



DISTRACTION OSTEOGENESIS IN ORO-FACIAL CLEFT

Plastic Surgery

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ABSTRACT

Orofacial clefts comprise a range of congenital deformities and are the most common congenital malformation. Clefting has significant psychological and socioeconomic effects on patient quality of life and require a multidisciplinary team approach for management. The complex interplay between genetic and environmental factors play a significant role in the incidence and cause of clefting. In this review, evolution of craniofacial distraction over conventional orthognathic surgery and its complications are discussed.

It has been suggested that DO offers several advantages over orthognathic surgeries in the treatment of patients with cleft lip and palate (CLP). The distraction osteogenesis (DO) is a method developed for induction of new tecidual formation between two segments of a bone for a slow and gradual force of traction (Ilizarov, 1989a; Ilizarov, 1989b; Meyer et al., 2001a).

Cleft care requires that the surgeon be a member of a collaborative multidisciplinary team. Through close self-scrutiny, disciplined evaluation of the results, and a great deal of imagination, a number of plastic surgeons continue to advance cleft care, seeing as many challenges ahead as they encountered at the beginning of their careers.

KEYWORDS

Oro-facial Cleft, Distraction Osteogenesis, Orthognathic Surgery

INTRODUCTION

Cleft lip and palate are common congenital deformities in the oromaxillary area. This birth defect causes several functional and aesthetic problems because of defects in the soft and hard tissue leading to nose deviation and formation of scar tissue after surgery. A systematic approach is thus required for cleft palate patients, which includes timing of surgery by a surgeon, caries control by pedodontist, attention to hearing problem by an ENT specialist, speech therapy, and growth modification by orthodontist. In cleft lip and palate patients, early surgical corrections are usually performed to improve esthetics and function.¹

These early surgeries tend to result in poor skeletal and dental growth in the transverse and antero posterior planes, especially in maxilla. The upper dentition often remains collapsed because of missing teeth. In children, orthodontics that uses orthopaedic means can be used to correct these problems. In adults, gingival recession, hearing problems, and relapse commonly follow arch expansion with quad-helix therapy or other type of conventional tooth movement appliances. In a dentition with missing lateral incisors in the cleft area, an autogenous bone graft is usually required before canine eruption. This, however, may lead to the occurrence of an oro-nasal fistula during expansion and tooth alignment and necessity for an autogenous bone graft.¹

Distractions osteogenesis (DO) was first used for correction of the craniofacial skeleton in early 1990s. Mc-Carthy et al reported using distraction to lengthen the mandible in patient with hemi-facial microsomia. Figuero and Polley reported success with no significant complications when DO was used to advance the maxilla in children with cleft lip and palate. Recently, DO was used to advance the maxilla in patients with cleft palate; however, little has been reported on the use of DO for maxillary expansion and closure of cleft alveolus.¹

The technique of DO takes advantage of the development of bone that

occurs when an osteotomized segment of bone is slowly moved, allowing new bone formation within the gap (Ilizarov, 1990). The gradual and incremental separation of bone segments is facilitated by the application of an appliance (internal or external), producing continuous bone formation parallel to the direction of distraction (Snyder et al., 1973).²

There are atleast two advantage in maxillary DO over conventional orthognathic surgeries in subjects with CLP. First, the soft tissue is remodelled in harmony with hard tissue. This may counteract relapse of maxillary bone more effectively than conventional surgical intervention. Second, the maxilla can be moved forward to greater extent than what can be obtained by orthognathic surgery. The greater anterior displacement of the maxilla may include more dramatic changes in the upper airway structure and functions, including an enlargement of the upper-airway caliber and a reduction in airway resistance.²

Bone lengthening by osteotomy (corticotomy) and distraction osteogenesis of the long bone was first described in 1905 by Codvilla and popularized by Ilizarov. In 1992 McCarthy et al successfully elongated the mandible by up to 24mm with gradual distraction of bone. It was proclaimed that distraction osteogenesis would affect the entire facial milieu with an increase in soft tissue envelop due to expansion and muscle hypertrophy. Molina and Monasterio stated that "skeletal distraction proceeds parallel to an expansion of all the soft tissue of face and upper neck (skin, muscles, vessels and nerves), achieving aesthetic results much superior to those obtained by skeletal surgery, by soft tissue surgery done independently, or by a combination of both." Since then numerous papers and reports have been published on distraction.³ Distraction osteogenesis has now been advocated as an effective and safe technique for mandibular lengthening.

HISTORICAL PERSPECTIVE AND EVOLUTION OF CRANIOFACIAL DISTRACTION OSTEOGENESIS

Distraction osteogenesis is a biological process of a new bone form

ation between the surface of bone segments that are gradually separated by incremental traction. Specifically, this process is initiated when a traction force is applied to the bone segments and continues as long as callous tissue are attached. This traction force in turn generates tension within the tissue that connects the bone segments which stimulates new bone formation parallel to vector of distraction.⁴

Importantly distraction force applied to bone also creates tension in the surrounding soft tissue initiating a sequence of adaptive changes termed "distraction histogenesis." Under the influence of tensional stress produced by gradual bone distraction, active histogenesis occurs in a different tissue, including gingival, blood vessels, ligaments, cartilage, muscles and nerves. This adaptive changes in soft tissue allow large skeletal movement while minimising the relapse seen in the acute orthopaedic corrections.⁴

Principle of mechanical manipulation of bone segments have been practiced in orthopaedics since ancient times when Hippocrates described the placement of traction forces on broken bones. He used an external apparatus consisting of two leather rings that were connected by four slightly bent rods made from elastic corner tree. The tension applied to the bone segment was controlled by amount of bending of the rod.⁴

Further evaluation of distraction osteogenesis involved the development and integration of the traction, bone fixation and osteotomy technique. The first occurrence of continuous traction for the long bone fracture can be treated to the work of de Chauliac in the fourteenth century, who used pulley system that consist of a weight attached to the leg by a cord, Barton, in 1826, is credited with being the first to perform the surgical division of bone, or osteotomy. The development of external skeletal fixation dates from the middle of the 19th century when the Malgaigne constructed an apparatus that was directly attached to bone, thereby allowing the direct transmission of a mechanical force to the skeleton. Considerable evolution of external skeletal fixation has occurred since then.⁴

Mechanical tension, one of the key signals of morphogenesis during natural bone growth and development was utilized by Ilizarov as the foundation of this distraction osteogenesis technique. Based on his clinical experience, Ilizarov discovered two biological principle of distraction osteogenesis known as "Ilizarov effects": (i) the tension stress effects on the genesis and growth of tissue and (ii) the influence of blood supply and loading on the shape of bone and joints.⁴

The first Ilizarov principle postulates that gradual traction creates stress that can stimulate and maintain regeneration and active growth of living tissues. The second Ilizarov principle theorized that the shape and mass of bones and joints are dependent on an interaction between the mechanical loading and blood supply. If blood supply is inadequate to support normal or increased mechanical loading then the bone cannot respond favourably, leading to atrophic or degenerative changes. In contrast, if blood supply is adequate to support increased mechanical loading, the bone will demonstrate compensatory hypertrophic changes. Several distraction osteogenesis technique were developed, depending on the place where tensional stress was induced, these techniques can be categorized as either callotasis, which means distraction of fracture callous or physical distraction, which is a distraction of the bone growth plate.⁴

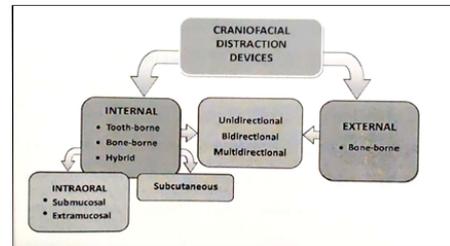
The DO application has modified the treatment form of the congenital and acquires craniofacial defects. With the use of force vector is possible to get a significant and steady bone remodel, in varied directions, without extensive surgical interventions (Klein& Howaldt, 1996; Mccarthy, 1994; Molina& Oritz Monasterio, 1995; Ortiz Monasterio et al., 1997; Pensler et al., 1995). According to recent studies re-absorption toothless alveolar rims or mandibular and maxillary atrophies caused by a syndrome can also be corrected successfully with this technique (Jazrayi et al, 1998, li et al, 1999, Welch et al, 1998, Yasui et al, 1997).⁵

DISTRACTION DEVICE CLASSIFICATION

In general, two types of device have been used for craniofacial osteodegeneration: external and internal. The external devices are attached to the bone by per-cutaneous pins connected externally to fixation clamps which are joined together by distraction rod that, with activation of device, it pushes the clamp and the attached bones segments apart, generating new bone in its path. Relative to the

direction of lengthening, they are divided into unidirectional, bidirectional and multidirectional devices.⁴

The internal devices are located either sub-cutaneously or within the oral cavity (intra orally), the intra oral device can be placed above (extra mucosal) or below (sub mucosal or buried) the soft tissues. These devices are attached to the bone (bone-borne), to the teeth (tooth-borne), or simultaneously to the teeth and bone (hybrid). A linear distractor, similar to an orthodontic expansion device, is often used despite the method of internal attachment.⁴

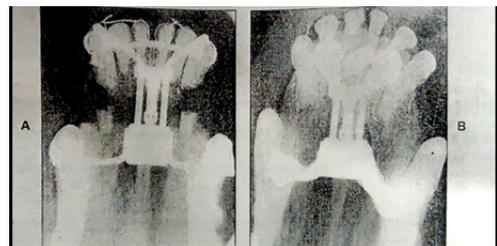


MAXILLARY AND MID FACE DISTRACTION

Maxillary distraction has been experimentally evaluated by Carls and colleagues⁴ as a potential treatment for velopharyngeal incompetence. They believed that distracting the hard palate towards the posterior pharyngeal wall would eliminate velopharyngeal incompetence providing that the short soft palate had satisfactory muscle function. Following posterior palatal distraction on six dogs, cephalometry and computed tomograms showed successful elongation of the posterior hard palate with gradual mineralization of the regenerate tissue in the distraction gap.⁴

One of the first clinical applications of mid-face distraction was reported in 1995 by Polley and co-authors⁴ who used an externally fixed cranial halo to distract the mid-face. The advantages of rigid external distraction device (RED) is that it is fairly simple to apply intra-operatively, easy to activate for patients and can be removed without the need for second operative procedures at the completion of consolidation. In several reports Polley and Figueroa's group⁴ demonstrated that full correction of the mid-face deficiency, including both the skeletal and soft tissue deficiencies was possible with their technique.⁴

About the same time Cohen developed the modular internal distraction (MID) system. Similar to the DynaForm device, this system consist of universally adaptable distractor that is made up of easily assembled tiny mesh plates based on the clinical application and/or anatomic location. In addition, the flexible activation cable allows easy activation through hidden pre-cutaneous site in the scalp, pre-auricular or post-auricular areas or intraoral regions.⁴



Radiographs demonstrating maxillary advancement using distraction technique. A: tooth borne distraction device B: Implant supported distraction device. (A from Block MS, Brister GD: J Oral Maxillofac Surg 52:282,1994. B from Block MS, Akin R, Chang A, et al: J Oral Maxillofac Surg 55:1433,1997.)

BONE TRANSPORT

Bone transport is a distraction osteogenesis technique that was first introduced by Ilizarov for treating long bone defects that resulted from trauma, oncologic resections or congenital anomalies, for the correction of large mandibular defects, reconstruction of nascondyles, cleft lip and palate and alveolar defects for dental implants.⁴

The concept includes resection of pathological bone followed by gradual transport of the osteomized healthy bone segments (transport disk) via a distraction device across the area of defect. As a transport bone segment is advanced, new bone tissue is generated, gradually

filling the defect. After the transport disk reaches the opposite host bone segment, the intervening fibrous tissue is removed followed by application of compression between the transport and host bone segments at the docking site.⁴

The first report of clinical application of bone transport was presented in 1995 by Costantino and co-workers who successfully applied transport distraction to restore the continuity of mandibular defect formed as a result of cancer resection following radiation therapy. A year later Block presented the result of four cases with bone transport using a Synthes lengthening device.⁴

Since these first reports, bone transport has been sporadically used to treat bone defects caused by trauma or bone resection. Distraction of bone segments in these cases has allowed mandibular reconstruction without bone grafting. Importantly, mandibular distraction recreates alveolar ridge with its attached mucosa.⁴

CEPHALOMETRIC EVALUATION OF AIRWAYS AFTER MAXILLARY ANTERIOR ADVANCEMENT BY DISTRACTION OSTEOGENESIS IN CLEFT LIP AND PALATE PATIENTS

Only a few studies have investigated morphological and functional changes in the upper airway longitudinally in subjects with CLP who underwent maxillary DO (Ko et al., 1990). In previous studies, the authors demonstrated longitudinal changes in velopharyngeal function by measuring cephalometric parameters at the level of the palate (Harada et al., 2002). Velopharyngeal function depends on three-dimensional (3D) movements of the velum and pharyngeal walls and has an important role in speech. In patients with cleft palate, palatal repair is performed during infancy primarily to close the cleft palate and to attain normal velopharyngeal function.

Although many comprehensive reviews on the applications of craniofacial DO have been published, neither respiratory functions nor cephalometric measurements of upper airway variables below the soft palate were evaluated in these studies. Also, it is unclear, regardless of the fact that maxillary DO can lead to soft tissue expansion, whether DO can lead to improvement of airway. Therefore, the objective of the study was to systematically review the evidence in the current literature regarding the possible changes in airway after maxillary anterior advancement by DO in cleft palate patients as evaluated cephalometrically.²

It has been widely accepted in the literature that DO can improve skeletal and soft tissue expansion in the affected bone and surrounding tissues. Nevertheless, there is little information available on how maxillary DO alter the upper-airway structure. Warren et al. (1969) reported that nasal resistance in subjects with CLP is 20% to 30% higher than that in age matched non-CLP subjects. Hairfield and Warren (1989) reported that there are dimensional and physiologic differences in the nasal airway between surgically repaired subjects with CLP and individuals without CLP. In this study, we systematically reviewed the changes in airway after maxillary anterior advancement by osteodistraction in CLP patients using cephalometric evaluations.² Despite the consistency of increasing the upper airway size and reducing nasal resistance. It was concluded that there is lack of evidence in this specific field of research in the form of higher-quality clinical trials (prospective, randomized controlled clinical trials) regarding the long term effectiveness of DO with CLP patients in increasing the upper airway size and reducing nasal resistance. Higher quality clinical trials (prospective, randomized controlled clinical trials) are needed to obtain more conclusive results and to evaluate the correlation between the long-term and short-term stability of changes in airway following DO in CLP patients and the other variables such as associated syndromes, amount of distracted bone, patient age and gender, technique and amount of distraction.²

STEPS OF DISTRACTION OSTEOGENESIS

Distraction osteogenesis begins with the development of reparative callus between the edges of two bone segments divided by a low energy osteotomy. After the callus has initially formed, a distraction force is applied to this bone segment and gradually pulls them apart. Gradual incremental separation of bone segment placed a callus under tension, this aligns the inter-segmentary gap tissues parallel to the direction of distraction. After desired amount of the bone length is achieved the distraction force is discontinued. The newly formed bone (distraction regenerate) undergoes maturation and remodelling until

it becomes undistinguishable from residual host bone.⁴

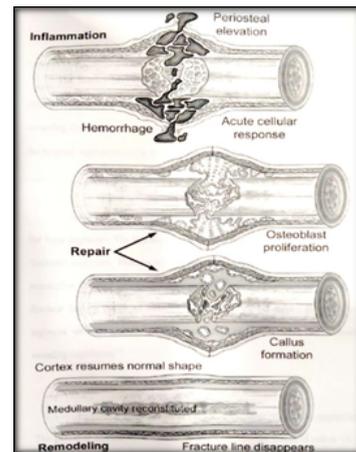
Clinically distraction osteogenesis consist of five sequential periods (i) osteotomy (ii) latency, duration from bone division to the onset of traction (iii) distraction, the time when gradual traction is applied and distraction regenerate is formed (iv) consolidation, a period that allows maturation and corticalization of the regenerate after traction force are discontinued and (v) remodelling, which extends from the initial application of full function loading to the completion of regenerate bone remodelling. This same temporal sequence will be followed by describing the biologic mechanism acting during the distraction osteogenesis.⁴

OSTEOTOMY

An osteotomy divides bone into two segments, resulting in the loss of continuity and mechanical integrity, this is also referred to as a fracture. This continuity of skeletal segments triggers an evolutionary process of bone repair known as a fracture healing. This process involves recruitment of osteoprogenitor cells, followed by cellular modulation or osteoinduction and establishment of environmental template (osteoconduction). As a result, a reparative callus is formed within and around the end of fractured bone segments, under normal conditions. The callus undergoes the gradual replacement by lamellar bone, which is mechanically more resistant.⁴

Traditionally, fracture healing has been described as consisting of six phases/stages:-
(i) impact (ii) induction (iii) inflammation (iv) soft callus (v) hard callus (vi) remodelling

The stage of impact takes place at the moment of stress and lasts until there is a complete dissipation of energy, which is absorbed by the bone until failure occurs. The stage of induction provides modulation of cell needed for the repair process possible inductors includes products of cell death, oxygen gradient, electric potential, non-collagenous proteins and others.⁴



LATENCY PERIOD

The latency period is the period from bone division to the onset of traction. This period represents the time allowed for reparative callus formation. The sequence of events occurring during the latency period is similar to that seen during fracture healing following the surgical separation of the bone into two segments, a cascade of events takes place.⁴

Initially, as a result of vascular disruption, a hematoma forms between and around the bone segments. The hematoma is converted to a clot. Bony necrosis occurs at the end of fractured segments. There is an ingrowth of vaso-formative elements and capillaries for the restoration of blood supply and a tremendous amount of cellular proliferation. This stage of fracture healing (stage of inflammation) lasts from 1-3 days, at which time the clot is replaced with the granulation tissue consisting of inflammatory cells, fibroblasts, collagen, invading capillaries.⁴ Following this, the soft callus has formed. On the 5th day of osteotomy a mini-cellular network of growing capillary loops is formed in the medullary canal of both proximal and distal segments in the area adjacent to the fracture line. During soft callus stage, granulation tissue is converted to fibrous tissue by fibroblast. Cartilage also replaces the granulation tissue. This occurs more towards the

periphery of inter-segmentary gap than in the central region by a front of endochondral ossification.⁴ Callus formation is the response of the determined osteoprogenitor cells, originating principally in the periosteum and endosteum. Histologically the callus formation occurs mainly by mixture of gap healing and direct oppositional bone formation and its main site of occurrence (outer and inner surface of the segment ends) serve as a solid base on which new bone tissue is deposited.⁴

DISTRACTION PERIOD

The distraction period is characterized by the application of traction force to osteotomise bone segments. Bone segments are gradually pulled apart, resulting in the formation of new bony tissues within the progressively increasing inter-segmentary gap.

During normal fracture healing, the fibro cartilaginous tissue of the soft callus is replaced by osteoblast into fiber bone (hard callus stage). The cartilage calcifies as capillaries invades and osteoblast lie down new bone on the calcified cartilage matrix. The stage of hard callus lasts 3-4 months for many fracture and is followed by a stage of remodelling when fibre bone is slowly remodelled to lamellar bone and medullary canal is reconstituted. The stage of remodelling ends when the bone has completely returned to normal with restoration of the medullary canal.⁴

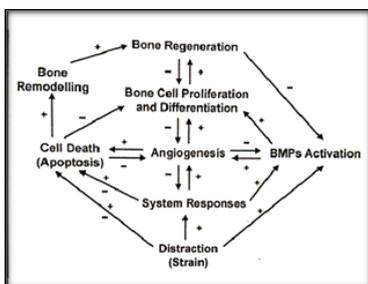
During osteodistraction, however, the normal process of fracture healing is interrupted by the application of gradual traction to the soft callus. Through the application of tensional stress to the inter-segmentary tissues of the soft callus, a dynamic micro-environment is created. The tension stress that develops in the gradually stretched tissue stimulates changes at the cellular and sub cellular levels. These changes can be characterized as a growth stimulating effects and a shape-forming effect.⁴ This includes (i) prolongation of angiogenesis with increased tissue oxygenation and (ii) increased fibroblast proliferation with intensification of bio-synthetic activity.⁴

The environment encourages new tissue formation in the distraction parallel to the vector of traction. As distraction begins the fibrous tissue of soft callus becomes longitudinally oriented along the excess of distraction. The spindle shaped fibroblast like cell located between the collagen fibres are also oriented along the direction of distraction.⁴

Between the third and seventh day of distraction, capillaries grow into the fibrous tissues, thereby extending the vascular network not only towards the centre of the gap but also the medullary canal of both adjacent bone segments. The newly formed capillaries are parallel to each other as well as to the long axis of distraction. Capillary terminals actively invade the fibrous tissue supplying them with less differentiated cells that differentiates into fibroblast, chondroblast or osteoblast.

During the second week of distraction, primary trabeculae begin to form. Osteogenesis is initiated at the existing bone wall and progress towards the center of the distraction gap. By the end of second week, the osteoid begins to mineralize.⁴

Bone formation occurs along the vector of tension and is maintained by the growing apexes of primary trabeculae, which remain open during the distraction period. These areas therefore function as the “growth zone” of distraction regenerate, providing active osteogenesis throughout the process of elongation. This zonal distribution of newly formed tissue in the distraction regenerate remains until the end of the distraction period. In addition, two new zones of primary trabeculae remodelling may become evident at the junction of the regenerate and host bone segments.⁴



CONSOLIDATION PERIOD

The consolidation period is that time between cessation of traction forces and removal of the distraction device. This period represents the time required complete mineralization of the distraction regenerate. After distraction ceases, the fibrous interzone gradually ossifies and one distinct zone of fibrous bone completely bridges the gap. In addition, focal regions of chondrocytes surrounded by a mineralized matrix maybe observed suggesting a third type (transchondroid)of bone formation, in which cartilage forms, possibly due to decreased oxygen tension, but is then directly transformed into bone, rather than the traditionally accepted endochondral pathway. As the regenerate matures, the zone of primary trabeculae significantly decreases and later is resorbed completely.⁴

REMODELING PERIOD

The remodelling period is the period from the application of full functional loading to complete remodelling of the newly formed bone. During this period, the initially formed bony scaffold is reinforced by parallel-fibered lamellar bone. Both the cortical bone and marrow cavity are restored. Haversian remodelling occurs which representing last stage of cortical reconstruction. It takes a year or more before the structure of newly formed bony tissue is comparable to that of pre-existing bone.⁴

USE OF DISTRACTION OSTEOGENESIS IN CLEFT PALATE PATIENTS

DO was used to advance the maxilla in patients with cleft palate; however, little has been reported on the use of DO for maxillary expansion and closure of the cleft alveolus. This article reports a case of dentoalveolar distraction in a repaired unilateral alveolar cleft patients using a tooth-borne-type distractor.¹

DO FOR MAXILLARY MOBILIZATION, EXPANSION, AND SEGMENTAL MESIAL TRANSPORTATION

In this patient with an arch length deficiency, it was chosen to address the transverse problem present with DO to correct the omega-shaped arch in the maxilla without the bending of bone and tissue tension. An osteotomy was performed by way of an enveloped soft tissue incision under 2% lidocaine infiltrations. A horizontal osteotomy was made 2mm above the canine to the first molar apex and must penetrate to the palatal cortex. The same procedure was performed on the contralateral side. A vertical osteotomy cut was made between the central incisor and canine and between first molar and second molar on both sides (Figure 2). A hyrax-type appliance was then cemented to the first premolars and first molars (Figure 3A). The patient tolerated the surgery well. A healing period of seven days was allowed, and in the eighth day the patient was instructed to turn the Hyrax appliance twice in the morning and twice in the evening until the next orthodontic visit, four days later. The patient was advised to continue turning the appliance in a similar fashion for three more days and then reduce the number of turns twice daily for total of 28 turns. A total of approximately 7 mm of expansion was achieved (Figure 3B). After a stabilizing period of three weeks, orthodontic brackets were bonded on the upper dentition to align the teeth. A light force with a 0.014-inch NiTi wire was applied. (Figure 3C).¹

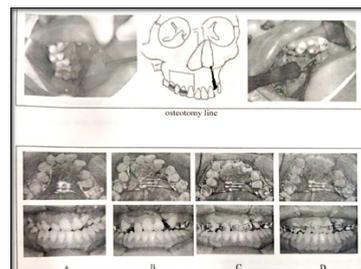


Figure 3: Photo of upper dentition (A) before distraction (B) Upper dentition after distraction (C) Initial alignment after a three week retention period (D) Increased left alveolus after the achieved upper arch

The period of alignment in the upper dentition was about five months (Figure 3D). During this period, the patient had no gingival recession, on arch collapse, and no alveolar crest resorption. After the surgically-assisted expansion and alignment of the upper arch, an increase in the size of the alveolar cleft, was noticed possibly due to the expansion. The cleft was closed by a forward transport of bone using a segment

from teeth 23 to 24 for which incision was made at the upper left side from the medial side of the canine to the distal side of the first premolar. A screw was implanted for verification of movement of the bony segment. A tooth-borne distraction device was constructed consisting of an orthodontic screw (Dentaurum Co), a 0.0180, 3.0250 tube, and a 0.0160 3.0220 stainless steel (SS) wire (Figure 4A). The construction of this appliance was simple in that the tube was welded to an orthodontic screw, and a properly bent SS wire was inserted into the tube.

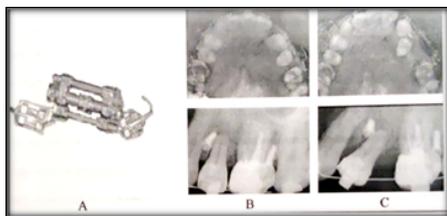


Figure 4: Closure mechanism of cleft alveolus with transport bone segment. (A) used distractor (B) Delivery tooth-borne distractor after corticotomy. (C) Tipping movement occurred after distraction for 14 days, and in X-ray view it was verified that the bone segment was tipped forward.

This appliance was placed on teeth 24 and 26 (Figure 4B). Following the same procedure of DO for transportation as was followed for maxillary expansion, the bone segment was moved mesially and the size of the cleft alveolus was decreased. The canine tipped forward, and tooth 24 showed a mesial-in rotation. Consequently, the mesial transportation of the bone segment was stopped and looked forward to some rotational relapse in the transported area (Figure 4C). After a consolidation period of two weeks, the first molar was moved into the newly created bone-regenerated area.¹

SKELTAL FACIAL BALANCE AND HARMONY IN THE CLEFT PATIENT

Facial balance and harmony are very important in society's acceptance of an individual. The cleft deformity frequently results in abnormalities that must be treated from the time of birth until facial growth is completed. Skeletal surgery is an important and integral part of cleft rehabilitation. The final surgery cannot be performed until growth is completed. In the senior author's (KES) experience using a surgical-orthodontic protocol, 30-40% of the patients required orthognathic surgery to achieve optimal facial balance, occlusion, and normal speech.⁶

SURGICAL ORTHODONTIC PLANNING AND PRINCIPLES

Passive orthodontic treatment was used in infancy in this series of patients. The treatment starts within a few days after birth with an expansible acrylic appliance. In infants with maxillary collapse, expansion is used to reposition the maxillary segments and create a more normal alveolar arch. Following lip/nose repair, it is important to maintain the alignment of the maxillary segments, for this purpose, the appliance is worn until palatoplasty is performed at the age of eight months. Cancellous bone grafting was performed at the time of tooth eruption in the defect of the alveolus. Prior to that time, orthodontic expansion was performed at about 5 and 1/2 years of age, and maintained until bone grafting was performed.⁶

In clinical situations where there was minimal (up to 4mm) class III discrepancy, the Delair facemask was used to improve the occlusion. It was not possible to predict which cases would need orthognathic correction. The cleft maxilla grows abnormally due to the cleft dysmorphogenesis and the inherited growth pattern of each particular patient, in addition to the influence of surgical scarring. These factors compound and contribute to the maxillary deficiency that is inherent in cleft patients. The search goes on for improved treatment protocols that will produce an optimal outcome of speech, occlusion, and facial balance. We prefer an attractive face, not just deformity correction.⁶

Prior to the completion of growth, these patients were treated with ongoing orthodontics with alignment and levelling of the teeth. Patients, who had occlusal discrepancies, were treated in preparation for orthognathic surgery.⁶ Cephalometric tracings, dental models, occlusal wafers, and other planning methods were utilized. Adjunctive planning methods included computer software packages that enabled

computer planning, supplementing the eye of the surgeon and orthodontist in determining optimal facial balance and harmony. Facial convexity and projection are very important in overcoming the stigmata of the cleft deformity. Maxillary projection, malar angularity with prominence, and proper show and projection of the upper teeth are important. The occlusion is then corrected by mandibular repositioning and possible genioplasty to create vertical and sagittal facial balance.⁶

In this series of patient receiving perforated, de-mineralized bone onlay grafts, none experienced any significant complications. Perforated, demineralized bone is an osteo-inductive, biocompatible material that was well accepted by the patient and underwent remodelling with minimal resorption of the implant.⁶

The secondary correction of the nose, septum, turbinates, and other paranasal skeletal deformity contributed to achieving an attractive face with normal function. All of these elements are important in achieving excellence in the surgical reconstruction of the cleft patients. Proper attention to the nasal malformation is how the senior surgeon has provided extensive, safe, and consistent aesthetic results in cases of cleft deformity.⁶

TREATMENT OF MAXILLARY CLEFT PALATE: DISTRACTION OSTEOGENESIS VS. CONVENTIONAL ORTHOGNATHIC SURGERIES

Maxillary hypoplasia in cleft lip and palate deformities results from congenital reduction in mid-facial growth and the effects of the surgical scar from cleft lip and palate repair. Maxillary advancement includes maxillary osteotomy and mini-plate fixation, along with interpositional bone grafting to improve support and prevent relapse. The purpose of this article was to present our experience using conventional orthognathic surgery vs distraction osteogenesis for maxillary cleft deficiency, in terms of stability and relapse.⁹

In cases of mild maxillary deformities without significant bone deficiency a one stage orthognathic surgery gave satisfactory results. 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.⁹

The maxilla in cleft lip and palate patients is often difficult to mobilize due to scarring from previous operations in the soft or hard palate or lip closure. The hypoplastic maxilla is usually advanced by one of the Le Fort osteotomies, with or without additional bone grafting in order to re-establish facial balance and occlusion. Newly formed bone can provide good, support and thus contribute to stability.

In the treatment of severe hypoplastic cleft palate with conventional Le Fort I osteotomy the major advancement and the extreme discrepancies made stabilization difficult, and the added effect of palatal scarring can result in significant postsurgical relapse.

In contrast, distraction osteogenesis provides an alternative method for maxillary advancement in patients with a great tendency to relapse, such as cleft palate patients. Experimental studies have demonstrated formation of mature lamellar bone by distraction osteogenesis.

In a study done on sheep, the maxilla was advanced 40 mm by distraction osteogenesis, with only 7% relapse at 1-year follow-up. In another experimental study using dogs, cephalometric evaluation of 14 mm of maxillary advancement by maxillary distraction demonstrated stable results at 1-year follow-up.⁹

In a meta-analysis of cleft maxillary osteotomy and distraction osteogenesis based on 98 articles from 1966 to 2003, Cheung and Chua found that 72 articles related to cleft maxillary osteotomy performed on 1,418 cleft patients, and that the other 26 articles described 276 cleft patients who had undergone maxillary distraction osteogenesis. This study concluded that distraction osteogenesis tends to be preferred to conventional osteotomy for younger cleft patients with more severe deformities. In such cases, it is feasible to use distraction to achieve moderate to large movement of the maxilla.⁹

In the present study the method of maxillary distraction in severe maxillary retrusion was gradual advancement with slight downward rotation of the maxilla permitting greater movement and during this

process concomitant new bone regeneration gradually became mature lamellar bone to maintain the final result. We conclude that distraction to correct the severe hypoplastic retruded cleft maxilla is superior to the conventional Le Fort I osteotomy.⁹

After period of growth with mild maxillary deficiency a one stage orthognathic surgery is preferable. However, in patients requiring moderate to large advancements with significant structural deficiencies of the maxilla or in growing patients the distraction technique is preferred.⁹

It has been suggested that DO offers several advantages over conventional, orthognathic surgeries in the treatment of patients with cleft lip and palate (CLP) like, the soft tissue is remodelled in harmony with the hard tissue. This may counteract relapse of the maxillary bone more effectively than conventional surgical intervention. Another, the maxilla can be moved forward to a greater extent than what can be obtained by orthognathic surgery. The greater anterior displacement of the maxilla may induce more dramatic changes in the upper airway structure and function, including an enlargement of the upper - airway caliber and a reduction in airway resistance.²

LONG-TERM FOLLOW-UP AFTER MAXILLARY DISTRACTION OSTEOGENESIS IN GROWING CHILDREN WITH CLEFT LIP AND PALATE

This study evaluated long-term positional changes of the maxilla and maxillary teeth in growing children with clefts who received maxillary distraction osteogenesis with RED devices to correct severe maxillary retrusion. In this study, it was reported that the maxilla could be lengthened horizontally and vertically by distraction secondary to the distraction vector. Other studies have reported similar findings (Cohen et al., 1997; Polley and Figueroa, 1997; Molina et al., 1998; Swennen et al., 2000; Krimmel et al., 2005; Rachmiel et al., 2005).

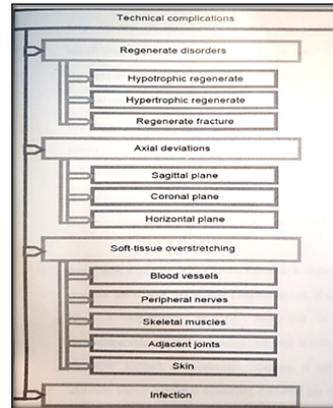
When maxillary changes after the distraction was examined, by the anterior and posterior maxilla, this two did not showed significant difference. In the horizontal direction, there was a posterior movement of 0.9 mm (A point) in the first 6 months. The posterior movement seen might be attributed to the relapse. Advancing the maxilla usually is met with resistance from the soft tissue and musculature. The amount of posterior relapse of the maxilla (9.6%) in the first 6 months that occurred in the present study was small when we considered the amount of distraction carried out. The small relapse might be explained by new bone formation in the distracted bone gap (i.e. pterygo maxillary region).

It was further observed that the maxilla continued to move backward until the 1 year time point. The period of the large posterior change did not correspond to the period of new bone formation (i.e 6 months postoperatively) in the distracted bone gap after the distraction. This further posterior movement suggests that pressure from the soft tissue and musculature may have a longer lasting effect, such that it could adversely affect the new maxillary position even after mature bone was formed. Except for Swennen et al. (2001), who reported no relapse 1 year postoperatively in two cases authors reported varying amount of relapse (4% to 42%) at 1 year after distraction (Harada et al., 2001; Figueroa et al., 2004; Kuroda et al., 2005). Cohen et al. (1997), although presenting no data, also noted that significant relapse occurred in a sample of two children, and they proposed to overcorrect in order to prevent a recurrence of the Class III situation. It also should be noted that forward growth of the maxilla ceased after the distraction in most cases. The critical finding opposes the view that "expansion of the soft tissue functional matrix by distraction" can enhance growth of the maxilla, and suggested by Swennen et al.⁸

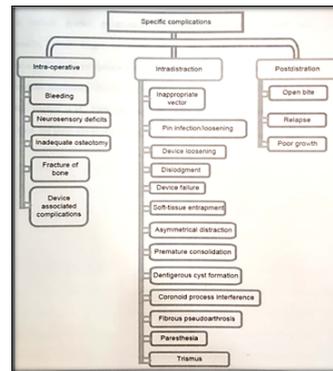
Figueroa et al. (2004) noted a further decrease of the SNA angle in the 3-year follow-up. Krimmel et al. (2005) also found a further decrease of the SNA and ANB angles after 1 year. Watzek et al. (1982), in an animal study, demonstrated that trauma or operation in the region of a suture has a considerable effect on growth in that area if it results in obliteration of the suture. Because the pterygomaxillary junction is an important growth site and is in the line of the osteotomy cut and the region of new bone formation during distraction, forward growth of the maxilla may be affected adversely due to disturbance of the growth site or obliteration of this junction. The second factor is pressure from the soft tissue and musculature, which may have a longer-lasting effect that could adversely affect maxillary forward growth.⁸

COMPLICATIONS

The complications that may occur during distraction osteogenesis are divided as (A) technical (B) specific.



A: Technical complications



B: Specific Complications

Distraction Osteogenesis Relapse

DO relapse is the piecemeal recurrence of the abnormality that the distraction was intended to correct. Relapse associated with DO has been an area of extensive research, owing to its multifactorial etiology (Grassmann et al., 1990; Simrmons et al., 1992; Yen, 1997; Davies et al., 1998; Taylor and Stal, 1998 ; Mobarak et al., 2001). The occurrence of relapse is influenced by several factors that can be related to either the patient or the surgical procedure. Patient-related factors include gender, preoperative mandibular plane angle (Arnett and Tamborello, 1990) degree of advancement, and presence of pre-existing temporomandibular joint dysfunction. Surgery related factors include fixation type and condylar positioning (McDonald , 1990 ; Longaker and Sicbert , 1996; Gateno et al., 2005; Bartlett et al., 2006; Jayade et al., 2006). Some of these factors can be controlled, but some obviously cannot.²

DISCUSSION

DO is a process of growing new bone by intentionally stretching pre-existing bone tissue. In routine DO, the bone is mechanically increased using a distractor across the osteotomy site and new bone is created during distraction. Many authors have reported successful results with corrective osteotomies followed by gradual bone distraction for mandibular lengthening and widening, alveolar ridge augmentation and forward movement of maxilla. DO can also be applied to patients with cleft lip and palate. A well-known modality is surgically assisted maxillary expansion in adults that transversely distracts the hard palate through the mid palatal suture. This technique reduces the complication of rapid maxillary expansion, which relies on tooth abutments alone without surgical assistance and can result in gingival recession, ankylosis, and root resorption. The technique reported in this study can be used for correction in collapsed arches in cleft palate patients.¹

After maxillary expansion was completed, the patient did not suffer any root resorption, tooth tipping, gingival recession, or none gap after osteotomy. We have also done rapid tooth movement into newly created bone areas without complication. However, the size of the cleft was increased after finishing tooth alignment.¹

In recent years, DO has been applied successfully to correct maxillary hypoplasia in cleft lip and palate patients with predictable and stable results. Subsequent research has reported on the mechanical considerations, phonetic changes, and profile changes after DO in cleft lip and palate patients. For successful results using this procedure, it is important to have an accurate prediction of the desired location and direction of action of the distractor.¹

For DO treatment of patients with cleft lip and palate, it is important to have a proper treatment plan based on biologic knowledge and mechanical consideration of this device to be used. If an orthodontist uses DO for cleft lip and palate patients with an appropriate device, it will open the way to supplement conventional treatment.¹

CONCLUSION

For DO treatment of patients with cleft lip and palate, it is important to have a proper treatment plan based on biologic knowledge and mechanical consideration of the device to be used. If an orthodontist uses DO for cleft lip and palate patients with an appropriate device, it will open the way to supplement conventional treatment.¹⁰

Cleft lip and palate patients normally undergo surgical soft tissue repair of the cleft lip and palate during infancy. The advantages of this surgical procedure shine brightly with the esthetic and functional improvement in the early days of the infant's life. Unfortunately, this pleasing effect is lost when impaired maxillary growth begins to make an appearance as the child grows. The resulting secondary deformities of the jaw and malocclusion are only a consequence of early soft tissue repair of the cleft palate. It has been reported that 25% to 60% of cleft lip and palate patients need to undergo maxillary advancement to correct the resulting midface hypoplasia. Ross et al showed that about 25% of patients with unilateral cleft lip and palate develop maxillary hypoplasia that does not respond to orthodontic treatment alone.¹⁰

Maxillary advancement using traditional one stage Le Fort I osteotomy is an accepted treatment modality in treating maxillary deficiencies in cleft patients. It has the advantage of performing a single surgical procedure to advance the maxilla with surgical repair of residual oroantral fistula. However, higher relapse tendency is the major disadvantage. Hochban noted a significantly higher relapse tendency in cleft patients who underwent maxillary Le Fort I advancement (20%-25%) compared to non cleft patients.¹⁰

The soft tissue changes associated with maxillary DO should be considered. The soft tissue drape covering the lower third of the face dictates the limits of the underlying skeletal advancement. A sudden instant advancement of the maxilla using conventional Le Fort I does not give the same aesthetic soft tissue results that DO offers.¹⁰

Although DO has several advantages over orthognathic surgery, its disadvantages and complications have been occasionally reported. DO requires a long duration to complete long with some difficulty to control the vector to achieve the favourable occlusion. The inability to guarantee formation of new bone in the osteotomy site is an issue of great importance. Nonunion has been re-reported in the literature and many contributing factors have been noted including age, mobile premaxilla and tooth loss. Some surgical factors that lead to malunion of maxillary osteotomies include violation of the vascular pedicles, fracture of bony segments and poor stabilization.¹⁰

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