

Distraction Osteogenesis of hypoplastic maxilla secondary to cleft lip / palate repair using rigid external device versus face mask in young age: A cohort retrospective study

Original
Article

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ABSTRACT

Background and objective: This study aimed at clinical assessment of maxillary distraction using rigid external distraction device (RED) versus face mask in young patients.

Materials and Methods: Fourteen patients were divided into 2 equal groups. Patients in both groups had maxillary hypoplasia secondary to cleft lip / palate repair. In group I, maxillary advancement was achieved using rigid external distraction device, while in group II, maxillary advancement was achieved using face mask therapy. Each patient was assessed in terms of relapse and improvement of facial measurements using cephalometric analysis.

Results: For all patients, the surgical procedures were performed without any major complications. The complications encountered during the follow up period were; apparent hypertrophic scars in 3 cases in group I, delayed union in one case in group I, skin injury in the chin area in group II and relapse in only one case in group I & also in only one case in group II. Postoperative improvement of maxillary measurements was achieved.

Conclusion: Maxillary advancement using rigid external distraction device is a reliable treatment modality with promising outcomes in management of patients with severe maxillary hypoplasia secondary to cleft lip / palate repair compared to face mask modality which is more reliable and valuable in mild to moderate maxillary hypoplasia cases.

Key Words: Distraction osteogenesis, rigid external distraction device & face mask.

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INTRODUCTION:

Maxillary hypoplasia in patients with cleft lip & palate (CLP) is a major outcome which is attributed to two main reasons which are: (1) the developmental defect & (2) the surgical scar from CLP repair. The degree of maxillary growth restriction depends largely on timing & the surgical intervention used for CLP repair. [1,2]

Orthognathic surgery using Le Fort I advancement is the classic technique in management of maxillary hypoplasia in CLP patients. However when the amount of maxillary advancement is 6-10mm; it becomes more challenging with a higher incidence of relapse. [2,3] Accordingly, an alternative treatment modality via maxillary distraction osteogenesis was introduced by Rachmiel and colleagues (1993). Thereafter, Polley & Figueroa (1997) introduced maxillary advancement using a rigid external distraction device (RED) to overcome the limitations of the orthognathic surgery. [4,5]

Distraction osteogenesis is a surgical technique that

allows a gradual maxillary distraction in both vertical & horizontal vectors through new bone formation between two bone segments with gradual soft tissue lengthening by application of tensile stresses and it involves four phases: creation of full osteotomy, latency phase, distraction phase & consolidation. Maxillary distraction can be achieved via two techniques; external distraction via face mask and RED & internal distraction [1,6,7]

Distraction osteogenesis is advocated when the desired amount of the maxillary advancement is > 10 mm in order to achieve long term stability. External distraction using RED device is a reliable treatment modality in cases of severe mid-face hypoplasia especially those with CLP with absence of maxillary and alveolar bone that required large maxillary advancement. Moreover, RED device is highly effective in cases of severe complex cranio-facial deformities and in cases with scarring due to the CLP repair. RED device is inserted via Le Fort I osteotomy & can be removed after achievement of the planned distraction as an outpatient procedure. [1,2,8,9]

RED device has many advantages including; (1) Ease of vector adjustment while moving the bones forward especially in cases of severe cranio-facial deformities, (2) lower rate of relapse which is attributed to the gradual advancement & lengthening of the soft tissue, (3) maxillary advancement > 10 mm and (4) The technique can be used in both growing & non growing patients with similar long term skeletal stability. [1,2,8,9]

RED device has its drawbacks including; (1) time intensive process, (2) psychological problem and (3) interference with daily living activities. The distraction using RED device has major and minor complications. Intra-cranial penetration/ migration of halo pins are the major complication encountered while using RED device that necessitates emergent neuro-surgical intervention. While the minor ones include superficial infections & pin loosening.^[8,9]

The other treatment modality of external distraction is face mask therapy that is applied with tooth-borne anchorage and is indicated in growing patients with more promising results in early mixed dentition. Moreover, face mask is widely used for retention for a period of six weeks to three months to maintain the achieved amount of maxillary advancement. The main advantage of using face mask is the non-surgical application that can treat maxillary hypoplasia in growing patients with more favorable outcomes in early mixed dentition. Different anchorage methods are used with face mask including tooth-borne anchorage, quad-helix device and rapid maxillary expansion (RME). Several drawbacks encountered with its application which include higher rate of relapse, long treatment period and lack of patient's compliance. ^[2,7,10]

MATERIAL AND METHOD

Materials

This retrospective study included 14 patients with maxillary hypoplasia secondary to cleft lip / palate repair. The age of patients ranged from 10 -18 years. Patients were selected from Out Patient Clinic of Oral Surgery Department, and Orthodontic Department, Faculty of Oral and Dental Medicine, Cairo University).

Patients included in the study underwent primary lip and/or palate repair in infancy or early childhood and had anteroposterior maxillary hypoplasia resulting in a concave profile with Class III malocclusion and negative overjet. Patients included in the study also had bone grafting for their alveolar defects.

Syndromic patients and patients who presented with systemic diseases that could interfere with bone healing process were excluded from the study.

Methods

All patients underwent distraction osteogenesis for correction of their concave profile. Le Fort I osteotomy without down fracturing the maxilla was performed in all patients. All complications either intraoperative or postoperative were recorded

Patients were divided into two groups; distraction was carried out using RED in the group I patients and using elastic traction with facial mask in the group II patients. Figure 1 & 2 A latent period was allowed before starting distraction in all cases. It ranged from 3 to 5 days (4 days in average). In all cases the distraction rate was 1 mm/day and all of them were done once/day. The consolidation period ranged from 8 to 12 weeks with an average of 10 weeks.

After this period, lateral cephalometric radiographs were taken to evaluate the distraction vector and quantity. Pre and post distraction clinical photographs were obtained in frontal and profile projections for all patients to document facial changes following distraction protocol. Follow up of patients ranged from 6 months to 1 year.



Figure 1: Photograph showing distraction using RED device in group I



Figure 2: Photograph showing distraction using face mask in group II

RESULT :

In group I, 4 females and 3 males were included in the study. The mean age of patients was 13 years old. The mean distraction distance was 10.7 mm. Table (1)

In group II, the majority of patients were females (5 patients) with only 2 male patients. The mean age of patients was 12.5 years old. The mean distraction distance was 8 mm. Table (2)

Table (1): Clinical data of patients and distraction distances achieved in Group I

Case No.	Sex	Age	Distraction distance(C) (mm)
1	M	10	9.5
2	F	18	12
3	M	14	14
4	M	13	9.5
5	F	7	9
6	F	17	12.5
7	F	14	8

Table (2): Clinical data of patients and distraction distances achieved in Group II

Case No.	Sex	Age	Distraction distance(C) (mm)
1	M	11	5
2	F	10	8
3	F	14	10
4	M	12	6.5
5	F	10	7
6	F	17	9
7	F	14	11

Surgical results

For all patients, the surgical procedures were performed without any major complications. No immediate postoperative surgical complications were observed except in two cases where minimal post-operative bleeding was noted

and were managed by using post-operative nasal packs.

Clinical results

Postoperative complications were observed in one case where a considerable edema was observed in which the intraoral appliance was removed to avoid exposing the lip to sever pressure.

The distraction process had been painless for most patients. In few cases the patients felt pain during the early distraction period and near the end of it. This was managed by injecting the patient with a sedative before the elongation process.

The complications encountered during the follow up period were; apparent hypertrophic scars caused by the metal traction of the trans-labial wires in 3 cases in group I, delayed union in one case in group I, skin injury in the chin area caused by face mask in group II which was attributed to excessive pressure from the device and relapse in only one case in group I & also in only one case in group II.

Radiographic results

Post-operative lateral cephalometric radiographs revealed improvement of the facial measurements. Postoperative improvement of maxillary measurements from lateral cephalometric analysis is shown in (Table 3)

Figure 3, 4 & 5.

Table (3): Mean of the surgical change & relapse in both groups

Skeletal Variable	Mean change (T2-T1)		Mean relapse (T3-T2)	
	Gp1	Gp2	Gp1	Gp2
SNA(o)	15.1	5.1	-1.2	-0.4
SNB(o)	-14.1	-0.6	0.5	-0.6
ANB(o)	11.1	5.1	0.3	0.05
N-A Perp(mm)	9.1	8	-0.2	0
Co-A(mm)	11.8	5.9	-0.7	-0.4
N-labial angle (o)	15.7	6.8	-4.6	1
Ls-E line(mm)	9.95	4	-4.05	0.2
Li- E line(mm)	2.1	-1.6	-1.7	1.25

T1: pre-distraction, **T2:** at end of distraction, **T3:** 6m-1yr follow-up. N: Nasion, A: A point, Perp: perpendicular, Co: condylion, N-labial angle: naso-labial angle, Ls: lip superior, Li: lip inferior and E line: esthetic line.

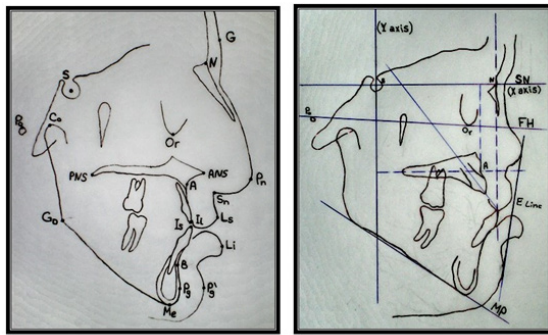


Figure 3: Diagram showing some of the points & lines used in the study.

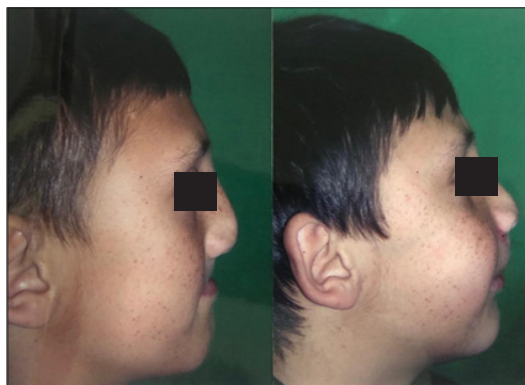
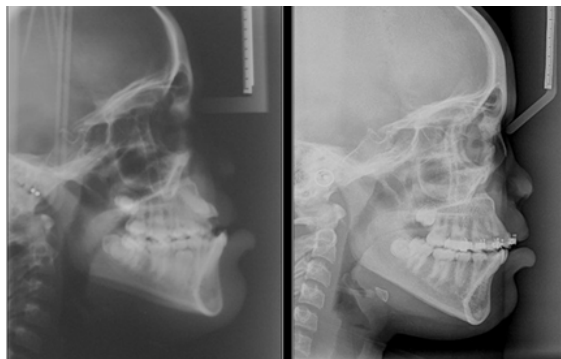


Figure 4: Post-operative clinical photograph & post-operative lateral cephalometric radiographs showing improvement of facial measurements in in group I



Figure 5: Post-operative clinical photograph & post-operative lateral cephalometric radiographs showing improvement of facial measurements in in group II

DISCUSSION

Maxillary hypoplasia in patients with cleft lip & palate (CLP) is a major outcome which necessitates correction using maxillary advancement. Traditionally, maxillary advancement is achieved using Le Fort I orthognathic surgery which is challenging in those patients due to presence of palatal scar tissues as a resultant of cleft repair that resist maxillary advancement and cause relapse especially in cases that require a major maxillary advancement with a reported rate of 25% relapse after a mean of 7.8 mm maxillary advancement. [2,6,7]

Accordingly, an alternative treatment modality via maxillary distraction osteogenesis (RED device & face mask therapy) was introduced to overcome the challenges encountered with the traditional maxillary advancement technique. Distraction osteogenesis is a reliable treatment modality that allows a gradual maxillary distraction in both vertical & horizontal vectors especially in cases that demand large maxillary advancements (> 10 mm) with good long term stability. [2,9]

The complications encountered during the follow up period in this study were; apparent hypertrophic scars caused by the metal traction of the trans-labial wires which were treated via surgical revision in 3 cases in group I, delayed union which required internal fixation in one case in group I and skin injury in the chin area caused by face mask in group II which was attributed to excessive pressure from the device which was treated by application of antiseptic solution locally and intermittent use of face mask. Dental compensation is another drawbacks which was encountered with some cases of Group II due to dental anchorage and excessive traction forces.

Finally relapse in only one case in group I that necessitated another distraction operation with the overcorrection done in that time & also in only one case in group II. The literature reported complications with RED device were pin loosening, superficial skin infections around pin sites, oral hardware malfunction and relapse as reported by Drew SJ et al. and Kim EN et al. [8,9]

In this study a relapse ranging from 10 % in group I & 15 % in group II. Consistent with these results, a horizontal skeletal relapse 12.6% to 26.0% were reported by Suzuki et al., Cho et al. and Meazzini MC et al. (11–13) Suzuki et al. performed a study to investigate longitudinal skeletal changes in patients with unilateral cleft lip and palate following maxillary distraction osteogenesis using the rigid external distraction device. The study reported a significant relapse occurred during the 1st 6 month with no relapse in the 6-12-month follow-up period and they attributed relapse to the amount of maxillary advancement and severity of pre-surgical maxillary hypoplasia. [11]

Cho et al. reported a relapse rate of 23 % in a study performed in patients with severe cleft maxillary hypoplasia who treated via distraction osteogenesis using RED. [12] In agreement with the previous study, Meazzini MC et al. reported a relapse rate of 16 % in the 1st year & 26% relapse in long-term follow up in growing children. [13]

Meanwhile, Richardson S. et al. reported 25 % relapse rate in patients treated via face mask. [7] Post-operative lateral cephalometric radiographs revealed that improvement of the facial measurements occurred with both RED device and face mask. Overcorrection was done in 3 cases of patients in group I, and 2 cases in group II. This overcorrection was preferred to make up for the soft tissue disparity and to achieve proper facial contour and form. In consistent with this study, literature reported the mean horizontal advancement at point A was 4–10 mm and 10-14 mm. [2]

Meazzini MC et al. [13] reported 22.2 ± 5.5 mm average total advancement of point A in the growing patients. Moreover, Tobolowsky W et al. [14] reported $+9.03^\circ$ average increase in SNA with no significant change in SNB and maxillary advancement of 14 mm in patients with cleft lip and palate following maxillary distraction osteogenesis using the rigid external distraction device.

Regarding maxillary advancement using face mask, D Cudziło et al. reported 3.84 mm mean maxillary advancement and mean of 2.76° advancement of SNA angle. Moreover, Nienkemper M et al. reported $+2.0^\circ$ increase in SNA, -1.2° decrease in SNB and $+3.2^\circ$ increase in ANB. [10,15]

CONCLUSION

Maxillary advancement using rigid external distraction device is a reliable treatment modality with promising outcomes in management of patients with maxillary hypoplasia secondary to cleft lip / palate repair compared to face mask modality which is more reliable and valuable in mild to moderate maxillary hypoplasia cases.

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Competing interests

No conflict of interest

Ethical approval

The Ethics and research committee, Faculty of Dentistry, Cairo University approved the study and patients' consent was obtained.

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