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ORIGINAL RESEARCH

Evaluation of Reduction in Relapse and Enhancement of Patient Compliance with Hybrid Technique of Maxillary Distraction Osteogenesis: A Long-term Study

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ABSTRACT

Introduction and objectives: Hybrid technique of maxillary distraction osteogenesis is the latest advance introduced to correct maxillary hypoplasia in cleft lip and palate patients. The objectives of this study was to clinically and cephalometrically evaluate the stability of advanced maxilla over a period of 3 years, after maxillary advancement with hybrid technique of distraction osteogenesis in cleft lip and palate patients, and to asses the patient compliance during the procedure.

Materials and methods: Ten cleft lip and palate patients having severe maxillary hypoplasia underwent surgical correction of maxillary hypoplasia using hybrid technique of distraction osteogenesis where the rigid external distraction device was immediately removed after the active distraction period, and the advanced maxilla was fixed with rigid internal fixation. Clinical and cephalometrical analyses of the craniofacial skeleton were done at the predistraction, after active distraction and 3 years postdistraction period.

Results: The results of the clinical and cephalometrical evaluation indicated that there was an effective horizontal advancement of maxilla, increase in the length of the maxilla and a positive correction of overjet all together esthetically improving the facial profile. Three years post distraction evaluation of both the hard and soft tissue profiles indicated a very minimal relapse. All the patients had greater level of compliance after the removal of rigid external distractor and fixation of the distracted maxilla.

Conclusion: This study concluded that hybrid technique of maxillary distraction osteogenesis in cleft lip and palate patients gave esthetically acceptable facial profile with minimal relapse after 3 years of follow-up and an increased level of patient compliance during the procedure.

Keywords: Maxillary distraction, Mid-face hypoplasia, Rigid external distraction device, Distraction osteogenesis, Hybrid technique of distraction osteogenesis.

INTRODUCTION

The application of maxillary distraction osteogenesis for reconstruction of the cleft patients with severe maxillary hypoplasia offers a successful treatment in which only the hypoplastic maxilla is addressed for avoiding the mandibular setback.[4,13,14] 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 esthetic outcomes.[1,27]

The principle is that osteogenesis can be induced, if bone is expanded. The distraction forces applied to bone create tension in the surrounding soft tissues initiating a sequence of adaptive changes in the soft tissues allowing larger skeletal movements while minimizing the relapse.[2,15,17]

Rigid external distraction device uses a skeletally fixed distraction device that allows predictable control over the distraction process. With the use of rigid extraoral distractor, a hypoplastic maxilla can be repositioned and maintained to the desired horizontal and vertical position without the use of bone grafting.[18,26] But the use of rigid external distraction has certain disadvantages, like the external device is conspicuous so patients dislike going out in public until it has been removed. The traction force delivered through the teeth can cause dental changes, especially in patients with poor root support and loosening of the device may be due to improper stabilization or during sleep due to improper position.[2,5,28]

To improve patient comfort and reduce the rate of relapse, the new technique of hybrid distraction osteogenesis was introduced. In this technique, after active distraction, the rigid external distraction device is removed and the advanced maxilla is fixed in its new position with rigid internal fixation. This technique has two advantages: Firstly, patient was comfortable as the rigid external distraction device will be removed immediately after fixing the maxilla and it is not necessary for the patient to wear it throughout the period of consolidation and secondly the rigidity of the palates prevents the relapse of the advanced maxilla.[20]

OBJECTIVES

The objectives of the present study were:
1. To clinically and cephalometrically evaluate the craniofacial region before and after maxillary advancement with hybrid technique of distraction osteogenesis
2. To evaluate the patient compliance during the procedure
3. To study the stability of the advanced maxilla over a period of 3 years.

MATERIALS AND METHODS

Around 10 patients with severe anteroposterior deficiency of the maxilla with surgically corrected cleft lip and palate in the age group of 16 to 25 years with sufficient dental support were included in the study.

Following study records were made:
1. Clinical photographs
2. Orthopantamogram and lateral cephalogram
3. Study models.

These records were made at the pre-distraction period, at the end of active distraction and fixation of the advanced maxilla, and 3 years post-distraction for the study purpose.

In order to apply traction to the maxilla through the dentition, a rigid intraoral splint was fabricated which acted as a link between maxillary skeleton and the distraction apparatus.

An indigenously made adjustable rigid external distraction device which was first designed and reported by Polley and Figueroa et al was used to distract the maxilla.

Surgical Technique

The procedure was done under general anesthesia, and the patients were intubated with a nasal endotracheal tube.

A vestibular incision was made through the mucoperiosteum above the level of the mucogingival junction extending from 16 to 26, subperiosteal flap was raised to expose the entire anterolateral aspect of the maxilla. Osteotomy cut was made at the Le Fort I level, maxilla was downfractured, separated from the pterygomaxillary junction and was completely mobilized with Tessier mobilizers to make sure that the osteotomized maxilla would easily move in the desired vector once the traction is applied. The wound was closed with a resorbable suture material (Fig. 1).

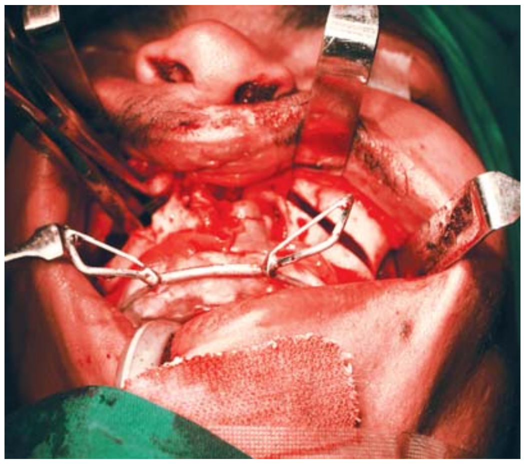

Fig. 1: Le Fort osteotomy and downfracture of the maxilla

Rigid External Distraction (RED) Device Placement

The adjustable rigid distraction device was symmetrically secured to the cranium using three scalp screws per side. The device was positioned 3 to 4 cm above the superior border of the helix on each side with device paralleling the Frankfort horizontal plane. The scalp screws were placed only onto the outer cortical plate of the skull using a screw driver. The external hooks of the intraoral splint were connected to the activating screws located on the horizontal bar of the distraction device using a 26 guage stainless steel wire.

Fig. 2: Active distraction of the osteotomized maxilla

Distraction Protocol

Active distraction was begun after a latency period of four days and from the 5th postoperative day distraction was started at a rate and frequency of one millimeter a day, until the predetermined amount of maxillary advancement in horizontal direction was achieved. Overcorrection of the hypoplasia was also achieved in all the 10 patients by taking into consideration of the anticipated relapse after removal of the distractor and fixation of the maxilla (Fig. 2).

Removal of the RED Device and Fixation of the Maxilla

Once appropriate predetermined advancement of the maxilla through distraction was achieved, then the patient was taken to operation theater, the rigid external distraction device was removed and the advanced maxilla was fixed in its new position with 4-hole, L-shaped, 1.5 mm diameter miniplates and 1.5 × 6 mm screws under general anesthesia. Postoperatively, class III elastics were used to stabilize the advanced maxilla for 3 weeks

Fig. 3: Rigid internal fixation of advanced maxilla

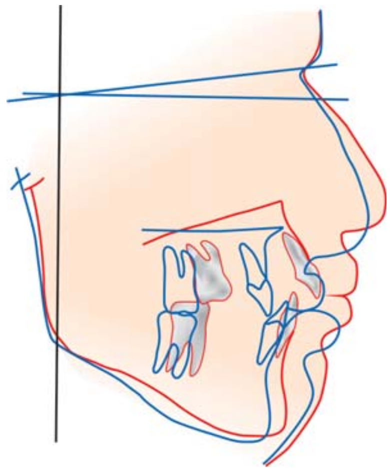

Fig. 4: Predistraction and 3 years follow-up cephalometric tracing

followed by the post-surgical orthodontics for the occlusal corrections (Fig. 3).

Cephalometric Evaluation

The preoperative and post-distraction lateral cephalometric radiographs were used for analysis. The radiographs were traced on 0.003 inch acetate paper, and 24 anatomic landmarks were recorded. Availability of serial radiographs in all patients permitted landmark verification. Based on the recorded anatomic landmarks, 21 measurements were calculated, seven angular measurements and 14 linear measurements. For the linear measurements X-Y coordinate system was used. A line drawn 7° below the SN plane (SN-7°) was used as the horizontal or x-axis. A line perpendicular to SN-7° through Sella-Hasion plane was used as vertical or y-axis line. The perpendicular distances to the landmarks from the y-axis and x-axis were obtained.[25]

RESULTS

In all the 10 patients treated with distraction osteogenesis using rigid external distraction device, an anteroposterior correction of midface deficiency was successfully achieved.

All the patients were compliant in wearing the rigid external distraction device for 2 to 3 weeks, there were no complications with wearing the external device, no pain or discomfort and there was no loosening of the distractor during the distraction process.

Cephalometric Analysis Immediately after the Active Distraction Period

The average SNA angle increased from 71.25° to 79.25° (increased by 8°), whereas the angle SNB showed a very minimal change by reducing to 74° from 76° (reduced by 2°) immediately after active distraction.

The average skeletal angle of facial convexity (NAPg) increased by 19.5° during the active distraction, and the MPA(SN/MP) opened by 4.5°. ANS and Point A moved anteriorly by 5.75 mm and 7.25 mm respectively, while the upper incisor moved anteriorly by 6.5 mm. The average increase of overjet was 6.25 mm. All the above-mentioned measurements were clinically significant and the desired treatment goals were obtained in all patients.

Cephalometric Analysis at the 3-Year Postdistraction Period

In 3-year follow-up after distraction, the average SNA angle decreased from 79.25° to 77° (decreased by 2.25°) and SNB increased by only 1° (Fig. 4). Facial convexity (NAPg) decreased by 1.5° and the MPA (SN/MP) demonstrated a 1° closure. The decrease in facial convexity probably resulted from a combination of anterior maxillary resorbtion, forward mandibular movement (growth) and closed rotation of the mandible. ANS and Point A decreased by 1 mm and 2 mm respectively. The mandible moved forward by 0.5 mm, as measured at Pogonion (Pg to X). This was due to both closed rotation of the mandible and anterior mandibular growth. The vertical position of all skeletal land marks remained stable, including ANS, Point A and Pogonion as well as upper and lower anterior facial height. During this time, the inclination of the upper incisors (PP/U1) did not change significantly. The overjet decreased by 1 mm.

Lateral cephalometric analysis during predistraction, immediate postdistraction and 3 years postdistraction were carried out and following observations were made.

- There was an effective horizontal advancement of maxilla which was clinically significant as noted by increase in the angle SNA and angle of facial convexity.
- There was a clockwise rotation of the mandible as reflected by the increase in the SN/MP angle which was clinically useful . There was an effective increase in the length of the maxilla.
- There was an effective increase in the length of the maxilla which was clinically significant.

- There was an increase in the anterior facial height due to clockwise rotation of mandible.
- The 3 years postdistraction evaluation indicated a very minimal degree of relapse which was clinically insignificant.
- The upper lip was more forwardly positioned with well-balanced posture with increase in nasolabial angle. Less relapse was seen following soft tissue changes.
- There was a positive correction of overjet with an increase in arch length.

DISCUSSION

There is a wide acceptance of the conventional osteotomies for treating mid-face 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 elongation known as distraction osteogenesis.[8,9]

By Definition

"Distraction osteogenesis is a biological process of new bone formation between the surfaces of bone segments that are gradually separated by incremental traction.[1]"

Importantly, distraction forces applied to the bone also create tension in the surrounding soft tissue, initiating a sequence of adaptive changes termed as distraction histogenesis.[1,5-7,10]

Among its innumerable clinical applications, craniofacial distraction procedures have been widely used for correction of severe anteroposterior, transverse and vertical deformities of craniofacial skeleton.[2,3]

The concept of gradually advancing the maxilla after Le Fort I corticotomy was originally presented by Molina and Ortiz-monasterio, where they used face masks with elastics in their technique, but it had several shortcomings, such as not delivering controlled forces, pressure sores on the chin and forehead, compliance and inability to advance the maxilla sufficiently.[14,23] These unfavorable experiences prompted them to modify the technique using distraction osteogenesis with a rigid external distraction device.[21,22]

The main principle behind maxillary distraction osteogenesis is that the patient creates stable autogenous bone in the location where it is needed for stability, the pterygo-maxillary region.[19,33]

Rigid external distraction device uses a skeletally fixed distraction device that allows predictable control over the distraction process. With the use of rigid extraoral distractor, a hypoplastic maxilla can be repositinoned and maintained to the desired horizontal and vertical position without the use of bone grafting. Polley JW, Figueroa AA et al (1998), used maxillary splint for stabilization of the maxilla and a high Le Fort I maxillary osteotomy was performed.[3]

Maxillary distraction with rigid extraoral distraction offers several unique advantages like:[2,31]

a. Freedom of osteotomy design
b. Allows predictable control over the distraction process
c. Rigid external distraction device is adjustable, offering the ability to change the vertical and horizontal vector of distraction at any time.

On the other hand, this procedure has the following disadvantages:[2,38]

a. The external device is conspicuous so patients dislike going out in public until it has been removed
b. The traction force delivered through the teeth can cause dental changes, especially in patients with poor root support or multiple missing teeth
c. Loosening of the device may be due to improper stabilization or during sleep due to improper position.

In order to overcome these disadvantages, the hybrid technique of distraction osteogenesis was introduced.[19,30] In this technique, to improve patient comfort during the procedure, after the active distraction of the maxilla, it was fixed with rigid internal fixation by using L-shaped, 4-holed, 1.5 mm diameter miniplates and 1.5 × 6 mm screws. This technique had two advantages: Firstly, patient was comfortable as the rigid external distraction device was removed immediately after fixing the maxilla and it was not necessary for the patient to wear it throughout the period of consolidation and secondly the rigidity of the palates prevented the relapse of the advanced maxilla.[19]

USES OF CEPHALOMETRY

Cephalometry is an effective tool to study the relationship of individual components of craniofacial skeleton in sagittal and vertical plane. It also helped us to evaluate the changes in skeletal and soft tissues following distraction osteogenesis. It also helps us to evaluate the immediate and late changes after distraction osteogenesis.[25]

Skeletal Changes

The present study showed a significant increase in the angle SNA during postdistraction period. This indicated the forward movement and placement of the maxilla achieved due to the distraction process and was clinically significant. The skeletal changes have resulted in the correction of facial profile as reflected in the significant improvement in the facial convexity angle (Table 1).

The amount and the degree of advancement achieved in this present study suggest that the distraction osteogenesis with the formation of the new bone can certainly be considered as the treatment of choice for severe maxillary hypoplasia.

The 3-year post-distraction evaluation showed minimal relapse which was not clinically significant. A very minimal decrease in the angle SNA and facial convexity suggested that the maxillary advancement achieved through rigid external distraction which was stable enough with the rigid internal fixation and clinically a pleasing profile was maintained even after 3 years.

Table 1: Skeletal analysis[4,25]

Skeletal	*Predistraction*	*Postdistraction*	*3 years follow-up*
SNA (deg)	79	88	84
SNB (deg)	81	78	79
NAPg (deg)	–6	12	12
SN/MP (deg)	25	28	27
Maxilla			
ANS-X (mm)	77	82	80
ANS-Y (mm)	47	49	49
A-X (mm)	72	77	75
A-Y (mm)	53	59	57
Mandible			
Pg-X (mm)	76	81	80
Pg-Y (mm)	115	118	117
Dental			
PP/UI (deg)	89	83	85
Is-X (mm)	64	71	69
Ii-X (mm)	80	77	78
OJ (mm)	–4	3	2

Linear Measurements

This study showed a significant amount of forward placement of apical base of the maxilla and increase in the length of maxilla during postdistraction period. This indicated that there was significant amount of new bone formation at the distraction site.

The 3-year post-distraction evaluation indicated very minimal degree of relapse which is clinically insignificant, and the relapse might be due to earlier operated soft tissue scar response.

There was an increased anterior facial height indicating the forward movement and placement of the maxilla. There was no change in the posterior facial height following distraction as the vector of pull during distraction was anteriorly placed causing only the forward movement of the posterior part of the maxilla.

Dental Changes

There was an increase in the maxillary incisor exposure with relative forward movement of upper incisors following distraction suggesting of anterior and inferior movement of dental relations. The 3-year post-distraction evaluation had a minimal amount of relapse which is clinically not significant.

Dental Cast Evaluation

There was a positive correction of overjet and overbite with increase in the arch length following distraction suggestive of forward movement of maxilla with clockwise rotation of mandible. The 3-year post-distraction evaluation had a minimal amount of relapse which is clinically not significant.

SUMMARY AND CONCLUSION

Patients with severe maxillary hypoplasia secondary to congenital cleft lip and palate present numerous challenging problems for the oral and maxillofacial surgeon. Distraction osteogenesis being a method of new bone formation between the surfaces of bone segments separated by incremental traction which was clinically used in 10 of our patients between the age group of 16 and 20 years who had severe anteroposterior deficiency of maxilla with greater than 8 to 10 mm of maxillary advancement required.

A high Le Fort I level osteotomy was performed in all the patients, and the rigid external distraction device was connected to the prefabricated intraoral splint which was cemented onto the maxilla. After a latency period of 4 days, 1 mm of distraction once daily was done until the required amount of maxillary advancement was achieved. After the active distraction, the advanced maxilla was fixed in the new advanced position with miniplates and screws and the rigid external distraction device was removed.

In the present study, distraction osteogenesis was effectively used for the correction of the midface hypoplasia in 10 cleft lip and palate patients. Hybrid technique of distraction osteogenesis proved to be the treatment of choice for the anterior linear advancement of the hypoplastic maxilla in cleft lip and palate patients in whom the maxillary advancement is highly difficult to be achieved by the conventional osteotomy procedures. Rigid fixation at the time of the removal of the rigid external distraction device had advantages of the patient compliance for not wearing the rigid external distraction device for 45 days as used in the regular distraction procedures and secondly the rigidity of the four miniplates used for fixing the advanced maxilla in the new position contributed in reducing the relapse.

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