

## Frequency of Fistula Formation in Primary Cleft Palate Repair in a Tertiary Care Hospital

Maimoona Goher, Saad Ur Rehman Sarwar, M Ibrahim Khan, Mamoon Rashid, Sakina Malik, Farwa Shabbir

Department of Plastic and Reconstructive Surgery, Shifa International Hospital, Islamabad, Pakistan

### ABSTRACT

**Objective:** To determine the frequency of fistula formation after primary cleft palate repair in a tertiary care facility.

**Study Design:** Retrospective Longitudinal Study.

**Place and Duration of Study:** Plastic and Reconstructive Surgery Department, Shifa International Hospital, Islamabad, Pakistan, from Jan 2017 to Dec 2021.

**Methodology:** A total of 176 patients were included. Data was extracted from the electronic medical record. Veau classification was used for identifying the severity of the cleft. The mean age of these children at the repair was 11 months. Techniques used for repair included Von Langenbeck, Bardach's, one-sided Von Langenbeck and one-sided Bardach (Hybrid) and Furlow's palatoplasty.

**Results:** The outcomes were assessed using Pittsburgh classification of fistula. Mean follow-up was 12 months. Eight out of 176 patients developed oronasal fistula, making the frequency of fistula to be 4.5%. The most common location for fistula formation was the hard palate 5(2.84%), followed by the split uvula 2(1.14%), and junction of the hard and soft palate 1(0.57%). Fistula occurrence was higher in Veau III and IV clefts ( $p=0.013$ ). However, the frequency of fistula correlates significantly among various surgical techniques.

**Conclusion:** The overall frequency of fistula formation was 4.5% in our study, with frequency increasing with the severity of the cleft. Key to decreasing the frequency of fistula in cleft palate patients is to observe good surgical practice by improved mobilization of flaps, dissection around the pedicle, tension-free layered closure, and post-operative care.

**Keywords:** Cleft Palate, Fistula, Frequency, Oronasal, Palate Repair

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### INTRODUCTION

Cleft lip and palate are among the most common congenital craniofacial anomalies managed by plastic surgeons, occurring in approximately <sup>1</sup> in 700 live births worldwide.<sup>1</sup> Numerous surgical techniques have been described for the repair of cleft palate, including the Von Langenbeck palatoplasty, V-Y pushback palatoplasty, Bardach two-flap palatoplasty, and Furlow's double-opposing Z-plasty.<sup>2,3</sup> The timing of surgical intervention remains an important consideration, with primary repair ideally performed between 9 and 12 months of age, before the development of palatal speech articulation. However, controversy persists regarding the optimal age for repair because of the need to balance favorable speech outcomes against the potential adverse effects on maxillary growth.<sup>4,5</sup>

The primary objective of cleft palate repair is to establish competent velopharyngeal function while effectively separating the oral and nasal cavities. Despite advances in surgical techniques, postoperative

complications remain a significant concern and may include hemorrhage, airway compromise, velopharyngeal insufficiency, and oronasal fistula formation. An oronasal fistula is defined as the failure of healing or breakdown of the surgical repair along the suture line, resulting in persistent communication between the oral and nasal cavities.<sup>6</sup> The Pittsburgh classification system categorizes fistulas into seven classes (I-VII) according to their anatomical location, ranging from the posterior to the anterior palate.<sup>7</sup>

The reported incidence of oronasal fistula following primary cleft palate repair has varied considerably in the literature. Earlier studies documented rates as high as 60%, whereas more recent reports and meta-analyses have demonstrated incidences ranging from 2% to 35%, reflecting improvements in surgical techniques and perioperative care.<sup>8</sup>

The wide phenotypic variation in cleft palate deformities presents considerable challenges in surgical management. Several factors have been implicated in increasing the risk of fistula formation, including inadequate surgical technique, limited surgeon experience, increased cleft width, the

**Correspondence:** Dr Maimoona Goher, Department of Plastic Surgery, Shifa International Hospital, Islamabad, Pakistan

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presence of associated syndromes, and older age at the time of repair.<sup>9</sup> Identification of these risk factors is essential for optimizing surgical outcomes and minimizing postoperative morbidity.

The present study was conducted to determine the frequency of oronasal fistula formation following primary cleft palate repair in a tertiary care facility and to compare the observed outcomes with those reported in previous studies and meta-analyses.

**METHODOLOGY**

This retrospective longitudinal study was conducted at the Plastic and Reconstructive Surgery department, Shifa International Hospital, Islamabad, Pakistan, from Jan 2017 to Dec 2021. Procedures were done by 3 different surgeons of same level of experience. The study was approved by the hospital's Ethical Committee and Institutional Review Board (IRB#0175-22). All patients who met the inclusion criteria were included in the study; therefore, no prior sample size calculation was performed.

**Inclusion Criteria:** All patients undergoing primary cleft palate repair without any associated syndromes, with repair age under 3 years, at least 3 months of follow-up, and Pittsburgh fistula class I through IV were included in the study.

**Exclusion Criteria:** Patients with submucous cleft palate, Pittsburgh fistula type V through VII and those who were lost to follow up were excluded from the study.

Follow-up assessment was done at 3, 6, and 12 months. For each patient data regarding the gender, age at the repair, type of the cleft and surgical technique used, and fistula formation was collected. Technique used was based on surgeon's preference. Pre operatively patients were referred for paediatric review and clearance, weight and nutrition optimization to improve the post operative outcomes. Anesthesia review was done pre operatively. Postoperatively patients were kept on a liquid diet at room temperature via spoon or dropper, and parents were counselled in detail regarding dietary precautions and taught to wash the palate with water after every diet. Nipple or bottle feed was avoided. These precautions were followed for two to three weeks with the gradual introduction of jellies and soft diet followed by normal diet after two to three weeks. Veau classification of the cleft was used to specify the cleft severity, summarized in Table-I.

**Table-I: Veau Classification of cleft lip and palate**

Class	Description
I	Cleft of the soft palate only.
II	Cleft involving the hard palate and the soft palate, not extending further than the incisive foramen.
III	Complete unilateral cleft, extending from the soft palate to the alveolus, usually involving the lip.
IV	Bilateral complete clefts.

Post-operative fistula formation was assessed using the Pittsburgh classification of fistula, summarized in Table-II.

**Table-II: Pittsburgh Classification of Oro-nasal Fistula**

Type of Fistula	Description
Type I	Bifid Uvula
Type II	Soft Palate
Type III	Junction of Soft and Hard Palate
Type IV	Hard Palate
Type V	Junction of Primary and Secondary Cleft Palate
Type VI	Lingual-Alveolar
Type VII	Labial-Alveolar

Statistical Package for the Social Sciences 26 was used for all the statistical analysis. qualitative data was represented by using percentage and frequency. Statistical significance of the difference in the outcome variables was analyzed, keeping statistical significance at p<0.05. Since >20% of the expected cell counts were less than 5, Fisher's exact tests were applied.

**RESULTS**

A total of 176 patients, including 92 (52.2%) male and 84 (47.7%) female patients. The median age at the time of repair was 11 (9-12) months. The results showed that out of 176, eight (4.5%) patients developed a palatal fistula. Five (2.84%) patients developed type IV fistula, two (1.14%) developed type I fistula, and one (0.74%) developed type III fistula. None of the patients had complete dehiscence of the repair.

Different techniques were utilized for repair according to the surgeon's preference. Patients with less severe types of clefts needing lesser mobilization of flaps were repaired with Von Langenbeck technique, wider clefts that needed bilateral flap mobilization for centralization were repaired using Bardach's technique, clefts that could be centralized with unilateral mobilization of flaps were repaired with composite technique, and secondary clefts that were not too wide were repaired utilizing Furlow's

double opposing palatoplasty. 52(29.55%) patients underwent cleft repair using the Von-Langenbeck technique, 85(48.30%) patients underwent Bardach technique, 24(13.64%) patients underwent Furlows' double opposing Z-plasty and 15(8.5%) patients underwent one-sided Bardach and one-sided Von Langenbeck repair. Fistula formation was found to be related to the severity of the cleft preoperatively. Table-III summarizes the correlation of fistula formation with cleft severity and techniques utilized for repair.

**Table-III: Comparison Of Frequency of Oronasal Fistula For Various Factors (N=176)**

Parameters	Study Groups Frequency (%)		p-value
	Group-A Fistula (n=8)	Group-B No fistula (n=168)	
Cleft Severity			
Veau-I	0 (0.0%)	40 (23.8%)	0.013
Veau-II	0 (0.0%)	24 (14.3%)	
Veau-III	3(37.5%)	78(46.4%)	
Veau-IV	5(62.5%)	26(15.5%)	
Repair Technique			
Von Langenback	3(37.5%)	49(29.2%)	0.763
Bardach	3(37.5%)	82(48.8%)	
Furrow	0(0.0%)	24(14.3%)	
Hybrid	0(0.0%)	15(8.9%)	

Significant values,  $p < 0.05$ . p-value calculated using Chi-square test (Fisher's exact test applied where expected cell counts were  $< 5$ ).

## DISCUSSION

In the present study, the frequency of oronasal fistula formation following primary cleft palate repair was found to be associated with the severity of the cleft. Oronasal fistula formation remains one of the most significant complications of cleft palate surgery, often resulting in considerable emotional distress for patients and caregivers, as well as an increased financial burden due to the need for additional corrective procedures.

Cleft lip and palate are the most common congenital craniofacial anomalies that result from failure of the fusion of the nasal and maxillary processes during embryologic development secondary to multifactorial etiologies.<sup>10</sup> Frequency of the cleft palate is different among races, being most common in the Asian population.<sup>11</sup> Cleft palate can be syndromic or can be non-syndromic. It can present as isolated cleft palate or along with cleft lip.<sup>12</sup>

Lang et al., had explained that treatment of the cleft palate is more focused on function in contrast to cleft lip which is a balance of aesthetics and function. Goals of cleft palate repair include the provision of competent velopharyngeal port with minimal compromise of the midfacial growth and separation of oral and nasal cavity.<sup>12</sup> Failure to achieve these goals would result in velopharyngeal insufficiency or palatal fistula formation.

The literature describes several techniques for closure of the soft and hard palate, including the Von Langenbeck bipedicle repair, V-Y pushback palatoplasty, Bardach's unipedicular repair, and Furlow's double-opposing Z-plasty.<sup>2,3</sup> Regardless of the technique used, key principles include careful dissection around the pedicle and meticulous, tension-free closure in two layers for the hard palate and three layers for the soft palate.<sup>8</sup> Lateral releasing incisions may be used when the central repair is under tension. In our study, lateral releasing incisions were performed in all cases.

There has been controversy over the ideal timing of the palate repair, keeping the goal of achieving palatal repair before speech with minimal disturbance of the midfacial growth.<sup>5</sup> In a study done by Sakran *et al.*, it was stated that there has been no significant difference in midfacial growth in early vs late repair.<sup>13</sup> Similarly, Sakran *et al.*, further reported that frequency of fistula to be associated with age at the repair of the palate.<sup>14</sup> However, Kim *et al.*, found no significant association of fistula with the age at the repair of the palate.<sup>16</sup> In our study we have preferred the repair between.<sup>9-12</sup> months in patients who presented to us timely. However, some patients presented later than the ideal age, thus timing of repair of our patients ranged from 8 to 36 months. We did not find any significant difference in the frequency of fistula formation in relation to the age at the repair.

In this study conducted by Park *et al.*, analyzed the fistula formation according to the Pittsburgh classification. Most common site of fistula formation in our study was at the hard palate, Pittsburgh type -IV, which coincides to be the most common site.<sup>17</sup>

Opris et al., reported the frequency of fistula formation ranging from zero to 60%. Overall fistula rate in our study was 4.5%, which is comparable to the recently done international studies and meta-analyses. The fistula formation in our study was

found to be associated with the severity of the cleft, being more common in Veau type IV.<sup>18</sup>

Worley et al., stated that 2 stage palatal repairs resulted in higher rate of post-operative oronasal fistula frequency when compared to single staged repairs.<sup>19</sup> This could be attributed to the scar tissue at the time of 2nd stage, which limits the dissection and flap mobility, increasing the risk of post-operative complications and fistula formation. All the patients in our study underwent single stage repair of the palatal cleft. Jodeh *et al.*, did a meta-analysis, which documented the rate of fistula formation to be 4.9%.<sup>20</sup> They have documented the severity of the cleft and difficulty of the repair to be a factor for risk of fistula formation.

Tache *et al.*, documented their rate of fistula to be 6.4 %, and stated a higher frequency of fistula formation in clefts associated with cleft lip when compared to isolated cleft palate, this compares favorably to our study as none of our patients with isolated cleft palate developed post-operative oronasal fistula <sup>21</sup>.

In a study done by Pollard *et al.*, found fistula frequency to be related to the surgical techniques used, being more common in Furlow's double opposing z plasty.<sup>22</sup> None of the patients in our study developed fistula in Furlow's double opposing z palsty, which could be attributed to limiting its use in unilateral incomplete and secondary cleft palates. Flap mobilization and lateral releasing incisions were made according to the case at hand. Furlow's palatoplasty was not attempted in wider clefts and Bardach's technique was utilized in such cases.

Preoperative counselling of the parents regarding postoperative outcomes, and dietary precautions,<sup>9</sup> careful introduction of soft diet and gradual introduction of normal diet and bottle feed helped in better outcomes in terms of reducing the frequency of fistula formation .

In attempts to reduce the frequency of fistula formation, many modifications of the currently available surgical options have been described. Rossell *et al.*, has explained, multiple hybrid techniques for the repair according to the type of cleft.<sup>23</sup> This hybrid technique has been used in our department as per the surgeon's preference, and none of the patients have had any fistula formation in those cases. However, it was done

according to the surgeon's preference, and the LIMA protocol was not used systematically, as explained in the study.

The overall frequency of fistula formation after primary cleft palate was 4.5% in our study, associated with the severity of the cleft. The limitation in our study would be, the retrospective nature of the study as it limited the data available. The width of the cleft could not be utilized as the risk factor for fistula formation due to a lack of data.

## CONCLUSION

Oronasal fistula formation results in the financial and emotional burden of additional surgery on the patient. selecting the right technique, timely repair, meticulous dissection, tension free layered closure and appropriate post operative care prevents fistula formation.

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## Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MG & SURS: Data acquisition, data analysis, critical review, approval of the final version to be published.

MIK & MR: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

SM & FS: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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