

Choice of Incision for Primary Repair of Unilateral Complete Cleft Lip: A Comparative Study of Outcomes in 796 Patients

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Background: No one technique of cleft lip repair consistently produces ideal aesthetic and functional results. This study was carried out in a developing, high-volume center. It compares outcomes attained using two different designs of skin incision used for primary closure of unilateral complete cleft lip and sought to identify the most appropriate technique for clefts of varying morphology.

Methods: Seven hundred ninety-six patients were entered into the study. In each group of slightly less than 400 patients, either a modified Millard or Pfeifer way line incision was used, both in conjunction with functional repair of the underlying tissues as described by Delaire. Soft-tissue measurements of the lip and nose were recorded preoperatively. Analysis was based on postoperative assessment of the white roll, vermillion border, scar, Cupid's bow, lip length, and nostril symmetry and appearance of the alar dome and base.

Results: Comparison of the two cohorts using Pearson chi-square testing for association and linear trend found a Millard incision gave significantly better results for vermillion match, whereas the Pfeifer method led to a better postoperative lip length. Preconceptions that one particular technique was better suited to certain preoperative cleft anatomical forms were not proven statistically.

Conclusions: Certain preoperative anatomical features may lead the surgeon to choose one particular incision pattern in preference to another, but in this study, it was found that one technique was essentially as good as the other. This suggests that the technique for closure of the underlying tissues is probably of more importance. (*Plast. Reconstr. Surg.* 121: 932, 2008.)

Surgeons have repaired the deformity of cleft lip for the past 2000 years, since the first attempt performed during the Chin Dynasty in China.¹ Many techniques have been used since that time, and it is clearly apparent that no agreement exists as to which represents the optimum method.

Historically, incisions have been either straight line or broken line, but more recently, in the twentieth century, flap design developed over two distinct periods. In the first, up to 1949, and including Le Mesurier,² lengthening of the lip on the cleft side was

achieved with some sacrifice of the ipsilateral Cupid's bow. This maneuver, however, tended to produce an aesthetically unfavorable peaking of the lip. In the second half of the century, several attempts were made to counter this shortcoming. Tennison³ utilized a triangular flap on the external surface of the lower margin of the lip, while Petit and Psaume⁴ used a superiorly based flap. Nevertheless, because of scar contracture, this latter approach also produced unacceptable aesthetic outcomes. A combination of superior and inferior flaps was used by Trauner⁵ and Skoog⁶ to counter these problems. A further alternative was described by Malek,⁷ who used a flap based on a precisely measured equilateral triangle to achieve perfect equality in the length of

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the lip on both sides of the cleft. No one technique of lip repair consistently produces ideal aesthetic and functional results.

This study was carried out in a developing, high-volume center receiving large numbers of children with clefts that were anecdotally severe in nature. It compared outcomes attained using two different designs of skin incision used in primary closure of unilateral complete cleft lip and sought to identify the most appropriate technique for clefts of varying morphology. It was designed to give an indication of the best techniques as quickly as possible and, as the study was carried out over the relatively short period of 15 months, by the same group of surgeons, using the same facilities, randomization was not considered necessary. The method adopted, of studying two successive groups of approximately 400 patients each, may not represent the standard in research, but the authors felt it was justified given the above considerations and the moral and ethical concerns of blinded randomization so well articulated by, among others, Berkowitz.⁸

Among European cleft centers, two now well-established incision patterns for primary unilateral cleft lip repair are represented by the techniques of Millard and Pfeifer. These are examples of rotation-advancement and straight line methods, respectively (Figs. 1 and 2). The Millard repair^{1,9} is based on a rotation flap on the noncleft (medial) side coupled with an advancement flap on the cleft (lateral) side. One of its main advantages is that the technique allows adjustment as the operation proceeds, with further rotation and advancement movements tailored to the individual case. It is the more difficult repair of the two, necessitating approximation of a pair of convex

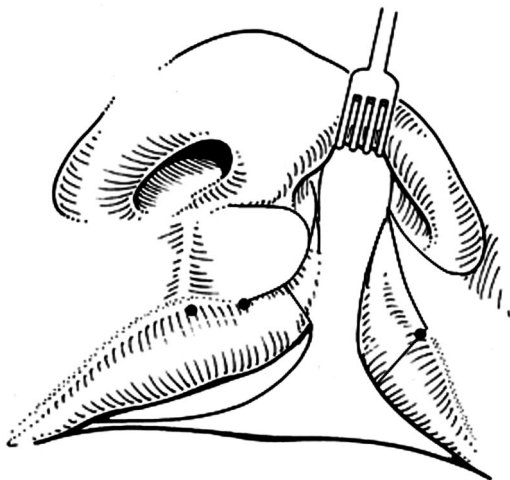


Fig. 1. Marking for the Millard incision.

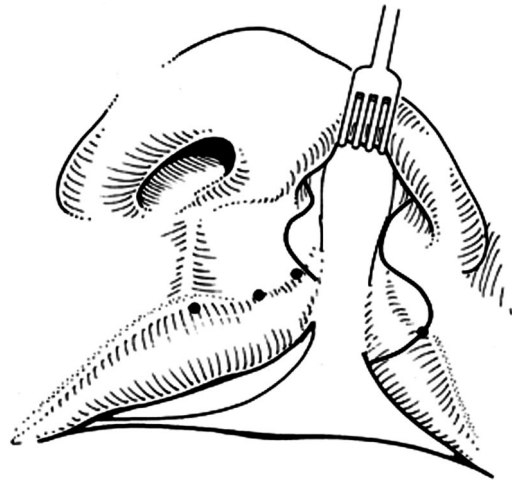


Fig. 2. Marking for the Pfeifer incision.

curves that ultimately may leave a scar crossing the midline at the base of the columella. Millard's technique represents a significant advance, elegantly overcoming many of the limitations of previously described methods. In one form or another, it is the most widely practiced method today. The ease with which this technique can be used provides a foundation from which surgeons may develop individual approaches to cheiloplasty as they become more experienced, including Delaire,¹⁰ who used a combination of Tennison, Petit and Psahme, Millard, Pfeifer, and, more recently, Mulliken and Martínez-Peréz.¹¹

Pfeifer designed his incision using the concept of "morphological order."¹² Measurements of non-cleft-side height and length are recorded and translated to the cleft side using a flexible wire, thus determining natural anatomical points. His "straight line" incisions on cleft and noncleft sides are made of equal lengths by incorporating a series of waves leading to a final scar that should follow the lateral line of the philtrum. This incision also frees the excess mucosa located lateral to the columella and medial to the base of the ala. As described below, the two curves are brought together such that the highest and lowest points of one curve are approximated with the corresponding highest and lowest points of the other, thus creating a straight line.

The repair of any cleft lip deformity should of course not just take incision lines into account. Manipulation and repositioning of the mucocutaneous tissues must only be addressed once sound foundations have been laid. A functional anatomical repair of the underlying hard and soft tissues is essential. A primary surgical approach that allows natural facial growth and development,

minimizing the need for future secondary procedures, should be every cleft surgeon's goal.¹³⁻¹⁵

In the center where this study was conducted, a number of techniques were explored. Initially, the technique of primary cheilorhinoplasty as described by Delaire was used with some success but, with the wide variation in severity of cleft seen in this region of India, some outcomes were less than satisfactory. In attempts to resolve some of the difficulties encountered by the surgeons, who were at that time relatively inexperienced, frequent variations of technique were made. This study arose out of an awareness that surgery needed to be rationalized and reliable protocols developed if there was to be consistency of outcome in the long term.

PATIENTS AND METHODS

Seven hundred ninety-six patients who required primary repair of a unilateral cleft lip deformity were enrolled into this study. All patients had a unilateral complete cleft lip defect with or without extension onto the alveolus and palate. Those whose cleft was part of a syndrome were excluded.

In the first cohort of consecutive patients ($n = 397$), a Millard rotation-advancement flap was used. The second group ($n = 399$) underwent a lip repair procedure with a Pfeifer wavy line incision. Irrespective of incision used, all underlying primary surgical repair followed the functional method of Delaire. Patients were grouped by age for preoperative assessment: 12 months or younger, and 12 to 60 months. Four surgeons were involved with individual caseloads of 432, 150, 112, and 102. Each surgeon's caseload was assessed separately by a single surgeon who was not part of the study. Linear measurements were obtained both directly on the patients and using standardized digital photographs (Figs. 3 and 4). Measurements were obtained before surgery and postoperatively at 6 and 12 months and the data recorded on a database.

The following parameters were assessed: accuracy of white roll and vermilion match, scar appearance, Cupid's bow form, length of lip, nostril symmetry, alar dome form, and alar base position. These eight superficial parameters were chosen because it was felt they represented appropriate, relevant indicators of both aesthetic and functional outcome that could be measured reliably. Each parameter was graded independently as good, average, or poor. Grading criteria are shown in Table 1 and examples of cases are illustrated in Figures 5 through 8.

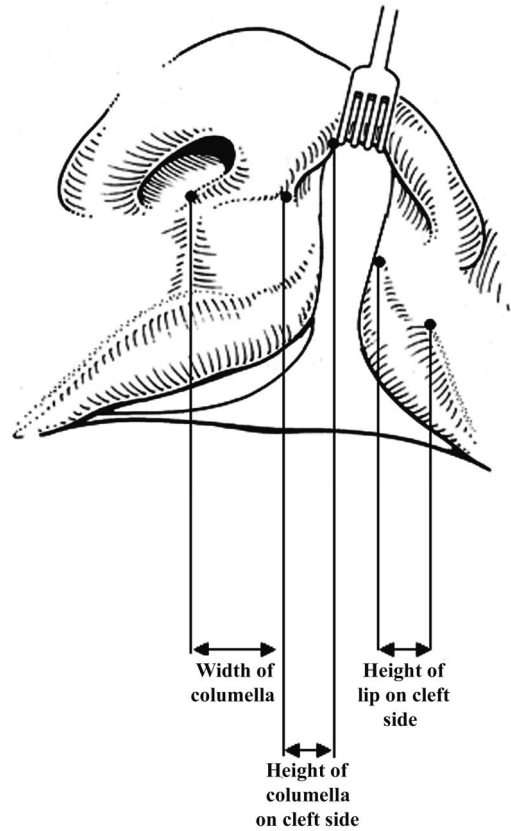


Fig. 3. First set of preoperative measurements.

The postoperative outcomes using the Millard and Pfeifer techniques were compared with regard to each of the eight parameters using the chi-square test for association and the chi-square test for linear trend. To assess whether the relative effectiveness of the two procedures depended on the preoperative cleft form, multinomial logistic regression was used. Medians for Cupid's bow and columella width, columella height, vertical height of lip, lip width, and nostril width on the cleft side were calculated, and for each characteristic, individuals in the sample were divided according to whether or not they fell above the median. This process was performed separately for children younger than 1 year and those aged 1 to 5 years. Using the eight three-category outcome measures as dependent variables, the relative effectiveness of the two procedures was tested using the interaction effect between procedure and preoperative cleft form. Thus, 48 such analyses were conducted (eight outcomes $\times$ six preoperative cleft forms). All analyses were conducted using SPSS for Windows Version 12 (SPSS, Inc., Chicago, Ill.) using a 5 percent significance level.

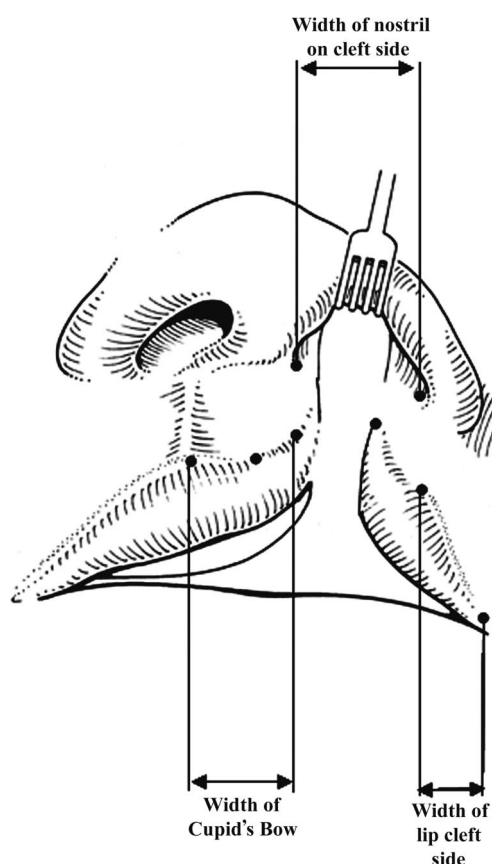


Fig. 4. Second set of preoperative measurements.

RESULTS

A summary of the results of all cases are shown in Table 2. This allows direct comparison of the Millard and Pfeifer cohorts for each postoperative parameter grading.

In performing chi-square tests for each parameter, it is shown that there are significant differ-

ences between the two techniques when assessing vermilion border approximation and lip length. A Millard design flap produced a better approximation of the vermilion ($p = 0.004$), whereas cases that were operated on with a Pfeifer incision resulted in a better length of lip ($p = 0.003$). There were no significant differences in outcome between the two techniques when assessing white roll match, scar appearance or form of Cupid's bow, nostril symmetry, alar dome, and alar base.

Median preoperative characteristics are listed in Table 3. Of the 48 interaction effects tested, only one was statistically significant ($p = 0.02$), and there is a high risk that this may be attributable to the large number of significance tests conducted. In this analysis, scar appearance appeared to be worse when vertical height of the lip was above the median than if it was below the median for the Pfeifer procedure but not the Millard procedure.

DISCUSSION

An important cause of the deformities in cleft lip–cleft palate patients is displacement and underdevelopment of the divided parts. Whether the global deformity is attributable to true hypoplasia, diminished function and associated underdevelopment, or a combination of both, the principal surgical goal is the same: to establish good function through careful muscle reconstruction, which in turn will permit optimum subsequent growth and development of the facial skeleton and promote good aesthetic outcomes.

Deformities of cleft lip–cleft palate are, therefore, best managed by adopting a method of primary surgery that not only recognizes the inherent problems but prevents them from occurring. Veau introduced the concept of embryologic surgery.

Table 1. Grading Criteria*

	Good	Average	Poor
White roll match	Perfect	Disparity of <1 mm	Disparity of >1 mm
Vermilion match	Perfect	Disparity of brown and pink mucosa <1 mm	Disparity of brown and pink mucosa >1 mm
Scar appearance	No hypertrophy	Hypertrophy with no disturbance of Cupid's bow or columella	Hypertrophy with disturbance of Cupid's bow or columella
Cupid's bow form	Perfect	Distortion on cleft side <2 mm	Distortion on cleft side >2 mm
Lip length	Equal length on cleft and noncleft sides	Shortening on cleft side >5 mm and <10 mm	Shortening on cleft side >10 mm
Nostril symmetry	Equal in height and width to normal side	>1 mm or <2 mm in either height or width to normal side	>2 mm in either height or width to normal side
Alar dome	Equal curvature to the normal side		Any depression compared with the normal side
Alar base	At the same level of the normal side	Difference of <1 mm compared to the normal side	Difference of >1 mm compared with the normal side

*Examples to illustrate the above criteria are shown in Figures 5 through 8.



Fig. 5. Example of repair using a Millard incision. Postoperatively, there is good approximation of the white roll and vermilion, with an average scar. The Cupid's bow form is good, with symmetry of lip lengths on the medial and lateral sides. Nasal dome form is good, but nostril symmetry and alar base both score poorly.

The surgeon must have a full understanding of all the anatomical elements involved in the cleft deformity, should seek to improve surgical methods where failure seems to be apparent, and must make every attempt to restore to normality all the tissues involved in the cleft and in particular the underlying musculature, rather than just confining activity to the overlying skin. Nevertheless, design of the skin incision is an important consideration in the attainment of good outcomes.¹⁶

It is important to include some discussion regarding limitations in our work. By operating on the two different cohorts successively (i.e., all the Millard incisions first, followed by the Pfeifer incisions), the learning curve for each method was improved with time but, bearing in mind that the

overall period of this study was 15 months, this curve was rapid. Outcomes for the individual surgeons, not reported here, confirm this to be the case. Although an ideal study would of course be randomized and blinded, the speed with which this high-volume study was conducted and the constancy of the team and its facilities lend credence to the outcomes. Cleft anatomy is unique in each case when considering the ratio of cleft space to volume of adjacent tissue available for closure. Different outcomes in terms of scarring, aesthetics, growth, and development may therefore be quite independent of the surgeon's skill level or the technique. In addition, it would have been impossible to blind the surgeon assessing results, as each technique has an instantly recognizable



Fig. 6. Example of repair using a Millard incision. Here, the white roll match and vermillion approximation are average. The scar is also graded as average. There is distortion of the Cupid's bow of more than 2 mm, which grades it as poor. The alar bases are symmetrical but the nasal dome is depressed on the cleft side, with a disparity of nostril height, leading to poor grading in the last two parameters.

scar. Also, as mentioned earlier, the moral and ethical issues surrounding the standard of care in research are difficult to justify in cleft surgery.⁸

This article forms part of a study aiming to identify the optimal incision design used in primary cleft lip repair, in a developing, very-high-volume cleft center. It was stimulated by an awareness of certain difficulties in achieving the optimal outcome using the Delaire cheilorhinoplasty, such as occasional shortening of lip height. The Eurocleft survey¹⁶ showed a wide diversity in models of care, national policies, and clinical practices in Europe. Of the 201 centers that registered with the network, the survey showed 194 different protocols being followed for only unilateral

clefts. Although there is no indication in the literature that all or none of these protocols produces satisfactory outcomes, the results of the six-center Eurocleft study¹⁷ suggest that constancy of protocol in a multidisciplinary setting leads to the best outcomes.

The two techniques considered here each have their own advantages and shortcomings but individually cannot necessarily be expected to produce the best results in all patients. There were three statistically significant outcomes in this study. First, when assessing postoperative results for vermillion match, the Millard technique produced a better outcome ($p = 0.004$). In this respect, it is rather more flexible than a straight line



Fig. 7. Example of repair using a Pfeifer incision with good results. White roll and vermilion match are good, but the scar shows some hypertrophy. Cupid's bow form and lip length are both average. The nostrils are asymmetric and are graded as poor because of the height disparity. The form of the alar dome is good but there is a discrepancy of the alar bases of over 1 mm, leading to a grade of poor.

design and the operator is able to position the rotation flap on the noncleft side where it is judged likely to produce the best outcome. Second, lip length was significantly better with the Pfeifer incision ($p = 0.003$). By its nature, the more waves incorporated in the incision, the greater the height of the lip. A prominent wave placed just above the mucocutaneous junction will tend to exaggerate this factor.

As the study developed, it was the belief of the four surgeons that each technique lent itself to certain preoperative morphologic characteristics of cleft anatomy. The Millard flap was considered to produce better results where, preoperatively, the width of lip and nostril on the cleft side fell in

the upper ranges of measurements (i.e., a wide lip) and the Cupid's bow was prominent. Where this was the case, it was deemed that there would be a natural reduction in rotational requirement of the flap on the medial side resulting in less distortion and a Cupid's bow with better form. The Pfeifer incision pattern seemed to be more appropriate when the vertical dimensions of lip and columella were above the mean.

However, these suppositions were not supported by robust statistical analysis. With respect to the median preoperative characteristics as shown in Table 3, of the 48 interaction effects tested, only one was statistically significant ($p = 0.02$), and there is a high risk that this may have been attrib-



Fig. 8. Example of a repair using a Pfeifer incision with suboptimal results. All eight postoperative parameters are graded as poor here.

utable to the large number of significance tests conducted. In this analysis, scar appearance appeared to be worse when vertical height of the lip was above the median than if it was below the

median for the Pfeifer procedure but not the Millard procedure. In other words, use of the Pfeifer incision certainly maintained lip length better than the Millard procedure as shown above, but

Table 2. Summary of Results

	Good		Average		Poor		Pearson Chi-Square	Linear by Linear Association
	Millard (%)	Pfeifer (%)	Millard (%)	Pfeifer (%)	Millard (%)	Pfeifer (%)		
White roll match	232 (58)	244 (62)	143 (36)	124 (31)	24 (6)	28 (7)	0.451	0.531
Vermilion match	231 (58)	223 (56)	147 (37)	128 (32)	20 (5)	46 (12)	0.004	0.048
Scar appearance	242 (61)	237 (59)	119 (30)	115 (29)	36 (9)	46 (12)	0.594	0.464
Cupid's bow form	211 (53)	225 (57)	162 (41)	152 (38)	24 (6)	21 (5)	0.654	0.379
Lip length	211 (53)	245 (62)	144 (36)	132 (33)	43 (11)	20 (5)	0.003	0.001
Nostril symmetry	129 (32)	108 (27)	215 (54)	231 (58)	54 (14)	58 (15)	0.314	0.198
Alar dome	274 (69)	266 (67)	—	—	124 (31)	131 (33)	0.525	0.526
Alar base	251 (63)	247 (62)	134 (34)	134 (34)	12 (3)	17 (4)	0.723	0.518

Table 3. Median Preoperative Measurements for Age Ranges

	<1 Year (mm)	1–5 Years (mm)
Width of Cupid's bow	7	8
Width of the lip on the cleft side	35	38
Nostril width on the cleft side	15.5	17
Columella height on cleft side	2	3
Columella width	4	5
Vertical height of lip on cleft side	8	10

where the initial length of the lip was above the median, the scar created is inevitably going to be longer and thus more noticeable.

The fact that otherwise the results were so similar lends credence to the importance of the method used to restore the underlying structural discontinuity, in this case, the method described by Delaire. Delaire himself incorporated methods used by Millard and Pfeifer in developing his now widely practiced technique.^{18–20} The authors feel that a sound underlying functional repair of muscle, cartilage, periosteum, and bone is the most important factor in cleft lip repair rather than one particular mucocutaneous flap design.

This study reviews early outcomes of particular techniques used in high volume, a volume not previously reported. Longer term outcomes would ideally be reported, but given the logistic and economic difficulties faced by many of the patients, this may not prove possible. However, in view of the findings of this study, modifications of technique will be made and reported in the future.

CONCLUSIONS

We feel that this large series lends support to the belief that no single technique of cleft lip repair is a panacea for all cases. Individual clefts need to be managed with a philosophy incorporating ideas from several methods that can be adapted in a flexible manner by the surgeon to fit a particular need.

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