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Original Article

Evaluation of the hard and soft tissue changes after maxillary advancement with rigid external distractor in unilateral cleft lip and palate induced maxillary hypoplasia

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ABSTRACT

Background: Midfacial growth retardation in cleft lip and palate (CLP) cases, is seen in all the three dimensions. Conventionally these cases are managed by orthographic surgery which has a high rate of relapse. The application of the distraction osteogenesis (DO) has revolutionized the management protocol. The aim of the study was to evaluate the efficacy of rigid external distractor (RED) in management of cleft induced maxillary hypoplasia.

Methods: Ten cases of unilateral CLP between 11 and 20 years of age having gross midfacial deficiency and those who have undergone presurgical orthodontic treatment were included in the study. The cases were operated for Le Fort 1 osteotomy and application of RED. DO was carried out through transnasal traction wires. Clinico-radiological evaluation of presurgical and 1, 6 and 12 months post distraction parameters were statistically analysed by application of paired 't'-test.

Result: There were 4 males and 6 females with a mean age of 15.1 years. The mean distraction carried out was 14.95 mm. There was a significant improvement in all the hard and soft tissue parameters except SNB. Facial profile improvement and stable occlusion was achieved in all the cases.

Conclusion: Midfacial DO using RED is a versatile procedure where the maxilla can be moved in multiple planes to achieve a functional, aesthetic and occlusal balance. Keeping in view of the significant relapse rate the clinicians are required to plan 15–20% excess amount of distraction.

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Introduction

In cleft lip and palate (CLP) cases, the growth retardation is seen in all the three dimensions, antero-posterior, transverse and vertical directions. Developmental defect and frequent surgical intervention of the maxilla and nasovomerine complex are known factors for growth retardation of the midfacial complex.¹

Clinically the midfacial deficiency or hypoplasia manifests extraorally as concave facial profile, wide alar base, inverted nasal tip, acute nasolabial angle and excessive exposure of sclera. Intraoral findings are anterior and posterior crossbite, malocclusion, and accentuated curve of Spee, multiple missing teeth, oronasal communication and residual cleft. The speech disturbances are due to velopharyngeal incompetency and oronasal communication. At the mixed dentition stage it is difficult to predict the pattern of growth and hence to assess the actual disability.

Midfacial deficiency is conventionally managed by orthognathic surgery. The literature documents 25%–40% relapse in cleft maxillary hypoplasia with conventional orthognathic surgery.² The application of the distraction osteogenesis (DO) has provided a better and suitable alternative to treat cleft induced midfacial hypoplasia. More predictable functional and aesthetic outcomes are envisaged with DO. The indications of midfacial DO in cleft maxillary hypoplasia are deficiency more than 7 mm, poor stock of basal bone, lack of soft tissue envelop, severe scarring, velopharyngeal insufficiency, and failure of orthognathic surgery.³

Polley and Figueroa developed the rigid external distractor system (RED) for the advancement of the maxilla.⁴ Cranial anchorage offered better multidirectional vector control with better results as compared to the intraoral distractor devices. The major drawbacks of internal distractors are poor vector control, differential movement within the midface, discomfort, infection and trauma during activation.^{5–7} RED is a highly effective technique for correction of midfacial hypoplasia both for the patients with clefts as well as non-cleft cases. This prospective study was carried out to critically analyse the hard and soft tissue changes in cleft cases when treated by RED.

The aims of the study were to evaluate the efficacy of RED in management of maxillary hypoplasia and to clinico-radiologically compare the pre and postoperative tissue changes. The objectives were to evaluate the changes in the position of maxilla and dentition, soft tissue facial profile and rate of relapse.

Material and methods

Ten operated cases of unilateral cleft lip and palate having midfacial deficiency were selected from the out patient department of oral and maxillofacial surgery after applying the following inclusion and exclusion criteria.

The inclusion criteria were both male and female unilateral CLP patients between 11 and 20 years of age, having gross midfacial deficiency and those who have undergone presurgical orthodontic treatment. Syndromic cases and cases

Fig. 1 – Cemented occlusal splint.

having associated systemic illness, bilateral cleft cases and cases with history of orthognathic surgery and DO were excluded from the study.

All patients underwent a thorough history, clinico-radio-logical evaluation and presurgical orthodontic intervention and reviewed by cephalogram (C1). Impressions of the upper and lower dental arches were taken. A closed occlusal splint was fabricated with hooks and cemented to the maxillary arch to maintain the continuity (Fig. 1). The cases were operated under general anaesthesia. Xylocaine 2% with adrenaline 1:80,000 was injected along the line of incision. Through a semicircular vestibular incision the anterolateral wall of maxillae and nasal floor was exposed and a high Le Fort I osteotomy was carried out. The osteotomised segments were minimally mobilised. A three to four hole mini bone plate was bent at 45° approximately at the terminal hole and the remaining portion was adapted and fixed with mini screws of 2 mm diameter and 7 mm length above the root apices of bicuspids keeping the bent portion projecting towards the nasal aperture (Fig. 2). Similar procedure was repeated on the other side. A 010 SS twisted spiral wire was passed through the free

Fig. 2 – Fixation of bone plates.

hole and brought out transnasally (Fig. 3). The distractor head frame was anchored to the parietal bone through the outer cortical plate with the help of three scalp screws on each side (Fig. 4). Haemostasis achieved and wound closure was done using 3–0 vicryl.

Routine antibiotics, analgesics and postoperative care were given. The transnasal wires were secured to the distraction ports. After 5 days of latency period, distraction was carried out at a rate of 0.5 mm two times a day as per the treatment plan in each case. After eight to twelve weeks of consolidation period the RED and bone plates were removed under local anaesthesia. On resolution of postoperative oedema after four weeks lateral cephalogram was taken (C2). Orthodontic face mask with 200–300 gm force was used during post distraction orthodontics and after debonding for 6–9 months in all the patients. Postoperative cephalometric radiographs were taken after 6 months (C3) and 12 months (C4). The cases were evaluated clinically (Fig. 5 a to e) and the cephalometric parameters of C1, C2, C3 and C4 stages were compared (Fig. 6).

Result

Ten operated cases of UCLP, 4 males and 6 females were included in the study. At the time of surgery mean age was 15.1 years with a range of 11.3 years–19.8 years. Eight cases had undergone secondary alveolar grafting before distraction. The mean distraction carried out was 14.95 mm. The patient database is shown in Table 1. The comparative data of soft tissue and hard tissue changes are shown in Tables 2 and 3 respectively. The results were statistically analysed by

Fig. 3 – Transnasal traction wires.

Fig. 4 – Fixation of head frame.

application of paired 't'-test. The p -value is <0.05 which is statistically significant.

The mean improvement (C4–C1) and relapse (C2–C4) of SNA was 10.70° and 2.3° respectively (Graph 1). The percentage of relapse was 2.78%. There was no statistically significant change in mandibular position (SNB) as per statistical analysis. The mean improvement in the ANB (C4–C1) was 7.70° . The mean relapse ANB (C2–C4) was 2.3° (Graph 2). The mean improvement in linear maxillary advancement (Dist A to N vertical) as denoted by (C4–C1) was 9.35 mm. The mean relapse in maxillary advancement (C2–C4) was -2.2 mm (Graph 3). The net increase in the vertical position of the maxilla (Dist A to True horizontal) was (C4–C1) 6.8 mm. The mean relapse in the vertical position of the maxilla was (C2–C4) 1.7 mm.

The mean improvement in relationship of the upper incisor to N vertical (C4–C1) was 8.3 mm. The mean relapse (C2–C4) in the horizontal position of the maxillary incisor was 2.5 mm. The improvement in vertical position of the maxillary incisor (C4–C1) was found to be 7.7 mm. The mean relapse (C2–C4) 2.0 mm.

The facial contour angle improved by mean of 10.80° (C4–C1) (Graph 4). The nasolabial angle improved by 8.45° . The mean improvement in the lip prominence (C4–C1) was 5.9 mm with relapse (C2–C4) of 2.1 mm.

There was a significant improvement in the facial profile from concave to straight or convex. The dental crossbite was corrected and stable occlusion achieved. In two cases the existing oronasal communication was accentuated leading to nasal regurgitation of fluids.

Discussion

To overcome the limitations of orthognathic surgery, distraction osteogenesis was introduced to lengthen the jaw

Fig. 5 – a to e – A representative case, a – preoperative, b – perioperative, c – postoperative profile photographs, d – preoperative & e – postoperative occlusion.

bones.⁸ DO is a biologic process of new bone formation between the surfaces of bone segments that are gradually separated by incremental traction.⁹ In CLP patients a splint is cemented to the teeth which not only unifies the segments but also for engaging the traction wires through hooks. The force exerted on the dentoalveolar segment by the splint may induce the orthodontic tooth movement and influence cephalometric analysis.¹⁰ To minimise the traction induced orthodontic movement on the maxillary teeth we used traction directly on the osteotomized segment with the help of bone plates secured to the centre of mass of maxilla. Centre of mass of the maxilla is located at the basal bone near the root apices

of premolars.¹¹ The traction wires were brought out transnasally hence avoiding injury to lip. Scarring due to traction wire is within the nasal floor which is of least aesthetic concern.

Significant improvement of hard and soft tissue parameters has been reported in a short term follow-up period which was not stable in long term.¹² We used five hard tissue (Sella, Nasion, A point, B point and Tip of maxillary incisor crown), five soft tissue (Soft tissue glabella, Subnasale, Labrale superius, Soft tissue pogonion and Pronasale) cephalometric landmarks and five reference planes and ten cephalometric measurements to evaluate the stability of the result.

Fig. 6 – C1 to C4 – Sequential lateral cephalogram. C1 – preoperative, C2 – three months, C3 – six months & C4 – twelve months post distraction.

Table 1 – Patients database.

Cases	Age (years)	Sex	Distraction in mm
Case1	16	F	14
Case2	14	F	8
Case3	14.9	M	8
Case4	12	F	24.5
Case5	16.5	F	10
Case6	11.3	M	13
Case7	14	M	15
Case8	15	F	19.5
Case9	17.5	M	21.5
Case10	19.8	F	16
Mean	15.1		14.95
SD			5.594889

The mean improvement of SNA was 10.70° and relapse 2.3° (2.78%). The change in mandibular position (SNB) was statistically not significant as the *p*-value was 0.0732. The mean improvement in the ANB was 7.70°. The *p*-value was <0.05 which was statistically significant showing change in the maxillo-mandibular position. The mean relapse of ANB was 2.3° which was statistically significant. Relapse of SNA and ANB value has been reported in a long term follow-up to 5 years.¹³

The linear maxillary advancement (distance from point A to N vertical) was 9.35 mm. The mean relapse in maxillary advancement was –2.2 mm. This was statistically significant as shown by *p*-value = 0.0001. The net increase in the vertical position of the maxilla was 6.8 mm which indicates the increase in the anterior facial height. In a five year follow-up study of maxillary DO in CLP cases, similar horizontal advancement and downward movement of the maxilla have been reported.¹⁴

The mean improvement the relationship of the upper incisor to N vertical was 8.3 mm. The net difference in vertical distance of the upper maxillary incisor was found to be 7.7 mm. The mean relapse of 2.0 mm which was also statistically significant (*p* value = 0.0001).

The angle of convexity or facial contour angle showed a mean improvement of 10.80°. The mean relapse was 2.1°. The mean improvement of nasolabial angle was 8.45° which showed advancement of maxilla along with its dental component and release of entrapment of upper lip. The relapse of nasolabial angle was only 2.1° which indicated relative stable position of the upper lip in relation to nasal tip.

Table 3 – Comparative analysis of hard tissue parameters at C1, C2, C3 and C4.

A to N vertical				
Periods/Means	0M(C1)/–9.65	3M(C2)/1.90	6M(C3)/0.90	
	3M(C2)/1.90	10.08/0.0001		
	6M(C3)/0.90	9.20/0.0001	–2.7021/0.0001	
	12M(C4)/–0.30	8.61/0.0001	–16.50/0.0001	–9.00/0.0001
A to True horizontal				
Periods/Means	0M(C1)/49.8	3M(C2)/58.30	6M(C3)/57.60	
	3M(C2)/58.30	9.89/0.0001		
	6M(C3)/57.60	8.63/0.0001	–4.58/0.001	
	12M(C4)/56.60	8.50/0.0001	–11.13/0.0001	–4.74/0.001
SNA				
Periods/Means	0M(C1)/69.60	3M(C2)/82.60	6M(C3)/81.40	
	3M(C2)/82.60	10.35/0.0001		
	6M(C3)/81.40	9.99/0.0001	83.43/0.0001	
	12M(C4)/80.30	9.04/0.0001	104.36/0.0001	–6.13/0.0001
ANB				
Period/Means	0M(C1)/–5.40	3M(C2)/4.60	6M(C3)/3.40	
	3M(C2)/4.60	3.72/0.005		
	6M(C3)/3.40	3.34/0.009	–9.00/0.0001	
	12M(C4)/2.30	2.94/0.017	–1078/0.0001	–6.13/0.0001
U1 to N vertical				
Period/Means	0M(C1)/–6.80	3M(C2)/4.00	6M(C3)/2.90	
	3M(C2)/4.00	10.95/0.0001		
	6M(C3)/2.90	10.41/0.0001	–11.00/0.0001	
	12M(C4)/1.50	8.59/0.0001	–15.00/0.0001	–8.57/0.0001
U1 to True horizontal				
Period/Means	0M(C1)/73.40	3M(C2)/83.10	6M(C3)/82.60	
	3M(C2)/83.10	11.87/0.0001		
	6M(C3)/82.60	10.17/0.0001	–3.00/0.015	
	12M(C4)/81.1	9.58/0.0001	–13.42/0.0001	–6.71/0.0001

The improvement of lip prominence by 5.9 mm indicated anterior repositioning of the upper lip. Similar soft tissue changes have been reported by authors in cases of CLP induced hypoplasia treated by RED.^{15,16}

Esthetically all the patients had significant improvement in the facial profile. Higher level osteotomy prevented damage to the root apices and permitted advancement of larger bony segment thereby addressing the para nasal deficiency. In four cases where the advancement was more than 15 mm there was unusual fullness of the upper lip leading to poor esthetics which settled in the postoperative phase due to muscular and functional adaptation and relapse. All the cases had improvement of the facial contour from concave to straight or convex.

Table 2 – Comparative analysis of soft tissue parameters at C1, C2, C3 and C4.

Lip prominence				
Periods/Means	0 M(C1)/5.00	3 M(C2)/13.00	6 M(C3)/11.90	
	3 M(C2)/13.00	10.73/0.0001		
	6 M(C3)/11.90	09.36/0.0001	–06.13/0.0001	
	12M(C4)/10.90	07.85/0.0001	–11.70/0.0001	–06.71/0.0001
Angle of convexity				
Periods/Means	0 M(C1)/–0.20	3 M(C2)/–13.10	6 M(C3)/–12.40	
	3M(C2)/–13.10	–10.54/0.0001		
	6M(C3)/–12.40	–10.76/0.0001	3.28/0.010	
	12M(C4)/–11.00	–8.80/0.0001	7.58/0.0001	6.33/0.0001
Nasolabial angle				
Period/Means	0 M(C1)/86.65	3 M(C2)/97.20	6 M(C3)/96.00	
	3M(C2)/97.20	9.24/0.0001		
	6M(C3)/96.00	8.10/0.0001	–4.13/0.003	
	12M(C4)/95.10	7.71/0.0001	–5.55/0.0001	–5.01/0.001

Graph 1 – Mean SNA value at different intervals.

Graph 2 – Mean ANB measurements.

All the cases were subjected to post surgical orthodontics for final settling of the occlusion. There was significant improvement of the dental occlusion. Anterior and posterior crossbite was corrected in all the cases. Class I molar relationship was achieved in 8 cases. Remaining 2 cases had Class II molar relationship. Orthodontic face mask was used in all our cases for 6–9 months to minimise relapse.

Complications of RED have been attributed to the placement of skull pins.¹⁷ There is a possibility of dural tear and CSF

Graph 3 – Mean values distance of point A to N vertical.

Graph 4 – Mean values – angle of convexity.

leak if the inner diploe is breached. Secondary infection in the region of the cranial anchorage, localised alopecia and scarring are other complications. None of our cases had perforation of the inner diploe. All our cases had scarring and loss of hair in the area of skull pins.

Restriction of the day-to-day activities is the main disadvantage associated with RED. Accidental fall leading to depressed skull fracture has also been reported by Rieger et al.¹⁸ Compliance of the patients and parents are of paramount importance to avoid such complications. The cases can be planned during the school term breaks so as to minimise the social interaction and thereby complications.

Conclusion

Traditional surgical/orthodontic approaches to treat multidimensional midface deficiency in CLP patients often fall short of expectations of patients as well as the clinicians. Maxillary DO using RED is a versatile procedure where the maxilla can be moved in multiple planes and moulded to achieve a functional, aesthetic and occlusal balance. In all our cases the concave profile improved to straight or convex profile and dental cross bites were corrected. Keeping in view of the significant relapse rate the clinicians are required to plan 15–20% excess amount of distraction.

Conflicts of interest

The authors have none to declare.

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