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Dr. Pooja Jain
Ex-Junior Resident, Department of Oral and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, Delhi, India

Dr. Rakesh Sharma
Professor and Head, Department of Oral and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, Delhi, India

Dr. Lucky Yadav
Ex-Senior Resident, Department of Oral and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, Delhi, India

Dr. Chhavi Juneja
Ex-Junior Resident, Department of Oral and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, Delhi, India

Dr. Divya Sharma
Ex-Junior Resident, Department of Oral and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, Delhi, India

Corresponding Author:
Dr. Pooja Jain
Ex-Junior Resident, Department of Oral and Maxillofacial Surgery, Lady Hardinge Medical College and Associated Hospitals, New Delhi, Delhi, India

Cleft lip and palate: A literature review and recent advances in management

Pooja Jain, Rakesh Sharma, Lucky Yadav, Chhavi Juneja and Divya Sharma

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Abstract
Cleft lip and palate are among the most common congenital anomalies affecting the face and oral cavity, resulting from the incomplete fusion of embryonic facial structures and leading to challenges in speech, hearing, dental health, nutrition, psychology, and aesthetics. The etiology is multifactorial and involves genetic and environmental factors such as maternal smoking, alcohol use, and folic acid deficiency. Treatment requires a multidisciplinary approach, including cheiloplasty, palatoplasty, alveolar bone grafting, and orthognathic surgery. This article presents an in-depth review and discusses the latest advancements, such as nasoalveolar molding 3D printing, botulinum toxin, and robotic-assisted cleft surgery. The proper timing of interventions optimizes facial growth and speech. Patient-reported outcome measures like CLEFT-Q and ICHOM aid in assessing surgical success and quality of life.

Keywords: Cleft lip, cleft palate, nasoalveolar molding, robotic-assisted cleft surgery

Introduction
Cleft lip and palate are among the most common congenital abnormalities affecting the face and oral cavity. They occur when the tissues that form the lip and roof of the mouth (Palate) fail to fuse properly during early fetal development. A cleft is an abnormal separation in a normal body structure. Clefts that occur in the orofacial region often involve the lips, alveolus, hard palate and soft palate. Two major types of orofacial clefts are cleft lip/palate and isolated cleft palate. Children with these anomalies often face numerous physical and developmental challenges, along with potential psychosocial and emotional concerns that can impact both patients and their families.

The failure of fusion between the frontonasal and maxillary processes in the cleft lip results in a cleft of varying severity that can affect the lip, alveolus, and nasal floor. An incomplete cleft does not extend through the nasal floor, whereas a complete cleft indicates a lack of connection between the alar base and the medial labial element. The cleft palate occurs due to failure of fusion of the palatal shelves of the maxillary processes, resulting in a cleft of hard and/ or soft palates [1]. Cleft lips can be unilateral or bilateral. They may be isolated or associated with cleft palate. Clefts of the lip and palate may also be associated with other congenital anomalies and may be a part of a genetic syndrome.

Comprehensive care for individuals with cleft lip and/or palate necessitates a multidisciplinary approach. According to the guidelines established by the American Cleft Palate Association, the care team may include professionals from various specialties such as anesthesiology, audiology, genetics, neurosurgery, nursing, ophthalmology, oral and maxillofacial surgery, orthodontics, otolaryngology-head and neck surgery, pediatrics, pediatric dentistry, physical anthropology, plastic surgery, prosthodontics, psychiatry, psychology, social work, and speech-language pathology [2]. While every specialty may not always be represented, the quality of care is significantly enhanced through collaborative discussions and coordinated efforts.

Epidemiology
The incidence of cleft lip and/or palate (CL/P) varies by population, being highest in Native Americans (3.74/1,000) and lowest in individuals of African descent (0.18-1.67/1,000). Rates for Japanese, Chinese, Caucasian, and Latin Americans range from 0.82-4.04/1,000. Globally, cleft-related complications caused 4,000 deaths in 2010, a significant decline from 8,400 in 1990, reflecting improvements in care and treatment [3].

The overall incidence of cleft lip and palate is approximately 1 in 600 to 800 live births (1.42 per 1,000), whereas isolated cleft palate occurs in approximately 1 in 2,000 live births. The typical distribution of cleft types is as follows: cleft lip alone (15%), cleft lip with palate (45%), and isolated cleft palate (40%) [4].

Isolated Cleft Lip (CL) accounts for approximately 25% of all clefts, whereas combined cleft lip and palate (CL/P) represent approximately 45%. CL/P is more common and severe in boys than in girls. Unilateral clefts are more common than bilateral clefts at a ratio of 4:1, with approximately 70% of unilateral clefts occurring on the left side of the face. Cleft palate alone is seen more often in females. CL/P is often associated with other developmental abnormalities and is commonly part of a syndrome, with syndromic clefts accounting for approximately 50% of cases and over 300 syndromes identified. Although approximately 40% of cleft cases are linked to genetic factors, a familial tendency is present in most cases [5].

Epidemiological studies have shown that a parent with a cleft has a 3.2% chance of having a child with CL/P and a 6.8% chance of having a child with an isolated cleft palate (Grosen *et al*., 2010). If one parent and one sibling are affected, the chance increases to a 15.8% chance that the next child will have a cleft lip or palate, and a 14.9% chance that the next child will have a cleft palate (Christensen *et al*., 1996). In cases where parents with one child are affected by cleft, there is a 4.4% chance of having another child with a cleft lip and palate and a 2.5% chance of having a child with an isolated cleft palate [6].

Embryology of cleft lip and palate

The normal development of the lip occurs between the 4th and 8th weeks of intrauterine life, during which the primary palate forms, creating an initial separation between the oral and nasal cavities. This process involves the fusion of the paired Median Nasal Prominences (MNPs), resulting in the central upper lip, the central maxillary alveolar arch, the central and lateral incisors, and the hard palate in front of the incisive foramen [7, 8]. Around weeks 8-12, the secondary palate develops after the primary palate has fully fused. The secondary palate forms through the growth and migration of the palatal shelves, which are projections from the maxillary processes. Since the lip (primary palate) and the palate (secondary palate) develop sequentially, rather than simultaneously, clefts can occur in the lip with or without a cleft palate. Disruptions during this process can lead to deformities in the lip, palate, and nose, with severity varying depending on the timing, extent, and location of the disruption [9].

Etiology

The etiology of cleft lip and palate is complex and involves genetic factors that interact variably with environmental influences. Fogh-Andersen first demonstrated a genetic link to Cleft Lip and Palate (CLP) through family studies, showing an increased occurrence among siblings [10]. This finding was later confirmed by research on familial distribution [11] and Dr. Clark Fraser emphasized multifactorial etiology of CLP in a review [12]. Further evidence from segregation analysis and twin studies, revealed a higher prevalence in monozygotic twins (40%) than in dizygotic twins (4%), supporting a strong genetic influence (Table 1).

Classification

Classifications made have been on three bases: laterality, severity and morphology of the cleft. Since 1922, several classification systems for cleft lip and palate have been proposed, with Veau's classification (Figure 1) being the most widely used.

- **Group I:** Defects of the soft palate only.
- **Group II:** Defects involving the hard palate and soft palate.
- **Group III:** Defects involving the soft palate to the alveolus, usually involving the lip.
- **Group IV:** Complete bilateral clefts.

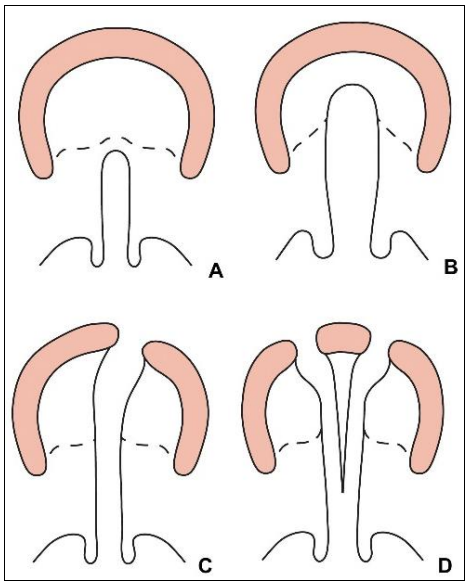

Fig 1: Veau's classification of cleft lip and palate (A- Group I, B- Group II, C- Group III, D- Group IV)

Common problems associated with cleft lip and palate

1. **Speech difficulties:** Dysfunction of the levator veli palatini muscle affects phonation, leading to difficulties in producing consonant sounds such as *p, b, t, d, k,* and *g*. Abnormal nasal resonance and articulation difficulties are also common characteristics in individuals with cleft lip and palate, resulting in hypernasality of speech [15].
2. **Hearing problems and ear infection:** Otitis media is a condition in which fluid accumulates in the middle ear and results in ear infection due to improper function of the m. tensor veli palatini muscle, which opens the eustachian tube [16].
3. **Dental problems:** Various abnormal dental conditions include the presence of natal and neonatal teeth, variations in tooth shape and size, taurodontism, ectopic eruption, enamel hypoplasia and delayed tooth maturation [17, 18].
4. **Feeding and nutritional problems:** Babies with cleft lip and palate struggle to suck from the breast or a bottle, leading to feeding difficulties that impact their growth and weight. To ensure adequate nutrition, various methods such as disposable syringes, spoons, cups, and prosthetic obturator devices can help facilitate proper feeding and weight gain [19].
5. **Cosmetic problems:** Patients with cleft lip experience cosmetic concerns and difficulties in producing labial sounds.

6. **Psychological problems:** Individuals with cleft lip often face psychological challenges, including depression, anxiety, and low self-esteem, which affect their ability to interact with peers at school. Additionally, many experience social anxiety due to concerns about others' reactions, making them hesitant to engage in social events and public interactions [20].

Timing of cleft repair [21] (Table 2)

Treatment of cleft lip and palate

The goals of treating a child with a cleft lip and palate are to provide normal speech, normal feeding, improved psychological side, normal dentition and occlusion, normal hearing and achieve normal aesthetics.

Between 18 and 24 weeks of pregnancy, 2D ultrasound can help detect clefts, identifying complete clefts at approximately 18 weeks and incomplete clefts by 24 weeks. A 3D-transvaginal ultrasound performed between 11 and 18 weeks can also aid in early diagnosis. Studies indicate that all cleft types, except isolated cleft palate, are detectable in 67-93% of cases. The ultrasonographic Surface-Rendered Oropalatal (SROP) technique enables simultaneous visualization of the upper lip, alveolar ridge, and secondary palate in a single scan. This imaging modality plays a crucial role in early diagnosis and allows timely parental counselling, helping families prepare for necessary medical interventions [22].

Optimal care for individuals with cleft conditions requires a multidisciplinary approach involving various clinical experts. The team may include specialists in dentistry (Orthodontics, oral surgery, pediatric dentistry, and prosthodontics), medicine (Genetics, otolaryngology, pediatrics, plastic surgery, and psychiatry), and allied health fields (Audiology, nursing, psychology, social work, and speech pathology) [23].

Pre-surgical Nasoalveolar Molding (PNAM)

The Nasoalveolar Molding (NAM) technique, pioneered by Grayson and Shetye, offers an innovative approach to minimize the severity of cleft alveolar and nasal deformities before surgery [24]. Nasoalveolar molding (NAM) is a non-invasive, passive technique that aligns the gums and lips via natural growth forces. This technique helps correct nasal flattening before surgery and enables simultaneous nose and lip repair. The presurgical NAM (PNAM) applies both "negative sculpturing" and "passive molding" to shape the alveolus and surrounding soft tissues [25]. This technique reduces tension during primary surgery, helping to minimize scar formation. Proper alignment of the alveolar segments is essential for achieving symmetrical lip appearance and enhancing bone formation by narrowing the cleft gap.

Surgical treatment

The primary surgical procedures for cleft patients include cheiloplasty, palatoplasty, and alveolar bone grafting. In most countries, lip and palate surgeries are performed separately, typically at 3-6 months for lip repair and 6-18 months for palatal closure [26, 27]. Jung *et al.* [28] recently introduced the C-flap technique, which creates a longer lip, reducing philtrum and Cupid's bow malformations compared with traditional methods. The choice of surgical technique depends on the surgeon's expertise and cleft type, with many favoring Fischer's technique combined with a modified Millard rotation-advancement flap for lip repair [29, 30, 31]. Among various palate closure methods, nonradical intravelar veloplasty is often used for restoration [32]. Postoperative care following lip surgery includes scar management, massage, wound monitoring, silicone gel application, and steroid treatment [26]. Advanced scar management techniques now incorporate laser therapy to soften and flatten scar tissue, enhancing healing outcomes [33].

Alveolar bone grafting

This surgical procedure involves filling a bony defect with cancellous bone, typically harvested from the iliac crest or tibial plateau, and is performed during the mixed dentition phase (7-14 years). The primary goals of this treatment are to facilitate the eruption of maxillary permanent teeth, particularly the canines and incisors, and to aid in orthodontic treatment when needed. Additionally, it provides structural support for the alar base, creates a stable foundation for prosthetic rehabilitation, and effectively closes the gap between the oral and nasal cavities.

Orthognathic surgery

Orthognathic surgery is performed when orthodontics alone cannot achieve optimal occlusion and aesthetics. It involves repositioning the upper and lower jaws. In cases of maxillary retrognathia, the maxilla is moved forward, whereas the mandible is shifted backward to achieve a class 1 relationship.

Maxillary distraction is increasingly used for the correction of severe maxillary retrusion in patients with cleft lip and palate [34].

Recent advancements in management protocols

A significant advancement in Presurgical Infant Orthopedics (PSIO) and Nasoalveolar Molding (NAM) is the use of custom 3D printing and digital orthodontics. Yu *et al*. introduced CAD/NAM, which uses a 3D laser scanner and reverse engineering software for simplified model construction [35]. A recent RCT demonstrated fully 3D-printed appliances, reducing manual labor, improving precision, and shortening appointment times (20-30 minutes), thereby easing the burden on families while optimizing treatment efficiency [36].

An interesting addition to cheiloplasty, by Chang *et al*., is the use of botulinum toxin. Injecting botulinum toxin into the orbicularis oris muscle helps reduce continuous muscle contraction and tension, creating a more favorable environment for wound healing and improving scar appearance [37]. The use of botulinum toxin appears to be a safe and promising efficacious adjunct in cheiloplasty.

Data suggests that early palatoplasty (<6 months of age) leads to midface growth disruption and maxillary arch constriction. However, late palatoplasty (>13-15 months of age) is associated with poorer long-term speech outcomes [38]. A significant advancement by Buchman and colleagues introduced the use of Buccal Fat Pad (BFP) flaps in palatoplasty and oronasal fistula repair. BFP flaps aid in covering the denuded hard palate (lateral relaxing incisions)

and serve as an interposition between oral and nasal layers in high-tension areas [39]. In a study by CC Lo *et al*. Buccal Fat Pad (BFP) flaps demonstrated significantly wider total transverse maxillary dimensions than Surgicel did, as assessed through standardized CBCT measurements, whereas the palatal length remained similar between both groups but was significantly shorter than that in the non-palatoplasty group [40]. Due to their easy harvest, minimal short-term donor site morbidity, vascularized autologous properties, and potential to enhance transverse maxillary development, BFP flaps are increasingly used as an adjunct in primary and secondary palatoplasty.

The use of Buccal Myomucosal Flaps (BMMFs) in augmentative palatoplasty, both primary and secondary, has gained increasing attention in recent studies. Buccinator Myomucosal (BMMF) flaps offer a promising alternative to pharyngoplasty, preserving a more anatomical and dynamic velum to support normal speech production [41, 42].

Robotic cleft surgery is an emerging and promising field that offers significant benefits for both patients and surgeons. Research in related medical specialties has contributed to feasibility studies supporting its potential use. However, current challenges include extended operating times and high capital and operational costs, making widespread implementation economically demanding. Over time, advancements in technology are expected to enhance performance and reduce costs, facilitating broader adoption of robotic-assisted cleft surgery [43].

Outcome measurements

Patient-Reported Outcome Measures (PROMs) assess the impact of surgeries or procedures on a patient's or caregiver's quality of life. These tools transform subjective experiences into quantifiable data, enabling objective evaluation. In cleft lip and palate care, two primary PROMs are widely used. The CLEFT-Q is a condition-specific PROM designed and validated for children and adolescents aged 8 to 29 with cleft lip and/or palate. It evaluates three key domains, each with independent scales [44]. (Figure 2) Additionally, the International Consortium for Health Outcomes Measurement (ICHOM) has developed a standard set of outcome measures, frequently used by cleft care teams for comprehensive assessments [45] (Figure 3)

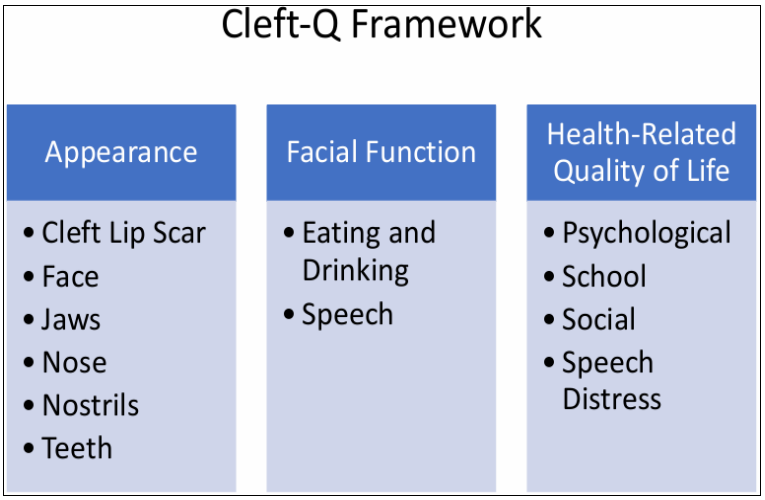

Fig 2: The CLEFT-Q framework consists of 12 scales across three domains, offering flexibility in selecting specific scales for various research and clinical applications

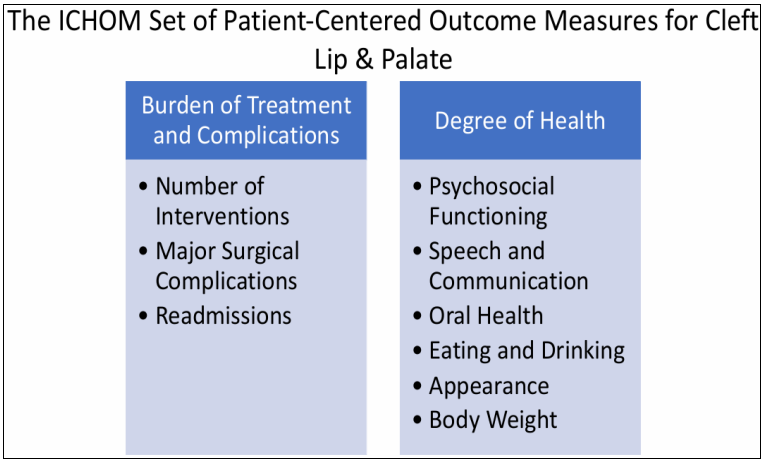

Fig 3: The ICHOM set of measures should be collected from patients, clinicians, and administrative sources. It includes recommended timings and age categories for assessment, starting with a baseline and followed by evaluations at 3 months, 5 years, 8 years, 12 years, 22 years, and within 30 days post-operation

Table 1: Various etiologies for cleft lip and palate

Genetic		Non- Genetic	
Syndromic	Non-Syndromic	In addition to genetic factors, various environmental factors also play an important role in etiology of CL/P like:	
The occurrence of cleft lip and palate is either associated with many syndromes like- 1. Pierre Robin syndrome 2. Stickler syndrome 3. Treacher Collins syndrome 4. Hemifacial microsomia 5. Ectodermal dysplasia 6. Velocardiofacial syndrome	Genetic factors play a significant role in the occurrence of cleft lip and palate. Family history is a key risk factor, as a parent with cleft lip and palate has a 9% chance of passing it on to their child. Additionally, if unaffected parents have one child with cleft lip and palate, the risk of their second child being affected is 4%.[14]	1. Alcohol use	Increases the risk of cleft lip and palate (CLP) by 1.5–4.7 times in a dose-dependent manner.
		2. Smoking	Maternal smoking and infant MSX1 genotypes acted together to increase the risk for CLP by 7.16 times.[13]
		3. Folate acid deficiency	
		4. Steroid use	three-fold increase
		5. Anticonvulsants such as phenobarbital and phenytoin	10-fold increase
		6. Hypoxia and retinoids (vitamin A)	

Table 2: Timing of cleft repair

Procedure	Age
Cleft lip repair	3 months
Tip rhinoplasty	
Tympanostomy tubes	
Palatoplasty	9–18 months
T-tube placement	
Speech evaluation	3–4 years
Velopharyngeal insufficiency workup and surgery (if necessary)	4–6 years
Alveolar bone grafting	9–11 years
Nasal reconstruction	12–18 years
Orthognathic surgery (if necessary)	At completion of mandibular growth (>16 years)

Conclusion

Cleft lip and palate are complex congenital conditions requiring a multidisciplinary approach for optimal care. Early diagnosis through ultrasound allows timely parental counselling and treatment planning. Repair of the cleft lip and palate deformity is a challenging and rewarding procedure. Advances in surgical techniques, nasoalveolar molding, and innovative interventions such as 3D printing, botulinum toxin, and robotic-assisted surgery have significantly improved outcomes. Continued research and technological innovations are essential to further enhance both functional and aesthetic outcomes for affected individuals.

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