Effect of Cleft Types on Outcome of Unilateral Cleft Lip Repair

Adekunle Moses Adetayo[1,2], Abdurazzak Olanrewaju Taiwo[3], Modupe Olusola Adetayo[4], Omotayo F. Salami[1,5]

[1]Department of Surgery, Benjamin Carson SNR School of Medicine, Babcock University, [2]Department of Dentistry, Babcock University Teaching Hospital, [4]Department of Biochemistry, Babcock University, [5]Department of Surgery, Anaesthesia Unit, Benjamin Carson School of Medicine, Babcock University, Ilisan-Remo, Ogun State, [3]Department of Surgery, Usmanu Danfodio University Sokoto, Sokoto State, Nigeria

Abstract

Introduction: It is generally assumed that the major phenotypes of unilateral cleft lip (UCL) represent its extent of severity. There are a few studies on this, but objectivity has been lacking. It was the aim of this study to assess the effect of different phenotypes of UCL on the outcome of surgical repair. **Methodology:** This study was a case series of the effect of phenotypes of cleft on the outcome of repair of UCL. Fifteen subjects each were in three UCL phenotype groups. Surgical outcome was assessed quantitatively with anthropometric measurements recorded from a full frontal face photograph of subjects. The analysis was done using Student's *t*-test and one-way ANOVA at $P = 0.05$. **Results:** The mean values of the preoperative horizontal and vertical lip height, and nasal width on the cleft side in the cleft lip (CL) group were closest to those of the noncleft side and control. The postoperative mean values of the horizontal and vertical lip height, and nasal width on the cleft side in the CL group were closest to those of the noncleft side and control, while those of the CL, alveolus and palate group were farthest from those of the noncleft side and the control. **Discussion:** The different phenotypes of UCL have different degrees of tissue distortion and deficiencies. CL group had its measurements closest to that of the noncleft sides and control, suggesting that it has the least distortion. **Conclusion:** The comparison between the three groups did not reveal any difference, suggesting that the skill of the surgeon and the selection of a well proven technique are more important factors in the outcome of repair of unilateral cleft lip.

Keywords: Anthropometry, cleft lip, cleft types, outcome of repair

INTRODUCTION

The facial muscles are divided into three muscular rings. The first ring is formed by the nasolabial group, second by the bilabial group and the third by the labiomental ring.[1,2] All the three rings are disrupted when cleft of the lip with/without palate occurs.[2] The resultant disturbance in muscular function within these anatomic muscular units secondarily produces distortions in the growth of surrounding skeletal and cartilaginous structures that theoretically escalate over time. Accurate reconstruction of these different muscular layers of the lip is important for normal lip function, and also to stop further distortion of underlying hard tissue structures.[2]

The severity of unilateral cleft lip (UCL) has been correlated with the extent of facial tissue distortion.[3] Even though no objective index is available, as at the time of this study, it is generally assumed that the major phenotypes of UCL (cleft lip [CL] only, cleft lip and alveolus [CLA], and CL alveolus and palate [CLAP]) represent the extent of severity in that order.[4] And so the degree of tissue distortion might affect the degree to which the tissue can be apposed in UCL repair, ultimately affecting the outcome of surgical repair.

The ideal operation for the repair of a UCL should result in a symmetrical upper lip and nose, with the equal philtral column length on either side.[5] In addition, the Cupid's bow should be of adequate proportions. These criteria should be obtainable in a single operation without multiple minor revisional procedures.[5] The range of outcome of the treatment of CL and palate can, however, be considerable due to many variables including types/severity of cleft, variation in the sequence, timing and technique of treatment, the organization and delivery of care, as well as in the skills and experience

Access this article online

Quick Response Code:

Website:
www.amsjournal.com

DOI:
10.4103/ams.ams_293_20

How to cite this article: Adetayo AM, Taiwo AO, Adetayo MO, Salami OF. Effect of cleft types on outcome of unilateral cleft lip repair. Ann Maxillofac Surg 2020;10:297-303.

in the individual surgeons.[6,7] On this premise, evaluation of treatment outcome is essential to allow for identification and implementation of the highest possible standards of care, as it gives a foreknowledge of area of cleft repair that are likely to necessitate the use of secondary techniques and adjunct flaps to achieve an ideal outcome. It has been reported that anthropometry and clinical examination best evaluate the morphology of repaired CL and nose[8] because anthropometry can show quantitatively the degree of deformity present in clefts

Justification

Studies that have quantitatively determined the extent of the effect of various types of UCL on the surgical outcome of repair of UCL are few,[9-11] and to the best of our knowledge, none at all in Nigeria and the sub-Saharan Africa, so this study aimed to determine if there is association between types of UCL and outcome of surgical repair.

Study hypothesis

The study was based on the hypothesis that the type of UCL has effect on the surgical outcome of repair of UCL.

METHODOLOGY

This study was a case series of effect of the three types of UCLs (CL only, CLA, and CLAP) on treatment outcome of surgical repair of UCL. It was carried out between January 1, 2013 and July 31, 2014. The study was approved by the Health Research and Ethics Committee on October 9, 2012 (IRB number 34,512).

Sample size for this study was determined by using the formula for cohort and case–control study as proposed by Schlesselman.[12] The attrition rate was taken as 10% to cater for dropouts, so the sample size was 27.5, approximated to 28, nevertheless, 45 were used. This was statistically stratified into three to make each group (CL only, CLA and CLAP) contain 15 participants.

The participants were recruited from the cleft clinic of a University Hospital.

The aim was to evaluate the effect of types of UCL on treatment outcome, following repair of UCL.

The objectives are

i.   To evaluate the surgical outcome of repair of CL only
ii.   To evaluate the surgical outcome of repair of CLA
iii. To evaluate the surgical outcome of repair of CLAP
iv.   To compare the surgical outcome of repair of CL only, CLA, and CLAP.

Inclusion criteria

1. Participants with complete UCL with or without alveolus and palate
2. Participants who were 3 months old and above.

Exclusion criteria

1. Individuals with bilateral CL with or without palate

2. Individuals with syndromic cleft of the lip and/or palate
3. Individuals who were <3 months old
4. Individuals who required CL revision following primary CL repair
5. Individuals who were not fit for general anesthesia.

Written informed consents were obtained from parents/guardian of all participants before enrolment in the study [Appendix I]. Prior to this, detailed information and explanations of the study were given to the parents or guardians. Every one of them was given an opportunity to ask questions concerning the study, and appropriate clarifications were given before the commencement of the study. Opportunity to withdraw at any stage of the study was also made known without victimization or denial of treatment.

Data collection

The following data were recorded preoperatively on a pro forma: age, sex, weight, height, and type of clefts.

Preoperative evaluation

Routine preoperative blood investigations including hemoglobin estimation, electrolyte, urea and creatinine level, and electrocardiography was done for each subject. Echocardiography was also done when indicated. Participants were referred to the pediatrician for clinical evaluation, to rule out cardiovascular congenital anomalies, upper respiratory tract infection, ear infection, and other congenital anomalies that may be of clinical significance. Participants were at least 3 months old, 4.5 kg (10 pounds) with a minimum hemoglobin concentration of 10 g/dL.

Standardized preoperative photographs were taken for all participants before the surgeries were performed from which preoperative anthropometry was done as explained below in postoperative anthropometry.

Operative procedure

All participants had their surgical repair done under general anesthesia with endotracheal intubation. Two oral and maxillofacial surgeons that were skilled in Millard-Rotation advancement technique of CL repair with the same number of years of experience performed the operation.

Surgical outcome was done by using anthropometry as stated by Cutting and Dayan,[13] because it employed two-dimensional (2D) (photography) anthropometry where image acquisition is relatively simple, equipment are cheap and a very high level of technical expertise is not needed. It also correlates very well with clinical assessment. Anthropometric measurements were recorded from a 2D full frontal face photograph of subjects taken with a digital camera (Canon PowerShot SX500 IS, 30x optical zoom, 16MP, 24–720 mm wide angle). For standardization, each photograph was taken with the camera placed at 45 cm from each participant and the interpupillary plane parallel to the floor (the subjects were positioned in a way that the lens of the camera is perpendicular to the interpupillary line). The photographs were then imported into Adobe Photoshop software (Adobe Systems, Mountain view, California, 2009), for analysis.

These anthropometric measurements were recorded [Figure 1a and b]:

Preoperatively;
1. Vertical lip height on the noncleft side: measured from the alar base to the peak of the Cupid's bow on the same side
2. Vertical lip height on the cleft side: measured from the alar base on the cleft side to a point where the white roll just starts to disappear
3. Horizontal lip height on the noncleft side: measured from the peak of the Cupid's bow on the noncleft side to the ipsilateral commissure of the mouth
4. Horizontal lip height on the cleft side: measured from where the white roll starts to fade out to the ipsilateral commissure
5. Nasal width: measured from the alar base to the mid-point of the columella for both sides
6. Total nasal width: measured from the alar base on cleft side to alar base on noncleft side.

Postoperative measurement; this was done 3 months after the surgery.
1. Vertical lip height: measured from the alar base to the peak of the Cupid's bow, for both cleft and noncleft sides
2. Horizontal lip height: measured from the peak of the Cupid's bow to the commissure for both cleft and noncleft sides
3. Nasal width: measured from the alar base to the mid-point of the columella for both cleft and noncleft sides

4. Total nasal width: measured from the alar base on cleft side to alar base on noncleft side
5. Philtral height: measured from the peak of the Cupid's bow to the mid-point of the columella for both cleft and noncleft sides
6. Cupid's bow width: measured from the peak of the Cupid's bow on one side to the peak on the other side.

Confounders

To minimize confounders as much as possible, the following steps were taken;
1. The camera has a stand that was permanently located at the distance, 45 cm, as stated above
2. Several photographs were taken of the participants out of which the best was chosen by the lead author and imported into the Adobe software, stated above
3. All participants with microform or incomplete CL phenotype were excluded from the study.

Age-matched controls were recruited from the outpatient immunization clinic of Community Health. Vertical lip height, horizontal lip height, nasal width, total nasal width, philtral height, and Cupid's bow width were measured as stated for postoperative measurement above.

Data analysis was performed using Statistical Package for Social Sciences (SPSS) for Windows (version 23.0, SPSS Inc., Chicago, IL, USA). Means of each variable measured preoperatively and postoperatively were generated for each group, and a comparison of these, cleft side with noncleft side

Point 13 = midpoint of the columella.

Point 4 to 2 = vertical lip height non-cleft side

Point 10 to 8 = vertical lip height cleft side

Point 6 to 2 = horizontal lip height non-cleft side

Point 8 to 7 = horizontal lip height cleft side

Point 4 to 13 = nasal width non-cleft side.

Point 10 to 13 = nasal width cleft side.

Point 4 to 10 = Total nasal width.

Point 1 to 2 = nasal width on non-cleft side

Point 2 to 3 = nasal width on cleft side.

Point 4 to 5 = Cupid's bow width

Point 1 to 4 = vertical lip height on non-cleft side

Point 3 to 5 = vertical lip height on cleft side

Point 4 to 6 = horizontal lip height on non-cleft side

Point 5 to 7 = horizontal lip height on cleft side.

Point 2 to 4 = philtral height non-cleft side.

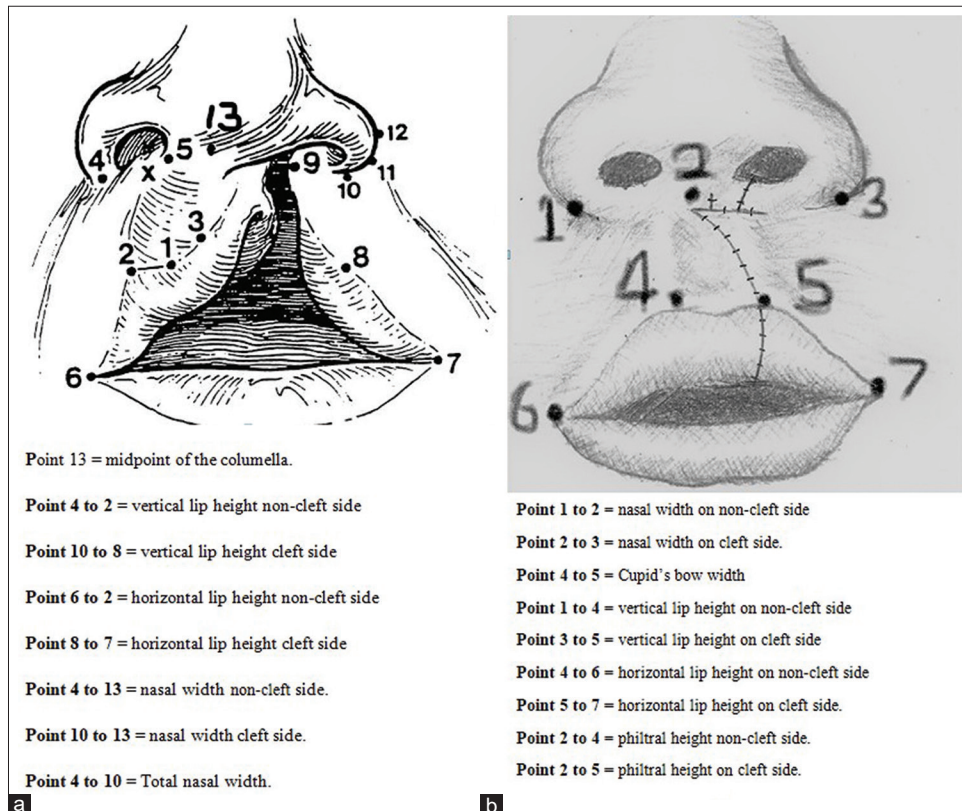Point 2 to 5 = philtral height on cleft side.

Figure 1: (a) Preoperative anthropometry. (b) Postoperative anthropometry reference point

and the control, was done, using Student's *t*-test. In addition, the mean values of the measured variables in each group were compared within the three groups using one-way ANOVA. Statistical significance was *P* ≤ 0.05.

RESULTS

A total of 45 participants requiring repair of UCL were enrolled for the study and analyzed. Fifteen participants each were in CL, CLA, and CL, alveolus and palate groups. Of the 45, 25 (55.6%) were males, and 20 (44.4%) were females, in the ratio of 1.3:1.

The preoperative mean values of the horizontal lip height, vertical lip height, and nasal width on the cleft side in the CL group were closest to those of the noncleft side and control. The comparisons did not show any statistically significant difference for horizontal lip height (cleft side and noncleft side and the control) and nasal width (cleft side and the control) in the CL group, as shown in Table 1.

Comparison of postoperative anthropometry measurement of cleft side with noncleft side and the control in the three groups

The mean values of the horizontal lip height, vertical lip height and nasal width on the cleft side in the CL group were closest to those of the noncleft side and control while those of the CL, alveolus and palate group were farthest from those of the noncleft side and the control [Table 2].

Cleft lip only

The comparison showed that, there was no difference between the horizontal lip lengths of the cleft side, noncleft side and the control; no difference between the vertical lip heights of the cleft side and the control; no difference between the nasal widths of the cleft side and the noncleft side, and also, no difference between the philtral heights of the cleft side, noncleft side and the control.

Cleft lip and alveolus

The comparison showed that, for both horizontal and vertical lip heights, there was no difference between those of the cleft side and the control and also no difference between the philtral heights of the cleft side and those of the control.

Cleft lip, alveolus, and palate

The comparison was essentially like that of CLAP. It showed that, for both horizontal and vertical lip heights, there was no difference between those of the cleft side and the control and also no difference between the philtral heights of the cleft side and those of the control.

Comparison of postoperative anthropometry variables of repaired cleft in cleft lip only, cleft lip and alveolus and cleft lip, alveolus and palate groups

The CL only group had the greatest increase in the postoperative vertical lip height and greatest decrease in nasal width, while the CLA group had the greatest increase in vertical lip height and the philtral height. The CL, alveolus and palate group had the greatest reduction in the cupid bow width. However, the comparison did not show any significant difference between the three groups (*P* > 0.005) [Table 3].

DISCUSSION

The impact of different types of cleft phenotypes on various treatment outcomes in UCLP patients has been assessed to some degree,[7] but objectivity has been lacking. Preoperative measurements and comparisons of the three types of UCL showed there was indeed varying degrees of tissue distortion and relative hypoplasia in all the 3 cleft types, with CLAP exhibiting greatest distortion and relative hypoplasia. This result echoed that of Chou *et al.*[14] and in agreement with Suzuki *et al.*;[3] Bishara[9] and Carroll and Mossey.[15] Carroll and mosey[15] observed that the severity of CL is greatest with CLAP subtype. Literature seems to agree on this observation

Table 1: Preoperative anthropometry measurements of cleft side and noncleft side and control in the three groups

Variables	CL group		CLA group		CLAP		P		
	Mean	SD	Mean	SD	Mean	SD	CL	CLA	CLAP
Horizontal lip height									
Cleft side	15.80	5.20	15.21	2.23	14.67	2.78			
Noncleft side	17.55	3.81	18.11	3.37	16.93	3.50	0.084	0.001*	0.013*
Control	18.04	2.72	19.10	3.48	18.24	2.98	0.182	0.003*	0.008*
Vertical lip height									
Cleft side	13.97	6.47	12.16	3.54	11.99	2.04			
Noncleft side	16.20	6.81	14.84	4.60	15.36	3.28	0.007*	0.001*	*0.001
Control	15.39	1.80	16.25	2.82	15.49	1.68	0.387	0.003*	0.001*
Nasal width									
Cleft side	22.45	5.59	22.40	3.79	24.31	3.14	0.001*	0.001*	0.001*
Noncleft	17.47	4.81	15.83	3.17	16.45	2.28			
Total nasal width of subject	38.99	10.46	38.79	6.47	40.09	5.35	0.011*	0.010*	0.001*
Total nasal width of control	31.73	2.81	31.45	5.93	31.14	1.70			

*Significant at *P*≤0.05. SD: Standard deviation, CL: Cleft lip, CLA: Cleft lip and alveolus, CLAP: Cleft lip, alveolus and palate

Table 2: Postoperative anthropometry measurements of cleft side and noncleft side and control

Variables	CL group		CLA group		CLAP		*P*		
	Mean	SD	Mean	SD	Mean	SD	CL	CLA	CLAP
Horizontal lip height									
Cleft side	17.60	2.86	19.19	4.11	17.36	3.22			
Noncleft side	18.55	3.06	20.50	3.85	19.38	3.00	0.082	0.034*	0.010*
Control	18.04	2.72	19.10	3.48	18.24	2.98	0.651	0.947	0.412
Vertical lip height									
Cleft side	16.98	3.17	16.48	4.21	16.76	3.03			
Noncleft side	18.77	3.88	18.37	3.61	18.80	2.60	0.038*	0.002*	0.001*
Control	15.39	1.80	16.25	2.82	15.49	1.68	0.138	0.838	0.180
Nasal width									
cleft side	17.89	2.84	20.06	4.19	18.79	3.15	0.527	0.003*	0.048*
Noncleft	17.52	2.48	17.00	2.71	17.42	2.20			
Total nasal width of subject	35.41	4.85	37.06	6.18	35.87	4.90			
Total nasal width of control	31.73	2.81	31.45	5.93	31.14	1.70	0.009*	0.012*	0.004*
Philtral height									
Cleft side	12.59	2.14	12.70	2.00	12.54	1.66			
With noncleft side	13.90	2.78	14.06	2.66	14.33	2.51	0.088	0.013*	0.001*
With control	12.07	1.03	12.43	2.25	11.88	1.86	0.314	0.718	0.295
Cupid's bow width									
Cleft subjects	12.02	2.66	12.08	1.95	11.76	2.34			
Control	10.08	1.25	10.27	1.39	9.37	1.17	0.029*	0.015*	0.007*

*Significant at *P*≤0.05. SD: Standard deviation, CL: Cleft lip, CLA: Cleft lip and alveolus, CLAP: Cleft lip, alveolus and palate

Table 3: Postoperative anthropometry variables of repaired cleft side in cleft lip, cleft lip and alveolus and cleft lip and alveolus groups

Variables	CL group		CLA group		CLAP		df	*P*
	Mean	SD	Mean	SD	Mean	SD		
Horizontal lip height	17.60	2.86	19.19	4.11	17.36	3.22	2	0.294
Vertical lip height	16.98	3.17	16.48	4.21	16.77	3.03	2	0.926
Nasal width	17.89	2.84	20.09	4.19	18.79	3.15	2	0.225
Total nasal width subject	35.41	4.85	37.06	6.18	35.87	4.90	2	0.687
Philtral height	12.59	2.14	12.70	2.00	12.54	1.66	2	0.974
Cupid's bow width	12.02	2.66	12.08	1.95	11.76	2.34	2	0.021

*Significant at *P* is ≤0.05. SD: Standard deviation, CL: Cleft lip, CLA: Cleft lip and alveolus, CLAP: Cleft lip, alveolus and palate

as we did not find a contrary opinion in literature. The reason for the least distortion and relative hypoplasia in CL only group is most likely to be because the cleft width is relatively small and so the displacement of the tissue is minimal as stated in Delaire and Precious.[1] It is also important to note that the cleft side of the CL only group is closest to its controls, further buttressing the fact that it has least tissue distortion.

Interestingly, the vertical lip heights in all the three groups were similar to those of the control and not to the noncleft side. This might be because the cleft is placed vertically in the lip tissue and so the hypoplasia effect is more pronounced vertically rather than horizontally. However, symmetry of cleft side with the control but not with the noncleft side has equally been reported in other studies.[16-18] It is consequently, now being speculated that the noncleft side may not be an appropriate control for the cleft side.[16,17]

Postoperatively, the distinction between the various CL types is still conspicuous. Most of the measurements in the CL only group were similar to those of the noncleft side and the control while the other groups were similar with only those of the control. This finding is similar to that of Hoh and Sulaiman[10] which reported different outcomes of surgical repair based on initial differing preoperative severities in UCL, and is completely in agreement with Campbell *et al*.[11] and Gundlach *et al*.[19] Abdurrazaq *et al*.[20] also alluded to the effect of cleft severity based on the different cleft phenotypes, on the outcome of surgical repair, especially that of the nose, even when primary rhinoplasty was done. The impact of surgery on the different types of UCL was however remarkable, as previously reported by Adetayo *et al*.[16] as the lip lengths, philtral heights were similar with those of the control, even in seemingly most severe CLAP group, which could mean that the surgeons were able to compensate for this differing severities because of their skills and experience.

Conclusion

The different phenotypes of UCL have different degree of tissue distortion and relative deficiencies which could be termed "severities" as shown by the preoperative measurements in Table 1, where minimum distortion was seen with CL only subtype. This group also has its measurements similar to those of the nonleft side and control, suggesting it has the least deviation from the normal. However, the comparison between the three groups did not reveal any difference, suggesting, again, that the outcome may not be entirely dependent on the UCL phenotypes. The skill of the surgeon and the selection of a well-proven technique can be considered as the more important factors in the outcome of repair of UCL. However, larger number of patients in each group might give a more reflective difference in outcome.

Limitation of the study

Low number of participants employed and nonuse of a standardized tool to measure the unilateral cleft severity might contribute to why a difference was not seen with all the parameters considered.

Future research

3D anthropometry measurement needs to be conducted to give a more accurate 3D evaluation of surgical outcome.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Delaire J, Precious D. Influence of the nasal septum on maxillonasal growth in patients with congenital labiomaxillary cleft. Cleft Palate J 1986;23:270-7.
2. Markus D, Smith WP. Facial balance in cleft lip and palate II, Cleft lip and palate and secondary deformities. Brit J of Oral Max Surg 1992;30:296-304.
3. Suzuki A, Mukai Y, Ohishi M, Miyanoshita Y, Tashiro H. Relationship between cleft severity and dentocraniofacial morphology in Japanese subjects with isolated cleft palate and complete unilateral cleft lip and palate. Cleft Palate Craniofac J 1993;30:175-81.
4. Allori AC, Kelley T, Meara JG, Albert A, Bonanthaya K, Chapman K, et al. A standard set of outcome measures for the comprehensive appraisal of cleft care. Cleft Palate Craniofac J 2017;54:540-54.
5. Christofides E, Potgieter A, Chait L. A long term subjective and objective assessment of the scar in unilateral cleft lip repairs using the Millard technique without revisional surgery. J Plast Reconstr Aesthet Surg 2006;59:380-6.
6. Kappen Bittermann D, Janssen L, Gerhard KP, Chantal B, Sarah H, Hester W. Long-term follow-up study of young adults treated for unilateral complete cleft lip, alveolus, and palate by a treatment protocol including two-stage palatoplasty: Speech outcomes. Arch Plast Surg 2017;44:202-9.
7. Campbell A, Restrepo C, Deshpande G, Tredway C, Bernstein SM, Patzer R, et al. Validation of a unilateral cleft lip surgical outcomes evaluation scale for surgeons and laypersons. Plast Reconstr Surg Glob Open 2017;5:e1472.
8. Bagante I, Akota I. Cleft-related nose deformation evaluation and measurement methods. Literature review. Stomatologija 2015;17:75-83.
9. Bishara SE. Variation in cleft width and its effect on facial and dental anomalies. Int J Oral Surg 1973b; 2:179-84.
10. Hoh EY, Sulaiman WA. Analysis of preoperative measurements in unilateral cleft lip patients toward the outcome of secondary cleft deformities. J Cleft Lip Palate Craniofac Anomal 2019;6:93-8.
11. Campbell A, Restrepo C, Park E, Navas G, Deshpande G, Swanson J, et al. Influence of severity on aesthetic outcomes of unilateral cleft lip repair in 1,823 patients. Plast Reconstr Surg Glob Open 2019;7:e2083.
12. Schlesselman JJ. Sample size requirements in cohort and case-control studies of disease. Am J Epidemiol 1974;99:381-4.
13. Cutting CB, Dayan JH. Lip height and lip width after extended Mohler unilateral cleft lip repair. Plast Reconstr Surg 2003;111:17-23.
14. Chou PY, Luo CC, Chen PK, Chen YR, Samuel Noordhoff M, Lo LJ. Preoperative lip measurement in patients with complete unilateral cleft lip/palate and its comparison with norms. J Plast Reconstr Aesthet Surg 2013;66:513-7.
15. Carroll K, Mossey PA. Anatomical variations in clefts of the lip with or without cleft palate. Plast Surg Int 2012;2:542078-6.
16. Adetayo AM, James O, Adeyemo WL, Ogunlewe MO, Butali A. Unilateral cleft lip repair: A comparison of treatment outcome with two surgical techniques using quantitative (anthropometry) assessment. J Korean Assoc Oral Maxillofac Surg 2018;44:3-11.
17. He X, Li H, Shao Y, Shi B. Objective measurements for grading the nasal esthetics on Basal view in individuals with secondary cleft nasal deformity. Cleft Palate Craniofac J 2015;52:66-9.
18. Hakim SG, Aschoff HH, Jacobsen HC, Sieg P. Unilateral cleft lip/nose repair using an equal bows/straight line advancement technique-A preliminary report and postoperative symmetry-based anthropometry. J Craniomaxillofac Surg 2014;42:e39-45.
19. Gundlach KK, Schmitz R, Maerker R, Bull HG. Late results following different methods of cleft lip repair. Cleft Palate J 1982;19:167-71.
20. Abdurrazaq TO, Micheal AO, Lanre AW, Olugbenga OM, Akin LL. Surgical outcome and complications following cleft lip and palate repair in a teaching hospital in Nigeria. Afr J Paediatr Surg 2013;10:345-57.

Appendix I

Informed Consent

I --, give my consent to participate in the study titled "Unilateral Cleft Repair: Evaluation and Comparison of Treatment Outcome of Two Surgical Techniques (Millard's rotational advancement and Tennison-Randall triangular techniques).

This study, and my child or legal dependent's part in the study, have been fully explained to me by the investigator. I have also been informed of the likely complications that might arise as a result of my child or legal dependent's participation in the study.

I further understand that I am free to withdraw my/child or legal dependent's participation from the study.

I agree to be part of this study after due consultation with my family/relatives.

-- --

--- Name of Investigator/Signature/Date

Signature of Subjects/Parents/Guardian and Date

        Name of Witness/Signature and Date