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IP Indian Journal of Orthodontics and Dentofacial Research

Journal homepage: <https://www.ijodr.com/>

Review Article

Protocols for management of cleft lip and palate around the world

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ARTICLE INFO

Article history:

Received 11-07-2023

Accepted 10-08-2023

Available online 19-01-2024

Keywords:

Protocol

Cleft lip

Cleft Palate

ABSTRACT

Individuals with cleft lip and palate require care from birth to childhood. Management of cleft lip and palate is complex because it involves structures that are mutually concerned with a number of functions vital to the well being of the individual. The methods of dealing with cleft lip and palate has shown remarkable progress with the advances made in anaesthesia and control of infection. This article aims to review the various protocol for the management of cleft lip and palate followed globally.

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1. Introduction

The therapeutic approach for cleft lip and palate patient is multidisciplinary and the cleft team is composed by the craniofacial surgeon, otolarygeologist, geneticist, anesthesiologist, speech –language pathologist, nutritionist, orthodontists, prosthodontist, psychologist ,neurosurgeons, ophthalmologist. Patient with cleft lip and palate require a continued follow-up throughout their development in order to achieve desirable treatment goals like normal facial esthetics, airway patency, normal speech and hearing, normal masticatory function and normal psychosocial development.

2. Discussion

The handling of cleft lip and palate cases varies across different treatment centers around the world. There are different treatment protocols which are followed across the globe and are based on established data and facts regarding the treatment outcome followed by different centers. Various protocols which are followed across the

world are enumerated below:

2.1. OSLO protocol^{1,2}

The early beginnings of Oslo's team approach to the management of cleft patients can be traced to the early 1930s. at that time Granhaug Speech Therapy Institute provided a small amount of specialized care for patient with clefts repaired at the University hospital in Oslo and formed a link with the ENT department of the same institution.

In 1935 the prosthodontist, Arne Bohn initiated a collaboration with the speech therapists. Later Egil Harvold, the orthodontist joined the group in 1945. Finally Wilhelm Loennecken, one of the first two Norwegian plastic surgeons, returning from training in England in 1948 , settled in Oslo and virtually all children with clefts were subsequently referred either to him or to the other plastic surgeon in Bergen.

Following is the treatment protocol for unilateral cleft lip and palate according to the OSLO Cleft Team.(Department of Plastic Surgery, University Hospital of Oslo, Norway)(Tables 1 and 2)¹

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UCLP, 1953, 1961, 1968, 1977

Table 1: OSLO protocol for unilateral cleft lip and palate

Lip and hard palate	Le Mesurier and Vomer Flap (6 months)	Millard and Vomer flap (6 months)	Millard and Vomer flap(3 months)
Posterior Palate	Von Langenbeck 3-4 years Gradually reduced	Von langenbeck (18 months)	Von Langenkeck (18 months)
Alveolus			Cancellous bone graft 8-11 years (initially and also in older subjects)

2.1.1. Orthodontic intervention

Table 2: OSLO protocol for orthodontic management of unilateral cleft lip and palate

Timing	Procedure
Neonatal-2 years	No orthopedic or orthodontic treatment
Mixed dentition	Cross-bite correction, minor incisor position correction, maxillary expansion
Permanent dentition	Comprehensive orthodontic treatment

Following is the treatment protocol for bilateral cleft lip and palate according to the OSLO Cleft Team: (Department of Plastic Surgery, University Hospital of Oslo, Norway) (Tables 3 and 4)²

BCLP, 1953, 1962, 1974, 1997

Table 3: OSLO protocol for bilateral cleft lip and palate orthodontic intervention

Lip and hard palate	One stage straight line and Vomer flap (6 months)	Two stage straight line and Vomer flap (3 months)
Posterior palate	Von langenbeck 3-4 years gradually reduced	Von langenbeck (18 months)
Alveolus		Cancellous bone graft 8-11 years (initially and in older subjects)

2.2. Schweckendiek protocol(1951)³

In this technique the soft palate is closed during infancy by means of primary veloplasty. The residual cleft in the hard

Table 4: OSLO protocol for orthodontic management of bilateral cleft lip and palate

Timing	Procedure
Neonatal-2 years	No orthopedic or orthodontic treatment
Mixed dentition	Cross-bite correction, minor incisor position correction, maxillary expansion
Permanent dentition	Comprehensive orthodontic treatment

palate remains. Cleft becomes narrower with growth of the palate without causing compression of the jaw. Thus both articulation and maxillary growth remains undisturbed.

Table 5: Schweckendiek protocol

Procedure	Timing
Two stage repair	Early the soft palate repair leaving the hard palate open Prosthetic rehabilitation of the fistula Hard Palate closure by 15 years

2.3. Jolleys protocol (1954)⁴

According to Jolley when treating a patient with cleft it is difficult to decide which should be preserved whether function and appearance. In his opinion appearance could be sacrificed in order to preserve the function.

Table 6: Jolleys protocol

Procedure	Timing
Surgical correction of the muscle of the palate	Shortly following birth.
Repair of the lip	Few weeks later
Repair of cleft palate	By 18 months using simplest technique
Prosthesis for anterior cleft closure	3 years
Final repair of the hard palate	5-10 years

2.4. All India Institute of Medical Sciences, India cleft lip and palate protocol (1970)⁵

AIIMS located in South Delhi, India is an autonomous institute which is a tertiary care centre too. The combined cleft clinic was established in the orthodontic unit in the 1970's.

2.5. The zurich approach (1976)⁶

The management of cleft lip and palate at Zurich University Dental Institute emphasized on the early orthopedics to take advantage of intrinsic growth potential which would allow the natural growth of maxillary segments to maximum

Table 7: AIIMS protocol for cleft lip and palate

Procedure	Timing
Palatal obturator /Feeding appliance	0-1 year
Primary cleft lip surgery	3 months
Palate repair	9 months -1 year
Tympanostomy	6 months -1 year
Speech therapy/ Pharyngoplasty	3 years-6 years
Bone grafting jaw	9 years -11 years
Orthodontics	7 years -18 years
Orthognathic Surgery and Rhinoplasty	15years- 18 years

extent.

Table 8: The zurich approach

Timing	Procedure
Feeding Plate (Soft and hard acrylic Resin)	24-48 hours after birth
Grinding the feeding plate	Every 4-6 weeks
Feeding plate to be replaced	After 4-5 months
Surgical closure of lips	5-6 months
Obturator	10-12 months
Velar closure for speech development	18 months
Speech	3-8 years
Hard Palate Closure	6-8 years
Interceptive Orthodontics	7-9 years
Orthodontic treatment	11-15 years

2.6. Bergen protocol (1977)⁷

The Bergen protocol is utilized since 1977 and is based on intermittent periods of active treatment followed by phases of fixed retention. The treatment procedures are coordinated between the Department of Plastic and Reconstructive Surgery, University Hospital of Bergen; the Cleft lip and Palate Center at the Department of Orthodontics and Facial Orthopedics, Faculty of Medicine and Dentistry, University of Bergen; and the Eikelund Center for Speech Pathology. This treatment is cost-effective and requires minimal patient cooperation.

Following is the treatment protocol for cleft lip and palate according to the Bergen Cleft Team: (Department of Plastic and Reconstructive Surgery, University Hospital of Bergen).

2.7. Warsaw protocol (1980)⁸

Warsaw Institute of Mother and Child (IMC) proposes one stage approach of cleft treatment.

Table 9: Bergen protocol for cleft lip and palate

Procedure	Timing
Orthopedic intervention of maxilla	0-3 months
Closure of lip and anterior hard palate (Millard flap and single layer vomeroplasty)	3 months
Closure of soft palate and residual palatal clefts(von Langenbeck technique)	12 months
Interceptive orthopedics (Transverse expansion and protraction)	6-7 years
Alignment of maxillary incisors	8-11 years
Secondary Alveolar bone grafting	12-16 years
Conventional orthodontics in permanent dentition	16-17 years (girls)
Dental adjustment before orthognathic surgery for correcting major skeletal jaw discrepancies	18-19 years (boys)

Table 10: Warsaw protocol for cleft lip and palate

Procedure	Timing
Lip and soft and hard palate closure	6-12 months
Alveolar bone grafting	8-12 years

2.8. Malek & psahme protocol (1983)⁹

This technique is based on the concept that in complete cleft lip and palate the tongue has a tendency to fall into the naso pharyngeal region. Thus the tongue does not apply the required pressure on the maxillary segment.

Table 11: Malek and psahme protocol for cleft lip and palate

Procedure	Timing
Use of orthodontic plate to prevent further closure of the cleft.	2months
Soft palate repair for better tongue position	3 months
Lip and hard palate repair	6 months

2.9. Denmark protocol (1990)¹⁰

Treatment of cleft patients in Denmark is centralised in two centers: for the eastern part of the country in Copenhagen and for the western part of the country in Aarhus.

2.10. Oxford cleft palate protocol (1996)¹¹

The Oxford Cleft palate Study team assessed the cleft patient. The multidisciplinary assessment included: Speech, maxillofacial growth evaluation, palatal assessment and hearing status.

Table 12: Denmark protocol for cleft lip and palate.

Procedure	Timing
Lip repair (Tennison Procedure) and hard palate repair (Vomer plasty)	10 weeks
Palatoplasty (Push –back procedure)	22 months
Speech evaluation	5 years
Orthodontic procedure (maxillary expansion)	Mixed dentition (6-12 years)
Alveolar bone grafting (2°)	Permanent dentition (12-16 years)

Table 13: Oxford cleft palate protocol

Procedure	Timing
Soft palate repair (early closure) 3 or 4 flap Wardill kilners procedure	6-18 months
Soft palate repair (late closure) Short Veau Flap	6-22 months
Hard palate repair (early closure)	6-18 months
Hard palate repair (late closure) –Vomer flap	30-57 months

2.11. Brazilian protocol (2003)¹²

This protocol based on a survey conducted on the Brazilian Society of Plastic Surgeons where surgeons work in co-ordination with the members of other departments to provide the best possible results for the patients.

Table 14: Oxford cleft palate protocol

Procedure	Timing
Lip repair	After 3 months
Palate repair	18 months
Alveolar bone grafts	After 8 years
Secondary operations	After 15 years

2.12. Protocol for cleft lip and palate in China (2009)¹³

This protocol for cleft lip and palate was deduced after carrying out a survey in 44 dental institutes through a questionnaire. The management of cleft patients involves oral and maxillofacial surgeons, plastic surgeons, pediatric surgeons, and otorhinolaryngologist, speech-language pathologists and orthodontists.

Table 15: Chinese cleft lip palate protocol

Procedure	Timing
Cleft lip repair	3-6 months
Cleft palate (Primary Repair)	Before 3 years
Alveolar cleft Repair	9-11 years

2.13. United states protocol (2009)¹⁴

The following protocol are followed by majority of the surgeons in the United States. Surgeons repair clefts in one stage by using Furlow palatoplasty and the Bardach style with intravelar veloplasty.

Table 16: United States protocol for cleft lip and palate

Procedure	Timing
One-stage repair techniques using Bardach style and the Furlow palatoplasty	6 and 12 months of age
Discharge uncomplicated cases	After 48 hours
Resumption of breast-feeding	ostoperative Management Immediately after surgery
Promote syringe or cup feeding	Post surgery
Avoid hard foods	3 to 6 weeks after surgery
Arm restraints	For 2 weeks

2.14. New York protocol (The Hansjo`rg Wyss department of plastic surgery at New York University Medical Center 2018)¹⁵

This protocol usually emphasizes on the correction of nasal asymmetry which usually remains after the primary repair of the lip.

Table 17: New York protocol for cleft lip and palate

Procedure	Timing
Presurgical infant orthopedic (Naso Alveolar Moulding Terapy)	1-2 months
Lip repair using either Millard technique or Mohler modification along with primary rhinoplasty	3 months
2-flap palatoplasty	11-24 months

2.15. Clinical practice guidelines (Netherland) 2021¹⁶

Clinical Practice Guidelines were formulated to give the standardized treatment to the patients of cleft lip and palate throughout Netherland. These guidelines were made to the Guidelines Advisory Committee of the Dutch Association of Medical Specialists’ Quality Council and the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument which is widely accepted for assessing the quality of guidelines.

Table 18: Netherland protocol for cleft lip and palate

Procedure	Timing
Genetic testing	Before the first operation
a) Single nucleotide polymorphism array	
b) Whole-exome sequencing	
c) Gene pane	
Primary cleft lip surgery	6 months
Soft Palate repair	Before 1 year
Hard Palate (If optimal speech is persued use Furlow or Von Langenbeck technique)	Before 1 year
Hard Palate (If optimal growth of maxilla is persued use combination of techniques except for Furlow double opposing Z-plasty and Wardill–Kilner pushback technique.	Repaired later than 1 year
Periodic audiology check-ups	3-4 years
Velopharyngeal dysfunction	After 6 months of Speech therapy
Bone grafting	2/3 rd root formation of canine on cleft side
Orthodontics	
a) Severe midfacial deficiency	Maxillary protraction
b) Mild midfacial deficiency	No Maxillary protraction
Orthodontic retention	Retainer through life.
Orthognathic Surgery	
a) Small Sagittal discrepencies	Le Fort 1 osteotomy or setback procedure
b) Large sagittal discrepencies	Distraction Osteogenesis
Rhinoplasty	Columella and caudal septum of nose should be positioned correctly during primary lip repair
Secondary nasal surgeries	To be done when midface growth is complete.

2.16. Protocol for cleft palate in Japan (2022)¹⁷

The following protocol has been deduced after observing the treatment protocol at 3 cleft centers in Japan.

Table 19: Protocol for cleft palate in Japan

Procedure	Timing
Lip Repair	3-6 months
Soft Palate Repair	12-18 month
Hard Palate Repair	5-8 years
Alveolar Bone Grafting	8-10 years

2.17. Standard treatment guidelines 2022 (India)¹⁸

According to Indian Academy of Paedritrics. There are six procedures in repair of CLP.

Table 20: Protocol for cleft palate in India

Procedure	Timing
Lip repair	3 months
Pal B ate Repair	9 months
Palatal Expansion	5-7 years
Alveolar Bone Grafting	9 years
Rhinoplasty	After 13 years
Scar revision of lip	14- 16 years

3. Conclusion

The management of cleft lip and palate varies among different countries around the globe. Treatment of cleft involves a multidisciplinary approach. The communication between the care giver and taker should be smooth at each level of treatment to maximize the benefit and minimize the apprehension regarding treatment. Different countries should collaborate and share their clinical experiences regarding the future in the management of cleft cases to enhance the skills related to different techniques thereby leading to best time management and enhancing the esthetic appearance and boosting the psychological morale of patients.

4. Source of Funding

None.

5. Conflict of Interest


None.

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Cite this article: Chauhan S. Protocols for management of cleft lip and palate around the world. *IP Indian J Orthod Dentofacial Res* 2023;9(4):245-250.