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ORIGINAL ARTICLE

Clinical Application and Cephalometric Evaluation of Intraoral Tooth Borne Maxillary Distractors in Cleft Patients

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ABSTRACT

Introduction**:** Distraction osteogenesis is considered as a valuable alternative for treating craniofacial anomalies, the efficacy of which is least researched. This study was designed to evaluate the skeletal and dental changes with intraoral tooth borne maxillary distractor in cleft patients with maxillary deficiency with the help of cephalometric data.

Materials and methods**:** Fifteen patients were selected between 12 and 18 years of age following strict inclusion criteria. A distraction device was placed and activated after a latency period of 7 days postsurgically. Lateral cephalometric radiograph was taken before distractor placement and immediately after its removal. The data obtained for the parameters were evaluated statistically with paired t-test ($p \leq 0.01$).

Results**:** SNA, ANB, N-A-Pog, Co-A and overjet were showing statistically significant change with 7.9°, 8.3°, 15.9°, 7.3 and 8.9 mm respectively. Overbite decreased by 0.9 mm, incisor to CT decreased by 0.77 mm and palatal plane to CT decreased by 0.73° mm after distraction. Mandibular plane angle and total facial height shows no statistically significant changes after distraction.

Conclusion**:** In all patients' positive overjet was attained after distraction due to the movement of the maxillary segment anterior to molar teeth which leads to the improvement in nose, lip and dental relationships. Patient with reverse overjet and positive overbite without posterior crossbite in relation to anchorage teeth can be considered ideal candidates for tooth borne distractors. Overall this technique is highly feasible, tolerable, and economical.

Keywords: Maxillary distraction, Cleft lip and palate, Cephalometrics, Intraoral distractor, Tooth-borne distractor.

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INTRODUCTION

Distraction osteogenesis (DO), the gradual mechanical traction of bone segments at an osteotomy site in order to generate new bone is a valuable alternative in treating craniofacial dysplasias associated with maxillary deficiency. Although initially reported by Codivilla in 1905,[1] the reintroduction of distraction protocol by Ilizarov in 1960s, stimulated interest in this technique.[2] Distraction in craniofacial region did not gain immediate acceptance because of lack of control over bony segments and inadequacy of distraction devices. As technology improved, these techniques became increasingly popular in craniofacial region and large numbers of studies have reported successful advancement of jaw bones with extraoral distraction devices. But due to problems like discomfort with head frame and social problems associated with extraoral distraction,[3-5] a better alternative could be internal and intraoral devices. With the help of tooth borne distracters, Block[6] could observe more amounts of dental than skeletal movements in dogs. But Dolanmaz,[7] Bengi,[8] Gunaseelan,[9] Alkan[10] reported acceptable clinical reports with tooth borne distractors. The present study was aimed at evaluating the skeletal and dental changes of intraoral tooth borne maxillary distractor in cleft patients with maxillary deficiency with the help of clinical and cephalometric data. Further, advantages of placing the distractor 1 day before the surgical procedure, modification for better anchorage control and limitations of the distractor were thoroughly discussed.

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MATERIALS AND METHODS

Patient Selection and Evaluation

Fifteen unilateral cleft lip and palate patients (12-18 years, M:F = 4:11) were selected with a strict inclusion criteria which included reverse overjet of more than 3 mm with or without posterior crossbite. Since, anchorage was to be obtained from teeth, only patients with good periodontal support and erupted maxillary permanent first and second molars as well as second premolar were included in the study. Further, no medications 3 weeks prior to the procedure, no other systemic illnesses affecting distraction procedure, good oral hygiene status and good compliance were also considered. The parents and patients were thoroughly familiarized with the mechanism of DO and the protocol followed, before the procedure and the informed consent was obtained. The procedure was approved by the Ethics Committee of Dr

Jeyasekharan Hospital and Nursing Home. In six patients, initial leveling and aligning of dentition was performed with fixed orthodontic procedure since, buccolingual discrepancy was seen in molar and premolar region which affects the positioning of the distractor. In rest of the nine patients, the distractor was applied directly. Lateral cephalometric radiograph and OPG were taken before distractor placement (T1) and immediately after its removal (T2).

Intraoral Distractor

A rigid and retentive intraoral distraction device was designed (Fig. 1). After initial separation with the help of elastic separators, orthodontic bands were seated in first, second premolar, first and second molars with alginate impression of the maxillary arch are obtained. Bands were transferred to the impression and a working model was created. Hyrax screw (Forestadent, Bernhard Forster GmbH, Westliche Karl-Friedrich-Str. 15175172 Pforzheim, Germany) with 12 mm expansion was selected considering the amount of advancement required. The screw was bent perpendicular to transpalatal plane (TPP), parallel to facial midline (FM) and occlusal plane horizontally (Fig. 2). Anterior and posterior legs of the screw were soldered with bands corresponding to premolar and molar regions respectively (Fig. 3). Three splints were constructed with chemical cured acrylic separately; one anterior (from right side second premolar to left side second premolar) and two posterior ones (includes first and second molars of the corresponding sides). Anterior and posterior splints were cemented separately above the previously cemented device.

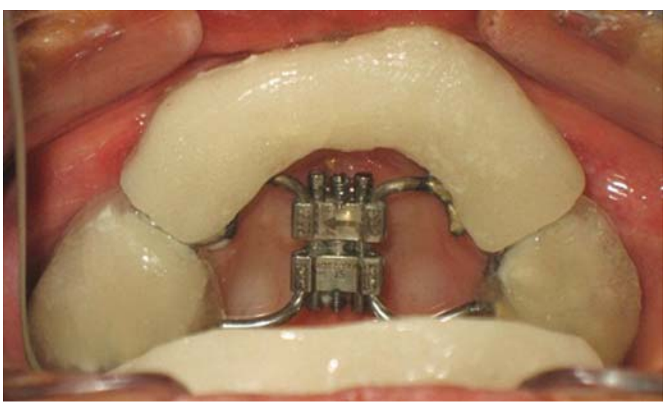

Fig. 1: Intraoral distractor with anterior and posterior splints

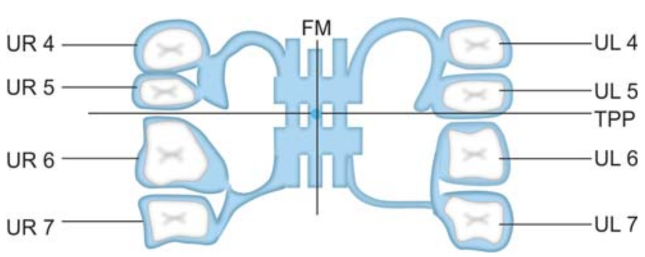

Fig. 2: Reference landmark and plane for screw placement. Abbreviations: UR 4: Upper right 1st premolar; UR 5: Upper right 2nd premolar; UR 6: Upper right 1st molar; UR 7: Upper right 2nd molar; UL 4: Upper left 1st premolar; UL 5: Upper left 2nd premolar; UL 6: Upper left 1st molar; UL 7: Upper left 2nd molar; FM: Facial midline; TPP: Transpalatal plane

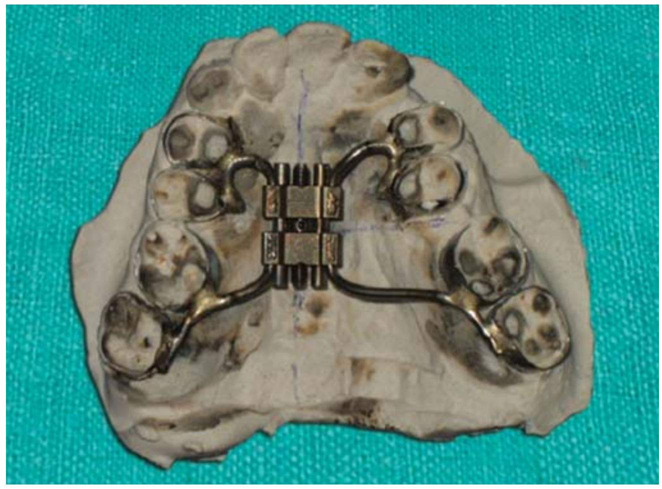

Fig. 3: Plaster model showing hyrax screw soldered to bands of molar and premolar teeth

Surgical Technique

Surgical procedure was similar to the technique proposed by Gunaseelan[9] except that distractor was modified with an acrylic splint, 1 day before surgery. After the surgery, to evaluate the completion of surgical cut, distractor was activated for 2 to 3 mm on the surgical table itself to verify for free movement of the anterior segment without resistance. Once satisfied with the surgical cut, the distractor was deactivated to the original position. Care was taken to keep the palatal tissue intact for vascularity and to prevent the development of fistula during distraction. None of the patients developed any infection, dislodgement of appliances, injuries to hard and soft tissues.

Distraction Protocols

After the latency period of 7 days, the distraction device was activated as per Ilizarov protocols. It is suggested that the formation of the new bone in the osteotomy or corticotomy site with a width of approximately 1 mm per day can be achieved by distraction method[11,12.] Activation (distraction period) was done in morning and evening to total amount of 1 mm per day for 10 ± 2 days based on previous reverse overjet and selective trimming of anterior acrylic segment was done to prevent interference with lower anterior teeth. Once positive overjet was established, posterior acrylic was trimmed for settling of occlusion. Finally, device was stabilized with cold cure acrylic and left in position for 112 ± 10 days (consolidation period) to permit bone mineralization.

Cephalometric Evaluation

Lateral cephalometric radiographs were taken before distractor placement (T1) and after its removal (T2). Cephalograms were

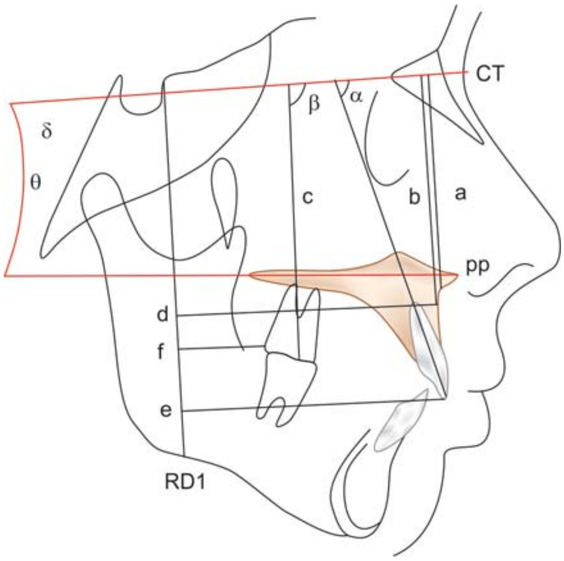

Fig. 4: Two reference planes, CT and RD1, were traced on lateral cephalogram. Perpendicular distance from point A to CT plane (a); perpendicular distance from incisor tip to CT plane (b); perpendicular distance from the mesiobuccal cusp of Ist molar to CT plane (c); perpendicular distance from point A to RD1 plane (d); perpendicular distance of incisor to RD1 plane (e); perpendicular distance of molar to RD1plane (f); angle between the axis of incisor and CT plane (α); angle between the axis of Ist molar and CT plane (β); angle between palatal plane and CT plane (θ)

digitized in Vistadent OC 1.1 software program (GAC International Inc, Bohemia, New York, USA). Two coordinate system CT and RD1 relating cranial base to maxilla were established[13] (Fig. 4). CT was a horizontal reference line passes through point C (the most anterior point of cribriform plate at the junction with the nasal bone) and point T (the most superior point of the anterior wall of sella tursica at the junction with tuberculum sella). RD1 was a vertical reference line drawn perpendicular to CT plane at point T. These reference lines were superimposed on pre- (T1) and post-distraction (T2) cephalograph for assessment of incisors and molar changes. Linear measurements including total facial height, Co-A point, overjet and overbite were measured in both the radiographs (T1 and T2). Angular measurements like SNA, SNB, ANB, facial, N-A-Pog, CT to palatal plane and SN - MP were also measured. The T1 and T2 values were statistically analyzed with the help of paired t-test for statistical significance with the help of statistical program for social sciences package (SPSS Version 13, Chicago, Ill, USA).

RESULTS

There was marked change in facial profile (Figs 5 and 6) with positive overjet relationship in all the patients after distraction (Figs 7 and 8). Angular and linear measurements of pre- and postdistraction (T1 and T2) were tabulated and presented in Table 1. The representative cephalometric radiographs (pre, between, postdistraction) are shown in Figures 9 to 11 and OPG (pre- and postdistraction) in Figures 12 and 13. The level of significance used as $p \leq 0.01$ was considered significant (S);

Fig. 5: Extraoral photograph—pretreatment phase

Fig. 6: Extraoral photograph—postdistraction phase

Fig. 7: Intraoral photograph—pretreatment phase

Fig. 8: Intraoral photograph—postdistraction phase

Table 1: Predistraction and postdistraction cephalometric values along with statistical significance with p-value ≤ 0.01

Cephalometric parameters	*Pretreatment (T1)*	*Post-treatment (T2)*	*Mean difference*	*p-value*	*Significance (≤0.01)*
SNA (°)	76.000	83.933	7.933	0.000	S
SNB (°)	81.367	81.000	0.367	0.038	NS
ANB (°)	–5.367	2.933	8.300	0.000	S
N-A-Pog (°)	–12.567	3.333	15.900	0.000	S
SN-MP (°)	32.300	32.833	0.533	0.016	NS
Total facial height (linear)	118.900	119.667	0.767	0.035	NS
Co-A (linear)	82.300	89.600	7.300	0.000	S
Over jet (linear)	–6.267	2.633	8.900	0.000	S
Overbite (linear)	1.367	0.467	0.900	0.000	S
Point A to CT (linear)	50.833	50.600	0.233	0.075	NS
Incisor to CT (linear)	70.300	69.533	0.767	0.005	S
Molar to CT (linear)	67.600	67.733	0.133	0.051	NS
Point A to RD1 (linear)	53.033	60.433	7.400	0.000	S
Incisor to RD1 (linear)	55.567	64.500	8.933	0.000	S
Molar to RD1 (linear)	24.2700	24.07	0.200	0.042	NS
Palatal plane to CT (°)	3.967	3.233	0.733	0.000	S
CT to incisor (°)	74.47	70.400	4.07	0.000	S
CT to molar (°)	90.967	92.533	1.567	0.038	NS

S: Significance; NS: Nonsignificance

Fig. 9: Cephalograph showing predistraction phase

Fig. 10: Cephalograph showing distractor in place

Fig. 11: Cephalograph showing postdistraction phase after appliance removal

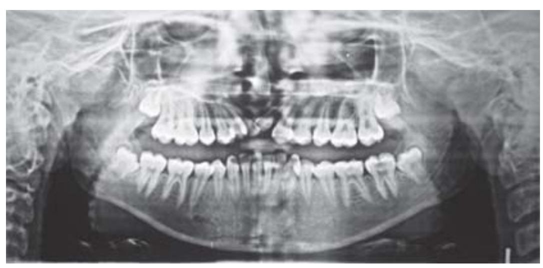

Fig. 12: Pretreatment OPG

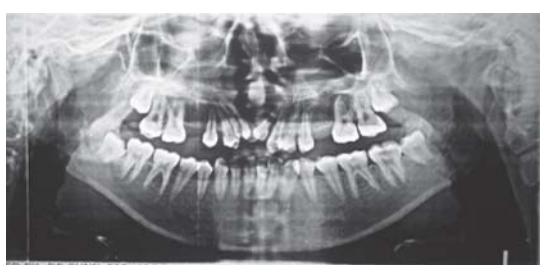

Fig. 13: Postdistraction OPG showing bone formation at the distraction site

$p \geq 0.01$ was considered not significant (NS). SNA, ANB, N-A-Pog, Co-A, Point A to RD1, Incisor to RD1 and overjet showed a statistically significant changes of 7.9°, 8.3°, 15.9°, and 7.3, 7.4, 8.93 and 8.9 mm respectively indicating increase in maxillary length. Overbite decreased by 0.9 mm, incisor to CT decreased by 0.77 mm and palatal plane to CT decreased by 0.73° mm after distraction. No statistically significant changes were observed in molar position, mandibular plane angle and total facial height.

DISCUSSION

Current protocols in surgical approach for skeletal dysplasia in cleft patients include Le Fort I maxillary advancement with or without mandibular setback.[14] But conventional osteotomy has a risk of limited maxillary advancement, requirement of bone graft and risk of bone necrosis.[15] Extraoral distraction has good vector control and it is possible to move the maxilla even during distraction procedure.[16] But problems associated with this were external scarring, discomfort with head frame,[3] social appearances, functional problems and pain.[4,5] Although internal distractors are less visible clinically, major problems were difficulty in placing them parallel to each other because of the complexity of maxillary morphology[17] and requirement of surgery during placement and removal of distractor. Main advantages of intraoral tooth borne distractors are that, there are less visible clinically, no surgical procedures are required during placement or removal of the device, are economical and show favorable results.[7-10] Review of literature on tooth borne premaxillary distraction shows no previous publication on cephalometric evaluation with clinical applications.[18]

In this present study, 15 patients were selected. A power analysis was done based on 1:1 ratio, a sample size of 10 patients would give more than 80% power to detect significant changes with 1.375 effect size and of $\alpha = 0.01$ significance level.

As we know, major limitations with intraoral tooth borne distractors were restricted movement to screw size, lack of three-dimensional control, movement of maxillary segment determined by osteotomy and position of screw, inability to adjust during distraction procedure and oral hygiene maintenance.

To overcome these problems in the present research, the screw size was selected based on pretreatment reverse overjet. Problems with unstable devices may cause failure of distraction and is commonly associated with fibrous union or pseudoarthritis in distraction gap. So we banded both first and second molars along with second premolar and adjacent mesial tooth to increase stability of the device. Further, anchorage was reinforced by anterior and posterior acrylic splints. Posterior acrylic splints not only served the purpose of anchorage but was also effective for bite opening. Screw was positioned parallel to occlusal plane and along the facial midline to obtain symmetrical maxillary movement. Alteration in angulations of the screw when cementing the appliance in relation to anterior and posterior segment would affect the predetermined movement of the maxillary segment. So in our technique, distractor was placed before surgery compared to other techniques[8-10] to avoid the difficulty of manipulating the mobile maxillary segments and maintenance of dry field which directly affects the movement of the maxillary segment and anchor unit. Since, the surgical cuts were placed along the buccal aspects and distractor was placed in palatal aspect it does not interfere during surgical procedure. The limitation was lack of tactile sensation during surgical cut due to the presence of the distractor.[19] But still none of the patients developed any laceration during surgery and fistula during distraction. Stepwise placement of the device components over the dentition has an advantage of easy removal of distractor after the procedure. Further, fixed bilateral bite blocks improved the chewing efficiency and none of the patients complaind of any discomfort with the appliance. Patients were well-motivated throughout the procedure for meticulous. Oral hygiene maintenance.

In all the patients, positive overjet was attained after distraction which can be attributed to the movement of the maxillary segment anterior to molar teeth. Amount of linear and angular incisor changes to CT shows significant vertical movement of 0.77 mm upward and labial tipping of incisors by 4.07°. But there was a difference between the distances of point A to RD1 of 7.4 mm and incisor to RD1 of 8.9 mm. The possible reason for this variation may be due to the rotational effect of the maxillary segment upward rather than true movement of incisors. This was confirmed by the tipping of the palatal plane upward by 0.73°, reduction of overbite by 0.9 mm and reduction of incisor to CT by 0.77 mm after distraction. This emphasizes the point that intraoral distractors are effective in moving the premaxillary segment forward and upward but not downward. Regarding molar movement, both the linear (CT and RD1 to molar) and angular (CT to molar) values of 0.13, 0.20 mm and 1.57° show anchorage was well-maintained. Further, maintenance of mandibular plane angle and total facial height before and after distraction implies anchorage conservation without causing much strain on the molars. Although the movement of the molar was not statistically significant, there was a tendency for the molar to extrude and tip distally (Table 1).

Ten patients with positive overbite before distraction showed good overjet and overbite relationship at the end of distraction. In five patients, negative overbite (open bite) seen after distraction was due to the preexistence of negative overbite. So clinicians should be very cautious when using intraoral distraction in patients in long face and openbite cases to avoid possible effects of tipping of palatal plane upward, molar extrusion and distal tipping which may further increase the open bite and facial height. Spaces developed with bone formation were highly evident between second premolar and first molar (Fig. 13).

Limitations of this technique are that the maxillary movement was restricted to screw dimension and the inability to correct severe skeletal dysplasia cases where total Le Fort I osteotomy was required. Since, it was a tooth borne distractor and it is applicable only after permanent tooth eruption. If teeth are missing or have existing periodontal disease, the procedure is difficult to apply. There is a possibility for root resorption and damage to periodontal structures because of the intermittent force generated by the device during distraction. These findings along with the stability of the procedure require periodical follow-ups.

CONCLUSION

Following conclusions were made from our study:

1. Tooth borne distractors are effective alternative technique for treating cleft patients in order to improve the skeletal dysplasia.
2. Modified distractor with acrylic splint reduces the unwanted tooth movement with favorable maxillary movement.
3. Placement of the distractor before surgery improves the stability if the distractor with good vector control.
4. Patients with preexisting open bite are not ideal candidates for tooth borne distraction.
5. Space created by distraction can be used for alignment of crowded maxillary dentition and to correct molar and canine relation with postorthodontic procedures. Further, space can be managed with prosthetic replacement depending upon the occlusal relationship.
6. Patients with reverse overjet and positive overbite without posterior crossbite in relation to anchorage teeth are ideal for tooth borne distractors.
7. Overall this modified technique is highly feasible, friendly and economical.

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