Distraction Osteogenesis of Cleft Hypoplastic Maxilla : A Clinical Study

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Introduction

There is a wide acceptance of the conventional osteotomies for treating midface deficiency but there are certain limitations pertaining to them. In order to overcome these limitations several new approaches with modifications have been introduced. One among these is the method of gradual bone distraction known as ***DISTRACTION OSTEOGENESIS***.

By definition;

"Distraction Osteogenesis is a biologic process of new bone formation between the surfaces of bone segments that are gradually separated by incremental traction."

Importantly, distraction forces applied to bone also create tension in the surrounding soft tissue, initiating a sequence of adaptive changes termed as ***DISTRACTION HISTOGENESIS***.

The initial clinical trials on humans by ***McCarthy et al***, where the hypoplastic mandible was elongated, were responsible for generating the interest in this approach and its application to other areas of the craniofacial skeleton. To date, the mandible, maxillas,

entire midface, and orbits, as well as cranial bones, have been successfully distracted. Patients with orofacial clefts commonly present with maxillary hypoplasia as a result of the cleft itself, the genotype of the patient, or influenced by the scarring associated with the various procedures the patients undergo during rehabilitation. In addition to the existing scarring, patients may have pharyngeal flaps that affect stability after conventional maxillary advancement with orthognathic surgery. Because of the skeletal hypoplasias, these patients also present poor bone structure, making current rigid fixation techniques with screws and plates a difficult and unreliable procedure. If the bone is too thin, the ratio between the screw threads and bone to be fixated might be too small for proper screw retention. The results of orthognathic surgery on cleft patients have been disappointing, with reported relapse rates of 25% to 40%. In addition, patients with severe maxillary deficiency and a normal or even retrognathic mandible, maxillary advancement has been combined with mandibular setback to minimize the strong tendency for relapse. The application of maxillary distraction osteogenesis for the reconstruction of the cleft patient with severe maxillary hypoplasia offers a powerful treatment alternative in which only the hypoplastic

maxilla is addressed. This approach enables the reconstructive team, through a minimally invasive procedure, to manage patients with severe maxillary hypoplasia from childhood to adulthood with excellent and predictable functional and aesthetic outcomes.

Review Of Literature

First occurrence of continuous traction for long bone fractures were by ***De Chauliac*** [25] way back in the 14th century, he used a pulley system that had weight attached to the leg by a cord.

Barton [25] was credited for the first surgical division of bone in 1826.

Malgaigne [25] , in the middle of 19th century constructed an apparatus which was attached to the bone directly. External skeletal fixation has taken way ever since.

In 20th century, ***Codvilla (1905)*** [25] combined the old techniques to perform the first limb lengthening procedure using an external skeletal traction after an oblique osteotomy of the femur.

Gavril Ilizarov (1951) [25], a Russian surgeon designed an apparatus with 2 rings joined by 3 or 4 threaded rods. Bone

segments were secured to the rings by 2 thin tensioned wires inserted into the bone at a right angle to each other. He introduced the unique protocol of 5-7 days latency period followed by distraction period at the rate of 1mm/day in 4 equal increments.

Adlam DM et al (1989) [1] investigated relapse following midface osteotomies in cleft lip and palate patients in a retrospective study. The amount of surgical movement and subsequent relapse was measured using a computer aided digitization programmer with reference to the cranial base. The mean maxillary surgical advance was 5.09 mm horizontally and 5.70 mm vertically. After a mean follow up period of 22 months the mean relapse of the anterior maxilla was 0.90 mm (17%) horizontally and 1.55 mm (27.2%) vertically. Preliminary indications are that direct skeletal fixation of the maxilla by bone plates results in less relapse than when cranio-maxillary fixation is employed.

Hochban W et al (1993) [18] **,** compared the relapse tendencies after maxillary advancement in cleft and noncleft patients, 31 patients were examined preoperatively, postoperatively, and 1 year postoperatively; 14 of whom had clefts of the lip, alveolus, and palate. Any patients with major vertical or transverse changes or

additional mandibular surgery were excluded. Maxillary advancement by Le Fort I osteotomy and miniplate fixation was performed. Besides clinical examination, skeletal and dental changes were assessed cephalometrically. Results revealed a certain relapse tendency of the displacement in the noncleft group but relapse favoured the cleft group. This relapse is dependent on the amount of advancement. Despite minor differences, the two groups did not differ significantly based on maxillary advancement, so besides advancement surgery there must be another factor, cleft, to explain the different relapse tendencies between patients with and without clefts.

Rachmiel et al (1993) [33]***,*** performed midface osteotomies on 5 adult sheep, in 4 animals midface advancement by gradual distractions was performed using external distraction device. The midface advancement of 42 mm at the rate of 2mm/day for 21 days was done. Consolidation after active distraction was maintained for 6 weeks. New bone formation in thedistracted area was obvious clinically , radiographically and histologically. The author concludes that midface advancement by osteotomy and gradual distractions is possible in sheep and may offer control correction of the deformity.

Ayliffe PR (1995) [2] studied the relapse of the maxilla retrospectively in a group of 61 patients with previously repaired cleft lip and palate who had undergone Le Fort I osteotomy. The extent of surgical move and relapse over a mean period of 28 months was measured with reference to the cranial base, and found to be unacceptable.

McCance AM et al (1997) [24]***,*** The three-dimensional, facial soft-tissue changes of 24 patients with various cleft types following transpalatal Le Fort I osteotomy were measured using laser scanning techniques, radial measurements, and a color millimetric scale. There was a varying degree of midface retrusion in the different cleft groups, and a very similar pattern of retrusion over the nasal complex. Each group of patients showed a varying degree of relapse postsurgically, but there was a failure in all the cleft groups to correct the lack of nasal projection.

Polley J W et al (1997) [28] presents a technique for maxillary distraction osteogenesis in patients with severe maxillary hypoplasia. With the use of external, adjustable and rigid distraction

device they could treat patients with severe maxillary hypoplasia with precise and controlled distraction process, obtaining predictable results, they also conclude that this procedure had allowed them to treat patients of all age groups.

Polley J W, Figueroa A A et al (1998) [12] presents their clinical experience and cephalometric results with the use of rigid external distraction for the treatment of patients with severe maxillary deficiency. Eighteen consecutive orofacial cleft patients with severe maxillary hypoplasia were treated with maxillary distraction osteogenesis. Criteria for patient selection included severe maxillary hypoplasia with negative overjet of 8 mm or greater, patients with normal mandibular morphology, and patients with full primary dentition or older. There were 10 unilateral cleft lip and palate patients, 6 bilateral cleft lip and palate patients, and 2 patients with severe congenital facial clefting. A maxillary splint was prepared for each patient, and all patients underwent a high Le Fort I maxillary osteotomy Two types of mechanical distraction were utilized in this series. In group 1 (n = 14), the patients underwent rigid external distraction with an external distraction device. In group 2 (n =4),

patients underwent face mask distraction with elastics. For the patients in the rigid external distraction group, the mean effective horizontal advancement of the maxilla was 11.7 mm. All of these patients had correction of their negative overjet. For patients in the face mask distraction group, the results were disappointing. The mean effective advancement of the maxilla in this group was only 5.2 mm. Maxillary distraction osteogenesis with rigid external distraction permits full correction of the midfacial deficiency, including both the skeletal and soft-tissue deficiencies. They conclude that rigid external distraction in patients with severe maxillary hypoplasia allows full correction of the deformity through treatment of the affected region only. It offers the distinct advantage of correcting these severe deformities through a minimal procedure. Rigid external distraction has dramatically improved their treatment results for patients with severe cleft maxillary hypoplasia.

Saelen R, Tornes K (1998) [36] Le Fort I osteotomies were performed in 20 patients with cleft lip and palate as a one segment movement, and the fragments were fixed with miniplates without bone grafting. Tracings of preoperative and serial

postoperative lateral cephalograms were used to determine changes in maxillary position. The posterior nasal spine, not subjected to extensive changes during surgical procedures and remodeling, was found to be the most reliable landmark for measuring maxillary advancement and stability. The mean maxillary advancement was 5.96 mm. Analysis did not reveal significant changes in linear and angular measurements from immediately postoperative to 6 months postoperative. A modest maxillary advancement by Le Fort I osteotomy, along with alleviation of palatal scar tissue tension and miniplate fixation, is a stable surgical method in patients with cleft lip and palate.

Yeow et al (1999) [43] presents a case of bilateral cleft lip & cleft palate with maxillary hypoplasia, aged 10 years. Maxillary advancement of 17mm. using the rigid external device was achieved. Results show that patient had improved facial esthetics and dental occlusion, velopharyngeal function was unaffected. He concludes that distraction osteogenesis of the mid facial skeleton in cleft patients offers possibility to remodel not only the underlying bony skeleton but also all the soft tissues of face and palate.

Swennen G et al (1999) [39] uses maxillary distraction osteogenesis with rigid external device in 6 non-syndromic cleft lip and cleft palate patients aged between 12-16 with a mean age of 13.8 yrs (4 unilateral & 2 bilateral). He says that this technique provides simultaneous skeletal advancement and expansion of soft tissue. He used a force of 900gms. /day. Esthetic improvement obtained by maxillary distraction osteogenesis was impressive.

Alvaro A Figueroa et al (1999) [29] presents their technique to distract the hypoplastic cleft maxilla using a rigid external device. They conclude that this technique allows the reconstructive team treats patients of all age groups with predictable and stable results.

Ilizarov (1999) [6] categorized the distraction devices as internal and external directional devices depending at the site of application, he adds that the devices are capable of unidirectional, bi-directional and multiplanar distraction. These devices are used to lengthen the mandibular ramus, widen the mandible, ridge augmentation, conduct bone transport and for advancement of the midface as monobloc.

Hierl T, Hemprich A (1999) [16] Maxillary hypoplasia is a common finding in patients with repaired orofacial clefts. Management of this condition has been a challenge to the reconstructive team. The introduction of distraction osteogenesis to treat craniofacial skeletal dysplasias has opened alternative approaches to manage these severe conditions. In this article, the authors present their technique to distract the hypoplastic cleft maxilla using a rigid external distraction device. The clinical assessment, indications, orthodontic procedure, surgical technique, and distraction protocol are reviewed. A case report shows the use of the technique. This technique allows the reconstructive team to treat patients in all age groups with predictable and stable results.

Alvaro A Figueroa et al (1999) [13] presents the technique of maxillary distraction with RED device. Cephalometric results of 14 consecutive patients were analysed, both pre distraction and post distraction revealed significant skeletal maxillary advancement. He concludes that morbidity of this procedure is minimal.

Albino Triaca et al (2000) treated a 20 year old patient for facial asymmetry with both maxillary and mandibular

osteotomies and later with distraction osteogenesis using intraoral devices, they conclude that results produced perfect facial symmetry.

Feng Y, Tang Y, Shen G. (2000) [11] demonstrates a practical method for advancement of the midface using Le Fort I osteotomy and gradual distraction technique. They used an external adjustable, rigid distraction device and treated 6 patients with severe maxillary hypoplasia. Ages ranged from 11 to 15 years. They all underwent modified Le Fort I osteotomies assisted by gradual distraction. Four days postoperatively, distraction began at the rate of 1 mm/day for about 2 weeks. 4 weeks with the fixed distraction appliance and 6 weeks with a removable night-time face-mask retention, they then analyzed all those preoperative and postoperative protocols. Predictable results with midface advancement ranged from 8 to 13 mm. with a satisfactory class I or II molar relationship is achieved. The aesthetic results are excellent, no relapses have been observed. They conclude that this method of modified Le Fort I midface advancement has been shown to be clinically practical and effective.

Figueroa AA et al (2000) [30] conducted a study to evaluate soft tissue profile changes after maxillary advancement with distraction osteogenesis. He concludes that maxillary distraction osteogenesis improved soft tissue profile by increase in nasal projection, normalizing the naso labial angle and making upper lip more prominent without any change in upper lip. The concave facial profile became convex with improved facial balance and esthetics.

Swennen G et al (2000) proves that maxillary advancement by distraction osteogenesis has the advantage to provide new bone with simultaneous expansion of soft tissue functional matrix. His study includes two; 13-year-old patients with non-synchronic cleft lip & cleft palate had undergone distraction [one patient bilateral cleft lip cleft palate, one patient unilateral cleft lip cleft palate]. Maxillary advancement was performed using an external distraction device in combination with titanium mini plates as a skeletal maxillary anchorage. Pre operative lateral cephalograms, post distraction cephalograms, post consolidation cephalograms, 6-12 months follow up lateral cephalograns was concerned. 8 and 7mm

advancement respectively was achieved. The esthetic outcome was excellent.

Fearon JA et al (2001) [10]***,*** conducted a retrospective clinical outcome study to evaluate a new technique for distracting the Le Fort III procedure and to compare its results in growing children with those of the standard Le Fort III osteotomy. The records of 22 children were reviewed; 10 patients (mean age,6.5 years) underwent a standard Le Fort III procedure, and 12 patients (mean age, 7.5 years) underwent a Le Fort III distraction procedure. The distraction group included two separate techniques, bilateral buried distraction (2) and halo distraction (10). Preoperative and 2- 3 month postoperative cephalograms were analyzed. The average horizontal advancement achieved in the standard Le Fort III group was 6 mm, compared with 19 mm of advancement in the distraction group. Complications were evenly distributed between the two groups (one infection and one tracheostomy in each group), and the lengths of hospitalization were similar. No documented improvement in sleep apnea was identified in the standard Le Fort III group. However, in the distraction group two patients experienced normalization of sleep

studies postoperatively as measured by respiratory disturbance index, and two patients underwent successful decannulation of tracheotomies. For aesthetic reasons, halo distraction was preferred over bilateral buried distraction. With halo distraction the vector of traction is focused in the facial midline, which helps to reposition the concave midface and to provide a more convex facial profile. In growing children, the ideal vector for distraction is determined by the malar position and not by dental occlusion. The amount of overcorrection can be calculated from tables of normal anthropologic data. On this preliminary review, it was concluded that the use of halo distraction, in combination with a modified Le Fort III osteotomy, provided a significantly further forward-positioned midface and seemed to offer a better correction of sleep apnea than did the standard Le Fort III osteotomy.

Kiyoshi Harada et al (2001) [14]***,*** in this study 2 cleft lip & palate children with severe maxillary hypoplasia had undergone maxillary distraction osteogenesis using RED system. Postoperative changes in maxilla were examined upto 1 year. Post surgically 3-dimentional computed tomography, lateral cephalograms were used

for the study. They conclude that this is an advantageous procedure in maxillary hypoplasia of the cleft patients.

Krimmel M et al (2001) [22]**,** the author feels that patients with severe maxillary hypoplasia secondary to craniofacial dysplasia present a challenge to the craniofacial surgeon. Maxillary distraction presents a promising tool to treat these patients more successfully. Fifteen patients aged 12 to 20 years with craniofacial dysplasia and maxillary retrusion were treated with two different techniques after complete Le Fort I osteotomy: one group underwent face mask protraction (2 patients), and the other group underwent rigid external distraction (13 patients). Cephalometric evaluation was performed before and after distraction. Rigid external distraction appeared to be superior to face mask protraction. Maxillary retrusion was fully corrected in this group. The path of maxillary positioning was well controlled by changing the traction force vector. Distraction osteogenesis has certainly improved treatment of these patients.

Rieger J (2001) [35] neurosurgery and orthopedic literature revealed that halo complications relate primarilyto the skull pins. In most cases, these complications can be prevented if the

device is carefully applied and monitored. Early recognition and prompt treatment of complications are important. After experience with this system for advancement at the Le Fort III level, six patients with various syndromes involving the craniofacial skeleton have undergone Le Fort III level distraction osteogenesis with the rigid external distraction device in combination with a planned and stabilized frontosupraorbital advancement. In one of these cases, a 7-year-old child fell on the device after discharge from the hospital and sustained a compound depressed skull fracture that required debridement and repair.

Heliovaara A, Ranta R et al (2002) [15]***,*** the skeletal stability of Le Fort I osteotomy was evaluated retrospectively in 14 patients with isolated cleft palate (CP, mean age 27.2 years) and 11 patients with bilateral cleft lip and palate (BCLP, mean age 23.7 years). The osteotomy was fixed with titanium plates and the osteotomy gap was grafted with autologous bone. Neither intermaxillary fixation nor occlusal splints were used postoperatively. Skeletal stability was analysed both horizontally and vertically by cephalograms taken shortly before operation, immediately

afterwards, and at six months and at one year postoperatively. In the CP group the mean maxillary horizontal advancement (point A) was 4.7 mm(range 0.3-7.8) and the mean vertical lengthening 3.6 mm (range 0.7-6.1). One year postoperatively the mean relapse was 8.5% (0.4 mm) horizontally and 16.7% (0.6 mm) vertically. In the BCLP group the mean horizontal advancement was 5.3 mm (range 0.2-10.7) and the mean vertical lengthening 7.3 mm (range 0.6-11.8). The mean postoperative relapse was 9.4% (0.5 mm) horizontally and 17.8% (1.3 mm) vertically. The skeletal stability and relapse were similar in both cleft types although BCLP patients had more residual cleft problems and their mean surgical advancement was greater. There was great individual variation.

Rachmiel et al (2002) [34], the purpose of this study is to follow early event in bone formation and neovascularisation during maxillary distraction and after the consolidation period and to define the characteristic of the new born in distracted area. Seven sheep were osteotomised and external RED fixation done, maxilla lengthened up to 20mm at the rate of one mm per day. For 20 days was done. Results proved impressive.

J Wiltfang et al (2002) [41], in his study 8 patients were treated by distraction osteogenesis to correct hypoplasia of maxilla and midface, 5 patients were treated with intra oral distraction device, 3 patients were treated with extra oral distraction device were applied after before I, II & III osteotomies. The author says that the procedure was successful in all cases with an advancement of 9 mm in the group treated with intra oral distractions and a mean of 20.3 mm in group treated with extra oral distractors long term cephalograms and clinical evaluation after a mean follow up period of 24 months in intra oral distraction group and 12 months in extra oral distraction group. They conclude that stable results were obtained concerning dental and skeletal relations.

Eric T Elwood (2003) [9]***,*** the author reviews the treatment of two patients with severe mid face hypoplasia and obstructive sleep apnoea secondary to achondroplasia using mid face distraction osteogenesis. He concludes after distraction of 25 mm this procedure is useful to alleviate upper airway obstruction from mid face hypoplasia seen in achondroplasia.

Hierl T, Klisch N, Kloppel R, Hemprich A.(Mund Kiefer Gesichtschir. 2003 Jan;7(1):7-13) (article in German):[17]

Between May 1998 and May 2002, 38 patients suffering from severe midfacial retrusion and atrophy were treated by way of midfacial distraction osteogenesis. Diagnoses included cleft lip and palate (32 patients) and one case of Crouzon's disease. Ages ranged from 6-65 years. A total of 28 patients presented a velopharyngeal flap and nine patients were almost or fully edentulous. Using an extraoral halo device, distraction was performed after a subtotal Le Fort-I/II/III or modified quadrangular osteotomy. Distraction ranged from 9 to 31 mm (17 mm average). Following the primary operation, seven patients underwent a second intervention due to problems with the procedure or the device. Two patients needed a secondary Le Fort-I-osteotomy. With respect to velopharyngeal insufficiency, 21% showed a deterioration and 8% an improvement. Postoperatively, a decrease of 15-20% in the attained sagittal advancement was seen during the first 6 months. This was attributed to relapses and postoperative orthodontics. Thereafter skeletal stability was maintained. The author concludes that distraction osteogenesis of the

midface can be the method of choice in severe midfacial retrusion. Due to the difficult patient situation and the technical intricacies a higher complication rate has to be accepted than for conventional operations.

Kitai N et al (2003) [21]**,** the author combines orthodontic treatment with rigid external distraction osteogenesis in a 5.5-year-old girl with midfacial hypoplasia and oligodontia. The child with a reduced maxilla, protruding lower lip, skeletal Class III jaw relationship with a low mandibular plane angle, a short and flattened nose, anterior crossbite, and aplasia of 16 permanent teeth.The patient was treated with rigid external maxillary distraction osteogenesis, maxillary protraction headgear, and Class III elastics. Following treatment, the maxilla was displaced in a forward direction with new bone formation at the tuberosities and the mandible rotated backward in relation to the anterior cranial base. The anterior crossbite was corrected, and the skeletal jaw relationship changed from a Class III to a Class I skeletal pattern. The soft tissue facial profile showed that the nasal projection had been increased, the nasolabial angle increased, and the lower lip protrusion was reduced

with acceptable postoperative treatment results were acceptable. He concludes that early maxillary advancement with rigid external osteogenesis offers a promising treatment alternative for a very young patient with maxillary hypoplasia and oligodontia.

Dimitri Karakasis et al (2004) [7] presents a technique of callus distraction applied in a specific care of hypoplasia of a cleft maxilla with a sagittal advancement of maxilla. He concludes that the advancement of anterior maxillary segment in cleft patients of few many advantages.

Karakasis D et al (2004) [20]**,** interprets that several techniques of distraction osteogenesis have been applied for the correction of compromised midface in patients with clefts of the lip, alveolus and palate. He presents a technique of callus distraction applied in a specific case of hypoplasia of a cleft maxilla with the sagittal advancement of the maxilla thus not affecting velopharyngeal function. He says that the decision to apply distraction osteogenesis for advancement of the anterior maxillary segment in cleft patients offers many advantages.

Molina F et al (2004) [27]**,** gradual maxillary distraction by modified osteotomies and external force systems is a procedure with minimal morbidity and few complications. The interaction between surgeons and orthodontists is critical, however. The wide range of possibilities for remodeling a hypoplastic maxilla by distraction allows the potential to simultaneously advance and to elongate the midface, thereby restructuring the skeletal framework with mature new bone. An expansion of all the soft tissues of the face and palate (muscles, nerves, vessels, mucosa, skin) occurs in conjunction with bone elongation. This process ultimately produces excellent functional and aesthetic results in patients with midface deficiency, thus restoring their facial appearance and avoiding many years of facial deformity and associated psychologic sequelae.

Suzuki E Y et al (2004) [38] analysed 12 Japanese non synchronic unilateral cleft lip palate patients who had undergone maxillary distraction at the mean age of 16.4 years were used as subjects, 4 sets of lateral cephalograms

1) Before osteotomy.

2) Immediately after distraction.

3) 6 months later.

4) 12 months later were analysed.

Statistical analysis, a paired ‘t’ test, Pearson correlation analysis and stepwise linear regression analysis, were performed to distinguish characteristic dento skeletal changes. Significant dento skeletal relapse was found during 0-6 months follow up period but no further relapse 6-12 months follow up period.

Yamaji KE, Gateno J, Xia JJ et al (2004) [42] A new Le Fort I internal distraction device was developed by one of the authors (J. G.) and successfully used on a patient with cleft lip and palate and severe maxillary hypoplasia. The device consisted of an upper plate and a lower plate, which were installed above and below the Le Fort I osteotomy. The upper plate was shaped like a "U," and the lower plate was shaped like an inverted "U." The design of the device was unique in that the distraction screws were placed in the maxillary sinus andorientated parallel to the sagittal plane. Presurgical planning used a stereolithographic(STL) model and the CASSOS software to calculate the distraction vector. The distractors

were prebent and installed on the STL model and activated to advance the maxilla 15.5 mm. Surgery was performed in a conventional manner, and distraction was started on the seventh day after surgery. At the completion of distraction, a total of 15.5 mm of distraction was achieved. The distractors were removed 3 months after surgery. Results showed that the patient's severe maxillary hypoplasia was corrected as predicted and there was excellent new bone formation between the edges of the osteotomy.

Summary & Conclusion

Patients with severe maxillary hypoplasia secondary to congenital facial clefting present numerous challenging problems for the reconstructive surgeon. In our experience, distraction osteogenesis for maxillary hypoplasia secondary to facial cleft, we infer that distraction procedure helps us to advance the cleft maxilla to a desired position that cannot be achieved by the conventional osteotomy procedures. Rigid fixation with mini plates would be ideal at the time of removal of the device that is towards the end of the consolidation phase, which was done in only one of the patients, and needs further study with a long term follow up. When one corrects the

defect it is always advised to overcorrect in order to compensate the minimal relapse that is to be anticipated ranging from 2-5 mms. The clinical results achieved with the rigid external distraction device in cleft maxilla appear to be superior to those obtained by conventional osteotomies, elastic traction and removable face mask, as well as those with internal distractors.

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