A clinical evaluation of midface advancement using intraoral distractors in management of bone stock deficiencies

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ABSTRACT

BACKGROUND

Cleft lip and palate patients present large osseous defects of the alveolus and midface hypoplasia. Traditional orthognathic surgery has limitations of relapse and limited age group. Distraction osteogenesis (DO) as a modality for midface advancement is relatively new. Modular internal distractor (MID) offers the advantage of patient compliance and minimal discomfort. The purpose of this study was to evaluate the versatility of intraoral distractors in midface advancement.

METHOD

Nineteen patients with midface bone stock deficiency were selected for maxillary advancement. At the first surgery under general anaesthesia, after the osteotomy (Le Fort I/II), MID system was used. After distraction, evaluation was done for ease of the procedure, stability, and complications. Lateral cephalograms were evaluated at three stages: T1, pre-distraction; T2, post-distraction; and T3, one year post-distraction.

RESULTS

Significant changes showed 13.3 mm mean midface advancement bone formation at the pterygomaxillary region. The results were stable even at one year follow-up.

CONCLUSION

Maxillary position improved in relation to the cranial base. This study showed that the MID was versatile in midface advancement in stability and patient compliance with minimal complications.

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Key Words: distraction osteogenesis (DO); maxillary hypoplasia; midface advancement

INTRODUCTION

Patients with orofacial clefts commonly present with maxillary hypoplasia either because of the cleft, or scarring due to early surgery. The primary cleft lip and palate repair done at early childhood improves the facial appearance, speech, and deglutition, but these surgeries cause impairment of maxillary growth and producing secondary jaw deformities.

Cleft patients with maxillary deficiency are difficult to treat with standard orthognathic surgery. Due to skeletal hypoplasia, poor bone stock make rigid fixation difficult and less reliable. It is difficult to mobilise the maxilla due to scarring. The hypoplastic maxilla is advanced by Le Fort I osteotomy, with or without bone graft, to establish the facial balance and occlusion. The results of orthognathic surgery on cleft patients have been disappointing, with reported relapse rates of 25–40% in spite of rigid internal fixation (RIF).^{1,2} Maxillary advancement has been combined with mandibular setback to minimise the relapse.

The use of distraction osteogenesis (DO) is a new and predictable method for maxillary bone elongation with new bone formation at the distraction site. In severe maxillary hypoplasia this offers a viable alternative in which only the hypoplastic maxilla is addressed.

Although rigid external distractor (RED) provides stability, it is bulky and demands patient compliance; the traction force can cause dental changes.³ Modular internal distractor (MID) introduced by Cohen in 1999, is a system for internal distraction that is applicable throughout the craniofacial region. It has the merits of smaller size, better patient compliance, and minimal discomfort.⁴ Although treatment with this system is useful and effective for maxillary hypoplasia in cleft lip and palate patients, follow-ups are required to study relapse.

This study aims in evaluating the versatility of intraoral distraction devices in the management of such bone stock deficiencies and determining the stability of advancement for one year.

MATERIALS AND METHOD

Nineteen patients with midface bone stock deficiency were selected from the outpatient department of the Department of Dental Surgery, AFMC Pune. The mean age of the patients was 20.1 years (range 11–25 years of age). The study group included 13 males and 6 females. Twelve patients had unilateral cleft lip and palate and seven had bilateral cleft lip and palate.

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The maxillary advancement was planned based on clinical evaluation for aesthetics, occlusion, and cephalometric values (Figures 1 and 2). Midface advancement surgery was performed under general anaesthesia (GA) utilising nasal intubation. The choice of osteotomy was dictated by patient's aesthetic and functional needs. Le Fort I osteotomy in 13 cases, modified quadrangular Le Fort osteotomy in four cases, high Le Fort II osteotomy in two cases was carried out.

Modular internal distraction system (Stryker Leibinger; Figure 3) was used in all cases. The ports were kept parallel to each other and the occlusal plane (Figure 4). Post-MID placement, a latency period of 5–7 days was followed. Distraction at the rate of 4–1.2 mm (12 hourly) for 7–12 days was achieved. A consolidation period of 6–8 weeks was allowed. The second surgery (Figure 5) was performed under GA for MID removal

Figure 1 Cephalometric landmarks.

Figure 2 Pre-operative appearance and cephalogram.

Figure 3 The modular internal distractor system.

Figure 4 (A–D) Osteotomy and modular internal distractor placement; orthopantomogram and cephalogram showing parallelism to the occlusal plane.

Figure 5 Post-consolidation modular internal distractor removal and rigid fixation.

Figure 6 (A–C) Post-consolidation appearance and cephalogram at six months.

Figure 7 (A–C) Post-consolidation appearance and cephalogram at 12 months.

and rigid internal fixation followed by retention with Delaire's reverse pull head gear/face mask for three months. Clinico-radiological follow-up for stability and soft tissue response for one year post-distraction was made (Figures 6 and 7).

Clinically MID was evaluated for ease in orientation, positioning, adaptability to the osteotomised segments, ease in distraction, vector control during distraction, post-distraction stability, and complications. The versatility of MID was assessed for additional applications.

Evaluation of lateral cephalograms was carried out at three different stages: T1, pre-distraction; T2, immediate post-distraction (on completion of advancement 12–15 days at the rate of 1 mm/day); and T3, one year post-distraction follow-up. The landmarks selected were (Figure 1): sella (S), centre of sella turcica; nasion (N); A point (A), the deepest point in the curved bony outline of maxilla; and B point (B), the most posterior point in the outer contour of the mandibular alveolar process. Reference planes selected were: sella–nasion plane (SN), plane representing the anterior cranial base; X axis (horizontal axis), constructed line at 7° relative to the S–N line; Y axis (vertical axis), vertical line through sella perpendicular to X axis; and mandibular plane, tangent to the lower border of the mandible. In a total of 57 cephalograms (three per patient) used, eight selected variables were measured as skeletal linear measurements, skeletal angular

measurements, and soft tissue measurements. Skeletal linear measurements were: A–X, the shortest distance between Y axis and A point along X axis indicating the position of maxilla in sagittal plane; and A–Y, the shortest distance between X axis and A point along Y axis indicating the position of maxilla in vertical plane. Skeletal angular measurements were: SNA and SNB angles, which denoted the position of the maxilla and mandible in relation to the anterior cranial base, respectively (normal $SNA=82^{\circ}+2^{\circ}$ and $SNB=80^{\circ}+2^{\circ}$); ANB denoting the relation of maxilla and mandible to each other (normal $2^{\circ}-4^{\circ}$); and SN mandibular plane denoting the growth pattern of mandible (normal $32^{\circ}+2^{\circ}$). Soft tissue measurements were nasolabial angle (Cm–Sn–Ls) formed between the columella tangent and the upper lip tangent (normal $102^{\circ}+2^{\circ}$) and the angle of facial convexity (G'–Sn–Pg') formed by the intersection of the soft tissues glabella–subnasale–pogonion (normal $-12^{\circ}+4^{\circ}$) (Figure 8).

RESULTS

Changes observed immediately after distraction showed a mean advancement of maxilla by 13.3 mm and a mean inferior movement of maxilla by 1.4 mm. Mean 1.5 mm posterior movement at a point was observed one year after distraction. All post-distraction

T1 Master chart (Pre-operative).

Pt. No.	Age	Sex	Diagnosis	Advancement plan (mm)	Procedure	A-X (mm)	A-Y (mm)	SNA*	SNB*	ANB*	SN-MPA*	NLA*	FCA*
1	22	M	UCLP	12	Le Fort I	49	49	72	87	15	28	38	-18
2	21	M	BCLP	15	High Le Fort II	44	46	75	82	72	38	70	-15
3	18	F	UCLP	10	Le Fort I	51	49	76	78	2	36	55	-10
4	11	M	BCLP	16	Le Fort I	46	51	75	87	15	36	70	-23
5	19	F	UCLP	8	Le Fort I	49	46	72	85	13	28	38	-10
6	19	M	UCLP	14	Quadrangular Le Fort II	44	46	70	78	8	28	75	-18
7	17	M	BCLP	15	Le Fort I	51	49	77	75	-2	36	75	-25
8	19	M	UCLP	12	Le Fort I	46	44	75	85	10	38	70	-15
9	22	F	UCLP	10	Le Fort I	51	49	70	75	5	36	70	-18
10	24	M	BCLP	10	Quadrangular Le Fort II	44	44	75	87	12	28	75	-15
11	24	M	UCLP	12	Le Fort I	49	51	72	85	13	28	55	-18
12	22	F	UCLP	13	Quadrangular Le Fort II	51	49	72	82	10	38	75	-15
13	21	M	UCLP	11	Le Fort I	46	51	76	78	2	38	75	-10
14	18	M	BCLP	12	Quadrangular Le Fort II	46	46	70	75	5	38	70	-15
15	23	F	UCLP	11	Le Fort I	49	46	72	78	6	36	70	-10
16	25	M	BCLP	9	Le Fort I	44	49	70	82	12	30	55	-15
17	20	M	UCLP	11	Le Fort I	49	44	75	78	3	28	75	-10
18	19	F	BCLP	16	High Le Fort II	42	49	72	85	13	36	70	-23
19	18	M	UCLP	11	Le Fort I	51	51	76	82	6	38	55	-15

NLA: Nasolabial angle; FCA: Facial convexity angle; UCLP: unilateral cleft of lip and palate; BCLP: bilateral cleft of lip and palate; SN-MPA: sella nasion plane-mandibular plane angle.

T2 Master chart (Immediate post distraction).

Pt. No.	Plan	Procedure	Latency (d)	Consolidation	Retention (wk)	A-X (mm)	A-Y (mm)	SNA*	SNB*	ANB*	SN-MPA*	NLA*	FCA*
1	12	Le Fort I	5	8	8	62	51	89	87	2	28	70	12
2	15	High Le Fort II	5	8	8	70	49	87	82	5	38	85	10
3	10	Le Fort I	5	6	6	62	49	84	78	6	36	95	10
4	16	Le Fort I	3	6	6	62	51	89	87	2	36	85	12
5	8	Le Fort I	5	6	6	59	51	87	85	2	28	75	8
6	14	Quadrangular Le Fort II	5	8	8	59	49	84	78	6	28	95	12
7	15	Le Fort I	4	8	8	69	49	84	75	9	36	85	12
8	12	Le Fort I	5	8	8	60	44	87	85	2	38	95	10
9	10	Le Fort I	5	6	6	62	49	84	75	9	36	85	10
10	10	Quadrangular Le Fort II	5	6	6	56	44	89	87	2	28	75	10
11	12	Le Fort I	5	6	6	64	51	87	85	2	28	95	12
12	13	Quadrangular Le Fort II	5	8	8	64	49	87	82	5	38	75	10
13	11	Le Fort I	5	6	6	58	51	84	78	6	38	85	8
14	12	Quadrangular Le Fort II	4	8	8	58	49	84	75	9	38	85	12
15	11	Le Fort I	5	6	6	62	49	84	78	6	36	95	8
16	9	Le Fort I	5	6	6	55	49	87	82	5	30	85	8
17	11	Le Fort I	5	6	6	62	49	84	78	6	28	95	12
18	16	High Le Fort II	5	2	-	48	51	76	85	-9	36	75	-5
19	11	Le Fort I	5	6	6	62	51	84	82	2	38	85	12

*Degrees, NLA: Nasolabial angle; FCA: Facial convexity angle; SN-MPA: sella nasion plane-mandibular plane angle.

T3 Master chart (1 year post distraction).

Pt. No.	Age	Plan	Procedure	A-X (mm)	A-Y (mm)	SNA*	SNB*	ANB*	SN-MPA*	NLA*	FCA*
1	22	12	Le Fort I	60	51	87	87	0	30	70	12
2	21	15	High Le Fort II	69	49	87	82	5	38	85	10
3	18	10	Le Fort I	60	49	84	80	4	36	95	10
4	11	16	Le Fort I	60	51	87	87	0	36	85	12
5	19	8	Le Fort I	56	51	87	85	2	30	75	10
6	19	14	Quadrangular Le Fort II	56	49	84	80	4	36	95	12
7	17	15	Le Fort I	69	49	84	80	4	36	85	12
8	19	12	Le Fort I	60	44	87	85	2	38	95	10
9	22	10	Le Fort I	60	49	84	75	9	36	85	10
10	24	10	Quadrangular Le Fort II	56	44	87	87	0	30	75	10
11	24	12	Le Fort I	60	51	87	85	2	30	95	12
12	22	13	Quadrangular Le Fort II	64	49	87	82	5	38	75	10
13	21	11	Le Fort I	56	51	84	80	4	38	85	8
14	18	12	Quadrangular Le Fort II	56	49	84	75	9	38	85	12
15	23	11	Le Fort I	60	49	84	80	4	36	95	8
16	25	9	Le Fort I	56	49	87	82	5	30	85	10
17	20	11	Le Fort I	60	49	84	80	4	30	95	12
18	19	9	High Le Fort II	48	51	76	85	–	–	–	–
19	18	11	Le Fort I	60	51	84	82	2	38	85	12

*Degrees, NLA: Nasolabial angle; FCA: Facial convexity angle; SN-MPA: sella nasion plane-mandibular plane angle.

Figure 8 Post-consolidation bone formation at pterygo-maxillary junction.

changes were stable at one year follow-up and the relapse was not significant. Bone formation at the pterygomaxillary region was noted in the study (Table 1). Post-consolidation cusp fossa occlusion was maintained in all cases (Figures 9, 10).

DISCUSSION

Cleft lip and palate is a common congenital defect in India. Along with a plethora of problems including speech, dental

defects, and psychosocial problems, they present with maxillary hypoplasia. Studies estimate that 25–50% of all patients with cleft lip and palate need maxillary advancement.^{5,6} Cleft patients are difficult to treat with traditional surgical/orthodontic approach.² Current surgical/orthodontic protocols rely on Le Fort I maxillary advancement. The palatal scarring resists acute advancement and causes relapse. Traditional maxillary surgeries in cleft patients have reported 25% relapse after a mean 7.8 mm advancement.¹

Severe cases require mandibular set back surgery. The drawback of this bi-jaw approach compromises the final lower facial balance and harmony. The age in which these surgeries can be carried out is limited. Orthopaedic appliances used to correct maxillary deformity during growing age only camouflage the skeletal discrepancy.⁷

Recently DO has been used as an alternative for correcting maxillary deficiency.⁷ DO overcomes most of the problems associated with conventional surgery, can be done at any age with fewer complications, and is a better choice for cleft patients as the gradual traction force causes the formation of membranous bone and eliminates the need for bone grafting and donor site morbidity.^{7,8} It also allows the growth of soft tissue, which yields long-term aesthetic facial balance.

Rigid external distractor system is effective for maxillary hypoplasia in these patients although it has the drawbacks of conspicuous external device, patient discomfort, and dental changes due to traction in addition to facial scarring caused by RED's external pins. Injuries to infraorbital nerve, nasolacrimal

Table 1 Parameters measured.

Variable (mean values)	T1 (pre-op)	T2 (post-DO)	T3 (1 year post-DO)	Remarks
Midface advancement	12.0 mm (planned)	13.3 mm (achieved)	11.8 mm (achieved)	-1.5 mm (relapse)
A-X (sagittal)	47.4 mm	60.7 mm	59.2 mm	11.8 mm
A-Y (vertical)	47.8 mm	49.2 mm	49.2 mm	1.4 mm
SNA	73.2°	85.3°	85.0°	+12.8°
SNB	81.2°	81.2°	82.0°	+0.8°
ANB	8.1°	4.0°	3.4°	-4.7°
SN-mandibular plane angle	33.7°	33.7°	34.6°	+0.9°
Naso labial angle	65.0°	85.2°	85.8°	+20.8°
Facial convexity angle	-15.6°	9.6°	10.6°	+26.2°

T1: pre-operative, T2: immediately after completion of distraction, T3: one year after distraction, T3-T2: changes between the two stages.

Figure 9 Relative midface position at T1, T2, T3. **Figure 10** Sagittal midface position at T1, T2, T3.

duct, tooth buds, root lesions, local inflammation and sinusitis, and pain have also been described to be associated with RED.⁹

Cohen developed a miniature distraction device, the modular internal distraction (MID) system.⁷ MID system allows custom internal distraction for virtually any region of the craniofacial skeleton up to 30 mm. Despite the inherent limitations of the internal device, some prefer the internal device over the external device for all the obvious the reasons mentioned.

In our MID cases common problems encountered were the vector determination and inability to change the vector after MID was applied. The extraoral port led to an unaesthetic scar in one case at the pre-auricular region. A need for more bone tissue for mesh adaptation was difficult in order to obtain hypoplastic maxillae. There was no difficulty in the application of distraction forces during bite jumping from class III to class II relation.

The second surgery for MID removal allowed the evaluation of regenerate, callus moulding, and rigid fixation for stability. Delaire's reverse pull head gear used for three months allowed consolidation.

The study showed no significant changes in the mandibular position indicating the improved profile and maxillo-mandibular

relation due to increase in the bony maxillary length. Soft tissue changes were corresponding to the hard tissues. The MID changed the concave profile into an aesthetic balanced profile. A significant reduction in the facial concavity by 24°, anterior movement of upper lip, and improvement of the nasolabial angle by 20.2° was observed as reported by various authors.^{10,11}

The midface advancement was uneventful in 18 cases. In one case complication was encountered as Le Fort II level distraction led to a fracture at the zygomatic body-arch junction. This was managed by open reduction of the fracture and re-osteotomy for using RED at Le Fort I level. Studies report that soft tissue tension during MID advancement with Le Fort II osteotomy causes caudal rotation of the midface which in turn displaces the zygomatico-maxillary complex anteriorly. Further lateral advancement leads to fracture at this junction.¹²

Changes One Year After Distraction

At T3, maxilla showed no relapse in the vertical plane; a mean sagittal relapse of 1.5 mm at point A was observed which was minimal compared to the amount of distraction. The results were stable one year after distraction in accordance with studies by

Wiltfang, who reported a 1.7 mm relapse at one year as statistically insignificant.¹¹

Pterygomaxillary region is the area where surgeon seeks to achieve stability by placement of bone graft.¹³ Studies show that DO provides a new sound bone in the pterygomaxillary area, providing stability.¹⁴ The new tissues are of the same morphology as the basic hard and soft tissues and are hence stable. Studies also report a late decrease in the SNA angle due to minimal growth of maxilla. We did not notice such changes in SNA and the reason being a shorter duration of the study. There were minimal dental changes one year after distraction. One year post-distraction revealed no significant change in the facial profile, upper lip protrusion, and nasolabial angle. This indicated that the soft tissue changes achieved after DO were stable in accordance with the other studies¹¹ (Figures 11, 12).

The limitation of this study is that we did not evaluate the quality of regenerate. Use of better and less invasive diagnostic tools such as 3D ultrasound scan reconstruction should be able to provide specific results.¹⁵ Although these results prove the reliability of MID for correction of maxillary hypoplasia, the individual risk of patient must be borne in mind. Studies recommend overcorrection in periods of growth to compensate for further facial growth in the surrounding tissues, particularly the mandible.¹¹ The inability to predict future growth of the associated anatomical structures is crucial for pre-operative planning. Long-term studies are required for need of additional procedures to finalise occlusion in the growing patient population.

Additional Applications of Modular Internal Distractor in Bone Stock Deficiency

In one craniosynostosis patient Le Fort III/monobloc osteotomy and facial asymmetry was done to distract and mobilise the midfacial complex. Advantage over the conventional synostosis release was observed. In yet another case, facial asymmetry was corrected and improved using MID with no requirement for subsequent orthognathic surgery. MID was also found to be versatile in the management of craniofacial bone stock deficiencies.

CONCLUSION

Patients with bone stock deficiencies in maxillary hypoplasia secondary to facial clefts present challenges to the surgeon. Maxillary DO permits a near normal correction of the midface deficiency in cleft patients. In the study, the results achieved were superior to the conventional osteotomies and orthopaedics. The cephalometric data showed stability after MID. Further long-term studies are recommended, with a larger sample size, randomised controlled samples, and longer follow-up to assess the quality of regenerate.

In the future, midface DO may benefit from automated light and continuous distraction. This will liberate patients from protracted distraction sessions and minimise discomfort. The procedure no longer would depend on activation of MID. Endoscopy as an adjunct for visualisation and minimal surgery are to be explored.

Figure 11 Stability of midface position at T2, T3.

Figure 12 Improvement in facial profile from negative at T1 to convex positive angle at T2 and T3.

Intellectual Contributions of Authors

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CONFLICTS OF INTEREST

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