

A Comparative Study of Two Different Techniques for Complete Bilateral Cleft Lip Repair Using Two-Dimensional Photographic Analysis

Srinivas Gosla Reddy,
M.B.B.S., M.D.S., Ph.D.

Rajgopal R. Reddy,
M.B.B.S., B.D.S.

Max J. Zinser, M.D., D.D.S.
Likith V. Reddy, M.D., D.D.S.

Anthony F. Markus,
F.D.S.R.C.S., F.D.S.R.C.P.S.,
F.R.C.S.

Stefaan J. Bergé, M.D.,
D.D.S., Ph.D.

Saidabad, Hyderabad, India;
Cologne, Germany; New Orleans, La.;
Bournemouth, United Kingdom; and
Nijmegen, The Netherlands



Background: The aim of this study was to compare the clinical outcomes of two techniques to repair complete bilateral cleft lip by using indirect two-dimensional photographic analysis.

Methods: One hundred eight bilateral cleft patients were included in this study, 54 patients operated on with the Millard technique and 54 patients operated on with the Afroze technique. Each group of patients was further separated into two subgroups containing symmetrical and asymmetrical cleft lips. All patients were photographed preoperatively and 4 years postoperatively in frontal and submentovertical views in a reproducible way. Eight measurements were performed on the photographs. From these measurements, seven ratios were calculated to compare the two techniques.

Results: The outcomes of the interobserver and intraobserver measurements were analyzed using the Pearson correlation test. There was a statistically significant reliability in the intraobserver and interobserver ratios. Analysis of the ratios was performed using the independent samples *t* test (5 percent level of significance). The authors found that the Afroze technique was better than the Millard technique in six of the seven parameters for symmetrical clefts and in four of the seven parameters for asymmetrical clefts; however, there was no statistically significant difference seen between the two techniques.

Conclusions: The Afroze technique seems to have good clinical outcomes on bilateral cleft lip patients, but more research and long-term follow-up are needed to determine the full outcome of the technique in various parameters. (*Plast. Reconstr. Surg.* 132: 634, 2013.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

No greater problem exists in the whole field of surgery than the successful treatment of patients suffering from complete, bilateral cleft lip–cleft palate repair.¹ The challenge is to construct the nasolabial complex in three dimensions, incorporating soft and hard tissue and

anticipating four-dimensional changes of growth and distortion.²

A number of surgical procedures with many variations for the repair of bilateral cleft lip are well described.^{3–5} The Millard technique and its variations are extensively used to repair bilateral cleft lips.⁶ The Afroze technique is based on a combination of a variation of the Millard technique on the cleft segment and a variation of the Pfeifer technique on the prolabium. The aim of this study was to compare the clinical outcomes of the Millard technique and the Afroze technique by using indirect photographic measurements in complete bilateral cleft lips.

From the G.S.R. Hospital, Institute of Cranio-Maxillofacial and Facial Plastic Surgery; the Department of Plastic Surgery, Clinic Cologne Merheim, University Witten-Herdecke; the Department of Oral and Maxillofacial Surgery, Louisiana State University Health Sciences Center; School of Dentistry; Nuffield Hospital; and Radboud University Nijmegen Medical Center.

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PATIENTS AND METHODS

One hundred eight patients were included in this retrospective cohort study (Table 1). The inclusion criteria for the study were that (1) the cleft lip was bilateral; (2) the child did not have any associated syndromes with the cleft; (3) the extent of the cleft was higher than the white roll on both sides and involved the whole nostril on at least one side; (4) the patient was operated on before the age of 1 year (between 3 months and 12 months after birth); (5) the follow-up two-dimensional photographs were taken at least 4 years after lip surgery; and (6) the lip surgery was the primary operation and no further operations were performed.

The patients treated with the Millard technique were operated on from January of 2002 to July of 2004, and the patients treated with the Afroze technique were operated on from November of 2004 to March of 2008. The research project was approved by the local ethical committee based on the guidelines declared by the government of India. All participants' parents or guardians were informed verbally about the study and signed a written informed consent.

Both symmetrical and asymmetrical bilateral cleft lip patients were included in this study. The symmetrical bilateral cleft lip was defined as the defect where the premaxilla was not deviated as compared with the asymmetrical bilateral cleft lip where the premaxilla was deviated.⁷ The criteria to differentiate an asymmetrical bilateral cleft lip from a symmetrical one were based on the classification proposed by Yuzuriha et al. in 2008, which was based on the position of the premaxilla.⁷ Table 1 lists the details of the different groups into which the patients included in the study were divided.

Surgical Technique

As in the Afroze incision described to repair the unilateral cleft lip,⁸ the incision to repair the primary bilateral cleft lip was also based on a combination of the Millard⁶ and the Pfeifer techniques.^{9,10} Here, the Millard incision was performed on the cleft segment and the Pfeifer incision was performed on the prolabium.

Table 1. Patient Distribution

Type of Repair	Total No. of Patients	Type of Cleft	
		Symmetrical	Asymmetrical
Millard	54	17	37
Afroze	54	17	37
Total	108	34	74

The marking for the incision is as follows (Fig. 1): the first line was drawn between two points that mark the midline of the base of the columella (point 1') to the middle of the prolabium at the mucocutaneous junction (point 1). This line was then extended to the vermillion to join it at point 1". The line 1'-1" is not an incision line and is drawn only as a reference line to mark the midline of the prolabium. Points 2 and 3 were marked equidistant from point 1 to mark the future Cupid's bow. Points 4 and 5 were marked equidistant from point 1' on the edge of the prolabium. Points 2 and 4 are connected with a curved line, which was replicated in a mirror image to join points 3 and 5. Both of these lines were continued along the junction of the nasal and oral mucosa into the nostril to stop behind the columella.

The left lateral segment was marked with point 6 to indicate the point on the white roll where it starts to disappear, and point 7 marks the point where the white roll completely disappears. Point 8 was marked on the vermillion in such a way that line 7-8 was perpendicular to the white roll. Point 9 was marked to indicate the alar base. A line was drawn to connect points 6, 7, and 8 along the mucocutaneous junction. From the base of the ala, a line was drawn along the junction of the nasal and oral mucosa into the nostril up to the point where the hair-bearing lining of the nostril ends. At this point, the marking was extended perpendicularly up the ala from inside the nostril to a distance of 3 mm. The process was repeated on the right side to join points 10, 11, and 13 on the lip and points 11 and 12 on the vermillion.

The lateral cutaneous incisions were made first along line 6-7-9. The nasal incision was then made followed by the incision along line 7-8. An

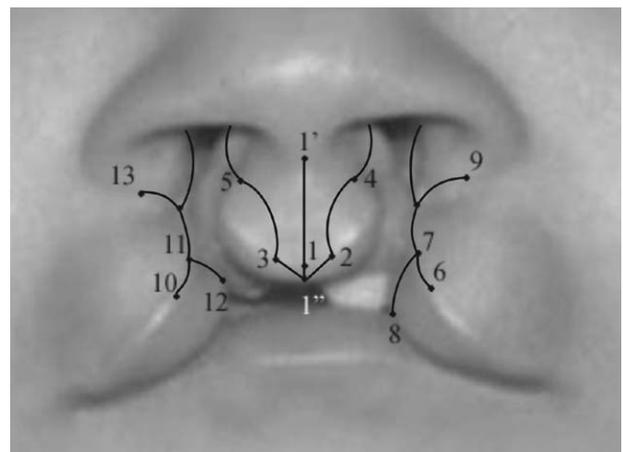


Fig. 1. Marking for the Afroze technique.

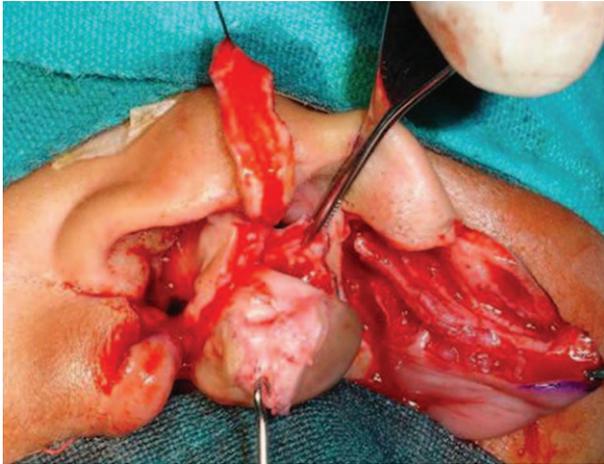


Fig. 2. Dissection of muscles using the Afroze technique.

intraoral relaxing incision was made along the gingivobuccal sulcus that stopped anterior to the canine eminence. Subperiosteal tunneling was performed to release the mucosal lining and to gain access to the lateral maxillary area. The tunneling was carried up to the infraorbital nerve and the zygomatic buttress to enable the proper advancement of the lateral segments. Lateral segment skin undermining and dissection of the orbicularis oris and alar nasalis muscles (Fig. 2) were carried out. The ala with muscular, ligamentous, and lining attachments was released from the pyriform rim and maxilla up to the level of the nasal bones. This procedure was repeated on the contralateral side.

Dissection of the prolabium was performed with the incision made along lines 1"-3-5 and 1"-2-4. The prolabium was raised to separate the vestibular mucosa from the skin, and all the fibroadipose tissue was removed from the prolabial flap. In patients who have associated cleft alveolus and/or cleft palate, a mucoperiosteal flap from the premaxilla was bridged with the corresponding mucoperiosteal flap from the lateral alveolar region. If the position of the nasal septum was deviated, it was corrected by apposition and elevation of mucoperichondrium and by sculpting the nasal soft tissues.

The nasal sill was repaired bilaterally using 6-0 Prolene (Ethicon, Inc., Somerville, N.J.) sutures. The vestibule was formed by suturing vestibular tissue from the prolabium to the corresponding labial mucosa using 4-0 Vicryl (Ethicon) sutures (Fig. 3). Muscle approximation was performed using 4-0 Vicryl sutures. The white roll was matched to maintain continuity between cleft sides and the prolabium. V extension of the prolabium reduces the pull on the columella and



Fig. 3. Reconstruction of vestibule using the Afroze technique.

rotates the lip downward. Skin closure was completed using 6-0 Prolene sutures (Fig. 4). The preoperative and 4-year postoperative results are shown in Figures 5 and 6.

The Millard technique that was used in this study is the one described by Millard in 1971. The only modification made in the incision described by Millard was that the extent of the incision around the ala was stopped at the alar base.¹¹

Photographic Analysis

All patients were photographed preoperatively and 4 years postoperatively with a Nikon D100 (Nikon Corp., Tokyo, Japan) digital camera by a single photographer (R.S.). All images had to satisfy predetermined criteria for frontal and submental views. The criteria that were followed for the frontal view required both ears to be visible to minimize rotation and to have the least possible nostril show to minimize tilt. The criteria that were followed for the submental view were that the nasal tip should be projected between the medial canthi and eyebrows with no head rotation. All anthropometric measurements were performed in a standardized way on these two photographic views.¹²

To test the reliability of this method of evaluating nasal asymmetry, the intraobserver and interobserver variances were tested. For the intraobserver variance, 30 randomly chosen photographs were measured twice, 3 weeks apart, by the first observer. For the interobserver variance, a second observer measured the same 30 photographs used in the measurement of the intraobserver variance. Statistical analysis of the intraobserver and interobserver variance was performed using the Pearson correlation test.

Indirect anthropometric measurements were performed on postoperative digital photographs



Fig. 4. Skin closure using the Afroze technique.

with Adobe Photoshop 7.0 (Adobe Systems, Inc., San Jose, Calif.) and Scion Image Software (National Institutes of Health, Bethesda, Md.).^{13,14} Adobe Photoshop 7.0 was used to identify predetermined landmarks and reference lines on the postoperative photographs of each patient.

On the frontal view photographs, the first line that was drawn was the bipupillary line (PPL). This line was drawn between the most inferior point of the right and left pupils (Fig. 7). The second line was drawn as a tangent to the columella and was parallel to the bipupillary line (CM) (Fig. 6). After the lines were drawn, four sets of

points were marked on either side. The first set of points marked the endocanthion bilaterally (EN_r and EN_l). The second set marked the alar base bilaterally (AB_r and AB_l), the third set marked the highest point on the Cupid's bow bilaterally (CB_r and CB_l), and the fourth set marked the lowest point of the lip mucosa perpendicularly below the third set of points (RM_r and RM_l) (Fig. 7).

After the two lines were drawn, the measurements were taken using the Scion Image Software. The first set of measurements was the shortest distance between AB_r and AB_l to the PPL ($AB-PPL$).^{13,14} The second set of measurements was the



Fig. 5. Frontal view preoperatively and 4 years postoperatively (Afroze technique).



Fig. 6. Worm's-eye view preoperatively and 4 years postoperatively (Afroze technique).

shortest distance between CB_r and CB_l to CM ($CB-CM$).^{13,14} The third set of measurements was the distance between RM_r and CB_r and RM_l and CB_l ($CB-RM$).¹⁵ The fourth set of measurements that were taken were the distances between AB_r and EN_r and between AB_l and EN_l ($AB-EN$)¹³⁻¹⁸ (Fig. 7).

On the worm's-eye view photographs, two sets of points were marked to measure the width of the nose and two sets of points were marked on each nostril to measure the height of the nose. This was done using Adobe Photoshop 7.0. The points to

measure the nostril width were marked as NL_r and NL_l for the most lateral point of the inner border of the nostril, and NM_r and NM_l for the most medial point of the inner border of the nostril.^{13,14} The points to measure the nostril height were marked NT_r and NT_l for the most cranial point of the inner border of the nostril, and NB_r and NB_l for the most basal point on the inner border of the nostril^{13,14} (Fig. 8).

The first measurement was to determine the nostril gap area (NGA) using the Adobe 7.0 Magic Wand tool.^{13,14} The second set of measurements was the distance between NL_r and NM_r and NL_l and NM_l ($NL-NM$). The third set of measurements

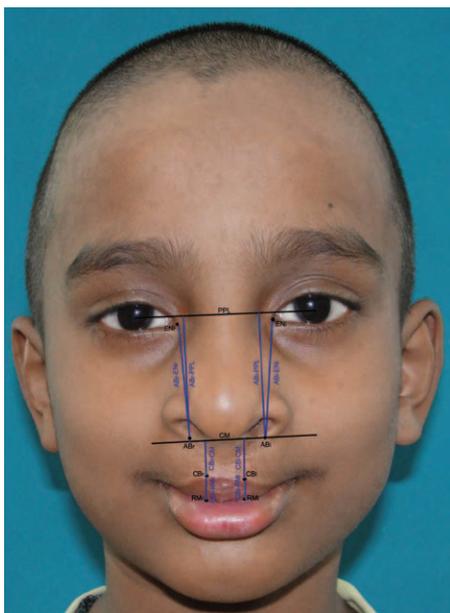


Fig. 7. Measurements and ratios on frontal view photographs taken 4 years postoperatively (Afroze technique).

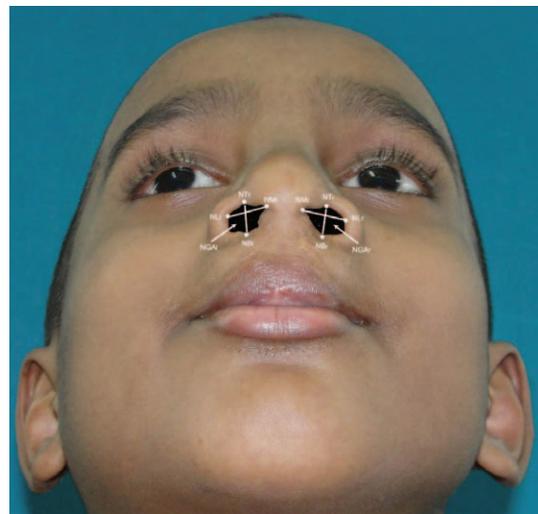


Fig. 8. Measurements and ratios on worm's-eye view photographs taken 4 years postoperatively (Afroze technique).

Table 2. Intraobserver Reliability (n = 30)

	Mean First Observer	Mean Second Observer	Pearson Correlation	<i>p</i> (two-tailed)
AB-PPL _r	26.267	26.367	0.999	0.000
AB-PPL _l	26.477	26.577	0.999	0.000
CB-CM _r	9.430	9.510	0.988	0.000
CB-CM _l	9.457	9.553	0.996	0.000
CB-RM _r	4.910	5.070	0.942	0.000
CB-RM _l	5.007	5.003	0.972	0.000
AB-EN _r	24.087	24.247	0.999	0.000
AB-EN _l	21.703	20.363	0.964	0.000
NGA _r	45.387	49.849	0.966	0.000
NGA _l	42.914	51.172	0.943	0.000
NL-NM _r	9.914	10.364	0.979	0.000
NL-NM _l	9.787	10.267	0.983	0.000
NT-NB _r	5.780	6.014	0.966	0.000
NT-NB _l	5.492	6.088	0.914	0.000

was the distance between NT_r and NB_r and NT_l and NB_l (NT-NB) (Fig. 8).

Statistical Analysis

To present the results of the measurements, ratios (larger side/smaller side) were calculated using the built-in mathematical tools of Microsoft Excel (Microsoft, Inc., Redmond, Wash.). The AB-PPL and AB-EN ratios were used to assess the symmetrical position of the nose. The CB-CM ratio was used to assess the vertical height of the lip and to assess the symmetry of the Cupid’s bow. The CB-RM ratio was used to assess the symmetry and vertical height of the vermillion. The AB-EN ratio was used to assess the nasal width symmetry and the NGA, NL-NM, and NT-NB ratios were used to assess nostril symmetry. Ratios were analyzed using the independent samples *t* test (5 percent level of significance).

RESULTS

After the photographic analysis, ratios were obtained and the comparison between the Millard and Afroze techniques was performed.

Intraobserver and Interobserver Analysis

There were highly significant intraobserver (0.972; *p* < 0.0001) and interobserver (0.972; *p* < 0.0001) reliabilities obtained. Ratios of the analysis were performed using the independent samples *t* test (5 percent level of significance). The outcomes of the intraobserver and interobserver measurements were analyzed using the Pearson correlation test. As shown in Table 2, the mean intraobserver correlation of all measurements combined is 0.972. The correlations differ from 0.914 to 0.999. All of these correlations were highly significant (*p* < 0.0001). As shown in Table 3, the mean interobserver correlation of all measurements combined is 0.972. The correlations differ from 0.915 to 0.997. These correlations were also highly significant (*p* < 0.0001). A detailed statistical analysis is provided in Tables 2 and 3 for intraobserver and interobserver correlations, respectively.

Comparison of the Two Techniques

Each parameter for symmetrical and asymmetrical bilateral cleft lips is shown in Tables 4 and 5, respectively. The distance AB-PPL is taken as an example: in symmetrical patients, the mean AB-PPL

Table 3. Interobserver Reliability (n = 30)

	Mean First Observer	Mean Second Observer	Pearson Correlation	<i>p</i> (two-tailed)
AB-PPL _r	26.267	26.147	0.997	0.000
AB-PPL _l	26.477	26.107	0.997	0.000
CB-CM _r	9.430	10.293	0.972	0.000
CB-CM _l	9.457	10.254	0.977	0.000
CB-RM _r	4.910	4.447	0.948	0.000
CB-RM _l	5.007	4.517	0.959	0.000
AB-EN _r	24.087	24.640	0.994	0.000
AB-EN _l	21.703	22.360	0.975	0.000
NGA _r	45.387	47.431	0.989	0.000
NGA _l	42.914	45.408	0.931	0.000
NL-NM _r	9.914	9.948	0.992	0.000
NL-NM _l	9.787	9.739	0.976	0.000
NT-NB _r	5.780	5.808	0.984	0.000
NT-NB _l	5.492	5.549	0.915	0.000

Table 4. Ratios for Patients with Symmetrical Bilateral Cleft Lip Repaired with the Millard ($n = 17$) and Afroze ($n = 17$) Techniques

Ratio	Mean	SD	p (two-tailed)	95% Confidence Limits	
				Lower	Upper
AB-PPL			0.056	-0.00051	0.04099
Millard	1.0379	0.382			
Afroze	1.0177	0.015			
CB-CM			0.056	-0.00228	0.1830
Millard	1.1386	0.156			
Afroze	1.0482	0.048			
CB-RM			0.512	-0.19430	0.0988
Millard	1.1663	0.099			
Afroze	1.2140	0.276			
AB-EN			0.866	-0.12211	0.1444
Millard	1.1300	0.103			
Afroze	1.1188	0.163			
NGA			0.048	0.00120	0.2558
Millard	1.2495	0.226			
Afroze	1.1210	0.131			
NL-NM			0.196	-0.02487	0.11656
Millard	1.1490	0.145			
Afroze	1.1032	0.769			
NT-NB			0.649	-0.08003	0.12670
Millard	1.1540	0.192			
Afroze	1.1306	0.118			

ratio in the Millard technique (1.0379) is higher than in the Afroze technique (1.0177) ($p = 0.056$). For the asymmetrical cleft lip patients, the mean AB-PPL ratio in the Millard technique (1.0454) is higher than in the Afroze technique (1.0379) ($p = 0.480$).

Similarly, in the ratios used for CB-CM, AB-EN, and NL-NM for both symmetric and asymmetric lips, the mean ratios were closer to 1 for the Afroze technique, which means that the results showed better inclination toward this incision technique.

For the ratios used for CB-RM in symmetrical cleft lip patients, the mean ratio in the Millard technique (1.1663) is lower than in the Afroze technique (1.2140) ($p = 0.512$). In asymmetrical patients, the mean CB-RM ratio in the Millard technique (1.1618) is lower than in the Afroze technique (1.2185) ($p = 0.268$). Here, the results showed a better inclination toward the Millard technique.

In the ratios of NGA, the mean ratio in symmetrical cleft lip patients was higher in the Millard

Table 5. Ratios for Patients with Asymmetrical Bilateral Cleft Lip Repaired with the Millard ($n = 37$) and Afroze ($n = 37$) Techniques

Ratio	Mean	SD	p (two-tailed)	95% Confidence Limits	
				Lower	Upper
AB-PPL			0.480	-0.01373	0.02892
Millard	1.0454	0.575			
Afroze	1.0379	0.266			
CB-CM			0.311	-0.01685	0.05225
Millard	1.0874	0.079			
Afroze	1.0697	0.650			
CB-RM			0.268	-0.15781	0.04449
Millard	1.1618	0.172			
Afroze	1.2185	0.171			
AB-EN			0.003	0.03333	0.15007
Millard	1.1730	0.109			
Afroze	1.0813	0.074			
NGA			0.528	-0.14894	0.07700
Millard	1.2027	0.184			
Afroze	1.2386	0.252			
NL-NM			0.126	-0.01853	0.14688
Millard	1.1810	0.233			
Afroze	1.1168	0.111			
NT-NB			0.847	-0.10356	0.08527
Millard	1.2070	0.183			
Afroze	1.2161	0.217			

technique (1.2495) than in the Afroze technique (1.1210) ($p = 0.048$). Similarly, in NT-NB, the mean ratio of the patients following the Millard technique (1.1540) is higher than that following the Afroze technique (1.1306) ($p = 0.649$). However, for the same ratios for the asymmetrical cleft lip patients, the Millard technique scored lower than the Afroze technique. The mean ratio of the NGA in the Millard technique (1.2027) is lower than in the Afroze technique (1.2386) ($p = 0.528$) and the mean NT-NB ratio in the Millard technique (1.2070) is lower than in the Afroze technique (1.2161) ($p = 0.847$). Although the Afroze technique performed better in some parameters than the Millard technique and vice versa, none of the differences was statistically significant ($p < 0.05$).

DISCUSSION

The problem of cleft lip and its management is of considerable surgical importance. A newborn child with cleft lip presents parents, doctors, and friends with deep immediate concern and lifelong involvement. Therefore, to achieve and maintain a high standard in surgery, it is necessary to compare results between techniques.¹⁹

In this study, we have compared the well-known Millard technique with a relatively new technique design, called the Afroze technique. The Afroze technique incorporates the Millard technique on the cleft sides but uses a Pfeifer technique design on the prolabium borders.⁹ The Millard technique in bilateral cleft lips is based on rotation and advancement, tailored to each individual case, but may result in a tight upper lip.^{11,20}

The Afroze technique was developed to overcome the problems seen in the Millard technique, where the forward extension of the prolabium is sometimes inadequate.^{6,11,20} The lateral segments in the cleft are rotated downward using the Millard technique and the prolabium is elongated using the Pfeifer way technique. Our approach to the bilateral lip uses a modification of the Millard incision design on the prolabium. The Pfeifer technique design allows greater movement of the prolabium, as it frees the tissue from behind the columella.⁹

Because the response to each technique design varies with any variations present in the defect preoperatively, we decided to divide the two groups (Millard and Afroze) into symmetrical and asymmetrical subgroups to see the response of the technique designs across variations in the presentation of the cleft defects. We have studied the effect of the two techniques 4 years postoperatively. There is a likelihood of further facial growth between adolescence and adulthood. A

further study using the same parameters will be performed after the children reach adulthood.

Objective evaluation of aesthetic outcome in cleft lip operations is difficult.⁸ To compare aesthetic outcome in cleft lip surgery, different evaluation methods have been described such as direct^{16,21} and indirect anthropometric analysis.²² Direct anthropometric analysis is accurate and well accepted by anthropologists, but it is very difficult to reproduce, especially in large numbers of patients because the recall might be ineffective and the patients grow during the periods of recall.^{13,14} In this study, we have used indirect photographic measurements. Indirect photographic measurements have some disadvantages. It is very difficult to standardize the photographic method, because it is hard to take the photographs from the same distances and with the head of the child in the same position. We did, however, ensure that the same photographer took the photographs with the same camera using the same focal distance. This was also a reason why the exact measurements were not used. In a unilateral lip, it is possible to compare the cleft side with the noncleft side. In a bilateral lip, this is impossible, as both are cleft sides. To eliminate these problems of observation bias, ratios between the larger side and the smaller side were used to present our results. The main advantage of indirect photographic analysis over direct measurements was the good reproducibility, and it was also appropriate for comparing results of different surgical techniques.¹³ However, three-dimensional stereophotogrammetry can be used to achieve the most optimal results to compare such techniques.²³

Although no statistically significant difference was found with the indirect anthropometric measurements between the Millard and Afroze techniques in this series of 108 patients, the results for the symmetrical lip showed that, for six of the seven ratios, the Afroze design performed better than the Millard design. The Millard design performed better for the CB-RM ratio. This might be construed to mean that, with the exception of the vermilion form, the labial, nasal, and nostril symmetry was better with the Afroze design. The results for the asymmetrical lip showed that the Afroze design performed better than the Millard design in the AB-PPL, CB-CM, AB-EN, and NL-NM ratios. The Millard design performed better in the CB-RM, NGA, and NT-NB ratios. This could mean that the alar base position and Cupid's bow position were more symmetrical with the Afroze design. In this study, the vermilion symmetry is more symmetrical with the Millard design. However, with regard to the nostril symmetry, it can be inferred that the

Afroze technique produces a wider nostril postoperatively and the Millard technique will produce a longer nostril in asymmetrical bilateral cleft lip.

This study is a retrospective cohort study. We waited before performing this study to attain a better understanding of the Afroze technique and to make the necessary modifications to achieve the right balance in the design. We then compared it with the Millard technique, which we had already been using for 8 years and which is a very prevalent design. Therefore, we chose the last 37 asymmetrical and 17 symmetrical clefts of the series of patients treated with the Millard technique with an identical number of consecutive patients treated with the Afroze technique after using it for 100 patients.

CONCLUSIONS

The Afroze technique seems to have good clinical outcomes on bilateral cleft lip patients. Although there were no statistical differences between the two techniques, a randomized, prospective, blinded study using three-dimensional stereophotogrammetry could yield more statistically significant results in determining a better technique design.

Srinivas Gosla Reddy, M.B.B.S., M.D.S., Ph.D.
G.S.R. Institute of Craniofacial Surgery
No. 17-1-383/55
Vinay Nagar Colony
I. S. Sadan
Saidabad, Hyderabad 500 059, India
gosla@craniofacialinstitute.org

PATIENT CONSENT

Parents or guardians provided written consent for use of the patients' images.

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