MIDFACE DISTRACTION IN MAXILLARY HYPOPLASIA SECONDARY TO CLEFT LIP AND PALATE

A Dissertation submitted in

partial fulfilment of the requirements

for the degree of

MASTER OF DENTAL SURGERY

BRANCH – III

ORAL AND MAXILLOFACIAL SURGERY

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

Chennai – 600 032

2010 - 2013

CERTIFICATE

This is to certify that **Dr. SENTIRENLA.R JAMIR**, P.G. Student (2010-2013) in the Department of Oral and maxillofacial surgery, Tamilnadu Government Dental College and Hospital, Chennai-600003, has done dissertation titled **"MIDFACE DISTRACTION IN MAXILLARY HYPOPLASIA SECONDARY TO CLEFT LIP AND PALATE**" under our direct guidance and Supervision in partial fulfillment of the regulations laid down by The Tamilnadu Dr.M.G.R. Medical University, Chennai, for MDS, Branch-III, Oral and Maxillofacial Surgery Degree Examination.

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Acknowledgement

As a sense of triumph is very much justified at this stage of completion of my dissertation, even more so is a sense of gratitude to all my peers, mentors and well wishers.

I gladly utilize this opportunity to express my deep sense of gratitude and indebtedness to my respected teacher and guide ***DR. B. Saravanan M.D.S, Phd.,*** *Professor, Department Of oral and maxillofacial surgery, Tamilnadu Government Dental College and Hospital, without whose everlasting inspiration, incessant encouragement, constructive criticism, and with valuable suggestions for improvement, the completion of this study would not have been possible. He gave me the inspiration to begin and the courage to sustain the effort, for which I am indebted to him.*

It has been my privilege to work under the guidance of ***DR. G. Umamaheshwari M.D.S.****, Professor and Head of Department of oral and maxillofacial surgery who has inspired me with her clear concepts while at the same time giving me the freedom to work, which helped me to develop my potential as a Research Worker. Because of her vast knowledge and his clear thinking every minute spent with her has saved me hours of work.*

I am immensely indebted to ***Dr. K.S.G.A. NASSER, M.D.S,*** *Principal, Tamilnadu Government Dental College and Hospital, for being a helping hand in providing required facilities and infrastructure.*

I express sincere and humble gratitude to my respected teacher, ***DR DURAIRAJAN M.D.S., professor, Department of oral and maxillofacial***

surgery, Tamilnadu Government Dental College and Hospital, *for his valuable support and help throughout the study.*

I am extremely grateful to my co-guide ***DR. SETHURAJAN M.D.S.****, for guiding me in the intricacies of qualitative research in which he is an expert. Without his contributions, this study would not have been possible. I am thankful to him for his constant support and encouragement.*

Indispensable help and cooperation extended by to ***DR.G. SURESHKUMAR, M.D.S., DR. G. KARTHIKEYAN M.D.S.*** *deserves a special mention, without the patience and the enthusiasm of whom this study would not have been possible.*

My sincere thanks to all the staff of Dept. of anesthesia, Government General Hospital, Chennai, for , their support and help throughout the study.

I am thankful to my colleagues, and others for their co-operation and help whenever I needed.

I dedicate this study to my Loving ***Parents, brother & sisters*** *and all my* ***Relatives*** *and* ***Friends*** *who have been on my side in times good and bad and boosted my morale constantly.*

My salutations to ***ALMIGHTY*** *– A tangent between zero and infinity – for his divine grace bestowed when needed.*

DECLARATION

I, **Dr.SENTIRENLA.R.JAMIR** do hereby declare that the dissertation titled "**MIDFACE DISTRACTION IN MAXILLARY HYPOPLASIA SECONDARY TO CLEFT LIP AND PALATE"** was done in the Department of Oral and Maxillo Facial Surgery, Tamil Nadu Government Dental College & Hospital, Chennai 600003. I have utilized the facilities provided in the Government dental college for the study in partial fulfillment of the requirements for the degree of Master of Dental Surgery in the speciality of Oral and MaxilloFacial Surgery (Branch III) during the course period 2010-2013 under the conceptualization and guidance of my dissertation guide, **Prof. Dr. B. SARAVANAN** MDS, Ph.D. I declare that no part of the dissertation will be utilized for gaining financial assistance for research or other promotions without obtaining prior permission from the Tamil Nadu Government Dental College & Hospital. I also declare that no part of this work will be published either in the print or electronic media except with those who have been actively involved in this dissertation work and I firmly affirm that the right to preserve or publish this work rests solely with the prior permission of the Principal, Tamil Nadu Government Dental College & Hospital, Chennai 600 003, but with the vested right that I shall be cited as the author(s).

Signature of the PG student

Signature of Guide

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This agreement herein after the "Agreement" is entered into on this day - Dec 2012 between the Tamil Nadu Government Dental College and Hospital represented by its **Principal** having address at Tamil Nadu Government Dental College and Hospital, Chennai - 600 003, (hereafter referred to as, 'the college')

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DR.B.SARAVANAN,52 yrs working as **professor** in the Department of Oral&Maxillofacial surgery, at the college, having residence address at35/2,(17),Barathi salai,Triplicane,Chennai.600005. (herein after referred to as thePrincipal investigator')

And

Dr. SENTIRENLA. R. JAMIR aged 29 years currently studying as **Post Graduate Student** in the Department of Oral&Maxillofacial surgery, Tamil Nadu Government Dental College and Hospital, Chennai-03 (herein after referred to as the 'PG Student and co- investigator').

Whereas the PG student as part of her curriculum undertakes to research on "MIDFACE DISTRACTION OSTEOGENESIS IN MIDFACE HYPOPLASIA SECONDARY TO CLEFT LIP AND PALATE"for which purpose the Principal Investigator shall act as principal investigator and the college shall provide the requisite infrastructure based on availability and also provide facility to the PG student as to the extent possible as a Co-investigator

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College represented by its **Principal** **PG Student**

Witnesses **Student Guide**

1.

2.

Content

ABSTRACT

BACKGROUND : cleft patients with moderate or severe maxillary hypoplasia has always been a challenge to treat by the orthognathic surgeon . These cases often require large movements but is always limited by the scar tissue. Conventional orthognathic surgery has been a choice of treatment but due to the high rate of relapse , distraction osteogenesis is preferred by many surgeons recently. The use of distraction osteogenesis over the facial region offers many advantages with lesser rate of relapse and the soft tissue adaptation to the soft tissue changes. Thus the use of distraction device is an alternative to orthognathic surgery for the correction of complex maxillofacial deformities

AIM: To study the outcome of mid face distraction using an intraoral device in maxillary hypoplasia secondary to cleft lip & palate to create a stable functional occlusion & good facial esthetic form

MATERIAL AND METHODS: This clinical studies was done on 4 patient with a custom made internal distraction device after a lefort 1 osteotomy cut. Pre-operative radiographs were done for many patient. After the surgery the patient were put on latency period for 5 to 7 days. The distraction was done at a rate of 1 mm per day. After the distraction the patient were kept on a consolidation period of 4 times the distraction period. The stage 2 surgery was done for distraction device removal after which patient have to wait for 6 months for lip revision and rhinoplasty.

RESULTS: All the 4 patient had maxillary hypoplasia secondary to cleft lip and palate. There was active movement of maxilla for all the patient. The midfacial movement was evaluated by using the following parameters clinical assessment, radiological assessments, Complication, Patient compliance, Overall patient satisfaction. The amount of maxilla advanced was around 20 mm.

INTERPRETATION AND CONCLUSION : In this study The amount of maxillary advancement achieved ranged between 15mm to 20mm for the patient which was clinically and radiologically satisfactory. There were few disadvantages that was encountered during the distraction period like pain during distraction which was bearable, stiffness of the device, impingement of the device over the buccal mucosa but overall the results that was achieved was quite satisfactory. The use of intraoral maxillary distraction device for correction of maxillary hypoplasia secondary to cleft lip and palate is a new paradigm shift in the treatment of maxillary defect over orthognathic surgery.

Introduction

INTRODUCTION:

Maxillary hypoplasia is defined as a clinical condition in which the maxillary bones are underdeveloped, causing midfacial deficiency and creates the illusion of protruding lower jaw even if it is anatomically normal. It is a common developmental problem in cleft lip and palate(CLP) deformities, and normally results from a combination of a congenital reduction in midfacial growth and the effects of the surgical scar from cleft palate repair. Cleft lip and Palate patients usually present with midfacial deficiency, narrow hard palate and class III malocclusions.

The major concern with maxillary hypoplasia is aesthetic. The under developed upper jaw giving a sunken appearance may attract unwanted attention and can make a patient feel uncomfortable. In addition, it can make it difficult to eat, and may cause problems in the future for the patient.

Corrective surgery is available to reposition the upper jaw in order to address the aesthetic and medical concerns associated with maxillary hypoplasia. It can be performed early in childhood to allow the jaw sufficient time to recover and develop as a child matures. A complete Evaluation can determine the cause, which may help the surgeon to identify other medical issues that might need attention. For both of these reasons, surgery may be recommended to correct the condition. This needs to be performed in consultation with an orthodontist who can work on repositioning the teeth in the mouth.

Surgical techniques to treat maxillary hypoplasia can vary, depending on the specifics of the case. Medical imaging can help the surgeon plan by illustrating the

specific areas of underdevelopment and providing information about the anatomy of the patient's upper jaw. Since the 1970s these deformities have traditionally been corrected by orthognathic Surgery, though distraction osteogenesis (1997) has become an alternative option for treatment of maxillary hypoplasia in CLP patients.

The aims of both techniques are to advance and down-graft the maxilla to a normal position in relation to the skull and the occlusion. A considerable number of literature now exists on the treatment of maxillary hypoplasia due to Cleft lip and palate by both conventional osteotomy and distraction osteogenesis.

Distraction osteogenesis is relatively a new surgical tool that has provided the craniofacial surgeon to treat dentofacial discrepancies. It is the process of generating new bone in a gap between two bone segments in response to the application of graduated tensile stress across the osteotomy site. The technique of bone lengthening by DO was first described in 1905 by CODIVILLA when he reported lengthening of a femur by axial distraction forces. Dr Gavriel.A. Ilizarov, a Russian physician, further developed the Distraction osteogenesis technique to the endochondral bone of the upper and lower extremities, in the 1950s in Kurgan in West Siberia. A unique feature of the distraction technique is that bone regeneration by DO is accompanied by simultaneous expansion of the functional soft tissue matrix, including blood vessels, nerves, muscles, skin, mucosa, fascia, ligaments, cartilage and periosteum, is called distraction histogenesis.

McCarthy et al (1992) reported the first clinical application in the Western literature of mandibular lengthening by gradual distraction in patients with hemifacial microsomia and Nagers' syndrome. Since then there has been many reports in the

literature on distraction osteogenesis of the craniofacial skeleton, the application of maxillary distraction have severely changed the treatment of maxillary retrusion in pattient with cleft lip and palate.

The aim of this study is to evaluate the efficacy of the Distraction Osteogenesis as a surgical modality for the maxillary hypoplasia secondary to the cleft lip and palate patients reported to the Department of Oral & Maxillofacial surgery, Tamilnadu Government Dental College & Hospital, Chennai,

Aim and Objectives

AIM

To study the outcome of mid face distraction using an intraoral device in maxillary hypoplasia secondary to cleft lip & palate to create a stable functional occlusion & good facial esthetic form

OBJECTIVES

To achieve a functional & aesthetic facial harmony with a marked correction of facial asymmetry.

- To evaluate clinical stability.
- To evaluate intraoperative risk factors and its after effects on clinical and functional recovery.

Embryology

EMBRYOLOGY

Growth and development of an individual can be divided into pre-natal and post-natal .The prenatal period of development is a dynamic phase in the development of human being because during these period the the height increase more rapidly than the post natal period. The prenatal life is divided into three

- Period of the ovum
- Period of the embryo
- Period of the fetus

Period of ovum

This period extends for a period of approximately two weeks from the time of fertilization. During these period the cleavage of the ovum and the attachment of the ovum to the intra- uterine wall occurs.

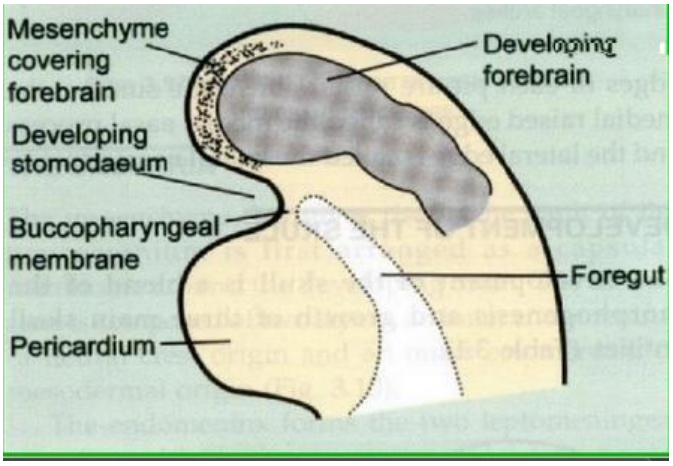
Period of embryo

This period extends from the fourteenth day to the fifty sixth day of intra-uterine life. During these period the major part of the development of the facial and the cranial region occurs

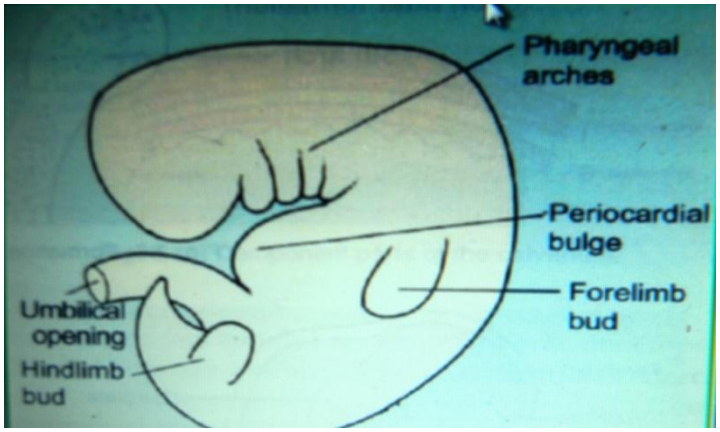
Period of fetus

This phase extends between the fifty sixth day of intra uterine life till the birth. In this period, accelerated growth of the cranio-facial structure occurs resulting in an increase in the size. in addition a change in proportion between the various structure also occurs

PRENATAL EMBRYOLOGY OF MAXILLA

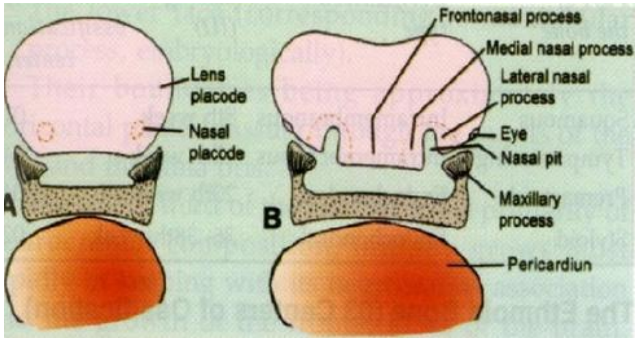


Around the fourth week of the floor of the stomadeum is formed by the buccopharyngeal membrane which saperates the stomadeum from the foregut Below the bulge a shallow depression which corresponds to the primitive mouth "STOMODEUM" appears. The floor of the stomadeum is formed by the buccopharyngeal membrane which saperates the stomodeum from the foregut.



By around the 4th week of the intra- uterine life, five branchial arches form in the region of the future head and the neck.each of these arches give rise to muscles , connective tissues, vasculature,skeletal components and the neural component of the the future face. The first branchial arch is called the mandibular arch and plays an important role in the development of the nasomaxillary region. The mesoderm covering the developing forebrain proliferate and forms a downward projection that overlaps the upper part of the stomodeum. This downward projection is called the fronto nasal process.

The stomodeum is thus overlapped superiorly by the frontonasal process. The mandibular arches of both the side form the lateral wall of the stomomadeum. The mandibular arch gives off a bud from its dorsal end called the maxillary process.

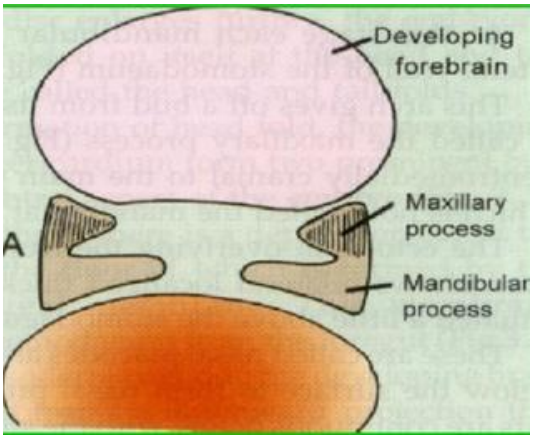


The maxillary process grow ventro-medio cranial to the main part of the mandibular arch which is now called the mandibular process. Thus at this stage the primitive mouth or stomodeum is overlapped from above by thefrontal process,below by the mandibular process and on either side by the maxillary process.The ectoderm overlying the fronto-nasal process shows bilateral localized thickening above the stomodeum . these are called the nasal placodes . these placodes soon sink and form the nasal pits. The formation of these nasal pits divide the frontonasal process into two parts

- The median nasal process
- The lateral nasal process

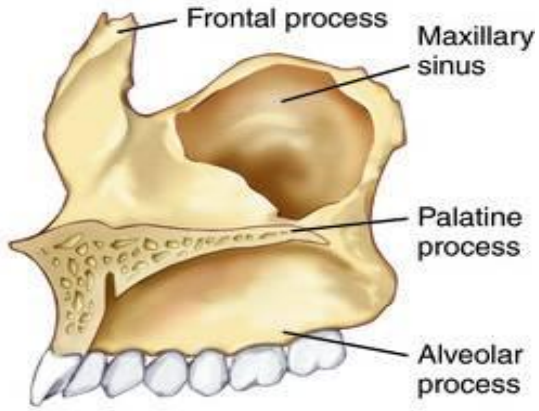
The two mandibular process grow medially and fuse to form the lower jaw and the lower lip as the maxillary process undergoes growth , the frontonasal process process become narrow so the the two nasal pits come closer. The line of fusion of the maxillary process and the medial nasal process corresponds to the naso-lacrimal duct

DEVELOPMENT OF MAXILLA

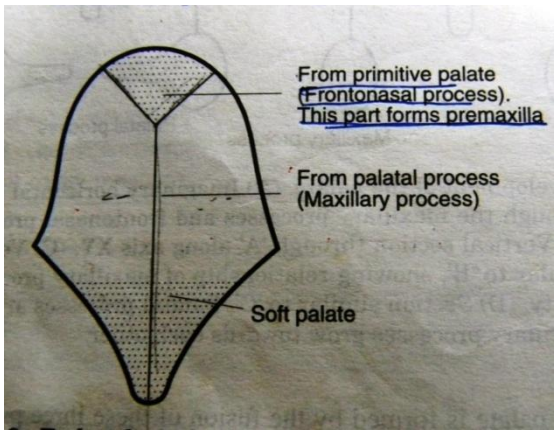


Develops from a centre of ossification in the mesenchyme of the maxillary process .No primary cartilage exists initially . the Centre of ossification is closely associated with the cartilage of the nasal capsule. Primary centre of ossification develops near the division of inferior orbital nerve into anterior superior alveolar nerve (future infra orbital region)

PRIMARY OSSIFICATION:



From the centre of ossification the bone formation extends posteriorly towards the developing zygoma and anteriorly towards the incisor region Ossification spreads superiorly to form the frontal process of maxilla. A bony trough is formed for the infra orbital nerve.From this trough lateral alveolar plate forms for the developing_tooth germs. Ossification spreads into the palatine processes to form the hard palate Medial alveolar plate develops from the palatal process .Medial and lateral alveolar plates form the trough for the tooth germs



SECONDARY CARTILAGE:

Also known as the zygomatic or the malar cartilage, appears in developing zygomatic process of maxilla .At birth body of maxilla is relatively small as it lacks the maxillary sinus

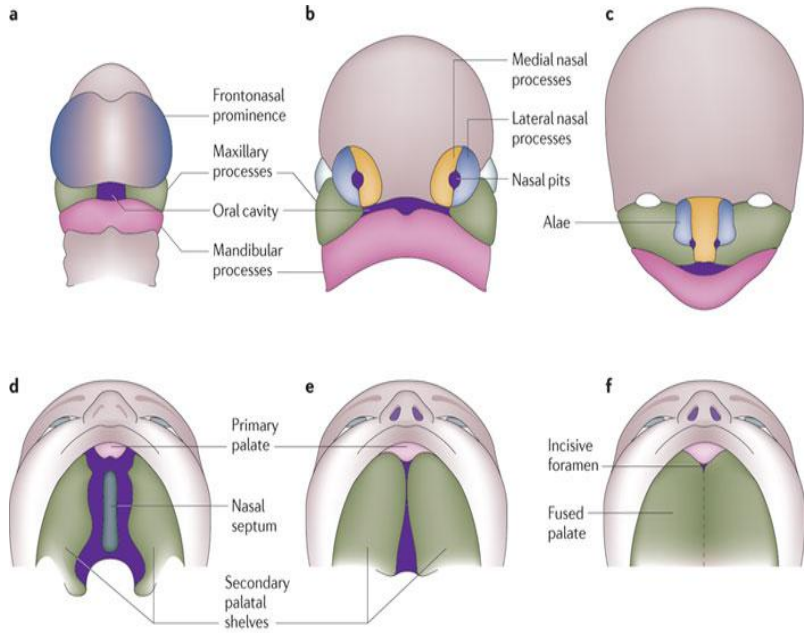
DEVELOPMENT OF MAXILLARY SINUS:

The maxillary sinus forms during the 16th week as shallow groove on the nasal aspect of the developing maxilla. Still rudimentary at birth and is that of a size of a pea

DEVELOPMENT OF PALATE

- The palate is formed by the contribution of the

1. Maxillary process
2. Palatal shelves given off by the maxillary process or the palatal process
3. Fronto-nasal process



From each maxillary process, a plate-like shelf grows medially. This is called the palatal process. so the palate is formed by

- The two palatal processes
- The primitive palate formed from the frontonasal process

The definitive palate is formed by the fusion of these three parts as follows

- Each palatal process fused with the posterior margin of the primitive palate
- The two palatal processes fuse with each other in the midline. Their fusion begins anteriorly and proceeds backwards
- The medial edges of the palatal processes fuse with the free lower edge of the nasal septum thus separating the two nasal cavities from each other and from the mouth

At a later stage, the mesoderm in the palate undergoes intra membranous ossification to form the hard palate. However ossification does not extend into the most posterior portion which remains as soft palate.the part of the palate derived from the frontonasal process forms the premaxilla which carries the incisor teeth

POST NATAL GROWTH OF MAXILLA

The growth of the naso maxillary complex is brought about by the following mechanism

- Displacement
- Growth of the sutures
- Surface remodeling

1. Displacement

Maxilla is attached to the cranial base by means of a number of sutures. Thus the growth of the cranial base has a direct bearing on the nasomaxillary growth. The growth occur by two types of displacement

- Secondary/ passive displacement
- Primary displacement

The secondary displacement occurs in a downward and forward direction as the cranial base grows. The nasomaxillary complex is moved anterorly as the middle cranial fossa grows in that direction.the passive displacement of the maxilla is an important growth mechanism during the the primary dentition years but becomes less important as growth of cranial base slow

The primary displacement is also seen in also seen in a forward direction. This occurs by the growth of the maxillary tuberosity in a posterior direction. This results in the whole maxilla being carried anteriorly. the amount of this forward displacement equals the amount of posterior lengthening. this results in the whole maxilla being carried anteriorly In this type of displacement the bone is displaced by its own enlargement.

2. Growth at sutures

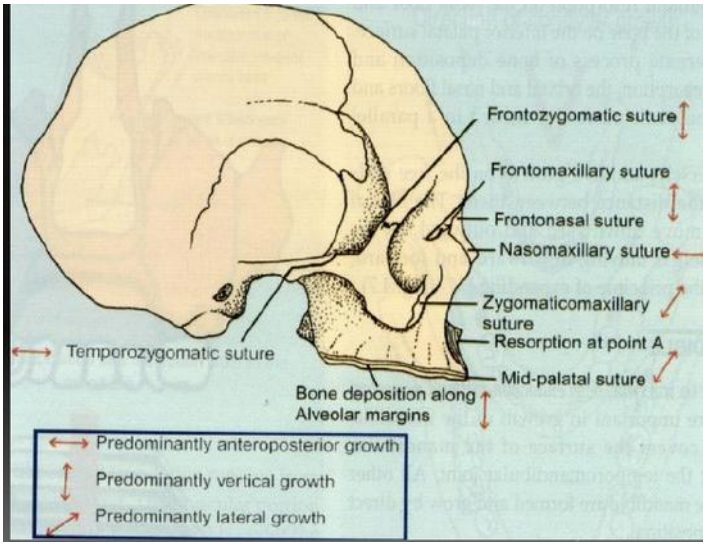
The maxilla is connected to the cranium and the cranial base by a number of sutures. These suture includes

- Fronto nasal suture
- Fronto maxillary suture
- Zygomatico temporal suture
- Zygomatico maxillary suture
- Pterygopalatine suture

The mechanism by which the suture connective tissue grow are

- Proliferation
- Ossification
- Surface apposition
- Resorption
- traslation

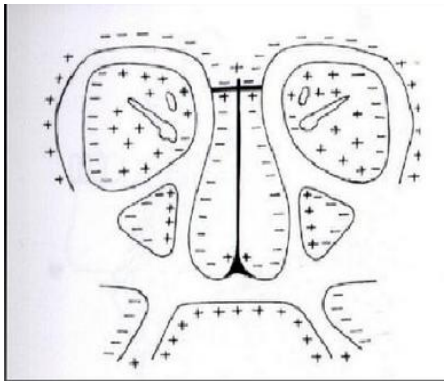
these sutures are all oblique and more or less parallel to each other .this allows the downward and forward repositioning of the maxilla as growth occurs at these sutures along with the soft tissue



3.<u>Surface remodeling</u>

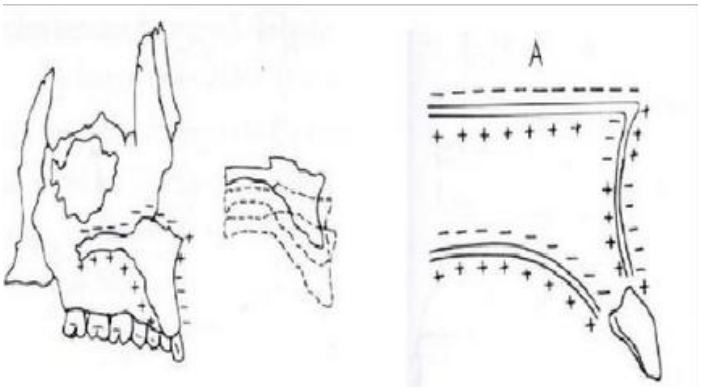
The surface remodeling of the bone occurs by bone deposition and resorption to bring about

- ❖ increase in size
- ❖ change in shape of the bone
- ❖ change in functional relationship

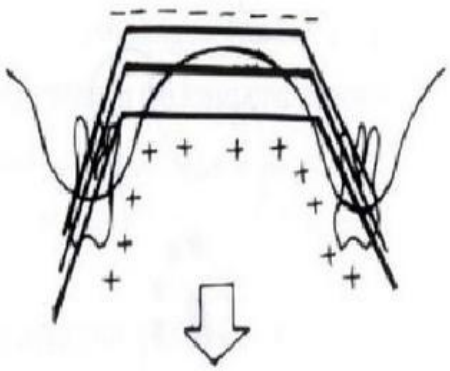


-----(resorption ++++deposition)

The bone remodeling of the palate that moves the maxilla downward and forward



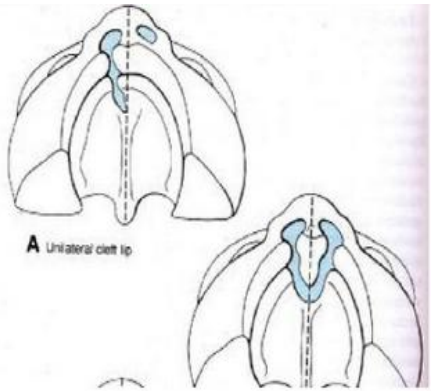
-Growth of the palate exhibiting v shape growth



DEVELOPMENT OF FACIAL ANOMALIES

1. Cleft palate

It occurs less common than cleft lip. It occurs due to



- ❖ lack or failure of fusion between medial and lateral palatine process and nasal septum.
- ❖ Interruption of the growth after initial fusion(at any point)
- ❖ Interference with palatal shelves elevation

It can occur as

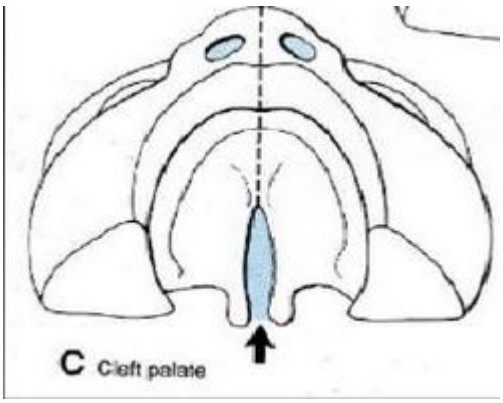
- ❖ Cleft primary palate
- ❖ Cleft secondary palate
- ❖ Cleft primary and secondary palate

Cleft primary palate

The Cleft occurs anterior to incisive foramen and it results from failure of lateral palatine process to meet and fuse with primary palate. It is often associated with missing or malformed teeth

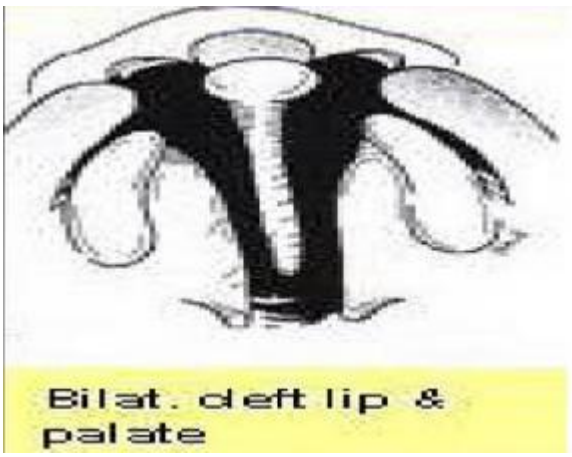
Cleft secondary palate

It occurs posterior to incisive foramen. As fusion of the secondary palate occurs at incisive papilla and proceed posteriorly. The cleft may vary from simplest form of bifid uvula to a complete cleft involving both hard and soft palate.



Cleft both primary and secondary palate

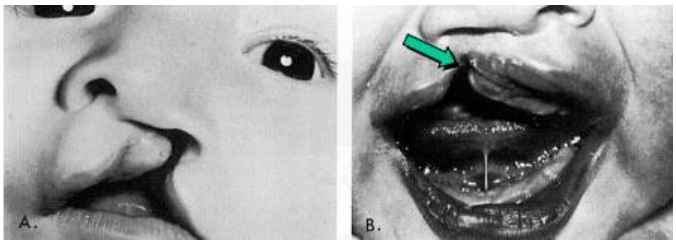
Complete palatal cleft which results from failure of growth or lack of fusion of 3 palatine process with each other and with the nasal septum.



2. Midface hypoplasia

Craniosynostosis and midface retrusion are common features of a number of specific syndromes, most of this also include deformities of the hands and feet. The membranous components of the facial skeleton fail to grow normally while the cartilaginous components are largely unaffected. Consequently, relative overgrowth of the nasal septum may produce a prominent, often deviated nose with obstruction of the nasal airway. Delaire et al (1963) have applied the term faciostenosis to describe these states of midface hypoplasia. While it is not yet certain that this hypoplasia results from premature fusion of the facial sutures,

3. Cleft lip

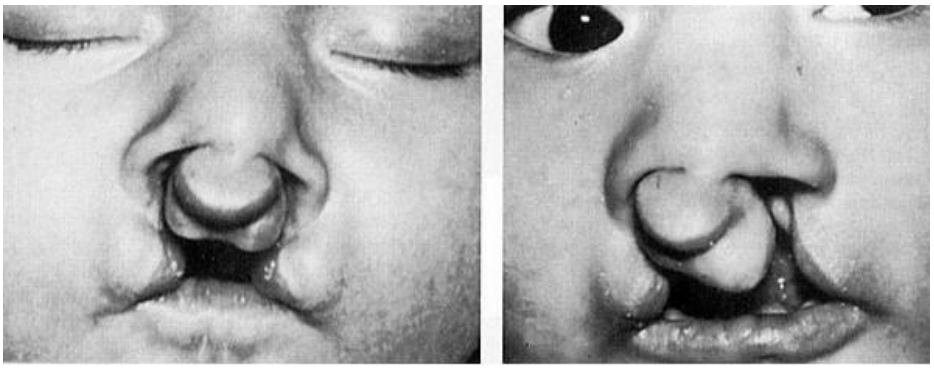


The cleft lip can either occur as a unilateral or bilateral cleft lip or in combination with a cleft palate

<u>Unilateral Cleft Lip</u>

•it Forms as a persistent labial groove.Labial groove should disappear as the maxillary prominence. fuse with merged medial nasal prominences Stretching of epithelium causes tissue breakdown and cleft formation happens. Simonart band: bridge of tissue spanning the cleft (arrow below)

Bilateral cleft lip



Similar to unilateral cleft lip. It occurs as a central soft-tissue mass that moves freely.

Surgical Anatomy

SURGICAL ANATOMY

The **maxilla** is a fusion of two bones along the palatal fissure that form the upper jaw. The alveolar process of the maxilla holds the upper teeth, and is referred to as the maxillary arch. The maxilla attaches laterally to the zygomatic bones (cheek bones). The maxilla assists in forming the boundaries of three cavities:

- the roof of the mouth
- the floor and lateral wall of the nasal antrum
- the wall of the orbit

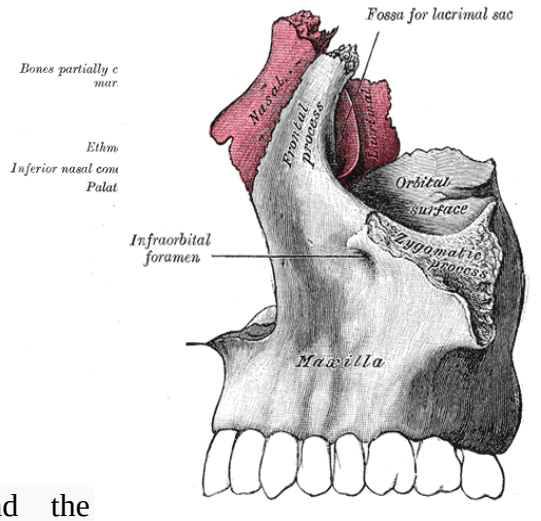
The maxilla also enters into the formation of two fossae: the infratemporal and pterygopalatine, and two fissures, the inferior orbital and pterygomaxillary

COMPONENTS:

Each half of the fused maxilla consists of:

1. The body of the maxilla
2. Four processes
    - The zygomatic process
    - The frontal process of maxilla
    - The alveolar process
    - The palatine process
3. Infraorbital foramen
4. The maxillary sinus

ARTICULATIONS



The maxilla articulates with nine bones:

- With two cranial bones : the frontal and ethmoid
- Seven facial bones: the nasal, zygomatic, lacrimal, inferio r nasal concha, palatine, vomer, and the adjacent fused maxillary bone.
- Sometimes it articulates with the orbital surface, and sometimes with the lateral pterygoid plate of the sphenoid.

BODY OF THE MAXILLA

- the body is the largest part and is pyramidal in shape
- interior part of the body is hollowed out by the maxillary paranasal air sinuses which defines its anterior surface and the canine fossa just above the alveolar process .above the canine fossa and just below the infraorbital rim , the infraorbital foramen is located between 8 to 20 mm from the nasal floor
- upper surface forms the floor of the orbit
- anterior surface forms the curved external surface of the upper jaw
- posterior surface provides the anterior wall of the infratemporal fossa
- medial surface forms structural component of the nose. superiomedially the frontal process of the maxilla extends upward between the nose and the orbit forming the lateral wall of the nasal cavity and articulate with the frontal and nasal bone. During osteotomy of the lateral nasal wall , care is taken not to extent

the osteotomy no farther than 25 to 30mm posteriorly from the piriform rim. The mean length of the medial sinus wall from the piriform rim to the descending palatine canal is approximately 34 mm.

BONY PALATINE PROCESS

– provides the floor of the nasal cavity

– provides the anterior ¾ of the hard palate (the remaining ¼ from the paired palatine bones)

POSTERIOR BORDER OF THE MAXILLA

The maxillary tuberosity defines the posterior border of the maxilla and the pterygomaxillary fissure lies between the maxillary tuberosity and the pterygoid plate of the sphenoid bone. This anatimis land mark is important in the pterygomaxillary dysjunction during Lefort 1 osteotomy because the descending palatine artery is located medially within 10mm from the maxillary tuberosity as the osteotome is driven anteriorly and medially through the pterygomaxillar articulation

PTERYGOPALATINE FOSSA

- It is located between infratemporal surface of maxilla and the pterygoid process and houses maxillary nerve
- The terminal part of the maxillary artery – the internal maxillary artery enter the pterygopalatine fossa approximately 16mm above the nasal floor
- within the pterygopalatine fossa the maxillary nerve is associated with the pterygopalataine ganglion (secretomotor) from which several other branches are given off before the nerve enters the orbit

- – posterior superior alveolar nerves (enter maxilla via post alveolar foramina)
- – greater palatine nerve
- – lesser palatine nerve
- – nasal nerves – lateral and medial posterior
- - superior nasal
- – nasopalatine

NASOLACRIMAL DUCT

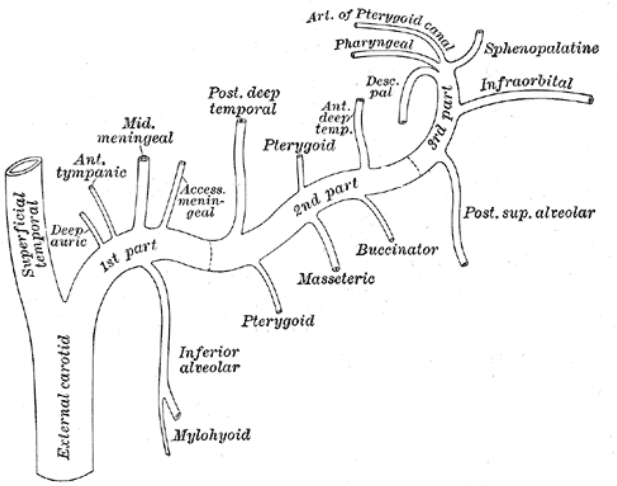
The nasolacrimal duct lies in the bony wall between the maxillary sinus and the nasal cavity. The duct terminates below the inferior turbinates I the inferior meatus. The location of the nasolacrimal duct underneath the inferior turbinate is 10 to 14 mm posterior from the piriform aperture and 10 to 21 mm from the nasal floor. Atrophic rhinitis is a potential complication of inferior turbinectomy performed during Le fort 1 superior repositioning

VASCULAR ANATOMY

The maxillary artery or internal maxillary artery is an artery that supplies deep structures of the face. it branches from the external carotid artery just deep to the neck of the mandible.

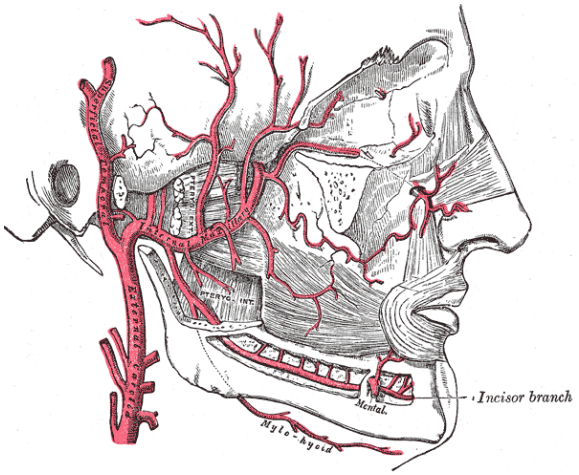
The maxillary artery, the larger of the two terminal branches of the external carotid artery, arises behind the neck of the mandible, and is at first imbedded in the substance of the parotid gland; it passes forward between the ramus of the mandible and the sphenomandibular ligament, and then runs, either superficial or deep to the lateral

pterygoid muscle, to the pterygopalatine fossa. It supplies the deep structures of the face, and may be divided into mandibular, pterygoid, and pterygopalatine portions.



First portion

The first or mandibular portion passes horizontally forward, between the neck of the mandible and the sphenomandibular ligament, where it lies parallel to and a little below the auriculotemporal nerve; it crosses the inferior alveolar nerve, and runs along the lower border of the lateral pterygoid muscle. Branches include:



- Deep auricular artery
- Anterior tympanic artery
- Middle meningeal artery
- Inferior alveolar artery which gives off its mylohyoid branch just prior to entering the mandibular foramen
- Accessory meningeal artery

Second portion

The **second or pterygoid portion** runs obliquely forward and upward under cover of the ramus of the mandible and insertion of the temporalis, on the superficial (very frequently on the deep) surface of the lateral pterygoid muscle; it then passes between the two heads of origin of this muscle and enters the fossa. The branches include:

- Masseteric artery
- Pterygoid branches
- Deep temporal arteries (anterior and posterior)

Third portion

The third or pterygopalatine portion lies in the pterygopalatine fossa in relation with the pterygopalatine ganglion. This is considered the terminal branch of the maxillary artery. The branches include:

- Sphenopalatine artery (Nasopalatine artery is the terminal branch of the Maxillary artery)
- Descending palatine artery
- Infraorbital artery
- Posterior superior alveolar artery
- Artery of pterygoid canal
- Pharyngeal artery
- Middle superior alveolar (a branch of the infraorbital artery)
- Anterior superior alveolar arteries (a branch of the infraorbital artery)

The internal maxillary artery enter pterygopalatine fossa approximately 16 mm above the nasal floor and gives posterior superior alveolar arteries that run downward on the posterior surface of the maxilla. In the deeper dissection infraorbital vessels can be found as it emerges at the infraorbital foramen. A large descending palatine artery which is the major vessels encountered during maxillary osteotomies descend throught the palate as greater and lesser palatine arteries. The average distance from the most inferior of the pterygomaxillary junction to

- Posterior superior alveolar nerve is - 15 mm
- Infraorbital artery is - 32 mm
- Descending palatine artery is- 25 mm

The pterygoid plexus is venous and surrounds the maxillary artery deep to lateral pterygoid muscle. It drains into the maxillary vein and into the facial vein via the deep fascial vein accompanying the branches of the maxillary artery. It reaches the cavernous sinus via the V3 nerve through the foramen ovale and to the middle minengeal veins through the foramen spinosum

In addition a vascular perfusion, pulpal blood flow to the dentition and the gingival tissue must be considered. Human research have shown that ischemic episode in mobilized maxillary segments can occur for a brief moment after Lefort 1 osteotomy . However laser doppler flowmeter have shown a significant increase in pulpal blood flow between the 1st and 3rd week after Lefort I osteotomy although gingival flow is not altered significantly.

Review of Literature

HISTORY OF DISTRACTION OSTEOGENESIS

Alessandro Codivilla[19] **(1905)** was the first surgeon to introduce distraction osteogenesis for lengthening of the lower limbs.

Gavril Ilizarov (1934) [45] developed a procedure based on the biology of the bone and on the ability of the surrounding soft-tissues to regenerate under tension.

Snyder (1973) [45] developed Swanson external fixator which was used to lengthen the canine mandible.

Michieli and moitti (1977)[5] reported on Distraction osteogenesis of the dog mandible, and found that the surgical procedure was successful.

Mc carthy et al (1992) did clinical application of mandibular elongation by gradual distraction in patient with hemificial microsomia and nager syndrome.

Block and co authors(1994 and 1997)[5] reported segmental maxillary distraction in a canine model.

CAUSES OF MAXILLARY HYPOPLASIA

Virchow in (1851)[9] coined the term craniosynostosis and formulated the classic theory known as Virchow"s law. This states that premature fusion of a cranial vault suture (cranoiosynostosis) inhibits skull growth perpendicular to the fused sutures and results in a compensatory growth at the open sutures. These disorders are characterized by sutural involvement that not only include the cranial vault but also extends into the skull base and midfacial structures that leads to cranial vault dysmorphology and total midface hypoplasia

Lisa H. Lowe, Timothy N. Booth, Jeanne M. Joglar,Nancy K. Rollins (2000)[25] wrote an article titled "midface anomalies in children" stated that The causes and embryogenesis of craniofacial syndromes are not well understood. Although many of these syndromes are congenital, most occur sporadically. They are thought to result from in adequate migration and formation of facial mesenchyma and the skull bases.

CLINICAL FEATURES OF MIDFACIAL HYPOPLASIA

Suresh menon. Ravi manireker and ramen sinha (2010)[31] in an article described various clinical features associated with midfacial hypoplasia. The Main Clinical Features of the Condition Could Include Para nasal hollowing, Narrow nasal base, Deepened nasolabial folds, Hypoplastic Zygoma ,Unilateral or bilateral posterior cross bite Narrow tapering maxillary arch form,Narrow and high palatal vault.

Y.-F. Liao, S. Numhom, L.-J. Lo, M. S. Noordhoff: (2011)[58] in an article described the various clinical features of midline facial deficiencies typified by nasolabiomaxillary hypoplasia: poorly developed septum, small alar cartilages, deficient columella, illdefined Cupid's bow, absent labial frenulum, and hypoplastic premaxilla, giving a concave profile and a Class III malocclusion

TREATMENT OF MAXILLARY HYPOPLASIA

Rachmiel, D. Aizenbud, M. Peled (2004)[39] in a study of Long-term results in maxillary deficiency suggested that possible treatment for patients suffering from maxillary hypoplasia or midface deficiency is maxillary distraction. This can be indicated in severe angle class III malocclusions, and severe maxillary hypoplasia among cleft patients and other craniofacial deformities.

L. K. Cheung, H. D. P. Chua(2006)[6] did an analysis of cleft maxillary osteotomy and distraction osteogenesis and concluded that that distraction osteogenesis tends to be preferred to conventional osteotomy for younger CLP patients with more severe deformities. In such cases it was feasible to use distraction to correct moderate to large movement of the maxilla by either complete or incomplete Le Fort I osteotomy, and a concurrent mandibular osteotomy was less frequently required.

K. Yamauchi, M. Mitsugi, T. Takahashi(2006)[57] stated that distraction osteogenesis is now being applied to midfacial deformities especially in maxillary hypoplasia, because of its ability to simultaneously address osseous and soft-tissue deficiencies during a single treatment regimen.

N. Nadjmi, F. Schutyser, R. Van Erum (2006)[33] suggested that a possible treatment for patients suffering from maxillary hypoplasia or midface deficiency is maxillary distraction. This can be indicated in severe angle class III malocclusions, and severe maxillary hypoplasia

Y. Mori, T. Eguchi et al (2006)[32]did a review on the conventional one-stage 2-jaw surgery combining Le Fort I osteotomy and mandibular setback surgery which has been used to treat severe maxillomandibular discrepancy in cleft lip/palate patients. The authors In some patients, stable occlusion and a good aesthetic outcome of this method are precluded by the presence of severely contracted soft tissue. Recently, maxillarydistraction has been used for midface advancement in such patients. This technique allows the overlying midface to be advanced, because distraction osteogenesis gradually lengthens both the bones and the soft tissues among cleft patients and othercraniofacial deformities.

X.-X. Wang, X. Wang, Z.-L. Li, B. Yi, C. Liang, Y.-L. Jia, B.-S. Zou (2009)[60] in an article Anterior maxillary segmental distraction for correction of maxillary

hypoplasia that these patients require orthognathic surgery for its correction. Le Fort I osteotomy is widely employed for this purpose, but poor maxillary and alveolar growth in the transverse and sagittal planes, and palatal scarring, make maxillary advancement greater than 6 mm difficult to achieve. A relatively high recurrence rate of 20–60% has been documented with conventional orthognathic surgery.

TIMING OF THE SURGERY

G. Swennen, H. Schliephake, R. Dempf, H. Schierle, C. Maleve(2001)[49] did a review of literature on Craniofacial distraction osteogenesis. The authors reported that craniofacial DO has been successfully in the paediatric, adolescent and adult patient population. Patient age at the time of distraction is the most important single variable with potentially the most profound effect on the outcome of DO. The authors recommended to perform maxillary advancement from the age of 5 years after a complete LeFort I osteotomy using an internal or external device, with 1 mm distraction rate, 4–5 days latency period and 2–3 months consolidation period.

Lim.K.Cheung and Hannah Daile (2006)[6] did a study on the midface distraction and discussed regarding the age of the patient when to start distraction osteogenesis. Conventional osteotomy cut are normally recommended in patient only when the mandibular growth has ceased. Most patient who receive such treatment are aged 16 years or more.

Few younger patient have maxillary osteotomies because of the fear that they might terminate maxillary growth prematurely. Conventional cleft osteotomies are performed on children and teenager only in exceptional circumstances such as if they face marked psychological pressure from peers or at school. The surgeon's who

performed distraction on teenagers younger than 16 years have aimed to minimize facial deformities.

ORTHOGNATHIC SURGERY VS DISTRACTION OSTEOGENESIS

H. D. P. Chua, T. L. Whitehill, N. Samman, L. K. Cheung(2010)[7] in a review of literature titled Maxillary distraction versus orthognathic surgery in cleft lip and palate patients effects on speech and velopharyngeal function concluded that distraction osteogenesis has no advantage over conventional orthognathic surgery for the purpose of preventing velopharyngeal incompetence and speech disturbance in moderate cleft maxillary advancement.

Kumar Dheeraj, Namrata Rastogi and Meenakshi Singh (2011)[10] in an article reviewed that the traditional orthognathic surgery and craniofacial reconstruction has gained generalized acceptance but it has its own limitations. Many congenital deformities require a large amount of skeletal movements and when acutely stretched, the surrounding soft tissues cannot adapt to their new position, resulting in regenerative changes, relapse, compromised function and aesthetics. Hence, they concluded that in light to this, new approaches have been developed amongst which the most suitable alternative approach is "distraction osteogenesis."

Adi Rachmiel et al (2012)[38] did a study on the treatment of maxillary cleft palate-Distraction osteogenesis vs. orthognathic surgery. The study results demonstrated that there is greater maxillary advancement using distraction osteogenesis with improved stability over time and further maxillary growth in growing patients . So the study concluded that in cases with mild maxillary deformities without significant bone deficiency a one stage orthognathic surgery gave satisfactory results and in moderate or severe maxillary deficiency or in growing patients the distraction

methods have showed advantages over conventional orthognathic surgery in terms of greater maxillary movement, skeletal stability, and soft tissue profile changes.

Ahmed Alyamani , Sondos Abuzinada (2012)[3] reviewed a literature and concluded that Patients with a severe maxillary hypoplasia of 6 mm or more and excessive palatal scaring are successfully treated with DO. Conventional le fort I is reserved for pa- tients with less severe maxillary hypoplasia. Both techniques gave promising results providing having followed the proper selection criteria.

Lim Kwong Cheung , Hannah Daile P Chua, Margarett Hagg(2006)[24] did a study aiming to compare the postoperative clinical morbidities in cleft lip and palate patients treated with distraction osteogenesis versus conventional orthognathic surgery and concluded that there were no major differences in the clinical morbidities between the osteotomy and distraction groups. Distraction provided better skeletal stability, whereas there was a significant amount of skeletal relapse in the first 12 weeks after conventional cleft maxillary osteotomy.

Chua Hd, Cheung Lk (2012)[8] did a study to compare soft tissue changes from maxillary distraction osteogenesis versus orthognathic surgery in patients with cleft lip and palate and concluded that both conventional orthognathic surgery and distraction osteogenesis can induce significant soft tissue changes of the upper lip and nose, particularly with maxillary advancement but distraction osteogenesis generates more consistent hard to soft tissue ratios.

Mario J. Imola (2002)[27] reviewed an article on versatility of distraction osteogenesis and stated that distraction osteogenesis has great potential for several congenital and acquired osseous defects that can be encountered within the craniofacial skeleton. Numerous advantages have been cited among the growing number of advocates for craniofacial DO: (1) The surgery is less invasive and associated with a shorter

hospital stay, less tissue dissection and bone manipulation, and decreased blood loss. (2) There is no need for bone grafting to maintain repositioned segments. (3) There is no risk of growth restrictions secondary to plate fixation. (4) In severe skeletal deficiencies, there is the potential for substantially larger osseous movements and greater stability postoperatively, especially in cases with a scarred soft tissue bed. (5) There is the potential for improved soft tissue augmentation associated with distraction histogenesis. (6) Finally, surgical intervention is possible in younger age groups.

CLASSIFICATION OF DISTRACTION DEVICE

Pereire et al (2007)[35] gave a brief classification of distraction device used in oral and maxillofacial surgery1)Relation with the skin surface-External – anchored to the distraction site by transcutaneous pins that are externally connected to the distraction device,Internal – the entire mechanism is inside the oral cavity or beneath cutaneous tissues 2)Type of anchoring tissues-Tooth borne – supported only by teeth , Bone borne- anchored exclusively on bone tissues, Hybrid- fixed to both bone and teeth 3)Number of vectors of movement-Monovectorial- provides only one possible direction of bone movement

Neelam Andrade et al (2011)[2] in an article classified distraction device into two basic types: external and internal devices. The external devices are attached to the bone by percutaneous pins connected externally to fixation clamps. The fixation clamps, in turn, are joined together by a distraction rod which when activated, effectively pushes the clamps and the attached bone segments apart,generating new bone in its path. Internal devices are placed subcutaneously or within the oral cavity i.e. intraorally. They can be placed above i.e. extra mucosal or below i.e. sub mucosal or buried under the soft tissue. Devices attached to the bone are bone-borne; to the

teeth are tooth-borne or attached to the teeth and bones are the hybrid type of distraction appliances. Depending on the direction of lengthening, devices have been classified as unidirectional, bidirectional, or multidirectional devices.

sandhya maheshwari , sanjeev k verma , mohd. tariq , kc prabhat, **shailendra kumar (2011)**[28] classified distraction device, **Based on site-** Mandibular ,Midface or maxillary, Alveolar ,Transport(Reconstruction of neo-mandible/ neo-condyle), Rigid external distractor (RED) **Based on use,** ***External distractor- 1)***Unidirectional (activated in one plane of space), 2)Bidirectional (activated in two plane of space), 3)Multiplanner (activated in three plane of space) 4)Rigid external distraction (RED) system.***Internal distractor-1)***Mandibular intraoral distraction device 2) Modular internal distractor (MID), 3) Tooth borne distractor e.g. rapid canine distractor, alveolar distractor.

DISTRACTION OSTEOGENESIS – EXTERNAL VS INTERNAL DEVICE

Joseph .E .Van et al (2006)[19] reviewed an article comparing the external and internal device. The external distracters allow change in the primary vectors during distraction and modification in osteotomy design but the disadvantage is that external distractor must be worn for several months. In contrast, internal device are less visible and patient acceptance is greater. However they are technically more difficult to place and changing of the primary vectors is more difficult

Stephanie Joy Drew (2008)[46] in an article stated that the external distractor device have the benefit of being able to be adjusted in 3 dimensions as the maxilla, midface, and orbits are moving forward. They have been used in children as well as adults. They can be attached to the bone or to the dentition. Disadvantages of these external devices are that they are worn as an external "halo" during the distraction and

consolidation period, creating a difficult psychosocial setting for children and adults already dealing with the stigma of a facial deformity.

The pins that secure the device to the skull can loosen and need to be tightened over the period of fixation. These constant tightening adjustments may lead to perforation of the inner table of the skull. Whereas internal devices are more stable compared with the wires that stretch off the maxilla attached to the external devices. Thus, during the period of consolidation the maxilla maintains stability better because the internal devices act more like rigid fixation. The greatest disadvantage of these internal devices is that most of these internal distraction devices are unidirectional and cannot be manipulated to move

the maxilla in 3 dimensions. Thus, the author concluded that if the treatment goal is to establish a final occlusion with 1 surgery, then these devices are not the answer; that is, unless a straightforward movement is all that is needed. However, these distracters can be used for a staging surgery, the final outcome will be the same: a functional and esthetic and stable result

T. R. Meling, H. ,E. Høgevold, B. J. Due,Tønnessen, P. Skjelbred(2010)[29] did a comparative study on Midface distraction osteogenesis: Internal vs. external devices. The two groups were compared regarding operation time, peroperative blood loss and complications. Operation time was shorter during the fixing of the external device than in the internal device. Peroperative blood loss and complication rates were similar. Th advantages of internal distraction are; elimination of skin scarring caused by translation of transcutaneous fixation pins,improved patient compliance during the consolidation phase; improved stability of the attachment of the device to the bone.

The major drawbacks are: the need for precise positioning of the device, regarding alignment between the two sides and the angulation, which can be

challenging in patients with numerous previous operations and subsequent cranial thinnings or deficiencies; the inability to alter the distraction vector during the distraction process; the need for a second major operation to remove the device, although this can be overcome by using biodegradable devices.

The potential benefits of external devices include: unsurpassed three dimensional(3D) control during distraction; the ability to alter the distraction vector during the process; and the avoidance of major resurgery for device removal after the consolidation phase. The major drawbacks are:skin scarring caused by translation of transcutaneous fixation pins and/or skin, infections around the pins and pin loosening, the need for patient compliance during the consolidation phase; and intracranial pin migration, either accidental or gradual patients needed halo adjustments under general anaesthesia at some point,representing a major disadvantage.

The authors concluded that, the internal distraction device can be considered the 'gold standard' for the treatment of midface retrusion. The use of an external distraction device in midface distraction osteogenesis was associated with a shorter operation time and the two devices were not dissimilar regarding peroperative blood loss or complications. An external device affords better 3D control during the distraction process, therefore external distraction seems to be preferable in patients who will tolerate this treatment.

Seji lida et al (2007)[24] did a study and cited the advantages of external distraction device . the external device can be use for severe maxillary deficiency because these distractor can change the vector of distraction and has less limitation on the vector of distraction. However wearing the device can cause psychological stress during the distraction and retention period . where as the internal device have less usage due to

the difficult placement of the 2 device for correct direction and to parallel the device on both side when two device have to be used .

Stuart super et al (2006)[50] did a study on the use of intraoral maxillary distraction and conclude that the extraoral provide significant stability , precise multiplanar vector control and unlimited potential for distraction but these appliance is advantages for severe hypoplastic in which lefort 2 or lefort 3 is indicated ,so in case for the treatment of the patient,s with moderate maxillary hypoplasia where a unidirectional advancement of 8mm to 12 mm is required the internal device is the treatment option

ORTHODONTIC MANAGEMENT

Lesne.V (2004)[23] in his article Orthodontic treatment of children with cleft palates continues through the periods of the three dentitions: temporary, mixed, and adult. Orthodontic interception at the time of the temporary dentition corrects the heart of the problem, the transverse insufficiency, but also addresses moderate maxillary retrusion.

Cooperation with a speech therapist at this stage is essential. In the mixed dentition, orthodontists correct incisal malalignment and, depending upon the severity of the deformity, consider surgical intervention. In the adult dentition, a variety of decisions must be made, whether to open or close the spaces left by absent lateral incisors; whether to accept an orthodontic compromise or to elect surgical advancement of the maxilla; and, if surgery is deemed appropriate, whether to embark on an early distraction procedure or to rely on a classical osteotomy.

Sandhya maheshwari et al (2011)[29] divided the orthodontic treatment into 4 phases Predistraction orthodontics, Orthodontics during distraction and consolidation phase, Post distraction orthodontics, Retention. predistraction orthodontics Maxillary and

mandibular dental arches are prepared for distraction osteogenesis by leveling and alignment, decompensation, and correction of curve of spee.

During distraction and consolidation phase, orthodontics' management aimed to direct the tooth bearing segment to their post distraction positions. Post distraction orthodontics should be initiated after the consolidation phase which is aimed at finishing and settling the occlusion.

Ki Chul Tae et al (2003)[21] presented a case report on the use of distraction osteogenesis in cleft palate patient and suggested that a systematic approach is thus required for cleft palate patients, which includes timing of surgery by a surgeon, caries control by a pedodontist, attention to hearing problem by an ENT specialist, speech therapy, and growth modification by an orthodontist.

COMPLICATION IN DISTRACTION OSTEOGENESIS

A. Suhr, Th. Kreusch (2003)[49] classified complication into immediate, early and late . **Immediate complication include** damage to the primary (1,9%) or secondary dentition including pulp necrosis and loosening**,** damage to the orthodontic appliance.

Inability to find the screw-holes after performing the osteotomy, Undercuts, Distractor plate or screw fracture .**Early complication includes** Infection ,Distractor loosening ,Paraesthesia ,Problems of compliance .**Late complication include** Occlusal disharmony,Tooth elongation by elastic traction, . Incorrect vector,Relapse, Premature bony consolidation1, Facial nerve, condylar resorption, alterations in the articulation, atypical facial pain, injury to the distractor , fibrous union, quadriparesis.

Mehmet Cemal Akay(2009)[31] classified complication into Intraoperative, Intradistraction, and Postdistraction complications.The intraoperative complications concern the surgical procedure (eg, malfracturing,incomplete fracture, nerve damage, and excessive bleeding) and device- related problems (eg, fracture and unstable placemen.Intradistraction complications concern those arising during distraction (eg, infection, device problems, pain, malnutrition, and premature consolidation Postdistraction complications concern the late problems arising during the period of splinting and after removal of the distraction devices (eg, malunion, relapse, and persistent nerve damage).

Samchukov et al. (2001)[43] Stated that the infection rate associated with distraction osteogenesis in general is reported as varying between 5% and 30% . However, these complications are mainly related to the application of external distraction devices. Infection is nevertheless mentioned as the most common complication during distraction. Notwithstanding that bacterial contamination is possible during the weeks of distraction and consolidation, the preventive administration of antibiotics during both the placement and the removal of the devices, along with good oral hygiene, appear to be sufficient to reduce the infection rate to acceptable rate.

Materials And Methods

Four patients with maxillary hypoplasia secondary to cleft lip and cleft palate who reported to the Department of Oral & Maxillofacial surgery, Tamilnadu Government Dental College and Hospital, Chennai, were included in this study. All the patients were previously treated for cleft lip and palate. Informed consent was obtained from all the patient as a part of the surgical procedure with prior clearance from ethical committee.

INCLUSION CRITERIA

The criteria for the selection of the patients includes,

- Maxillary hypoplasia secondary to cleft lip and palate
- Patient presenting no systemic contraindication for surgical procedure.
- Patient who were motivated enough to comply with the distraction regime.
- Patient who are willing for regular follow up.

EXCLUSION CRITERIA

- Maxillary excess
- Medically compromised patient.

Four patients (3 female and one male) with age ranging from 15 to 21 years. Thorough preoperative evaluation of the patient.s general condition was done for the surgical procedure under general anaesthesia and the patient's were explained about the treatment, since they had to undergo two surgical procedure- one for device fixation followed by distraction and the second procedure for distraction device removal after the completion of the consolidation period.

In all our cases custom made internal maxillary distraction device of different distracting length were used depending on the case, which was adapted after a lefort 1 osteotomy in the maxilla. Correction of the hypoplastic maxilla was done in sagittal direction.

METHODOLOGY

1. Preoperative orthodontics
2. Pre operative Assessment
3. Radiographic evaluation
4. Study model preparation,
5. Selection of the device,
6. Surgical procedure,
7. Post operative Evaluation,
8. Post surgical orthodontics,
9. Follow up & observation.

1.PREOPERATIVE ORTHODONTIC TREATMENT:

All the patient under went preoperative orthodontic treatment for the alignment of the permanent teeth. Maxillary and mandibular teeth are prepared for distraction osteogenesis of the maxilla by levelling and alignment, decomposition and correction of the curve of spee. Standard pre distraction orthodontic protocol include

appropriate transverse arch width, and coordination of both maxilla and mandibular arches during and after distraction.

2.PREOPERATIVE ASSESSMENT

Evaluation of the patient included

A. Thorough and detailed history,
B. Clinical examination,
C. Extraoral examination
D. Intraoral examination

History includes chief complain, history of present illness, previous medical and surgical history. Clinically the Patients general condition, mental disposition and their attitude towards the treatment with regard to compliance for the entire period of treatment were assessed,

Extraoral examination

- Class 3 malocclusion
- Soft tissue involvement and the scar formation after cleft lip and palate repair
- Lip competence
- The relationship of the maxilla to the mandible
- The nose deformity due to cleft lip and palate

Intraoral examination;

- The molar relationship(class 111 molar relation)
- The relationship of the maxilla to the mandible
- The amount of anterior reverse over jet and overbite

- Presence of palatal fistula
- The pre surgical orthodontic teeth alignment
- The palatal arch dimention
- The maxillary discrepiencies

3**) RADIOGRAPHIC ASSESSMENT**

The following radiographs were taken pre-operatively for all the patient,

- OPG
- Lateral Cephalogram
- Posterior Anterior Cephalogram
- CT Scan- plain and 3D reconstruction

Cephalometric analysis was done for all the patient prior to the surgery using Burstone's analysis (Cephalometric analysis for orthognathic surgery) to determine,

1. The amount of maxillary distraction to be done,
2. The relationship of the maxilla with the mandible in anterior posterior plane.

AMOUNT TO BE DISTRACTED:

The following parameters were taken into account for the cephalometric analysis using COGS analysis in skeletal profile,

- Pog-N-A
- A -N perpendicular to HP (Normal value; -2 ± 3.7)
- B - N perpendicular to HP (Normal value; -6.9 ± 4.3)
- Pog – N perpendicular ti HP (normal value; -6.5 ± 5.1).

THE RELATIONSHIP OF THE MAXILLA WITH THE MANDIBLE IN ANTERIOR POSTERIOR PLANE

The maxillary – mandibular measurements were as follows

- ANS – PNS (Normal value; 52.5 ± 3.5mm)
- Ar – Go ramus length (Normal value; 46.8 ± 2.5mm)
- Go - Pog mandibular body length (Normal valve; 74.3 ± 5.8mm).

4) **MODEL ANALYSIS (Stereolithographic Model):-**

Stereolithographic model was fabricated for presurgical evaluation and planning that includes, a) assessment of the maxillary retrusion and discrepencies, b) for planning the vectors of midface distraction c) adaptation and assessment of the device to the maxillary bone and the zygomatic bone, d) planning for the lefort 1 osteotomy cut, e)planning for the repair of the palatal defect if present. Fabrication of the stereolithographic model involve the following steps,

- Acquirement of CD scan in digital imaging and communications in medicine format(DICOM)
- Using MIMICS software data interpolation and image processing was done to create virtual model and was stored in STL format.
- The virtual image was converted into actual model, using a thermoplastic material, acrylonitrile butadiene styrene resin.

Dental Cast And Facial Model:-

One working model and study model were made for all the patient. The working model was then articulated in an articulator which was used for the analysis of the maxillary advancement to be done, and for the fabrication of the custom made internal distraction device. The facial model also was used as an aid for the

adaptation and for the selection of the custom made device. In this study an intraoral distractor was used as it was less visible and better tolerated by the patient and can be left in place for longer consolidation period.

INTERNAL MIDFACE DISTRACTION DEVICE

The fabrication of the custom made distraction device was designed according to the stereolitheographic model, assisted with facial models. The internal maxillary distraction device consist of three arms, activating arm, vertical arm, and the horizontal arm.

The vertical arm is contoured to be adapted over the zygomatic buttress, the horizontal arm is adapted over the maxilla below the lefort 1 osteotomy cut and the activating arm is exposed to the oral cavity which is placed parallel to the occlusal plane and to each other bilaterally.

PRE-OPERATIVE PLANNING USING LATERAL CEPHALOGRAM

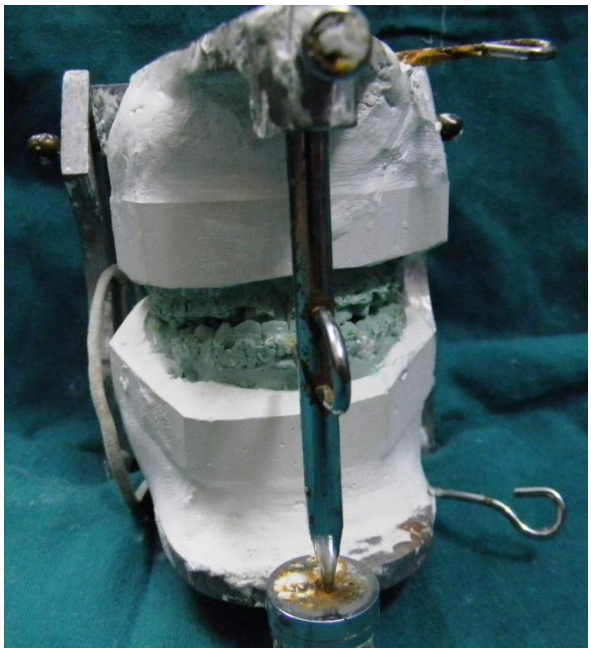
POSTERIOR ANTERIOR CEPHALOGRAM

CT SCAN

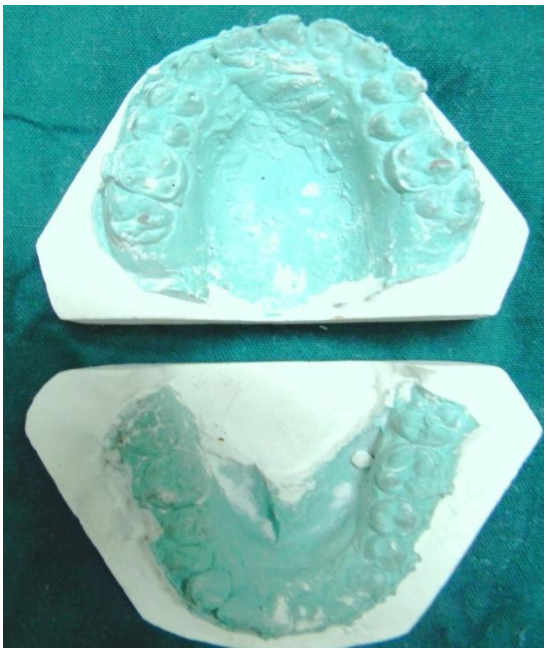
OPG

MODEL ANALYSIS

WORKING MODEL

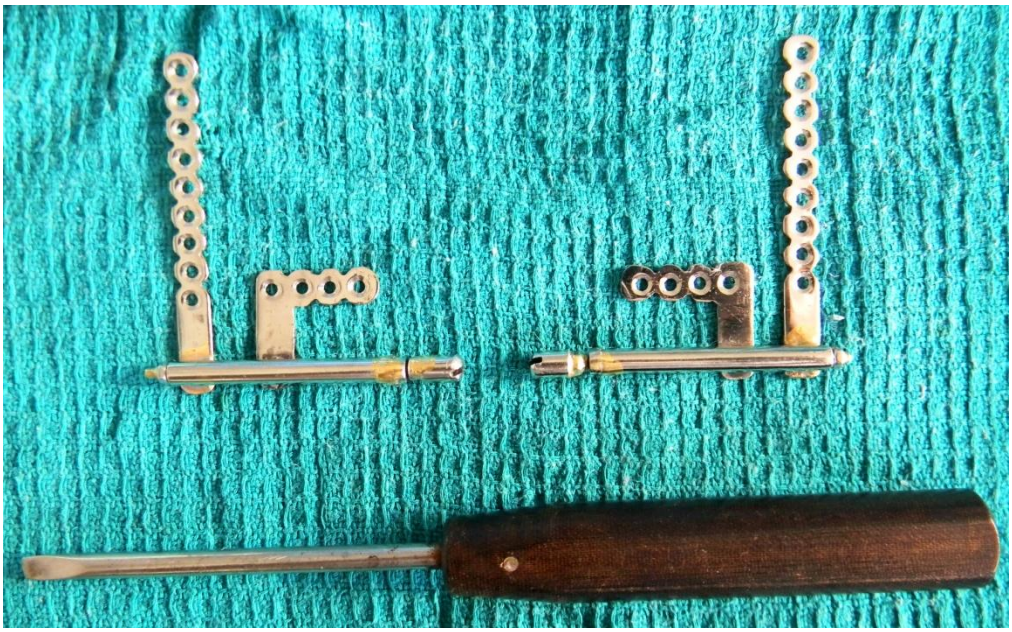


STUDY MODEL

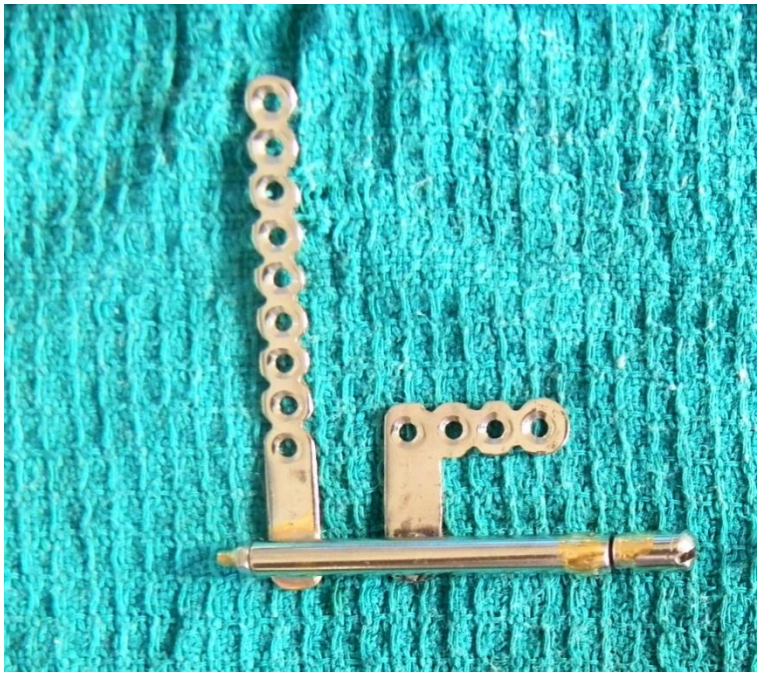


STEREO LITHOGRAPHIC MODEL

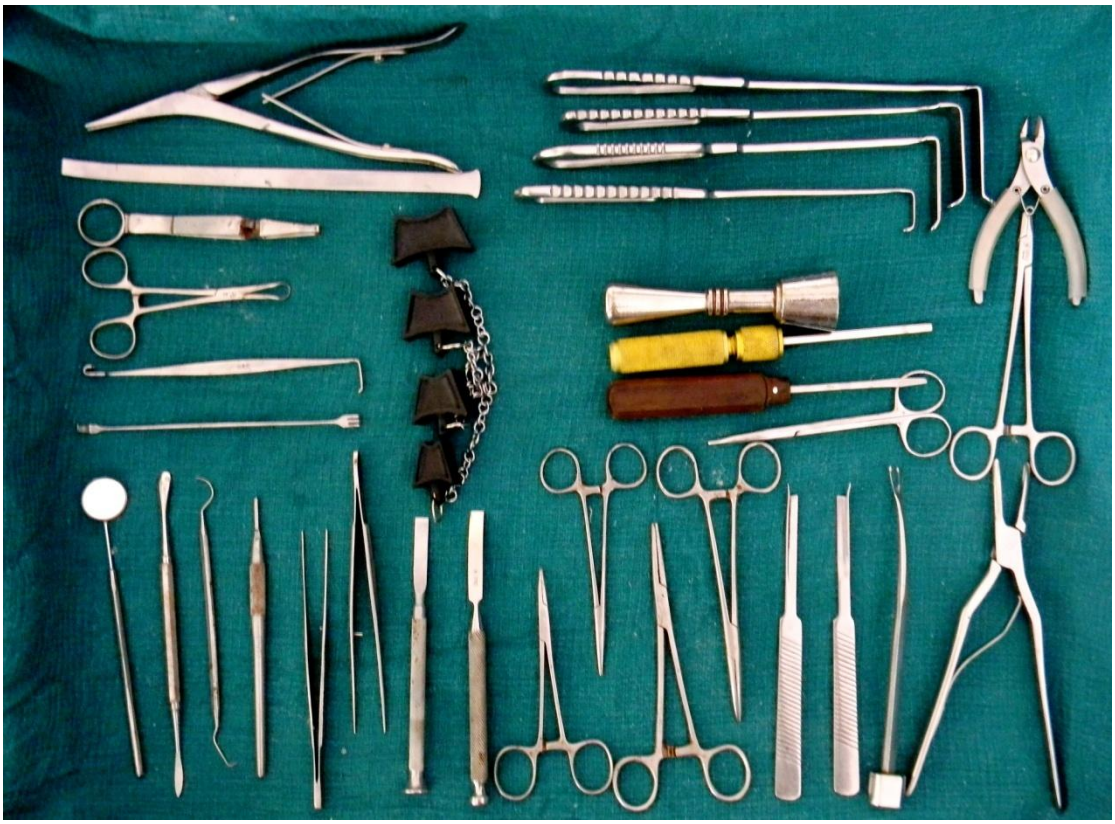
CUSTOM MADE MAXILLARY INTERNAL DISTRACTION DEVICE AND DEVICE ACTIVATOR



DESIGN OF THE DEVICE (RIGHT SIDE)



SURGICAL ARMAMENTARIUM



HANDPIECE AND MICROMOTOR

Surgical Procedure

SURGICAL PROCEDURE:-

All surgical procedure was done under naso endotracheal intubation general anesthesia. The surgery was performed in two stages, distraction device fixation and distraction device removal.

First surgical step: distraction device fixation

Step 1: preparation and marking of incision

Conventional preoperative surgical site preparation was done. Throat pack was placed. Intra oral preparation of the patient was done. Sub mucosal infiltration of the adrenaline with saline of 1:2,00,000 concentration was injected for vasoconstriction.

Step 2: transoral incision and dissection

The maxilla was exposed using the buccal vestibular approach. The incision was placed approximately 5 mm superior to the mucogingival junction from first molar of one side to the first molar of the opposite side . Leaving unattached mucosa on the alveolus facilitates closure, during closure, the tissue can be grasped and holds sutures well. The incision should not be made more superior in the anterior region because entrance into the piriform aperture, with puncture of the nasal mucosa, may result. . The incision was placed through the mucosa, submucosa ,facial muscle and periosteum, exposing the maxilla.

Step 3: Subperiosteal Dissection of Anterior Maxilla and Zygoma

Periosteal elevators are used to elevate the tissues in the subperiosteal plane. Dissection, was done orderly, first elevating tissues superiorly, then along the

piriform aperture, then posteriorly behind the zygomaticomaxillary buttress. When the tissues are elevated superiorly in the subperiosteal plane, small perforating vessels are encountered and was easily distinguishable from the infraorbital neurovascular bundle. The bundle was encountered and the periosteum is dissected completely around the foramen. Dissection proceeded superiorly to the infraorbital rim.

Subperiosteal dissection along the piriform aperture strips the attachments of the nasolabial musculature, allowing upward and lateral retraction of the muscles. Subperiosteal dissection was done posteriorly to the pterygomaxillary fissure. Perforation of the periosteum at or behind the zygomaticomaxillary buttress produces herniation of the buccal fat pad into the surgical field, which may act as a nuisance during surgery so careful dissection was done. Dissection below the piriform aperture upto the anterior nasal spine was performed carefully to maintain the integrity of the nasal mucosa.

Step 4: Submucosal Dissection of Nasal Cavity

The nasal mucosa from the lateral wall, floor, or septum of the nose was dissected with periosteal elevator. Austin retractor was placed over the anterior nasal spine and subperiosteal dissection was done superiorly to allow the retractor to retract the septum and nasal mucosa above the level of the anterior nasal spine. A scalpel was used to make a horizontal incision on top of the anterior nasal spine, freeing the cartilaginous septum from the top of the spine and attachment of the nasal mucosa from the anterior nasal spine. The rim of the piriform aperture is thin and sharp, and the nasal mucosa is adherent. Periosteal elevators was then used to strip the mucosa from the entire circumference of the piriform rim. After freeing the nasal mucosa from the piriform rim, the elevators was then inserted inferiorly before advancing posteriorly .

Dissection of the lateral wall of the nose was performed by gently inserting a periosteal elevator between the nasal mucosa and the lateral wall of the nasal cavity. . The elevator was then advanced in a sweeping motion to free the entire lateral wall and floor of its mucosa to the level of the inferior turbinate. Once the lateral wall and floor of the nose were stripped of mucosa, the elevator is placed at the junction of the floor of the nose and the nasal septum. A tenacious attachment of the mucosa to the septal crest of the maxilla was carefully elevated to prevent perforation.

step 5: marking of the osteotomy cut:

After the elevation of the mucoperiosteal flap the maxilla is exposed .At this point internal reference line was marked on the lateral maxillary wall. The osteotomy mark is placed 4 to 5 mm above the apices of the maxillary canine and the first molar with the help of the bone marking pencil.

Step 6: Distraction device fixation:-

After making the lefort I level osteotomy cut the distraction device is adapted, the superior vertical arm is adapted to the zygomatic buttress and the inferior horizontal arm to the maxilla below the osteotomy cut. After adapting, the device is fixed to the maxilla with screws, then the device is removed, and lefort – I osteotomy cut is completed. The osteotomised maxilla is downfractured with the help of smith spreader. The mobilised maxilla is readapted to the original position and the device is fixed to the zygomatic buttress and the maxilla with monocortical 2mm × 8mm screws.

Step 7: primary closure

A V-Y technique is utilised for the closure of the incision. The incision is sutured in an interrupted manner with 3-0 vicryl. The body of the device gets buried in the soft tissue and only the activation arm gets exposed for activation.

POST OPERATIVE CARE

- All patient had ryles tube feeding for the five days followed by fluids and soft diet for a period of 2 weeks.
- Oral hygiene maintenance was monitored

DISTRACTION PROTOCOL:

- After a latency period of 7 days distraction activation was done at the rate of I mm per day
- During the distraction period, all the patient were subjected to weekly supervision to assess the device position , length of the distraction.
- Periodically radiographs were taken for the assessment of the regenerate and device position(during the distraction period, end of distraction and the end of consolidation period)
- The distraction was continued until the desired maxillary advancement was achieved
- After the completion of the distraction phase, a consolidation period of 4 times the period of distraction activation period was observed.
- After the completion of the distraction lateral cephalograms were taken for the assessment of the maxillary movements

SECOND SURGICAL STAGE: DISTRACTION DEVICE REMOVAL

Exposure and distraction device removal:-

Through the same intraoral incision the distraction device was removed after the consolidation period. The distraction site was checked for bone regenerate formation around the osteotomy cut region. Closure of the surgical site was done through interrupted suturing technique using 3-0 vicryl. All the patient were followed up for a period of six months at an interval of one month, third month and six months.

Case Reports

CASE REPORT-1

NAME: Miss Nagaveni

AGE/ SEX: 21 Years/ Female

CHIEF COMPLAINT: Midface Deficiency

HISTORY OF PRESENT ILLNESS:

Patient had congenital cleft lip and palate. she was operated for the cleft lip and palate at the age of 5 months. she was reported to orthodontic department in tamilnadu government dental college and hospital for correction of the malocclusion. from orthodontic department she was referred to oral surgery department for correction of skeletal midface deficiency

PAST MEDICAL HISTORY; Not Relevant

PAST SURGICAL HISTORY; patient did surgery for cleft lip and palate at the age of 6 months

PAST MEDICAL HISTORY: Not Relevant

GENERAL EXAMINATION:

Patient is moderately build ,Gait: Normal

LOCAL EXAMINATION

1. Extraoral Examination;
    - Mid facial deformity
    - Face symmetry

-Concave facial profile

- Competent lip
- Asymmetrical nose due to cleft lip and palate
- Mouth opening adequate
- Bilateral condylar movement – palpaple
- Nasal tone voice

2. Intraoral Examination
   - Class 111 molar relationship
   - Retruted maxilla
   - Normal mandible
   - Presence of cleft palate
   - Anterior cross bite
   - Reverse overjet and overbite

RADIOLOGICAL INVESTIGATIONS:

Lateral cephalograms shows normal mandible and retruded maxilla.

Posterior anterior cephalograms shows decrease maxillary width in relation to the mandible.

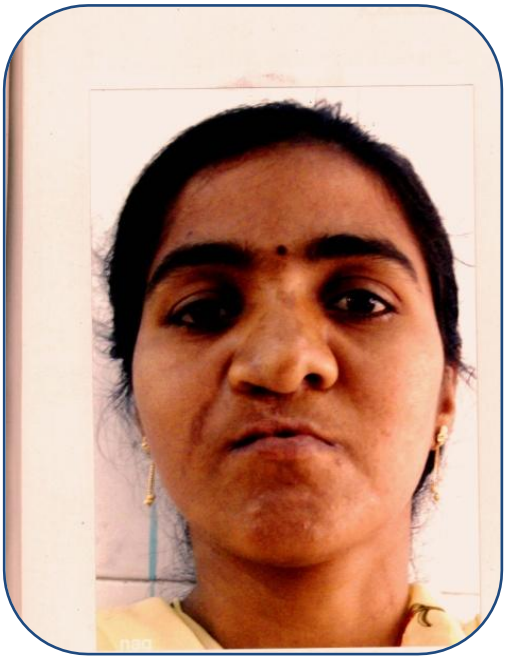
CT scan shows midface deficiency with cleft maxilla

DIAGNOSIS: Midfacial deficiency secondary to cleft lip and palate

TREATMENT PLAN; midface distraction osteogenesis using a custom made internal distraction device

PRE OPERATIVE PHOTOS AND X-RAYS

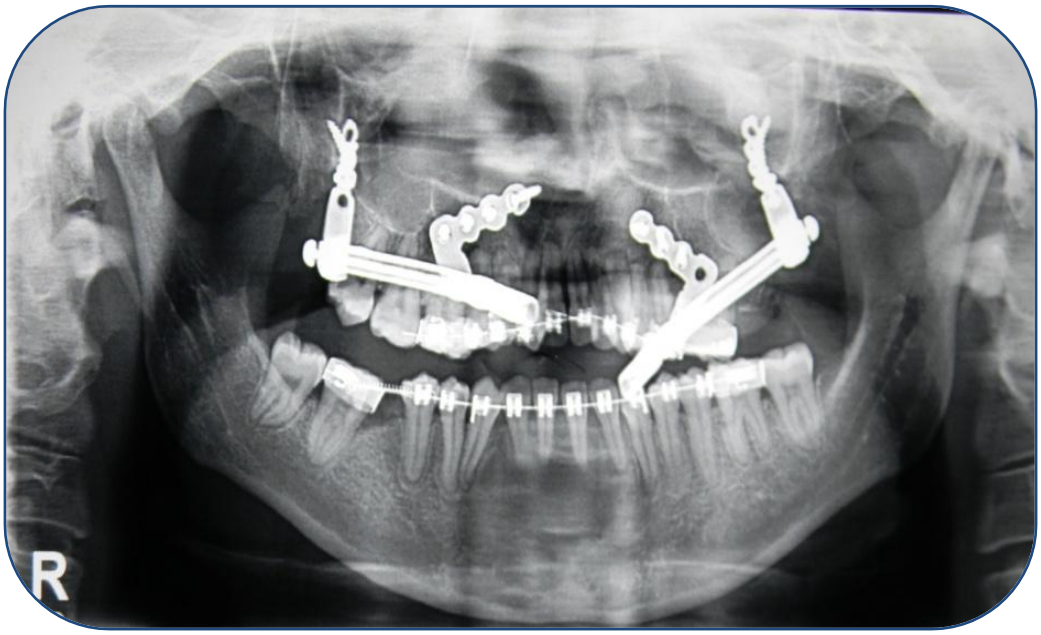
CASE -1



PRE OPERATIVE CT SCAN AND X RAYS

DISTRACTION AND CONSOLIDATION PHASE

DISTRACTION AND CONSOLIDATION X-RAYS



POST OPERATIVE PHOTOS

POST OPERATIVE X RAYS

CASE REPORT- 3

NAME: Mr Thangaraj

AGE/ SEX: 20 Years/ Male

CHIEF COMPLAIN:Midface deformity secondary to cleft lip and palate

HISTORY OF PRESENT ILLNESS:

Patient had congenital cleft lip and palate which he operated at the age of one and half year. patient did orthodontic correction tamilnadu government dental college and hospital and was reported to the department of oral surgery for the correction of midfacial deficiency for esthetic reason

PAST SURGICAL HISTORY: Surgery for cleft lip and palate at the age of 1 year

PAST MEDICAL HISTORY: Not Relevant

GENERAL EXAMINATION

Patient is medium build

Gait – normal

No signs of anaemia, palpable lymphadenopathy, icterus, pallor and clubbing

Blood pressure; 120/80

Pulse rate- 75 beats/ min

LOCAL EXAMINATION

Extraoral Examination

- Mid facial deformity
- Face symmetry
- Concave facial profile

  Incompetent lip
- Asymmetrical nose due to cleft lip and palate
- Mouth opening adequate
- Bilateral condylar movement – palpaple
- Nasal tone voice

Intraoral Examination

- Class 111 molar relationship
- Retruted maxilla
- Normal mandible
- Presence of cleft palate
- Anterior cross bite
- Reverse overjet and overbite
- Missing- 21, 22, 11,12

RADIOLOGICAL INVESTIGATIONS:

Lateral cephalograms shows normal mandible and retruded maxilla

Posterior anterior cephalograms shows decrease maxillary width in relation to the mandible

CT scan shows midface deficiency

DIAGNOSIS: Midfacial deficiency secondary to cleft lip and palate

TREATMENT PLAN: Midface distraction osteogenesis using a custom made internal distraction device

-

PRE OPERATIVE PHOTOS

CASE -3

PRE OPERATIVE X RAYS

DISTRACTION AND CONSOLIDATION PHASE

DISTRACTION AND CONSOLIDATION PHASE X RAYS

WHIPLASH SPRING FOR CORRECTION OF MAXILLARY ARCH COLLAPSE

AFTER IMMEDIATE APPLICATION OF THE SPRING

AFTER 2 MONTHS OF APPLICATION OF SPRING

CASE REPORT- 4

NAME: Miss Bhuvaneshwari

AGE/ SEX: 15 Years/ Female

CHIEF COMPLAIN: Midface deformity secondary to cleft lip and palate

HISTORY OF PRESENT ILLNESS:

Patient had congenital cleft lip and palate which he operated at the age of one year. patient did orthodontic correction tamilnadu government dental college and hospital and was reported to the department of oral surgery for the correction of midfacial deficiency for esthetic reason

PAST SURGICAL HISTORY: Surgery for cleft lip and palate at the age of 1 year

PAST MEDICAL HISTORY: Not Relevant

GENERAL EXAMINATION

Patient is thin build

Gait – normal

No signs of anaemia, palpable lymphadenopathy, icterus, pallor and clubbing

Blood pressure; 110/80

Pulse rate- 70 beats/ min

LOCAL EXAMINATION

Extraoral Examination

- Mid facial deformity
- Face symmetry
- Foncave facial profile
- Incompetent lip
- Asymmetrical nose due to cleft lip and palate
- Mouth opening adequate
- Bilateral condylar movement – palpaple
- Nasal tone voice

Intraoral Examination

- Class 111 molar relationship
- Retruted maxilla
- Normal mandible
- Presence of cleft palate
- Anterior cross bite
- Reverse overjet and overbite

RADIOLOGICAL INVESTIGATIONS:

lateral cephalograms shows normal mandible and retruded maxilla

posterior anterior cephalograms shows decrease maxillary width in relation to the mandible

CT scan shows midface deficiency

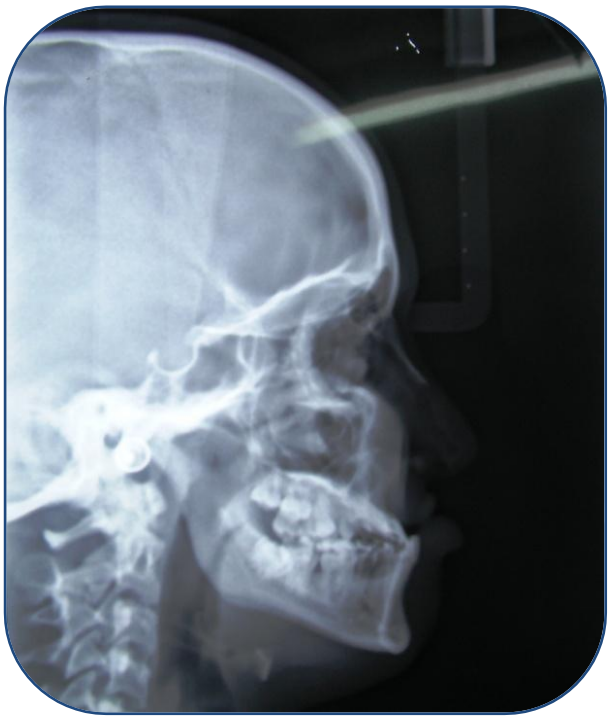
DIAGNOSIS: Midfacial deficiency secondary to cleft lip and palate

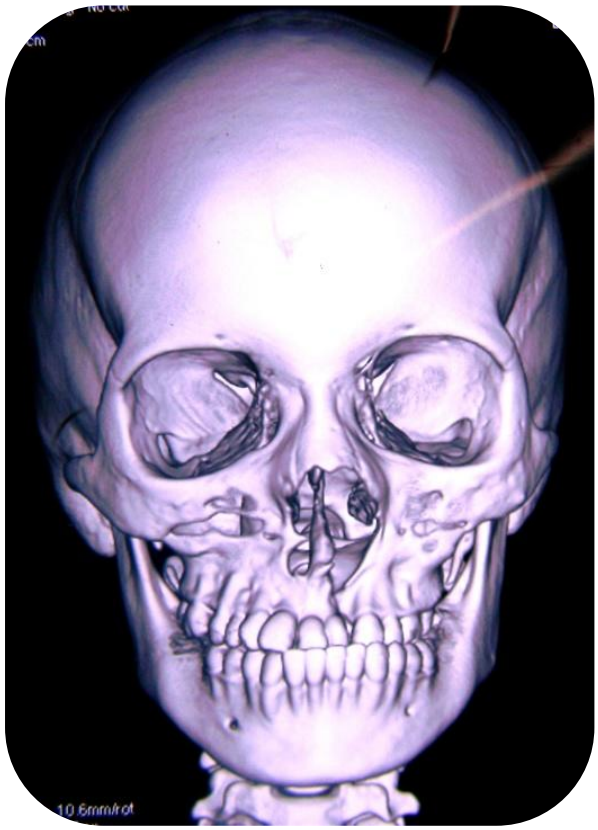
TREATMENT PLAN; Midface distraction osteogenesis using a custom made internal distraction device

PRE OPERATIVE PHOTOS

CASE -4

PRE OPERATIVE x RAYS





DISTRACTION AND CONSOLIDATION PERIOD

DISTRACTION AND CONSOLIDATION PHASE
RADIOGRAPH

CASE REPORT-2

NAME: Miss Deepika

AGE/ SEX: 17 Years/ Female

CHIEF COMPLAIN: Midface deformity secondary to cleft lip and palate

HISTORY OF PRESENT ILLNESS:

Patient had congenital cleft lip and palate which she operated at the age of 1 year. patient did orthodontic correction in a private clinic and she was reported to tamilnadu government dental college and hospital for the treatment of midfacial deficiency to improve her esthetics

PAST SURGICAL HISTORY: Surgery for cleft lip and palate at the age of 1 year

PAST MEDICAL HISTORY: Not Relevant

GENERAL EXAMINATION

Patient is medium build

Gait – normal

No signs of anaemia, palpable lymphadenopathy, icterus, pallor and clubbing

Blood pressure; 110/ 70,

Pulse rate- 72 beats/ min

LOCAL EXAMINATION

1. Extraoral Examination
    - Mid facial deformity
    - Face symmetry
    - Concave facial profile
    - Competent lip
    - Asymmetrical nose due to cleft lip and palate
    - Mouth opening adequate
    - Bilateral condylar movement – palpaple
2. Intraoral Examination
    - Class 111 molar relationship
    - Retruted maxilla
    - Normal mandible
    - Presence of cleft palate
    - Anterior cross bite
    - Reverse overjet and overbite

RADIOLOGICAL INVESTIGATIONS:

Lateral cephalograms shows normal mandible and retruded maxilla

Posterior anterior cephalograms shows decrease maxillary width in relation to the mandible

CT scan shows midface deficiency

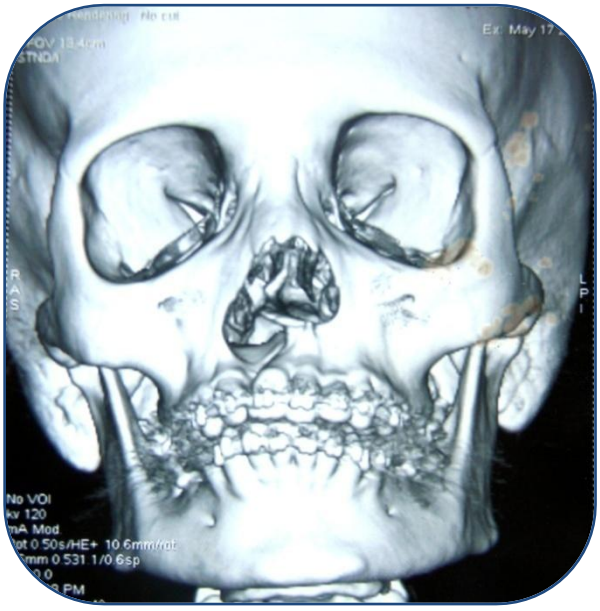
DIAGNOSIS: Midfacial deficiency secondary to cleft lip and palate

TREATMENT PLAN; Midface distraction osteogenesis using a custom made internal distraction device

PRE OPERATIVE PHOTOS

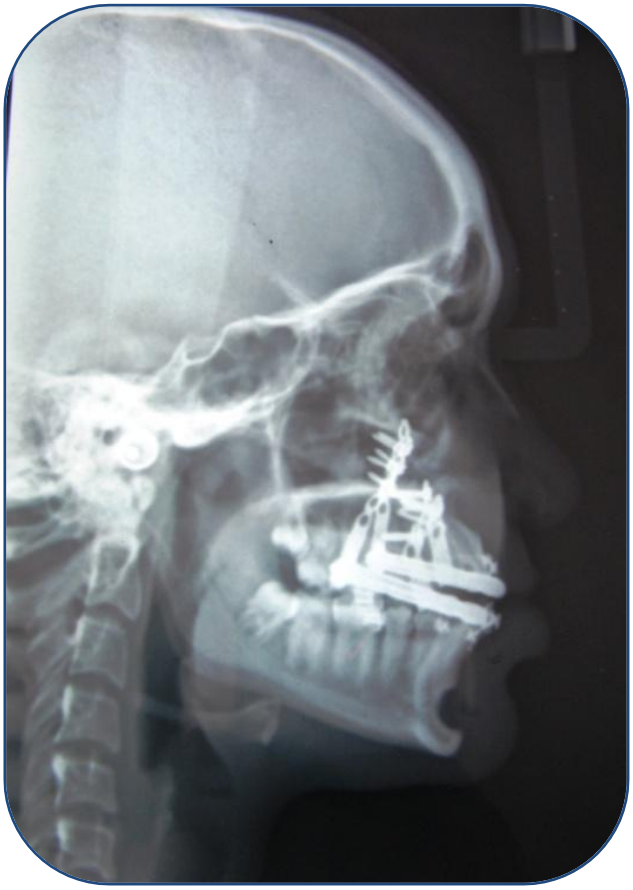
CASE -2

PRE- OPERATIVE RADIOGRAPH



DISTRACTION AND CONSOLIDATION PICTURES

CONSOLIDATION AND DISTRACTION PHASE X-RAYS



Observation And Results

In this study, distraction of the midfacial region was done in four patient using a custom made internal maxillary distraction device. All the patient had midfacial deficiency secondary to cleft lip and palate and all the patient underwent treatment for esthetic reasons.

In all the four cases there was active movement of the maxilla. In case 2 there was a collapse of arch during the distraction, which was treated with whiplash spring for the arch expansion and prevention of further collapse, with the help of the orthodontist. The amount of maxillary distraction planned for each patient was carried out, and subsequently followed by longer consolidation period (i.e., three months).

The midfacial movement was evaluated by using the following parameters

A. Clinical assessment,
B. Radiological assessments,
C. Complication,
D. Patient compliance,
E. Overall patient satisfaction.

A. CLINICAL ASSESSMENT

Facial symmetry :

Post operatively after the distraction phase the patient midfacial contour was restored in all the patient. The facial esthetic was acceptable and the soft also tissue adapted well to the distraction of the midface region. However there was a mild collapse of the arch which was corrected post surgically by orthodontic treatment after the removal of device.

Mouth opening:

Post operatively all the patient had limited mouth opening in the immediate postoperative period, due to surgery and the presence of distraction device in the mouth. The patient compliance to the distraction device at the end of the latency period and during the distraction period and become quite comfortable to the device. There was no significant changes found in the speech of the patient.

Quality of the regenerated bone:

The quality of the regenerated bone assessed was similar to the adjacent host bone clinically at the end of the consolidation period. This clinical findings was evaluated during the removal of the distraction device. The maxilla was moved to the desired distance and blended well with the normal adjacent bone

Restoration of the arch form

In two cases there was a mild collapse of the arch form. Both the patient were kept under observation to be corrected after the completion of the consolidation period by post orthodontic treatment. However in one patient whiplash spring was put for the expansion of the maxillary arch before proceeding with the orthodontic treatment

A.RADIOGRAPHIC ASSESSMENT

At the end of the consolidation period all the cases showed regenerated bone similar to the density of the host bone . Radiologically the bone regenerate were seen as a band of radiopacity. Lateral cephalogram showed maxillary movement ranging between 14 mm to 20mm. During the distraction phase, opg and lateral

cephalogram was taken for all the patient which showed the active movement of the distraction device.

COMPLICATIONS;

complication encountered during distraction can be placed in 4 groups

1.Distraction phase,

2.Consolidation phase,

3.Device related complication,

Distraction phase:

The patient experienced mild pain during the distraction period and the mouth opening was also limited in all the cases which gradually improved. In two of our cases the distraction became very difficult and the activation arm was very stiff, probably because the device was entagled with the soft tissue. But the distraction was carried out completely inspite of the stiffness with the help of radiological assessment during the distraction phase. Maintenance of the oral hygiene was very difficult with the intra oral distraction device, but the patient were advised to do brushing twice a day, gargling of mouth after every meals and frequent mouthrinsing with mouthwash.

Consolidation period:

The presence of the device intraorally during consolidation phase caused the patient mild discomfort. There was no infection or exposure of the device during the consolidation period

Device related problem:

During the distraction phase all the patient experienced mild pain and the distraction arm which was exposed to the oral cavity caused impingement of the buccal mucosa in 2 patient(case 2 and 4). During the distraction phase there was difficulty in distraction due the stiffness of the device.

PATIENT COMPLAINCE

During the latency period all the patient had limited mouth opening because of the presence of intra oral device, scarring of the corner of the mouth during the placement of the device. However the patient complained only of mild pain after the placement which subsided with suitable analgesics.

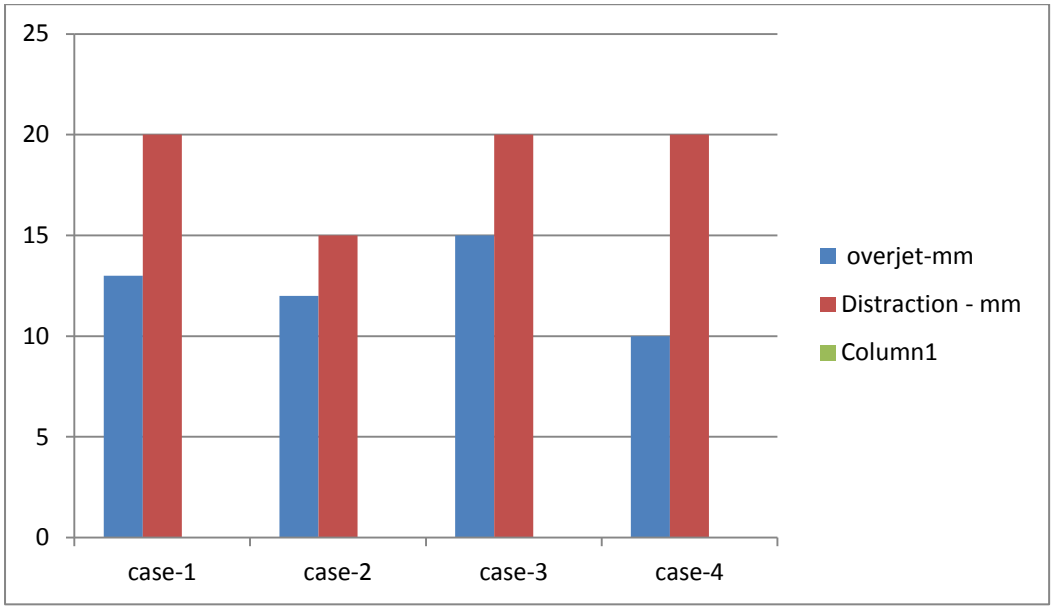
Post surgical recovery was uneventfull in all the cases. Though the patient complain of mild discomfort during the latency, distraction and consolidation period because of the presence of the intraoral distraction device, patient acceptance was quite good and the patient were quit cooperative during the entire process.

OVERALL PATIENT SATISFACTION

All the patients were reviewed post operatively. The patient were advised for post surgical orthodontic treatment after consolidaton period. Lip revision for one patient and rhinoplasty for three patient were suggested after 6 months of completion of the distraction protocol of the maxillary hypoplasia. The patient were quite satisfied with the outcome of the surgical procedure.

The Distraction protocol for maxillary hypoplasia

Sl.No.	Name	Age / Sex	Amount of reverse over jet	Amount of advancement	Latency period
1	Nagaveni	20 / F	13 mm	20 mm	7 days
2	Thangaraj	19/ M	12 mm	15mm	6 days
3	Deepika	20/ F	15 mm	20 mm	5 days
4	Bhhuvaneswari	15/ F	10 mm	20 mm	7 days



X- axis – Maxillary Hpoplasia patients. Y-axis – Distraction achieved in mm.

Discussion

Cleft lip and palate are common congenital defect which causes several functional and esthetic problems because of defects in the soft and hard tissues leading to nose deviation and formation of scar tissue after surgery. In cleft lip and palate patients, early surgical corrections are usually performed to improve esthetics and function .[42]

The early surgeries tend to result in poor skeletal and dental growth in the transverse and anteroposterior planes, especially in the maxilla.[34] Also, the upper dentition is often collapsed because of missing teeth. In children, orthodontics that uses orthopedic means can be used to correct these problems. In adults, gingival recession, hearing problem, and relapse commonly follow arch expansion with quidhelix therapy or other types of conventional tooth movement appliances, thereby necessitating the need for surgical expansion the cleft lip and palate patients who present with a maxillary retrusion and a tendency to class ш malocclusion after cleft repair.

Traditionally conventiontional orthognathic surgery have been popularly used to correct the defect but recently after the application of distraction osteogenesis in the midfacial region, DO has become the new paradigm shift for treatment in maxillary hypoplasia secondary to cleft lip and palate. The study conducted by Adi Rachmiel et al (2012)[39] on the treatment of maxillary cleft palate-Distraction osteogenesis vs. orthognathic surgery concluded that in cases with mild maxillary deformities without significant bone deficiency a one stage orthognathic surgery gave satisfactory results and in moderate or severe maxillary deficiency or in growing patients the distraction methods have showed advantages over conventional orthognathic surgery in terms of greater maxillary movement, skeletal stability, and soft tissue profile changes. This

led us to take up a study on intraoral distraction for four cases with maxillary hypoplasia secondary to cleft lip and palate.

The soft tissue changes that occurs with distraction osteogenesis is another added advantage of this method . Apaydin (2011)[22] quoted that one of the important problems in orthognathic surgery is adaptation of the soft tissues. In some cases, the soft tissues surrounding the bone do not adapt to the new position during the massive bone movements resulting in functional and aesthetic problem. So distraction osteogenesis is the new answer since during the distraction procedure adaptive changes occur in the soft tissues by a process known as distraction histogenesis.

BIOLOGICAL BASIS OF DISTRACTION OSTEOGENESIS

In its simplest form, distraction osteogenesis describes the generation of new bone in the stretched fracture callus When a fracture occurs, the bony ends are usually set and stabilized so that the bony ends align and form one continuous length of bone. If the two bony ends are slowly pulled apart by a screw-driven appliance after the callus forms, then new bone can fill in the stretched callus tissue. This process is called distraction osteogenesis. Success of new bone formation is influenced by the rate and rhythm of the separating forces. The sequential period in distraction osteogenesis is as follows,[29]

- Osteotomy
- Latency
- Distraction
- Consolidation and remodeling

1. Osteotomy;

   Each osteotomies bone segment must contain sufficient number of viable osteocytes to initiate and perpetuate the distraction osteogenesis. In our studies a lefort 1 osteotomy cut and complete downfracture of the maxillary bone was done for all the patient

2. Latency period:

   Ilazorov protocol established a latency period of 5 to 7 days but more recent works used latency period of 0 to 5 or 7 to 14 days. Latency period should be set in such a way that it is not too long so as to permit calcification and not too short as to avoid formation of a primary callous. The patient who underwent distraction osteogenesis in our hospital were kept for a latency period of 5 to 7 day.

3. Distraction period;

   Ilizarov suggest that a distraction rate at 1mm a day in 4 increments a day of 0.25 mm each offers better results. Although many literature suggested a distraction rate of 1 mm a day and others followed 3 mm a day, the protocol followed in our study was a distraction period rate of 1mm per day gave a consistent clinical results.

4. Consolidation and remodeling:

   According to literature the length of the consolidation period varies from 4 to 12 weeks but 12 weeks seems to be sufficient for bone maturation. Swennen et al suggested that longer consolidation period is required when distraction osteogenesis is applied to the middle-third of the face when compared with the mandible and other bone . The consolidation period in our study was 12 weeks after the distraction period. Since most of the patient

underwent a distraction period of 20 mm for around 20 days the consoldation period was kept for 12 weeks after the distraction period.

INDICATION OF DISTRACTION OSTEOGENESIS

Distraction osteogenesis is indicated in all cases of mandibular shortening or maxillary hypoplasia where orthognathic surgery is not first choice. Various acquired and congenital condition in which distraction osteogenesis is indicated are as follows:

Congenital deformities

- Pierre- Robin Syndrome
- Severe retrognathic syndrome e. g. Treachers Collins and Goldenhar syndrome
- Non-syndromic congenital micrognathia
- Severely constricted mandible/ maxilla
- Craniofacial microsomia unilateral/bilateral
- Midfacial hypoplasia
- Obstructive sleep apnea (OSA)
- Facial asymmetry

Acquired conditions

- Post-traumatic growth disturbances of mandible, e.g. temporomandibular joint ankylosis
- Non union fractures
- Atrophy of edentulous segments
- Oncologic mandibular osseous defects

Others

- Rapid canine distraction for rapid distalization of canine to reduce orthodontic treatment time
- Distraction for ankylosed teeth to create optimum height of alveolar bone

There are many types of distraction device that are used in the maxillofacial region and a broad classification based on use is given below

Based on use[29]

External distracter

- Unidirectional (activated in one plane of space)
- Bidirectional (activated in two plane of space)
- Multiplanner (activated in three plane of space)
- Rigid external distraction (RED) system

Internal distracter

- Mandibular intraoral distracter
- Modular internal distracter (MID)
- Tooth borne distracter e.g. rapid canine distracter, alveolar distracter

In our study an internal device was used to address the midfacial deformities after assessing the various advantage it offers over the external devices.

T. R. Meling (2010) [30] did a study to compare internal and external distraction devices in the treatment of midface retrusion. The potential benefits of internal devices include elimination of skin scarring caused by translation of transcutaneous fixation pins, improved patient compliance during the consolidation

phase, and improved stability of the attachment of the device to the bone. The major drawbacks are, the need for precise positioning of the device, regarding alignment between the two sides and the angulation, which can be challenging in patients with numerous previous operations and subsequent cranial thinning or deficiencies, the inability to alter the distraction vector during the distraction process, and the need for a second major operation to remove the device, although this can be overcome by using biodegradable devices.

In the study done above an internal custom made distraction device was which was adapted to the maxilla after Lefort 1 osteotomy cut and down fracture of the maxilla. In all the patient cephalometric analysis was done, reverse over jet was measured, study models were made preoperatively. Postoperatively the desired movement of the maxilla was achieved in almost all the patient where an advancement of almost 15 to 20 mm was done in all the patient. During the distraction period the problems encountered were mild pain during the distraction period but tolerable pain, stiffness of the device that sometimes hampered the activation of the device properly, the frequent visit the patient have to make for activation., impinging of the device over the buccal mucosa and limited mouth opening, all the complication were treated symptomatically.

In most of the cases the patient had a compromised dental occlusion which needed orthodontics intervention after a period of 4 to 6 months. Most of the patient were satisfied with the amount of maxilla advancement as their facial profile improved.

Combined surgical and orthodontic treatment of cleft lip and palate with maxillary retrusion is a challenge . Gradual maxillary advancement with distraction

provides an excellent method of treating maxillary retrusion in cleft lip and palate patient in permanent dentition. Maxillary advancement with distraction osteogenesis is a minimally invasive technique that reduces the need for bone graft, rigid fixation system or intermaxillary fixation.

Summary And Conclusion

Maxillary hypoplasia is a common developmental problem in individuals with cleft lip and palate (CLP) and is thought to result from a combination of a congenital reduction in midfacial growth and the effects of the surgical scarring from cleft palate repair. Many patients with this problem can benefit aesthetically and functionally from surgical correction.

In this study of four cases with maxillary hypoplasia a lefort 1 osteotomy with down fracturing and distraction osteogenesis of the downfractured fragment was carried out. Careful examination and evaluation was done for all the patient preoperatively including all the radiographs, models and cephalometric analysis.

The amount of maxillary advancement achieved ranged between 15mm to 20mm for the patient which was clinically and radiologically satisfactory. There were few disadvantages that was encountered during the distraction period like pain during distraction which was bearable, stiffness of the device, impingement of the device over the buccal mucosa but overall the results that was achieved was quite satisfactory. The malocclusion that is associated with distraction osteogenesis need to be addressed by an orthodontist so it is of utmost important to consult an orthodontist and do the surgery in collaboration.

The use of intraoral maxillary distraction device for correction of maxillary hypoplasia secondary to cleft lip and palate is a new paradigm shift in the treatment of maxillary defect over orthognathic surgery.

Annexures

Annexure 1

INFORMED CONSENT

MID FACE DISTRACTION OSTEOGENESIS SECONDARY IN MAXILLARY HYPOPLASIA SECONDARY TO CLEFT LIP & PALATE

Patient's Identification No:_____ Patient's Name:_____

Patient's DOB: _____ _____ _____

dd mm yyyy

I confirm that I have read and understood the Information Sheet for the above study. I have had the opportunity to ask questions and all my questions and doubts have been answered to my complete satisfaction.

I understand that my participation in the study is voluntary and that I am free to withdrew at enytime, without giving any reason, without my legal rights being affected.

I understand that the Clinical study personnel, the Ethics Committee and the Regulatory Authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if withdrew from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to the third parties or published, unless as required under the law. I agree not to restrict the use of any date or results that arise from this study.

I agree not to withhold any information about my health from the investigator and will 'convey the same truthfully.

I agree to take part in the above study and to comply with the instructions given during the study and to faithfully co-operate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms.

I hereby consent to participate in this study & understand that I'll be treated by surgical procedure under general anaesthesia for my facial deformity and I was well informed about the complications associated with it & I agree for the same.

I consent to give my medical history, undergo complete physical examination and diagnostic tests including hematological, biochemical and urine examination etc.

Patient's Name & Address:

Patients (Where thumb impression has been provided above)

Signature / Thumb Impression: _____ *Place Date*_____

Signature of the Investigator: _____

Study Investigator's Name:

*Institution:*_____*Place*_____ *Date*_____

* *Signature of the Witness: Place*_____ *Date* _____

Name & Address of the Witness _____* Mendatory for uneducated

Annexure 2

<u>கய ஒப்புதல் படிவம்</u>

ஆய்வு செய்யப்படும் தலைப்பு

"அண்ணையிளவு உதட்டுபிளவு காரணமாக ஏற்பட்டுள்ள மேல்தாடை எலும்பிலுள்ள குறைபாட்டை நடுமுக எலும்பு விலக்கல் வழியாக சரி செய்தல்"

ஆராய்ச்சி நிலையம் : தமிழ்நாடு அரசு பல் மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை, சென்னை-3.

பங்கு பெறுபவரின் பெயர் :

பங்குபெறுபவரின் எண் :

பங்கு பெறுவர் இதனை (✓) குறிக்கவும்.

அறுவை சிகிச்சை சம்பந்தமாக நான் மேலே கூறப்பட்ட தகவல் படிவத்தை முழுமையாக படித்துப் பார்த்தேன் என்று உறுதி கூறுகிறேன்.

நான் இது தொடர்பான அனைத்து கேள்விகளுக்கும் நிறைவான பதில்கள் பெறப்பட்டேன்.

இந்த ஆய்வின் எனது பங்கு தன்னிச்சையானது என்றும் எந்த நேரத்திலும் இந்த ஆய்வில் இருந்து சட்ட உரிமைகள் பாதிக்கப்படாமல் விலகிக் கொள்ள சம்மதிக்கிறேன்.

மருத்துவ ஆய்வு அதிகாரிகள், எனது சிகிச்சை தொடர்பான பதிவேடுகளை பார்வையிடவும் எந்த நேரத்திலும், ஆய்வில் இருந்து நான் விலகினாலும் பார்வையிட சம்மதிக்கிறேன். எனது அடையாள குறிப்புகள் மூன்றாவது நபருக்கு தெரிவிக்கப்பட மாட்டாது என்று புரிந்து கொண்டேன்.

இந்த ஆய்வு அறிக்கைகளை பயன்படுத்தவும், வெளியிடவும், நான் சம்மதிக்கிறேன். ஆய்வாளர் எனது மருத்துவக் குறிப்புகளை வெளியிட தடையாக இருக்க மாட்டேன் என உண்மையாக சம்மதிக்கிறேன். மேலும், எனக்கு உடல்நிலை சரியில்லாதக பட்சத்தில் ஆய்வாளர்களுக்கு தெரியப்படுத்த சம்மதிக்கிறேன்.

பொது உணர்வு அகற்றல் மருத்துவமுறையில் அண்ணபிளவு உதட்டுபிளவு காரணமாக ஏற்பட்டுள்ள மேல்தாடை எலும்பிலுள்ள குறைபாட்டை வாயில் பொறுத்தப்படும் எலும்பு விலக்க கருவின் வழியாக நடுமுக எலும்பை எலும்பு விலக்கல் மூலமாக சரி செய்தல் என்பதை அறிந்து கொண்டேன்.

நான் எனது மருத்துவ குறிப்புகளை தரவும், மேலும் முழு உடல் பரிசோதனைக்கும் இரத்தம், சிறுநீர் மற்றும் உயிர் வேதியியல் நோய் அறிதல் சோதனைகளுக்கும் முழுஒப்புதல் அளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் ..... இடம் ..... தேதி

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம் ..... தேதி

ஆய்வாளரின் பெயர் .....

Annexure 3

INFORMATION SHEET

We are conducting a study on midface distraction osteogenesis in maxillary hypoplasia secondary to cleft lip and palate among patients attending TNGDC&H, Chennai-3, and for that study we are selecting patients.The purpose of this study is to assess 1) to achieve a functional & aesthetic facial harmony with a marked correction of facial asymmetry. 2).to evaluate clinical stability. 3)to evaluate intraoperative risk factors and its after effects on clinical and functional recovery. .The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of participant

Date:

Annexure 4

CASE REPORT FORM

"MIDFACE DISTRACTION OSTEOGENESIS IN MAXILLARY HYPOPLASIA SECONDARY TO CLEFT LIP AND PALATE".

Patient's Name : _____

Age/ Sex : _____

Patient's Identification No : _____

Contact Address : _____
_____
_____

Contact No : _____

Institution : Tamilnadu Govt. Dental College & Hospital, Chennai - 600 003

Centre : Dept. of Oral & Maxillofacial Surgery, TN. Govt. Dental College and Hospital, Chennai - 600 003.

Patient's Identification / O P No: _____ Date : _____

DETAILS OF SURGERY

Procedure followed : MIDFACE DISTRACTION OSTEOGENESIS SECONDARY TO CLEFT LIP AND PALATE

Duration of Surgery :

Any other information :

Details of Drug therapy :

Name of the Investigator :

Signature of Investigator :