Journal of Cranio-Maxillo-Facial Surgery 47 (2019) 1083–1091

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

The absolute and relative effects of presurgical nasoalveolar moulding in bilateral cleft lip and palate patients compared with nasal growth in healthy newborns

Florian D. Grill [a], Andrea Rau [b], Franz X. Bauer [c], Fiona Hellmundt [c], Bettina Hilmer [a], Maximilian Roth [a], Alexandra V. Behr [a, b], Klaus-Dietrich Wolff [a], Denys J. Loeffelbein [d], Lucas M. Ritschl [a, *]

[a] Department of Oral and Maxillofacial Surgery, Technische Universität München, Germany
[b] Department of Oral and Maxillofacial Surgery, Friedrich-Alexander-University Nürnberg-Erlangen, Germany
[c] Institute of Medical and Polymer Engineering, Technische Universität München, Germany
[d] Department of Oral and Maxillofacial Surgery, Helios Klinikum München West, München, Germany

ARTICLE INFO

Article history:
Paper received 11 November 2018
Accepted 29 January 2019
Available online 11 February 2019

Keywords:
Cleft lip and palate
Nasal growth
Nasoalveolar moulding
Newborn

ABSTRACT

Background: This study investigated the efficiency of nasoalveolar moulding (NAM) in patients presenting with bilateral cleft lip and palate (BCLP). It focused explicitly on nasal outcome and therefore made comparisons with healthy age-matched infants with normal nasal development.
Methods: Nasal impressions from 19 BCLP patients were analysed at the beginning and at the end of NAM treatment. In addition, nasal impressions from 32 healthy newborns were taken monthly for 4 months. The casts were digitalized and analysed, using defined anatomic landmarks, by two independent observers. Initial values were compared with outcome parameters at the end of NAM therapy and with the healthy cohort.
Results: NAM significantly elongated the columella in BCLP patients, with an increase of 106.5% versus 14.5% in healthy newborns. Nostril height showed significant expansion from 4.2 mm to 5.6 mm on the right side, and from 4.3 mm to 6.2 mm on the left side.
Conclusion: NAM significantly elongated columella length and increased nostril height. The comparison with healthy newborns showed the effectiveness of early cartilage moulding. Detailed knowledge about absolute and relative early nasal growth was gained. However, despite highly effective NAM treatment in BCLP, nasal dimensions will not reach healthy proportions.

1. Introduction

Nasoalveolar moulding (NAM) has gained broad acceptance and become established in the presurgical treatment of newborns with cleft lip and palate (CLP). NAM has been shown to improve long-term symmetry and nasal projection (Barillas et al., 2009) (Shetty et al., 2017) (Mancini et al., 2018). This effect can be seen in unilateral as well as in bilateral cases (Rau et al., 2015). Patients who received presurgical NAM treatment have even been shown to be less likely to require secondary corrections (Rubin et al., 2015), with primary lip closure seemingly easier to perform (Prasad et al., 2017). Nevertheless, its presurgical effect has mostly been described in studies comparing NAM and non-NAM cohorts (Rau et al., 2015) (Kinouchi et al., 2018) (Peanchitlertkajorn, 2018). However, both these cohorts have the limitation of an already reduced columella length at the beginning of treatment. We think that initial growth and nasal development are important for the later course of treatment, but descriptions of the first months of life are lacking in the literature, especially in making a direct comparison between NAM-treated patients and healthy newborns with assumed 'normal' and 'natural' nasal development. Krimmel et al. have gathered extensive, representative data on nasal development

* Corresponding author. Department of Oral and Maxillofacial Surgery, Klinikum rechts der Isar, Technische Universität München, Ismaninger Str. 22, 81675, Munich, Germany.
E-mail address: lucas.ritschl@tum.de (L.M. Ritschl).

https://doi.org/10.1016/j.jcms.2019.01.044
1010-5182/

at yearly intervals, while Farkas et al. focused their investigations on an older cohort (Farkas et al., 1992). We therefore collected data on normal nasal development during the first months of life in order to compare NAM treatment cases with normal and healthy development. Data from patients with bilateral cleft lip and palate (BCLP) treated with NAM, as described by Grayson et al., were collected at the beginning and at the end of NAM treatment and were juxtaposed with the age-matched healthy cohort (Grayson et al., 1993).

The purpose of this study was to describe the initial deficiencies in columella length in patients with BCLP, and the absolute and relative columella elongation during NAM therapy. Further, we aimed to provide reference data for other comparative studies because the results were juxtaposed with a healthy age-matched cohort.

2. Methods and materials

2.1. Ethical statement and patient recruitment

All clinical investigations and procedures were conducted according to the principles expressed in the Declaration of Helsinki. Ethical approval for the prospective study was granted by the Ethical Committee of the Technische Universität München (approval Nos. 67/15S and 275/18S). All interactions with each patient were performed with parental consent.

2.2. Study cohort and 3-dimensional model generation

In total, 32 healthy newborns and 27 newborns with BCLP were included in this study.

Nasal impressions from healthy newborns were taken monthly up to an age of 4 months, resulting in five impressions, including the one from the first days of life. Extra- and intraoral impressions were taken from the BCLP cohort as soon as possible after birth and at the end of NAM treatment, before surgical primary lip closure.

The virtual three-dimensional (3D) model production was carried out using a 3D triangulation scanner (3Shape D700, 3Shape A/S, Denmark). Landmark analysis was performed using Spyder software (PYthon Software Foundation, version 2.7, Netherlands; The Scientific PYthon Development EnviRonment, Spyder Developer Community, version 2.3.4) and Mayavi software (ETS Project, version 4.4.3), as described and published earlier (Bauer et al., 2017).

The following defined anatomical landmarks and areas were selected in our healthy cohort: alar bases (AB and AB'), right side of each nostril (NR and NR'), left side of each nostril (NL and NL'), nostril bottoms (NB and NB'), nostril tops (NT and NT'), subnasal area (Sn), and anterior columella at nasal top level (Ca).

The following landmarks and areas were additionally selected in the BCLP cohort: left side of premaxilla (LPL), right side of premaxilla (RPL), right cleft lip (RL), left cleft lip (LL) (Fig. 1).

In order to display the overall clinical outcome, alveolar growth was included in the analysis. Landmark positioning and analysis were carried out as published earlier (Bauer et al., 2017). The following landmarks were added: anterior nasal septum (VA), dorsal nasal septum (VD), premaxilla left side (PCL), premaxilla right side (PCR), alveolar crest right side (RAC), and alveolar crest left side (LAC).

2.3. Patient treatment

The BCLP cohort was treated with the NAM technique as described by Grayson et al. (Grayson et al., 1993). The NAM device was produced conventionally with acrylic resin by a dental laboratory. The nasal stent had a spring-hard stainless steel wire

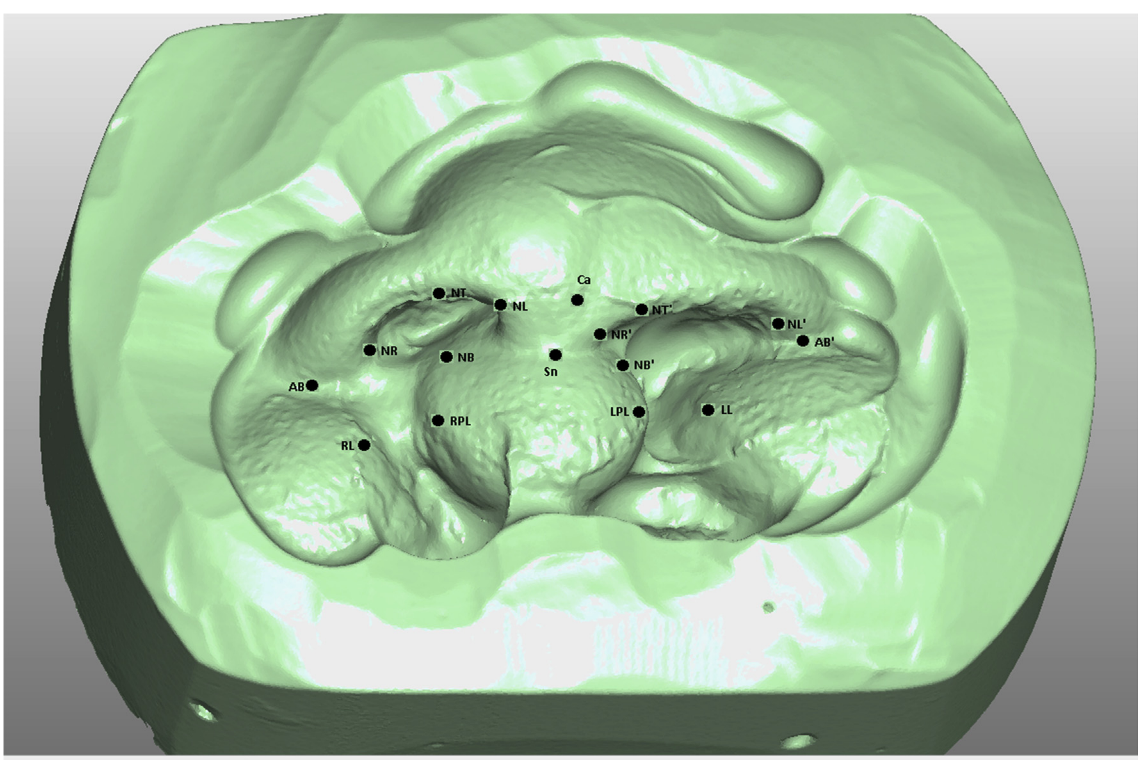

Fig. 1. Selected anatomical landmarks in digital plaster models of patients with bilateral cleft lip and palate. Alar bases (AB, AB'), anterior columella point (Ca), subnasal point (Sn), nostril bottoms (NB, NB'), nostril tops (NT, NT'), right side of each nostril (NR and NR'), left side of each nostril (NL and NL'), left side of premaxilla (LPL), right side of premaxilla (RPL), right cleft lip (RL), left cleft lip (LL).

(0.9 mm diameter), as used in orthodontic treatments. This cohort was documented by taking intra- and extraoral impressions whenever possible within the first days of life, and at the end of NAM treatment before surgical primary lip closure at the age of 3 months, and with a minimum of 5 kg body weight.

In line with the standard treatment at our centre, the protocol began with extraoral tapings and an intraoral moulding device, which was extended using a nasal stent at the age of approximately 6 weeks (Loeffelbein et al., 2013) (Rau et al., 2015). The parents were instructed to handle the administration of the buccal tapings at home. Weekly clinical follow-ups to check for mucosal ulcerations and adjustments of the plate or nasal stents were performed.

2.4. Statistical analysis

Statistical analysis was carried out using the R statistical environment with the user interface R Studio. Differences between the initial and final impression takings were calculated using the Wilcoxon-signed rank test and the Wilcoxon exact test. A p-value of <0.05 was considered statistically significant. For visualization of the statistical results, box plots were used, with the upper and lower borders indicating the first and third quartiles. The bar within the box represents the median (R-Development-Core-Team, 2008) (R-Studio-Team, 2012). All values provided in the descriptive tables are summary values. The differences seen in the descriptive tables are calculated at patient level. This means that for one patient the distance in impression 1 is subtracted from impression 2. This then gives one difference for each patient. The tables show the descriptive results for these patient-level differences. This implies that the differences provided in the tables, which are in fact summary statistics, cannot be calculated directly using the summary values given for impressions 1 and 2.

3. Results

3.1. Healthy cohort — nasal development (Table 1)

Digital 3D nasal models from 32 healthy newborns were included in this study. The median age was 4.3 months (range: 4.0–5.2 months). Some plaster models were excluded because of inaccuracies and artefacts in the areas where our landmarks were intended to be. In order to achieve as high a number of distances as possible, individual plaster models were removed without removing the associated plaster models. If only single landmarks were not available, the remaining landmarks on the plaster model were included. The actual number of impressions included in the respective statistical analysis is indicated by the number in the plots and tables provided below. For the number of excluded patients for each distance, refer to the ‘NA’ (not available) field.

Over the observation period, nasal width, represented by the distance [AB–AB′], increased by a median of 2.2 mm (−1.1 to 7.3). The columella [Sn–Ca] was measured at a length of 5.0 mm around birth and 5.7 mm after 4 months, which was a relative growth of 14.5%. Nostril height increased by a median of 1.1 mm (−0.4 to 2.9) on the right side [NB–NT] and 1.0 mm (−0.3 to 2.3) on the left side [NB′–NT′]. Nostril width increased by a median of 1.1 mm (−2.0 to 4.8) on the right side [NR–NL] and 0.8 mm (−0.4 to 2.8) on the left side [NR′–NL′]. Overall healthy columella expansion is shown in Fig. 2B, with the calculated absolute and relative development in Fig. 3B.

3.2. BCLP cohort — nasal development (Table 2, Figs. 4 and 5)

In the BCLP treatment group, 19 of the 27 patients could be included in this study. The median age was 3.9 months (range: 1.4–5.4 months). Exclusion criteria included inaccuracies in the

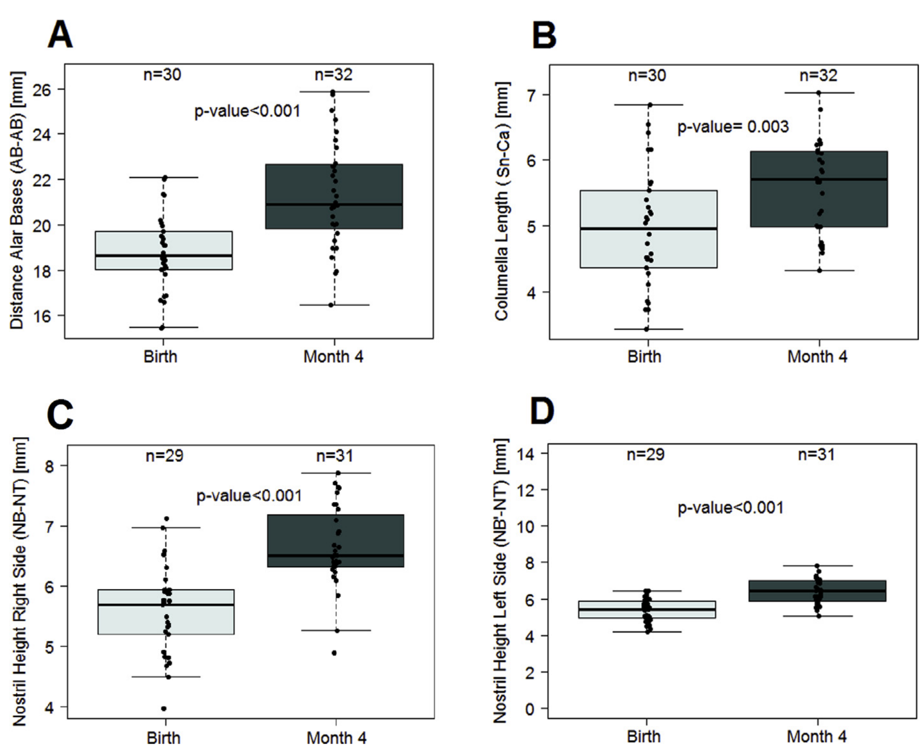

Fig. 2. Nasal development in the healthy cohort at two time points: 1) first days of life; 2) at 4 months of age. A: alar bases [AB–AB′], B: columella length [Sn–Ca], C: nostril height right side [NB-NT], D: nostril height left side [NB′-NT′].

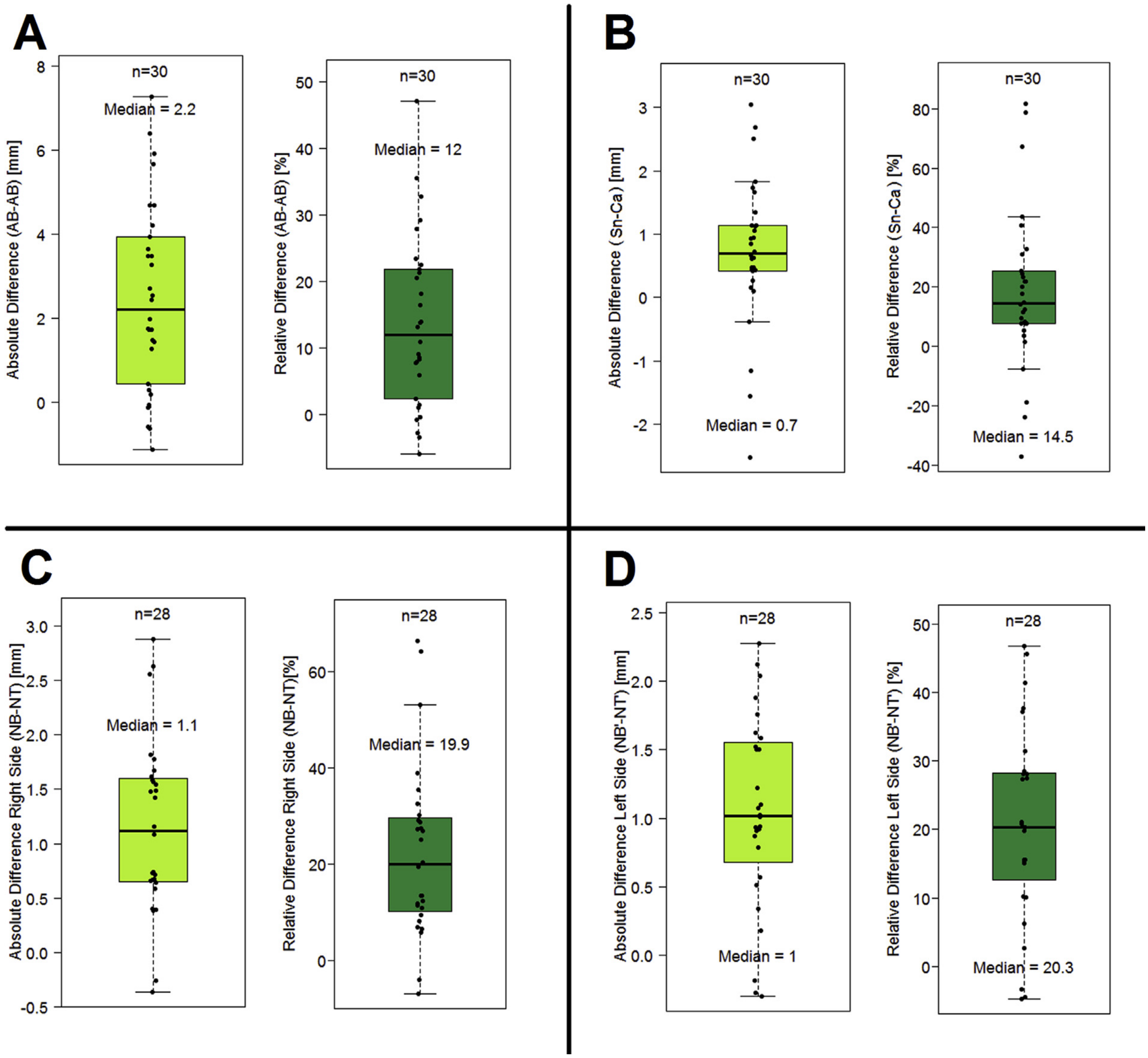

Fig. 3. Relative and absolute nasal growth in the healthy cohort. A: alar bases [AB–AB′], B: columella length [Sn–Ca], C: nostril height right side [NB-NT], D: nostril height left side [NB′-NT′]. Light green = absolute difference; dark green = relative difference.

plaster models, as well as missing impression takings from the nose or the upper jaw, or a variance between the dates of impression takings and the endpoint of NAM therapy.

Nasal width, as indicated by the distance [AB–AB′], showed a median expansion from 27.5 mm (20.9–33.5) to 28.7 mm (25.0–31.3) within 4 months. The columella elongation [Sn–Ca] within the same period of time was statistically significant ($p < 0.001$) (Table 3), with an increase of 106.5%, from a median of 1.6 mm (0.7–2.6) to 3.5 mm (1.8–4.2). Median nostril height (NB–NT) increased by 43.7%, from 4.2 mm (0.9–10.3) to 5.6 mm (4.3–8.6) on the right side. On the left side (NB′–NT′), median nostril height increased by 74.9%, from 4.3 mm (2.1–9.2) to 6.2 mm (4.1–12.3). Nostril width on the right side [NR–NL] remained the same, with a median of 16.5 mm between impression 1 (13.5–18.1) and 2 (11.2–19.1). On the left side [NR′–NL′] a slight decrease from a median of 17.1 (12.1–21.4) to 16.5 (11.2–19.1) was observed. Both cleft lips decreased in their distances, on the right side [RL–RPL] by a median difference of −0.7 mm, and on the left side [LPL–LL] by −1.3 mm. The premaxilla [RPL–LPL] expanded between impressions 1 and 2 by a median of 1.2 mm.

It was evident that columella length in BCLP patients started out at a lower level and, despite a great increase of more than 100%, was still lower after NAM treatment (Fig. 6).

3.3. Alveolar development (Table 4 and Fig. 7)

As supplementary data and for a complete display of the results of our NAM treatment, alveolar growth was also measured. In our treatment group, longitudinal development decreased in the observation period from a median length [A–VD] of 28.4 mm (20.2–35.9) to 26.8 mm (17.4–32.7). The alveolar cleft size decreased on the right side [RAC–PCR] from a median of 4.9 mm (1.4–14.8) to 3.8 mm (1.3–10.1), and on the left side [LAC–PCL] from 5.0 mm (1.6–19.0) to 3.7 mm (1.4–13.9). The alveolar crest [RAC–LAC] converged from a median distance of 21.5 mm (16.4–28.2) to 19.1 mm (14.6–25.4). The width of the premaxilla [PCR–PCL] remained the same, at 15.5 mm.

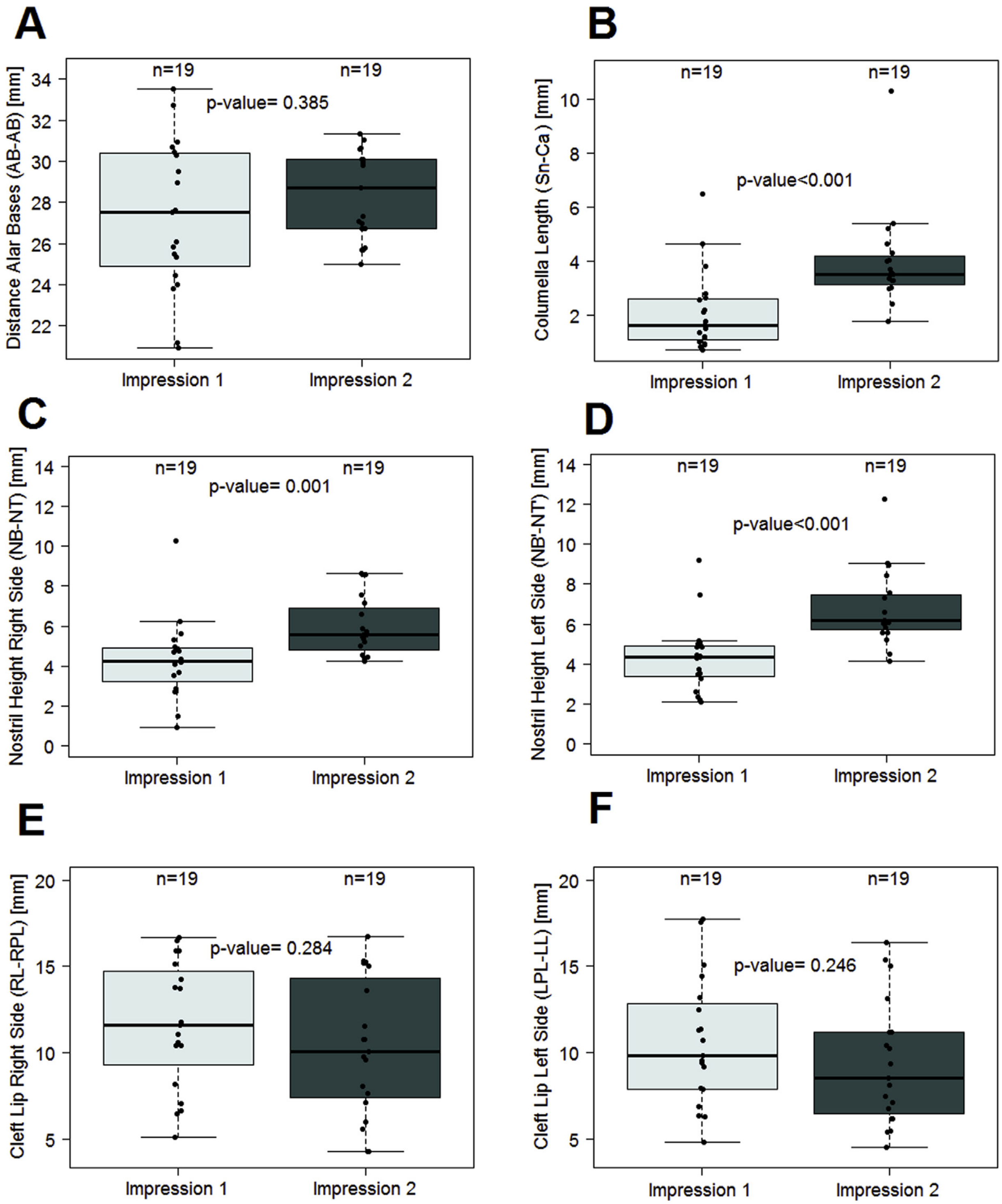

Fig. 4. Nasal development of patients with bilateral cleft lip and palate at two time points: 1) at the beginning and 2) at the end of NAM therapy. A: alar bases [AB–AB], B: columella length [Sn–Ca], C: nostril height right side [NB-NT], D: nostril height left side [NB′-NT′], E: cleft lip right side [RL-RPL], F: cleft lip left side [LPL-LL]. Grey = impression 1; dark green = impression 2.

4. Discussion

This study juxtaposes noses of newborns with BCLP with healthy, age-matched neonates in order to compare columella elongation during normal somatic growth and active columella elongation with NAM treatment. Most investigations have compared the initial columella length with the results after treatment with a non-NAM cohort (Suri et al., 2012), or different NAM treatment strategies (Liao et al., 2014). This highlights the efficiency of NAM therapy in general, but does not show the overall deficiency of nasal proportions in patients with BCLP, despite treatment. Moreover, since non-treatment groups are usually provided with feeding plates, the possible effect of these plates might not be taken into account and, consequently, the effect of NAM might be underestimated. The feeding plates might themselves have an influence on the positioning of the premaxilla — despite facial

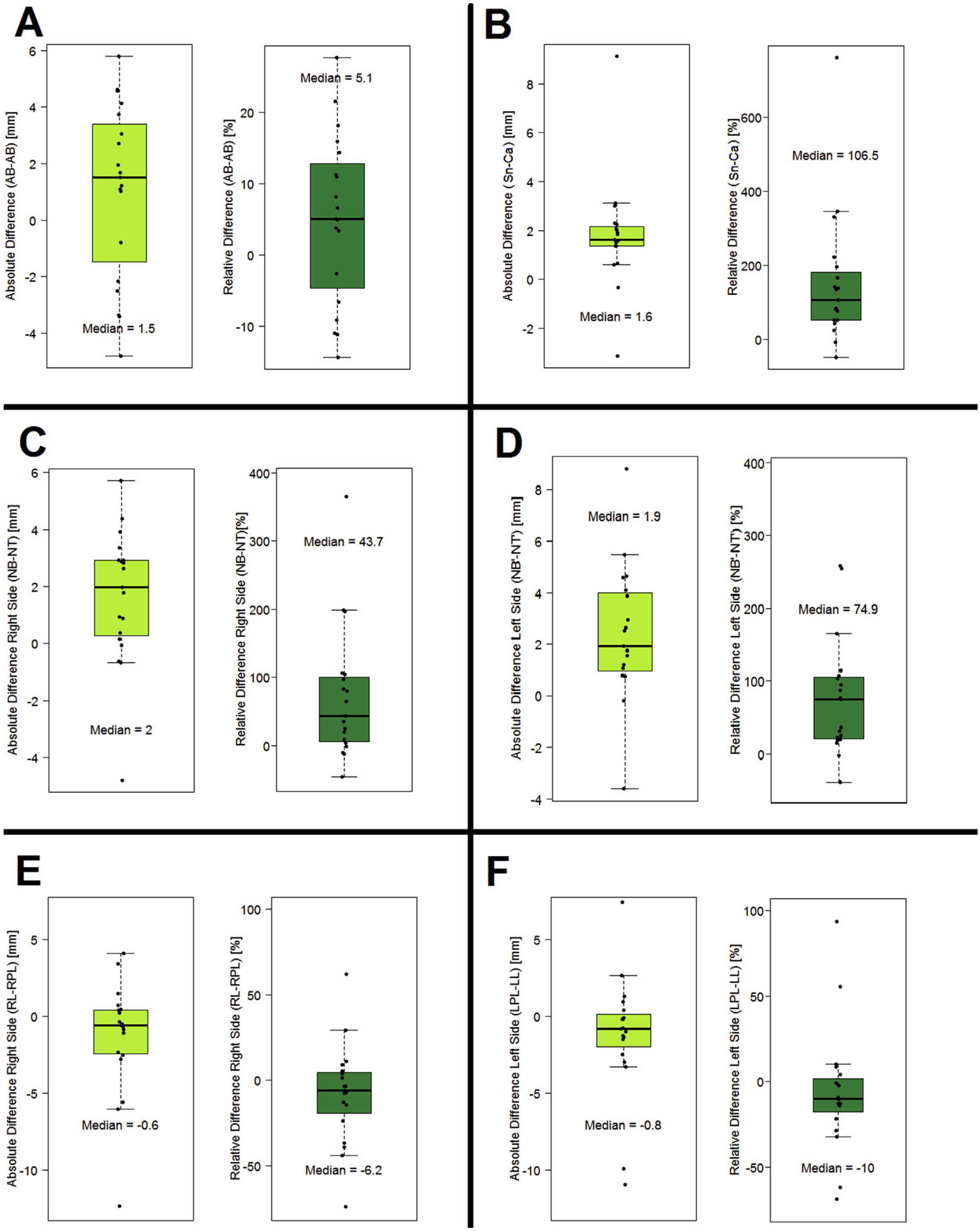

Fig. 5. Relative and absolute nasal growth in patients with bilateral cleft lip and palate. A: alar bases [AB–AB], B: columella length [Sn–Ca], C: nostril height right side [NB-NT], D: nostril height left side [NB′-NT′], E: cleft lip right side [RL-RPL], F: cleft lip left side [LPL-LL] Light green = absolute difference; dark green = relative difference. Grey = impression 1; dark green = impression 2.

growth and expansion — due to its static size and fixation of the premaxilla. A secondary tear may therefore develop on the columella, affecting the position of the premaxilla. As a result, we decided to compare our NAM treatment group with a healthy, age-matched cohort. Moreover, the healthy control group might serve as a general reference data group for normal nasal development in the first few weeks of life.

The median of the NAM cohort shows a columella length [Sn–Ca] of 3.5 mm at the time of primary lip closure, while the healthy babies showed a [Sn–Ca] length of 5.6 mm. Relative

Table 1
Nasal growth in the healthy cohort (mm).

Variables	Median	Minimum	Maximum	NA
AB–AB′ month 1	18.6	15.4	22.1	2
AB–AB′ month 4	20.9	16.5	25.9	0
AB–AB′ difference	2.2	−1.1	7.3	2
NR–NL month 1	6.5	1.5	11.0	2
NR–NL month 4	7.5	6.0	9.8	1
NR–NL difference	1.1	−2.0	4.8	3
NR′–NL′ month 1	7.1	5.1	8.5	3
NR′–NL′ month 4	7.8	6.2	9.9	1
NR′–NL′ difference	0.8	−0.4	2.8	4
NB–NT month 1	5.7	4.0	7.1	3
NB–NT month 4	6.5	4.9	7.9	1
NB–NT difference	1.1	−0.4	2.9	4
NB′–NT′ month 1	5.4	4.2	6.5	3
NB′–NT′ month 4	6.4	5.0	7.8	1
NB′–NT′ difference	1.0	−0.3	2.3	4
Sn–Ca month1	5.0	3.4	6.8	2
Sn–Ca month 4	5.7	4.3	7.0	0
Sn–Ca difference	0.7	−2.5	3.0	2

Table 2
Overall nasal growth in patients with bilateral cleft lip and palate (mm).

Variables	Median	Minimum	Maximum
AB–AB′ impression 1	27.5	20.9	33.5
AB–AB′ impression 2	28.7	25.0	31.3
AB–AB′ difference	1.5	−4.8	5.8
NB–NT impression 1	4.2	0.9	10.3
NB–NT impression 2	5.6	4.3	8.6
NB–NT difference	2.0	−4.8	5.7
NB′–NT′ impression 1	4.3	2.1	9.2
NB′–NT′ impression 2	6.2	4.1	12.3
NB′–NT′ difference	1.9	−3.6	8.8
Sn–Ca impression 1	1.6	0.7	6.5
Sn–Ca impression 2	3.5	1.8	10.3
Sn–Ca difference	1.6	−3.1	9.1
NR–NL impression 1	16.5	13.5	21.4
NR–NL impression 2	16.5	11.2	22.0
NR–NL difference	1.1	−2.9	4.0
NR′–NL′ impression 1	17.1	12.1	23.6
NR′–NL′ impression 2	16.5	10.4	20.4
NR′–NL′ difference	−0.3	−7.6	5.0
RL–LL impression 1	25.4	20.2	35.1
RL–LL impression 2	22.9	16.9	30.0
RL–LL difference	−2.0	−8.4	6.2
RL–RPL impression 1	11.6	5.1	16.7
RL–RPL impression 2	10.1	4.3	16.7
RL–RPL difference	−0.6	−12.3	4.1
RPL–LPL impression 1	10.9	7.8	13.1
RPL–LPL impression 2	12.1	7.7	14.1
RPL–LPL difference	1.0	−1.8	3.3
LPL–LL impression 1	9.8	4.8	17.8
LPL–LL impression 2	8.5	4.5	16.4
LPL–LL difference	−0.8	−10.9	7.4

Table 3
Statistical analysis of differences in distances for impressions 1 and 2 in BCLP.

Differences in distances for impressions 1 and 2	*p*-value
SN–CA	<0.001*
AB–AB	0.385
NB–NT	0.001*
NB′–NT′	<0.001*
NR–NL	0.402
NR′–NL′	0.470
RL–RPL	0.284
LPL–LL	0.246

*p-values of <0.05 were considered statistically significant.

Table 4
Alveolar development in patients with bilateral cleft lip and palate in (mm).

Variables	Median	Minimum	Maximum	NA
RAC–LAC impression 1	21.5	16.4	28.2	0
RAC–LAC impression 2	19.1	14.6	25.4	1
RAC–LAC difference	−2.6	−9.1	4.0	1
LAC–PCL impression 1	5.0	1.6	19.0	0
LAC–PCL impression 2	3.7	1.4	13.9	1
LAC–PCL difference	−1.1	−9.6	1.7	1
PR–PL impression 1	15.5	8.0	22.2	0
PCR–PCL impression 2	15.5	11.7	21.3	1
PR–PL difference	0.8	−3.4	6.5	1
A–VD impression 1	28.4	20.2	35.9	0
A–VD impression 2	26.8	17.4	32.7	1
A–VD difference	−1.5	−9.7	4.5	1
RAC–PCR impression 1	4.9	1.4	14.8	0
RAC–PCR impression 2	3.8	1.3	10.1	1
RAC–PCR difference	−1.1	−8.0	1.4	1

columella growth was significantly much greater in the NAM treatment group, at more than 100%, versus approximately 14% in the healthy control group. Despite NAM treatment however, the columella length could not reach normal nasal dimensions. The relative growth was still much greater even though the mean age of the BLCP group was slightly younger by approximately 2 weeks (13 days). We therefore conclude that a goal of overcorrection, if possible, seems more than appropriate (Chang et al., 2010), because columella length will still not reach age-matched, healthy dimensions. Further, some of the gained columella length might be lost at primary lip closure, and possibly result in a lowered or flattened nasal tip postoperatively (Farkas et al., 1993). Just recently, Patil and Nimbalkar-Patil published another promising technique for effective columella lengthening, in order to possibly overcome some of these mentioned limitations. The described nasal stent is swan-neck shaped, with the middle connecting portion prepared with a circular cross-section, with a close fit to the columella. An additional 1 mm of a long-term resilient liner is added (Patil and Nimbalkar-Patil, 2018).

In order to complete our investigations, data for the corresponding alveolar development were supplemented. Alveolar development can be described as almost symmetrical, considering the similar closure of the alveolar cleft sizes. The negative longitudinal development measured from points A to VD represents and includes the integration of the premaxilla. The integration seems to happen to a greater extent than longitudinal alveolar growth; however, the integration of the premaxilla to close the alveolar

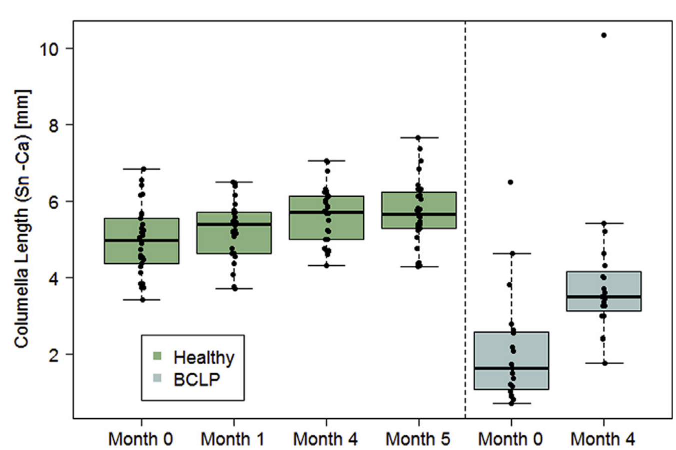

Fig. 6. Direct comparison of columella elongation in patients with bilateral cleft lip and palate (BCLP) and in healthy newborns. Light green = healthy cohort; grey-olive = BCLP patients.

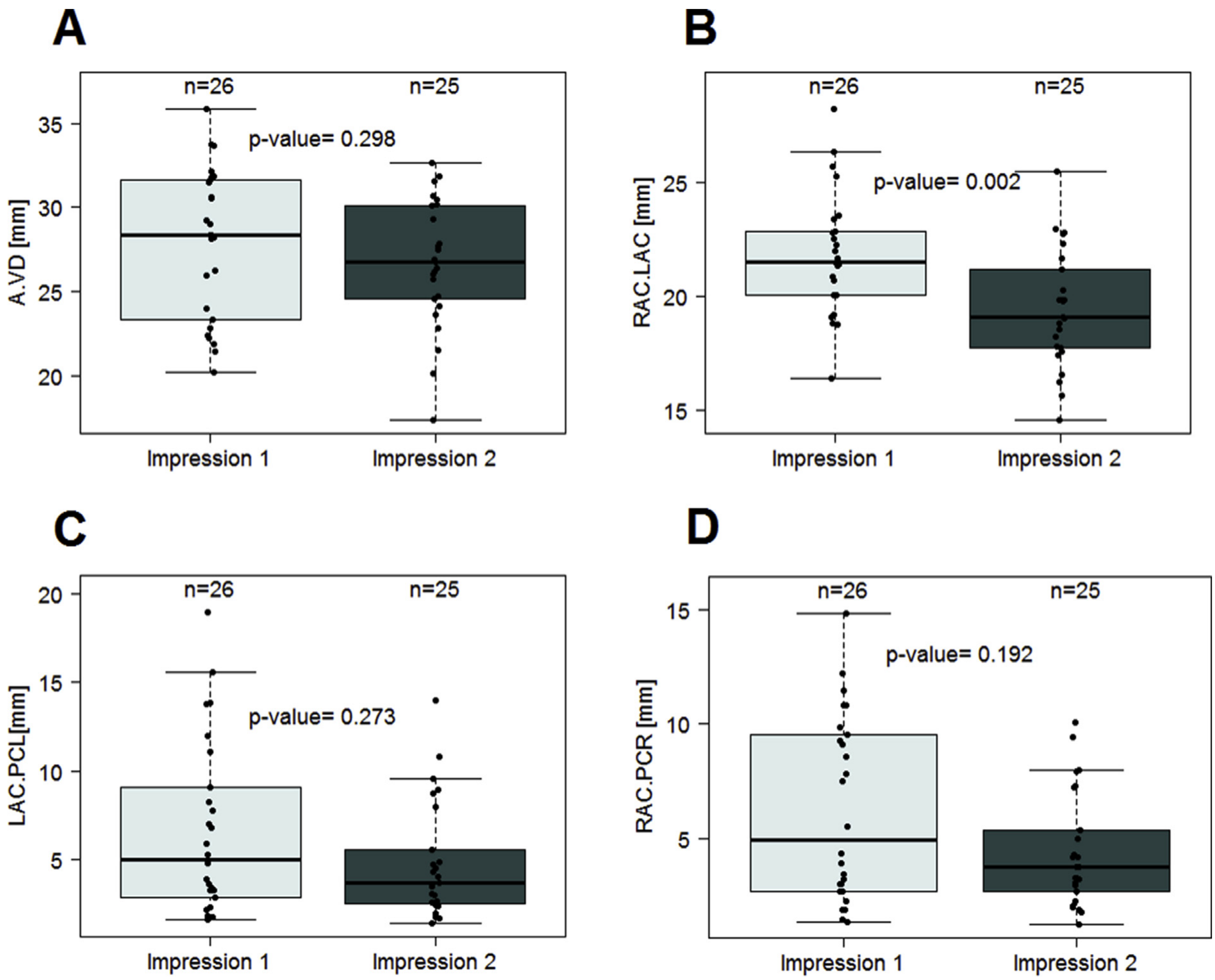

Fig. 7. Alveolar development between two time points: 1) at the beginning and 2) at the end of NAM therapy. A: maxillary length [A–VD], B: distances between anterior alveolar crest [RAC–LAC], C: cleft width left side [LAC–PCL], D: cleft width right side [RAC–PCR]. Grey = impression 1, dark green = impression 2.

crest is one of the main goals of alveolar moulding. Nevertheless, the risk of overcorrection, with consequential risk of midfacial recessiveness and anterior crossbite, has to be kept in mind and must be minimized (Berkowitz, 2016).

The initially included 32 healthy newborns and 27 patients with BCLP experienced some exclusions. This was mainly due to artefacts in the plaster models and, in the case of BCLP patients, a second impression taking that was performed before the end of NAM therapy. The interpretation of the data for the healthy cohort is therefore limited. The measured minimum and maximum values for the columella length had the same range in healthy newborns and in the NAM cohort, but at a noticeably higher level, and so the measured distances seem reasonable. The data can serve as a reference for evaluating treatment outcomes in comparison with ‘normal’ growth.

4.1. Limitations

This was a retrospective study of the NAM treatment group, and therefore affected by the usual drawbacks of such a protocol. Further, we did not subdivide our cohort into males and females, or into different ethnicities. The resulting groups would have been too small for further statistical analysis, and we believe that there are no dramatic differences in absolute and relative nasal growth in the first few weeks of life between male and female noses. Plaster production, with impression takings, is generally susceptible to inaccuracies and artefacts because of modification of the soft tissue, and facial movement or grimacing (Tzou et al., 2014) (Ritschl et al., 2018). In addition, hardening of the materials takes time, and is also associated with known changes, as described by others (Wassell and Abuasi, 1992). Another source of error is the grouting of plaster to produce plaster models. Therefore, the use of modern 3D photography seems to be a suitable and feasible solution for future extraoral registration and documentation.

5. Conclusion

NAM as a presurgical treatment modality seems highly effective when cases are compared with normal and healthy nasal columella development. However, despite the effectiveness NAM offers, normal nasal dimensions cannot be achieved because of the short columella lengths before treatment. Nevertheless, NAM appears to be essential for improving the initial clinical situation as much as possible.

Competing financial and non-financial interests

The study was financed by the non-profit Zeidler-Forschungs-Stiftung, Waldkraiburg, Germany. There are no non-financial competing interests.

Data availability

The distances analysed in this study are published in the provided tables.

Contributions

FDG: study design and administration, plaster model digitalization, data cohort and analysis, writing of manuscript, statistical analysis, patient treatment; **AR:** patient treatment, manuscript revision and editing, study design; **FXB:** software script writing, technical support; **FH:** data analysis, technical support; **BH:** impression takings, plaster model digitalization, analysis; **MR:** plaster model digitalization, study design and technical consultations; **AVB:** manuscript revisions, plaster model digitalization, administrative study organization; **KDW:** patient treatment and BCLP surgery; **DJL:** study design and administration, manuscript revisions; **LMR:** manuscript revisions, study design, plaster model analysis, patient treatment.

Acknowledgements

Excerpts from this publication form parts of the bachelor's thesis of Fiona Hellmundt, BSc, and of the doctorate thesis of Bettina Hilmer, DMD. We thank Dr Sonja Grill, MSc, for statistical consultations and Mr Daniel Ross for his language corrections. Many thanks to Eduard Zweigardt for organizing multiple plaster models. Finally, we thank Rebecca Wenokor for assisting with the nasal analysis.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.01.044.

References

Barillas I, Dec W, Warren SM, Cutting CB, Grayson BH: Nasoalveolar molding improves long-term nasal symmetry in complete unilateral cleft lip-cleft palate patients. Plast ReConstr Surg 123: 1002–1006, 2009

Bauer FX, Güll FD, Roth M, Ritschl LM, Rau A, Gau D, et al: A prospective longitudinal study of postnatal dentoalveolar and palatal growth: the anatomical basis for CAD/CAM-assisted production of cleft-lip-palate feeding plates. Clin Anat 30: 846–854, 2017

Berkowitz S: The facial growth pattern and the amount of palatal bone deficiency relative to cleft size should be considered in treatment planning. Plast ReConstr Surg Glob Open 4: e705, 2016

Chang CS, Por YC, Liou EJ, Chang CJ, Chen PK, Noordhoff MS: Long-term comparison of four techniques for obtaining nasal symmetry in unilateral complete cleft lip patients: a single surgeon's experience. Plast ReConstr Surg 126: 1276–1284, 2010

Farkas LG, Hajnis K, Posnick JC: Anthropometric and anthroposcopic findings of the nasal and facial region in cleft patients before and after primary lip and palate repair. Cleft Palate Craniofacial J 30: 1–12, 1993

Farkas LG, Posnick JC, Hreczko TM, Pron GE: Growth patterns of the nasolabial region: a morphometric study. Cleft Palate-Craniofacial J 29: 318–324, 1992

Grayson BH, Cutting C, Wood R: Preoperative columella lengthening in bilateral cleft lip and palate. Plast ReConstr Surg 92: 1422–1423, 1993

Kinouchi N, Horiuchi S, Yasue A, Kuroda Y, Kawai N, Watanabe K, et al: Effectiveness of presurgical nasoalveolar molding therapy on unilateral cleft lip nasal deformity. Saudi Med J 39: 169–178, 2018

Loeffelbein DJ, Rau A, Wolff KD: Impression technique for monitoring and virtual treatment planning in nasoalveolar moulding. Br J Oral Maxillofac Surg 51: 898–901, 2013

Mancini L, Gibson TL, Grayson BH, Flores RL, Staffenberg D, Shetye PR: Three-dimensional soft tissue nasal changes after nasoalveolar molding and primary cheilorhinoplasty in infants with unilateral cleft lip and palate. Cleft Palate Craniofac J, 2018 1055665618771427

Patil PG, Nimbalkar-Patil SP: Modified activation technique for nasal stent of nasoalveolar molding appliance for columellar lengthening in bilateral cleft lip/palate. J Prosthodont 27: 94–97, 2018

Peanchitlertkajorn S: Presurgical nasal molding with a nasal spring in patients with mild-to-moderate nasal deformity with incomplete unilateral cleft lip with or without cleft palate. Cleft Palate Craniofac J, 2018 1055665618774773

Prasad S, Ravindran S, Radhakrishnan V, Hazarey PV, Vanka A, Rajan B: Initial experiences with NAM-assisted primary repair of the BCLP deformity. Spec Care Dent 37: 304–308, 2017

R-Development-Core-Team: R: a language and environment for statistical computing. Vienna, Austria: R Foundation for Statistical Computing, 2008

Rau A, Ritschl LM, Mücke T, Wolff KD, Loeffelbein DJ: Nasoalveolar molding in cleft care — experience in 40 patients from a single centre in Germany. PLoS One 10: e0118103, 2015

Ritschl LM, Roth M, Fichter AM, Mittermeier F, Kuschel B, Wolff KD, et al: The possibilities of a portable low-budget three-dimensional stereo-photogrammetry system in neonates: a prospective growth analysis and analysis of accuracy. Head Face Med 14: 11, 2018

R-Studio-Team: Integrated development for R. Boston, MA: RStudio, Inc., 2012

Rubin MS, Clouston S, Ahmed MM, ML K, Shetye PR, Broder HL, et al: Assessment of presurgical clefts and predicted surgical outcome in patients treated with and without nasoalveolar molding. J Craniofac Surg 26: 71–75, 2015

Shetty V, Agrawal RK, Sailer HF: Long-term effect of presurgical nasoalveolar molding on growth of maxillary arch in unilateral cleft lip and palate: randomized controlled trial. Int J Oral Maxillofac Surg 46: 977–987, 2017

Suri S, Disthaporn S, Atenafu EG, Fisher DM: Presurgical presentation of columellar features, nostril anatomy, and alveolar alignment in bilateral cleft lip and palate after infant orthopedics with and without nasoalveolar molding. Cleft Palate Craniofac J 49: 314–324, 2012

Tzou CH, Artner NM, Pona I, Hold A, Placheta E, Kropatsch WG, et al: Comparison of three-dimensional surface-imaging systems. J Plast ReConstr Aesthet Surg 67: 489–497, 2014

Wassell RW, Abuasi HA: Laboratory assessment of impression accuracy by clinical simulation. J Dent 20: 108–114, 1992