Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParCare 2017)

CLEFT AND CRANIOFACIAL SURGERY

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THIS SECTION IS 1 OF 11 CLINICAL SECTIONS INCLUDED IN AAOMS PARCARE 2017, WHICH IS VIEWED AS A LIVING DOCUMENT APPLICABLE TO THE PRACTICE OF ORAL AND MAXILLOFACIAL SURGERY. IT WILL BE UPDATED AT DESIGNATED INTERVALS TO REFLECT NEW INFORMATION CONCERNING THE PRACTICE OF ORAL AND MAXILLOFACIAL SURGERY.
INTRODUCTION

The optimal management of patients with cleft and craniofacial deformities has traditionally been under the direction of a multidisciplinary team. The American Cleft Palate-Craniofacial Association (ACPA) Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies and Standards for Cleft Palate and Craniofacial Teams have provided guidelines for these activities. This document more specifically addresses the optimal surgical management of individuals who have these conditions.

The AAOMS ParCare 2017 chapters on Surgical Correction of Maxillofacial Skeletal Deformities and Facial Cosmetic Surgery will not be supplanted by this section; in fact, cross-references to these sections are included for thoroughness. The Oral and Maxillofacial Surgeon is referred to the Special Considerations for Pediatric Cleft and Craniofacial Surgery section for the management of pediatric patients with cleft and craniofacial deformities.

Parameters of care for cleft lip and palate deformities and for craniofacial deformities are described separately. The management of cleft lip and palate deformities is divided into the following conditions:

- Primary Cleft Lip Deformities
- Primary Cleft Palate Deformities
- Velopharyngeal Dysfunction
- Residual Cleft Lip and/or Nasal Deformities Requiring Secondary Management
- Maxillary Alveolar Cleft Deformities
- Residual Maxillofacial Skeletal Deformities Requiring Secondary Management

The craniofacial surgery section is divided into the following conditions:

- Craniofacial Deformities: Those Not Requiring an Intracranial Approach for Repair
- Craniofacial Deformities: Primary Cranial Deformities Requiring Treatment Through an Intracranial Approach
- Craniofacial Deformities: Secondary Cranial Deformities Requiring Treatment Through an Intracranial Approach
- Orbital and/or Naso-orbital Deformities

These parameters were prepared with the appreciation that there is more than one approach to treating certain clinical problems; consequently, flexibility has been allowed so that the practitioner may select different therapeutic options. Future changes in this area of Oral and Maxillofacial Surgery, resulting from new research findings and evolving technologic developments, will undoubtedly extend and expand the capabilities for treatment and enable an even higher quality of patient care.

The surgical correction of these deformities requires a clear understanding, by the surgeon and patient and/or family, of the therapeutic goals. In turn, the Oral and Maxillofacial Surgeon should determine through careful dialogue that the patient and/or family have realistic expectations regarding the proposed therapy.

GENERAL CRITERIA, PARAMETERS, AND CONSIDERATIONS FOR CLEFT AND CRANIOFACIAL SURGERY

INFORMED CONSENT: All surgery must be preceded by the patient's or legal guardian’s consent, unless an emergent situation dictates otherwise. These circumstances should be documented in the patient’s record.

Informed consent is obtained after the patient or the legal guardian has been informed of the indications for the procedure(s), the goals of treatment, the known benefits and risks of the procedure(s), the factors that may affect the risk, the treatment options, and the favorable outcomes.

PERIOPERATIVE ANTIBIOTIC THERAPY: In certain circumstances, the use of antimicrobial rinses and systemic antibiotics may be indicated to prevent infections related to surgery. The decision to employ
prophylactic perioperative antibiotics is at the discretion of the treating surgeon and should be based on the patient’s clinical condition as well as other comorbidities which may be present.

DEALING WITH NEUROLOGIC DEFECITS: Injuries to the terminal branches of the trigeminal nerve (eg, lingual, inferior alveolar, long buccal nerves), as well as the facial nerve, are known risks of oral and maxillofacial surgery. It should be noted that the presence of a pathologic craniomaxillofacial condition, dentoskeletal or craniofacial abnormality, or traumatic craniomaxillofacial injury may result in nerve injury prior to surgical management. In addition, the use of local anesthesia (eg, mandibular block) may increase the risk of nerve injury. Most nerve injuries resolve spontaneously, but some do not, and these may require consideration for non-surgical and/or surgical intervention. Microneurosurgical repair should be considered when the disability is of concern to the patient, and there is clinical evidence of moderate, severe, or complete neurosensory impairment of various areas of the orofacial region (eg, lips, chin, tongue); paresis or paralysis of facial muscles; loss, decreased, or abnormal taste sensation; or neuropathic pain of peripheral origin. Surgical repair should incorporate specialized microsurgical techniques (eg, operating magnification, nerve grafting), when indicated. Also see the Reconstructive Surgery chapter.

USE OF IMAGING MODALITIES: Imaging modalities may include panoramic radiograph, periapical and/or occlusal radiographs, maxillary and/or mandibular radiographs, computed tomography, cone beam computed tomography, positron emission tomography, positron emission tomography/computed tomography, and magnetic resonance imaging. In determining studies to be performed for imaging purposes, principles of ALARA (as low as reasonably achievable) should be followed.

DOCUMENTATION: The AAOMS ParCare 2017 includes documentation of objective findings, diagnoses, and patient management interventions. The ultimate judgment regarding the appropriateness of any specific procedure must be made by the individual surgeon in light of the circumstances presented by each patient. Understandably, there may be good clinical reasons to deviate from these parameters. When a surgeon chooses to deviate from an applicable parameter based on the circumstances of a particular patient, he/she is well advised to note in the patient’s record the reason for the procedure followed. Moreover, it should be understood that adherence to the parameters does not guarantee a favorable outcome.

TEAM APPROACH: Favorable therapeutic outcomes are optimized when a multidisciplinary team plans the treatment.

GENERAL THERAPEUTIC GOALS FOR CLEFT AND CRANIOFACIAL SURGERY:

A. Appropriate understanding by patient (family) of treatment options and acceptance of treatment plan
B. Appropriate understanding and acceptance by patient (family) of favorable outcomes and known risks and complications
C. Optimizing the psychological impact on patient and family
D. Improved social and psychological development
E. Limited period of disability
F. Absence of infection
G. Minimal scar formation
H. Limited adverse maxillofacial growth and development
I. Optimizes function

GENERAL FACTORS AFFECTING RISK DURING CLEFT AND CRANIOFACIAL SURGERY:

A. Degree of patient and/or family understanding of the origin and natural course of the condition or disorder and therapeutic goals and acceptance of proposed treatment
B. Degree of patient’s and/or family’s cooperation and/or compliance
C. Presence of coexisting major systemic disease (eg, disease that increases a patient’s American Society of Anesthesiologists classification to II, III, or IV), as detailed in the Patient Assessment chapter
D. Presence of local or systemic conditions that may interfere with the normal healing process and subsequent tissue homeostasis (eg, previously irradiated tissue, diabetes mellitus, chronic renal disease,
liver disease, blood disorders, steroid therapy, contraceptive medication, immunosuppression, malnutrition)

E. Presence of behavioral, psychological, neurologic, and/or psychiatric disorders, including habits (eg, substance abuse), seizure disorders, and self-mutilation, that may affect surgery, healing, and/or response to therapy

F. Hospital and professional staff's familiarity and experience with pediatric anesthesia, surgery, and perioperative care

G. Severity of deformity

H. Presence of syndrome and/or other congenital or acquired craniofacial deformities (eg, Crouzon disease)

I. Age of patient

J. Inadequate nutrition and/or growth and development

K. Communication problems (eg, language differences)

L. Hearing impairment

M. Problems with the physical environment

N. Regulatory and/or third-party decisions concerning access to care, indicated therapy, drugs, devices, and/or materials

GENERAL FAVORABLE THERAPEUTIC OUTCOMES FOR CLEFT AND CRANIOFACIAL SURGERY:

A. Patient (family) acceptance of procedure and understanding of outcomes

B. Satisfactory surgical wound healing

C. Limited period of disability

D. Minimal scar formation

E. Improved nutritional status and systemic growth and development

F. Limited adverse effect on maxillofacial growth and development

G. Improved social and psychological status

GENERAL KNOWN RISKS AND COMPLICATIONS FOR CLEFT AND CRANIOFACIAL SURGERY:

A. Unplanned admission to intensive care unit after elective surgery

B. Unplanned intubation for longer than 12 hours after surgery

C. Reintubation or tracheostomy after surgery

D. Use of parenteral drugs and/or fluids for longer than 72 hours after elective surgery

E. Facial and/or trigeminal nerve dysfunction after surgery

F. Facial fracture during or after surgery

G. Unplanned Caldwell-Luc, bronchoscopy, or other exploratory procedures associated with surgery

H. Dental injury during surgery

I. Ocular injury during surgery

J. Repeat oral and/or maxillofacial surgery

K. Core temperature of greater than 101°F 72 hours after elective surgery

L. Postradiograph indicating presence of foreign body

M. Unplanned transfusion(s) of blood or blood components during or after surgery

N. Readmission for complications or incomplete management of problems during previous hospitalization

O. Respiratory and/or cardiac arrest

P. Wound dehiscence

Q. Infection

R. Postsurgical nasal deformity (may be predicted in some cases)

S. Residual lip and/or nose deformity (may be predicted in some cases)

T. Adverse effect on the patient's and family's psychological well-being

U. Impaired healing

V. Prolonged period of disability

W. Hypertrophic and/or keloid scar formation

X. Postoperative hemorrhage

Y. Pain
SPECIAL CONSIDERATIONS FOR PEDIATRIC CLEFT AND CRANIOFACIAL SURGERY

Cleft and craniofacial surgery corrects congenital and developmental deformities, most of which occur in children. All the special pediatric considerations described in the Patient Assessment chapter are applicable to children with cleft and craniofacial anomalies.

In the pediatric patient with cleft/craniofacial anomalies, particular attention must be paid to the interaction among the primary deformity, treatment, and facial growth. The Oral and Maxillofacial Surgeon must determine whether the treatment will adversely affect growth and then ascertain the ideal time for treatment. It is not uncommon for the family to push for treatment at a time that may not be ideal, and the surgeon must resist this pressure. On the other hand, timing may be altered for a child with significant psychosocial problems and the surgery undertaken at a time that is not ideal relative to facial growth. Especially in these cases, clear documentation of treatment decisions and indications must be included within the informed consent recordings.

In the pediatric patient with cleft lip/palate, the Oral and Maxillofacial Surgeon must be aware of the effects of the deformity and its treatment on middle ear function, speech-airway, and facial growth. Timing is also important relative to alveolar cleft bone grafting, placement of dental implants, and orthognathic surgery. Secondary revisions of the lip and nose may be judiciously performed at any time during growth, although final revision should be deferred until growth has ceased.

In the pediatric patient with congenital craniofacial anomalies, genetic evaluation is critical to determine the genetic (chromosome and gene location) basis for the anomaly when possible. This provides useful information for treating professionals in regard to possible future stigmata associated with some syndromes, for the family with regard to future children, and for the patient to make decisions about having offspring in the future. Advances in molecular genetics will aid in the understanding, prevention, and molecular treatment of craniofacial defects in the future.

The most significant difference between managing children and adults with cleft and craniofacial anomalies is the need to consider the fourth dimension of time/growth and development during treatment planning. This information affects the timing of operation and choice of proper procedure and proper hardware for stabilization. Genetic evaluation and counseling are also critical, as are psychological counseling and speech therapy when indicated. Outcomes assessment must include evaluation at the end of growth, number of operations required to achieve the final result, and success of preventive measures.

PRIMARY CLEFT LIP DEFORMITIES

I. Indications for Therapy for Primary Cleft Lip Deformities

May include one or more of the following:

A. Evidence of anatomical and/or functional lip deformity
B. Evidence of anatomical and/or functional nasal deformity

II. Specific Therapeutic Goals for Primary Cleft Lip Deformities

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Restoration of lip function and anatomical features
C. Restoration of nasal form and/or function
III. Specific Factors Affecting Risk for Primary Cleft Lip Deformities

Severity factors that increase risk and the potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Severity of the cleft deformity (e.g., width, unilateral vs bilateral, complete vs incomplete)
C. Potential for hypertrophic and/or keloid scar formation

IV. Indicated Therapeutic Parameters for Primary Cleft Lip Deformities

The presurgical assessment includes, at a minimum, both a history and a clinical evaluation. Also see the Patient Assessment chapter.

The lip is repaired within the first 6 months of life, if possible.

The following procedures for the management of primary cleft lip deformities are not listed in order of preference:

A. Unilateral cleft lip/nose
1. Presurgical orthopedics or nasal alveolar molding in selected cases
2. Insertion of nasal conformers
3. Lip adhesion in selected cases
4. Lip/nasal repair
5. Excision of lip pits
6. Instructions for posttreatment care and follow-up

B. Bilateral cleft lip/nose
1. Presurgical orthopedics or nasal alveolar molding in selected cases
2. Insertion of nasal conformers
3. Lip adhesion in selected cases
4. Definitive lip/nose repair
5. Excision of lip pits
6. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Primary Cleft Lip Deformities

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Restoration of lip form and function
3. Lip symmetry with alignment of anatomical landmarks
4. Improved symmetry and position of nostrils/nostril sills
5. Patent nasal passages

B. Known risks and complications associated with therapy
1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Postsurgical functional or anatomical lip deformity
3. Postsurgical functional or anatomical nasal deformity
4. Hypertrophic and/or keloid scar formation

PRIMARY CLEFT PALATE DEFORMITIES
I. Indications for Therapy for Primary Cleft Palate Deformities

May include one or more of the following:

A. Physical evidence of palatal cleft
B. Feeding abnormality
C. Developing or existing speech abnormality
D. Abnormal oral and/or nasal function (e.g., reflux)

II. Specific Therapeutic Goals for Primary Cleft Palate Deformities

The goal of therapy is to restore form and/or function; however, risk factors and potential complications may preclude complete restoration of form and/or function.

A. The presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Restoration of palatal form and/or function
C. Provision of mechanism for improved speech development
D. Improved feeding
E. Improved oral and/or nasal function
F. Separate oral and nasal cavities
G. Elimination of need for prosthetic appliances
H. Improved eustachian tube and middle ear function
I. Provide for improved dental management

III. Specific Factors Affecting Risk for Primary Cleft Palate Deformities

Severity factors that increase risk and the potential for known complications:

A. The presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Severity of the cleft deformity (e.g., width, unilateral vs bilateral, complete vs incomplete)
C. Potential major vascular abnormalities
D. Known or suspected airway abnormalities (Robin sequence)
E. Presence of a syndrome
F. Concurrent systemic syndromic abnormalities
G. Severity of the malformation/deformation

IV. Indicated Therapeutic Parameters for Primary Cleft Palate Deformities

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

Palatal repair is performed by 18 months of age in the normally developing child. The exact age will vary according to general development, systemic abnormalities, and speech and language development. Submucous clefts should be repaired on the basis of documented evidence of speech abnormalities.

The following procedures are indicated for the management of primary cleft palate deformities (not listed in order of preference):

A. Primary repair of the hard and soft palate utilizing one or two stage procedure
B. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Primary Cleft Palate Deformities

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
VELOPHARYNGEAL DYSFUNCTION

I. Indications for Therapy for Velopharyngeal Dysfunction

May include one or more of the following:

A. Hypernasal speech that has detrimental effects on communication and does not respond to a reasonable period of speech therapy
B. Clinical and/or imaging evidence of velopharyngeal incompetence (eg, nasoendoscopy, videofluoroscopy, air pressure studies)
C. Hypernasal speech documented to be due to the palatal fistulae
D. Enlarged tonsils and adenoids affecting velopharyngeal function

II. Specific Therapeutic Goals for Velopharyngeal Dysfunction

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Improved mechanism for improved speech production
C. Avoidance of airway obstruction
D. Avoidance of hyponasality
E. Reduction of hypernasality

III. Specific Factors Affecting Risk for Velopharyngeal Dysfunction

Severity factors that increase risk and the potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Severity of velopharyngeal dysfunction
C. Presence of enlarged tonsils and/or adenoids
D. Known or suspected airway abnormalities
E. Limited patient cognitive abilities
F. Pharyngeal hypomobility disorders
G. Hearing disorders
H. Known obstructive sleep apnea

IV. Indicated Therapeutic Parameters for Velopharyngeal Dysfunction

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.
The determination for surgery is made by a team that includes a speech pathologist who has assessed the patient and agrees with the need for surgical management.

The following procedures for the management of velopharyngeal incompetence are not listed in order of preference:

A. Pharyngeal flap
B. Pharyngoplasty
C. Pharyngeal wall augmentation
D. Revision palatoplasty
E. Tonsillectomy and/or adenoidectomy may be indicated in combination and sequenced with a pharyngeal flap or other type of pharyngoplasty
F. Speech prosthesis
G. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Velopharyngeal Dysfunction

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
   1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Reduction of hypernasal speech
   3. No hyponasal speech
   4. No adverse impact on the airway
   5. No adverse impact on swallowing
B. Known risks and complications associated with therapy
   1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Hyponasal speech
   3. Persistent hypernasal speech
   4. Obstructive sleep apnea

RESIDUAL CLEFT LIP AND/OR NASAL DEFORMITIES REQUIRING SECONDARY MANAGEMENT

I. Indications for Therapy for Residual Cleft Lip and/or Nasal Deformities Requiring Secondary Management

May include one or more of the following:

A. Patient's and/or family's desire for improvement of deformities
B. Evidence of anatomical and/or functional lip deformities
C. Evidence of anatomical and/or functional nasal deformities

II. Specific Therapeutic Goals for Residual Cleft Lip and/or Nasal Deformities Requiring Secondary Management

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Restoration of lip function and anatomical features
C. Restoration of nasal form and/or function

III. Specific Factors Affecting Risk for Residual Cleft Lip and/or Nasal Deformities Requiring Secondary Management

Severity factors that increase risk and the potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Severity of the secondary cleft lip and/or nasal deformities
C. Number of previous operative procedures in the region
D. Potential for hypertrophic or keloid scar formation

IV. Indicated Therapeutic Parameters for Residual Cleft Lip and/or Nasal Deformities Requiring Secondary Management

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

For a comprehensive review, see the Facial Cosmetic Surgery chapter.

The following procedures for the secondary management of residual cleft lip and/or nasal deformities are not listed in order of preference:

A. Cheiloplasty
B. Rhinoplasty (primary and revision)
C. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Residual Cleft Lip and/or Nasal Deformities Requiring Secondary Management

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
   1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Restored lip form and/or function
   3. Restored nasal form and/or function
B. Known risks and complications associated with therapy
   1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Residual lip and/or nasal deformity
   3. Postsurgical functional or cosmetic lip and/or nasal deformity
   4. Restricted nasal airway

MAXILLARY ALVEOLAR CLEFT DEFORMITIES

I. Indications for Therapy for Maxillary Alveolar Cleft Deformities

May include one or more of the following:

A. Clinical and imaging evidence of maxillary alveolar cleft deformity
B. Inadequate bone to support erupting teeth
C. Inadequate bone for orthodontic correction of dental deformity
D. Inadequate ridge for prosthetic reconstruction (eg, implant placement)
E. Dental arch collapse
F. Oroonasal communication
G. Nasal deformity and/or inflammation
H. Speech abnormalities
I. Mobility of the premaxilla

II. Specific Therapeutic Goals for Maxillary Alveolar Cleft Deformities

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

Reconstruction of the maxilla and/or alveolus to allow and/or provide for:

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Maxillary alveolar ridge continuity for tooth eruption and indicated orthodontic correction of malocclusions and crossbites
C. Alveolar bone support of adjacent teeth
D. Restoration of alveolar ridge form
E. Elimination of need for prosthetic tooth replacement in cases where teeth are present and can be brought into occlusion
F. Stabilization of the premaxilla in bilateral clefts
G. Alar base support
H. Elimination of oronasal communication and inflammation
I. Improved appearance of lip (nasolabial support)
J. Improved speech
K. Minimal bone graft donor site morbidity

III. Specific Factors Affecting Risk for Maxillary Alveolar Cleft Deformities

Severity factors that increase risk and the potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Number of previous operative procedures involving this region
C. Health of the gingiva and periodontium
D. Teeth in the cleft region
E. Exposed dental roots in the area of the bone graft
F. Lack of orthodontic and/or surgical treatment coordination
G. Narrow or wide defect and interdental gap
H. Lack of adequate healthy cleft adjacent tissue required for closure of defect
I. Inferior turbinate hypertrophy into the defect
J. Age-related factors

IV. Indicated Therapeutic Parameters for Maxillary Alveolar Cleft Deformities

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

Timing of grafting is determined primarily by the state of dental development and in a coordinated team effort with planned orthodontic treatment.

The following procedures for the management of maxillary alveolar cleft deformities are not listed in order of preference:

A. Maxillary expansion when indicated
B. Closure of oronasal fistula with local or distant tissue
C. Graft to alveolar cleft
V. Outcome Assessment Indices for Maxillary Alveolar Cleft Deformities

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
   1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Restoration and preservation of anatomical form
   3. Elimination of the oronasal fistulae
   4. Primary soft tissue healing
   5. Healthy periodontal bone and soft tissue support for teeth
   6. Maintenance of bone
   7. Improved nasal aesthetics and function
   8. Ability of the patient to undergo indicated orthodontic treatment
   9. Minimal donor site morbidity
   10. Stabilization of the premaxilla
   11. Adequate bone for implant placement
   12. Improved speech

B. Known risks and complications associated with therapy
   1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Partial or complete loss of bone graft
   3. Residual oronasal fistulae
   4. Lack of adequate periodontal bone and/or soft tissue support
   5. Soft tissue necrosis
   6. External root resorption
   7. Failure of dental eruption into and through graft
   8. Donor site morbidity
   9. Collapse of dento-osseous segments
   10. Loss of vestibular depth
   11. Inadequate attached gingiva adjacent to teeth in bone graft area

RESIDUAL MAXILLOFACIAL SKELETAL DEFORMITIES REQUIRING SECONDARY MANAGEMENT

I. Indications for Therapy for Residual Maxillofacial Skeletal Deformities Requiring Secondary Management

May include one or more of the following:

A. Physical evidence of musculoskeletal, dento-osseous, and/or soft tissue deformity
B. Imaging evidence of musculoskeletal, dento-osseous, and/or soft tissue deformity
   1. Deviation from cephalometric norms
   2. Other imaging disclosure of abnormality
C. Malocclusions that cannot be reasonably corrected by orthodontic and/or prosthetic means alone
D. Social and psychological impairment
E. Masticatory and/or swallowing abnormalities
F. Speech pathology (eg, defects in articulation)
G. Incomplete correction or unstable result of previous treatment
H. Dental and/or periodontal pathology
I. Airway obstruction (eg, peripheral obstructive sleep apnea, snoring)
J. Chin deformity (eg, microgenia, macrogenia, asymmetry)
K. Associated soft tissue deformities (eg, paranasal, labiomental fold, chin-neck contour, nasolabial and melolabial folds)

II. Specific Therapeutic Goals for Residual Maxillofacial Skeletal Deformities Requiring Secondary Management

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Improved musculoskeletal, dento-osseous, and/or soft tissue relationships
C. Improved mastication and/or swallowing
D. Improved occlusion
E. Improved dental and periodontal health
F. Improved appearance
G. Improved quality of speech
H. Improved airway
I. Improved self-esteem
J. Closed oronasal fistulae and residual maxillary alveolar cleft
K. Stabilization of maxillary segments

III. Specific Factors Affecting Risk for Residual Maxillofacial Skeletal Deformities Requiring Secondary Management

Severity factors that increase risk and the potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Presence and severity of coexisting maxillary and/or mandibular skeletal, dento-osseous, or soft tissue deformities (eg, vertical maxillary hypoplasia, congenital absence of dentition, neuromuscular disorders)
C. Presence and severity of localized conditions or disorders (eg, nasal airway)
D. Active maxillofacial growth
E. Number of previous operations
F. Severity of lip, palate, or vestibular scarring
G. Presence of parafunctional habits (eg, bruxism, clenching, tongue thrusting, finger sucking)
H. Because of the higher incidence of morbidity in orthognathic surgery performed in the cleft patient, evaluation of the following factors is indicated:
   1. Presence of a pharyngeal flap
   2. Marginal velopharyngeal function
   3. Severely scarred soft tissues
   4. Unrepaired alveolar cleft and/or oronasal fistulae
   5. Nasal septal deformity
   6. Enlarged nasal turbinate(s)
   7. Number of previous palatal and/or maxillary procedures performed
   8. Severity of anterior-posterior discrepancy
   9. Tight upper lip and vestibular deformity
   10. Status of the dentition
   11. Vascular supply to maxilla
   12. Bilateral vs unilateral cleft

IV. Indicated Therapeutic Parameters for Residual Maxillofacial Skeletal Deformities Requiring Secondary Management
The presurgical evaluation includes, at a minimum, a history, physical examination, and diagnostic records, including a panoramic radiograph, cephalometric radiograph and analysis, photographic documentation, and dental model assessment, and speech evaluation. After evaluation of factors affecting risk, an orthognathic surgical approach should be developed that takes into account the identified risk factors, thereby maximizing favorable outcomes and minimizing known risks and complications. (Also see the Surgical Correction of Maxillofacial Skeletal Deformities, Dental and Craniomaxillofacial Implant Surgery, Temporomandibular Joint Surgery, and Patient Assessment chapters.)

V. Outcome Assessment Indices for Residual Maxillofacial Skeletal Deformities Requiring Secondary Management

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Permanent improvement in the musculoskeletal, dento-osseous, and/or soft tissue relationships
3. Improved function
   a. Improved masticatory function (e.g., mastication, swallowing, deglutition)
   b. Improved speech
   c. Improved airway
4. Enhanced orthodontic result
5. Improved dental and periodontal health
6. Improved appearance

B. Known risks and complications associated with therapy
1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Impaired masticatory function
3. Impaired dental occlusion
4. Impaired speech
5. Deterioration of facial appearance
6. Onset or exacerbation of temporomandibular disorders, restricted mandibular range of motion
7. Clinically significant neurologic deficit
8. Failure of bone to heal (e.g., delayed or nonunion)
9. Unanticipated loss of teeth, bone, and/or soft tissue
10. Dental pathology requiring treatment
11. Skeletal relapse
12. Onset of parafunctional habits
13. Development of hypernasal speech
14. Increased incidence of skeletal relapse
15. Increased potential for avascular sequelae when maxillary surgery is performed, especially in bilateral cleft with a mobile premaxilla
16. Failure to correct oronasal communications
17. Creation and/or enlargement of oronasal communications
18. Airway obstruction
19. Adverse psychological sequelae

CRANIOFACIAL DEFORMITIES: THOSE NOT REQUIRING AN INTRACRANIAL APPROACH FOR REPAIR

I. Indications for Therapy for Craniofacial Deformities: Those Not Requiring an Intracranial Approach for Repair
May include one or more of the following:

A. Physical or imaging evidence of deformity of cranial or orbital bones
B. Physical or imaging evidence of cosmetic and/or functional deformity of the nose secondary to developmental or acquired anomalies
C. Evidence of anatomical and/or functional deformity of the ears secondary to developmental or acquired anomalies
D. Evidence of anatomical and/or functional deformity of soft tissue, skeletal, and/or dento-osseous structures of the face secondary to developmental or acquired anomalies
E. Evidence of airway obstruction secondary to developmental or acquired anomalies
F. Evidence of abnormal masticatory and/or jaw function secondary to developmental or acquired anomalies
G. Evidence of abnormal speech and/or swallowing secondary to developmental or acquired anomalies

II. Specific Therapeutic Goals for Craniofacial Deformities: Those Not Requiring an Intracranial Approach for Repair

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Improved function and appearance of the cranial and orbital areas
C. Improved nasal form and/or function
D. Improved ear appearance and function
E. Improved appearance and function of the soft tissue, skeletal, and/or dento-osseous structures of the face
F. Absence of upper airway problems
G. Improved masticatory and/or jaw function
H. Improved speech and swallowing

III. Specific Factors Affecting Risk for Craniofacial Deformities: Those Not Requiring an Intracranial Approach for Repair

Severity factors that increase risk and potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Severity of deformity
C. Presence of a syndrome
D. Number of previous operative procedures involving this region
E. Presence of airway abnormalities
F. Potential for hypertrophic or keloid scar formation

IV. Indicated Therapeutic Parameters for Craniofacial Deformities: Those Not Requiring an Intracranial Approach for Repair

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

Timing of surgery is determined by the nature of the abnormality, which requires evaluation of growth and function. Deformities involving growth should be treated at a time that would minimize adverse effects on facial growth.

The following procedures for the management of craniofacial deformities not requiring an intracranial approach for repair are not listed in order of preference:

A. Diagnostic records, including a panoramic radiograph, cephalometric analysis, photographic documentation, and dental model assessment. In most cases, computed tomography (CT) scans (possibly
3-dimensional CT scans), magnetic resonance imaging, and the use of computer assisted planning may be indicated.

B. Extracranial procedures:

1. Le Fort I, II, or III with or without grafting
2. Rhinoplasty
3. Naso-orbital reconstruction with or without grafting
4. Malar reconstruction
5. Frontal bone reconstruction
6. Otoplasty
7. Temporal fossa reconstruction
8. Implants to the craniomaxillofacial region
9. Mandibular reconstruction with or without grafting
10. Tissue expansion
11. Local or free tissue transfer to correct deformity of the craniomaxillofacial region
12. Midfacial and mandibular distraction osteogenesis

C. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Craniofacial Deformities: Those Not Requiring an Intracranial Approach for Repair

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes

1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Improved airway function
3. Stability of changes in soft tissue, skeletal, and/or dento-osseous structures of the craniomaxillofacial area
4. Improved ocular, nasal, and ear form and/or function
5. Improved appearance
6. Improved speech, mastication and/or swallowing

B. Known risks and complications associated with therapy

1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Skeletal relapse
3. Loss of teeth, bone, and/or soft tissue
4. Postsurgical functional or anatomical deformity of cranium, eyes, nose, and ears
5. Postsurgical functional and anatomical deformity of the face or jaws
6. Blindness, diplopia, and/or other ocular changes
7. Neurologic injury
8. Ptosis
9. Eyelid ptosis
10. Incisional alopecia

CRANIOFACIAL DEFORMITIES: PRIMARY CRANIAL DEFORMITIES REQUIRING TREATMENT THROUGH AN INTRACRANIAL APPROACH

I. Indications for Therapy for Craniofacial Deformities: Primary Cranial Deformities Requiring Treatment Through an Intracranial Approach

May include one or more of the following:

A. Evidence on examination of cranio-orbital malformation or craniosynostosis
II. Specific Therapeutic Goals for Craniofacial Deformities: Primary Cranial Deformities Requiring Treatment Through an Intracranial Approach

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Release of prematurely fused suture to allow for improved cranial growth when indicated
C. Improved head shape
D. Improved intracranial volume
E. Reconstruction to improve skull, forehead, and/or orbital shape
F. Improved neurologic function (eg, improved cerebrospinal fluid dynamics)

III. Specific Factors Affecting Risk for Craniofacial Deformities: Primary Cranial Deformities Requiring Treatment Through an Intracranial Approach

Severity factors that increase risk and potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Severity of condition and extent of suture involvement
C. Multiple suture involvement
D. Presence of a syndrome
E. Presence of neurologic symptoms or failure to meet developmental milestones
F. Presence of hydrocephalus
G. Presence of increased intracranial pressure or symptoms that may indicate possible increased intracranial pressure (eg, papilledema, engorged scalp veins, bulging fontanelle)

IV. Indicated Therapeutic Parameters for Craniofacial Deformities: Primary Cranial Deformities Requiring Treatment through an Intracranial Approach

A team approach is encouraged, and consultations with the appropriate pediatric subspecialty should be obtained. A neurologic surgeon should be involved when intracranial surgery is undertaken. The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

A. Craniectomy/suturectomy for craniosynostosis
B. Cranial orthotic in select cases
C. Bifrontal bone flap
D. Recontouring with multiple osteotomies and bone autografts
E. Encephaloceles, dermoid cysts, gliomas, or other pathological conditions
F. Endoscopic strip craniectomy with cranial molding helmet
G. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Craniofacial Deformities: Primary Cranial Deformities Requiring Treatment Through an Intracranial Approach

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
   1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Improved head, forehead, and orbital shape
3. Improved intracranial volume
4. Improved neurologic function (e.g., improved cerebrospinal fluid dynamics)

B. Known risks and complications associated with therapy
1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
2. Need for additional surgery
3. Neurologic disorders
4. Skull and/or forehead defects and irregularities
5. Eyelid dysfunction (e.g., ptosis)
6. Anosmia
7. Lacrimal dysfunction (e.g., dacryocystitis)
8. Canthal displacement
9. Diplopia
10. Blindness
11. Death

CRANIOFACIAL DEFORMITIES: SECONDARY CRANIAL DEFORMITIES REQUIRING TREATMENT THROUGH AN INTRACRANIAL APPROACH

I. Indications for Therapy for Craniofacial Deformities: Secondary Cranial Deformities Requiring Treatment Through an Intracranial Approach

May include one or more of the following:

A. Presence of increased intracranial pressure
B. Neurologic deterioration
C. Abnormal cranial development, with normal brain growth
D. Abnormal frontal and/or orbital development
E. Abnormal facial development
F. Malocclusion
G. Abnormal nasal development
H. Eyelid dysfunction
I. Diplopia, visual field loss, and progressive visual loss
J. Upper airway dysfunction
K. Abnormal speech and swallowing

II. Specific Therapeutic Goals for Craniofacial Deformities: Secondary Cranial Deformities Requiring Treatment Through an Intracranial Approach

The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.

A. Presence of a general therapeutic goal, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Improved neurologic function and development
C. Improved head shape
D. Improved forehead-orbital shape
E. Improved facial harmony
F. Improved occlusion
G. Improved upper airway
H. Improved eyelid function
I. Improved speech and swallowing
J. Improved vision

III. Specific Factors Affecting Risk for Craniofacial Deformities: Secondary Cranial Deformities Requiring
Treatment Through an Intracranial Approach

Severity factors that increase risk and potential for known complications:

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
B. Extent of neurologic impairment
C. Number and type of previous operations
D. Presence of shunts and/or alloplasts
E. Lacrimal dysfunction and/or dacryocystitis
F. Increased intracranial pressure
G. Presence of hydrocephalus
H. Sinus and nasal disease

IV. Indicated Therapeutic Parameters for Craniofacial Deformities: Secondary Cranial Deformities Requiring Treatment Through an Intracranial Approach

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

A pediatric ophthalmologic consultation may be considered when indicated, and a pediatric neurologic surgeon should be involved when intracranial surgery is undertaken. Timing of surgery is determined by the nature of the abnormality that requires evaluation of growth and function. Deformities involving growth should be treated at a time that would minimize adverse effects on growth.

A. Craniectomy for craniosynostosis
B. Bifrontal bone flap
C. Recontouring with multiple osteotomies and bone autografts
D. Extracranial procedures
   1. Le Fort I, II, or III with or without grafting
   2. Rhinoplasty
   3. Naso-orbital reconstruction with or without grafting
   4. Malar reconstruction
   5. Frontal bone reconstruction
   6. Otoplasty
   7. Temporal fossa reconstruction
   8. Implants to the craniomaxillofacial region
   9. Reconstruction with or without grafting as an adjunctive procedure
  10. Tissue expansion
  11. Local or free tissue transfer to correct deformity of the craniomaxillofacial region
  12. Midfacial and mandibular distraction osteogenesis
E. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Craniofacial Deformities: Secondary Cranial Deformities Requiring Treatment Through an Intracranial Approach

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
   1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Improved head, forehead-orbital, nasal, and facial harmony
   3. Improved masticatory function
   4. Improved eyelid function
   5. Improved upper airway, speech and swallowing
   6. Improved neurologic function (eg, improved cerebrospinal fluid dynamics and meets developmental
B. Known risks and complications associated with therapy
   1. Presence of a general known risk and/or complication, as listed in the section entitled General
      Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Anosmia
   3. Eye muscle imbalance
   4. Diplopia
   5. Ocular injury
   6. Globe position
   7. Neurologic deficit
   8. Impaired speech and swallowing
   9. Lacrimal dysfunction
   10. Loss of teeth, bone, and/or soft tissue
   11. Canthal dystopia and/or telecanthus
   12. Blindness
   13. Ptosis
   14. Cerebrospinal leak

**ORBITAL AND/OR NASO-ORBITAL DEFORMITIES**

I. Indications for Therapy for Orbital and/or Naso-orbital Deformities

*May include one or more of the following:*

A. Malpositioned orbits, with CT scan documentation
B. Naso-orbital deformity (eg, encephalocele or nasofrontal dysplasia)
C. Microphthalmia
D. Visual impairment (eg, diplopia and/or muscle imbalance)

II. Specific Therapeutic Goals for Orbital and/or Naso-orbital Deformities

*The goal of therapy is to restore form and/or function. However, risk factors and potential complications may preclude complete restoration of form and/or function.*

A. Presence of a general therapeutic goal as listed in the section entitled General Criteria, Parameters, and
   Considerations for Cleft and Craniofacial Surgery
B. Improved orbital position
C. Improved nasal form
D. Improved visual function
E. Improved canthal position
F. Improved sinus and/or nasal function

III. Specific Factors Affecting Risk for Orbital and/or Naso-orbital Deformities

*Severity factors that increase risk and potential for known complications:*

A. Presence of a general factor affecting risk, as listed in the section entitled General Criteria, Parameters, and
   Considerations for Cleft and Craniofacial Surgery
B. Extent of neurologic impairment
C. Number and type of previous operations
D. Telecanthus and/or canthal dystopia
E. Soft tissue excess
F. Soft tissue hypoplasia
G. Adnexal conditions
H. Sinus and/or nasal disease
I. Lacrimal dysfunction
J. Ocular cleft

IV. Indicated Therapeutic Parameters for Orbital and/or Naso-orbital Deformities

The presurgical assessment includes, at a minimum, a history and both a clinical and an imaging evaluation. Also see the Patient Assessment chapter.

An ophthalmologic consultation should be considered when indicated, and a neurologic surgeon should be involved when intracranial surgery is undertaken.

A. Surgical correction of orbital deformity and position by osteotomy with or without graft
B. Surgical correction of naso-orbital deformity by osteotomy with or without graft
C. Surgical correction of microphthalmia
D. Repair of encephalocele
E. Instructions for posttreatment care and follow-up

V. Outcome Assessment Indices for Orbital and/or Naso-orbital Deformities

Indices are used by the specialty to assess aggregate outcomes of care. Outcomes are assessed through clinical evaluation and may include an imaging evaluation.

A. Favorable therapeutic outcomes
   1. General favorable therapeutic outcomes, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Improved orbital form and position
   3. Improved eyelid position and function
   4. Improved vision
   5. Improved nasal form and function
   6. Improved eyelid position and function

B. Known risks and complications associated with therapy
   1. Presence of a general known risk and/or complication, as listed in the section entitled General Criteria, Parameters, and Considerations for Cleft and Craniofacial Surgery
   2. Eye muscle imbalance
   3. Diplopia
   4. Lacrimal dysfunction and/or obstruction
   5. Canthal dystopia and/or telecanthus
   6. Ptosis
   7. Nasal airway impairment
   8. Sinus disease
   9. Anosmia
   10. Interference with dental development
   11. Blindness

SELECTED REFERENCES – CLEFT AND CRANIOFACIAL SURGERY

This list of selected references is intended only to acknowledge some of the sources of information drawn on in the preparation of this document. Citation of the reference material is not meant to imply endorsement of any statement contained in the reference material. The list is not an exhaustive compilation of information on the topic. Readers should consult other sources to obtain a complete bibliography.

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RESIDUAL CLEFT LIP AND/OR NASAL DEFORMITIES REQUIRING SECONDARY MANAGEMENT


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**ORBITAL AND/OR NASO-ORBITAL DEFORMITIES**


