1: Center point of nose outline at a midpoint of nasal tip.
2: Point goes to left superior outline of nasal dome.
3: Point made on outline of nasal ala at inferior point of any "sag".
4: Point made on outline of nasal ala at the most lateral position.
5: Point made on outline of nasal ala base at area of facial attachment.
6, 7, 8, 9 points go to right; To Mirror horizontally points 5 to 2, respectively.
10: Midpoint of columella determined by visual judgment.
11: Centroid of line connecting points 5 & 6 defines ideal midpoint of nasal base.
12: Midpoint between most medial and superior outline of nares, left.
13: Midpoint between most superior and lateral outline of nares, left.
14: Midpoint between most lateral and inferior outline of nares, left.
15: Midpoint between most inferior and medial outline of nares, left.
16, 17, 18, 19, right: Mirror images of points 12 to 15.
20: Centroid of right nares area defined at point equidistant to opposite lines defined by points 16 to 19.
21: Centroid of left nares area, as in 20 above, defined by points 12 to 15.

Table 4
Photographic measurements with legend below.

Frontal view			
1.		(NTVA:ICP) Nasal tip vertical axis angle to intercanthi plane: Angle*	(3–5) Δ (1–2)
2.		(AlbPs:ICP) Ala base positions, Lt/Rt vertical to intercanthi plane: Quotient**	(2–7)/(1–6)
3.		(ALBP:ICP) Ala base plane horizontal angle to intercanthi plane: Angle	(6–7) Δ (1–2)
4.		(ALRP:ALBP) Ala rim plane horizontal angle to ala base plane: Angle	(10–11) Δ (6–7)
5.		(ALRP:ICP) Ala rim plane horizontal angle to intercanthi plane: Angle	(10–11) Δ (1–2)
Sub-nasal view			
1.		(NDom:IABC) Nasal domes Rt/Lt positions to alar base centroid: Quotient	(2–11) + (3–11)/(8–11) + (9–11)
2.		(NarCnt:CImC) Naris-centroid to columella center Lt/Rt symmetry: Quotient	(21–10)/(20–10)
3.		(CLMP:ALBP) Columella axis vertical angle with ala base plane: Angle	(1–10) Δ (5–6)
4.		(Nara:Nara) Nares Lt/Rt area size symmetry: Quotient	(12_15)/(16_19)***
5.		(Sill:Sill) Sill Lt/Rt nostril size symmetry: Quotient	(14–15)/(18–19)
6.		(CImI:CIm) Columella Lt/Rt size symmetry: Quotient	(12–15)/(16–19)

(¹) Enclosed “number points” make up the non-parametric measurement.

* “ Δ ” Direct angle measurement, (*parameter plane* Δ *reference plane*).

** “/” Quotient: Mathematical “division function”, herein using the greater segment (GS) measurement as denominator and lesser segment (LS) as numerator (LS/GS).

*** “_” connecting those consecutive numbers.

- Nasal tip vertical angle to intercanthi plane (NTVA:ICP): no difference was found between AAGs.
- Ala base Lt/Rt vertical position to intercanthi plane (AlbPs:ICP) and -Ala base horizontal angle to intercanthi plane (ALBP:ICP): significant differences between AAGs were found for vertical position ($p = 0.00065$) and for horizontal angle ($p = 0.00073$) respectively.
- Ala rim horizontal angle to ala base plane (ALRP:ALBP): no difference was observed between the AAGs.
- Ala rim horizontal angle to intercanthi plane (ALRP:ICP): significantly greater asymmetry found in NADA-TG5 ($p = 0.0071$).

- Naris-centroid to columella center (naris offset) Lt/Rt symmetry (NarCnt:CImC): sufficient evidence to support the claim that the mean measurements for AAGs are not equal and very significantly different ($p = 0.002$).
- Columella axis vertical angle with ala-base plane (CLMP:ALBP): the mean vertical angle toward the cleft side is not equal and very significantly different between AAGs ($p = 0.0015$).
- Columella Lt/Rt size symmetry (CIm:CIm): there is sufficient evidence to support the claim that columella symmetry with nose assistance therapy was significantly greater than for no nose assistance therapy ($p = 0.022$).
- Nasal dome Lt/Rt vertical position symmetry to ala base centroid (NDom:IABC), -Naris Lt/Rt area size symmetry (Nara:Nara), and -Sill Lt/Rt nostril size symmetry (Sill:Sill): there is insufficient evidence to support the claim that the mean symmetry scores are different between AAGs.

3.3. Sub-nasal photographic assessment

Differences assessed showed a native and less distorted columella alignment (columella axis angle), a broader cleft-side nose hole (naris-centroid to columella), and a more symmetrical columella (Lt-Rt length-size) in the group who received nasal assistance compared to the group without nose therapies; observations are supported by the following measurements (Table 5, Sub-nasal view):

4. Discussion

The aim of craniofacial anomaly care should be rehabilitation before school-entering age in order to promote normal psychological development (Murray et al., 1979), wherein nose deformity plays a critical role. In contrary, the option to wait exposes the child

to a more drastic deformity from infancy throughout adolescence into adulthood. In the present study, a nearly symmetric nose shape was achieved in the infant. If the focus is the nose in cleft surgery, it is clearly proven that the introduction of naso-alveolar molding (Barillas et al., 2009) or like the present study with three presurgical levels of intention, provides a perspective for patients. Furthermore, corrective surgery of the cleft nasal deformity without primary therapy is well known to implicate an extensive surgery of the septo-premaxillary junction, making necessary an extracorporeal septoplasty (Gubisch et al., 1998) or other extraordinary means to restore the nasal floor (Rahpeyma and Khajehahmadi, 2014). Furthermore, improving nasal symmetry reduces revision rate (Brusse et al., 1999) with financial and psychological savings for the patient (Murray et al., 1979; Pfeifer et al., 2002; Noor and Musa, 2007).

Study Critique: First, this study has disadvantages of any retrospective protocol with a mix of random or imperfect consecutive sampling and standardized record taking in the study groups. Yet, the present study has the advantage of multiple surgeons (10) crossing over between study groups, that nullifies a confounding “surgeon” variable as would occur in a prospective protocol with likely one surgeon for each isolated cohort group in an indicated multi-centered study. Second, without longitudinal follow-up stability of treatment cannot be absolutely known. However, long term studies (Maull et al., 1999; Lee et al., 2008; Barillas et al., 2009) show retention of induced treatment effects of nasal alveolar molding. Treatment effects of NSBP with the locus of anatomic change at the skeletal platform level are assumed to be stable, as shown with DMA platform treatment effects by means of bone marker studies (Spolyar et al., 1997).

In the present study, the key effort to advance nose aesthetics is found in the effect of the novel *nasal septum buttonhead pin* on septo-premaxillary junction molding and of the *nasal molding*, both integrated with the platform correction effect of the Latham appliance (Table 5).

4.1. Frontal view observations

No difference between AAGs was found for nasal tip-angle (NTVA:ICP) presenting like the non-cleft control group reported

by Russell and Tompson (2009), unlike their significant cleft group tip angle (4°) or the reported angle (2°) for a NAM group (Barillas et al., 2009). The normal tip-angle in AAGs is best explained by Latham appliance corrective mechanics (40/47 subjects) as reported in bone marker studies (Spolyar et al., 1992, 1993) with the GS-complex medial rotation of 7°, and by a net 6–7 mm mean differential dorsoventral “normalizing” relocation of the paired piriform rims. Those corrective mechanics well compensate for a stigmatizing abnormal 4° tip angle (Russell and Tompson, 2009), and 3.2 mm dorsal translocation of cleft-side lateral piriform rim in 3D COMOS studies at age 3 months (Zemann et al., 2002) and 3.0 mm in anthropometric study (Farkas et al., 2000).

Nasal height and vertical symmetry relate anatomically to the anterior maxillary platform. Native ala base vertical asymmetry was retained without septo-premaxillary and nasal molding treatment (NADA-TG5, Fig. 4) with asymmetry values like reported patient outcomes treated by NAM (Barillas et al., 2009). However, *nasal septum buttonhead pin* use (NASA-TG6, Figs. 5–7) achieved ideal mean ala base vertical symmetry with a very high degree of statistical confidence (p = 0.00065 and 0.00073), consistent with pilot study, and inferred applied vector of force. The ala bases have an “a priori” symmetry requirement for routinely successful cleft nasal deformity treatment (Wu et al., 2013; Bardach and Cutting, 1990; Cohen et al., 2003) with inferior dislocation associated with alar disfigurement (Lindsay and Farkas, 1972). Presciently stated by Millard (1990), ‘as in most architectural constructions, the platform deserves priority’.

Related indirectly to the anterior maxilla, the ala rim “slump” angle referenced to inter-ala-base plane was the same for AAGs. However, when referenced to intercanthi plane, NADA-TG5 had significantly greater ala rim slump angle tilting at 5.5° exacerbated by the group’s ala base asymmetry, not present with nasal septum buttonhead pin treatment (NASA-TG6) providing ala base harmony.

4.2. Sub-nasal view observations

Mean symmetry measurements for nasal dome position, nares area, and nostril sill’s size are not unequal in AAGs, although NASA-TG6 had consistently larger cleft-side relative size. These retained features of AAGs at this age are consistent with other studies

Table 5
Frontal and sub-nasal view data analysis with header legend below.

View	Parameter	SymV	Grp	Mean	SD	Size	Grp	Mean	SD	size	T Stat	Conf	Signf	Claim
Frontal	ICPc-tip:ICP	VA	5	89.83	7.45	23	6	90.53	3.09	24	-0.42	.68	ns	3
	AlbPs:ICP	VP	5	1.04	0.05	23	6	1.00	0.04	24	3.43	.00065	***	1
	ALBP:ICP	HA	5	2.14	2.90	23	6	-0.25	1.77	24	3.39	.00073	***	1
	ALRP:ALBP	HA	5	3.38	2.78	23	6	3.47	2.48	24	-0.12	.91	ns	3
	ALRP:ICP	HA	5	5.53	3.95	23	6	3.00	2.68	24	2.55	.0071	**	1
Sub-nasal	Doms:IABC	VP	5	0.94	0.06	12	6	0.97	0.08	23	1.48	.148	ns	2
	NarCnt:CmC	HP	5	0.95	0.17	12	6	1.17	0.23	23	3.35	.0020	**	3
	CLMP:ALBP	VA	5	92.52	4.49	12	6	86.17	6.24	23	3.45	.0015	**	3
	Nara:Nara	S	5	1.00	0.38	12	6	1.23	0.29	23	1.88	.068	ns	3
	Sill:Sill	S	5	1.13	0.40	12	6	1.31	0.34	23	1.39	.174	ns	3
	Cm:Cm	S	5	0.81	0.14	12	6	0.92	0.17	23	2.09	.022	*	2

Parameter: ICPc – intercanthi plane centroid; tip – nasal tip; ICP – intercanthi plane; AlbPs – ala base positions; ALBP – ala bases horizontal plane; ALRP – ala rims horizontal plane; Doms – composite points; IABC – inter-ala-base centroid; NarCnt – naris centroid; CmC – columella center; CLMP – columella plane; Nara – naris area; Sill – nostril sill size; Cm – columella size.

SymV, Symmetry view; VA, Vertical angle; VP, Vertical position; HA, Horizontal angle; HP, Horizontal position; S, Size; Grp: Group: 5 = NADA-TG5 without NSBP or NM treatment. 6 = NASA-TG6 with NSBP and NM treatment.

Mean: Number representing the parameter mean.

SD: Standard deviation of the population mean.

Size: The sample size for the group.

T Stat: Statistical score used to enter the t distribution table at .05 confidence level.

Conf: Confidence level for the mean differences, divided into 1.00 give the chance rate for null hypothesis to be true.

Signf: Visual indicator of evidence to support respective claim, ns – not significant, * < .05, ** < .01, *** < .001.

Claim: Hypothetical claim made for the respective parameter, 1: right-tailed, 2: left-tailed, 3: two-tailed.

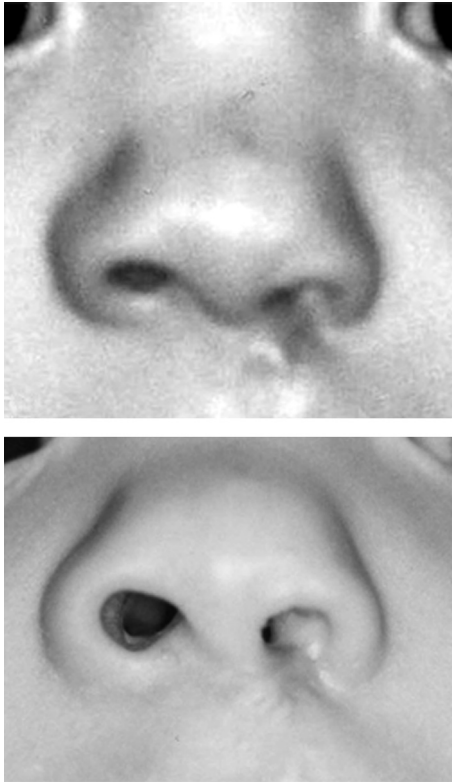


Fig. 4. No nose assistance therapy NADA-TG5 case example and view of 7 month old patient, 4.5 months after presurgical DMA treatment, alone. (*Top*) Frontal view displays a well centered nose, degree of vertical asymmetry sloped to cleft-side, nasal tip and rim asymmetry, good bilateral shape symmetry but size asymmetry. (*Bottom*) Sub-nasal view shows balanced ala base support, reduced cleft side naris offset, columella asymmetry with base toward cleft-side and cleft-side naris constriction.



Fig. 5. NASA-TG6 case example at age 27 months, 23 months after DMA + NSBP treatment. (*Top*) Frontal view shows nicely centered nose with excess non-cleft-side ala base height from robust NSBP response, good bilateral size symmetry with some tip and rim asymmetry. (*Bottom*) Sub-nasal view shows balanced ala base support, offset cleft side naris, columella base toward non cleft side, well supported rim with tip and dome somewhat dorsal on cleft side and degree of columella asymmetry.

without presurgical therapy (Farkas et al., 2000; Kyrkanides et al., 1996). Surprising was the non-significant finding for NASA-TG6 dome height asymmetry reduction to near ideal (0.97), perhaps little influenced by platform balancing or due to insufficient nasal molding duration (Ezzat et al., 2014). However, dome height symmetry (0.97) compared well with (96.3%) for NAM treated cases (Barillas et al., 2009).

Columella symmetry was near ideal in the septo-premaxillary junction and nasal molding NASA-TG6 cases (0.92 symmetry score) compared to NADA-TG5 (0.81 score) without nasal assistance ($p = 0.022$). Better NM compliance (good in 10, fair in 5, poor in 2, no NM in 7) should be possible to improve columella outcome. No statistical difference between NASA-TG6 cohorts found directly, and yet, significant difference, found indirectly compared to cohort Group-1 suggest some improvement in columella symmetry occurs with septo-premaxillary treatment alone but with greater variability as seen in Fig. 5, than when nasal molding is added, Figs. 6 and 7. Nevertheless, the over-all columella improvement from NM therapy in NASA-TG6 cases is not unlike other studies (Maull et al., 1999; Grayson and Cutting, 2001; Lee et al., 2008).

Naris offset ($p = 0.002$) and columella angle ($p = 0.0015$) were very significantly different with greater asymmetry scores in NASA-TG6, which likely reflect presurgical outcome differences. Septo-premaxillary junction and nose molding therapies further improve the cleft gap, cleft margins vertical alignment, and cleft side nasal rim support with columella lengthening. These dynamics indicate less subperiosteal release sufficient to relocate the cleft ala base flap to its medial insertion is needed, while attaining an “ideal” nasal shape, as it relates to the surgeon’s intraoperative aesthetic

judgment. Further, minimizing repair site strain and latent contracture should promote a more lateral naris offset and a native columella base position toward non-cleft-side, consistent with findings. In (NADA-TG5) cases without septo-premaxillary and nasal molding therapies, more subperiosteal release with more distant flap relocation should manifest to achieve a similar intraoperative aesthetic state. In addition, greater residual load and contracture should further constrain naris offset and relocate columella base toward cleft-side, consistent with findings and reported by Thomson and Reinders (1995).

Symmetry should have a positive influence on esthetic judgments (Mealey et al., 1999; Faure et al., 2002; Ramsey et al., 2004); other studies dispute this (Laitung et al., 1993; Sarver and Johnstonh, 1993; Perrett et al., 1994; Kowner, 1998); another reports facial asymmetry to be relatively normal (Kwon et al., 2006). Notwithstanding, nasal symmetry has importance for perception of the UCLP face (Meyer-Mascotty et al., 2011). In reality, facial symmetry is an “ideally imperfect” state within a limit of “normal imperfection”, once exceeded, imperfection is perceived, in part, or whole. Lu (1965) reported that facial asymmetries greater than 3% are clinically detectable. Parameters statistically significant and exceeding a 3% asymmetry difference are: ala base vertical position improved 4% achieving ideal symmetry, columella length improved 11% to within 8%, and naris offset shifted 22% to within 17% of ideal mean symmetry, all related to septo-premaxillary and nose assistance, indicating clinically detectable asymmetry differences within AAGs for those parameters. In a rank-order parent panel study (Mommaerts and Nagy, 2008) of 10 distinct cleft nose deformities, the most highly rated were for asymmetric nose within

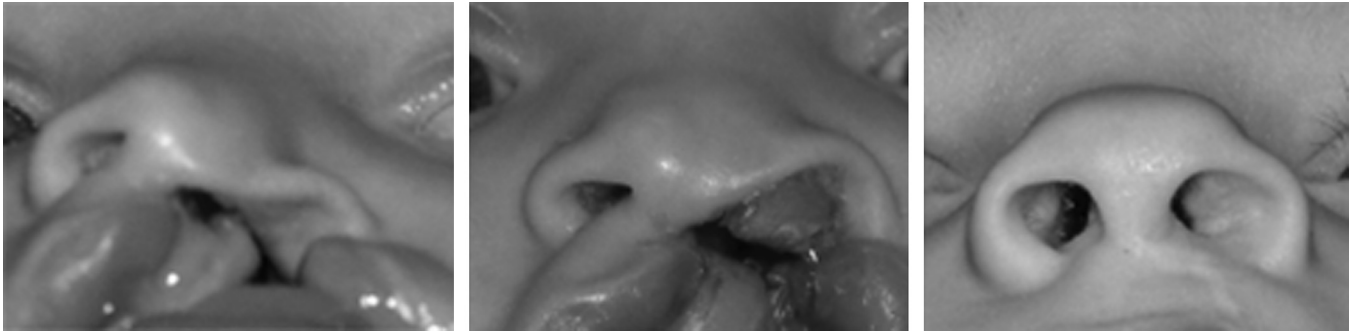


Fig. 6. NASA-TG6 case example demonstrates DMA, NSBP, and NM presurgical procedures seen in sub-nasal view being applied at three levels of anatomic distortions. (Left) pre-treatment view, age 6 months with evident nasal platform distortions, (middle) during active presurgical treatment, age 7 months, note improvement in ala base platform support, height symmetry and inframalar fullness, nasal asymmetry reduction and NM supporting cleft side nose as the GS-nose is rotated to caudal and medial and LS-nose to ventral, (right) after primary repair at age 31 months with good nose size symmetry, ideal columella balance with columella base well centered and modest cleft side naris offset.

the facial frame and nose ala positioning, whereas nostril form was least important. Those most highly rated deformities are addressed by the significant treatment corrections reported herein. Residual deformity of nose, not lip, continues to be the greater challenge (Thomson and Reinders, 1995).

Beyond esthetics, impaired nasal function correlates with decreased physical health quality of life (Mani et al., 2013). Septo-premaxillary and nose assistance should improve the cleft-side nasal port airflow. Those without such treatment should be limited by constrained cleft-side naris, shorter and shifted columella, and small cleft-side size asymmetry problems resulting in

either enhanced liminal valve effect, or obstruction at the nostril-level on inspiration with draw-in, or both adding nasal airway impedance (Sandham and Solow, 1987).

Septo-premaxillary and nose molding carry little burden beyond Latham procedure. The routine good achievement of these procedures is significantly related to factors advantageous to “fixed mechanotherapy”. The procedures are well performed beyond the neonatal period, and generally avoid other reported nasoalveolar molding, “removable mechanotherapy”, limitations as with soft tissue irritation and ulceration, fungal infections, eruptive interferences, hand and tongue removal, or facial “tape” dermatitis (Levy-Bercowski et al., 2009; Li et al., 2014), and the procedures are less likely to be compromised by reported broken appointment, parental assistance, or treatment termination problems (Levy-Bercowski et al., 2009). The procedures are seamlessly incorporated within presurgical treatment with proper placement and essential light force application. The presented protocol routinely addresses the deformity residing in three-dimensions and at three anatomic levels. Treatment is routinely done at age 6–8 weeks or older for duration 6–10 weeks, differing from other more limited naso-alveolar molding (NAM) and nasal molding protocols (Matsuo et al., 1989; Grayson et al., 1999; Grayson and Cutting, 2001; Berggren, 2001; Monasterio et al., 2008) considered too late for NAM treatment beyond age 12 weeks (Barillas et al., 2009).

5. Conclusions

- The nose treatment and no nose treatment groups both benefited from indicated Latham treatment influencing horizontal platform balance, wherein the nose framed within the face was comparatively normal in both groups.
- The novel *nasal septum buttonhead pin* is very significantly related to achieving ideal nasal height symmetry.
- *Nose molding* is significantly related to improving nasal columella balance to near ideal symmetry.
- The three procedures done together within a well defined treatment window significantly influenced nasal symmetry achievement by means of fixed directional mechanics applied in three dimensions and at three distorted anatomic-levels native to UCCLP cases.

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Fig. 7. NASA-TG6 case example with presurgical treatment using DMA, NSBP, and NM. (Top) Frontal view at age 5 years and 56 months postoperative reveals ideal nasal height symmetry with a degree excess height on non-cleft-side, minimal rim or dome dorsal slump. (Bottom) Sub-nasal view shows good nasal tip support and symmetry including rim and dome, near ideal columella with its base toward non cleft side and observable excess naris offset on cleft side with balanced nose size symmetry.

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