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Assessment of outcome following two-flap palatoplasty in 1184 patients with cleft palate: A retrospective study

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ABSTRACT

Aim: The aim of this study is to assess three speech defects, growth impairment, and fistula formation in cleft palate patients after two-flap palatoplasty.

Materials and Methods: A total of 1184 patients were included in the study and were followed up for 5–10 years with the minimum age at assessment being 5 years. Speech assessment was done by Perkins perceptual speech assessment. Cast analysis was done to check growth of the patient, and clinically, the presence of fistula was recorded. Wherever needed statistical analysis using SPSS software was done.

Results: Speech defects were found in 14.8% of cases. About 75% of these cases were those cases of cleft palate repaired after the age of 2. The rate of fistula formation was 4.3%. Growth impairment as seen by reduced intercanine and intermolar width as well as reduced arch length was seen to be statistically significant. **Conclusion:** Two-flap palatoplasty is a good technique for cleft palate repair with low rate of speech defects and fistula formation. Growth impairment can be managed by other means. Correct timing of palate surgery is of essence.

Key words: Cast analysis, cleft palate, speech assessment, two-flap palatoplasty

INTRODUCTION

Cleft lip and palate anomaly is one of the most common birth defects, and the incidence reported in India is 0.93 in 1000 births.^[1] Nonsyndromic orofacial clefting is a polygenic, multifactorial disorder, and both genetic and environmental factors contribute to its etiology. The main environmental factors which have been reported

to be possibly implicated are tobacco smoking, alcohol consumption, solvents, and agricultural chemicals.^[2-4] Certain types of antiepileptic drugs have also been reported to increase the risk.^[4]

Facial clefting leads to esthetic and functional issues for the patients.^[5] The aim of cleft palate repair is to achieve normal speech without disturbing the growth of the facial structures.^[6] The timing of palatal surgery has seen a shift from 18 to 24 months before the 1980s to 9–12 months in the present, in favor of speech-related outcomes.^[7]

Most of the studies assessing clinical outcome after primary cleft palate repair focus on the speech development, postoperative fistula formation, and effect of surgery on the growth of the upper jaw. The average rate of postoperative fistula formation has been found to be 4.9%.^[8] The incidence of postoperative velopharyngeal incompetence after primary palatal repair has been reported to be as high as 30%.^[9]

It is very important to know the clinical outcomes of primary palate repair as it is the foundation on which depends the speech and growth of the child. It will also guide the changes or modifications in the surgical technique if required. Hence, we have undertaken this study to assess the outcomes with respect to the speech problems, fistula formation, and effect on growth on 1184 patients of cleft palate following the two-flap palatoplasty repair.

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MATERIALS AND METHODS

The study was approved by the institutional review board and followed the “Declaration of Helsinki” guidelines. A total of 1388 patients were evaluated in the study retrospectively. Of these, 148 patients were of incomplete cleft palate and the remaining 1240 were of complete cleft palate; hence, 148 patients were excluded from the study. All these cases of complete cleft palate were treated by the two-flap palatoplasty method with radical muscle dissection. Minimum follow-up was 5 years up to 10 years. The age range was between 10 months and 58 years.

Three parameters were adjudged at a minimum age of 5 years which were speech, growth, and fistula formation. Speech was assessed by perceptual speech evaluations using Perkins scoring system.^[10] Further, the patients were divided into two groups:

- Group 1: Those that were operated within 2-year age (814)
- Group 2: Those that were operated after the age of 2 (370).

Two-tailed *P* value analysis was done by Student's *t*-test using SPSS for Windows, 19.0 (SPSS, Inc., Chicago, IL, USA) with significance value set at *P* < 0.05.

Growth was assessed by doing cast analysis and measuring intercanine width, intermolar width, and arch length. The values obtained were compared to the population analysis done by Bishara *et al.*^[11] One-way ANOVA analysis was done for all age groups using SPSS for Windows, 19.0 (SPSS, Inc., Chicago, IL) with significance value set at *P* < 0.05.

The presence of fistula formation was done by clinical evaluation. Fistulae associated with symptoms were noted.

RESULTS

A total of 1240 cases of cleft palate ± cleft lip were assessed in the study. Fifty-six cases were lost to follow-up, and finally, 1184 cases of complete cleft palate ± lip were included in the study. The age range of the patients at the time of palatoplasty was 10 months–58 years (mean = 2.3 years). Of the 1184 cases of complete cleft palate, 370 cases were operated after the age of 2 years. Patients were assessed in two groups for assessing speech:

- Group 1: Those that were operated within 2-year age (814)

- Group 2: Those that were operated after the age of 2 (370).

Out of these, complete cleft lip and palate were 840 (71%) cases and complete palate was 344 (29%) cases. Unilateral cases were 864 (73%) and bilateral cases were 320 (27%). Total males in our study were 736 (62.1%) and total females were 448 (37.8%).

Perceptual speech assessments were carried out for all patients using the scoring system of Perkins *et al.* that evaluated velopharyngeal insufficiency, resonance, nasal air emission, articulation errors, and intelligibility by a speech pathologist. An overall rate of 14.8% (175 patients) had poor speech outcome. Of these, 131 patients (75%) were in Group 2, i.e., were operated after 2 years of age. The result of Student's *t*-test was <0.001, which was statistically significant. Furthermore, 103 (58.8%) of those patients with poor speech outcome were suffering from bilateral cleft palate ± lip [Table 1].

It was found that all the parameters measured in the cast analysis were statistically lower in the cleft palate population as compared to the normal population^[11] [Table 2-4]. *P* value seen on ANOVA analysis was also statistically significant (<0.001) showing the significantly reduced dimensions of intercanine width, intermolar width, and arch length both in males and females as compared to the normal population. Out of 1184 patients, 658 (55.6%) patients needed some form of treatment for the associated cleft maxillary hypoplasia.

The rate of fistula formation in our study was 4.3% (51 patients). Of these, most were seen in the cases

Table 1: Speech outcome for Group 1 and Group 2

	Group 1 (%)	Group 2 (%)	Total
Poor speech outcome	85 (10.4)	255 (69)	340 (28.7)
Normal speech outcome	729 (89.6)	115 (31)	844 (71.3)
Total	814	370	340

Table 2: Intercanine width of normal population as seen by Bishara *et al.*^[11] and our study population according to the sex and age group

	Normal population (mm)		Cleft population (mm)	
	Males	Females	Males	Females
3 years	28.8	27.4	23.2	22.1
5 years	30.3	28.4	25.4	24.8
8 years	32.5	30.7	27.2	26.3
13 years	35.1	33.1	31.4	29.8
26 years	34	32.3	29.6	27.5
45 years	33.7	31.9	29.2	27.6

Table 3: Intermolar width of normal population as seen by Bishara *et al.*^[11] and our study population according to the sex and age group

	Normal population (mm)		Cleft population (mm)	
	Males	Females	Males	Females
3 years	40.9	39.3	34.6	34.1
5 years	43.5	40.8	38.7	36.6
8 years	51.0	48.1	48.6	44.7
13 years	53.4	50.1	48.5	45.3
26 years	53.6	48.3	48.9	43.6
45 years	53.4	48.4	47.2	43.2

Table 4: Arch length of normal population as seen by Bishara *et al.*^[11] and our study population according to the sex and age group

	Normal population (mm)		Cleft population (mm)	
	Males	Females	Males	Females
3 years	73.9	72.3	67.1	66.2
5 years	74.6	72.9	69.1	67.1
8 years	76.9	74.0	71.3	69.9
13 years	77.9	74.7	72.2	70.3
26 years	73.2	71.1	67.5	67.1
45 years	72.2	70.1	67.1	66.2

of bilateral cleft lip and palate (31 patients, 61.42%). Most of the fistulae were located posterior to the incisive foramen (32 patients, 62.8%).

DISCUSSION

No actual consensus exists on the optimum timeframe for cleft palate repair. The balance between avoiding restriction in facial growth after early surgery and speech development, which requires an intact palate, should be considered. Most children will need an intact palate to produce definite speech sounds at the age of 18 months. There is little evidence to suggest any benefit of palatoplasty before the age of 9 months. Surgical repair before this time point is associated with a higher incidence of maxillary hypoplasia later in life and leads to no improvements in speech. For these reasons, cleft palate repair is usually performed at ~9–18 months of age.^[12]

The overall number of patients with speech defects was low (175 patients, 14.8%) as compared to other studies.^[13] Further, it was seen that 75% of those patients with poor speech outcome were operated for primary cleft. Hence, cleft palate repair should be done between 9 and 12 months to achieve better speech results. We try to do all cleft palate cases at 10-month age.

The literature has reported various rates of oronasal fistula, ranging from 0% to 12.8% in the recent

studies.^[14] We had a modest rate of fistula formation at 4.3%. Most of the fistulae were asymptomatic (75%).

Growth impairment was 55.6%. All patients of cleft maxillary hypoplasia were treated by one of the following methods: orthodontics, facemask therapy, RED, Le Fort 1 osteotomy, or anterior maxillary distraction. This number is similar to other studies where close to 25%–50% of cases require intervention for the cleft maxillary hypoplasia.^[15]

These results show minimal complication rates and good results for two-flap palatoplasty. We regularly use this procedure for all cases of complete cleft palate. Bilateral cleft palate is more challenging, and the chances for fistula formation, speech irregularities, and growth disturbances are higher.

CONCLUSION

Two-flap palatoplasty is an excellent technique. Careful muscle dissection and correct timing of surgery can reduce complication rates and give the patient a reasonable speech with minimal growth interferences.

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Conflicts of interest

There are no conflicts of interest.

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